# *ANNEX II + III:* TECHNICAL SPECIFICATIONS + TECHNICAL OFFER

**Contract title: Supply of Vaccines and Syringes (Injectors)**

**Publication reference:** SIHHAT/2025/SUP/INT/07

**Columns 1-2 should be completed by the contracting authority**

**Columns 3-4 should be completed by the tenderer**

**Column 5 is reserved for the evaluation committee**

Annex III - the contractor's technical offer

*The tenderers are requested to complete the template on the next pages:*

* *Column 2 is completed by the Contracting Authority shows the required specifications (not to be modified by the tenderer),*
* *Column 3 is to be filled in by the tenderer and shall detail what is offered (for example the words “compliant” or “yes” are not sufficient)*
* *Column 4 allows the tenderer to make comments on its proposed supply and to make eventual references to the documentation*

The eventual documentation supplied should clearly indicate (highlight, mark) the models offered and the options included, if any, so that the evaluators can see the exact configuration. Offers that do not permit to identify precisely the models and the specifications may be rejected by the evaluation committee.

The offer shall be clear enough to allow the evaluators to make an easy comparison between the requested specifications and the offeredspecifications.

All specifications of a product should be shown in detail in the documentation to be provided. Answering technical specifications by phrases such as “yes”, “accepted”, etc. **are not acceptable**.

Copying the required specifications from Column 2 to the offered specifications in Column 3 should be avoided. Column 3 shall be filled by the Tenderer with the exact/real specification of the offered goods (not the range or the min. max. threshold provided in the specifications). For instance, if the required specification is “length between 100 and 120 cm”, the specification offered shall be i.e. “110 cm or 110 cm ±2”.

Unless otherwise specified, the requirements in these Technical Specifications are presented as a minimum standard which the offered goods shall meet.

Whenever a specific brand is used in these technical specifications for which a sufficiently precise and fully intelligible description is not possible, it means that the specifications shall meet the brand or its equivalent in terms of functionality.

Unless specifically manufactured for the tendered project, each offered good shall be stated with brand/product name, product version and product/part number. The tenderer shall identify the model and manufacturer of each item in their technical offer. In the case of specifically manufacturing, it shall be clearly stated in columns 3 and/or 4.

**GENERAL REQUIREMENTS**

**Technical**

* All goods shall be provided complete with the necessary accessories and/or parts to ensure that the unit is capable of operating to the required technical and quality specifications immediately.
* The supplies shall be compliant with EN standards and EU regulations/certifications (such as CE norm, energy efficiency, environmental management, etc.) and international standards or equivalents. Tenderers shall state in their offers the standards/regulations valid for the offered items. Wherever reference is made in the Technical Specifications to specific standards and codes to be met by the goods and materials to be furnished or tested, the provisions of the latest current edition or revision of the relevant standards in effect shall apply unless otherwise stated in this technical specification.

**Visibility**

* + All supplies shall comply with the generic visibility policies in force within the scope of external aid contracts financed from the EU general budget; tenderers will thus be aware that certain visibility rules apply and that the guidelines and manuals concerned may be found on the EuropeAid website at:

<https://international-partnerships.ec.europa.eu/knowledge-hub/communicating-and-raising-eu-visibility-guidance-external-actions_en>

<http://www.avrupa.info.t>r

* + The label shall be designed in accordance with the following sign without any distortion.
  + Proper material and size compatible with specifications and dimensions of goods shall be offered and approved by the Contractor. The label shall be coloured, readable, visible and durable.



**Instrument for Pre-accession Assistance (IPA III)**

**SIHHAT/2025/SUP/INT/07**

Lot No:

Item No:

Serial No:

%100 Avrupa Birliği Katkısı ile alınmıştır.

EU Contribution 100%

***Abbreviation List***

GDPB: Turkish Ministry of Health, General Directorate of Public Health

Department : Department of Vaccine-Preventable Diseases

TİTCK : Turkish Medicines and Medical Devices Agency

WHO : World Health Organization

TRS : Technical Report Series

EMA : European Medicines Agency

US-FDA : United States Food and Drug Administration

GMP : Good Manufacturing Practices

NRA : National Regulatory Authority

NCL : National Control Laboratory

BRC : Batch Release Certificate

CPP : Certificate of Pharmaceutical Product

IFU : Instructions for Use (Patient)

SPC : Summary of Product Characteristics

SOP : Standard Operating Procedures

TSE : Transmissible Spongiform Encephalopathy

SGK : Social Security Institution

BCG : Bacillus Calmette-Guérin

OCABR : EU-Official Control Authority Batch Release (European Union Batch Release Official Authority)

| **LOT 1 - DABT-IPV-HIB-HEPATITIS B VACCINE (6-IN-1 VACCINE)** | | | | |
| --- | --- | --- | --- | --- |
| **Item No** | **Specifications** | **Specifications Offered** | **Notes, remarks,  ref to documentation** | **Evaluation Committee’s notes** |
| **1.** | **VACCINE TECHNICAL SPECIFICATIONS** |  |  |  |
| **1.1.** | The product shall comply with vaccine production, quality control parameters, methods, and specifications in World Health Organization (WHO) Technical Report Series (TRS) No:980 Annex 4 and 5, 979 Annex 4, 897 Annex 1, 993 Annex 3, 1024 Annex 3, 978 Annex 4 **European Pharmacopoeia 11.0 07/2022:2067 and** **11.0 01/2020:2920 Monograph** |  |  |  |
| **1.2.** | One dose of vaccine (0.5 mL) shall contain the following:  **Diphtheria Toxoid**…………………………………………………(P:0,95) lower confidence limit 20 IU  **Tetanus Toxoid**……………………………………………………(P:0,95) lower confidence limit 40 IU **Bordetella pertussis antigens**  Pertussis Toxoid…………………………………………………….25 micrograms  Filamentöz Hemaglutinin………………………………………………25 microgram  **Poliovirus (Inactive)**  Type 1 (Mahoney)……………………………………………………… 40 D antigen unit  Type 2 (MEF-1)…………………………………………………………. 8 D antigen unit  Type 3 (Saukett) ………………………………………….……………..32 Dantigen unit  **HBsAg**………………………………………….………………………...10 micrograms  **Haemophilus influenzae type b polysaccharide**…………………….……at least10 micrograms  (Polyribosyl-ribitol-phosphate -PRP) (HIB polysaccharide shall be conjugated to tetanus toxoid..) |  |  |  |
| **1.3.** | The vaccine shall be packaged in a single-dose, ready-to-use syringe (injector) containing all antigen components, or in a secondary package containing a single-dose, ready-to-use syringe (injector) containing all antigens except Hib and a lyophilised vial containing the Hib antigen. |  |  |  |
| **1.4.** | The vaccine shall maintain its stability to its expiration date at temperatures between (+2) - (+8) OC from the last successful potency test. |  |  |  |
| **1.5.** | The vaccine shall not contain thiomersal. |  |  |  |
| **2.** | **DOCUMENTS TO BE INCLUDED IN THE FILE TO BE REVIEWED BY THE TENDER COMMITTEE** |  |  |  |
| **2.1.** | The product in question;   * + 1. shall have a license issued by the Turkish Ministry of Health,     2. If it does not have a license issued by the Turkish Ministry of Health;   + It shall be included in the latest pre-qualification list published by the World Health Organization (<https://extranet.whoint/prequal/vaccines/prequalified-vaccines)> or,   + It shall have a license from the European Medicines Agency (EMA) and be manufactured in European Union countries, or   + It shall have a license from the US-FDA and be manufactured in the United States, **or**   + It shall be licensed by the Pharmaceuticals and Medical Devices Agency (PMDA) and manufactured in Japan, or   + It shall be licensed by the South Korean Food and Drug Administration and manufactured in South Korea, **or**   + It shall be licensed by the Canadian Food and Drugs Act and Regulations and manufactured in Canada, **or**   The product shall be licensed by the Australian Department of Health Therapeutic Goods Administration and manufactured in Australia. |  |  |  |
| **2.2.** | The product shall be accompanied by a certificate (GMP certificate) showing that the factory producing it complies with the **good manufacturing practices (**GMP) standards approved by the State Control Agency of the country where the product is manufactured. If the product is filled or manufactured in our country, there shall be a document showing that the factory where the production/filling is carried out, approved by the Turkish Ministry of Health, Turkish Medicines and Medical Devices Agency, manufactures in accordance with good manufacturing practices (GMP) rules. |  |  |  |
| **2.3.** | For any batch produced within the last two years, the 'National Regulatory Authority' (NRA) or the Batch Release Certificate issued by the EMA (from the locations specified in the annex to the European Union's 2001/83/EC directive), US-FDA, Japan, South Korea, Canada, and Australian state authorities, as specified in 2.1. If the product is manufactured in Türkiye, it shall be a marketing authorization certificate issued by the Turkish Medicines and Medical Devices Agency of the Ministry of Health of the Republic of Türkiye. The analysis report for the same series shall also be included in the BRC annex. |  |  |  |
| **2.4.** | A valid Pharmaceutical Product Certificate (CPP) approved by the manufacturer's country authority. |  |  |  |
| **2.5.** | A **manufacturer-approved** document showing that the risk of Transmissible Spongiform Encephalopathy (TSE) has been minimized at every stage of the product's production. |  |  |  |
| **2.6.** | If the product is licensed in Türkiye, it shall have a "Summary of Product Characteristics" (SPC) or package insert or "Patient Information Leaflet" (PIL) approved by the Turkish Medicines and Medical Devices Agency (TİTCK), or if it is not licensed in Türkiye, it shall have one approved by the relevant country's authority, along with Turkish translations. |  |  |  |
| **2.7.** | If applicable, a list of tasks to be performed by subcontractors shall be provided. |  |  |  |
| **2.8.** | The tenderer shall declare in writing how many batches of the product they can deliver |  |  |  |
| **2.9.** | If the product is used outside the country of manufacture, a document shall be submitted containing the list of countries where the product is used, approved by the manufacturer, along with the usage permits (import permits) or license numbers for these products, and information on the total number of doses used in countries other than the country of manufacture for the last two calendar years prior to the year of the tender. |  |  |  |
| **2.10.** | The tenderer shall declare that if the manufacturer or another country where the product is used suspends the use of the product for any reason, or if they receive any news in this regard, they shall inform the Ministry within 24 hours (product name, serial number, reason for discontinuation, etc.) and that if the information is not provided within 24 hours, the administration has the right to unilaterally terminate the contract. It also indicates that in the event of discontinuation of the product, after the unused products are collected by the Ministry and sent to the Central Warehouse, the Tenderer undertakes to bring a new product from a different series that complies with the specifications within 90 (ninety) calendar days from the date the replacement request is notified. In addition, the Tenderer shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date of notification of the product replacement request after the unused products are collected by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **2.11.** | The Tenderer shall submit the original or notarized copies of the required documents, along with their certified Turkish translations, to the tender committee. |  |  |  |
| **3.** | **DELIVERY OF PRODUCTS** |  |  |  |
| **3.1.** | If the products are imported, the tenderer's representative shall be present when the products are collected from customs and shall ensure that the goods are collected in accordance with the required specifications and delivered to the location deemed appropriate by GDPB without delay. |  |  |  |
| **3.2.** | The contractor shall provide the Department with the shipment details 3 days prior to the delivery date of the product. |  |  |  |
| **3.3.** | Product delivery shall be made in such a way that it does not coincide with holidays, official holidays, or the end of working hours in Türkiye. |  |  |  |
| **3.4.** | To clear products purchased by GDPB through customs, the Contractor shall enter the product information (batch release certificate and quantity for the lot/serial number for which import permission is requested) via the Single Window Portal System (<https://uygulama.gtb.gov.tr/TekPencere>). The Single Window approval request shall be submitted to the Department electronically (to the Department's official e-mail address) or in writing at least 3 days in advance. Products purchased by the General Directorate of Public Health shall be delivered to the GDPB Vaccine and Drug Warehouse within 48 hours after being cleared through customs (except for products filled in Türkiye) if they are imported. Any changes required after the initial inspection (packaging, barcode, etc.) may also be made at the Central Vaccine and Drug Warehouse with the approval of the GDPB. If storage exceeds 48 hours, it is mandatory to submit temperature records approved by the Contractor's quality manager from the production site until the Ministry of Health Vaccine Storage arrives, to use a warehouse licensed by the Turkish Ministry of Health, and, if "temperature monitoring cards" are installed at the production facility, not to change them. |  |  |  |
| **3.5.** | If the packaging of the imported product (including barcoding) is to be changed at a different location after the contract is signed, this situation shall be reported to the Department. The temporary storage location shall be licensed by the Turkish Ministry of Health, the initial opening of the packaging of the product withdrawn from customs shall be carried out under the supervision of GDPB or its authorized personnel, and the shipment and temporary storage temperature records shall also be submitted during the inspection phase. GDPB may inspect this entire process at any time and on any day after customs clearance. Intermediate storage shall be possible if the application made to GDPB and the storage period are found to be appropriate. For products imported prior to the signing of the contract, it is sufficient to submit approved storage temperature records documenting all processes and to document that the product has been kept in storage facilities licensed by the Ministry of Health until the delivery stage. |  |  |  |
| **3.6.** | Products filled in our country shall be delivered to the GDPB Vaccine and Drug Warehouse within 24 hours of leaving the filling facility. If the product is not delivered to the GDPB Vaccine and Drug Warehouse within 24 hours after leaving the filling facility and is to be stored in another warehouse, the organization performing the intermediate storage shall be licensed by the Turkish Ministry of Health, temperature records from the production site to the warehouse and within the warehouse shall be kept, and certified copies from the product quality representative shall be delivered to GDPB upon product delivery. These stages shall be open to inspection by GDPB if required. The Department shall be notified if temporary storage is required. Products shall not be accepted if the specified conditions cannot be met. |  |  |  |
| **3.7.** | If the products are filled/manufactured in Türkiye, the time limit specified in Article 3, except for 3.2 and 3.3, and the restrictions at shall not apply. |  |  |  |
| **4.** | **DOCUMENTS REQUIRED DURING INSPECTION AND PRODUCT CHARACTERISTICS** |  |  |  |
| **4.1.** | Products shall have **a shelf life of at least 18 (eighteen) months** from the date of delivery to our warehouse. |  |  |  |
| **4.1.1.** | **Documents required during the product inspection phase:**  The documents specified in Article 2 of the Technical Specifications and the documents specific to the delivered series/lot shall be submitted during the inspection stage. These documents are:   * Product License * Current GMP certificate for the production site, * Analysis report for the delivered batch (document containing information such as composition, analysis results, reference values, production/expiration dates, etc.), * BRC for the delivered batch, * Current Pharmaceutical Product Certificate (CPP) * TSE declaration (item 2.5), * List of tasks to be performed by subcontractors, * Package Insert or Prospectus or IFU (Article 2.6), * List of countries where the product is used and import permit/license number and the number of doses used in each country in the last two calendar years prior to the year of the offer (Article 2.9), * Commitment letter (Article 2.10). |  |  |  |
| **4.2.** | The Contractor, manufacturer or any other country where this product is used shall notify the Ministry within 24 hours if the use of the product is suspended for any reason or if they receive any information in this regard (product name, serial number, reason for discontinuation, etc.) and acknowledges that the administration has the right to unilaterally terminate the contract if such information is not provided within 24 hours. In the event of discontinuation of the product, the Contractor shall be required to bring a manufacturer-approved commitment letter to the Ministry within 90 (ninety) calendar days from the date the replacement request is notified to the Contractor. Additionally, the Contractor shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date the request for product replacement is notified, following the collection of unused products by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **4.3.** | Stability studies and results proving the actual shelf life of the product in question shall be submitted. If the product is filled or manufactured in our country and stability studies are still ongoing, the TİTCK-approved study results shall be submitted to the Department as they are completed. |  |  |  |
| **4.4.** | Along with the product, all technical documents required in the tender for the product (Good Manufacturing Practices, analysis report, SPC, certificates, etc.) and detailed SOP (may be provided in the original license), **stability results (showing real-time and accelerated stability shelf life),** product photos, and all documents containing technical information about the packaging (dimensions, volume, etc.) shall be submitted to the inspection commission in duplicate on CD/DVD/flash drive. Each heading shall be indicated with a separate folder name, and the relevant documents shall be found under the relevant folder. If deemed necessary, other documents and information related to the product may be requested in physical or digital form. |  |  |  |
| **4.5.** | Documents that do not change with each shipment shall be submitted once, with the first shipment. If deemed necessary, documents may be requested again. |  |  |  |
| **4.6.** | **Required Packaging Characteristics** |  |  |  |
| **4.6.1.** | The product shall be packaged in vials or tubes containing a single dose, 10 doses, or a maximum of 20 doses. If the products are packaged in packs of ten, the packs shall contain foam or cardboard separators to prevent the vials or ampoules from breaking due to contact. If the product is packaged individually, the packages shall then be bundled in packs of ten. If diluents are separate, 5 additional diluents shall be delivered with every 1,000 doses of vaccine. |  |  |  |
| **4.6.2.** | The inner and outer packaging of licensed products in Türkiye shall comply with the current "Regulation on Packaging Information, Instructions for Use, and Tracking of Human Medicinal Products" published by the Turkish Ministry of Health. If the product is not licensed in our country, the inner packaging of the ready-to-use syringe (injector), ampoule, or vial shall bear, at a minimum, the manufacturer's and product name, dosage, amount of content per dose, method of administration (IM/IV/SC/ID, etc.), lot (batch) number, and expiration date, printed in indelible ink. The package shall also contain storage temperature information in addition to the inner packaging. The product package shall bear the statement "Property of the Turkish Ministry of Health, NOT FOR SALE." |  |  |  |
| **4.6.3.** | Each product package shall contain at least one "Summary of Product Characteristics" (SPC) or Turkish package insert or "Patient Information Leaflet" (PIL) prepared in accordance with the "Regulation on the Packaging and Labelling of Human Medicinal Products" dated 25.04.2017 and numbered 30048. Additionally, the following text shall be added to the beginning of the “"Summary of Product Characteristics" (SPC)” or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention. "In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration. For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates***."*** |  |  |  |
| **4.6.4.** | The packages shall then be placed in boxes. The names and addresses of the manufacturer and representative company of the product, the name of the product, the lot number, the storage temperature, the expiration date, and the number of doses in the box shall be written on these boxes. If the products are packaged individually, ten packages shall be placed in each box. If the products are packaged in packs of ten, five packages shall be placed in each box. |  |  |  |
| **4.6.5.** | The packaging boxes shall be placed in styrofoam. The styrofoam shall then be placed inside cartons. The carton dimensions shall be 40X60X40 ±20 (Width, Length, Height) cm. A sufficient number of ice packs or gel packs, etc., shall be placed in the cartons. The ice packs or gel packs, etc.**,** placed in the cartons shall be **unfrozen and cooled**. If the products are not sensitive to freezing (lyophilized), dry ice or frozen ice packs or gel may be used during transport. The names and addresses of the manufacturer and representative company, the product name, serial number, storage temperature, expiration date, dose quantity in the carton, carton dimensions, and weight shall be written on these cartons. |  |  |  |
| **4.6.6.** | The boxes shall then be placed on pallets. The pallets shall be euro pallets (120cm±2cmx80cm±2cmx10-15cm). After the boxes are placed on the pallets, the height together with the pallet shall not exceed 2 (two) meters. The boxes may protrude from the pallet by a maximum of 5 cm. There shall be a maximum of 16 (sixteen) boxes on the pallet. |  |  |  |
| **4.6.7.** | There shall be a 2D barcode on the packages, boxes, cartons, and pallets. The barcode prepared for the ready-to-use syringe (injector) inside each individually packaged product (these barcodes shall also have HL7 and 97 breakdown values) shall be on the product's package. The packages shall then be tied in sets of ten, and the package label shall be affixed to a different area than the barcode affixed to each product. If the product is packaged in sets of ten, the barcode prepared for the ready-to-use syringe (injector) (these barcodes shall also have HL7 and 97 breakdown values) shall be placed inside the package, and the barcode corresponding to the package breakdown shall be on the package. For the information to be included in the barcode, the information specified in the Guide for Barcode Application to Vaccines, Antiserums, and Diluents published by the Turkish Ministry of Health shall be used as a basis, and any additional information required shall be determined by GDPB. **The barcode area for the dose shall be at least 12X12 mm in accordance with the Guide**. If GDPB makes changes to the system instead of the barcode, the contractor shall be obliged to comply with the requirements of the newly created system without requesting a price difference. |  |  |  |
| **4.6.8.** | Even after acceptance, if any faulty operations related to the barcode system are detected later, the costs of changing the product packaging and, if deemed necessary, collecting the products from the field shall be borne by the Contractor. If this process exceeds one-month, new products with a new expiration date may be requested at the request of the Department to avoid any problems related to the expiration date. |  |  |  |
| **4.6.9.** | **Temperature monitoring during transportation:** |  |  |  |
| **4.6.9.1.** | The freeze indicator, temperature monitoring card, and digital temperature recording devices used **shall be listed in the WHO "E006: Temperature monitoring devices"** (https://extranet.who.int/prequal/immunization-devices/prequalified/imd-products)**.** |  |  |  |
| **4.6.9.2.** | If the product(s) are sensitive to freezing, each box shall contain a freeze indicator. |  |  |  |
| **4.6.9.3.** | If the product(s) are sensitive to high temperatures, each box shall contain a temperature monitoring card **with the date it was activated and the name/code of the activator written on it**. |  |  |  |
| **4.6.9.4.** | If the product(s) are sensitive to both freezing and high temperatures, or if they are packaged together, each box shall contain both a freeze indicator and a temperature monitor card with the date of activation and the name/code of the activator written on it. |  |  |  |
| **4.6.9.5.** | In addition, each pallet shall have an electronic, temperature, and freeze-sensitive digital monitor capable of long-term recording. The electronic, temperature, and freeze-sensitive digital monitors capable of long-term recording placed on the pallet shall be read during the inspection phase, the outputs shall be recorded in a report and signed by the company, and if there are no deviations, they can be filed electronically. If requested by the company, these devices shall be returned for storage without destruction for at least three months. Upon return, the pallet numbers and device serial numbers shall be recorded in a report.  If the pallets consist of insulated boxes, each containing heat tracking material (such as a digital recording device, heat monitoring card, or freeze indicator), and conflicting results are found between the digital heat records on or inside the pallet and the heat records inside the box when evaluating the heat records, the temperature monitoring results inside the boxes shall be considered when processing. |  |  |  |
| **4.6.9.6.** | Products found not to have been transported under appropriate conditions (Guidelines for th international packaging and shipping of vaccines, sixth edition. Geneva: World Health Organization; 2020. Licence: BY-NC-SA 3.0 IGO) as monitored by these heat trackers shall be returned. The evaluation of temperature monitoring equipment shall be carried out in accordance with the operating instructions for the relevant equipment. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **4.6.10.** | Each product shall be delivered with a Material Safety Data Sheet (MSDS). The contractor is responsible for the “Transportation, packaging, and labelling of hazardous materials” and completing any shortfalls if there is any. |  |  |  |
| **4.6.11.** | The contractor's representative shall be present during the delivery or return of the products. The representative shall submit a letterhead, stamped, and signed authorization document belonging to the contractor and a photocopy of their photo ID to the Warehouse Manager. The contractor is responsible for unloading the products from the vehicle into the warehouse or loading them back onto the vehicle for return. A list of the names, telephone numbers, and addresses of all employees and subcontractor personnel who shall perform work on behalf of the contractor shall be submitted to the Warehouse Manager, signed by the contractor's representative, prior to unloading. The contractor shall be responsible for any damage that may be caused to the warehouse or equipment and for all liabilities arising from "Occupational Health and Safety Regulations." The contractor shall submit a stamped and signed commitment stating that it has assumed the SSI, occupational health and safety, and work accident liabilities of its employees for unloading the products from the vehicle or loading them in case of return, and that it has assumed the liability for compensation in case of damage to the warehouse or any equipment inside the warehouse. Responsibility begins upon entry into the Warehouse area after the security check. |  |  |  |
| **4.6.12.** | Except in emergencies, no contractor employees other than the vehicle drivers and those declared shall enter the climate-controlled warehouse. |  |  |  |
| **4.6.13.** | If barcoding, packaging, or prospectus changes are to be performed in the GDPB warehouse, the documents belonging to the subcontractors shall be as follows:   * + - * shall be a contract demonstrating the availability of occupational safety expertise and workplace physician support services as required by the "Occupational Health and Safety Law" No. 6331.       * The contractor's structure shall include at least one coordinator, one operations manager, one quality control and GMP manager, and one warehouse manager. These personnel shall be present during the execution of the work. There shall be a document or documents proving that the personnel included in the company structure have received GMP and Good Warehouse Practices Training organized by the Turkish Ministry of Health or an organization that has received a GMP Certificate from the Turkish Ministry of Health.       * There shall be standard operating procedures (SOPs) prepared by a pharmacist and approved by the company representative, covering barcode printing and affixing procedures and cold storage room operating rules. |  |  |  |
| **5.** | **DOCUMENTS AND MATERIALS REQUIRED FOR LABORATORY ANALYSES AND METHODS TO BE FOLLOWED** |  |  |  |
| **5.1.** | **General principles of product safety;**  The analysis reports for the product are part of the batch release certificate, and both documents shall be considered together in the evaluations. |  |  |  |
| **5.1.1.** | The product shall be manufactured in our country, have a manufacturing license from the Turkish Medicines and Medical Devices Agency (TİTCK), and present the SBB certificate for the delivered batch obtained from the TİTCK/Analysis and Control Laboratories Department. In addition, if there is no break in the cold chain during product transfer, the physical examination is appropriate, and the commission grants approval, the inspection acceptance process can be completed. |  |  |  |
| **5.1.2.** | If the product is manufactured outside our country and has an import license from TİTCK or is on the WHO's prequalification list (Prequalified vaccines), the Series Release Certificate for the delivered series shall be obtained from WHO/ Reference Laboratories/institutions, provided that the analyses are performed in accordance with the OCABR guidelines at the TİTCK/Analysis and Control Laboratories Directorate. The inspection acceptance process for products found to be suitable through analysis can be completed. |  |  |  |
| **5.1.3.** | If the product is not licensed in our country, but is licensed by the authorities in EMA, US-FDA, Japan, Canada, South Korea, and Australia as specified in Article 2.1 of the technical specifications, tests may be performed in accordance with the OCABR guidelines by the TİTCK/Analysis and Control Laboratories Department. The inspection and acceptance process for products with suitable analyses can be completed. |  |  |  |
| **5.2.** | If there are any doubts regarding product safety within the scope of the cold chain or other matters specified in the technical specifications, new samples may be taken if necessary, and analyses may be performed as required, including analyses based on batch release. |  |  |  |
| **5.3.** | These products are subject to the *"Regulations on Market Surveillance and Control Procedures and Principles to be Implemented by the Ministry of Health*." GDPB reserves the right to conduct analyses in case of possible suspicion or complaint. The Contractor shall provide the required number of product doses for analysis and the materials required for the analysis specified in Article 5 free of charge. If the analysis result is found to be unsatisfactory, even if the product in question has been accepted, the Contractor shall deliver the same quantity from different series within 90 calendar days. |  |  |  |
| **5.4.** | If the product does not comply with Article 5.1, after the inspection is completed, a sample shall be taken from each batch using the random sampling method and delivered to the laboratory with a report signed by the Contractor's representative and one of the inspection members. |  |  |  |
| **5.5.** | Since the physical appearance of the products requires expertise, it shall be assessed by specialized personnel at the National Reference Laboratory within the TİTCK in accordance with the current Turkish/European Pharmacopoeia. Products that are not suitable in terms of physical appearance shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. After the physical tests of the products are found to be suitable, other tests shall be performed in accordance with Article 5. |  |  |  |
| **5.6.** | The vaccine shall comply with the characteristics and conditions specified in **World Health Organization** **(WHO) Technical Report Series** 980 Annex 4, Annex 5, Annex 6 979 Annex 4, 897 Annex 1,993 Annex 3, 1024 Annex 3, 978 Annex 4 and **European Pharmacopoeia** **11.0 07/2022:2067 and** **11.0 01/2020:2920 monograph** in terms of physical appearance and laboratory analyses. |  |  |  |
| **5.7.** | The Contractor shall deliver two reference vaccines free of charge for each batch, along with reagents and chemical materials deemed necessary for testing the potency and identity of the vaccine, to be used in conjunction with the vaccines to be tested. Additionally, for every four batches of the six-component (Hexavalent) combination vaccine to undergo quality control, the following shall be delivered:  Diphtheria – Tetanus Vaccine Potency and Identity Test:  Two diphtheria standard vaccines (in-house)  Two tetanus standard vaccines (in-house)  2 ml diphtheria toxin (in-house)  2 ml tetanus toxin (in-house)  Two Diphtheria Vaccine (Absorbed) (BRP or NIBSC)  Two Tetanus Vaccine (Absorbed) (BRP or NIBSC)  Diphtheria antitoxin for the flocculation test (NIBSC or BPR) (one unit is sufficient for each annual purchase quantity)  Tetanus antitoxin for the flocculation test (NIBSC or BPR) (one unit is sufficient for each annual purchase quantity)  Diphtheria toxin (NIBSC or BRP); (one unit is sufficient for each annual purchase quantity)  Tetanus toxin (one unit is sufficient for each annual purchase quantity)  For Potency Testing of the Acellular Pertussis Vaccine;  Lyophilised Acellular Pertussis Standard Vaccine; One (1) vial  Liquid Acellular Pertussis Standard Vaccine (0.5 mL / syringe (injector)): 5 mL  Ag FHA Glycerol 50%3 mL  Ag PT Glycerol 50% 4 mL  Ag PRN Glycerol 50% 3 mL  Calibration Standard (PT) 1.5 mL  Calibration Standard (FHA) 1.5 mL  Calibration Standard (PRN) 1.5 mL  Positive Control (PT) 1.5 mL  Positive Control (FHA) 1.5 mL  Positive Control (PRN) 1.5 mL  Pertussis Toxin (for histamine sensitivity test) 2 vials  Acellular pertussis International Standard Vaccine (NIBSC or BRP) (1 vial/10 series)  Bordetella pertussis, filamentous haemagglutinin (FHA) Antigen ELISA (NIBSC or BRP) (1 unit/10 series)  Bordetella pertussis 69kD-Pertactin (PRN) Antigen ELISA (NIBSC or BRP) (1 unit/10 series)  Calibration Standard (FHA, PT, PRN) (BRP) (2 units/10 series)  Positive Control (NIBSC or BRP) (1 unit/10 series)  For the Identity Test of the Acellular Pertussis Vaccine;  FHA Reference Antigen 0.5 mL  FHA Antiserum 0.5 mL  PT Reference Antigen 0.5 mL  PT Antiserum 0.5 mL  PRN Reference Antigen 0.5 mL  PRN Antiserum 0.5 mL  The aforementioned standards (NIBSC or BRP) (1 unit/20 series)  For IPV Vaccine Potency Test:  2 in-house standards  2 in-house validity control standards (in-house vaccine) 1.5 mL  Coating Antibody Type I 200 μL  Coating Antibody Type II 500 μL  Coating Antibody Type III 500 μL  Revelation Antibody Type I 200 μL  100 μL Type II Revelation Antibody  400 μL Type III Revelation Antibody  \*Quantities may vary depending on the concentration of the reagent and changes in its use in the SOP. For every 10 vaccine series, 2 vials (0.5 mL) Ph.Eur. Reference Standard Poliomyelitis Vaccine (Inactivated) Types 1, 2, 3 BRP.  For Hib vaccine PRP quantity determination and Identity Test:  2 PRP standards  100 μL Hib antiserum (NIBS or equivalent)  Hib antiserum (NIBSC or equivalent, 1 vial/10 series)  100 μL tetanus antiserum  2 positive controls  International RPR standard (NIBSC 02/2028 or equivalent, 1 vial/10 series) shall be supplied free of charge.  Two reference vaccines for the hepatitis B antigen, along with the necessary reagents and chemical materials to be used in the potency and identity testing of the vaccine, shall be delivered together with the vaccines to be tested. |  |  |  |
| **5.8.** | Where necessary, the same quantities of Standard Vaccine, Antigen, Antiserum, and other relevant standards and international standards shall be provided free of charge and promptly by the Contractor. |  |  |  |
| **5.8.1.** | Documents to be delivered to the laboratory with the product:  -Protocols related to production methods and processes, as well as quality control protocols,  -Standard Operating Procedure (SOP) documents related to the product's quality control tests, current validation reports, and validation procedure documents shall be provided with the product. |  |  |  |
| **5.8.2.** | If the reference vaccine and chemicals are imported from abroad, customs clearance procedures shall be carried out by the contractors. |  |  |  |
| **5.8.3.** | For each batch of vaccine delivered, the Contractor shall provide a sufficient number of samples free of charge for physical examination and laboratory analysis. |  |  |  |
| **5.8.4.** | If changes are made to the analysis methods, the standards and quantities requested from the Contractor may be re-evaluated. |  |  |  |
| **5.8.5.** | In addition, official documents (official certificates) containing the reference vaccine and/or reference unit values shall also be submitted. The reagents, chemical materials, detailed test SOPs (latest updated version), current validation and validation procedure documents, and calculation documents sent shall be delivered complete with the vaccines to be tested. |  |  |  |
| **5.9.** | If vaccines are prepared in vacuum-sealed ampoules/vials, and if the number of non-vacuum ampoules/vials exceeds 1% in the vacuum control performed on vaccine lot samples taken for inspection, the vaccine lot in question shall be rejected and returned due to the number of non-vacuum ampoules/vials. If the number of non-vacuum ampoules/vials is less than 1%, the vaccine supplier shall deliver the equivalent number of non-vacuum ampoules/vials free of charge within 120 calendar days from the date of notification by the General Directorate of Public Health to the supplier. |  |  |  |
| **5.10.** | Biological controls of products to be delivered shall be carried out at the Turkish Medicines and Medical Devices Agency, but in order to prevent interruption of vaccine and antiserum administration due to potential difficulties in the analysis process, a WHO-approved reference laboratory (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies) ([https://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)](http://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)) may also be conducted, and the costs shall be borne by the Contractor. The results of the control reports of the producer country shall be consistent with the results of the control reports of the Turkish Medicines and Medical Devices Agency or WHO-approved reference laboratories (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies). |  |  |  |
| **5.11.** | The Contractor may object to the results within 15 days. Upon such objection, product samples shall be sent to a second laboratory from among the WHO Reference Laboratories designated ex officio by GDPB or deemed appropriate by GDPB upon the Contractor's recommendation, with the shipping and analysis costs borne by the Contractor. If inconsistencies are detected following analyses conducted by WHO Reference Laboratories and the Turkish Medicines and Medical Devices Agency, the second report shall be accepted as the final report. |  |  |  |
| **6.** | **OTHER PROVISIONS** |  |  |  |
| **6.1.** | Due to delays caused by incorrect or incomplete materials and documents specified in Article 5, such as references, standards, and SOPs required for analysis, which are the responsibility of the contractor to deliver, the product's shelf life shall be shortened by the duration of the delay. The shelf life suitability specified in Article 4 shall be reduced by the duration of the delay. If the shelf life falls below the specified duration, return and exchange processes shall be initiated. For example, if the specification requires a minimum shelf life of 18 months upon delivery to the warehouse, but the product has a shelf life of 20 months at the time of delivery, and the SOP, references, etc. are delivered 70 days later due to a reason attributable to the contractor that prevented the completion of the analyses, the products shall be subject to processing due to shelf life non-compliance and shall be returned. |  |  |  |
| **6.2.** | Batches of products deemed unsuitable based on biological or chemical control results shall be returned. The contractor shall collect these products from the GDPB warehouse where they are located, transport them to the country of origin, and deliver the same quantity of products from a different batch that comply with the specifications to GDPB free of charge within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **6.3.** | In the event of product return (rejection or lot change), the products shall be collected from the warehouse within 30 calendar days after the notification date, during official working hours and days. If not collected, the contractor shall bear the storage and/or disposal costs for the delayed period. |  |  |  |
| **6.4.** | In the event that the products are returned to the Contractor, the relevant official documents proving that the products have been removed from Türkiye or destroyed shall be submitted to the administration within 120 calendar days after the products are collected from the warehouse. If no notification is made, the procedures shall be carried out in accordance with customs regulations. |  |  |  |
| **6.5.** | After acceptance of the products, if any physical deficiencies (barcode errors, packaging, labels, etc.) are detected, the contractor shall remedy the deficiency free of charge. |  |  |  |

| **LOT 2 - BACILLUS CALMETTE-GUERIN (BCG) VACCINE** | | | | |
| --- | --- | --- | --- | --- |
| **Item No** | **Specifications** | **Specifications Offered** | **Notes, remarks,  ref to documentation** | **Evaluation Committee’s notes** |
| **1.** | **VACCINE TECHNICAL SPECIFICATIONS** |  |  |  |
| **1.1.** | The product shall comply with vaccine production, quality control parameters, methods, and specifications in World Health Organization (WHO) Technical Report Series (TRS) No:979 annex 3, European Pharmacopoeia 11.0 Volume 1 Monograph 01/2012:0163 and the characteristics specified in the Communiqué No. 96/4 published in the Official Journal dated 16.01.1996 and numbered 22525. |  |  |  |
| **1.2.** | Vaccines shall be prepared from a freeze-dried strain of Calmette-Guerin origin using the Seed-Lot system. |  |  |  |
| **1.3.** | The vaccine dose shall be 0.05 ml for applications at "0" years of age (0-11 months) and 0.1 ml for older age groups. |  |  |  |
| **1.4.** | Depending on the strain used, 1 ml of vaccine shall contain live bacteria within the expected limits. |  |  |  |
| **1.5.** | Vaccines shall be supplied in dark-coloured vials or ampoules that do not allow light to pass through. |  |  |  |
| **1.6.** | The vaccine shall maintain its stability from the date of the manufacturer's last successful potency test until its expiration date at temperatures between (+) 2 °C and (+) 8 °C. |  |  |  |
| **2.** | **DOCUMENTS TO BE INCLUDED IN THE FILE TO BE REVIEWED BY THE TENDER COMMITTEE** |  |  |  |
| **2.1.** | The product in question;   * + 1. shall have a license issued by the Turkish Ministry of Health,     2. If it does not have a license issued by the Turkish Ministry of Health;   + It shall be included in the latest pre-qualification list published by the World Health Organization (<https://extranet.whoint/prequal/vaccines/prequalified-vaccines)> or,   + It shall have a license from the European Medicines Agency (EMA) and be manufactured in European Union countries, or   + It shall have a license from the US-FDA and be manufactured in the United States, or   + It shall be licensed by the Pharmaceuticals and Medical Devices Agency (PMDA) and manufactured in Japan, or   + It shall be licensed by the South Korean Food and Drug Administration and manufactured in South Korea, **or**   + It shall be licensed by the Canadian Food and Drugs Act and Regulations and manufactured in Canada, **or**   + The product shall be licensed by the Australian Department of Health Therapeutic Goods Administration and manufactured in Australia. |  |  |  |
| **2.2.** | The product shall be accompanied by a certificate (GMP certificate) showing that the factory producing it complies with the **good manufacturing practices (**GMP) standards approved by the State Control Agency of the country where the product is manufactured. If the product is filled or manufactured in our country, there shall be a document showing that the factory where the production/filling is carried out, approved by the Turkish Ministry of Health, Turkish Medicines and Medical Devices Agency, manufactures in accordance with good manufacturing practices (GMP) rules. |  |  |  |
| **2.3.** | For any batch produced within the last two years, the 'National Regulatory Authority' (NRA) or the Batch Release Certificate issued by the EMA (from the locations specified in the annex to the European Union's 2001/83/EC directive), US-FDA, Japan, South Korea, Canada, and Australian state authorities, as specified in 2.1. If the product is manufactured in Türkiye, it shall be a marketing authorization certificate issued by the Turkish Medicines and Medical Devices Agency of the Ministry of Health of the Republic of Türkiye. The analysis report for the same series shall also be included in the BRC annex. |  |  |  |
| **2.4.** | A valid Pharmaceutical Product Certificate (CPP) approved by the manufacturer's country authority. |  |  |  |
| **2.5.** | A **manufacturer-approved** document showing that the risk of Transmissible Spongiform Encephalopathy (TSE) has been minimized at every stage of the product's production. |  |  |  |
| **2.6.** | If the product is licensed in Türkiye, it shall have a "Summary of Product Characteristics" (SPC) or package insert or "Patient Information Leaflet" (PIL) approved by the Turkish Medicines and Medical Devices Agency (TİTCK), or if it is not licensed in Türkiye, it shall have one approved by the relevant country's authority, along with Turkish translations. |  |  |  |
| **2.7.** | If applicable, a list of tasks to be performed by subcontractors shall be provided. |  |  |  |
| **2.8.** | The tenderer shall declare in writing how many batches of the product they can deliver. |  |  |  |
| **2.9.** | If the product is used outside the country of manufacture, a document shall be submitted containing the list of countries where the product is used, approved by the manufacturer, along with the usage permits (import permits) or license numbers for these products, and information on the total number of doses used in countries other than the country of manufacture for the last two calendar years prior to the year of the tender. |  |  |  |
| **2.10.** | The tenderer shall declare that if the manufacturer or another country where the product is used suspends the use of the product for any reason, or if they receive any news in this regard, they shall inform the Ministry within 24 hours (product name, serial number, reason for discontinuation, etc.) and that if the information is not provided within 24 hours, the administration has the right to unilaterally terminate the contract. It also indicates that in the event of discontinuation of the product, after the unused products are collected by the Ministry and sent to the Central Warehouse, the Tenderer undertakes to bring a new product from a different series that complies with the specifications within 90 (ninety) calendar days from the date the replacement request is notified. In addition, the Tenderer shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date of notification of the product replacement request after the unused products are collected by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **2.11.** | The Tenderer shall submit the original or notarized copies of the required documents, along with their certified Turkish translations, to the tender committee. |  |  |  |
| **3.** | **DELIVERY OF PRODUCTS** |  |  |  |
| **3.1.** | If the products are imported, the tenderer's representative shall be present when the products are collected from customs and shall ensure that the goods are collected in accordance with the required specifications and delivered to the location deemed appropriate by GDPB without delay. |  |  |  |
| **3.2.** | The contractor shall provide the Department with the shipment details 3 days prior to the delivery date of the product. |  |  |  |
| **3.3.** | Product delivery shall be made in such a way that it does not coincide with holidays, official holidays, or the end of working hours in Türkiye. |  |  |  |
| **3.4.** | To clear products purchased by GDPB through customs, the Contractor shall enter the product information (batch certificate and quantity for the lot/serial number for which import permission is requested) via the Single Window Portal System (<https://uygulama.gtb.gov.tr/TekPencere>). The Single Window approval request shall be submitted to the Department electronically (to the Department's official e-mail address) or in writing at least 3 days in advance. Products purchased by the General Directorate of Public Health shall be delivered to the GDPB Vaccine and Drug Warehouse within 48 hours after being cleared through customs (except for products filled in Türkiye) if they are imported. Any changes required after the initial inspection (packaging, barcode, etc.) may also be made at the Central Vaccine and Drug Warehouse with the approval of the GDPB. If storage exceeds 48 hours, it is mandatory to submit temperature records approved by the Contractor's quality manager from the production site until the Ministry of Health Vaccine Storage arrives, to use a warehouse licensed by the Turkish Ministry of Health, and, if "temperature monitoring cards" are installed at the production facility, not to change them. After the contract is signed, if the packaging of the imported product (including barcoding) is to be changed at a different location, this situation shall be reported to the Department. The intermediate storage location shall be licensed by the Turkish Ministry of Health. The initial opening of the packaging of the product cleared through customs shall be carried out under the supervision of GDPB or its authorized personnel. The shipment and intermediate storage temperature records shall also be submitted during the inspection phase. GDPB may inspect this entire post-customs process at any time and on any day. Intermediate storage may be carried out if the application made to GDPB and the storage period are deemed appropriate. |  |  |  |
| **3.5.** | If the packaging of the imported product (including barcoding) is to be changed at a different location after the contract is signed, this situation shall be reported to the Department. The temporary storage location shall be licensed by the Turkish Ministry of Health, the initial opening of the packaging of the product withdrawn from customs shall be carried out under the supervision of GDPB or its authorized personnel, and the shipment and temporary storage temperature records shall also be submitted during the inspection phase. GDPB may inspect this entire process at any time and on any day after customs clearance. Intermediate storage shall be possible if the application made to GDPB and the storage period are found to be appropriate. For products imported prior to the signing of the contract, it is sufficient to submit approved storage temperature records documenting all processes and to document that the product has been kept in storage facilities licensed by the Ministry of Health until the delivery stage. |  |  |  |
| **3.6.** | Products filled in our country shall be delivered to the GDPB Vaccine and Drug Warehouse within 24 hours of leaving the filling facility. If the product is not delivered to the GDPB Vaccine and Drug Warehouse within 24 hours after leaving the filling facility and is to be stored in another warehouse, the organization performing the intermediate storage shall be licensed by the Turkish Ministry of Health, temperature records from the production site to the warehouse and within the warehouse shall be kept, and certified copies from the product quality representative shall be delivered to GDPB upon product delivery. These stages shall be open to inspection by GDPB if required. The Department shall be notified if temporary storage is required. Products shall not be accepted if the specified conditions cannot be met. |  |  |  |
| **3.7.** | If the products are filled/manufactured in Türkiye, the time limit specified in Article 3, except for 3.2 and 3.3, and the restrictions at shall not apply. |  |  |  |
| **4.** | **DOCUMENTS REQUIRED DURING INSPECTION AND PRODUCT CHARACTERISTICS** |  |  |  |
| **4.1.** | Products shall have a shelf life of at least 18 (eighteen) months from the date of delivery to our warehouse. |  |  |  |
| **4.1.1.** | **Documents required during the product inspection phase:**  The documents specified in Article 2 of the Technical Specifications and the documents specific to the delivered series/lot shall be submitted during the inspection stage. These documents are:   * Product License * Current GMP certificate for the production site, * Analysis report for the delivered batch (document containing information such as composition, analysis results, reference values, production/expiration dates, etc.), * BRC for the delivered batch, * Current Pharmaceutical Product Certificate (CPP) * TSE declaration (item 2.5), * List of tasks to be performed by subcontractors, * Package Insert or Prospectus or IFU (Article 2.6), * List of countries where the product is used and import permit/license number and the number of doses used in each country in the last two calendar years prior to the year of the offer (Article 2.9), * Commitment letter (Article 2.10). |  |  |  |
| **4.2.** | The Contractor, manufacturer or any other country where this product is used shall notify the Ministry within 24 hours if the use of the product is suspended for any reason or if they receive any information in this regard (product name, serial number, reason for discontinuation, etc.) and acknowledges that the administration has the right to unilaterally terminate the contract if such information is not provided within 24 hours. In the event of discontinuation of the product, the Contractor shall be required to bring a manufacturer-approved commitment letter to the Ministry within 90 (ninety) calendar days from the date the replacement request is notified to the Contractor. Additionally, the Contractor shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date the request for product replacement is notified, following the collection of unused products by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **4.3.** | Stability studies and results proving the actual shelf life of the product in question shall be submitted. If the product is filled or manufactured in our country and stability studies are still ongoing, the TİTCK-approved study results shall be submitted to the Department as they are completed. |  |  |  |
| **4.4.** | Along with the product, all technical documents required in the tender for the product (Good Manufacturing Practices, analysis report, SPC, certificates, etc.) and detailed SOP (may be provided in the original license), **stability results** (**showing real-time and accelerated stability shelf life**), product photos, and all documents containing technical information about the packaging (dimensions, volume, etc.) shall be submitted to the inspection commission in duplicate on CD/DVD/flash drive. Each heading shall be indicated with a separate folder name, and the relevant documents shall be found under the relevant folder. If deemed necessary, other documents and information related to the product may be requested in physical or digital form. |  |  |  |
| **4.5.** | Documents that do not change with each shipment shall be submitted once, with the first shipment. If deemed necessary, documents may be requested again. |  |  |  |
| **4.6.** | **Required Packaging Characteristics** |  |  |  |
| **4.6.1.** | Products shall be in single or multi-dose ampoules, vials, flacons, or ready-to-use syringes (injectors). Ready-to-use syringes (injectors), ampoules, or flacons shall be packaged in single or ten-packs. If products are packaged in ten-packs, there shall be foam, cardboard, plastic, or other separators to prevent breakage due to contact. If the product is packaged individually, the packages shall then be bundled in packs of ten. If diluents are separate, 5 additional diluents shall be delivered with every 1000 doses of vaccine. |  |  |  |
| **4.6.2.** | The inner and outer packaging of licensed products in Türkiye shall comply with the current "Regulation on Packaging Information, Instructions for Use, and Tracking of Human Medicinal Products" published by the Turkish Ministry of Health.  If the product is not licensed in our country, the inner packaging of the ready-to-use syringe (injector), ampoule, or vial shall bear, at a minimum, the manufacturer's and product name, dosage, amount of content per dose, method of administration (IM/IV/SC/ID, etc.), lot (batch) number, and expiration date, printed in indelible ink. The package shall also contain storage temperature information in addition to the inner packaging. The product package shall bear the statement "**Property of the Turkish Ministry of Health, NOT FOR SALE**.**"** |  |  |  |
| **4.6.3.** | Each product package shall contain at least one "Summary of Product Characteristics" (SPC) or Turkish package insert or "Patient Information Leaflet" (PIL) prepared in accordance with the "Regulation on the Packaging and Labelling of Human Medicinal Products" dated 25.04.2017 and numbered 30048. Additionally, the following text shall be added to the beginning of the “"Summary of Product Characteristics" (SPC)” or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention.  "In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration. For any questions or problems encountered in this regard, contact the Tuberculosis Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates***."*** |  |  |  |
| **4.6.4.** | The packages shall then be placed in boxes. The names and addresses of the manufacturer and representative company of the product, the name of the product, the lot number, the storage temperature, the expiration date, and the number of doses in the box shall be written on these boxes. If the products are packaged individually, ten packages shall be placed in each box. If the products are packaged in packs of ten, five packages shall be placed in each box. |  |  |  |
| **4.6.5.** | The packaging boxes shall be placed in styrofoam. The styrofoam shall then be placed inside cartons. The carton dimensions shall be 40X60X40 ±2 (Width, Length, Height) cm. A sufficient number of ice packs or gel packs, etc., shall be placed in the cartons. The ice packs or gel packs, etc.**,** placed in the cartons shall be **unfrozen and cooled**. If the products are not sensitive to freezing (lyophilized), dry ice or frozen ice packs or gel may be used during transport. The names and addresses of the manufacturer and representative company, the product name, serial number, storage temperature, expiration date, dose quantity in the carton, carton dimensions, and weight shall be written on these cartons. |  |  |  |
| **4.6.6.** | The boxes shall then be placed on pallets. The pallets shall be euro pallets (120cm±2cmx80cm±2cmx10-15cm). After the boxes are placed on the pallets, the height together with the pallet shall not exceed 2 (two) meters. The boxes may protrude from the pallet by a maximum of 5 cm. There shall be a maximum of 16 (sixteen) boxes on the pallet. |  |  |  |
| **4.6.7.** | There shall be a 2D barcode on the packages, boxes, cartons, and pallets. The barcode prepared for the ready-to-use syringe (injector) inside each individually packaged product (these barcodes shall also have HL7 and 97 breakdown values) shall be on the product's package. The packages shall then be tied in sets of ten, and the package label shall be affixed to a different area than the barcode affixed to each product. If the product is packaged in sets of ten, the barcode prepared for the ready-to-use syringe (injector) (these barcodes shall also have HL7 and 97 breakdown values) shall be placed inside the package, and the barcode corresponding to the package breakdown shall be on the package. For the information to be included in the barcode, the information specified in the Guide for Barcode Application to Vaccines, Antiserums, and Diluents published by the Turkish Ministry of Health shall be used as a basis, and any additional information required shall be determined by GDPB. **The barcode area for the dose shall be at least 12X12 mm in accordance with the Guide.** If GDPB makes changes to the system instead of the barcode, the contractor shall be obliged to comply with the requirements of the newly created system without requesting a price difference. |  |  |  |
| **4.6.8.** | Even after acceptance, if any faulty operations related to the barcode system are detected later, the costs of changing the product packaging and, if deemed necessary, collecting the products from the field shall be borne by the Contractor. If this process exceeds one-month, new products with a new expiration date may be requested at the request of the Department to avoid any problems related to the expiration date. |  |  |  |
| **4.6.9.** | **Temperature monitoring during transportation:** |  |  |  |
| **4.6.9.1.** | The freeze indicator, temperature monitoring card, and digital temperature recording devices used **shall be listed in the WHO "E006: Temperature monitoring devices"** (https://extranet.who.int/prequal/immunization-devices/prequalified/imd-products)**.** |  |  |  |
| **4.6.9.2.** | If the product(s) are sensitive to freezing, each box shall contain a freeze indicator. |  |  |  |
| **4.6.9.3.** | If the product(s) are sensitive to high temperatures, each box shall contain a temperature monitoring card **with the date it was activated and the name/code of the activator written on it**. |  |  |  |
| **4.6.9.4.** | If the product(s) are sensitive to both freezing and high temperatures, or if they are packaged together, each box shall contain both a freeze indicator and a temperature monitor card with the date of activation and the name/code of the activator written on it. |  |  |  |
| **4.6.9.5.** | In addition, each pallet shall have an electronic, temperature, and freeze-sensitive digital monitor capable of long-term recording. The electronic, temperature, and freeze-sensitive digital monitors capable of long-term recording placed on the pallet shall be read during the inspection phase, the outputs shall be recorded in a report and signed by the company, and if there are no deviations, they can be filed electronically. If requested by the company, these devices shall be returned for storage without destruction for at least three months. Upon return, the pallet numbers and device serial numbers shall be recorded in a report.  If the pallets consist of insulated boxes, each containing heat tracking material (such as a digital recording device, heat monitoring card, or freeze indicator), and conflicting results are found between the digital heat records on or inside the pallet and the heat records inside the box when evaluating the heat records, the temperature monitoring results inside the boxes shall be taken into account when processing. |  |  |  |
| **4.6.9.6.** | Products found not to have been transported under appropriate conditions (temperature limits according to World Health Organization publication WHO/IVB/05.23 for vaccines) as monitored by these heat trackers shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **4.6.10.** | Each product shall be delivered with a Material Safety Data Sheet (MSDS). The contractor is responsible for the transportation, packaging, and labeling of hazardous materials. |  |  |  |
| **4.6.11.** | The contractor's representative shall be present during the delivery or return of the products. The representative shall submit a letterhead, stamped, and signed authorization document belonging to the contractor and a photocopy of their photo ID to the Warehouse Manager. The contractor is responsible for unloading the products from the vehicle into the warehouse or loading them back onto the vehicle for return. A list of the names, telephone numbers, and addresses of all employees and subcontractor personnel who shall perform work on behalf of the contractor shall be submitted to the Warehouse Manager, signed by the contractor's representative, prior to unloading. The contractor shall be responsible for any damage that may be caused to the warehouse or equipment and for all liabilities arising from "Occupational Health and Safety Regulations." The contractor shall submit a stamped and signed commitment stating that it has assumed the SSI, occupational health and safety, and work accident liabilities of its employees for unloading the products from the vehicle or loading them in case of return, and that it has assumed the liability for compensation in case of damage to the warehouse or any equipment inside the warehouse. Responsibility begins upon entry into the warehouse area after the security check. |  |  |  |
| **4.6.12.** | Except in emergencies, no contractor employees other than the vehicle drivers and those declared shall enter the climate-controlled warehouse. |  |  |  |
| **4.6.13.** | If barcoding, packaging, or prospectus changes are to be performed in the GDPB warehouse, the documents belonging to the subcontractors shall be as follows:   * + - * shall be a contract demonstrating the availability of occupational safety expertise and workplace physician support services as required by the "Occupational Health and Safety Law" No. 6331.       * The contractor's structure shall include at least one coordinator, one operations manager, one quality control and GMP manager, and one warehouse manager. These personnel shall be present during the execution of the work. There shall be a document or documents proving that the personnel included in the company structure have received GMP and Good Warehouse Practices Training organized by the Turkish Ministry of Health or an organization that has received a GMP Certificate from the Turkish Ministry of Health.       * There shall be standard operating procedures (SOPs) prepared by a pharmacist and approved by the company representative, covering barcode printing and affixing procedures and cold storage room operating rules. |  |  |  |
| **5.** | **DOCUMENTS AND MATERIALS REQUIRED FOR LABORATORY ANALYSES AND METHODS TO BE FOLLOWED** |  |  |  |
| **5.1.** | **General principles of product safety;**  The analysis reports for the product are part of the batch release certificate, and both documents shall be considered together in the evaluations. |  |  |  |
| **5.1.1.** | The product shall be manufactured in our country, have a manufacturing license from the Turkish Medicines and Medical Devices Agency (TİTCK), and present the SBB certificate for the delivered batch obtained from the TİTC/Analysis and Control Laboratories Department. In addition, if there is no break in the cold chain during product transfer, the physical examination is appropriate, and the commission grants approval, the inspection acceptance process can be completed. |  |  |  |
| **5.1.2.** | If the product is manufactured outside our country and has an import license from TİTCK or is on the WHO's prequalification list (Prequalified vaccines), the Series Batch Certificate for the delivered series shall be obtained from WHO/ Reference Laboratories/institutions, provided that the analyses are performed in accordance with the OCABR guidelines at the TİTCK/Analysis and Control Laboratories Directorate. The inspection acceptance process for products found to be suitable through analysis can be completed. |  |  |  |
| **5.1.3.** | If the product is not licensed in our country, but is licensed by the authorities in EMA, US-FDA, Japan, Canada, South Korea, and Australia as specified in Article 2.1 of the technical specifications, tests may be performed in accordance with the OCABR guidelines by the TİTCK/Analysis and Control Laboratories Department. The inspection and acceptance process for products with suitable analyses can be completed. |  |  |  |
| **5.2.** | If there are any doubts regarding product safety within the scope of the cold chain or other matters specified in the technical specifications, new samples may be taken if necessary, and analyses may be performed as required, including analyses based on batch release. |  |  |  |
| **5.3.** | These products are subject to the *"Regulations on Market Surveillance and Control Procedures and Principles to be Implemented by the Ministry of Health*." GDPB reserves the right to conduct analyses in case of possible suspicion or complaint. The Contractor shall provide the required number of product doses for analysis and the materials required for the analysis specified in Article 5 free of charge. If the analysis result is found to be unsatisfactory, even if the product in question has been accepted, the Contractor shall deliver the same quantity from different series within 90 calendar days. |  |  |  |
| **5.4.** | If the product does not comply with Article 5.1, after the inspection is completed, a sample shall be taken from each batch using the random sampling method and delivered to the laboratory with a report signed by the Contractor's representative and one of the inspection members. |  |  |  |
| **5.5.** | Since the physical appearance of the products requires expertise, it shall be assessed by specialized personnel at the National Reference Laboratory within the TİTCK in accordance with the current Turkish/European Pharmacopoeia. Products that are not suitable in terms of physical appearance shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. After the physical tests of the products are found to be suitable, other tests shall be performed in accordance with Article 5. |  |  |  |
| **5.6.** | The vaccine shall comply with the characteristics and conditions specified in European Pharmacopoeia 11.0 01/2020:20920 monograph in terms of physical appearance and laboratory analyses. |  |  |  |
| **5.7.** | The tenderer shall send 1 vial/ampoule of BCG in-house standard vaccine free of charge for each of the two lots requested, along with the products. |  |  |  |
| **5.8.** | The tenderer shall send 1 vial/ampoule of BCG in-house standard vaccine free of charge with the products for each of the two lots requested. |  |  |  |
| **5.9.** | Where necessary, the same quantities of Standard Vaccine, Antigen, Antiserum, and other relevant standards and international standards shall be provided free of charge and promptly by the Contractor. |  |  |  |
| **5.10.** | Documents to be delivered to the laboratory with the product: |  |  |  |
| **5.10.1.** | Protocols related to production methods and processes, as well as quality control protocols,  -Standard Operating Procedure (SOP) documents related to the product's quality control tests, current validation reports, and validation procedure documents shall be provided with the product. |  |  |  |
| **5.10.2.** | If the reference vaccine and chemicals are imported from abroad, customs clearance procedures shall be carried out by the contractors. |  |  |  |
| **5.10.3.** | For each batch of vaccine delivered, the Contractor shall provide a sufficient number of samples free of charge for physical examination and laboratory analysis. |  |  |  |
| **5.10.4.** | If changes are made to the analysis methods, the standards and quantities requested from the Contractor may be reevaluated. |  |  |  |
| **5.10.5.** | In addition, official documents (official certificates) containing the reference vaccine and/or reference unit values shall also be submitted. The reagents, chemical materials, detailed test SOPs (latest updated version), current validation and validation procedure documents, and calculation documents sent shall be delivered complete with the vaccines to be tested. |  |  |  |
| **5.11.** | If vaccines are prepared in vacuum-sealed ampoules/vials, and if the number of non-vacuum ampoules/vials exceeds 1% in the vacuum control performed on vaccine lot samples taken for inspection, the vaccine lot in question shall be rejected and returned due to the number of non-vacuum ampoules/vials. If the number of non-vacuum ampoules/vials is less than 1%, the vaccine supplier shall deliver the equivalent number of non-vacuum ampoules/vials free of charge within 120 calendar days from the date of notification by the General Directorate of Public Health to the supplier. |  |  |  |
| **5.12.** | Biological controls of products to be delivered shall be carried out at the Turkish Medicines and Medical Devices Agency, but in order to prevent interruption of vaccine and antiserum administration due to potential difficulties in the analysis process, a WHO-approved reference laboratory (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies) ([https://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)](http://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)) may also be conducted, and the costs shall be borne by the Contractor. The results of the control reports of the producer country shall be consistent with the results of the control reports of the Turkish Medicines and Medical Devices Agency or WHO-approved reference laboratories (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies). |  |  |  |
| **5.13.** | The Contractor may object to the results within 15 days. Upon such objection, product samples shall be sent to a second laboratory from among the WHO Reference Laboratories designated ex officio by GDPB or deemed appropriate by GDPB upon the Contractor's recommendation, with the shipping and analysis costs borne by the Contractor. If inconsistencies are detected following analyses conducted by WHO Reference Laboratories and the Turkish Medicines and Medical Devices Agency, the second report shall be accepted as the final report. |  |  |  |
| **6.** | **OTHER PROVISIONS** |  |  |  |
| **6.1.** | Due to delays caused by incorrect or incomplete materials and documents specified in Article 5, such as references, standards, and SOPs required for analysis, which are the responsibility of the contractor to deliver, the product's shelf life shall be shortened by the duration of the delay. The shelf life suitability specified in Article 4 shall be reduced by the duration of the delay. If the shelf life falls below the specified duration, return and exchange processes shall be initiated. For example, if the specification requires a minimum shelf life of 18 months upon delivery to the warehouse, but the product has a shelf life of 20 months at the time of delivery, and the SOP, references, etc. are delivered 70 days later due to a reason attributable to the contractor that prevented the completion of the analyses, the products shall be subject to processing due to shelf life non-compliance and shall be returned. |  |  |  |
| **6.2.** | Batches of products deemed unsuitable based on biological or chemical control results shall be returned. The contractor shall collect these products from the GDPB warehouse where they are located, transport them to the country of origin, and deliver the same quantity of products from a different batch that comply with the specifications to GDPB free of charge within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **6.3.** | In the event of product return (rejection or lot change), the products shall be collected from the warehouse within 30 calendar days after the notification date, during official working hours and days. If not collected, the contractor shall bear the storage and/or disposal costs for the delayed period. |  |  |  |
| **6.4.** | In the event that the products are returned to the Contractor, the relevant official documents proving that the products have been removed from Türkiye or destroyed shall be submitted to the administration within 120 calendar days after the products are collected from the warehouse. If no notification is made, the procedures shall be carried out in accordance with customs regulations. |  |  |  |
| **6.5.** | After acceptance of the products, if any physical deficiencies (barcode errors, packaging, labels, etc.) are detected, the contractor shall remedy the deficiency free of charge. |  |  |  |

| **LOT 3 - ORAL POLIO (OPV) VACCINE** | | | | |
| --- | --- | --- | --- | --- |
| **Item No** | **Specifications** | **Specifications Offered** | **Notes, remarks,  ref to documentation** | **Evaluation Committee’s notes** |
| **1.** | **VACCINE TECHNICAL SPECIFICATIONS** |  |  |  |
| **1.1.** | Vaccine production, quality control parameters, methods, and specifications comply with World Health Organization (WHO) Technical Report Series No:980 annex 2, European Pharmacopoeia 10.0 and Monograph 10.0 01/2020 and 01/2020:20920. |  |  |  |
| **1.2.** | The vaccine shall be of the Sabin type, live attenuated, bivalent (Type 1 and Type 3). |  |  |  |
| **1.3.** | Each dose of the vaccine shall contain at least 106 TCID50 Type 1 and 105.5 TCID50 Type 3 polio vaccine virus. |  |  |  |
| **1.4.** | The vaccine shall contain MgCl₂ or another substance as a stabiliser. |  |  |  |
| **1.5.** | The product shall maintain its stability for at least two years at -20°C from the date of the manufacturer's last successful potency control. |  |  |  |
| **1.6.** | Vaccines shall be packaged in vials or tubes containing single, 10 or a maximum of 20 doses. |  |  |  |
| **2.** | **DOCUMENTS TO BE INCLUDED IN THE FILE TO BE REVIEWED BY THE TENDER COMMITTEE** |  |  |  |
| **2.1.** | The product in question;   * + 1. shall have a license issued by the Turkish Ministry of Health,     2. If it does not have a license issued by the Turkish Ministry of Health;   + It shall be included in the latest pre-qualification list published by the World Health Organization (<https://extranet.whoint/prequal/vaccines/prequalified-vaccines)> or,   + It shall have a license from the European Medicines Agency (EMA) and be manufactured in European Union countries, or   + It shall have a license from the US-FDA and be manufactured in the United States, **or**   + It shall be licensed by the Pharmaceuticals and Medical Devices Agency (PMDA) and manufactured in Japan, or   + It shall be licensed by the South Korean Food and Drug Administration and manufactured in South Korea, **or**   + It shall be licensed by the Canadian Food and Drugs Act and Regulations and manufactured in Canada, **or**   + The product shall be licensed by the Australian Department of Health Therapeutic Goods Administration and manufactured in Australia. |  |  |  |
| **2.2.** | The product shall be accompanied by a certificate (GMP certificate) showing that the factory producing it complies with the **good manufacturing practices (**GMP) standards approved by the State Control Agency of the country where the product is manufactured. If the product is filled or manufactured in our country, there shall be a document showing that the factory where the production/filling is carried out, approved by the Turkish Ministry of Health, Turkish Medicines and Medical Devices Agency, manufactures in accordance with good manufacturing practices (GMP) rules. |  |  |  |
| **2.3.** | For any batch produced within the last two years, the 'National Regulatory Authority' (NRA) or the Batch Release Certificate issued by the EMA (from the locations specified in the annex to the European Union's 2001/83/EC directive), US-FDA, Japan, South Korea, Canada, and Australian state authorities, as specified in 2.1. If the product is manufactured in Türkiye, it shall be a marketing authorization certificate issued by the Turkish Medicines and Medical Devices Agency of the Ministry of Health of the Republic of Türkiye. The analysis report for the same series shall also be included in the BRC annex. |  |  |  |
| **2.4.** | A valid Pharmaceutical Product Certificate (CPP) approved by the manufacturer's country authority. |  |  |  |
| **2.5.** | A **manufacturer-approved** document showing that the risk of Transmissible Spongiform Encephalopathy (TSE) has been minimized at every stage of the product's production. |  |  |  |
| **2.6.** | If the product is licensed in Türkiye, it shall have a "Summary of Product Characteristics" (SPC) or package insert or "Patient Information Leaflet" (PIL) approved by the Turkish Medicines and Medical Devices Agency (TİTCK), or if it is not licensed in Türkiye, it shall have one approved by the relevant country's authority, along with Turkish translations. |  |  |  |
| **2.7.** | If applicable, a list of tasks to be performed by subcontractors shall be provided. |  |  |  |
| **2.8.** | The tenderer shall declare in writing how many batches of the product they can deliver. |  |  |  |
| **2.9.** | If the product is used outside the country of manufacture, a document shall be submitted containing the list of countries where the product is used, approved by the manufacturer, along with the usage permits (import permits) or license numbers for these products, and information on the total number of doses used in countries other than the country of manufacture for the last two calendar years prior to the year of the tender. |  |  |  |
| **2.10.** | The tenderer shall declare that if the manufacturer or another country where the product is used suspends the use of the product for any reason, or if they receive any news in this regard, they shall inform the Ministry within 24 hours (product name, serial number, reason for discontinuation, etc.) and that if the information is not provided within 24 hours, the administration has the right to unilaterally terminate the contract. It also indicates that in the event of discontinuation of the product, after the unused products are collected by the Ministry and sent to the Central Warehouse, the Tenderer undertakes to bring a new product from a different series that complies with the specifications within 90 (ninety) calendar days from the date the replacement request is notified. In addition, the Tenderer shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date of notification of the product replacement request after the unused products are collected by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **2.11.** | The Tenderer shall submit the original or notarized copies of the required documents, along with their certified Turkish translations, to the tender committee. |  |  |  |
| **3.** | **DELIVERY OF PRODUCTS** |  |  |  |
| **3.1.** | If the products are imported, the tenderer's representative shall be present when the products are collected from customs and shall ensure that the goods are collected in accordance with the required specifications and delivered to the location deemed appropriate by GDPB without delay. |  |  |  |
| **3.2.** | The contractor shall provide the Department with the shipment details 3 days prior to the delivery date of the product. |  |  |  |
| **3.3.** | Product delivery shall be made in such a way that it does not coincide with holidays, official holidays, or the end of working hours in Türkiye. |  |  |  |
| **3.4.** | To clear products purchased by GDPB through customs, the Contractor shall enter the product information (batch release certificate and quantity for the lot/serial number for which import permission is requested) via the Single Window Portal System (<https://uygulama.gtb.gov.tr/TekPencere>). The Single Window approval request shall be submitted to the Department electronically (to the Department's official e-mail address) or in writing at least 3 days in advance. Products purchased by the General Directorate of Public Health shall be delivered to the GDPB Vaccine and Drug Warehouse within 48 hours after being cleared through customs (except for products filled in Türkiye) if they are imported. Any changes required after the initial inspection (packaging, barcode, etc.) may also be made at the Central Vaccine and Drug Warehouse with the approval of the GDPB. If storage exceeds 48 hours, it is mandatory to submit temperature records approved by the Contractor's quality manager from the production site until the Ministry of Health Vaccine Storage arrives, to use a warehouse licensed by the Turkish Ministry of Health, and, if "temperature monitoring cards" are installed at the production facility, not to change them. |  |  |  |
| **3.5.** | If the packaging of the imported product (including barcoding) is to be changed at a different location after the contract is signed, this situation shall be reported to the Department. The temporary storage location shall be licensed by the Turkish Ministry of Health, the initial opening of the packaging of the product withdrawn from customs shall be carried out under the supervision of GDPB or its authorized personnel, and the shipment and temporary storage temperature records shall also be submitted during the inspection phase. GDPB may inspect this entire process at any time and on any day after customs clearance. Intermediate storage shall be possible if the application made to GDPB and the storage period are found to be appropriate. For products imported prior to the signing of the contract, it is sufficient to submit approved storage temperature records documenting all processes and to document that the product has been kept in storage facilities licensed by the Ministry of Health until the delivery stage. |  |  |  |
| **3.6.** | Products filled in our country shall be delivered to the GDPB Vaccine and Drug Warehouse within 24 hours of leaving the filling facility. If the product is not delivered to the GDPB Vaccine and Drug Warehouse within 24 hours after leaving the filling facility and is to be stored in another warehouse, the organization performing the intermediate storage shall be licensed by the Turkish Ministry of Health, temperature records from the production site to the warehouse and within the warehouse shall be kept, and certified copies from the product quality representative shall be delivered to GDPB upon product delivery. These stages shall be open to inspection by GDPB if required. The Department shall be notified if temporary storage is required. Products shall not be accepted if the specified conditions cannot be met. |  |  |  |
| **3.7.** | If the products are filled/manufactured in Türkiye, the time limit specified in Article 3, except for 3.2 and 3.3, and the restrictions at shall not apply. |  |  |  |
| **4.** | **DOCUMENTS REQUIRED DURING INSPECTION AND PRODUCT CHARACTERISTICS** |  |  |  |
| **4.1.** | Products shall have a shelf life of at least 18 (eighteen) months from the date of delivery to our warehouse. |  |  |  |
| **4.1.1.** | **Documents required during the product inspection phase:**  The documents specified in Article 2 of the Technical Specifications and the documents specific to the delivered series/lot shall be submitted during the inspection stage. These documents are:   * Product License * Current GMP certificate for the production site, * Analysis report for the delivered batch (document containing information such as composition, analysis results, reference values, production/expiration dates, etc.), * BRC for the delivered batch, * Current Pharmaceutical Product Certificate (CPP) * TSE declaration (item 2.5), * List of tasks to be performed by subcontractors, * Package Insert or Prospectus or IFU (Article 2.6), * List of countries where the product is used and import permit/license number and the number of doses used in each country in the last two calendar years prior to the year of the offer (Article 2.9), * Commitment letter (Article 2.10). |  |  |  |
| **4.2.** | The Contractor, manufacturer or any other country where this product is used shall notify the Ministry within 24 hours if the use of the product is suspended for any reason or if they receive any information in this regard (product name, serial number, reason for discontinuation, etc.) and acknowledges that the administration has the right to unilaterally terminate the contract if such information is not provided within 24 hours. In the event of discontinuation of the product, the Contractor shall be required to bring a manufacturer-approved commitment letter to the Ministry within 90 (ninety) calendar days from the date the replacement request is notified to the Contractor. Additionally, the Contractor shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date the request for product replacement is notified, following the collection of unused products by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **4.3.** | Stability studies and results proving the actual shelf life of the product in question shall be submitted. If the product is filled or manufactured in our country and stability studies are still ongoing, the TİTCK-approved study results shall be submitted to the Department as they are completed. |  |  |  |
| **4.4.** | Along with the product, all technical documents required in the tender for the product (Good Manufacturing Practices, analysis report, SPC, certificates, etc.) and detailed SOP (may be provided in the original license), **stability results (showing real-time and accelerated stability shelf life),** product photos, and all documents containing technical information about the packaging (dimensions, volume, etc.) shall be submitted to the inspection commission in duplicate on CD/DVD/flash drive. Each heading shall be indicated with a separate folder name, and the relevant documents shall be found under the relevant folder. If deemed necessary, other documents and information related to the product may be requested in physical or digital form. |  |  |  |
| **4.5.** | Documents that do not change with each shipment shall be submitted once, with the first shipment. If deemed necessary, documents may be requested again. |  |  |  |
| **4.6.** | **Required Packaging Characteristics** |  |  |  |
| **4.6.1.** | The product shall be packaged in vials or tubes containing a single dose, 10 doses, or a maximum of 20 doses. If the products are packaged in packs of ten, the packs shall contain foam or cardboard separators to prevent the vials or ampoules from breaking due to contact. If the product is packaged individually, the packages shall then be bundled in packs of ten. Vaccine droppers shall also be supplied in packs of ten in sterile blister packs or packages. The company shall supply an additional 2% of vaccine droppers in excess of the purchased vial or tube quantity. |  |  |  |
| **4.6.2.** | The inner and outer packaging of licensed products in Türkiye shall comply with the current "Regulation on Packaging Information, Instructions for Use, and Tracking of Human Medicinal Products" published by the Turkish Ministry of Health. If the product is not licensed in our country, the inner packaging of the ready-to-use syringe (injector), ampoule, or vial shall bear, at a minimum, the manufacturer's and product name, dosage, amount of content per dose, method of administration (IM/IV/SC/ID, etc.), lot (batch) number, and expiration date, printed in indelible ink. The package shall also contain storage temperature information in addition to the inner packaging. The product package shall bear the statement **"Property of the Turkish Ministry of Health, NOT FOR SALE."** |  |  |  |
| **4.6.3.** | Each product package shall contain at least one "Summary of Product Characteristics" (SPC) or Turkish package insert or "Patient Information Leaflet" (PIL) prepared in accordance with the "Regulation on the Packaging and Labelling of Human Medicinal Products" dated 25.04.2017 and numbered 30048. Additionally, the following text shall be added to the beginning of the “"Summary of Product Characteristics" (SPC)” or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention: "In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration. For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates***."*** |  |  |  |
| **4.6.4.** | The packages shall then be placed in boxes. The names and addresses of the manufacturer and representative company of the product, the name of the product, the lot number, the storage temperature, the expiration date, and the number of doses in the box shall be written on these boxes. If the products are packaged individually, ten packages shall be placed in each box. If the products are packaged in packs of ten, five packages shall be placed in each box. |  |  |  |
| **4.6.5.** | The packaging boxes shall be placed in styrofoam. The styrofoam shall then be placed inside cartons. The carton dimensions shall be 40X60X40 ±20 (Width, Length, Height) cm. A sufficient number of ice packs or gel packs, etc., shall be placed in the cartons. The ice packs or gel packs, etc.**,** placed in the cartons shall be **unfrozen and cooled**. If the products are not sensitive to freezing (lyophilized), dry ice or frozen ice packs or gel may be used during transport. The names and addresses of the manufacturer and representative company, the product name, serial number, storage temperature, expiration date, dose quantity in the carton, carton dimensions, and weight shall be written on these cartons. |  |  |  |
| **4.6.6.** | The boxes shall then be placed on pallets. The pallets shall be euro pallets (120cm±2cmx80cm±2cmx10-15cm). After the boxes are placed on the pallets, the height together with the pallet shall not exceed 2 (two) meters. The boxes may protrude from the pallet by a maximum of 5 cm. There shall be a maximum of 16 (sixteen) boxes on the pallet. |  |  |  |
| **4.6.7.** | There shall be a 2D barcode on the packages, boxes, cartons, and pallets. The barcode prepared for the ready-to-use syringe (injector) inside each individually packaged product (these barcodes shall also have HL7 and 97 breakdown values) shall be on the product's package. The packages shall then be tied in sets of ten, and the package label shall be affixed to a different area than the barcode affixed to each product. If the product is packaged in sets of ten, the barcode prepared for the ready-to-use syringe (injector) (these barcodes shall also have HL7 and 97 breakdown values) shall be placed inside the package, and the barcode corresponding to the package breakdown shall be on the package. For the information to be included in the barcode, the information specified in the Guide for Barcode Application to Vaccines, Antiserums, and Diluents published by the Turkish Ministry of Health shall be used as a basis, and any additional information required shall be determined by GDPB. **The barcode area for the dose shall be at least 12X12 mm in accordance with the Guide**. If GDPB makes changes to the system instead of the barcode, the contractor shall be obliged to comply with the requirements of the newly created system without requesting a price difference. |  |  |  |
| **4.6.8.** | Even after acceptance, if any faulty operations related to the barcode system are detected later, the costs of changing the product packaging and, if deemed necessary, collecting the products from the field shall be borne by the Contractor. If this process exceeds one-month, new products with a new expiration date may be requested at the request of the Department to avoid any problems related to the expiration date. |  |  |  |
| **4.6.9.** | **Temperature monitoring during transportation:** |  |  |  |
| **4.6.9.1.** | The freeze indicator, temperature monitoring card, and digital temperature recording devices used **shall be listed in the WHO "E006: Temperature monitoring devices"** (https://extranet.who.int/prequal/immunization-devices/prequalified/imd-products)**.** |  |  |  |
| **4.6.9.2.** | If the product(s) are sensitive to freezing, each box shall contain a freeze indicator. |  |  |  |
| **4.6.9.3.** | If the product(s) are sensitive to high temperatures, each box shall contain a temperature monitoring card **with the date it was activated and the name/code of the activator written on it**. |  |  |  |
| **4.6.9.4.** | If the product(s) are sensitive to both freezing and high temperatures, or if they are packaged together, each box shall contain both a freeze indicator and a temperature monitor card with the date of activation and the name/code of the activator written on it. |  |  |  |
| **4.6.9.5.** | In addition, each pallet shall have an electronic, temperature, and freeze-sensitive digital monitor capable of long-term recording. The electronic, temperature, and freeze-sensitive digital monitors capable of long-term recording placed on the pallet shall be read during the inspection phase, the outputs shall be recorded in a report and signed by the company, and if there are no deviations, they can be filed electronically. If requested by the company, these devices shall be returned for storage without destruction for at least three months. Upon return, the pallet numbers and device serial numbers shall be recorded in a report.  If the pallets consist of insulated boxes, each containing heat tracking material (such as a digital recording device, heat monitoring card, or freeze indicator), and conflicting results are found between the digital heat records on or inside the pallet and the heat records inside the box when evaluating the heat records, the temperature monitoring results inside the boxes shall be taken into account when processing. |  |  |  |
| **4.6.9.6.** | Products found not to have been transported under appropriate conditions (Guidelines for th international packaging and shipping of vaccines, sixth edition. Geneva: World Health Organization; 2020. Licence: BY-NC-SA 3.0 IGO) as monitored by these heat trackers shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **4.6.10.** | Each product shall be delivered with a Material Safety Data Sheet (MSDS). The contractor is responsible for the “Transportation, packaging, and labelling of hazardous materials” and completing any shortfalls if there is any. |  |  |  |
| **4.6.11.** | The contractor's representative shall be present during the delivery or return of the products. The representative shall submit a letterhead, stamped, and signed authorization document belonging to the contractor and a photocopy of their photo ID to the Warehouse Manager. The contractor is responsible for unloading the products from the vehicle into the warehouse or loading them back onto the vehicle for return. A list of the names, telephone numbers, and addresses of all employees and subcontractor personnel who shall perform work on behalf of the contractor shall be submitted to the Warehouse Manager, signed by the contractor's representative, prior to unloading. The contractor shall be responsible for any damage that may be caused to the warehouse or equipment and for all liabilities arising from "Occupational Health and Safety Regulations." The contractor shall submit a stamped and signed commitment stating that it has assumed the SSI, occupational health and safety, and work accident liabilities of its employees for unloading the products from the vehicle or loading them in case of return, and that it has assumed the liability for compensation in case of damage to the warehouse or any equipment inside the warehouse. Responsibility begins upon entry into the Warehouse area after the security check. |  |  |  |
| **4.6.12.** | Except in emergencies, no contractor employees other than the vehicle drivers and those declared shall enter the climate-controlled warehouse. |  |  |  |
| **4.6.13.** | If barcoding, packaging, or prospectus changes are to be performed in the GDPB warehouse, the documents belonging to the subcontractors shall be as follows:   * + - * shall be a contract demonstrating the availability of occupational safety expertise and workplace physician support services as required by the "Occupational Health and Safety Law" No. 6331.       * The contractor's structure shall include at least one coordinator, one operations manager, one quality control and GMP manager, and one warehouse manager. These personnel shall be present during the execution of the work. There shall be a document or documents proving that the personnel included in the company structure have received GMP and Good Warehouse Practices Training organized by the Turkish Ministry of Health or an organization that has received a GMP Certificate from the Turkish Ministry of Health.       * There shall be standard operating procedures (SOPs) prepared by a pharmacist and approved by the company representative, covering barcode printing and affixing procedures and cold storage room operating rules. |  |  |  |
| **5.** | **DOCUMENTS AND MATERIALS REQUIRED FOR LABORATORY ANALYSES AND METHODS TO BE FOLLOWED** |  |  |  |
| **5.1.** | **General principles of product safety;**  The analysis reports for the product are part of the batch release certificate, and both documents shall be considered together in the evaluations. |  |  |  |
| **5.1.1.** | The product shall be manufactured in our country, have a manufacturing license from the Turkish Medicines and Medical Devices Agency (TİTCK), and present the BRC certificate for the delivered batch obtained from the TİTCK/Analysis and Control Laboratories Department. In addition, if there is no break in the cold chain during product transfer, the physical examination is appropriate, and the commission grants approval, the inspection acceptance process can be completed. |  |  |  |
| **5.1.2.** | If the product is manufactured outside our country and has an import license from TİTCK or is on the WHO's prequalification list (Prequalified vaccines), the Batch Release Certificate for the delivered series shall be obtained from WHO/ Reference Laboratories/institutions, provided that the analyses are performed in accordance with the OCABR guidelines at the TİTCK/Analysis and Control Laboratories Directorate. The inspection acceptance process for products found to be suitable through analysis can be completed. |  |  |  |
| **5.1.3.** | If the product is not licensed in our country, but is licensed by the authorities in EMA, US-FDA, Japan, Canada, South Korea, and Australia as specified in Article 2.1 of the technical specifications, tests may be performed in accordance with the OCABR guidelines by the TİTCK/Analysis and Control Laboratories Department. The inspection and acceptance process for products with suitable analyses can be completed. |  |  |  |
| **5.2.** | If there are any doubts regarding product safety within the scope of the cold chain or other matters specified in the technical specifications, new samples may be taken if necessary, and analyses may be performed as required, including analyses based on batch release. |  |  |  |
| **5.3.** | These products are subject to the *"Regulations on Market Surveillance and Control Procedures and Principles to be Implemented by the Ministry of Health*." GDPB reserves the right to conduct analyses in case of possible suspicion or complaint. The Contractor shall provide the required number of product doses for analysis and the materials required for the analysis specified in Article 5 free of charge. If the analysis result is found to be unsatisfactory, even if the product in question has been accepted, the Contractor shall deliver the same quantity from different series within 90 calendar days. |  |  |  |
| **5.4.** | If the product does not comply with Article 5.1, after the inspection is completed, a sample shall be taken from each batch using the random sampling method and delivered to the laboratory with a report signed by the Contractor's representative and one of the inspection members. |  |  |  |
| **5.5.** | Since the physical appearance of the products requires expertise, it shall be assessed by specialized personnel at the National Reference Laboratory within the TİTCK in accordance with the current Turkish/European Pharmacopoeia. Products that are not suitable in terms of physical appearance shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. After the physical tests of the products are found to be suitable, other tests shall be performed in accordance with Article 5. |  |  |  |
| **5.6.** | The vaccine shall comply with the characteristics and conditions specified in World Health Organization Technical Report Series 980 Annex 2, and European Pharmacopoeia 10.0.01/2020:0215 monograph in terms of physical appearance and laboratory analyses. |  |  |  |
| **5.7.** | For both vaccine series to be delivered to the laboratory for use in Quality Control tests;  2 vials of Hep2C cells  3 in-house reference vaccines (bivalent)   1. mL Type I antiserum (4 Units/mL)   150 mL Type III antiserum (4 Units/mL)  50 mL Type I, Type II, Type III antiserum (4 Units/mL)  For annual procurement, 1 International Standard Vaccine (bivalent) shall be delivered to the laboratory free of charge along with the samples. |  |  |  |
| **5.8.** | Where necessary, the same quantities of **Standard Vaccine (Inhouse/International), Cell, Antigen, Antiserum,** and other relevant standards and international standards shall be provided free of charge and promptly by the Contractor. |  |  |  |
| **5.8.1.** | Documents to be delivered to the laboratory with the product:  -Protocols related to production methods and processes, as well as quality control protocols,  -Standard Operating Procedure (SOP) documents related to the product's quality control tests, current validation reports, and validation procedure documents shall be provided with the product. |  |  |  |
| **5.8.2.** | If the reference vaccine and chemicals are imported from abroad, customs clearance procedures shall be carried out by the contractors. |  |  |  |
| **5.8.3.** | For each batch of vaccine delivered, the Contractor shall provide a sufficient number of samples free of charge for physical examination and laboratory analysis. |  |  |  |
| **5.8.4.** | If changes are made to the analysis methods, the standards and quantities requested from the Contractor may be re-evaluated. |  |  |  |
| **5.8.5.** | In addition, official documents (official certificates) containing the reference vaccine and/or reference unit values shall also be submitted. The reagents, chemical materials, detailed test SOPs (latest updated version), current validation and validation procedure documents, and calculation documents sent shall be delivered complete with the vaccines to be tested. |  |  |  |
| **5.9.** | If vaccines are prepared in vacuum-sealed ampoules/vials, and if the number of non-vacuum ampoules/vials exceeds 1% in the vacuum control performed on vaccine lot samples taken for inspection, the vaccine lot in question shall be rejected and returned due to the number of non-vacuum ampoules/vials. If the number of non-vacuum ampoules/vials is less than 1%, the vaccine supplier shall deliver the equivalent number of non-vacuum ampoules/vials free of charge within 120 calendar days from the date of notification by the General Directorate of Public Health to the supplier. |  |  |  |
| **5.10.** | Biological controls of products to be delivered shall be carried out at the Turkish Medicines and Medical Devices Agency, but in order to prevent interruption of vaccine and antiserum administration due to potential difficulties in the analysis process, a WHO-approved reference laboratory (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies) ([https://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)](http://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)) may also be conducted, and the costs shall be borne by the Contractor. The results of the control reports of the producer country shall be consistent with the results of the control reports of the Turkish Medicines and Medical Devices Agency or WHO-approved reference laboratories (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies). |  |  |  |
| **5.11.** | The Contractor may object to the results within 15 days. Upon such objection, product samples shall be sent to a second laboratory from among the WHO Reference Laboratories designated ex officio by GDPB or deemed appropriate by GDPB upon the Contractor's recommendation, with the shipping and analysis costs borne by the Contractor. If inconsistencies are detected following analyses conducted by WHO Reference Laboratories and the Turkish Medicines and Medical Devices Agency, the second report shall be accepted as the final report. |  |  |  |
| **6.** | **OTHER PROVISIONS** |  |  |  |
| **6.1.** | Due to delays caused by incorrect or incomplete materials and documents specified in Article 5, such as references, standards, and SOPs required for analysis, which are the responsibility of the contractor to deliver, the product's shelf life shall be shortened by the duration of the delay. The shelf life suitability specified in Article 4 shall be reduced by the duration of the delay. If the shelf life falls below the specified duration, return and exchange processes shall be initiated. For example, if the specification requires a minimum shelf life of 18 months upon delivery to the warehouse, but the product has a shelf life of 20 months at the time of delivery, and the SOP, references, etc. are delivered 70 days later due to a reason attributable to the contractor that prevented the completion of the analyses, the products shall be subject to processing due to shelf life non-compliance and shall be returned. |  |  |  |
| **6.2.** | Batches of products deemed unsuitable based on biological or chemical control results shall be returned. The contractor shall collect these products from the GDPB warehouse where they are located, transport them to the country of origin, and deliver the same quantity of products from a different batch that comply with the specifications to GDPB free of charge within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **6.3.** | In the event of product return (rejection or lot change), the products shall be collected from the warehouse within 30 calendar days after the notification date, during official working hours and days. If not collected, the contractor shall bear the storage and/or disposal costs for the delayed period. |  |  |  |
| **6.4.** | In the event that the products are returned to the Contractor, the relevant official documents proving that the products have been removed from Türkiye or destroyed shall be submitted to the administration within 120 calendar days after the products are collected from the warehouse. If no notification is made, the procedures shall be carried out in accordance with customs regulations. |  |  |  |
| **6.5.** | After acceptance of the products, if any physical deficiencies (barcode errors, packaging, labels, etc.) are detected, the contractor shall remedy the deficiency free of charge. |  |  |  |

| **LOT 4 - CHICKENPOX (VARICELLA) VACCINE** | | | | |
| --- | --- | --- | --- | --- |
| **Item No** | **Specifications** | **Specifications Offered** | **Notes, remarks,  ref to documentation** | **Evaluation Committee’s notes** |
| **1.** | **VACCINE TECHNICAL SPECIFICATIONS** |  |  |  |
| **1.1.** | The product shall comply with the specifications and requirements set out in World Health Organization (WHO) Technical Report Series No. 848 Annex I and monograph 10.0 01/2020:0648 of the European Pharmacopoeia. |  |  |  |
| **1.2.** | Vaccines shall be included in phylogenetic “Clade 2” (OKA, pOKA, vOKA, OKA/RIT, MAV/06, OKA/Merck etc.) group. |  |  |  |
| **1.3.** | The vaccine shall be manufactured from thermo-stable strains, and this shall be proved by thermo-stable tests. Relevant documents shall be submitted to the Tender Committee during the delivery of samples. |  |  |  |
| **1.4.** | The vaccine shall be attenuated, purified and lyophilised, and shall be accompanied by a diluent. |  |  |  |
| **1.5.** | Each dose of the vaccine shall contain at least 1350 PFU antigen or 2.13 log PFU of live Varicella-Herpes Zoster virus. |  |  |  |
| **1.6.** | The vaccine shall maintain its stability from the date of the manufacturer's last successful potency test until its expiration date at temperatures between (+) 2 °C and (+) 8 °C. |  |  |  |
| **1.7.** | Vaccines shall be supplied in single-dose vials. |  |  |  |
| **2.** | **DOCUMENTS TO BE INCLUDED IN THE FILE TO BE REVIEWED BY THE TENDER COMMITTEE** |  |  |  |
| **2.1.** | The product in question;   * + 1. shall have a license issued by the Turkish Ministry of Health,     2. If it does not have a license issued by the Turkish Ministry of Health;   + It shall be included in the latest pre-qualification list published by the World Health Organization (<https://extranet.whoint/prequal/vaccines/prequalified-vaccines)> or,   + It shall have a license from the European Medicines Agency (EMA) and be manufactured in European Union countries, or   + It shall have a license from the US-FDA and be manufactured in the United States, or   + It shall be licensed by the Pharmaceuticals and Medical Devices Agency (PMDA) and manufactured in Japan, or   + It shall be licensed by the South Korean Food and Drug Administration and manufactured in South Korea, **or**   + It shall be licensed by the Canadian Food and Drugs Act and Regulations and manufactured in Canada, **or**   + The product shall be licensed by the Australian Department of Health Therapeutic Goods Administration and manufactured in Australia. |  |  |  |
| **2.2.** | The product shall be accompanied by a certificate (GMP certificate) showing that the factory producing it complies with the **Good Manufacturing Practices (**GMP) standards approved by the State Control Agency of the country where the product is manufactured. If the product is filled or manufactured in our country, there shall be a document showing that the factory where the production/filling is carried out, approved by the Turkish Ministry of Health, Turkish Medicines and Medical Devices Agency, manufactures in accordance with good manufacturing practices (GMP) rules. |  |  |  |
| **2.3.** | For any batch produced within the last two years, the 'National Regulatory Authority' (NRA) or the Batch Release Certificate issued by the EMA (from the locations specified in the annex to the European Union's 2001/83/EC directive), US-FDA, Japan, South Korea, Canada, and Australian state authorities, as specified in 2.1. If the product is manufactured in Türkiye, it shall be a marketing authorization certificate issued by the Turkish Medicines and Medical Devices Agency of the Ministry of Health of the Republic of Türkiye. The analysis report for the same series shall also be included in the BRC annex. |  |  |  |
| **2.4.** | A valid Pharmaceutical Product Certificate (CPP) approved by the manufacturer's country authority. |  |  |  |
| **2.5.** | A **manufacturer-approved** document showing that the risk of Transmissible Spongiform Encephalopathy (TSE) has been minimized at every stage of the product's production. |  |  |  |
| **2.6.** | If the product is licensed in Türkiye, it shall have a "Summary of Product Characteristics" (SPC) or package insert or "Patient Information Leaflet" (PIL) approved by the Turkish Medicines and Medical Devices Agency (TİTCK), or if it is not licensed in Türkiye, it shall have one approved by the relevant country's authority, along with Turkish translations. |  |  |  |
| **2.7.** | If applicable, a list of tasks to be performed by subcontractors shall be provided. |  |  |  |
| **2.8.** | The tenderer shall declare in writing how many batches of the product they can deliver. |  |  |  |
| **2.9.** | If the product is used outside the country of manufacture, a document shall be submitted containing the list of countries where the product is used, approved by the manufacturer, along with the usage permits (import permits) or license numbers for these products, and information on the total number of doses used in countries other than the country of manufacture for the last two calendar years prior to the year of the tender. |  |  |  |
| **2.10.** | The tenderer shall declare that if the manufacturer or another country where the product is used suspends the use of the product for any reason, or if they receive any news in this regard, they shall inform the Ministry within 24 hours (product name, serial number, reason for discontinuation, etc.) and that if the information is not provided within 24 hours, the administration has the right to unilaterally terminate the contract. It also indicates that in the event of discontinuation of the product, after the unused products are collected by the Ministry and sent to the Central Warehouse, the Tenderer undertakes to bring a new product from a different series that complies with the specifications within 90 (ninety) calendar days from the date the replacement request is notified. In addition, the Tenderer shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date of notification of the product replacement request after the unused products are collected by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **2.11.** | The Tenderer shall submit the original or notarized copies of the required documents, along with their certified Turkish translations, to the tender committee. |  |  |  |
| **3.** | **DELIVERY OF PRODUCTS** |  |  |  |
| **3.1.** | If the products are imported, the tenderer's representative shall be present when the products are collected from customs and shall ensure that the goods are collected in accordance with the required specifications and delivered to the location deemed appropriate by GDPB without delay. |  |  |  |
| **3.2.** | The contractor shall provide the Department with the shipment details 3 days prior to the delivery date of the product. |  |  |  |
| **3.3.** | Product delivery shall be made in such a way that it does not coincide with holidays, official holidays, or the end of working hours in Türkiye. |  |  |  |
| **3.4.** | To clear products purchased by GDPB through customs, the Contractor shall enter the product information (batch release certificate and quantity for the lot/serial number for which import permission is requested) via the Single Window Portal System (<https://uygulama.gtb.gov.tr/TekPencere>). The Single Window approval request shall be submitted to the Department electronically (to the Department's official e-mail address) or in writing at least 3 days in advance. Products purchased by the General Directorate of Public Health shall be delivered to the GDPB Vaccine and Drug Warehouse within 48 hours after being cleared through customs (except for products filled in Türkiye) if they are imported. Any changes required after the initial inspection (packaging, barcode, etc.) may also be made at the Central Vaccine and Drug Warehouse with the approval of the GDPB. If storage exceeds 48 hours, it is mandatory to submit temperature records approved by the Contractor's quality manager from the production site until the Ministry of Health Vaccine Storage arrives, to use a warehouse licensed by the Turkish Ministry of Health, and, if *"temperature monitoring cards"* are installed *at the production facility, not to change them*. |  |  |  |
| **3.5.** | *If the packaging of the imported product* (including barcoding) is to be changed at a different location after the contract is signed, this situation shall be reported to the Department. The temporary storage location shall be licensed by the Turkish Ministry of Health, the initial opening of the packaging of the product withdrawn from customs shall be carried out under the supervision of GDPB or its authorized personnel, and the shipment and temporary storage temperature records shall also be submitted during the inspection phase. GDPB may inspect this entire process at any time and on any day after customs clearance. Intermediate storage shall be possible if the application made to GDPB and the storage period are found to be appropriate. *For products imported prior to the signing of the contract, it is sufficient to submit approved storage temperature records documenting all processes and to document that the product has been kept in storage facilities licensed by the Ministry of Health until the delivery stage.* |  |  |  |
| **3.6.** | Products filled in our country shall be delivered to the GDPB Vaccine and Drug Warehouse within 24 hours of leaving the filling facility. If the product is not delivered to the GDPB Vaccine and Drug Warehouse within 24 hours after leaving the filling facility and is to be stored in another warehouse, the organization performing the intermediate storage shall be licensed by the Turkish Ministry of Health, temperature records from the production site to the warehouse and within the warehouse shall be kept, and certified copies from the product quality representative shall be delivered to GDPB upon product delivery. These stages shall be open to inspection by GDPB if required. The Department shall be notified if temporary storage is required. Products shall not be accepted if the specified conditions cannot be met. |  |  |  |
| **3.7.** | If the products are filled/manufactured in Türkiye, the time limit specified in Article 3, except for 3.2 and 3.3, and the restrictions at shall not apply. |  |  |  |
| **4.** | **DOCUMENTS REQUIRED DURING INSPECTION AND PRODUCT CHARACTERISTICS** |  |  |  |
| **4.1.** | Products shall have a shelf life of at least **18 (eighteen) months** from the date of delivery to our warehouse. |  |  |  |
| **4.1.1.** | **Documents required during the product inspection phase:**  The documents specified in Article 2 of the Technical Specifications and the documents specific to the delivered series/lot shall be submitted during the inspection stage. These documents are:   * Product License * Current GMP certificate for the production site, * Analysis report for the delivered batch (document containing information such as composition, analysis results, reference values, production/expiration dates, etc.), * BRC for the delivered batch, * Current Pharmaceutical Product Certificate (CPP) * TSE declaration (item 2.5), * List of tasks to be performed by subcontractors, * Package Insert or Prospectus or IFU (Article 2.6), * List of countries where the product is used and import permit/license number and the number of doses used in each country in the last two calendar years prior to the year of the offer (Article 2.9), * Commitment letter (Article 2.10). |  |  |  |
| **4.2.** | The Contractor, manufacturer or any other country where this product is used shall notify the Ministry within 24 hours if the use of the product is suspended for any reason or if they receive any information in this regard (product name, serial number, reason for discontinuation, etc.) and acknowledges that the administration has the right to unilaterally terminate the contract if such information is not provided within 24 hours. In the event of discontinuation of the product, the Contractor shall be required to bring a manufacturer-approved commitment letter to the Ministry within 90 (ninety) calendar days from the date the replacement request is notified to the Contractor. Additionally, *the Contractor shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date the request for product replacement is notified, following the collection of unused products by the Ministry to the Central Warehouse, without the requirement of manufacturer approval.* |  |  |  |
| **4.3.** | Stability studies and results proving the actual shelf life of the product in question shall be submitted. If the product is filled or manufactured in our country and stability studies are still ongoing, the TİTCK-approved study results shall be submitted to the Department as they are completed. |  |  |  |
| **4.4.** | Along with the product, all technical documents required in the tender for the product (Good Manufacturing Practices, analysis report, SPC, certificates, etc.) and detailed SOP (may be provided in the original license), **stability results (showing real-time and accelerated stability shelf life)**, product photos, and all documents containing technical information about the packaging (dimensions, volume, etc.) shall be submitted to the inspection commission in duplicate on CD/DVD/flash drive. Each heading shall be indicated with a separate folder name, and the relevant documents shall be found under the relevant folder. If deemed necessary, other documents and information related to the product may be requested in physical or digital form. |  |  |  |
| **4.5.** | Documents that do not change with each shipment shall be submitted once, with the first shipment. If deemed necessary, documents may be requested again. |  |  |  |
| **4.6.** | **Required Packaging Characteristics** |  |  |  |
| **4.6.1.** | Products shall be in single or multi-dose ampoules, vials, flacons, or ready-to-use syringes (injectors). Ready-to-use syringes (injectors), ampoules, or flacons shall be packaged in single or ten-packs. If products are packaged in ten-packs, there shall be foam, cardboard, plastic, or other separators to prevent breakage due to contact. If the product is packaged individually, the packages shall then be bundled in packs of ten. If diluents are separate, 5 additional diluents shall be delivered with every 1000 doses of vaccine. |  |  |  |
| **4.6.2.** | *The inner and outer packaging of licensed products in Türkiye* shall comply with the current "Regulation on Packaging Information, Instructions for Use, and Tracking of Human Medicinal Products" published by the Turkish Ministry of Health. *If the product is not licensed in our country*, the inner packaging of the ready-to-use syringe (injector), ampoule, or vial shall bear, at a minimum, the manufacturer's and product name, dosage, amount of content per dose, method of administration (IM/IV/SC/ID, etc.), lot (batch) number, and expiration date, printed in indelible ink. The package shall also contain storage temperature information in addition to the inner packaging. The product package shall bear the statement "**Property of the Turkish Ministry of Health, NOT FOR SALE**.**"** |  |  |  |
| **4.6.3.** | Each product package shall contain at least one "Summary of Product Characteristics" (SPC) or Turkish package insert or "Patient Information Leaflet" (PIL) prepared in accordance with the "Regulation on the Packaging and Labelling of Human Medicinal Products" dated 25.04.2017 and numbered 30048. Additionally, the following text shall be added at the beginning of the SIP, Turkish package insert, or PUI in bold and coloured font to draw attention:  "In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration. For any questions or problems encountered in this regard, contact the Tuberculosis Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates***."*** |  |  |  |
| **4.6.4.** | The packages shall then be placed in boxes. The names and addresses of the manufacturer and representative company of the product, the name of the product, the lot number, the storage temperature, the expiration date, and the number of doses in the box shall be written on these boxes. If the products are packaged individually, ten packages shall be placed in each box. If the products are packaged in packs of ten, five packages shall be placed in each box. |  |  |  |
| **4.6.5.** | The packaging boxes shall be placed in styrofoam. The styrofoam shall then be placed inside cartons. The carton dimensions shall be 40X60X40 ±20 (Width, Length, Height) cm. A sufficient number of ice packs or gel packs, etc., shall be placed in the cartons. The ice packs or gel packs, etc.**,** placed in the cartons shall be **unfrozen and cooled**. If the products are not sensitive to freezing (lyophilized), dry ice or frozen ice packs or gel may be used during transport. The names and addresses of the manufacturer and representative company, the product name, serial number, storage temperature, expiration date, dose quantity in the carton, carton dimensions, and weight shall be written on these cartons. |  |  |  |
| **4.6.6.** | The boxes shall then be placed on pallets. The pallets shall be euro pallets (120cm±2cmx80cm±2cmx10-15cm). After the boxes are placed on the pallets, the height together with the pallet shall not exceed 2 (two) meters. The boxes may protrude from the pallet by a maximum of 5 cm. There shall be a maximum of 16 (sixteen) boxes on the pallet. |  |  |  |
| **4.6.7.** | There shall be a 2D barcode on the packages, boxes, cartons, and pallets. The barcode prepared for the ready-to-use syringe (injector) inside each individually packaged product (these barcodes shall also have HL7 and 97 breakdown values) shall be on the product's package. The packages shall then be tied in sets of ten, and the package label shall be affixed to a different area than the barcode affixed to each product. If the product is packaged in sets of ten, the barcode prepared for the ready-to-use syringe (injector) (these barcodes shall also have HL7 and 97 breakdown values) shall be placed inside the package, and the barcode corresponding to the package breakdown shall be on the package. For the information to be included in the barcode, the information specified in the Guide for Barcode Application to Vaccines, Antiserums, and Diluents published by the Turkish Ministry of Health shall be used as a basis, and any additional information required shall be determined by GDPB. ***The barcode area for the dose shall be at least 12X12 mm in accordance with the Guide.*** If GDPB makes changes to the system instead of the barcode, the contractor shall be obliged to comply with the requirements of the newly created system without requesting a price difference. |  |  |  |
| **4.6.8.** | Even after acceptance, if any faulty operations related to the barcode system are detected later, the costs of changing the product packaging and, if deemed necessary, collecting the products from the field shall be borne by the Contractor. If this process exceeds one-month, new products with a new expiration date may be requested at the request of the Department to avoid any problems related to the expiration date. |  |  |  |
| **4.6.9.** | **Temperature monitoring during transportation:** |  |  |  |
| **4.6.9.1.** | The freeze indicator, temperature monitoring card, and digital temperature recording devices used **shall be listed in the WHO "E006: Temperature monitoring devices"** (https://extranet.who.int/prequal/immunization-devices/prequalified/imd-products)**.** |  |  |  |
| **4.6.9.2.** | If the product(s) are sensitive to freezing, each box shall contain a freeze indicator. |  |  |  |
| **4.6.9.3.** | If the product(s) are sensitive to high temperatures, each box shall contain a temperature monitoring card **with the date it was activated and the name/code of the activator written on it**. |  |  |  |
| **4.6.9.4.** | If the product(s) are sensitive to both freezing and high temperatures, or if they are packaged together, each box shall contain both a freeze indicator and a temperature monitor card with the date of activation and the name/code of the activator written on it. |  |  |  |
| **4.6.9.5.** | In addition, each pallet shall have an electronic, temperature, and freeze-sensitive digital monitor capable of long-term recording. The electronic, temperature, and freeze-sensitive digital monitors capable of long-term recording placed on the pallet shall be read during the inspection phase, the outputs shall be recorded in a report and signed by the company, and if there are no deviations, they can be filed electronically. If requested by the company, these devices shall be returned for storage without destruction for at least three months. Upon return, the pallet numbers and device serial numbers shall be recorded in a report.  If the pallets consist of insulated boxes, each containing heat tracking material (such as a digital recording device, heat monitoring card, or freeze indicator), and conflicting results are found between the digital heat records on or inside the pallet and the heat records inside the box when evaluating the heat records, the temperature monitoring results inside the boxes shall be taken into account when processing. |  |  |  |
| **4.6.9.6.** | Products found not to have been transported under appropriate conditions (*Guidelines for the international packaging and shipping of vaccines, sixth edition. Geneva: World Health Organization;2020. Licence: CC BY-NC-SA 3.0 IGO)* as monitored by these heat trackers shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **4.6.10.** | Each product shall be delivered with a Material Safety Data Sheet (MSDS). The contractor is responsible for the “Transportation, packaging, and labelling of hazardous materials” and completing any shortfalls if there is any. |  |  |  |
| **4.6.11.** | The contractor's representative shall be present during the delivery or return of the products. The representative shall submit a letterhead, stamped, and signed authorization document belonging to the contractor and a photocopy of their photo ID to the Warehouse Manager. The contractor is responsible for unloading the products from the vehicle into the warehouse or loading them back onto the vehicle for return. A list of the names, telephone numbers, and addresses of all employees and subcontractor personnel who shall perform work on behalf of the contractor shall be submitted to the Warehouse Manager, signed by the contractor's representative, prior to unloading. The contractor shall be responsible for any damage that may be caused to the warehouse or equipment and for all liabilities arising from "Occupational Health and Safety Regulations." The contractor shall submit a stamped and signed commitment stating that it has assumed the SSI, occupational health and safety, and work accident liabilities of its employees for unloading the products from the vehicle or loading them in case of return, and that it has assumed the liability for compensation in case of damage to the warehouse or any equipment inside the warehouse. Responsibility begins upon entry into the warehouse area after the security check. |  |  |  |
| **4.6.12.** | Except in emergencies, no contractor employees other than the vehicle drivers and those declared shall enter the climate-controlled warehouse. |  |  |  |
| **4.6.13.** | * + 1. If barcoding, packaging, or prospectus changes are to be performed in the GDPB warehouse, the documents belonging to the subcontractors shall be as follows:        - shall be a contract demonstrating the availability of occupational safety expertise and workplace physician support services as required by the "Occupational Health and Safety Law" No. 6331.        - The contractor's structure shall include at least one coordinator, one operations manager, one quality control and GMP manager, and one warehouse manager. These personnel shall be present during the execution of the work. There shall be a document or documents proving that the personnel included in the company structure have received GMP and Good Warehouse Practices Training organized by the Turkish Ministry of Health or an organization that has received a GMP Certificate from the Turkish Ministry of Health.        - There shall be standard operating procedures (SOPs) prepared by a pharmacist and approved by the company representative, covering barcode printing and affixing procedures and cold storage room operating rules. |  |  |  |
| **5.** | **DOCUMENTS AND MATERIALS REQUIRED FOR LABORATORY ANALYSES AND METHODS TO BE FOLLOWED** |  |  |  |
| **5.1.** | General principles of product safety;  The analysis reports for the product are part of the batch release certificate, and both documents shall be considered together in the evaluations. |  |  |  |
| **5.1.1.** | The product shall be manufactured in our country, have a manufacturing license from the Turkish Medicines and Medical Devices Agency (TİTCK), and present the BRC certificate for the delivered batch obtained from the TİTC/Analysis and Control Laboratories Department. In addition, if there is no break in the cold chain during product transfer, the physical examination is appropriate, and the commission grants approval, the inspection acceptance process can be completed. |  |  |  |
| **5.1.2.** | If the product is manufactured outside our country and has an import license from TİTCK or is on the WHO's prequalification list (Prequalified vaccines), the Batch Release Certificate for the delivered series shall be obtained from WHO/ Reference Laboratories/institutions, provided that the analyses are performed in accordance with the OCABR guidelines at the TİTCK/Analysis and Control Laboratories Directorate. The inspection acceptance process for products found to be suitable through analysis can be completed. |  |  |  |
| **5.1.3.** | If the product is not licensed in our country, but is licensed by the authorities in EMA, US-FDA, Japan, Canada, South Korea, and Australia as specified in Article 2.1 of the technical specifications, tests may be performed in accordance with the OCABR guidelines by the TİTCK/Analysis and Control Laboratories Department. The inspection and acceptance process for products with suitable analyses can be completed. |  |  |  |
| **5.1.4.** | If the product **is** **not** **licensed** by the Turkish Medicines and Medical Devices Agency (TİTCK) and is not included in the WHO PQ list, and if it is not licensed by the authorities in Japan, Canada, South Korea, and Australia as stated in Article 2.1, Japan, Canada, South Korea, and Australia, the product may undergo the inspection and acceptance process if the results of analyses conducted by the TİTCK/Directorate of Analysis and Control Laboratories in accordance with the current WHO Technical Series Reports/European Pharmacopoeia monographs (including in vivo potency tests) are deemed suitable. |  |  |  |
| **5.2.** | If there are any doubts regarding product safety within the scope of the cold chain or other matters specified in the technical specifications, new samples may be taken if necessary, and analyses may be performed as required, including analyses based on batch release. |  |  |  |
| **5.3.** | These products are subject to the *"Regulations on Market Surveillance and Control Procedures and Principles to be Implemented by the Ministry of Health*." GDPB reserves the right to conduct analyses in case of possible suspicion or complaint. The Contractor shall provide the required number of product doses for analysis and the materials required for the analysis specified in Article 5 free of charge. If the analysis result is found to be unsatisfactory, even if the product in question has been accepted, the Contractor shall deliver the same quantity from different series within 90 calendar days. |  |  |  |
| **5.4.** | If the product does not comply with Article 5.1, after the inspection is completed, a sample shall be taken from each batch using the random sampling method and delivered to the laboratory with a report signed by the Contractor's representative and one of the inspection members. |  |  |  |
| **5.5.** | Since the physical appearance of the products requires expertise, it shall be assessed by specialized personnel at the National Reference Laboratory within the TİTCK in accordance with the current Turkish/European Pharmacopoeia. Products that are not suitable in terms of physical appearance shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. After the physical tests of the products are found to be suitable, other tests shall be performed in accordance with Article 5. |  |  |  |
| **5.6.** | The vaccine shall comply with the characteristics and conditions specified in World Health Organization **Technical Report Series 980 Annex 4, Annex 5, Annex 6, and European Pharmacopoeia 11.0 01/2020:20920** monograph in terms of physical appearance and laboratory analyses. |  |  |  |
| **5.7.** | For the quality control of the varicella vaccine, the laboratory shall provide, free of charge, the declared quantity of samples for each series, one cryovial cell (MRC-5) for the control of each vaccine lot, antiserum (0.5 mL), one reference vaccine for each of the two vaccine lots, and, if deemed necessary, reagents/chemical materials for potency and identity tests to the laboratory. |  |  |  |
| **5.8.** | Where necessary, the same quantities of Standard Vaccine, Antigen, Antiserum, and other relevant standards and international standards shall be provided free of charge and promptly by the Contractor. |  |  |  |
| **5.8.1.** | Documents to be delivered to the laboratory with the product:  -Protocols related to production methods and processes, as well as quality control protocols,  -Standard Operating Procedure (SOP) documents related to the product's quality control tests, current validation reports, and validation procedure documents shall be provided with the product. |  |  |  |
| **5.8.2.** | If the reference vaccine and chemicals are imported from abroad, customs clearance procedures shall be carried out by the contractors. |  |  |  |
| **5.8.3.** | For each batch of vaccine delivered, the Contractor shall provide a sufficient number of samples free of charge for physical examination and laboratory analysis. |  |  |  |
| **5.8.4.** | If changes are made to the analysis methods, the standards and quantities requested from the Contractor may be reevaluated. |  |  |  |
| **5.8.5.** | In addition, official documents (official certificates) containing the reference vaccine and/or reference unit values shall also be submitted. The reagents, chemical materials, detailed test SOPs (latest updated version), current validation and validation procedure documents, and calculation documents sent shall be delivered complete with the vaccines to be tested. |  |  |  |
| **5.9.** | If vaccines are prepared in vacuum-sealed ampoules/vials, and if the number of non-vacuum ampoules/vials exceeds 1% in the vacuum control performed on vaccine lot samples taken for inspection, the vaccine lot in question shall be rejected and returned due to the number of non-vacuum ampoules/vials. If the number of non-vacuum ampoules/vials is less than 1%, the vaccine supplier shall deliver the equivalent number of non-vacuum ampoules/vials free of charge within 120 calendar days from the date of notification by the General Directorate of Public Health to the supplier. |  |  |  |
| **5.10.** | Biological controls of products to be delivered shall be carried out at the Turkish Medicines and Medical Devices Agency, but in order to prevent interruption of vaccine and antiserum administration due to potential difficulties in the analysis process, a WHO-approved reference laboratory (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies) ([https://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)](http://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)) may also be conducted, and the costs shall be borne by the Contractor. The results of the control reports of the producer country shall be consistent with the results of the control reports of the Turkish Medicines and Medical Devices Agency or WHO-approved reference laboratories (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies). |  |  |  |
| **5.11.** | The Contractor may object to the results within 15 days. Upon such objection, product samples shall be sent to a second laboratory from among the WHO Reference Laboratories designated ex officio by GDPB or deemed appropriate by GDPB upon the Contractor's recommendation, with the shipping and analysis costs borne by the Contractor. If inconsistencies are detected following analyses conducted by WHO Reference Laboratories and the Turkish Medicines and Medical Devices Agency, the second report shall be accepted as the final report. |  |  |  |
| **6.** | **OTHER PROVISIONS** |  |  |  |
| **6.1.** | Due to delays caused by incorrect or incomplete materials and documents specified in Article 5, such as references, standards, and SOPs required for analysis, which are the responsibility of the contractor to deliver, the product's shelf life shall be shortened by the duration of the delay. The shelf life suitability specified in Article 4 shall be reduced by the duration of the delay. If the shelf life falls below the specified duration, return and exchange processes shall be initiated. For example, if the specification requires a minimum shelf life of 18 months upon delivery to the warehouse, but the product has a shelf life of 20 months at the time of delivery, and the SOP, references, etc. are delivered 70 days later due to a reason attributable to the contractor that prevented the completion of the analyses, the products shall be subject to processing due to shelf life non-compliance and shall be returned. |  |  |  |
| **6.2.** | Batches of products deemed unsuitable based on biological or chemical control results shall be returned. The contractor shall collect these products from the GDPB warehouse where they are located, transport them to the country of origin, and deliver the same quantity of products from a different batch that comply with the specifications to GDPB free of charge within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **6.3.** | In the event of product return (rejection or lot change), the products shall be collected from the warehouse within 30 calendar days after the notification date, during official working hours and days. If not collected, the contractor shall bear the storage and/or disposal costs for the delayed period. |  |  |  |
| **6.4.** | In the event that the products are returned to the Contractor, the relevant official documents proving that the products have been removed from Türkiye or destroyed shall be submitted to the administration within 120 calendar days after the products are collected from the warehouse. If no notification is made, the procedures shall be carried out in accordance with customs regulations. |  |  |  |
| **6.5.** | After acceptance of the products, if any physical deficiencies (barcode errors, packaging, labels, etc.) are detected, the contractor shall remedy the deficiency free of charge. |  |  |  |

| **LOT 5 - PAEDIATRIC HEPATITIS B VACCINE** | | | | |
| --- | --- | --- | --- | --- |
| **Item No** | **Specifications** | **Specifications Offered** | **Notes, remarks,  ref to documentation** | **Evaluation Committee’s notes** |
| **1.** | **VACCINE TECHNICAL SPECIFICATIONS** |  |  |  |
| **1.1.** | The product shall comply with vaccine production, quality control parameters, methods, and specifications in World Health Organization (WHO) Technical Report Series (TRS) No:978 Annex 4 and European Pharmacopoeia 11.0 01/2019:1056 and 01/2020:2920 Monograph. |  |  |  |
| **1.2.** | The vaccine shall be produced using recombinant DNA technology. |  |  |  |
| **1.3.** | The vaccine shall be purified. |  |  |  |
| **1.4.** | The vaccine shall be packaged in a single-dose, ready-to-use syringe (injector) containing, vial or ampule. |  |  |  |
| **1.5.** | The vaccine shall maintain its stability to its expiration date at temperatures between (+2) - (+8)OC from the last successful potency test. |  |  |  |
| **2.** | **DOCUMENTS TO BE INCLUDED IN THE FILE TO BE REVIEWED BY THE TENDER COMMITTEE** |  |  |  |
| **2.1.** | The product in question;   * + 1. shall have a license issued by the Turkish Ministry of Health,     2. If it does not have a license issued by the Turkish Ministry of Health;   + It shall be included in the latest pre-qualification list published by the World Health Organization (<https://extranet.whoint/prequal/vaccines/prequalified-vaccines)> or,   + It shall have a license from the European Medicines Agency (EMA) and be manufactured in European Union countries, or   + It shall have a license from the US-FDA and be manufactured in the United States, **or**   + It shall be licensed by the Pharmaceuticals and Medical Devices Agency (PMDA) and manufactured in Japan, or   + It shall be licensed by the South Korean Food and Drug Administration and manufactured in South Korea, **or**   + It shall be licensed by the Canadian Food and Drugs Act and Regulations and manufactured in Canada, **or**   + The product shall be licensed by the Australian Department of Health Therapeutic Goods Administration and manufactured in Australia. |  |  |  |
| **2.2.** | The product shall be accompanied by a certificate (GMP certificate) showing that the factory producing it complies with the **Good Manufacturing Practices (**GMP) standards approved by the State Control Agency of the country where the product is manufactured. If the product is filled or manufactured in our country, there shall be a document showing that the factory where the production/filling is carried out, approved by the Turkish Ministry of Health, Turkish Medicines and Medical Devices Agency, manufactures in accordance with good manufacturing practices (GMP) rules. |  |  |  |
| **2.3.** | For any batch produced within the last two years, the 'National Regulatory Authority' (NRA) or the Batch Release Certificate issued by the EMA (from the locations specified in the annex to the European Union's 2001/83/EC directive), US-FDA, Japan, South Korea, Canada, and Australian state authorities, as specified in 2.1. If the product is manufactured in Türkiye, it shall be a marketing authorization certificate issued by the Turkish Medicines and Medical Devices Agency of the Ministry of Health of the Republic of Türkiye. The analysis report for the same series shall also be included in the BRC annex. |  |  |  |
| **2.4.** | A valid Pharmaceutical Product Certificate (CPP) approved by the manufacturer's country authority. |  |  |  |
| **2.5.** | A **manufacturer-approved** document showing that the risk of Transmissible Spongiform Encephalopathy (TSE) has been minimized at every stage of the product's production. |  |  |  |
| **2.6.** | If the product is licensed in Türkiye, it shall have a "Summary of Product Characteristics" (SPC) or package insert or "Patient Information Leaflet" (PIL) approved by the Turkish Medicines and Medical Devices Agency (TİTCK), or if it is not licensed in Türkiye, it shall have one approved by the relevant country's authority, along with Turkish translations. |  |  |  |
| **2.7.** | If applicable, a list of tasks to be performed by subcontractors shall be provided. |  |  |  |
| **2.8.** | The tenderer shall declare in writing how many batches of the product they can deliver. |  |  |  |
| **2.9.** | If the product is used outside the country of manufacture, a document shall be submitted containing the list of countries where the product is used, approved by the manufacturer, along with the usage permits (import permits) or license numbers for these products, and information on the total number of doses used in countries other than the country of manufacture for the last two calendar years prior to the year of the tender. |  |  |  |
| **2.10.** | The tenderer shall declare that if the manufacturer or another country where the product is used suspends the use of the product for any reason, or if they receive any news in this regard, they shall inform the Ministry within 24 hours (product name, serial number, reason for discontinuation, etc.) and that if the information is not provided within 24 hours, the administration has the right to unilaterally terminate the contract. It also indicates that in the event of discontinuation of the product, after the unused products are collected by the Ministry and sent to the Central Warehouse, the Tenderer undertakes to bring a new product from a different series that complies with the specifications within 90 (ninety) calendar days from the date the replacement request is notified to the Tenderer. In addition, the Tenderer shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date of notification of the product replacement request after the unused products are collected by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **2.11.** | The Tenderer shall submit the original or notarized copies of the required documents, along with their certified Turkish translations, to the tender committee. |  |  |  |
| **3.** | **DELIVERY OF PRODUCTS** |  |  |  |
| **3.1.** | If the products are imported, the tenderer's representative shall be present when the products are collected from customs and shall ensure that the goods are collected in accordance with the required specifications and delivered to the location deemed appropriate by GDPB without delay. |  |  |  |
| **3.2.** | The contractor shall provide the Department with the shipment details 3 days prior to the delivery date of the product. |  |  |  |
| **3.3.** | Product delivery shall be made in such a way that it does not coincide with holidays, official holidays, or the end of working hours in Türkiye. |  |  |  |
| **3.4.** | To clear products purchased by GDPB through customs, the Contractor shall enter the product information (serial release certificate and quantity for the lot/serial number for which import permission is requested) via the Single Window Portal System (<https://uygulama.gtb.gov.tr/TekPencere>). The Single Window approval request shall be submitted to the Department electronically (to the Department's official e-mail address) or in writing at least 3 days in advance. Products purchased by the General Directorate of Public Health shall be delivered to the GDPB Vaccine and Drug Warehouse within 48 hours after being cleared through customs (except for products filled in Türkiye) if they are imported. Any changes required after the initial inspection (packaging, barcode, etc.) may also be made at the Central Vaccine and Drug Warehouse with the approval of the GDPB. If storage exceeds 48 hours, it is mandatory to submit temperature records approved by the Contractor's quality manager from the production site until the Ministry of Health Vaccine Storage arrives, to use a warehouse licensed by the Turkish Ministry of Health, and, if "temperature monitoring cards" are installed at the production facility, not to change them. |  |  |  |
| **3.5.** | If the packaging of the imported product (including barcoding) is to be changed at a different location after the contract is signed, this situation shall be reported to the Department. The temporary storage location shall be licensed by the Turkish Ministry of Health, the initial opening of the packaging of the product withdrawn from customs shall be carried out under the supervision of GDPB or its authorized personnel, and the shipment and temporary storage temperature records shall also be submitted during the inspection phase. GDPB may inspect this entire process at any time and on any day after customs clearance. Intermediate storage shall be possible if the application made to GDPB and the storage period are found to be appropriate. |  |  |  |
| **3.6.** | Products filled in our country shall be delivered to the GDPB Vaccine and Drug Warehouse within 24 hours of leaving the filling facility. If the product is not delivered to the GDPB Vaccine and Drug Warehouse within 24 hours after leaving the filling facility and is to be stored in another warehouse, the organization performing the intermediate storage shall be licensed by the Turkish Ministry of Health, temperature records from the production site to the warehouse and within the warehouse shall be kept, and certified copies from the product quality representative shall be delivered to GDPB upon product delivery. These stages shall be open to inspection by GDPB if required. The Department shall be notified if temporary storage is required. Products shall not be accepted if the specified conditions cannot be met. |  |  |  |
| **3.7.** | If the products are filled/manufactured in Türkiye, the time limit specified in Article 3, except for 3.2 and 3.3, and the restrictions at shall not apply. |  |  |  |
| **4.** | **DOCUMENTS REQUIRED DURING INSPECTION AND PRODUCT CHARACTERISTICS** |  |  |  |
| **4.1.** | Products shall have **a shelf life of at least 18 (eighteen) months** from the date of delivery to our warehouse. |  |  |  |
| **4.1.1.** | **Documents required during the product inspection phase:**  The documents specified in Article 2 of the Technical Specifications and the documents specific to the delivered series/lot shall be submitted during the inspection stage. These documents are:   * Product License * Current GMP certificate for the production site, * Analysis report for the delivered batch (document containing information such as composition, analysis results, reference values, production/expiration dates, etc.), * BRC for the delivered batch, * Current Pharmaceutical Product Certificate (CPP) * TSE declaration (item 2.5), * List of tasks to be performed by subcontractors, * Package Insert or Prospectus or IFU (Article 2.6), * List of countries where the product is used and import permit/license number and the number of doses used in each country in the last two calendar years prior to the year of the offer (Article 2.9), * Commitment letter (Article 2.10).   The original documents or notarised copies and the certified Turkish version shall be submitted to the Tender Committee. |  |  |  |
| **4.2.** | The contractor, manufacturer, or another country where this product is used agrees that if the use of the product is discontinued for any reason or if they receive any news in this regard, they shall inform our Ministry within 24 hours (product name, serial number, reason for discontinuation, etc.), and that if information is not provided within 24 hours, the administration has the right to unilaterally terminate the contract. In the event that the use of the product is discontinued, the Ministry shall collect unused products to the Central Warehouse, and the Contractor shall be notified of the replacement request. Starting from the date of notification, the Contractor shall be given 90 (ninety) calendar days from the date the replacement request is notified to the Contractor. In addition, the Contractor shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date of notification of the request for replacement of the product after the unused products have been collected by the Ministry to the Central Warehouse, without the condition of manufacturer approval. |  |  |  |
| **4.3.** | Stability studies and results proving the actual shelf life of the product in question shall be submitted. If the product is filled or manufactured in our country and stability studies are still ongoing, the TİTCK-approved study results shall be submitted to the Department as they are completed. |  |  |  |
| **4.4.** | Along with the product, all technical documents required in the tender for the product (Good Manufacturing Practices, analysis report, SPC, certificates, etc.) and detailed SOP (may be provided in the original license), **stability results (showing real-time and accelerated stability shelf life),** product photos, and all documents containing technical information about the packaging (dimensions, volume, etc.) shall be submitted to the inspection commission in duplicate on CD/DVD/flash drive. Each heading shall be indicated with a separate folder name, and the relevant documents shall be found under the relevant folder. If deemed necessary, other documents and information related to the product may be requested in physical or digital form. |  |  |  |
| **4.5.** | Documents that do not change with each shipment shall be submitted once, with the first shipment. If deemed necessary, documents may be requested again. |  |  |  |
| **4.6.** | **Required Packaging Characteristics** |  |  |  |
| **4.6.1.** | The products shall be packaged in vials, flacons or ready-to-use syringe (injector) containing a single dose. Those ready-to-use syringe (injector)s shall be single packed or provided in ten packs. If the products are packaged in packs of ten, the packs shall contain foam or cardboard separators to prevent the vials or ampoules from breaking due to contact. If the product is packaged individually, the packages shall then be bundled in packs of ten. If diluents are separate, 5 additional diluents shall be delivered with every 1000 doses of vaccine. |  |  |  |
| **4.6.2.** | The inner and outer packaging of licensed products in Türkiye shall comply with the current "Regulation on Packaging Information, Instructions for Use, and Tracking of Human Medicinal Products" published by the Turkish Ministry of Health. If the product is not licensed in our country, the inner packaging of the ready-to-use syringe (injector), ampoule, or vial shall bear, at a minimum, the manufacturer's and product name, dosage, amount of content per dose, method of administration (IM/IV/SC/ID, etc.), lot (batch) number, and expiration date, printed in indelible ink. The package shall also contain storage temperature information in addition to the inner packaging. The product package shall bear the statement "Property of the Turkish Ministry of Health, NOT FOR SALE." |  |  |  |
| **4.6.3.** | Each product package shall contain at least one "Summary of Product Characteristics" (SPC) or Turkish package insert or "Patient Information Leaflet" (PIL) prepared in accordance with the "Regulation on the Packaging and Labelling of Human Medicinal Products" dated 25.04.2017 and numbered 30048. Additionally, the following text shall be added to the beginning of the “"Summary of Product Characteristics" (SPC)” or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention:  "In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration.  For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates***."*** |  |  |  |
| **4.6.4.** | The packages shall then be placed in boxes. The names and addresses of the manufacturer and representative company of the product, the name of the product, the lot number, the storage temperature, the expiration date, and the number of doses in the box shall be written on these boxes. If the products are packaged individually, ten packages shall be placed in each box. If the products are packaged in packs of ten, five packages shall be placed in each box. |  |  |  |
| **4.6.5.** | The packaging boxes shall be placed in styrofoam. The styrofoam shall then be placed inside cartons. The carton dimensions shall be 40X60X40 ±2 (Width, Length, Height) cm. A sufficient number of ice packs or gel packs, etc., shall be placed in the cartons. The ice packs or gel packs, etc.**,** placed in the cartons shall be **unfrozen and cooled**. If the products are not sensitive to freezing (lyophilized), dry ice or frozen ice packs or gel may be used during transport. The names and addresses of the manufacturer and representative company, the product name, serial number, storage temperature, expiration date, dose quantity in the carton, carton dimensions, and weight shall be written on these cartons. |  |  |  |
| **4.6.6.** | The boxes shall then be placed on pallets. The pallets shall be euro pallets (120cm±2cmx80cm±2cmx10-15cm). After the boxes are placed on the pallets, the height together with the pallet shall not exceed 2 (two) meters. The boxes may protrude from the pallet by a maximum of 5 cm. There shall be a maximum of 16 (sixteen) boxes on the pallet. |  |  |  |
| **4.6.7.** | There shall be a 2D barcode on the packages, boxes, cartons, and pallets. The barcode prepared for the ready-to-use syringe (injector) inside each individually packaged product (these barcodes shall also have HL7 and 97 breakdown values) shall be on the product's package. The packages shall then be tied in sets of ten, and the package label shall be affixed to a different area than the barcode affixed to each product. If the product is packaged in sets of ten, the barcode prepared for the ready-to-use syringe (injector) (these barcodes shall also have HL7 and 97 breakdown values) shall be placed inside the package, and the barcode corresponding to the package breakdown shall be on the package. For the information to be included in the barcode, the information specified in the Guide for Barcode Application to Vaccines, Antiserums, and Diluents published by the Turkish Ministry of Health shall be used as a basis, and any additional information required shall be determined by GDPB. **The barcode area for the dose shall be at least 12X12 mm in accordance with the Guide**. If GDPB makes changes to the system instead of the barcode, the contractor shall be obliged to comply with the requirements of the newly created system without requesting a price difference. |  |  |  |
| **4.6.8.** | Even after acceptance, if any faulty operations related to the barcode system are detected later, the costs of changing the product packaging and, if deemed necessary, collecting the products from the field shall be borne by the Contractor. If this process exceeds one-month, new products with a new expiration date may be requested at the request of the Department to avoid any problems related to the expiration date. |  |  |  |
| **4.6.9.** | **Temperature monitoring during transportation:** |  |  |  |
| **4.6.9.1.** | The freeze indicator, temperature monitoring card, and digital temperature recording devices used **shall be listed in the WHO "E006: Temperature monitoring devices"** (https://extranet.who.int/prequal/immunization-devices/prequalified/imd-products)**.** |  |  |  |
| **4.6.9.2.** | If the product(s) are sensitive to freezing, each box shall contain a freeze indicator. |  |  |  |
| **4.6.9.3.** | If the product(s) are sensitive to high temperatures, each box shall contain a temperature monitoring card **with the date it was activated and the name/code of the activator written on it**. |  |  |  |
| **4.6.9.4.** | If the product(s) are sensitive to both freezing and high temperatures, or if they are packaged together, each box shall contain both a freeze indicator and a temperature monitor card with the date of activation and the name/code of the activator written on it. |  |  |  |
| **4.6.9.5.** | In addition, each pallet shall have an electronic, temperature, and freeze-sensitive digital monitor capable of long-term recording. The electronic, temperature, and freeze-sensitive digital monitors capable of long-term recording placed on the pallet shall be read during the inspection phase, the outputs shall be recorded in a report and signed by the company, and if there are no deviations, they can be filed electronically. If requested by the company, these devices shall be returned for storage without destruction for at least three months. Upon return, the pallet numbers and device serial numbers shall be recorded in a report.  If the pallets consist of insulated boxes, each containing heat tracking material (such as a digital recording device, heat monitoring card, or freeze indicator), and conflicting results are found between the digital heat records on or inside the pallet and the heat records inside the box when evaluating the heat records, the temperature monitoring results inside the boxes shall be considered when processing. |  |  |  |
| **4.6.9.6.** | Products found not to have been transported under appropriate conditions (Guidelines for the international packaging and shipping of vaccines, sixth edition. Geneva: World Health Organization, 2020. Licence: CC BY-NC-SA 3.0 IGO) as monitored by these heat trackers shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **4.6.10.** | Each product shall be delivered with a Material Safety Data Sheet (MSDS). The contractor is responsible for the “Transportation, packaging, and labelling of hazardous materials” and completing any shortfalls if there is any. |  |  |  |
| **4.6.11.** | The contractor's representative shall be present during the delivery or return of the products. The representative shall submit a letterhead, stamped, and signed authorization document belonging to the contractor and a photocopy of their photo ID to the Warehouse Manager. The contractor is responsible for unloading the products from the vehicle into the warehouse or loading them back onto the vehicle for return. A list of the names, telephone numbers, and addresses of all employees and subcontractor personnel who shall perform work on behalf of the contractor shall be submitted to the Warehouse Manager, signed by the contractor's representative, prior to unloading. The contractor shall be responsible for any damage that may be caused to the warehouse or equipment and for all liabilities arising from "Occupational Health and Safety Regulations." The contractor shall submit a stamped and signed commitment stating that it has assumed the SSI, occupational health and safety, and work accident liabilities of its employees for unloading the products from the vehicle or loading them in case of return, and that it has assumed the liability for compensation in case of damage to the warehouse or any equipment inside the warehouse. Responsibility begins upon entry into the Warehouse area after the security check. |  |  |  |
| **4.6.12.** | Except in emergencies, no contractor employees other than the vehicle drivers and those declared shall enter the climate-controlled warehouse. |  |  |  |
| **4.6.13.** | If barcoding, packaging, or prospectus changes are to be performed in the GDPB warehouse, the documents belonging to the subcontractors shall be as follows:   * + - * shall be a contract demonstrating the availability of occupational safety expertise and workplace physician support services as required by the "Occupational Health and Safety Law" No. 6331.       * The contractor's structure shall include at least one coordinator, one operations manager, one quality control and GMP manager, and one warehouse manager. These personnel shall be present during the execution of the work. There shall be a document or documents proving that the personnel included in the company structure have received GMP and Good Warehouse Practices Training organized by the Turkish Ministry of Health or an organization that has received a GMP Certificate from the Turkish Ministry of Health.       * There shall be standard operating procedures (SOPs) prepared by a pharmacist and approved by the company representative, covering barcode printing and affixing procedures and cold storage room operating rules. |  |  |  |
| **5.** | **DOCUMENTS AND MATERIALS REQUIRED FOR LABORATORY ANALYSES AND METHODS TO BE FOLLOWED** |  |  |  |
| **5.1.** | General principles of product safety;  The analysis reports for the product are part of the batch release certificate, and both documents shall be considered together in the evaluations. |  |  |  |
| **5.1.1.** | The product shall be manufactured in our country, have a manufacturing license from the Turkish Medicines and Medical Devices Agency (TİTCK), and present the BRC certificate for the delivered batch obtained from the TİTCK/Analysis and Control Laboratories Department. In addition, if there is no break in the cold chain during product transfer, the physical examination is appropriate, and the commission grants approval, the inspection acceptance process can be completed. |  |  |  |
| **5.1.2.** | If the product is manufactured outside our country and has an import license from TİTCK or is on the WHO's prequalification list (Prequalified vaccines), the Series Release Certificate for the delivered series shall be obtained from WHO/ Reference Laboratories/institutions, provided that the analyses are performed in accordance with the OCABR guidelines at the TİTCK/Analysis and Control Laboratories Directorate. The inspection acceptance process for products found to be suitable through analysis can be completed. |  |  |  |
| **5.1.3.** | If the product is not licensed in our country, but is licensed by the authorities in EMA, US-FDA, Japan, Canada, South Korea, and Australia as specified in Article 2.1 of the technical specifications, tests may be performed in accordance with the OCABR guidelines by the TİTCK/Analysis and Control Laboratories Department. The inspection and acceptance process for products with suitable analyses can be completed. |  |  |  |
| **5.2.** | If there are any doubts regarding product safety within the scope of the cold chain or other matters specified in the technical specifications, new samples may be taken if necessary, and analyses may be performed as required, including analyses based on batch release. |  |  |  |
| **5.3.** | These products are subject to the *"Regulations on Market Surveillance and Control Procedures and Principles to be Implemented by the Ministry of Health*." GDPB reserves the right to conduct analyses in case of possible suspicion or complaint. The Contractor shall provide the required number of product doses for analysis and the materials required for the analysis specified in Article 5 free of charge. If the analysis result is found to be unsatisfactory, even if the product in question has been accepted, the Contractor shall deliver the same quantity from different series within 90 calendar days. |  |  |  |
| **5.4.** | If the product does not comply with Article 5.1, after the inspection is completed, a sample shall be taken from each batch using the random sampling method and delivered to the laboratory with a report signed by the Contractor's representative and one of the inspection members. |  |  |  |
| **5.5.** | Since the physical appearance of the products requires expertise, it shall be assessed by specialized personnel at the National Reference Laboratory within the TİTCK in accordance with the current Turkish/European Pharmacopoeia. Products that are not suitable in terms of physical appearance shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. After the physical tests of the products are found to be suitable, other tests shall be performed in accordance with Article 5. |  |  |  |
| **5.6.** | The vaccine shall comply with the characteristics and conditions specified in **World Health Organization** **(WHO) Technical Report Series** 980 Annex 4 and **European Pharmacopoeia** **11.0 01/2019:1056 and** **01 /2020:2920** monograph in terms of physical appearance and laboratory analyses. |  |  |  |
| **5.7.** | The Contractor shall deliver two reference vaccines free of charge for each batch, along with reagents and chemical materials deemed necessary for testing the potency and identity of the vaccine, to be used in conjunction with the vaccines to be tested. Additionally, for every four batches of the vaccine to undergo quality control, the following shall be delivered: |  |  |  |
| **5.8.** | Where necessary, the same quantities of Standard Vaccine, Antigen, Antiserum, and other relevant standards and international standards shall be provided free of charge and promptly by the Contractor. |  |  |  |
| **5.8.1.** | Documents to be delivered to the laboratory with the product:  -Protocols related to production methods and processes, as well as quality control protocols,  -Standard Operating Procedure (SOP) documents related to the product's quality control tests, current validation reports, and validation procedure documents shall be provided with the product. |  |  |  |
| **5.8.2.** | If the reference vaccine and chemicals are imported from abroad, customs clearance procedures shall be carried out by the contractors. |  |  |  |
| **5.8.3.** | For each batch of vaccine delivered, the Contractor shall provide a sufficient number of samples free of charge for physical examination and laboratory analysis. |  |  |  |
| **5.8.4.** | If changes are made to the analysis methods, the standards and quantities requested from the Contractor may be re-evaluated. |  |  |  |
| **5.8.5.** | In addition, official documents (official certificates) containing the reference vaccine and/or reference unit values shall also be submitted. The reagents, chemical materials, detailed test SOPs (latest updated version), current validation and validation procedure documents, and calculation documents sent shall be delivered complete with the vaccines to be tested. |  |  |  |
| **5.9.** | If vaccines are prepared in vacuum-sealed ampoules/vials, and if the number of non-vacuum ampoules/vials exceeds 1% in the vacuum control performed on vaccine lot samples taken for inspection, the vaccine lot in question shall be rejected and returned due to the number of non-vacuum ampoules/vials. If the number of non-vacuum ampoules/vials is less than 1%, the vaccine supplier shall deliver the equivalent number of non-vacuum ampoules/vials free of charge within 120 calendar days from the date of notification by the General Directorate of Public Health to the supplier. |  |  |  |
| **5.10.** | Biological controls of products to be delivered shall be carried out at the Turkish Medicines and Medical Devices Agency, but in order to prevent interruption of vaccine and antiserum administration due to potential difficulties in the analysis process, a WHO-approved reference laboratory (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies) ([https://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)](http://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)) may also be conducted, and the costs shall be borne by the Contractor. The results of the control reports of the producer country shall be consistent with the results of the control reports of the Turkish Medicines and Medical Devices Agency or WHO-approved reference laboratories (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies). |  |  |  |
| **5.11.** | The Contractor may object to the results within 15 days. Upon such objection, product samples shall be sent to a second laboratory from among the WHO Reference Laboratories designated ex officio by GDPB or deemed appropriate by GDPB upon the Contractor's recommendation, with the shipping and analysis costs borne by the Contractor. If inconsistencies are detected following analyses conducted by WHO Reference Laboratories and the Turkish Medicines and Medical Devices Agency, the second report shall be accepted as the final report. |  |  |  |
| **6.** | **OTHER PROVISIONS** |  |  |  |
| **6.1.** | Due to delays caused by incorrect or incomplete materials and documents specified in Article 5, such as references, standards, and SOPs required for analysis, which are the responsibility of the contractor to deliver, the product's shelf life shall be shortened by the duration of the delay. The shelf life suitability specified in Article 4 shall be reduced by the duration of the delay. If the shelf life falls below the specified duration, return and exchange processes shall be initiated. For example, if the specification requires a minimum shelf life of 18 months upon delivery to the warehouse, but the product has a shelf life of 20 months at the time of delivery, and the SOP, references, etc. are delivered 70 days later due to a reason attributable to the contractor that prevented the completion of the analyses, the products shall be subject to processing due to shelf life non-compliance and shall be returned. |  |  |  |
| **6.2.** | Batches of products deemed unsuitable based on biological or chemical control results shall be returned. The contractor shall collect these products from the GDPB warehouse where they are located, transport them to the country of origin, and deliver the same quantity of products from a different batch that comply with the specifications to GDPB free of charge within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **6.3.** | In the event of product return (rejection or lot change), the products shall be collected from the warehouse within 30 calendar days after the notification date, during official working hours and days. If not collected, the contractor shall bear the storage and/or disposal costs for the delayed period. |  |  |  |
| **6.4.** | In the event that the products are returned to the Contractor, the relevant official documents proving that the products have been removed from Türkiye or destroyed shall be submitted to the administration within 120 calendar days after the products are collected from the warehouse. If no notification is made, the procedures shall be carried out in accordance with customs regulations. |  |  |  |
| **6.5.** | After acceptance of the products, if any physical deficiencies (barcode errors, packaging, labels, etc.) are detected, the contractor shall remedy the deficiency free of charge. |  |  |  |

| **LOT 6 - PAEDIATRIC HEPATITIS A VACCINE** | | | | |
| --- | --- | --- | --- | --- |
| **Item No** | **Specifications** | **Specifications Offered** | **Notes, remarks,  ref to documentation** | **Evaluation Committee’s notes** |
| **1.** | **VACCINE TECHNICAL SPECIFICATIONS** |  |  |  |
| **1.1.** | The product shall comply with vaccine production, quality control parameters, methods, and specifications in World Health Organization (WHO) Technical Report Series (TRS) No:858 Annex II, European Pharmacopoeia 11.0 01/2019:1107 Monograph. |  |  |  |
| **1.2.** | The vaccine shall be purified, inactivated and adsorbed. |  |  |  |
| **1.3.** | The paediatric dose of the product shall be 0.5 ml. One dose of Paediatric Hepatitis A Vaccine shall contain ≥ 720 EU/dose or 250 U/dose or ≥ 80 U/dose or ≥ 25 U/dose of antigen. The vaccine shall be packaged as a single dose. |  |  |  |
| **1.4.** | The vaccine shall be packaged in a single-dose, ready-to-use syringe (injector) containing, vial or ampule. |  |  |  |
| **1.5.** | The vaccine shall maintain its stability to its expiration date at temperatures between (+2) - (+8) OC from the last successful potency test. |  |  |  |
| **2.** | **DOCUMENTS TO BE INCLUDED IN THE FILE TO BE REVIEWED BY THE TENDER COMMITTEE** |  |  |  |
| **2.1.** | The product in question;   * + 1. shall have a license issued by the Turkish Ministry of Health,     2. If it does not have a license issued by the Turkish Ministry of Health;   + It shall be included in the latest pre-qualification list published by the World Health Organization (<https://extranet.whoint/prequal/vaccines/prequalified-vaccines)> **or**,   + It shall have a license from the European Medicines Agency (EMA) and be manufactured in European Union countries, or   + It shall have a license from the US-FDA and be manufactured in the United States, **or**   + It shall be licensed by the Pharmaceuticals and Medical Devices Agency (PMDA) and manufactured in Japan, or   + It shall be licensed by the South Korean Food and Drug Administration and manufactured in South Korea, **or**   + It shall be licensed by the Canadian Food and Drugs Act and Regulations and manufactured in Canada, **or**   + The product shall be licensed by the Australian Department of Health Therapeutic Goods Administration and manufactured in Australia. |  |  |  |
| **2.2.** | The product shall be accompanied by a certificate (GMP certificate) showing that the factory producing it complies with the **Good Manufacturing Practices (**GMP) standards approved by the State Control Agency of the country where the product is manufactured. If the product is filled or manufactured in our country, there shall be a document showing that the factory where the production/filling is carried out, approved by the Turkish Ministry of Health, Turkish Medicines and Medical Devices Agency, manufactures in accordance with good manufacturing practices (GMP) rules. |  |  |  |
| **2.3.** | For any batch produced within the last two years, the 'National Regulatory Authority' (NRA) or the Batch Release Certificate issued by the EMA (from the locations specified in the annex to the European Union's 2001/83/EC directive), US-FDA, Japan, South Korea, Canada, and Australian state authorities, as specified in 2.1. If the product is manufactured in Türkiye, it shall be a marketing authorization certificate issued by the Turkish Medicines and Medical Devices Agency of the Ministry of Health of the Republic of Türkiye. The analysis report for the same series shall also be included in the BRC annex. |  |  |  |
| **2.4.** | A valid Pharmaceutical Product Certificate (CPP) approved by the manufacturer's country authority. |  |  |  |
| **2.5.** | A **manufacturer-approved** document showing that the risk of Transmissible Spongiform Encephalopathy (TSE) has been minimized at every stage of the product's production. |  |  |  |
| **2.6.** | If the product is licensed in Türkiye, it shall have a "Summary of Product Characteristics" (SPC) or package insert or "Patient Information Leaflet" (PIL) approved by the Turkish Medicines and Medical Devices Agency (TİTCK), or if it is not licensed in Türkiye, it shall have one approved by the relevant country's authority, along with Turkish translations. |  |  |  |
| **2.7.** | If applicable, a list of tasks to be performed by subcontractors shall be provided. |  |  |  |
| **2.8.** | The tenderer shall declare in writing how many batches of the product they can deliver. |  |  |  |
| **2.9.** | If the product is used outside the country of manufacture, a document shall be submitted containing the list of countries where the product is used, approved by the manufacturer, along with the usage permits (import permits) or license numbers for these products, and information on the total number of doses used in countries other than the country of manufacture for the last two calendar years prior to the year of the tender. |  |  |  |
| **2.10.** | The tenderer shall declare that if the manufacturer or another country where the product is used suspends the use of the product for any reason, or if they receive any news in this regard, they shall inform the Ministry within 24 hours (product name, serial number, reason for discontinuation, etc.) and that if the information is not provided within 24 hours, the administration has the right to unilaterally terminate the contract. It also indicates that in the event of discontinuation of the product, after the unused products are collected by the Ministry and sent to the Central Warehouse, the Tenderer undertakes to bring a new product from a different series that complies with the specifications within 90 (ninety) calendar days from the date the replacement request is notified to the Tenderer. In addition, the Tenderer shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date of notification of the product replacement request after the unused products are collected by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **2.11** | The Tenderer shall submit the original or notarized copies of the required documents, along with their certified Turkish translations, to the tender committee. |  |  |  |
| **3.** | **DELIVERY OF PRODUCTS** |  |  |  |
| **3.1.** | If the products are imported, the tenderer's representative shall be present when the products are collected from customs and shall ensure that the goods are collected in accordance with the required specifications and delivered to the location deemed appropriate by GDPB without delay. |  |  |  |
| **3.2.** | The contractor shall provide the Department with the shipment details 3 days prior to the delivery date of the product. |  |  |  |
| **3.3.** | Product delivery shall be made in such a way that it does not coincide with holidays, official holidays, or the end of working hours in Türkiye. |  |  |  |
| **3.4.** | To clear products purchased by GDPB through customs, the Contractor shall enter the product information (batch release certificate and quantity for the lot/serial number for which import permission is requested) via the Single Window Portal System (<https://uygulama.gtb.gov.tr/TekPencere>). The Single Window approval request shall be submitted to the Department electronically (to the Department's official e-mail address) or in writing at least 3 days in advance. Products purchased by the General Directorate of Public Health shall be delivered to the GDPB Vaccine and Drug Warehouse within 48 hours after being cleared through customs (except for products filled in Türkiye) if they are imported. Any changes required after the initial inspection (packaging, barcode, etc.) may also be made at the Central Vaccine and Drug Warehouse with the approval of the GDPB. If storage exceeds 48 hours, it is mandatory to submit temperature records approved by the Contractor's quality manager from the production site until the Ministry of Health Vaccine Storage arrives, to use a warehouse licensed by the Turkish Ministry of Health, and, if "temperature monitoring cards" are installed at the production facility, not to change them. |  |  |  |
| **3.5.** | If the packaging of the imported product (including barcoding) is to be changed at a different location after the contract is signed, this situation shall be reported to the Department. The temporary storage location shall be licensed by the Turkish Ministry of Health, the initial opening of the packaging of the product withdrawn from customs shall be carried out under the supervision of GDPB or its authorized personnel, and the shipment and temporary storage temperature records shall also be submitted during the inspection phase. GDPB may inspect this entire process at any time and on any day after customs clearance. Intermediate storage shall be possible if the application made to GDPB and the storage period are found to be appropriate. |  |  |  |
| **3.6.** | Products filled in our country shall be delivered to the GDPB Vaccine and Drug Warehouse within 24 hours of leaving the filling facility. If the product is not delivered to the GDPB Vaccine and Drug Warehouse within 24 hours after leaving the filling facility and is to be stored in another warehouse, the organization performing the intermediate storage shall be licensed by the Turkish Ministry of Health, temperature records from the production site to the warehouse and within the warehouse shall be kept, and certified copies from the product quality representative shall be delivered to GDPB upon product delivery. These stages shall be open to inspection by GDPB if required. The Department shall be notified if temporary storage is required. Products shall not be accepted if the specified conditions cannot be met. |  |  |  |
| **3.7.** | If the products are filled/manufactured in Türkiye, the time limit specified in Article 3, except for 3.2 and 3.3, and the restrictions at shall not apply. |  |  |  |
| **4.** | **DOCUMENTS REQUIRED DURING INSPECTION AND PRODUCT CHARACTERISTICS** |  |  |  |
| **4.1.** | Products shall have **a shelf life of at least 18 (eighteen) months** from the date of delivery to our warehouse. |  |  |  |
| **4.1.1.** | **Documents required during the product inspection phase:**  The documents specified in Article 2 of the Technical Specifications and the documents specific to the delivered series/lot shall be submitted during the inspection stage. These documents are:   * Product License * Current GMP certificate for the production site, * Analysis report for the delivered batch (document containing information such as composition, analysis results, reference values, production/expiration dates, etc.), * BRC for the delivered batch, * Current Pharmaceutical Product Certificate (CPP) * TSE declaration (item 2.5), * List of tasks to be performed by subcontractors, * Package Insert or Prospectus or IFU (Article 2.6), * List of countries where the product is used and import permit/license number and the number of doses used in each country in the last two calendar years prior to the year of the offer (Article 2.9), * Commitment letter (Article 2.10).   The original documents or notarised copies and the certified Turkish version shall be submitted to the Tender Committee. |  |  |  |
| **4.2.** | The Contractor, manufacturer or any other country where this product is used shall notify the Ministry within 24 hours if the use of the product is suspended for any reason or if they receive any information in this regard (product name, serial number, reason for discontinuation, etc.) and acknowledges that the administration has the right to unilaterally terminate the contract if such information is not provided within 24 hours. In the event of discontinuation of the product, the Contractor shall be required to bring a manufacturer-approved commitment letter to the Ministry within 90 (ninety) calendar days from the date the replacement request is notified to the Contractor. Additionally, the Contractor shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date the request for product replacement is notified, following the collection of unused products by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **4.3.** | Stability studies and results proving the actual shelf life of the product in question shall be submitted. If the product is filled or manufactured in our country and stability studies are still ongoing, the TİTCK-approved study results shall be submitted to the Department as they are completed. |  |  |  |
| **4.4.** | Along with the product, all technical documents required in the tender for the product (Good Manufacturing Practices, analysis report, SPC, certificates, etc.) and detailed SOP (may be provided in the original license), **stability results (showing real-time and accelerated stability shelf life),** product photos, and all documents containing technical information about the packaging (dimensions, volume, etc.) shall be submitted to the inspection commission in duplicate on CD/DVD/flash drive. Each heading shall be indicated with a separate folder name, and the relevant documents shall be found under the relevant folder. If deemed necessary, other documents and information related to the product may be requested in physical or digital form. |  |  |  |
| **4.5.** | Documents that do not change with each shipment shall be submitted once, with the first shipment. If deemed necessary, documents may be requested again. |  |  |  |
| **4.6.** | **Required Packaging Characteristics** |  |  |  |
| **4.6.1.** | The products shall be packaged in vials, flacons or ready-to-use syringe (injector) containing a single dose. Those ready-to-use syringe (injector)s shall be single packed or provided in ten packs. If the products are packaged in packs of ten, the packs shall contain foam or cardboard separators to prevent the vials or ampoules from breaking due to contact. If the product is packaged individually, the packages shall then be bundled in packs of ten. If diluents are separate, 5 additional diluents shall be delivered with every 1000 doses of vaccine. |  |  |  |
| **4.6.2.** | The inner and outer packaging of licensed products in Türkiye shall comply with the current "Regulation on Packaging Information, Instructions for Use, and Tracking of Human Medicinal Products" published by the Turkish Ministry of Health. If the product is not licensed in our country, the inner packaging of the ready-to-use syringe (injector), ampoule, or vial shall bear, at a minimum, the manufacturer's and product name, dosage, amount of content per dose, method of administration (IM/IV/SC/ID, etc.), lot (batch) number, and expiration date, printed in indelible ink. The package shall also contain storage temperature information in addition to the inner packaging. The product package shall bear the statement "Property of the Turkish Ministry of Health, NOT FOR SALE." |  |  |  |
| **4.6.3.** | Each product package shall contain at least one "Summary of Product Characteristics" (SPC) or Turkish package insert or "Patient Information Leaflet" (PIL) prepared in accordance with the "Regulation on the Packaging and Labelling of Human Medicinal Products" dated 25.04.2017 and numbered 30048. Additionally, the following text shall be added to the beginning of the “"Summary of Product Characteristics" (SPC)” or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention:  "In vaccine and serum applications, the EXPANDED PROGRAM ON IMMUNIZATION (EPI) CIRCULAR shall be taken into consideration.  For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates***."*** |  |  |  |
| **4.6.4.** | The packages shall then be placed in boxes. The names and addresses of the manufacturer and representative company of the product, the name of the product, the lot number, the storage temperature, the expiration date, and the number of doses in the box shall be written on these boxes. If the products are packaged individually, ten packages shall be placed in each box. If the products are packaged in packs of ten, five packages shall be placed in each box. |  |  |  |
| **4.6.5.** | The packaging boxes shall be placed in styrofoam. The styrofoam shall then be placed inside cartons. The carton dimensions shall be 40X60X40 ±2 (Width, Length, Height) cm. A sufficient number of ice packs or gel packs, etc., shall be placed in the cartons. The ice packs or gel packs, etc.**,** placed in the cartons shall be **unfrozen and cooled**. If the products are not sensitive to freezing (lyophilized), dry ice or frozen ice packs or gel may be used during transport. The names and addresses of the manufacturer and representative company, the product name, serial number, storage temperature, expiration date, dose quantity in the carton, carton dimensions, and weight shall be written on these cartons. |  |  |  |
| **4.6.6.** | The boxes shall then be placed on pallets. The pallets shall be euro pallets (120cm±2cmx80cm±2cmx10-15cm). After the boxes are placed on the pallets, the height together with the pallet shall not exceed 2 (two) meters. The boxes may protrude from the pallet by a maximum of 5 cm. There shall be a maximum of 16 (sixteen) boxes on the pallet. |  |  |  |
| **4.6.7.** | There shall be a 2D barcode on the packages, boxes, cartons, and pallets. The barcode prepared for the ready-to-use syringe (injector) inside each individually packaged product (these barcodes shall also have HL7 and 97 breakdown values) shall be on the product's package. The packages shall then be tied in sets of ten, and the package label shall be affixed to a different area than the barcode affixed to each product. If the product is packaged in sets of ten, the barcode prepared for the ready-to-use syringe (injector) (these barcodes shall also have HL7 and 97 breakdown values) shall be placed inside the package, and the barcode corresponding to the package breakdown shall be on the package. For the information to be included in the barcode, the information specified in the Guide for Barcode Application to Vaccines, Antiserums, and Diluents published by the Turkish Ministry of Health shall be used as a basis, and any additional information required shall be determined by GDPB. **The barcode area for the dose shall be at least 12X12 mm in accordance with the Guide**. If GDPB makes changes to the system instead of the barcode, the contractor shall be obliged to comply with the requirements of the newly created system without requesting a price difference. |  |  |  |
| **4.6.8.** | Even after acceptance, if any faulty operations related to the barcode system are detected later, the costs of changing the product packaging and, if deemed necessary, collecting the products from the field shall be borne by the Contractor. If this process exceeds one-month, new products with a new expiration date may be requested at the request of the Department to avoid any problems related to the expiration date. |  |  |  |
| **4.6.9.** | **Temperature monitoring during transportation:** |  |  |  |
| **4.6.9.1.** | The freeze indicator, temperature monitoring card, and digital temperature recording devices used **shall be listed in the WHO "E006: Temperature monitoring devices"** (https://extranet.who.int/prequal/immunization-devices/prequalified/imd-products)**.** |  |  |  |
| **4.6.9.2.** | If the product(s) are sensitive to freezing, each box shall contain a freeze indicator. |  |  |  |
| **4.6.9.3.** | If the product(s) are sensitive to high temperatures, each box shall contain a temperature monitoring card **with the date it was activated and the name/code of the activator written on it**. |  |  |  |
| **4.6.9.4.** | If the product(s) are sensitive to both freezing and high temperatures, or if they are packaged together, each box shall contain both a freeze indicator and a temperature monitor card with the date of activation and the name/code of the activator written on it. |  |  |  |
| **4.6.9.5.** | In addition, each pallet shall have an electronic, temperature, and freeze-sensitive digital monitor capable of long-term recording. The electronic, temperature, and freeze-sensitive digital monitors capable of long-term recording placed on the pallet shall be read during the inspection phase, the outputs shall be recorded in a report and signed by the company, and if there are no deviations, they can be filed electronically. If requested by the company, these devices shall be returned for storage without destruction for at least three months. Upon return, the pallet numbers and device serial numbers shall be recorded in a report.  If the pallets consist of insulated boxes, each containing heat tracking material (such as a digital recording device, heat monitoring card, or freeze indicator), and conflicting results are found between the digital heat records on or inside the pallet and the heat records inside the box when evaluating the heat records, the temperature monitoring results inside the boxes shall be considered when processing. |  |  |  |
| **4.6.9.6.** | Products found not to have been transported under appropriate conditions (Guidelines for the international packaging and shipping of vaccines, sixth edition. Geneva: World Health Organization, 2020. Licence: CC BY-NC-SA 3.0 IGO) as monitored by these heat trackers shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **4.6.10.** | Each product shall be delivered with a Material Safety Data Sheet (MSDS). The contractor is responsible for the “Transportation, packaging, and labelling of hazardous materials” and completing any shortfalls if there is any. |  |  |  |
| **4.6.11.** | The contractor's representative shall be present during the delivery or return of the products. The representative shall submit a letterhead, stamped, and signed authorization document belonging to the contractor and a photocopy of their photo ID to the Warehouse Manager. The contractor is responsible for unloading the products from the vehicle into the warehouse or loading them back onto the vehicle for return. A list of the names, telephone numbers, and addresses of all employees and subcontractor personnel who shall perform work on behalf of the contractor shall be submitted to the Warehouse Manager, signed by the contractor's representative, prior to unloading. The contractor shall be responsible for any damage that may be caused to the warehouse or equipment and for all liabilities arising from "Occupational Health and Safety Regulations." The contractor shall submit a stamped and signed commitment stating that it has assumed the SSI, occupational health and safety, and work accident liabilities of its employees for unloading the products from the vehicle or loading them in case of return, and that it has assumed the liability for compensation in case of damage to the warehouse or any equipment inside the warehouse. Responsibility begins upon entry into the Warehouse area after the security check. |  |  |  |
| **4.6.12.** | Except in emergencies, no contractor employees other than the vehicle drivers and those declared shall enter the climate-controlled warehouse. |  |  |  |
| **4.6.13.** | If barcoding, packaging, or prospectus changes are to be performed in the GDPB warehouse, the documents belonging to the subcontractors shall be as follows:   * + - * shall be a contract demonstrating the availability of occupational safety expertise and workplace physician support services as required by the "Occupational Health and Safety Law" No. 6331.       * The contractor's structure shall include at least one coordinator, one operations manager, one quality control and GMP manager, and one warehouse manager. These personnel shall be present during the execution of the work. There shall be a document or documents proving that the personnel included in the company structure have received GMP and Good Warehouse Practices Training organized by the Turkish Ministry of Health or an organization that has received a GMP Certificate from the Turkish Ministry of Health.       * There shall be standard operating procedures (SOPs) prepared by a pharmacist and approved by the company representative, covering barcode printing and affixing procedures and cold storage room operating rules. |  |  |  |
| **5.** | **DOCUMENTS AND MATERIALS REQUIRED FOR LABORATORY ANALYSES AND METHODS TO BE FOLLOWED** |  |  |  |
| **5.1.** | General principles of product safety;  The analysis reports for the product are part of the batch release certificate, and both documents shall be considered together in the evaluations. |  |  |  |
| **5.1.1.** | The product shall be manufactured in our country, have a manufacturing license from the Turkish Medicines and Medical Devices Agency (TİTCK), and present the BRC certificate for the delivered batch obtained from the TİTCK/Analysis and Control Laboratories Department. In addition, if there is no break in the cold chain during product transfer, the physical examination is appropriate, and the commission grants approval, the inspection acceptance process can be completed. |  |  |  |
| **5.1.2.** | If the product is manufactured outside our country and has an import license from TİTCK or is on the WHO's prequalification list (Prequalified vaccines), the Batch Release Certificate for the delivered series shall be obtained from WHO/ Reference Laboratories/institutions, provided that the analyses are performed in accordance with the OCABR guidelines at the TİTCK/Analysis and Control Laboratories Directorate. The inspection acceptance process for products found to be suitable through analysis can be completed. |  |  |  |
| **5.1.3.** | If the product is not licensed in our country, but is licensed by the authorities in EMA, US-FDA, Japan, Canada, South Korea, and Australia as specified in Article 2.1 of the technical specifications, tests may be performed in accordance with the OCABR guidelines by the TİTCK/Analysis and Control Laboratories Department. The inspection and acceptance process for products with suitable analyses can be completed. |  |  |  |
| **5.2.** | If there are any doubts regarding product safety within the scope of the cold chain or other matters specified in the technical specifications, new samples may be taken if necessary, and analyses may be performed as required, including analyses based on batch release. |  |  |  |
| **5.3.** | These products are subject to the *"Regulations on Market Surveillance and Control Procedures and Principles to be Implemented by the Ministry of Health*." GDPB reserves the right to conduct analyses in case of possible suspicion or complaint. The Contractor shall provide the required number of product doses for analysis and the materials required for the analysis specified in Article 5 free of charge. If the analysis result is found to be unsatisfactory, even if the product in question has been accepted, the Contractor shall deliver the same quantity from different series within 90 calendar days. |  |  |  |
| **5.4.** | If the product does not comply with Article 5.1, after the inspection is completed, a sample shall be taken from each batch using the random sampling method and delivered to the laboratory with a report signed by the Contractor's representative and one of the inspection members. |  |  |  |
| **5.5.** | Since the physical appearance of the products requires expertise, it shall be assessed by specialized personnel at the National Reference Laboratory within the TİTCK in accordance with the current Turkish/European Pharmacopoeia. Products that are not suitable in terms of physical appearance shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. After the physical tests of the products are found to be suitable, other tests shall be performed in accordance with Article 5. |  |  |  |
| **5.6.** | The vaccine shall comply with the characteristics and conditions specified in World Health Organization (WHO) Technical Report Series 858 Annex II and European Pharmacopoeia 11.0 01/2019:1107 and 01 /2020:20920monograph in terms of physical appearance and laboratory analyses. |  |  |  |
| **5.7.** | The Contractor shall deliver two reference vaccines free of charge for each batch, along with reagents and chemical materials deemed necessary for testing the potency and identity of the vaccine, to be used in conjunction with the vaccines to be tested. |  |  |  |
| **5.8.** | Where necessary, the same quantities of Standard Vaccine, Antigen, Antiserum, and other relevant standards and international standards shall be provided free of charge and promptly by the Contractor. |  |  |  |
| **5.8.1.** | Documents to be delivered to the laboratory with the product:  -Protocols related to production methods and processes, as well as quality control protocols,  -Standard Operating Procedure (SOP) documents related to the product's quality control tests, current validation reports, and validation procedure documents shall be provided with the product. |  |  |  |
| **5.8.2.** | If the reference vaccine and chemicals are imported from abroad, customs clearance procedures shall be carried out by the contractors. |  |  |  |
| **5.8.3.** | For each batch of vaccine delivered, the Contractor shall provide a sufficient number of samples free of charge for physical examination and laboratory analysis. |  |  |  |
| **5.8.4.** | If changes are made to the analysis methods, the standards and quantities requested from the Contractor may be re-evaluated. |  |  |  |
| **5.8.5.** | In addition, official documents (official certificates) containing the reference vaccine and/or reference unit values shall also be submitted. The reagents, chemical materials, detailed test SOPs (latest updated version), current validation and validation procedure documents, and calculation documents sent shall be delivered complete with the vaccines to be tested. |  |  |  |
| **5.9.** | If vaccines are prepared in vacuum-sealed ampoules/vials, and if the number of non-vacuum ampoules/vials exceeds 1% in the vacuum control performed on vaccine lot samples taken for inspection, the vaccine lot in question shall be rejected and returned due to the number of non-vacuum ampoules/vials. If the number of non-vacuum ampoules/vials is less than 1%, the vaccine supplier shall deliver the equivalent number of non-vacuum ampoules/vials free of charge within 120 calendar days from the date of notification by the General Directorate of Public Health to the supplier. |  |  |  |
| **5.10.** | Biological controls of products to be delivered shall be carried out at the Turkish Medicines and Medical Devices Agency, but in order to prevent interruption of vaccine and antiserum administration due to potential difficulties in the analysis process, a WHO-approved reference laboratory (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies) ([https://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)](http://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)) may also be conducted, and the costs shall be borne by the Contractor. The results of the control reports of the producer country shall be consistent with the results of the control reports of the Turkish Medicines and Medical Devices Agency or WHO-approved reference laboratories (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies). |  |  |  |
| **5.11.** | The Contractor may object to the results within 15 days. Upon such objection, product samples shall be sent to a second laboratory from among the WHO Reference Laboratories designated ex officio by GDPB or deemed appropriate by GDPB upon the Contractor's recommendation, with the shipping and analysis costs borne by the Contractor. If inconsistencies are detected following analyses conducted by WHO Reference Laboratories and the Turkish Medicines and Medical Devices Agency, the second report shall be accepted as the final report. |  |  |  |
| **6.** | **OTHER PROVISIONS** |  |  |  |
| **6.1.** | Due to delays caused by incorrect or incomplete materials and documents specified in Article 5, such as references, standards, and SOPs required for analysis, which are the responsibility of the contractor to deliver, the product's shelf life shall be shortened by the duration of the delay. The shelf life suitability specified in Article 4 shall be reduced by the duration of the delay. If the shelf life falls below the specified duration, return and exchange processes shall be initiated. For example, if the specification requires a minimum shelf life of 18 months upon delivery to the warehouse, but the product has a shelf life of 20 months at the time of delivery, and the SOP, references, etc. are delivered 70 days later due to a reason attributable to the contractor that prevented the completion of the analyses, the products shall be subject to processing due to shelf life non-compliance and shall be returned. |  |  |  |
| **6.2.** | Batches of products deemed unsuitable based on biological or chemical control results shall be returned. The contractor shall collect these products from the GDPB warehouse where they are located, transport them to the country of origin, and deliver the same quantity of products from a different batch that comply with the specifications to GDPB free of charge within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **6.3.** | In the event of product return (rejection or lot change), the products shall be collected from the warehouse within 30 calendar days after the notification date, during official working hours and days. If not collected, the contractor shall bear the storage and/or disposal costs for the delayed period. |  |  |  |
| **6.4.** | In the event that the products are returned to the Contractor, the relevant official documents proving that the products have been removed from Türkiye or destroyed shall be submitted to the administration within 120 calendar days after the products are collected from the warehouse. If no notification is made, the procedures shall be carried out in accordance with customs regulations. |  |  |  |
| **6.5** | After acceptance of the products, if any physical deficiencies (barcode errors, packaging, labels, etc.) are detected, the contractor shall remedy the deficiency free of charge. |  |  |  |

| **LOT 7 - MEASLES- MUMPS- RUBELLA VACCINE** | | | | |
| --- | --- | --- | --- | --- |
| **Item No** | **Specifications** | **Specifications Offered** | **Notes, remarks,  ref to documentation** | **Evaluation Committee’s notes** |
| **1.** | **VACCINE TECHNICAL SPECIFICATIONS** |  |  |  |
| **1.1.** | The product shall comply with specifications and conditions in World Health Organization (WHO) Technical Report Series (TRS) No:840 Annex III and European Pharmacopoeia 11.0/2023 and 04/2022 Monograph. |  |  |  |
| **1.2.** | Mumps component of the vaccine shall be Jeryl Lynn. |  |  |  |
| **1.3.** | It shall be produced of thermo stable strains, and this shall be proved by Thermo-stabile tests. Relevant documents shall be submitted to the Tender Committee during the delivery of samples. |  |  |  |
| **1.4.** | Each dose shall contain minimum of 103.0 CCID50 live attenuated measles, minimum 103.0 PFU/CCID50 live attenuated rubella and minimum of 103,7 PFU/CCID50 live attenuated mumps virus. |  |  |  |
| **1.5.** | The vaccine shall maintain its stability to its expiration date at temperatures between (+2) - (+8) OC from the last successful potency test. |  |  |  |
| **1.6.** | Vaccines shall be supplied in ready-to-use single-dose injector, vial or ampoule. |  |  |  |
| **2.** | **DOCUMENTS TO BE INCLUDED IN THE FILE TO BE REVIEWED BY THE TENDER COMMITTEE** |  |  |  |
| **2.1.** | The product in question;   * + 1. shall have a license issued by the Turkish Ministry of Health,     2. If it does not have a license issued by the Turkish Ministry of Health;   + It shall be included in the latest pre-qualification list published by the World Health Organization (<https://extranet.whoint/prequal/vaccines/prequalified-vaccines)> or,   + It shall have a license from the European Medicines Agency (EMA) and be manufactured in European Union countries, or   + It shall have a license from the US-FDA and be manufactured in the United States, **or**   + It shall be licensed by the Pharmaceuticals and Medical Devices Agency (PMDA) and manufactured in Japan, or   + It shall be licensed by the South Korean Food and Drug Administration and manufactured in South Korea, **or**   + It shall be licensed by the Canadian Food and Drugs Act and Regulations and manufactured in Canada, **or**   + The product shall be licensed by the Australian Department of Health Therapeutic Goods Administration and manufactured in Australia. |  |  |  |
| **2.2.** | The product shall be accompanied by a certificate (GMP certificate) showing that the factory producing it complies with the **Good Manufacturing Practices (**GMP) standards approved by the State Control Agency of the country where the product is manufactured. If the product is filled or manufactured in our country, there shall be a document showing that the factory where the production/filling is carried out, approved by the Turkish Ministry of Health, Turkish Medicines and Medical Devices Agency, manufactures in accordance with good manufacturing practices (GMP) rules. |  |  |  |
| **2.3.** | For any batch produced within the last two years, the 'National Regulatory Authority' (NRA) or the Batch Release Certificate issued by the EMA (from the locations specified in the annex to the European Union's 2001/83/EC directive), US-FDA, Japan, South Korea, Canada, and Australian state authorities, as specified in 2.1. If the product is manufactured in Türkiye, it shall be a marketing authorization certificate issued by the Turkish Medicines and Medical Devices Agency of the Ministry of Health of the Republic of Türkiye. The analysis report for the same series shall also be included in the BRC annex. |  |  |  |
| **2.4.** | A valid Pharmaceutical Product Certificate (CPP) approved by the manufacturer's country authority. |  |  |  |
| **2.5.** | A **manufacturer-approved** document showing that the risk of Transmissible Spongiform Encephalopathy (TSE) has been minimized at every stage of the product's production. |  |  |  |
| **2.6.** | If the product is licensed in Türkiye, it shall have a "Summary of Product Characteristics" (SPC) or package insert or "Patient Information Leaflet" (PIL) approved by the Turkish Medicines and Medical Devices Agency (TİTCK), or if it is not licensed in Türkiye, it shall have one approved by the relevant country's authority, along with Turkish translations. |  |  |  |
| **2.7.** | If applicable, a list of tasks to be performed by subcontractors shall be provided. |  |  |  |
| **2.8.** | The tenderer shall declare in writing how many batches of the product they can deliver. |  |  |  |
| **2.9.** | If the product is used outside the country of manufacture, a document shall be submitted containing the list of countries where the product is used, approved by the manufacturer, along with the usage permits (import permits) or license numbers for these products, and information on the total number of doses used in countries other than the country of manufacture for the last two calendar years prior to the year of the tender. |  |  |  |
| **2.10.** | The tenderer shall declare that if the manufacturer or another country where the product is used suspends the use of the product for any reason, or if they receive any news in this regard, they shall inform the Ministry within 24 hours (product name, serial number, reason for discontinuation, etc.) and that if the information is not provided within 24 hours, the administration has the right to unilaterally terminate the contract. It also indicates that in the event of discontinuation of the product, after the unused products are collected by the Ministry and sent to the Central Warehouse, the Tenderer undertakes to bring a new product from a different series that complies with the specifications within 90 (ninety) calendar days from the date the replacement request is notified to the Tenderer. In addition, the Tenderer shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date of notification of the product replacement request after the unused products are collected by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **2.11.** | The Tenderer shall submit the original or notarized copies of the required documents, along with their certified Turkish translations, to the tender committee. |  |  |  |
| **3.** | **DELIVERY OF PRODUCTS** |  |  |  |
| **3.1.** | If the products are imported, the tenderer's representative shall be present when the products are collected from customs and shall ensure that the goods are collected in accordance with the required specifications and delivered to the location deemed appropriate by GDPB without delay. |  |  |  |
| **3.2.** | The contractor shall provide the Department with the shipment details 3 days prior to the delivery date of the product. |  |  |  |
| **3.3.** | Product delivery shall be made in such a way that it does not coincide with holidays, official holidays, or the end of working hours in Türkiye. |  |  |  |
| **3.4.** | To clear products purchased by GDPB through customs, the Contractor shall enter the product information (batch release certificate and quantity for the lot/serial number for which import permission is requested) via the Single Window Portal System (<https://uygulama.gtb.gov.tr/TekPencere>). The Single Window approval request shall be submitted to the Department electronically (to the Department's official e-mail address) or in writing at least 3 days in advance. Products purchased by the General Directorate of Public Health shall be delivered to the GDPB Vaccine and Drug Warehouse within 48 hours after being cleared through customs (except for products filled in Türkiye) if they are imported. Any changes required after the initial inspection (packaging, barcode, etc.) may also be made at the Central Vaccine and Drug Warehouse with the approval of the GDPB. If storage exceeds 48 hours, it is mandatory to submit temperature records approved by the Contractor's quality manager from the production site until the Ministry of Health Vaccine Storage arrives, to use a warehouse licensed by the Turkish Ministry of Health, and, if "temperature monitoring cards" are installed at the production facility, not to change them. |  |  |  |
| **3.5.** | If the packaging of the imported product (including barcoding) is to be changed at a different location after the contract is signed, this situation shall be reported to the Department. The temporary storage location shall be licensed by the Turkish Ministry of Health, the initial opening of the packaging of the product withdrawn from customs shall be carried out under the supervision of GDPB or its authorized personnel, and the shipment and temporary storage temperature records shall also be submitted during the inspection phase. GDPB may inspect this entire process at any time and on any day after customs clearance. Intermediate storage shall be possible if the application made to GDPB and the storage period are found to be appropriate. |  |  |  |
| **3.6.** | Products filled in our country shall be delivered to the GDPB Vaccine and Drug Warehouse within 24 hours of leaving the filling facility. If the product is not delivered to the GDPB Vaccine and Drug Warehouse within 24 hours after leaving the filling facility and is to be stored in another warehouse, the organization performing the intermediate storage shall be licensed by the Turkish Ministry of Health, temperature records from the production site to the warehouse and within the warehouse shall be kept, and certified copies from the product quality representative shall be delivered to GDPB upon product delivery. These stages shall be open to inspection by GDPB if required. The Department shall be notified if temporary storage is required. Products shall not be accepted if the specified conditions cannot be met. |  |  |  |
| **3.7.** | If the products are filled/manufactured in Türkiye, the time limit specified in Article 3, except for 3.2 and 3.3, and the restrictions at shall not apply. |  |  |  |
| **4** | **DOCUMENTS REQUIRED DURING INSPECTION AND PRODUCT CHARACTERISTICS** |  |  |  |
| **4.1.** | Products shall have **a shelf life of at least 18 (eighteen) months** from the date of delivery to our warehouse. |  |  |  |
| **4.1.1.** | **Documents required during the product inspection phase:**  The documents specified in Article 2 of the Technical Specifications and the documents specific to the delivered series/lot shall be submitted during the inspection stage. These documents are:   * Product License * Current GMP certificate for the production site, * Analysis report for the delivered batch (document containing information such as composition, analysis results, reference values, production/expiration dates, etc.), * BRC for the delivered batch, * Current Pharmaceutical Product Certificate (CPP) * TSE declaration (item 2.5), * List of tasks to be performed by subcontractors, * Package Insert or Prospectus or IFU (Article 2.6), * List of countries where the product is used and import permit/license number and the number of doses used in each country in the last two calendar years prior to the year of the offer (Article 2.9), * Commitment letter (Article 2.10).   The original documents or notarised copies and the certified Turkish version shall be submitted to the Tender Committee. |  |  |  |
| **4.2.** | The Contractor, manufacturer or any other country where this product is used shall notify the Ministry within 24 hours if the use of the product is suspended for any reason or if they receive any information in this regard (product name, serial number, reason for discontinuation, etc.) and acknowledges that the administration has the right to unilaterally terminate the contract if such information is not provided within 24 hours. In the event of discontinuation of the product, the Contractor shall be required to bring a manufacturer-approved commitment letter to the Ministry within 90 (ninety) calendar days from the date the replacement request is notified to the Contractor. Additionally, the Contractor shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date the request for product replacement is notified, following the collection of unused products by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **4.3.** | Stability studies and results proving the actual shelf life of the product in question shall be submitted. If the product is filled or manufactured in our country and stability studies are still ongoing, the TİTCK-approved study results shall be submitted to the Department as they are completed. |  |  |  |
| **4.4.** | Along with the product, all technical documents required in the tender for the product (Good Manufacturing Practices, analysis report, SPC, certificates, etc.) and detailed SOP (may be provided in the original license), **stability results (showing real-time and accelerated stability shelf life),** product photos, and all documents containing technical information about the packaging (dimensions, volume, etc.) shall be submitted to the inspection commission in duplicate on CD/DVD/flash drive. Each heading shall be indicated with a separate folder name, and the relevant documents shall be found under the relevant folder. If deemed necessary, other documents and information related to the product may be requested in physical or digital form. |  |  |  |
| **4.5.** | Documents that do not change with each shipment shall be submitted once, with the first shipment. If deemed necessary, documents may be requested again. |  |  |  |
| **4.6.** | **Required Packaging Characteristics** |  |  |  |
| **4.6.1.** | The products shall be packaged in vials, flacons or ready-to-use syringe containing a single dose. Those ready-to-use syringes (injectors) shall be single packed or provided in ten packs. If the products are packaged in packs of ten, the packs shall contain foam or cardboard separators to prevent the vials or ampoules from breaking due to contact. If the product is packaged individually, the packages shall then be bundled in packs of ten. If diluents are separate, 5 additional diluents shall be delivered with every 1000 doses of vaccine. |  |  |  |
| **4.6.2.** | The inner and outer packaging of licensed products in Türkiye shall comply with the current "Regulation on Packaging Information, Instructions for Use, and Tracking of Human Medicinal Products" published by the Turkish Ministry of Health. If the product is not licensed in our country, the inner packaging of the ready-to-use syringe (injector), ampoule, or vial shall bear, at a minimum, the manufacturer's and product name, dosage, amount of content per dose, method of administration (IM/IV/SC/ID, etc.), lot (batch) number, and expiration date, printed in indelible ink. The package shall also contain storage temperature information in addition to the inner packaging. The product package shall bear the statement **"Property of the Turkish Ministry of Health, NOT FOR SALE**." |  |  |  |
| **4.6.3.** | Each product package shall contain at least one "Summary of Product Characteristics" (SPC) or Turkish package insert or "Patient Information Leaflet" (PIL) prepared in accordance with the "Regulation on the Packaging and Labelling of Human Medicinal Products" dated 25.04.2017 and numbered 30048. Additionally, the following text shall be added to the beginning of the “"Summary of Product Characteristics" (SPC)” or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention:  "In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration.  For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates***."*** |  |  |  |
| **4.6.4.** | The packages shall then be placed in boxes. The names and addresses of the manufacturer and representative company of the product, the name of the product, the lot number, the storage temperature, the expiration date, and the number of doses in the box shall be written on these boxes. If the products are packaged individually, ten packages shall be placed in each box. If the products are packaged in packs of ten, five packages shall be placed in each box. |  |  |  |
| **4.6.5.** | The packaging boxes shall be placed in styrofoam. The styrofoam shall then be placed inside cartons. The carton dimensions shall be 40X60X40 ±2 (Width, Length, Height) cm. A sufficient number of ice packs or gel packs, etc., shall be placed in the cartons. The ice packs or gel packs, etc.**,** placed in the cartons shall be **unfrozen and cooled**. If the products are not sensitive to freezing (lyophilized), dry ice or frozen ice packs or gel may be used during transport. The names and addresses of the manufacturer and representative company, the product name, serial number, storage temperature, expiration date, dose quantity in the carton, carton dimensions, and weight shall be written on these cartons. |  |  |  |
| **4.6.6.** | The boxes shall then be placed on pallets. The pallets shall be euro pallets (120cm±2cmx80cm±2cmx10-15cm). After the boxes are placed on the pallets, the height together with the pallet shall not exceed 2 (two) meters. The boxes may protrude from the pallet by a maximum of 5 cm. There shall be a maximum of 16 (sixteen) boxes on the pallet. |  |  |  |
| **4.6.7.** | There shall be a 2D barcode on the packages, boxes, cartons, and pallets. The barcode prepared for the ready-to-use syringe (injector) inside each individually packaged product (these barcodes shall also have HL7 and 97 breakdown values) shall be on the product's package. The packages shall then be tied in sets of ten, and the package label shall be affixed to a different area than the barcode affixed to each product. If the product is packaged in sets of ten, the barcode prepared for the ready-to-use syringe (injector) (these barcodes shall also have HL7 and 97 breakdown values) shall be placed inside the package, and the barcode corresponding to the package breakdown shall be on the package. For the information to be included in the barcode, the information specified in the Guide for Barcode Application to Vaccines, Antiserums, and Diluents published by the Turkish Ministry of Health shall be used as a basis, and any additional information required shall be determined by GDPB. **The barcode area for the dose shall be at least 12X12 mm in accordance with the Guide**. If GDPB makes changes to the system instead of the barcode, the contractor shall be obliged to comply with the requirements of the newly created system without requesting a price difference. |  |  |  |
| **4.6.8.** | Even after acceptance, if any faulty operations related to the barcode system are detected later, the costs of changing the product packaging and, if deemed necessary, collecting the products from the field shall be borne by the Contractor. If this process exceeds one-month, new products with a new expiration date may be requested at the request of the Department to avoid any problems related to the expiration date. |  |  |  |
| **4.6.9.** | **Temperature monitoring during transportation:** |  |  |  |
| **4.6.9.1.** | The freeze indicator, temperature monitoring card, and digital temperature recording devices used **shall be listed in the WHO "E006: Temperature monitoring devices"** (https://extranet.who.int/prequal/immunization-devices/prequalified/imd-products)**.** |  |  |  |
| **4.6.9.2.** | If the product(s) are sensitive to freezing, each box shall contain a freeze indicator. |  |  |  |
| **4.6.9.3.** | If the product(s) are sensitive to high temperatures, each box shall contain a temperature monitoring card **with the date it was activated and the name/code of the activator written on it**. |  |  |  |
| **4.6.9.4.** | If the product(s) are sensitive to both freezing and high temperatures, or if they are packaged together, each box shall contain both a freeze indicator and a temperature monitor card with the date of activation and the name/code of the activator written on it. |  |  |  |
| **4.6.9.5.** | In addition, each pallet shall have an electronic, temperature, and freeze-sensitive digital monitor capable of long-term recording. The electronic, temperature, and freeze-sensitive digital monitors capable of long-term recording placed on the pallet shall be read during the inspection phase, the outputs shall be recorded in a report and signed by the company, and if there are no deviations, they can be filed electronically. If requested by the company, these devices shall be returned for storage without destruction for at least three months. Upon return, the pallet numbers and device serial numbers shall be recorded in a report.  If the pallets consist of insulated boxes, each containing heat tracking material (such as a digital recording device, heat monitoring card, or freeze indicator), and conflicting results are found between the digital heat records on or inside the pallet and the heat records inside the box when evaluating the heat records, the temperature monitoring results inside the boxes shall be considered when processing. |  |  |  |
| **4.6.9.6.** | Products found not to have been transported under appropriate conditions (Guidelines for the international packaging and shipping of vaccines, sixth edition. Geneva: World Health Organization, 2020. Licence: CC BY-NC-SA 3.0 IGO) as monitored by these heat trackers shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **4.6.10.** | Each product shall be delivered with a Material Safety Data Sheet (MSDS). The contractor is responsible for the “Transportation, packaging, and labelling of hazardous materials” and completing any shortfalls if there is any. |  |  |  |
| **4.6.11.** | The contractor's representative shall be present during the delivery or return of the products. The representative shall submit a letterhead, stamped, and signed authorization document belonging to the contractor and a photocopy of their photo ID to the Warehouse Manager. The contractor is responsible for unloading the products from the vehicle into the warehouse or loading them back onto the vehicle for return. A list of the names, telephone numbers, and addresses of all employees and subcontractor personnel who shall perform work on behalf of the contractor shall be submitted to the Warehouse Manager, signed by the contractor's representative, prior to unloading. The contractor shall be responsible for any damage that may be caused to the warehouse or equipment and for all liabilities arising from "Occupational Health and Safety Regulations." The contractor shall submit a stamped and signed commitment stating that it has assumed the SSI, occupational health and safety, and work accident liabilities of its employees for unloading the products from the vehicle or loading them in case of return, and that it has assumed the liability for compensation in case of damage to the warehouse or any equipment inside the warehouse. Responsibility begins upon entry into the Warehouse area after the security check. |  |  |  |
| **4.6.12.** | Except in emergencies, no contractor employees other than the vehicle drivers and those declared shall enter the climate-controlled warehouse. |  |  |  |
| **4.6.13.** | * + 1. If barcoding, packaging, or prospectus changes are to be performed in the GDPB warehouse, the documents belonging to the subcontractors shall be as follows:        - shall be a contract demonstrating the availability of occupational safety expertise and workplace physician support services as required by the "Occupational Health and Safety Law" No. 6331.        - The contractor's structure shall include at least one coordinator, one operations manager, one quality control and GMP manager, and one warehouse manager. These personnel shall be present during the execution of the work. There shall be a document or documents proving that the personnel included in the company structure have received GMP and Good Warehouse Practices Training organized by the Turkish Ministry of Health or an organization that has received a GMP Certificate from the Turkish Ministry of Health.        - There shall be standard operating procedures (SOPs) prepared by a pharmacist and approved by the company representative, covering barcode printing and affixing procedures and cold storage room operating rules. |  |  |  |
| **5.** | **DOCUMENTS AND MATERIALS REQUIRED FOR LABORATORY ANALYSES AND METHODS TO BE FOLLOWED** |  |  |  |
| **5.1.** | General principles of product safety;  The analysis reports for the product are part of the batch release certificate, and both documents shall be considered together in the evaluations. |  |  |  |
| **5.1.1.** | The product shall be manufactured in our country, have a manufacturing license from the Turkish Medicines and Medical Devices Agency (TİTCK), and present the BRC certificate for the delivered batch obtained from the TİTCK/Analysis and Control Laboratories Department. In addition, if there is no break in the cold chain during product transfer, the physical examination is appropriate, and the commission grants approval, the inspection acceptance process can be completed. |  |  |  |
| **5.1.2.** | If the product is manufactured outside our country and has an import license from TİTCK or is on the WHO's prequalification list (Prequalified vaccines), the Batch Release Certificate for the delivered series shall be obtained from WHO/ Reference Laboratories/institutions, provided that the analyses are performed in accordance with the OCABR guidelines at the TİTCK/Analysis and Control Laboratories Directorate. The inspection acceptance process for products found to be suitable through analysis can be completed. |  |  |  |
| **5.1.3.** | If the product is not licensed in our country, but is licensed by the authorities in EMA, US-FDA, Japan, Canada, South Korea, and Australia as specified in Article 2.1 of the technical specifications, tests may be performed in accordance with the OCABR guidelines by the TİTCK/Analysis and Control Laboratories Department. The inspection and acceptance process for products with suitable analyses can be completed. |  |  |  |
| **5.2.** | If there are any doubts regarding product safety within the scope of the cold chain or other matters specified in the technical specifications, new samples may be taken if necessary, and analyses may be performed as required, including analyses based on batch release. |  |  |  |
| **5.3.** | These products are subject to the *"Regulations on Market Surveillance and Control Procedures and Principles to be Implemented by the Ministry of Health*." GDPB reserves the right to conduct analyses in case of possible suspicion or complaint. The Contractor shall provide the required number of product doses for analysis and the materials required for the analysis specified in Article 5 free of charge. If the analysis result is found to be unsatisfactory, even if the product in question has been accepted, the Contractor shall deliver the same quantity from different series within 90 calendar days. |  |  |  |
| **5.4.** | If the product does not comply with Article 5.1, after the inspection is completed, a sample shall be taken from each batch using the random sampling method and delivered to the laboratory with a report signed by the Contractor's representative and one of the inspection members. |  |  |  |
| **5.5.** | Since the physical appearance of the products requires expertise, it shall be assessed by specialized personnel at the National Reference Laboratory within the TİTCK in accordance with the current Turkish/European Pharmacopoeia. Products that are not suitable in terms of physical appearance shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. After the physical tests of the products are found to be suitable, other tests shall be performed in accordance with Article 5. |  |  |  |
| **5.6.** | The vaccine shall comply with the characteristics and conditions specified in World Health Organization (WHO) Technical Report Series 840 Annex 3 and European Pharmacopoeia 11.0 01/2023 04 /2022:1057monograph in terms of physical appearance and laboratory analyses. |  |  |  |
| **5.7.** | The manufacturer shall deliver, free of charge, three (3) reference vaccines per lot, three (3) reference monovalent immunoserums for use in potency and identity testing of the vaccine, together with the vaccines to be tested. |  |  |  |
| **5.8.** | Taking into account the total series to be delivered under the tender, for every 5 (five) series of MMR vaccine, 1 (one) International Reference Measles Vaccine (Live) 2nd International Reference (92/648), 1st International Reference Reagent Rubella Vaccine (91/688), Mumps Vaccine (Live) WHO Reference Reagent (90/534). |  |  |  |
| **5.9.** | For the total series to be delivered under the tender, 3 (three) cryovials of Vero CCL-81 and 3 (three) cryovials of RK13 CCL-37 cell products, obtained from ATCC and transferred under appropriate storage conditions, shall be delivered to the Analysis and Control Laboratories. |  |  |  |
| **5.10.** | Where necessary, the same quantities of Standard Vaccine, Antigen, Antiserum, and other relevant standards and international standards shall be provided free of charge and promptly by the Contractor. |  |  |  |
| **5.10.1.** | Documents to be delivered to the laboratory with the product:  -Protocols related to production methods and processes, as well as quality control protocols,  -Standard Operating Procedure (SOP) documents related to the product's quality control tests, current validation reports, and validation procedure documents shall be provided with the product. |  |  |  |
| **5.10.2.** | If the reference vaccine and chemicals are imported from abroad, customs clearance procedures shall be carried out by the contractors. |  |  |  |
| **5.10.3.** | For each batch of vaccine delivered, the Contractor shall provide a sufficient number of samples free of charge for physical examination and laboratory analysis. |  |  |  |
| **5.10.4.** | If changes are made to the analysis methods, the standards and quantities requested from the Contractor may be re-evaluated. |  |  |  |
| **5.10.5.** | In addition, official documents (official certificates) containing the reference vaccine and/or reference unit values shall also be submitted. The reagents, chemical materials, detailed test SOPs (latest updated version), current validation and validation procedure documents, and calculation documents sent shall be delivered complete with the vaccines to be tested. |  |  |  |
| **5.11.** | If vaccines are prepared in vacuum-sealed ampoules/vials, and if the number of non-vacuum ampoules/vials exceeds 1% in the vacuum control performed on vaccine lot samples taken for inspection, the vaccine lot in question shall be rejected and returned due to the number of non-vacuum ampoules/vials. If the number of non-vacuum ampoules/vials is less than 1%, the vaccine supplier shall deliver the equivalent number of non-vacuum ampoules/vials free of charge within 120 calendar days from the date of notification by the General Directorate of Public Health to the supplier. |  |  |  |
| **5.12.** | Biological controls of products to be delivered shall be carried out at the Turkish Medicines and Medical Devices Agency, but in order to prevent interruption of vaccine and antiserum administration due to potential difficulties in the analysis process, a WHO-approved reference laboratory (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies) ([https://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)](http://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)) may also be conducted, and the costs shall be borne by the Contractor. The results of the control reports of the producer country shall be consistent with the results of the control reports of the Turkish Medicines and Medical Devices Agency or WHO-approved reference laboratories (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies). |  |  |  |
| **5.13.** | The Contractor may object to the results within 15 days. Upon such objection, product samples shall be sent to a second laboratory from among the WHO Reference Laboratories designated ex officio by GDPB or deemed appropriate by GDPB upon the Contractor's recommendation, with the shipping and analysis costs borne by the Contractor. If inconsistencies are detected following analyses conducted by WHO Reference Laboratories and the Turkish Medicines and Medical Devices Agency, the second report shall be accepted as the final report. |  |  |  |
| **6.** | **OTHER PROVISIONS** |  |  |  |
| **6.1.** | Due to delays caused by incorrect or incomplete materials and documents specified in Article 5, such as references, standards, and SOPs required for analysis, which are the responsibility of the contractor to deliver, the product's shelf life shall be shortened by the duration of the delay. The shelf life suitability specified in Article 4 shall be reduced by the duration of the delay. If the shelf life falls below the specified duration, return and exchange processes shall be initiated. For example, if the specification requires a minimum shelf life of 18 months upon delivery to the warehouse, but the product has a shelf life of 20 months at the time of delivery, and the SOP, references, etc. are delivered 70 days later due to a reason attributable to the contractor that prevented the completion of the analyses, the products shall be subject to processing due to shelf life non-compliance and shall be returned. |  |  |  |
| **6.2.** | Batches of products deemed unsuitable based on biological or chemical control results shall be returned. The contractor shall collect these products from the GDPB warehouse where they are located, transport them to the country of origin, and deliver the same quantity of products from a different batch that comply with the specifications to GDPB free of charge within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **6.3.** | In the event of product return (rejection or lot change), the products shall be collected from the warehouse within 30 calendar days after the notification date, during official working hours and days. If not collected, the contractor shall bear the storage and/or disposal costs for the delayed period. |  |  |  |
| **6.4.** | In the event that the products are returned to the Contractor, the relevant official documents proving that the products have been removed from Türkiye or destroyed shall be submitted to the administration within 120 calendar days after the products are collected from the warehouse. If no notification is made, the procedures shall be carried out in accordance with customs regulations. |  |  |  |
| **6.5** | After acceptance of the products, if any physical deficiencies (barcode errors, packaging, labels, etc.) are detected, the contractor shall remedy the deficiency free of charge. |  |  |  |

| **LOT 8 - ADULT-TYPE TETANUS-DIPHTHERIA COMBINATION VACCINE** | | | | |
| --- | --- | --- | --- | --- |
| **Item No** | **Specifications** | **Specifications Offered** | **Notes, remarks,  ref to documentation** | **Evaluation Committee’s notes** |
| **1.** | **VACCINE TECHNICAL SPECIFICATIONS** |  |  |  |
| **1.1.** | The product shall comply with the conditions and characteristics specified in DST/WHO TRS 980 Annex 4, Annex 5, Annex 6 WHO/IVB/11.11, /WHO/VSQ/97.04, and 11.0 07/2022:2764 monograph of European Pharmacopoeia in terms of physical appearance and laboratory analyses. |  |  |  |
| **1.2.** | The dual combination vaccine shall be adsorbed. |  |  |  |
| **1.3.** | Single-dose of the vaccine shall be 0.5 mL, and shall be packaged within a ready-to-use syringe (injector) or single-dose. |  |  |  |
| **1.4.** | In one administratipn dose of the vaccine; the diphtheria toxoid potency shall be at least 2 IU/dose and the tetanus toxoid potency shall be at least 40 IU/dose. These units and flocculation unit (Lf) information shall be included in the analysis certificate and on the label. |  |  |  |
| **1.5.** | The combination vaccine shall maintain its stability to its expiration date at temperatures between (+2) - (+8) OC. |  |  |  |
| **2.** | **DOCUMENTS TO BE INCLUDED IN THE FILE TO BE REVIEWED BY THE TENDER COMMITTEE** |  |  |  |
| **2.1.** | The product in question;   * + 1. shall have a license issued by the Turkish Ministry of Health,     2. If it does not have a license issued by the Turkish Ministry of Health;   + It shall be included in the latest pre-qualification list published by the World Health Organization (<https://extranet.whoint/prequal/vaccines/prequalified-vaccines)> or,   + It shall have a license from the European Medicines Agency (EMA) and be manufactured in European Union countries, or   + It shall have a license from the US-FDA and be manufactured in the United States, **or**   + It shall be licensed by the Pharmaceuticals and Medical Devices Agency (PMDA) and manufactured in Japan, or   + It shall be licensed by the South Korean Food and Drug Administration and manufactured in South Korea, **or**   + It shall be licensed by the Canadian Food and Drugs Act and Regulations and manufactured in Canada, **or**   + The product shall be licensed by the Australian Department of Health Therapeutic Goods Administration and manufactured in Australia. |  |  |  |
| **2.2.** | The product shall be accompanied by a certificate (GMP certificate) showing that the factory producing it complies with the **Good Manufacturing Practices (**GMP) standards approved by the State Control Agency of the country where the product is manufactured. If the product is filled or manufactured in our country, there shall be a document showing that the factory where the production/filling is carried out, approved by the Turkish Ministry of Health, Turkish Medicines and Medical Devices Agency, manufactures in accordance with good manufacturing practices (GMP) rules. |  |  |  |
| **2.3.** | For any batch produced within the last two years, the 'National Regulatory Authority' (NRA) or the Batch Release Certificate issued by the EMA (from the locations specified in the annex to the European Union's 2001/83/EC directive), US-FDA, Japan, South Korea, Canada, and Australian state authorities, as specified in 2.1. If the product is manufactured in Türkiye, it shall be a marketing authorization certificate issued by the Turkish Medicines and Medical Devices Agency of the Ministry of Health of the Republic of Türkiye. The analysis report for the same series shall also be included in the BRC annex. |  |  |  |
| **2.4.** | A valid Pharmaceutical Product Certificate (CPP) approved by the manufacturer's country authority. |  |  |  |
| **2.5.** | A **manufacturer-approved** document showing that the risk of Transmissible Spongiform Encephalopathy (TSE) has been minimized at every stage of the product's production. |  |  |  |
| **2.6.** | If the product is licensed in Türkiye, it shall have a "Summary of Product Characteristics" (SPC) or package insert or "Patient Information Leaflet" (PIL) approved by the Turkish Medicines and Medical Devices Agency (TİTCK), or if it is not licensed in Türkiye, it shall have one approved by the relevant country's authority, along with Turkish translations. |  |  |  |
| **2.7.** | If applicable, a list of tasks to be performed by subcontractors shall be provided. |  |  |  |
| **2.8.** | The tenderer shall declare in writing how many batches of the product they can deliver. |  |  |  |
| **2.9.** | If the product is used outside the country of manufacture, a document shall be submitted containing the list of countries where the product is used, approved by the manufacturer, along with the usage permits (import permits) or license numbers for these products, and information on the total number of doses used in countries other than the country of manufacture for the last two calendar years prior to the year of the tender. |  |  |  |
| **2.10.** | The tenderer shall declare that if the manufacturer or another country where the product is used suspends the use of the product for any reason, or if they receive any news in this regard, they shall inform the Ministry within 24 hours (product name, serial number, reason for discontinuation, etc.) and that if the information is not provided within 24 hours, the administration has the right to unilaterally terminate the contract. It also indicates that in the event of discontinuation of the product, after the unused products are collected by the Ministry and sent to the Central Warehouse, the Tenderer undertakes to bring a new product from a different series that complies with the specifications within 90 (ninety) calendar days from the date the replacement request is notified to the Tenderer. In addition, the Tenderer shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date of notification of the product replacement request after the unused products are collected by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **2.11.** | The Tenderer shall submit the original or notarized copies of the required documents, along with their certified Turkish translations, to the tender committee. |  |  |  |
| **3.** | **DELIVERY OF PRODUCTS** |  |  |  |
| **3.1.** | If the products are imported, the tenderer's representative shall be present when the products are collected from customs and shall ensure that the goods are collected in accordance with the required specifications and delivered to the location deemed appropriate by GDPB without delay. |  |  |  |
| **3.2.** | The contractor shall provide the Department with the shipment details 3 days prior to the delivery date of the product. |  |  |  |
| **3.3.** | Product delivery shall be made in such a way that it does not coincide with holidays, official holidays, or the end of working hours in Türkiye. |  |  |  |
| **3.4.** | To clear products purchased by GDPB through customs, the Contractor shall enter the product information (batch release certificate and quantity for the lot/serial number for which import permission is requested) via the Single Window Portal System (<https://uygulama.gtb.gov.tr/TekPencere>). The Single Window approval request shall be submitted to the Department electronically (to the Department's official e-mail address) or in writing at least 3 days in advance. Products purchased by the General Directorate of Public Health shall be delivered to the GDPB Vaccine and Drug Warehouse within 48 hours after being cleared through customs (except for products filled in Türkiye) if they are imported. Any changes required after the initial inspection (packaging, barcode, etc.) may also be made at the Central Vaccine and Drug Warehouse with the approval of the GDPB. If storage exceeds 48 hours, it is mandatory to submit temperature records approved by the Contractor's quality manager from the production site until the Ministry of Health Vaccine Storage arrives, to use a warehouse licensed by the Turkish Ministry of Health, and, if "temperature monitoring cards" are installed at the production facility, not to change them. |  |  |  |
| **3.5.** | If the packaging of the imported product (including barcoding) is to be changed at a different location after the contract is signed, this situation shall be reported to the Department. The temporary storage location shall be licensed by the Turkish Ministry of Health, the initial opening of the packaging of the product withdrawn from customs shall be carried out under the supervision of GDPB or its authorized personnel, and the shipment and temporary storage temperature records shall also be submitted during the inspection phase. GDPB may inspect this entire process at any time and on any day after customs clearance. Intermediate storage shall be possible if the application made to GDPB and the storage period are found to be appropriate. |  |  |  |
| **3.6.** | Products filled in our country shall be delivered to the GDPB Vaccine and Drug Warehouse within 24 hours of leaving the filling facility. If the product is not delivered to the GDPB Vaccine and Drug Warehouse within 24 hours after leaving the filling facility and is to be stored in another warehouse, the organization performing the intermediate storage shall be licensed by the Turkish Ministry of Health, temperature records from the production site to the warehouse and within the warehouse shall be kept, and certified copies from the product quality representative shall be delivered to GDPB upon product delivery. These stages shall be open to inspection by GDPB if required. The Department shall be notified if temporary storage is required. Products shall not be accepted if the specified conditions cannot be met. |  |  |  |
| **3.7.** | If the products are filled/manufactured in Türkiye, the time limit specified in Article 3, except for 3.2 and 3.3, and the restrictions at shall not apply. |  |  |  |
| **4.** | **DOCUMENTS REQUIRED DURING INSPECTION AND PRODUCT CHARACTERISTICS** |  |  |  |
| **4.1.** | Products shall have **a shelf life of at least 18 (eighteen) months** from the date of delivery to our warehouse. |  |  |  |
| **4.1.1.** | **Documents required during the product inspection phase:**  The documents specified in Article 2 of the Technical Specifications and the documents specific to the delivered series/lot shall be submitted during the inspection stage. These documents are:   * Product License * Current GMP certificate for the production site, * Analysis report for the delivered batch (document containing information such as composition, analysis results, reference values, production/expiration dates, etc.), * BRC for the delivered batch, * Current Pharmaceutical Product Certificate (CPP) * TSE declaration (item 2.5), * List of tasks to be performed by subcontractors, * Package Insert or Prospectus or IFU (Article 2.6), * List of countries where the product is used and import permit/license number and the number of doses used in each country in the last two calendar years prior to the year of the offer (Article 2.9), * Commitment letter (Article 2.10). |  |  |  |
| **4.2.** | The Contractor, manufacturer or any other country where this product is used shall notify the Ministry within 24 hours if the use of the product is suspended for any reason or if they receive any information in this regard (product name, serial number, reason for discontinuation, etc.) and acknowledges that the administration has the right to unilaterally terminate the contract if such information is not provided within 24 hours. In the event of discontinuation of the product, the Contractor shall be required to bring a manufacturer-approved commitment letter to the Ministry within 90 (ninety) calendar days from the date the replacement request is notified to the Contractor. Additionally, the Contractor shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date the request for product replacement is notified, following the collection of unused products by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **4.3.** | The Contractor, manufacturer or any other country where this product is used shall notify the Ministry within 24 hours if the use of the product is suspended for any reason or if they receive any information in this regard (product name, serial number, reason for discontinuation, etc.) and acknowledges that the administration has the right to unilaterally terminate the contract if such information is not provided within 24 hours. In the event of discontinuation of the product, the Contractor shall be required to bring a manufacturer-approved commitment letter to the Ministry within 90 (ninety) calendar days from the date the replacement request is notified to the Contractor. Additionally, the Contractor shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date the request for product replacement is notified, following the collection of unused products by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **4.4.** | Along with the product, all technical documents required in the tender for the product (Good Manufacturing Practices, analysis report, SPC, certificates, etc.) and detailed SOP (may be provided in the original license), stability results (showing real-time and accelerated stability shelf life), product photos, and all documents containing technical information about the packaging (dimensions, volume, etc.) shall be submitted to the inspection commission in duplicate on CD/DVD/flash drive.  Each heading shall be indicated with a separate folder name, and the relevant documents shall be found under the relevant folder. If deemed necessary, other documents and information related to the product may be requested in physical or digital form. |  |  |  |
| **4.5.** | Documents that do not change with each shipment shall be submitted once, with the first shipment. If deemed necessary, documents may be requested again. |  |  |  |
| **4.6.** | **Required Packaging Characteristics** |  |  |  |
| **4.6.1.** | The products shall be packaged in vials, flacons or ready-to-use syringe (injector) containing a single dose. Those ready-to-use syringe (injector)s shall be single packed or provided in ten packs. If the products are packaged in packs of ten, the packs shall contain foam or cardboard separators to prevent the vials or ampoules from breaking due to contact. If the product is packaged individually, the packages shall then be bundled in packs of ten. If diluents are separate, 5 additional diluents shall be delivered with every 1000 doses of vaccine. |  |  |  |
| **4.6.2.** | The inner and outer packaging of licensed products in Türkiye shall comply with the current "Regulation on Packaging Information, Instructions for Use, and Tracking of Human Medicinal Products" published by the Turkish Ministry of Health. If the product is not licensed in our country, the inner packaging of the ready-to-use syringe (injector), ampoule, or vial shall bear, at a minimum, the manufacturer's and product name, dosage, amount of content per dose, method of administration (IM/IV/SC/ID, etc.), lot (batch) number, and expiration date, printed in indelible ink. The package shall also contain storage temperature information in addition to the inner packaging. The product package shall bear the statement **"Property of the Turkish Ministry of Health, NOT FOR SALE**." |  |  |  |
| **4.6.3.** | Each product package shall contain at least one "Summary of Product Characteristics" (SPC) or Turkish package insert or "Patient Information Leaflet" (PIL) prepared in accordance with the "Regulation on the Packaging and Labelling of Human Medicinal Products" dated 25.04.2017 and numbered 30048. Additionally, the following text shall be added to the beginning of the “"Summary of Product Characteristics" (SPC)” or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention:  "In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration.  For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates***."*** |  |  |  |
| **4.6.4.** | The packages shall then be placed in boxes. The names and addresses of the manufacturer and representative company of the product, the name of the product, the lot number, the storage temperature, the expiration date, and the number of doses in the box shall be written on these boxes. If the products are packaged individually, ten packages shall be placed in each box. If the products are packaged in packs of ten, five packages shall be placed in each box. |  |  |  |
| **4.6.5.** | The packaging boxes shall be placed in styrofoam. The styrofoam shall then be placed inside cartons. The carton dimensions shall be 40X60X40 ±20 (Width, Length, Height) cm. A sufficient number of ice packs or gel packs, etc., shall be placed in the cartons. The ice packs or gel packs, etc.**,** placed in the cartons shall be **unfrozen and cooled**.  The names and addresses of the manufacturer and representative company, the product name, serial number, storage temperature, expiration date, dose quantity in the carton, carton dimensions, and weight shall be written on these cartons. |  |  |  |
| **4.6.6.** | The boxes shall then be placed on pallets. The pallets shall be euro pallets (120cm±2cmx80cm±2cmx10-15cm). After the boxes are placed on the pallets, the height together with the pallet shall not exceed 2 (two) meters. The boxes may protrude from the pallet by a maximum of 5 cm. There shall be a maximum of 16 (sixteen) boxes on the pallet. |  |  |  |
| **4.6.7.** | There shall be a 2D barcode on the packages, boxes, cartons, and pallets. The barcode prepared for the ready-to-use syringe (injector) inside each individually packaged product (these barcodes shall also have HL7 and 97 breakdown values) shall be on the product's package. The packages shall then be tied in sets of ten, and the package label shall be affixed to a different area than the barcode affixed to each product. If the product is packaged in sets of ten, the barcode prepared for the ready-to-use syringe (injector) (these barcodes shall also have HL7 and 97 breakdown values) shall be placed inside the package, and the barcode corresponding to the package breakdown shall be on the package. For the information to be included in the barcode, the information specified in the Guide for Barcode Application to Vaccines, Antiserums, and Diluents published by the Turkish Ministry of Health shall be used as a basis, and any additional information required shall be determined by GDPB. **The barcode area for the dose shall be at least 12X12 mm in accordance with the Guide**. If GDPB makes changes to the system instead of the barcode, the contractor shall be obliged to comply with the requirements of the newly created system without requesting a price difference. |  |  |  |
| **4.6.8.** | Even after acceptance, if any faulty operations related to the barcode system are detected later, the costs of changing the product packaging and, if deemed necessary, collecting the products from the field shall be borne by the Contractor. If this process exceeds one-month, new products with a new expiration date may be requested at the request of the Department to avoid any problems related to the expiration date. |  |  |  |
| **4.6.9.** | **Temperature monitoring during transportation:** |  |  |  |
| **4.6.9.1.** | The freeze indicator, temperature monitoring card, and digital temperature recording devices used **shall be listed in the WHO "E006: Temperature monitoring devices"** (https://extranet.who.int/prequal/immunization-devices/prequalified/imd-products)**.** |  |  |  |
| **4.6.9.2.** | If the product(s) are sensitive to freezing, each box shall contain a freeze indicator. |  |  |  |
| **4.6.9.3.** | If the product(s) are sensitive to high temperatures, each box shall contain a temperature monitoring card **with the date it was activated and the name/code of the activator written on it**. |  |  |  |
| **4.6.9.4.** | If the product(s) are sensitive to both freezing and high temperatures, or if they are packaged together, each box shall contain both a freeze indicator and a temperature monitor card with the date of activation and the name/code of the activator written on it. |  |  |  |
| **4.6.9.5.** | In addition, each pallet shall have an electronic, temperature, and freeze-sensitive digital monitor capable of long-term recording. The electronic, temperature, and freeze-sensitive digital monitors capable of long-term recording placed on the pallet shall be read during the inspection phase, the outputs shall be recorded in a report and signed by the company, and if there are no deviations, they can be filed electronically. If requested by the company, these devices shall be returned for storage without destruction for at least three months. Upon return, the pallet numbers and device serial numbers shall be recorded in a report.  If the pallets consist of insulated boxes, each containing heat tracking material (such as a digital recording device, heat monitoring card, or freeze indicator), and conflicting results are found between the digital heat records on or inside the pallet and the heat records inside the box when evaluating the heat records, the temperature monitoring results inside the boxes shall be considered when processing. |  |  |  |
| **4.6.9.6.** | Products found not to have been transported under appropriate conditions (Guidelines for the international packaging and shipping of vaccines, sixth edition. Geneva: World Health Organization, 2020. Licence: CC BY-NC-SA 3.0 IGO) as monitored by these heat trackers shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **4.6.10.** | Each product shall be delivered with a Material Safety Data Sheet (MSDS). The contractor is responsible for the “Transportation, packaging, and labelling of hazardous materials” and completing any shortfalls if there is any. |  |  |  |
| **4.6.11.** | The contractor's representative shall be present during the delivery or return of the products. The representative shall submit a letterhead, stamped, and signed authorization document belonging to the contractor and a photocopy of their photo ID to the Warehouse Manager. The contractor is responsible for unloading the products from the vehicle into the warehouse or loading them back onto the vehicle for return. A list of the names, telephone numbers, and addresses of all employees and subcontractor personnel who shall perform work on behalf of the contractor shall be submitted to the Warehouse Manager, signed by the contractor's representative, prior to unloading. The contractor shall be responsible for any damage that may be caused to the warehouse or equipment and for all liabilities arising from "Occupational Health and Safety Regulations." The contractor shall submit a stamped and signed commitment stating that it has assumed the SSI, occupational health and safety, and work accident liabilities of its employees for unloading the products from the vehicle or loading them in case of return, and that it has assumed the liability for compensation in case of damage to the warehouse or any equipment inside the warehouse. Responsibility begins upon entry into the Warehouse area after the security check. |  |  |  |
| **4.6.12.** | Except in emergencies, no contractor employees other than the vehicle drivers and those declared shall enter the climate-controlled warehouse. |  |  |  |
| **4.6.13.** | If barcoding, packaging, or prospectus changes are to be performed in the GDPB warehouse, the documents belonging to the subcontractors shall be as follows:   * + - * shall be a contract demonstrating the availability of occupational safety expertise and workplace physician support services as required by the "Occupational Health and Safety Law" No. 6331.       * The contractor's structure shall include at least one coordinator, one operations manager, one quality control and GMP manager, and one warehouse manager. These personnel shall be present during the execution of the work. There shall be a document or documents proving that the personnel included in the company structure have received GMP and Good Warehouse Practices Training organized by the Turkish Ministry of Health or an organization that has received a GMP Certificate from the Turkish Ministry of Health.       * There shall be standard operating procedures (SOPs) prepared by a pharmacist and approved by the company representative, covering barcode printing and affixing procedures and cold storage room operating rules. |  |  |  |
| **5.** | **DOCUMENTS AND MATERIALS REQUIRED FOR LABORATORY ANALYSES AND METHODS TO BE FOLLOWED** |  |  |  |
| **5.1.** | General principles of product safety;  The analysis reports for the product are part of the batch release certificate, and both documents shall be considered together in the evaluations. |  |  |  |
| **5.1.1.** | The product shall be manufactured in our country, have a manufacturing license from the Turkish Medicines and Medical Devices Agency (TİTCK), and present the BRC certificate for the delivered batch obtained from the TİTCK/Analysis and Control Laboratories Department. In addition, if there is no break in the cold chain during product transfer, the physical examination is appropriate, and the commission grants approval, the inspection acceptance process can be completed. |  |  |  |
| **5.1.2.** | If the product is manufactured outside our country and has an import license from TİTCK or is on the WHO's prequalification list (Prequalified vaccines), the Batch Release Certificate for the delivered series shall be obtained from WHO/ Reference Laboratories/institutions, provided that the analyses are performed in accordance with the OCABR guidelines at the TİTCK/Analysis and Control Laboratories Directorate. The inspection acceptance process for products found to be suitable through analysis can be completed. |  |  |  |
| **5.1.3.** | If the product is not licensed in our country, but is licensed by the authorities in EMA, US-FDA, Japan, Canada, South Korea, and Australia as specified in Article 2.1 of the technical specifications, tests may be performed in accordance with the OCABR guidelines by the TİTCK/Analysis and Control Laboratories Department. The inspection and acceptance process for products with suitable analyses can be completed. |  |  |  |
| **5.2.** | If there are any doubts regarding product safety within the scope of the cold chain or other matters specified in the technical specifications, new samples may be taken if necessary, and analyses may be performed as required, including analyses based on batch release. |  |  |  |
| **5.3.** | These products are subject to the *"Regulations on Market Surveillance and Control Procedures and Principles to be Implemented by the Ministry of Health*." GDPB reserves the right to conduct analyses in case of possible suspicion or complaint. The Contractor shall provide the required number of product doses for analysis and the materials required for the analysis specified in Article 5 free of charge. If the analysis result is found to be unsatisfactory, even if the product in question has been accepted, the Contractor shall deliver the same quantity from different series within 90 calendar days. |  |  |  |
| **5.4.** | If the product does not comply with Article 5.1, after the inspection is completed, a sample shall be taken from each batch using the random sampling method and delivered to the laboratory with a report signed by the Contractor's representative and one of the inspection members. |  |  |  |
| **5.5.** | Since the physical appearance of the products requires expertise, it shall be assessed by specialized personnel at the National Reference Laboratory within the TİTCK in accordance with the current Turkish/European Pharmacopoeia. Products that are not suitable in terms of physical appearance shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. After the physical tests of the products are found to be suitable, other tests shall be performed in accordance with Article 5. |  |  |  |
| **5.6.** | The vaccine shall comply with the characteristics and conditions specified in World Health Organization (WHO) Technical Report Series 980 Annex 4, Annex 5, Annex 6 WHO/IVB/11.11, /WHO/VSQ/97,04 European Pharmacopoeia 10.08 07/2022: 0647 monograph in terms of physical appearance and laboratory analyses. |  |  |  |
| **5.7.** | The Contractor shall deliver two (2) reference vaccines free of charge for each batch, along with reagents and chemical materials deemed necessary for testing the potency and identity of the vaccine, to be used in conjunction with the vaccines to be tested. |  |  |  |
| **5.7.1.** | Additionally, for every three (3) batches of the bivalent vaccine to undergo Tetanus, Diphtheria Vaccine Potency and identity testing the following shall be delivered:  Two diphtheria standard vaccines (in-house)  Two tetanus standard vaccines (in-house)  4 ml diphtheria toxin (in-house)  4 ml tetanus toxin (in-house)  For each ten batches vaccine  One Diphtheria Vaccine (Adsorbed) (BRP or NIBSC)  One Tetanus Vaccine (Adsorbed) (BRP or NIBSC)  One Diphtheria antitoxin for the flocculation test (NIBSC or BRP)  One Tetanus antitoxin for the flocculation test (NIBSC or BRP)  One Diphtheria toxin (NIBSC or BRP)  One Tetanus toxin (NIBSC or BRP). |  |  |  |
| **5.8.** | Where necessary, the same quantities of Standard Vaccine, Antigen, Antiserum, and other relevant standards and international standards shall be provided free of charge and promptly by the Contractor. |  |  |  |
| **5.8.1.** | Documents to be delivered to the laboratory with the product:  -Protocols related to production methods and processes, as well as quality control protocols,  -Standard Operating Procedure (SOP) documents related to the product's quality control tests, current validation reports, and validation procedure documents shall be provided with the product. |  |  |  |
| **5.8.2.** | If the reference vaccine and chemicals are imported from abroad, customs clearance procedures shall be carried out by the contractors. |  |  |  |
| **5.8.3.** | For each batch of vaccine delivered, the Contractor shall provide a sufficient number of samples free of charge for physical examination and laboratory analysis. |  |  |  |
| **5.8.4.** | If changes are made to the analysis methods, the standards and quantities requested from the Contractor may be re-evaluated. |  |  |  |
| **5.8.5.** | In addition, official documents (official certificates) containing the reference vaccine and/or reference unit values shall also be submitted. The reagents, chemical materials, detailed test SOPs (latest updated version), current validation and validation procedure documents, and calculation documents sent shall be delivered complete with the vaccines to be tested. |  |  |  |
| **5.9.** | If vaccines are prepared in vacuum-sealed ampoules/vials, and if the number of non-vacuum ampoules/vials exceeds 1% in the vacuum control performed on vaccine lot samples taken for inspection, the vaccine lot in question shall be rejected and returned due to the number of non-vacuum ampoules/vials. If the number of non-vacuum ampoules/vials is less than 1%, the vaccine supplier shall deliver the equivalent number of non-vacuum ampoules/vials free of charge within 120 calendar days from the date of notification by the General Directorate of Public Health to the supplier. |  |  |  |
| **5.10.** | Biological controls of products to be delivered shall be carried out at the Turkish Medicines and Medical Devices Agency, but in order to prevent interruption of vaccine and antiserum administration due to potential difficulties in the analysis process, a WHO-approved reference laboratory (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies) ([https://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)](http://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)) may also be conducted, and the costs shall be borne by the Contractor. The results of the control reports of the producer country shall be consistent with the results of the control reports of the Turkish Medicines and Medical Devices Agency or WHO-approved reference laboratories (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies). |  |  |  |
| **5.11.** | The Contractor may object to the results within 15 days. Upon such objection, product samples shall be sent to a second laboratory from among the WHO Reference Laboratories designated ex officio by GDPB or deemed appropriate by GDPB upon the Contractor's recommendation, with the shipping and analysis costs borne by the Contractor. If inconsistencies are detected following analyses conducted by WHO Reference Laboratories and the Turkish Medicines and Medical Devices Agency, the second report shall be accepted as the final report. |  |  |  |
| **6.** | **OTHER PROVISIONS** |  |  |  |
| **6.1.** | Due to delays caused by incorrect or incomplete materials and documents specified in Article 5, such as references, standards, and SOPs required for analysis, which are the responsibility of the contractor to deliver, the product's shelf life shall be shortened by the duration of the delay. The shelf life suitability specified in Article 4 shall be reduced by the duration of the delay. If the shelf life falls below the specified duration, return and exchange processes shall be initiated. For example, if the specification requires a minimum shelf life of 18 months upon delivery to the warehouse, but the product has a shelf life of 20 months at the time of delivery, and the SOP, references, etc. are delivered 70 days later due to a reason attributable to the contractor that prevented the completion of the analyses, the products shall be subject to processing due to shelf life non-compliance and shall be returned. |  |  |  |
| **6.2.** | Batches of products deemed unsuitable based on biological or chemical control results shall be returned. The contractor shall collect these products from the GDPB warehouse where they are located, transport them to the country of origin, and deliver the same quantity of products from a different batch that comply with the specifications to GDPB free of charge within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **6.3.** | In the event of product return (rejection or lot change), the products shall be collected from the warehouse within 30 calendar days after the notification date, during official working hours and days. If not collected, the contractor shall bear the storage and/or disposal costs for the delayed period. |  |  |  |
| **6.4.** | In the event that the products are returned to the Contractor, the relevant official documents proving that the products have been removed from Türkiye or destroyed shall be submitted to the administration within 120 calendar days after the products are collected from the warehouse. If no notification is made, the procedures shall be carried out in accordance with customs regulations. |  |  |  |
| **6.5.** | After acceptance of the products, if any physical deficiencies (barcode errors, packaging, labels, etc.) are detected, the contractor shall remedy the deficiency free of charge. |  |  |  |

| **LOT 9 - ADULT TYPE TETANUS, DIPHTHERIA, ACELLULAR PERTUSSIS (TDAP) VACCINE** | | | | |
| --- | --- | --- | --- | --- |
| **Item No** | **Specifications** | **Specifications Offered** | **Notes, remarks,  ref to documentation** | **Evaluation Committee’s notes** |
| **1.** | **VACCINE TECHNICAL SPECIFICATIONS** |  |  |  |
| **1.1.** | The product shall comply with the conditions and characteristics specified in World Health Organisation WHO TRS 980 Annex 4, Annex 5, Annex 6 and European Pharmacopoeia 11.0 07/2022:2764 monograph in terms of physical appearance and laboratory analyses. |  |  |  |
| **1.2.** | Single-dose of the vaccine shall be 0.5 mL. In a single dose of the vaccine, the contents corresponding to the reference acellular pertussis (FHA, PT, PRN, etc. antigen contents) shall be μg, and the contents corresponding to diphtheria and tetanus shall be Lf/IU. |  |  |  |
| **1.3.** | The vaccine shall not contain thiomersal |  |  |  |
| **1.4.** | The vaccine shall be an adsorbed vaccine. |  |  |  |
| **1.5.** | The vaccine shall maintain its stability to its expiration date at temperatures between (+2) - (+8) OC. |  |  |  |
| **2.** | **DOCUMENTS TO BE INCLUDED IN THE FILE TO BE REVIEWED BY THE TENDER COMMITTEE** |  |  |  |
| **2.1.** | The product in question;   * + 1. shall have a license issued by the Turkish Ministry of Health,     2. If it does not have a license issued by the Turkish Ministry of Health;   + It shall be included in the latest pre-qualification list published by the World Health Organization (<https://extranet.whoint/prequal/vaccines/prequalified-vaccines)> or,   + It shall have a license from the European Medicines Agency (EMA) and be manufactured in European Union countries, or   + It shall have a license from the US-FDA and be manufactured in the United States, **or**   + It shall be licensed by the Pharmaceuticals and Medical Devices Agency (PMDA) and manufactured in Japan, or   + It shall be licensed by the South Korean Food and Drug Administration and manufactured in South Korea, **or**   + It shall be licensed by the Canadian Food and Drugs Act and Regulations and manufactured in Canada, **or**   + The product shall be licensed by the Australian Department of Health Therapeutic Goods Administration and manufactured in Australia. |  |  |  |
| **2.2.** | The product shall be accompanied by a certificate (GMP certificate) showing that the factory producing it complies with the **Good Manufacturing Practices (**GMP) standards approved by the State Control Agency of the country where the product is manufactured. If the product is filled or manufactured in our country, there shall be a document showing that the factory where the production/filling is carried out, approved by the Turkish Ministry of Health, Turkish Medicines and Medical Devices Agency, manufactures in accordance with good manufacturing practices (GMP) rules. |  |  |  |
| **2.3.** | For any batch produced within the last two years, the 'National Regulatory Authority' (NRA) or the Batch Release Certificate issued by the EMA (from the locations specified in the annex to the European Union's 2001/83/EC directive), US-FDA, Japan, South Korea, Canada, and Australian state authorities, as specified in 2.1. If the product is manufactured in Türkiye, it shall be a marketing authorization certificate issued by the Turkish Medicines and Medical Devices Agency of the Ministry of Health of the Republic of Türkiye. The analysis report for the same series shall also be included in the BRC annex. |  |  |  |
| **2.4.** | A valid Pharmaceutical Product Certificate (CPP) approved by the manufacturer's country authority. |  |  |  |
| **2.5.** | A **manufacturer-approved** document showing that the risk of Transmissible Spongiform Encephalopathy (TSE) has been minimized at every stage of the product's production. |  |  |  |
| **2.6.** | If the product is licensed in Türkiye, it shall have a "Summary of Product Characteristics" (SPC) or package insert or "Patient Information Leaflet" (PIL) approved by the Turkish Medicines and Medical Devices Agency (TİTCK), or if it is not licensed in Türkiye, it shall have one approved by the relevant country's authority, along with Turkish translations. |  |  |  |
| **2.7.** | If applicable, a list of tasks to be performed by subcontractors shall be provided. |  |  |  |
| **2.8.** | The tenderer shall declare in writing how many batches of the product they can deliver. |  |  |  |
| **2.9.** | If the product is used outside the country of manufacture, a document shall be submitted containing the list of countries where the product is used, approved by the manufacturer, along with the usage permits (import permits) or license numbers for these products, and information on the total number of doses used in countries other than the country of manufacture for the last two calendar years prior to the year of the tender. |  |  |  |
| **2.10.** | The tenderer shall declare that if the manufacturer or another country where the product is used suspends the use of the product for any reason, or if they receive any news in this regard, they shall inform the Ministry within 24 hours (product name, serial number, reason for discontinuation, etc.) and that if the information is not provided within 24 hours, the administration has the right to unilaterally terminate the contract. It also indicates that in the event of discontinuation of the product, after the unused products are collected by the Ministry and sent to the Central Warehouse, the Tenderer undertakes to bring a new product from a different series that complies with the specifications within 90 (ninety) calendar days from the date the replacement request is notified to the Tenderer. In addition, the Tenderer shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date of notification of the product replacement request after the unused products are collected by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **2.11.** | The Tenderer shall submit the original or notarized copies of the required documents, along with their certified Turkish translations, to the tender committee. |  |  |  |
| **3.** | **DELIVERY OF PRODUCTS** |  |  |  |
| **3.1.** | If the products are imported, the tenderer's representative shall be present when the products are collected from customs and shall ensure that the goods are collected in accordance with the required specifications and delivered to the location deemed appropriate by GDPB without delay. |  |  |  |
| **3.2.** | The contractor shall provide the Department with the shipment details 3 days prior to the delivery date of the product. |  |  |  |
| **3.3.** | Product delivery shall be made in such a way that it does not coincide with holidays, official holidays, or the end of working hours in Türkiye. |  |  |  |
| **3.4.** | To clear products purchased by GDPB through customs, the Contractor shall enter the product information (batch release certificate and quantity for the lot/serial number for which import permission is requested) via the Single Window Portal System (<https://uygulama.gtb.gov.tr/TekPencere>). The Single Window approval request shall be submitted to the Department electronically (to the Department's official e-mail address) or in writing at least 3 days in advance. Products purchased by the General Directorate of Public Health shall be delivered to the GDPB Vaccine and Drug Warehouse within 48 hours after being cleared through customs (except for products filled in Türkiye) if they are imported. Any changes required after the initial inspection (packaging, barcode, etc.) may also be made at the Central Vaccine and Drug Warehouse with the approval of the GDPB. If storage exceeds 48 hours, it is mandatory to submit temperature records approved by the Contractor's quality manager from the production site until the Ministry of Health Vaccine Storage arrives, to use a warehouse licensed by the Turkish Ministry of Health, and, if "temperature monitoring cards" are installed at the production facility, not to change them. |  |  |  |
| **3.5.** | If the packaging of the imported product (including barcoding) is to be changed at a different location after the contract is signed, this situation shall be reported to the Department. The temporary storage location shall be licensed by the Turkish Ministry of Health, the initial opening of the packaging of the product withdrawn from customs shall be carried out under the supervision of GDPB or its authorized personnel, and the shipment and temporary storage temperature records shall also be submitted during the inspection phase. GDPB may inspect this entire process at any time and on any day after customs clearance. Intermediate storage shall be possible if the application made to GDPB and the storage period are found to be appropriate. |  |  |  |
| **3.6.** | Products filled in our country shall be delivered to the GDPB Vaccine and Drug Warehouse within 24 hours of leaving the filling facility. If the product is not delivered to the GDPB Vaccine and Drug Warehouse within 24 hours after leaving the filling facility and is to be stored in another warehouse, the organization performing the intermediate storage shall be licensed by the Turkish Ministry of Health, temperature records from the production site to the warehouse and within the warehouse shall be kept, and certified copies from the product quality representative shall be delivered to GDPB upon product delivery. These stages shall be open to inspection by GDPB if required. The Department shall be notified if temporary storage is required. Products shall not be accepted if the specified conditions cannot be met. |  |  |  |
| **3.7.** | If the products are filled/manufactured in Türkiye, the time limit specified in Article 3, except for 3.2 and 3.3, and the restrictions at shall not apply. |  |  |  |
| **4.** | **DOCUMENTS REQUIRED DURING INSPECTION AND PRODUCT CHARACTERISTICS** |  |  |  |
| **4.1.** | Products shall have **a shelf life of at least 18 (eighteen) months** from the date of delivery to our warehouse. |  |  |  |
| **4.1.1.** | **Documents required during the product inspection phase:**  The documents specified in Article 2 of the Technical Specifications and the documents specific to the delivered series/lot shall be submitted during the inspection stage. These documents are:   * Product License * Current GMP certificate for the production site, * Analysis report for the delivered batch (document containing information such as composition, analysis results, reference values, production/expiration dates, etc.), * BRC for the delivered batch, * Current Pharmaceutical Product Certificate (CPP) * TSE declaration (item 2.5), * List of tasks to be performed by subcontractors, * Package Insert or Prospectus or IFU (Article 2.6), * List of countries where the product is used and import permit/license number and the number of doses used in each country in the last two calendar years prior to the year of the offer (Article 2.9), * Commitment letter (Article 2.10). |  |  |  |
| **4.2.** | The Contractor, manufacturer or any other country where this product is used shall notify the Ministry within 24 hours if the use of the product is suspended for any reason or if they receive any information in this regard (product name, serial number, reason for discontinuation, etc.) and acknowledges that the administration has the right to unilaterally terminate the contract if such information is not provided within 24 hours. In the event of discontinuation of the product, the Contractor shall be required to bring a manufacturer-approved commitment letter to the Ministry within 90 (ninety) calendar days from the date the replacement request is notified to the Contractor. Additionally, the Contractor shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date the request for product replacement is notified, following the collection of unused products by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **4.3.** | Stability studies and results proving the actual shelf life of the product in question shall be submitted. If the product is filled or manufactured in our country and stability studies are still ongoing, the TİTCK-approved study results shall be submitted to the Department as they are completed. |  |  |  |
| **4.4.** | Along with the product, all technical documents required in the tender for the product (Good Manufacturing Practices, analysis report, SPC, certificates, etc.) and detailed SOP (may be provided in the original license), **stability results (showing real-time and accelerated stability shelf life),** product photos, and all documents containing technical information about the packaging (dimensions, volume, etc.) shall be submitted to the inspection commission in duplicate on CD/DVD/flash drive. |  |  |  |
| **4.5.** | Documents that do not change with each shipment shall be submitted once, with the first shipment. If deemed necessary, documents may be requested again. |  |  |  |
| **4.6.** | **Required Packaging Characteristics** |  |  |  |
| **4.6.1.** | The products shall be packaged in vials, flacons or ready-to-use syringe (injector) containing a single dose. Those ready-to-use syringes (injectors) shall be single packed or provided in ten packs. If the products are packaged in packs of ten, the packs shall contain foam or cardboard separators to prevent the vials or ampoules from breaking due to contact. If the product is packaged individually, the packages shall then be bundled in packs of ten. If diluents are separate, 5 additional diluents shall be delivered with every 1000 doses of vaccine. |  |  |  |
| **4.6.2.** | The inner and outer packaging of licensed products in Türkiye shall comply with the current "Regulation on Packaging Information, Instructions for Use, and Tracking of Human Medicinal Products" published by the Turkish Ministry of Health. If the product is not licensed in our country, the inner packaging of the ready-to-use syringe (injector), ampoule, or vial shall bear, at a minimum, the manufacturer's and product name, dosage, amount of content per dose, method of administration (IM/IV/SC/ID, etc.), lot (batch) number, and expiration date, printed in indelible ink. The package shall also contain storage temperature information in addition to the inner packaging. The product package shall bear the statement **"Property of the Turkish Ministry of Health, NOT FOR SALE**." |  |  |  |
| **4.6.3.** | Each product package shall contain at least one "Summary of Product Characteristics" (SPC) or Turkish package insert or "Patient Information Leaflet" (PIL) prepared in accordance with the "Regulation on the Packaging and Labelling of Human Medicinal Products" dated 25.04.2017 and numbered 30048. Additionally, the following text shall be added to the beginning of the “"Summary of Product Characteristics" (SPC)” or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention:  "In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration.  For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates***."*** |  |  |  |
| **4.6.4.** | The packages shall then be placed in boxes. The names and addresses of the manufacturer and representative company of the product, the name of the product, the lot number, the storage temperature, the expiration date, and the number of doses in the box shall be written on these boxes. If the products are packaged individually, ten packages shall be placed in each box. If the products are packaged in packs of ten, five packages shall be placed in each box. |  |  |  |
| **4.6.5.** | The packaging boxes shall be placed in styrofoam. The styrofoam shall then be placed inside cartons. The carton dimensions shall be 40X60X40 ±20 (Width, Length, Height) cm. A sufficient number of ice packs or gel packs, etc., shall be placed in the cartons. The ice packs or gel packs, etc.**,** placed in the cartons shall be **unfrozen and cooled**.  The names and addresses of the manufacturer and representative company, the product name, serial number, storage temperature, expiration date, dose quantity in the carton, carton dimensions, and weight shall be written on these cartons. |  |  |  |
| **4.6.6.** | The boxes shall then be placed on pallets. The pallets shall be euro pallets (120cm±2cmx80cm±2cmx10-15cm). After the boxes are placed on the pallets, the height together with the pallet shall not exceed 2 (two) meters. The boxes may protrude from the pallet by a maximum of 5 cm. There shall be a maximum of 16 (sixteen) boxes on the pallet. |  |  |  |
| **4.6.7.** | There shall be a 2D barcode on the packages, boxes, cartons, and pallets. The barcode prepared for the ready-to-use syringe (injector) inside each individually packaged product (these barcodes shall also have HL7 and 97 breakdown values) shall be on the product's package. The packages shall then be tied in sets of ten, and the package label shall be affixed to a different area than the barcode affixed to each product. If the product is packaged in sets of ten, the barcode prepared for the ready-to-use syringe (injector) (these barcodes shall also have HL7 and 97 breakdown values) shall be placed inside the package, and the barcode corresponding to the package breakdown shall be on the package. For the information to be included in the barcode, the information specified in the Guide for Barcode Application to Vaccines, Antiserums, and Diluents published by the Turkish Ministry of Health shall be used as a basis, and any additional information required shall be determined by GDPB. **The barcode area for the dose shall be at least 12X12 mm in accordance with the Guide**. If GDPB makes changes to the system instead of the barcode, the contractor shall be obliged to comply with the requirements of the newly created system without requesting a price difference. |  |  |  |
| **4.6.8.** | Even after acceptance, if any faulty operations related to the barcode system are detected later, the costs of changing the product packaging and, if deemed necessary, collecting the products from the field shall be borne by the Contractor. If this process exceeds one-month, new products with a new expiration date may be requested at the request of the Department to avoid any problems related to the expiration date. |  |  |  |
| **4.6.9.** | **Temperature monitoring during transportation:** |  |  |  |
| **4.6.9.1.** | The freeze indicator, temperature monitoring card, and digital temperature recording devices used **shall be listed in the WHO "E006: Temperature monitoring devices"** (https://extranet.who.int/prequal/immunization-devices/prequalified/imd-products)**.** |  |  |  |
| **4.6.9.2.** | If the product(s) are sensitive to freezing, each box shall contain a freeze indicator. |  |  |  |
| **4.6.9.3.** | If the product(s) are sensitive to high temperatures, each box shall contain a temperature monitoring card **with the date it was activated and the name/code of the activator written on it**. |  |  |  |
| **4.6.9.4.** | If the product(s) are sensitive to both freezing and high temperatures, or if they are packaged together, each box shall contain both a freeze indicator and a temperature monitor card with the date of activation and the name/code of the activator written on it. |  |  |  |
| **4.6.9.5.** | In addition, each pallet shall have an electronic, temperature, and freeze-sensitive digital monitor capable of long-term recording. The electronic, temperature, and freeze-sensitive digital monitors capable of long-term recording placed on the pallet shall be read during the inspection phase, the outputs shall be recorded in a report and signed by the company, and if there are no deviations, they can be filed electronically. If requested by the company, these devices shall be returned for storage without destruction for at least three months. Upon return, the pallet numbers and device serial numbers shall be recorded in a report.  If the pallets consist of insulated boxes, each containing heat tracking material (such as a digital recording device, heat monitoring card, or freeze indicator), and conflicting results are found between the digital heat records on or inside the pallet and the heat records inside the box when evaluating the heat records, the temperature monitoring results inside the boxes shall be considered when processing. |  |  |  |
| **4.6.9.6.** | Products found not to have been transported under appropriate conditions (Guidelines for the international packaging and shipping of vaccines, sixth edition. Geneva: World Health Organization, 2020. Licence: CC BY-NC-SA 3.0 IGO) as monitored by these heat trackers shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **4.6.10.** | Each product shall be delivered with a Material Safety Data Sheet (MSDS). The contractor is responsible for the “Transportation, packaging, and labelling of hazardous materials” and completing any shortfalls if there is any. |  |  |  |
| **4.6.11.** | The contractor's representative shall be present during the delivery or return of the products. The representative shall submit a letterhead, stamped, and signed authorization document belonging to the contractor and a photocopy of their photo ID to the Warehouse Manager. The contractor is responsible for unloading the products from the vehicle into the warehouse or loading them back onto the vehicle for return. A list of the names, telephone numbers, and addresses of all employees and subcontractor personnel who shall perform work on behalf of the contractor shall be submitted to the Warehouse Manager, signed by the contractor's representative, prior to unloading. The contractor shall be responsible for any damage that may be caused to the warehouse or equipment and for all liabilities arising from "Occupational Health and Safety Regulations." The contractor shall submit a stamped and signed commitment stating that it has assumed the SSI, occupational health and safety, and work accident liabilities of its employees for unloading the products from the vehicle or loading them in case of return, and that it has assumed the liability for compensation in case of damage to the warehouse or any equipment inside the warehouse. Responsibility begins upon entry into the Warehouse area after the security check. |  |  |  |
| **4.6.12.** | Except in emergencies, no contractor employees other than the vehicle drivers and those declared shall enter the climate-controlled warehouse. |  |  |  |
| **4.6.13.** | If barcoding, packaging, or prospectus changes are to be performed in the GDPB warehouse, the documents belonging to the subcontractors shall be as follows:   * + - * shall be a contract demonstrating the availability of occupational safety expertise and workplace physician support services as required by the "Occupational Health and Safety Law" No. 6331.       * The contractor's structure shall include at least one coordinator, one operations manager, one quality control and GMP manager, and one warehouse manager. These personnel shall be present during the execution of the work. There shall be a document or documents proving that the personnel included in the company structure have received GMP and Good Warehouse Practices Training organized by the Turkish Ministry of Health or an organization that has received a GMP Certificate from the Turkish Ministry of Health.       * There shall be standard operating procedures (SOPs) prepared by a pharmacist and approved by the company representative, covering barcode printing and affixing procedures and cold storage room operating rules. |  |  |  |
| **5.** | **DOCUMENTS AND MATERIALS REQUIRED FOR LABORATORY ANALYSES AND METHODS TO BE FOLLOWED** |  |  |  |
| **5.1.** | General principles of product safety;  The analysis reports for the product are part of the batch release certificate, and both documents shall be considered together in the evaluations. |  |  |  |
| **5.1.1.** | The product shall be manufactured in our country, have a manufacturing license from the Turkish Medicines and Medical Devices Agency (TİTCK), and present the BRC certificate for the delivered batch obtained from the TİTCK/Analysis and Control Laboratories Department. In addition, if there is no break in the cold chain during product transfer, the physical examination is appropriate, and the commission grants approval, the inspection acceptance process can be completed. |  |  |  |
| **5.1.2.** | If the product is manufactured outside our country and has an import license from TİTCK or is on the WHO's prequalification list (Prequalified vaccines), the Batch Release Certificate for the delivered series shall be obtained from WHO/ Reference Laboratories/institutions, provided that the analyses are performed in accordance with the OCABR guidelines at the TİTCK/Analysis and Control Laboratories Directorate. The inspection acceptance process for products found to be suitable through analysis can be completed. |  |  |  |
| **5.1.3.** | If the product is not licensed in our country, but is licensed by the authorities in EMA, US-FDA, Japan, Canada, South Korea, and Australia as specified in Article 2.1 of the technical specifications, tests may be performed in accordance with the OCABR guidelines by the TİTCK/Analysis and Control Laboratories Department. The inspection and acceptance process for products with suitable analyses can be completed. |  |  |  |
| **5.2.** | If there are any doubts regarding product safety within the scope of the cold chain or other matters specified in the technical specifications, new samples may be taken if necessary, and analyses may be performed as required, including analyses based on batch release. |  |  |  |
| **5.3.** | These products are subject to the *"Regulations on Market Surveillance and Control Procedures and Principles to be Implemented by the Ministry of Health*." GDPB reserves the right to conduct analyses in case of possible suspicion or complaint. The Contractor shall provide the required number of product doses for analysis and the materials required for the analysis specified in Article 5 free of charge. If the analysis result is found to be unsatisfactory, even if the product in question has been accepted, the Contractor shall deliver the same quantity from different series within 90 calendar days. |  |  |  |
| **5.4.** | If the product does not comply with Article 5.1, after the inspection is completed, a sample shall be taken from each batch using the random sampling method and delivered to the laboratory with a report signed by the Contractor's representative and one of the inspection members. |  |  |  |
| **5.5.** | Since the physical appearance of the products requires expertise, it shall be assessed by specialized personnel at the National Reference Laboratory within the TİTCK in accordance with the current Turkish/European Pharmacopoeia. Products that are not suitable in terms of physical appearance shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. After the physical tests of the products are found to be suitable, other tests shall be performed in accordance with Article 5. |  |  |  |
| **5.6.** | The vaccine shall comply with the characteristics and conditions specified in World Health Organization (WHO) Technical Report Series 980 Annex 4, Annex 5, Annex 6 Technical Report Series No: 979 Annex 4 European Pharmacopoeia 11.0 07/2022: 2764 monograph in terms of physical appearance and laboratory analyses. |  |  |  |
| **5.7.** | The Contractor shall deliver two (2) reference vaccines free of charge for each batch, along with reagents and chemical materials deemed necessary for testing the potency and identity of the vaccine, to be used in conjunction with the vaccines to be tested. Additionally, for every two (2) batches of the vaccine to undergo Tetanus, Diphtheria, Acellular Pertussis Vaccine Potency and identity testing and quality control, the following shall be delivered:  Two diphtheria standard vaccines (in-house)  Two tetanus standard vaccines (in-house)  Two acellular pertussis standart vaccine (in house)  At least 4 ml diphtheria toxin (in-house)  At least 4 ml tetanus toxin (in-house)  For each ten batches vaccine  One Diphtheria Vaccine (Adsorbed) (BRP or NIBSC)  One Tetanus Vaccine (Adsorbed) (BRP or NIBSC)  One Diphtheria antitoxin for the flocculation test (NIBSC or BRP)  One Tetanus antitoxin for the flocculation test (NIBSC or BRP)  One Diphtheria toxin (NIBSC or BRP)  One Tetanus toxin (NIBSC or BRP)  Five monovalent serums shall be placed for each pertussis component contained within the vaccine. |  |  |  |
| **5.8.** | Where necessary, the same quantities of Standard Vaccine, Antigen, Antiserum, and other relevant standards and international standards shall be provided free of charge and promptly by the Contractor. |  |  |  |
| **5.8.1.** | Documents to be delivered to the laboratory with the product:  -Protocols related to production methods and processes, as well as quality control protocols,  -Standard Operating Procedure (SOP) documents related to the product's quality control tests, current validation reports, and validation procedure documents shall be provided with the product. |  |  |  |
| **5.8.2.** | If the reference vaccine and chemicals are imported from abroad, customs clearance procedures shall be carried out by the contractors. |  |  |  |
| **5.8.3.** | For each batch of vaccine delivered, the Contractor shall provide a sufficient number of samples free of charge for physical examination and laboratory analysis. |  |  |  |
| **5.8.4.** | If changes are made to the analysis methods, the standards and quantities requested from the Contractor may be re-evaluated. |  |  |  |
| **5.8.5.** | In addition, official documents (official certificates) containing the reference vaccine and/or reference unit values shall also be submitted. The reagents, chemical materials, detailed test SOPs (latest updated version), current validation and validation procedure documents, and calculation documents sent shall be delivered complete with the vaccines to be tested. |  |  |  |
| **5.9.** | If vaccines are prepared in vacuum-sealed ampoules/vials, and if the number of non-vacuum ampoules/vials exceeds 1% in the vacuum control performed on vaccine lot samples taken for inspection, the vaccine lot in question shall be rejected and returned due to the number of non-vacuum ampoules/vials. If the number of non-vacuum ampoules/vials is less than 1%, the vaccine supplier shall deliver the equivalent number of non-vacuum ampoules/vials free of charge within 120 calendar days from the date of notification by the General Directorate of Public Health to the supplier. |  |  |  |
| **5.10.** | Biological controls of products to be delivered shall be carried out at the Turkish Medicines and Medical Devices Agency, but in order to prevent interruption of vaccine and antiserum administration due to potential difficulties in the analysis process, a WHO-approved reference laboratory (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies) ([https://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)](http://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)) may also be conducted, and the costs shall be borne by the Contractor. The results of the control reports of the producer country shall be consistent with the results of the control reports of the Turkish Medicines and Medical Devices Agency or WHO-approved reference laboratories (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies). |  |  |  |
| **5.11.** | The Contractor may object to the results within 15 days. Upon such objection, product samples shall be sent to a second laboratory from among the WHO Reference Laboratories designated ex officio by GDPB or deemed appropriate by GDPB upon the Contractor's recommendation, with the shipping and analysis costs borne by the Contractor. If inconsistencies are detected following analyses conducted by WHO Reference Laboratories and the Turkish Medicines and Medical Devices Agency, the second report shall be accepted as the final report. |  |  |  |
| **6.** | **OTHER PROVISIONS** |  |  |  |
| **6.1.** | Due to delays caused by incorrect or incomplete materials and documents specified in Article 5, such as references, standards, and SOPs required for analysis, which are the responsibility of the contractor to deliver, the product's shelf life shall be shortened by the duration of the delay. The shelf life suitability specified in Article 4 shall be reduced by the duration of the delay. If the shelf life falls below the specified duration, return and exchange processes shall be initiated. For example, if the specification requires a minimum shelf life of 18 months upon delivery to the warehouse, but the product has a shelf life of 20 months at the time of delivery, and the SOP, references, etc. are delivered 70 days later due to a reason attributable to the contractor that prevented the completion of the analyses, the products shall be subject to processing due to shelf life non-compliance and shall be returned. |  |  |  |
| **6.2.** | Batches of products deemed unsuitable based on biological or chemical control results shall be returned. The contractor shall collect these products from the GDPB warehouse where they are located, transport them to the country of origin, and deliver the same quantity of products from a different batch that comply with the specifications to GDPB free of charge within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **6.3.** | In the event of product return (rejection or lot change), the products shall be collected from the warehouse within 30 calendar days after the notification date, during official working hours and days. If not collected, the contractor shall bear the storage and/or disposal costs for the delayed period. |  |  |  |
| **6.4.** | In the event that the products are returned to the Contractor, the relevant official documents proving that the products have been removed from Türkiye or destroyed shall be submitted to the administration within 120 calendar days after the products are collected from the warehouse. If no notification is made, the procedures shall be carried out in accordance with customs regulations. |  |  |  |
| **6.5.** | After acceptance of the products, if any physical deficiencies (barcode errors, packaging, labels, etc.) are detected, the contractor shall remedy the deficiency free of charge. |  |  |  |

| **LOT 10 - DIPHTHERIA, PERTUSSIS, TETANUS, INACTIVE POLIO (DABT-IPV) VACCINE** | | | | |
| --- | --- | --- | --- | --- |
| **Item No** | **Specifications** | **Specifications Offered** | **Notes, remarks,  ref to documentation** | **Evaluation Committee’s notes** |
| **1.** | **VACCINE TECHNICAL SPECIFICATIONS** |  |  |  |
| **1.1.** | The product shall comply with the conditions and characteristics specified in World Health Organization Technical Report Series 979 Annex IV, Technical Report Series 980, Annex IV, V, and 11.0 07/2022:1934 and 01/2020:2.9.20 monographs of European Pharmacopoeia in terms of physical appearance and laboratory analyses. |  |  |  |
| **1.2.** | The vaccine shall be adsorbed. |  |  |  |
| **1.3.** | Single-dose of the vaccine shall be 0.5 mL, and shall be packaged within a ready-to-use syringe (injector) or single-dose. |  |  |  |
| **1.4.** | Diphtheria, acellular Pertussis, Tetanus, Inactive Polio (type 1,2,3) combination vaccine shall maintain its stability to its expiration date from the last successful potency test at temperatures between (+2) - (+8) OC. |  |  |  |
| **2.** | **DOCUMENTS TO BE INCLUDED IN THE FILE TO BE REVIEWED BY THE TENDER COMMITTEE** |  |  |  |
| **2.1.** | * 1. The product in question;      1. shall have a license issued by the Turkish Ministry of Health,      2. If it does not have a license issued by the Turkish Ministry of Health;   + It shall be included in the latest pre-qualification list published by the World Health Organization (<https://extranet.whoint/prequal/vaccines/prequalified-vaccines)> or,   + It shall have a license from the European Medicines Agency (EMA) and be manufactured in European Union countries, or   + It shall have a license from the US-FDA and be manufactured in the United States, **or**   + It shall be licensed by the Pharmaceuticals and Medical Devices Agency (PMDA) and manufactured in Japan, or   + It shall be licensed by the South Korean Food and Drug Administration and manufactured in South Korea, **or**   + It shall be licensed by the Canadian Food and Drugs Act and Regulations and manufactured in Canada, **or**   + The product shall be licensed by the Australian Department of Health Therapeutic Goods Administration and manufactured in Australia. |  |  |  |
| **2.2.** | The product shall be accompanied by a certificate (GMP certificate) showing that the factory producing it complies with the **Good Manufacturing Practices (**GMP) standards approved by the State Control Agency of the country where the product is manufactured. If the product is filled or manufactured in our country, there shall be a document showing that the factory where the production/filling is carried out, approved by the Turkish Ministry of Health, Turkish Medicines and Medical Devices Agency, manufactures in accordance with good manufacturing practices (GMP) rules. |  |  |  |
| **2.3.** | For any batch produced within the last two years, the 'National Regulatory Authority' (NRA) or the Batch Release Certificate issued by the EMA (from the locations specified in the annex to the European Union's 2001/83/EC directive), US-FDA, Japan, South Korea, Canada, and Australian state authorities, as specified in 2.1. If the product is manufactured in Türkiye, it shall be a marketing authorization certificate issued by the Turkish Medicines and Medical Devices Agency of the Ministry of Health of the Republic of Türkiye. The analysis report for the same series shall also be included in the BRC annex. |  |  |  |
| **2.4.** | A valid Pharmaceutical Product Certificate (CPP) approved by the manufacturer's country authority. |  |  |  |
| **2.5.** | A **manufacturer-approved** document showing that the risk of Transmissible Spongiform Encephalopathy (TSE) has been minimized at every stage of the product's production. |  |  |  |
| **2.6.** | If the product is licensed in Türkiye, it shall have a "Summary of Product Characteristics" (SPC) or package insert or "Patient Information Leaflet" (PIL) approved by the Turkish Medicines and Medical Devices Agency (TİTCK), or if it is not licensed in Türkiye, it shall have one approved by the relevant country's authority, along with Turkish translations. |  |  |  |
| **2.7.** | If applicable, a list of tasks to be performed by subcontractors shall be provided. |  |  |  |
| **2.8.** | The tenderer shall declare in writing how many batches of the product they can deliver. |  |  |  |
| **2.9.** | If the product is used outside the country of manufacture, a document shall be submitted containing the list of countries where the product is used, approved by the manufacturer, along with the usage permits (import permits) or license numbers for these products, and information on the total number of doses used in countries other than the country of manufacture for the last two calendar years prior to the year of the tender. |  |  |  |
| **2.10.** | The tenderer shall declare that if the manufacturer or another country where the product is used suspends the use of the product for any reason, or if they receive any news in this regard, they shall inform the Ministry within 24 hours (product name, serial number, reason for discontinuation, etc.) and that if the information is not provided within 24 hours, the administration has the right to unilaterally terminate the contract. It also indicates that in the event of discontinuation of the product, after the unused products are collected by the Ministry and sent to the Central Warehouse, the Tenderer undertakes to bring a new product from a different series that complies with the specifications within 90 (ninety) calendar days from the date the replacement request is notified to the Tenderer. In addition, the Tenderer shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date of notification of the product replacement request after the unused products are collected by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **2.11.** | The Tenderer shall submit the original or notarized copies of the required documents, along with their certified Turkish translations, to the tender committee. |  |  |  |
| **3.** | **DELIVERY OF PRODUCTS** |  |  |  |
| **3.1.** | If the products are imported, the tenderer's representative shall be present when the products are collected from customs and shall ensure that the goods are collected in accordance with the required specifications and delivered to the location deemed appropriate by GDPB without delay. |  |  |  |
| **3.2.** | The contractor shall provide the Department with the shipment details 3 days prior to the delivery date of the product. |  |  |  |
| **3.3.** | Product delivery shall be made in such a way that it does not coincide with holidays, official holidays, or the end of working hours in Türkiye. |  |  |  |
| **3.4.** | To clear products purchased by GDPB through customs, the Contractor shall enter the product information (batch release certificate and quantity for the lot/serial number for which import permission is requested) via the Single Window Portal System (<https://uygulama.gtb.gov.tr/TekPencere>). The Single Window approval request shall be submitted to the Department electronically (to the Department's official e-mail address) or in writing at least 3 days in advance. Products purchased by the General Directorate of Public Health shall be delivered to the GDPB Vaccine and Drug Warehouse within 48 hours after being cleared through customs (except for products filled in Türkiye) if they are imported. Any changes required after the initial inspection (packaging, barcode, etc.) may also be made at the Central Vaccine and Drug Warehouse with the approval of the GDPB. If storage exceeds 48 hours, it is mandatory to submit temperature records approved by the Contractor's quality manager from the production site until the Ministry of Health Vaccine Storage arrives, to use a warehouse licensed by the Turkish Ministry of Health, and, if "temperature monitoring cards" are installed at the production facility, not to change them. |  |  |  |
| **3.5.** | If the packaging of the imported product (including barcoding) is to be changed at a different location after the contract is signed, this situation shall be reported to the Department. The temporary storage location shall be licensed by the Turkish Ministry of Health, the initial opening of the packaging of the product withdrawn from customs shall be carried out under the supervision of GDPB or its authorized personnel, and the shipment and temporary storage temperature records shall also be submitted during the inspection phase. GDPB may inspect this entire process at any time and on any day after customs clearance. Intermediate storage shall be possible if the application made to GDPB and the storage period are found to be appropriate. |  |  |  |
| **3.6.** | Products filled in our country shall be delivered to the GDPB Vaccine and Drug Warehouse within 24 hours of leaving the filling facility. If the product is not delivered to the GDPB Vaccine and Drug Warehouse within 24 hours after leaving the filling facility and is to be stored in another warehouse, the organization performing the intermediate storage shall be licensed by the Turkish Ministry of Health, temperature records from the production site to the warehouse and within the warehouse shall be kept, and certified copies from the product quality representative shall be delivered to GDPB upon product delivery. These stages shall be open to inspection by GDPB if required. The Department shall be notified if temporary storage is required. Products shall not be accepted if the specified conditions cannot be met. |  |  |  |
| **3.7.** | If the products are filled/manufactured in Türkiye, the time limit specified in Article 3, except for 3.2 and 3.3, and the restrictions at shall not apply. |  |  |  |
| **4.** | **DOCUMENTS REQUIRED DURING INSPECTION AND PRODUCT CHARACTERISTICS** |  |  |  |
| **4.1.** | Products shall have **a shelf life of at least 18 (eighteen) months** from the date of delivery to our warehouse. |  |  |  |
| **4.1.1.** | **Documents required during the product inspection phase:**  The documents specified in Article 2 of the Technical Specifications and the documents specific to the delivered series/lot shall be submitted during the inspection stage. These documents are:   * Product License * Current GMP certificate for the production site, * Analysis report for the delivered batch (document containing information such as composition, analysis results, reference values, production/expiration dates, etc.), * BRC for the delivered batch, * Current Pharmaceutical Product Certificate (CPP) * TSE declaration (item 2.5), * List of tasks to be performed by subcontractors, * Package Insert or Prospectus or IFU (Article 2.6), * List of countries where the product is used and import permit/license number and the number of doses used in each country in the last two calendar years prior to the year of the offer (Article 2.9), * Commitment letter (Article 2.10). |  |  |  |
| **4.2.** | The Contractor, manufacturer or any other country where this product is used shall notify the Ministry within 24 hours if the use of the product is suspended for any reason or if they receive any information in this regard (product name, serial number, reason for discontinuation, etc.) and acknowledges that the administration has the right to unilaterally terminate the contract if such information is not provided within 24 hours. In the event of discontinuation of the product, the Contractor shall be required to bring a manufacturer-approved commitment letter to the Ministry within 90 (ninety) calendar days from the date the replacement request is notified to the Contractor. Additionally, the Contractor shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date the request for product replacement is notified, following the collection of unused products by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **4.3.** | Stability studies and results proving the actual shelf life of the product in question shall be submitted. If the product is filled or manufactured in our country and stability studies are still ongoing, the TİTCK-approved study results shall be submitted to the Department as they are completed. |  |  |  |
| **4.4.** | Along with the product, all technical documents required in the tender for the product (Good Manufacturing Practices, analysis report, SPC, certificates, etc.) and detailed SOP (may be provided in the original license), **stability results (showing real-time and accelerated stability shelf life)**, product photos, and all documents containing technical information about the packaging (dimensions, volume, etc.) shall be submitted to the inspection commission in duplicate on CD/DVD/flash drive.  Each heading shall be indicated with a separate folder name, and the relevant documents shall be found under the relevant folder. If deemed necessary, other documents and information related to the product may be requested in physical or digital form. |  |  |  |
| **4.5** | Documents that do not change with each shipment shall be submitted once, with the first shipment. If deemed necessary, documents may be requested again. |  |  |  |
| **4.6.** | **Required Packaging Characteristics** |  |  |  |
| **4.6.1.** | The products shall be packaged in vials, flacons or ready-to-use syringe (injector) containing a single dose. Those ready-to-use syringes (injectors) shall be single packed or provided in ten packs. If the products are packaged in packs of ten, the packs shall contain foam or cardboard separators to prevent the vials or ampoules from breaking due to contact. If the product is packaged individually, the packages shall then be bundled in packs of ten. If diluents are separate, 5 additional diluents shall be delivered with every 1000 doses of vaccine. |  |  |  |
| **4.6.2.** | The inner and outer packaging of licensed products in Türkiye shall comply with the current "Regulation on Packaging Information, Instructions for Use, and Tracking of Human Medicinal Products" published by the Turkish Ministry of Health. If the product is not licensed in our country, the inner packaging of the ready-to-use syringe (injector), ampoule, or vial shall bear, at a minimum, the manufacturer's and product name, dosage, amount of content per dose, method of administration (IM/IV/SC/ID, etc.), lot (batch) number, and expiration date, printed in indelible ink. The package shall also contain storage temperature information in addition to the inner packaging. The product package shall bear the statement **"Property of the Turkish Ministry of Health, NOT FOR SALE**." |  |  |  |
| **4.6.3.** | Each product package shall contain at least one "Summary of Product Characteristics" (SPC) or Turkish package insert or "Patient Information Leaflet" (PIL) prepared in accordance with the "Regulation on the Packaging and Labelling of Human Medicinal Products" dated 25.04.2017 and numbered 30048. Additionally, the following text shall be added to the beginning of the “"Summary of Product Characteristics" (SPC)” or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention:  "In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration.  For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates***."*** |  |  |  |
| **4.6.4.** | The packages shall then be placed in boxes. The names and addresses of the manufacturer and representative company of the product, the name of the product, the lot number, the storage temperature, the expiration date, and the number of doses in the box shall be written on these boxes. If the products are packaged individually, ten packages shall be placed in each box. If the products are packaged in packs of ten, five packages shall be placed in each box. |  |  |  |
| **4.6.5.** | The packaging boxes shall be placed in styrofoam. The styrofoam shall then be placed inside cartons. The carton dimensions shall be 40X60X40 ±20 (Width, Length, Height) cm. A sufficient number of ice packs or gel packs, etc., shall be placed in the cartons. The ice packs or gel packs, etc.**,** placed in the cartons shall be **unfrozen and cooled**.  The names and addresses of the manufacturer and representative company, the product name, serial number, storage temperature, expiration date, dose quantity in the carton, carton dimensions, and weight shall be written on these cartons. |  |  |  |
| **4.6.6.** | The boxes shall then be placed on pallets. The pallets shall be euro pallets (120cm±2cmx80cm±2cmx10-15cm). After the boxes are placed on the pallets, the height together with the pallet shall not exceed 2 (two) meters. The boxes may protrude from the pallet by a maximum of 5 cm. There shall be a maximum of 16 (sixteen) boxes on the pallet. |  |  |  |
| **4.6.7.** | There shall be a 2D barcode on the packages, boxes, cartons, and pallets. The barcode prepared for the ready-to-use syringe (injector) inside each individually packaged product (these barcodes shall also have HL7 and 97 breakdown values) shall be on the product's package. The packages shall then be tied in sets of ten, and the package label shall be affixed to a different area than the barcode affixed to each product. If the product is packaged in sets of ten, the barcode prepared for the ready-to-use syringe (injector) (these barcodes shall also have HL7 and 97 breakdown values) shall be placed inside the package, and the barcode corresponding to the package breakdown shall be on the package. For the information to be included in the barcode, the information specified in the Guide for Barcode Application to Vaccines, Antiserums, and Diluents published by the Turkish Ministry of Health shall be used as a basis, and any additional information required shall be determined by GDPB. **The barcode area for the dose shall be at least 12X12 mm in accordance with the Guide**. If GDPB makes changes to the system instead of the barcode, the contractor shall be obliged to comply with the requirements of the newly created system without requesting a price difference. |  |  |  |
| **4.6.8.** | Even after acceptance, if any faulty operations related to the barcode system are detected later, the costs of changing the product packaging and, if deemed necessary, collecting the products from the field shall be borne by the Contractor. If this process exceeds one-month, new products with a new expiration date may be requested at the request of the Department to avoid any problems related to the expiration date. |  |  |  |
| **4.6.9.** | **Temperature monitoring during transportation:** |  |  |  |
| **4.6.9.1.** | The freeze indicator, temperature monitoring card, and digital temperature recording devices used **shall be listed in the WHO "E006: Temperature monitoring devices"** (https://extranet.who.int/prequal/immunization-devices/prequalified/imd-products)**.** |  |  |  |
| **4.6.9.2.** | If the product(s) are sensitive to freezing, each box shall contain a freeze indicator. |  |  |  |
| **4.6.9.3.** | If the product(s) are sensitive to high temperatures, each box shall contain a temperature monitoring card **with the date it was activated and the name/code of the activator written on it**. |  |  |  |
| **4.6.9.4.** | If the product(s) are sensitive to both freezing and high temperatures, or if they are packaged together, each box shall contain both a freeze indicator and a temperature monitor card with the date of activation and the name/code of the activator written on it. |  |  |  |
| **4.6.9.5.** | In addition, each pallet shall have an electronic, temperature, and freeze-sensitive digital monitor capable of long-term recording. The electronic, temperature, and freeze-sensitive digital monitors capable of long-term recording placed on the pallet shall be read during the inspection phase, the outputs shall be recorded in a report and signed by the company, and if there are no deviations, they can be filed electronically. If requested by the company, these devices shall be returned for storage without destruction for at least three months. Upon return, the pallet numbers and device serial numbers shall be recorded in a report.  If the pallets consist of insulated boxes, each containing heat tracking material (such as a digital recording device, heat monitoring card, or freeze indicator), and conflicting results are found between the digital heat records on or inside the pallet and the heat records inside the box when evaluating the heat records, the temperature monitoring results inside the boxes shall be considered when processing. |  |  |  |
| **4.6.9.6.** | Products found not to have been transported under appropriate conditions (Guidelines for the international packaging and shipping of vaccines, sixth edition. Geneva: World Health Organization, 2020. Licence: CC BY-NC-SA 3.0 IGO) as monitored by these heat trackers shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **4.6.10.** | Each product shall be delivered with a Material Safety Data Sheet (MSDS). The contractor is responsible for the “Transportation, packaging, and labelling of hazardous materials” and completing any shortfalls if there is any. |  |  |  |
| **4.6.11.** | The contractor's representative shall be present during the delivery or return of the products. The representative shall submit a letterhead, stamped, and signed authorization document belonging to the contractor and a photocopy of their photo ID to the Warehouse Manager. The contractor is responsible for unloading the products from the vehicle into the warehouse or loading them back onto the vehicle for return. A list of the names, telephone numbers, and addresses of all employees and subcontractor personnel who shall perform work on behalf of the contractor shall be submitted to the Warehouse Manager, signed by the contractor's representative, prior to unloading. The contractor shall be responsible for any damage that may be caused to the warehouse or equipment and for all liabilities arising from "Occupational Health and Safety Regulations." The contractor shall submit a stamped and signed commitment stating that it has assumed the SSI, occupational health and safety, and work accident liabilities of its employees for unloading the products from the vehicle or loading them in case of return, and that it has assumed the liability for compensation in case of damage to the warehouse or any equipment inside the warehouse. Responsibility begins upon entry into the Warehouse area after the security check. |  |  |  |
| **4.6.12.** | Except in emergencies, no contractor employees other than the vehicle drivers and those declared shall enter the climate-controlled warehouse. |  |  |  |
| **4.6.13.** | If barcoding, packaging, or prospectus changes are to be performed in the GDPB warehouse, the documents belonging to the subcontractors shall be as follows:   * + - * shall be a contract demonstrating the availability of occupational safety expertise and workplace physician support services as required by the "Occupational Health and Safety Law" No. 6331.       * The contractor's structure shall include at least one coordinator, one operations manager, one quality control and GMP manager, and one warehouse manager. These personnel shall be present during the execution of the work. There shall be a document or documents proving that the personnel included in the company structure have received GMP and Good Warehouse Practices Training organized by the Turkish Ministry of Health or an organization that has received a GMP Certificate from the Turkish Ministry of Health.       * There shall be standard operating procedures (SOPs) prepared by a pharmacist and approved by the company representative, covering barcode printing and affixing procedures and cold storage room operating rules. |  |  |  |
| **5.** | **DOCUMENTS AND MATERIALS REQUIRED FOR LABORATORY ANALYSES AND METHODS TO BE FOLLOWED** |  |  |  |
| **5.1.** | General principles of product safety;  The analysis reports for the product are part of the batch release certificate, and both documents shall be considered together in the evaluations. |  |  |  |
| **5.1.1.** | The product shall be manufactured in our country, have a manufacturing license from the Turkish Medicines and Medical Devices Agency (TİTCK), and present the BRC certificate for the delivered batch obtained from the TİTCK/Analysis and Control Laboratories Department. In addition, if there is no break in the cold chain during product transfer, the physical examination is appropriate, and the commission grants approval, the inspection acceptance process can be completed. |  |  |  |
| **5.1.2.** | If the product is manufactured outside our country and has an import license from TİTCK or is on the WHO's prequalification list (Prequalified vaccines), the Batch Release Certificate for the delivered series shall be obtained from WHO/ Reference Laboratories/institutions, provided that the analyses are performed in accordance with the OCABR guidelines at the TİTCK/Analysis and Control Laboratories Directorate. The inspection acceptance process for products found to be suitable through analysis can be completed. |  |  |  |
| **5.1.3.** | If the product is not licensed in our country, but is licensed by the authorities in EMA, US-FDA, Japan, Canada, South Korea, and Australia as specified in Article 2.1 of the technical specifications, tests may be performed in accordance with the OCABR guidelines by the TİTCK/Analysis and Control Laboratories Department. The inspection and acceptance process for products with suitable analyses can be completed. |  |  |  |
| **5.2.** | If there are any doubts regarding product safety within the scope of the cold chain or other matters specified in the technical specifications, new samples may be taken if necessary, and analyses may be performed as required, including analyses based on batch release. |  |  |  |
| **5.3.** | These products are subject to the *"Regulations on Market Surveillance and Control Procedures and Principles to be Implemented by the Ministry of Health*." GDPB reserves the right to conduct analyses in case of possible suspicion or complaint. The Contractor shall provide the required number of product doses for analysis and the materials required for the analysis specified in Article 5 free of charge. If the analysis result is found to be unsatisfactory, even if the product in question has been accepted, the Contractor shall deliver the same quantity from different series within 90 calendar days. |  |  |  |
| **5.4.** | If the product does not comply with Article 5.1, after the inspection is completed, a sample shall be taken from each batch using the random sampling method and delivered to the laboratory with a report signed by the Contractor's representative and one of the inspection members. |  |  |  |
| **5.5.** | Since the physical appearance of the products requires expertise, it shall be assessed by specialized personnel at the National Reference Laboratory within the TİTCK in accordance with the current Turkish/European Pharmacopoeia. Products that are not suitable in terms of physical appearance shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. After the physical tests of the products are found to be suitable, other tests shall be performed in accordance with Article 5. |  |  |  |
| **5.6.** | The vaccine shall comply with the characteristics and conditions specified in World Health Organization (WHO) Technical Report Series 979 Annex IV, Technical Report Series 980 Annex IV, Technical Report Series 993 Annex III, Technical Report Series 1024 Annex III and European Pharmacopoeia 11.0 07/2022: 1934 and 01/2020:2.9.20 monographs in terms of physical appearance and laboratory analyses. |  |  |  |
| **5.7.** | The Contractor shall deliver two (2) reference vaccines free of charge for each batch, along with reagents and chemical materials deemed necessary for testing the potency and identity of the vaccine, to be used in conjunction with the vaccines to be tested.  Additionally, **for every four (4) batches of the tetravalent vaccine** the following shall be delivered:  **For Diphtheria-Tetanus Vaccine Potency and Identity Tests:**  Two diphtheria standard vaccines (in-house)  Two tetanus standard vaccines (in-house)  4 ml diphtheria toxin (in-house)  4 ml tetanus toxin (in-house)  For each ten batches vaccine  One Diphtheria Vaccine (Adsorbed) (BRP or NIBSC)  One Tetanus Vaccine (Adsorbed) (BRP or NIBSC)  One Diphtheria antitoxin for the flocculation test (NIBSC or BRP)  One Tetanus antitoxin for the flocculation test (NIBSC or BRP)  One Diphtheria toxin (NIBSC or BRP)  One Tetanus toxin (NIBSC or BRP).  **For Each (4) series of Acellular Pertussis Vaccine Potency Test:**  One Lyophhilise Acellular Pertussis Standard Vaccine (in house)  10 units of Liquid Acellular Pertussis Standard Vaccine (0.5 mL/syringe) (in house)  3 mL Ag FHA Glycerol 50%  4 mL Ag PT Glycerol 50%  1.5 mL Calibration Standard (PT)  1.5 mL Calibration Standard” (FHA)  1.5 mL Positive Control (FHA)  2 vial Pertussis Toxin (For Histamine sensitivity test)  **For Each (10) series of Acellular Pertussis Vaccine Potency Test:**  One Lyophhilise Acellular Pertussis Standard Vaccine (in house)  One Bordetella pertussis, filamentous haemagglutinin (FHA) Antigen  ELISA (NIBSC or BRP)  OneBordetella pertussis, Pertussis Toxin (PT) (NIBSC or BRP)  One Positive Control (NIBSC or BRP)  **Acellular Pertussis Vaccine for Identity Test:**  0.5 Ml FHA Reference Antigen  FHA Antiserum 0.5 Ml  0.5 mL PT Reference Antigen  0.5 mL PT Antiserum  ( NIBSC or BRP) From relevant Standards (1 pc/20 series)  **For IPV Vaccine Potency Test:**  2 In-house standard  2 In-house  2 in-house validity control standard (in house vaccine) 1.5 mL  Coating Anbibody Typle I 200 μl  Coating Anbibody Type II 500 μl  Coating Anbibody Type III 500 μl  Revelation antibody Type I 200 μl  Revelation antibody Type II 100 μl  Revelation antibody Type III 400 μl  For each 10 series of vaccine 1 vial (0.5 mL) Ph. Eur. Reference Standard Poliomyelitis  Vaccine (Inactivated) Types 1,2,3 BRP. Shall be submitted free of charge. |  |  |  |
| **5.8.** | Where necessary, the same quantities of Standard Vaccine, Antigen, Antiserum, and other relevant standards and international standards shall be provided free of charge and promptly by the Contractor. |  |  |  |
| **5.8.1.** | Documents to be delivered to the laboratory with the product:  -Protocols related to production methods and processes, as well as quality control protocols,  -Standard Operating Procedure (SOP) documents related to the product's quality control tests, current validation reports, and validation procedure documents shall be provided with the product. |  |  |  |
| **5.8.2.** | If the reference vaccine and chemicals are imported from abroad, customs clearance procedures shall be carried out by the contractors. |  |  |  |
| **5.8.3.** | For each batch of vaccine delivered, the Contractor shall provide a sufficient number of samples free of charge for physical examination and laboratory analysis. |  |  |  |
| **5.8.4.** | If changes are made to the analysis methods, the standards and quantities requested from the Contractor may be re-evaluated. |  |  |  |
| **5.8.5.** | In addition, official documents (official certificates) containing the reference vaccine and/or reference unit values shall also be submitted. The reagents, chemical materials, detailed test SOPs (latest updated version), current validation and validation procedure documents, and calculation documents sent shall be delivered complete with the vaccines to be tested. |  |  |  |
| **5.9.** | If vaccines are prepared in vacuum-sealed ampoules/vials, and if the number of non-vacuum ampoules/vials exceeds 1% in the vacuum control performed on vaccine lot samples taken for inspection, the vaccine lot in question shall be rejected and returned due to the number of non-vacuum ampoules/vials. If the number of non-vacuum ampoules/vials is less than 1%, the vaccine supplier shall deliver the equivalent number of non-vacuum ampoules/vials free of charge within 120 calendar days from the date of notification by the General Directorate of Public Health to the supplier. |  |  |  |
| **5.10.** | Biological controls of products to be delivered shall be carried out at the Turkish Medicines and Medical Devices Agency, but in order to prevent interruption of vaccine and antiserum administration due to potential difficulties in the analysis process, a WHO-approved reference laboratory (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies) ([https://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)](http://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)) may also be conducted, and the costs shall be borne by the Contractor. The results of the control reports of the producer country shall be consistent with the results of the control reports of the Turkish Medicines and Medical Devices Agency or WHO-approved reference laboratories (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies). |  |  |  |
| **5.11.** | The Contractor may object to the results within 15 days. Upon such objection, product samples shall be sent to a second laboratory from among the WHO Reference Laboratories designated ex officio by GDPB or deemed appropriate by GDPB upon the Contractor's recommendation, with the shipping and analysis costs borne by the Contractor. If inconsistencies are detected following analyses conducted by WHO Reference Laboratories and the Turkish Medicines and Medical Devices Agency, the second report shall be accepted as the final report. |  |  |  |
| **6.** | **OTHER PROVISIONS** |  |  |  |
| **6.1.** | Due to delays caused by incorrect or incomplete materials and documents specified in Article 5, such as references, standards, and SOPs required for analysis, which are the responsibility of the contractor to deliver, the product's shelf life shall be shortened by the duration of the delay. The shelf life suitability specified in Article 4 shall be reduced by the duration of the delay. If the shelf life falls below the specified duration, return and exchange processes shall be initiated. For example, if the specification requires a minimum shelf life of 18 months upon delivery to the warehouse, but the product has a shelf life of 20 months at the time of delivery, and the SOP, references, etc. are delivered 70 days later due to a reason attributable to the contractor that prevented the completion of the analyses, the products shall be subject to processing due to shelf life non-compliance and shall be returned. |  |  |  |
| **6.2.** | Batches of products deemed unsuitable based on biological or chemical control results shall be returned. The contractor shall collect these products from the GDPB warehouse where they are located, transport them to the country of origin, and deliver the same quantity of products from a different batch that comply with the specifications to GDPB free of charge within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **6.3.** | In the event of product return (rejection or lot change), the products shall be collected from the warehouse within 30 calendar days after the notification date, during official working hours and days. If not collected, the contractor shall bear the storage and/or disposal costs for the delayed period. |  |  |  |
| **6.4.** | In the event that the products are returned to the Contractor, the relevant official documents proving that the products have been removed from Türkiye or destroyed shall be submitted to the administration within 120 calendar days after the products are collected from the warehouse. If no notification is made, the procedures shall be carried out in accordance with customs regulations. |  |  |  |
| **6.5.** | After acceptance of the products, if any physical deficiencies (barcode errors, packaging, labels, etc.) are detected, the contractor shall remedy the deficiency free of charge. |  |  |  |

| **LOT 11 - HUMAN TETANUS IMMUNOGLOBULIN (HTIG)** | | | | |
| --- | --- | --- | --- | --- |
| **Item No** | **Specifications** | **Specifications Offered** | **Notes, remarks,  ref to documentation** | **Evaluation Committee’s notes** |
| **1.** | **TECHNICAL SPECIFICATIONS OF PRODUCT** |  |  |  |
| **1.1.** | The product shall comply with the conditions and characteristics specified in World Health Organization Technical Report Series (TRS) 980 Annex 5, (TRS) 941, Annex 4 and 11.0 01/2015:0398 monograph of European Pharmacopoeia. |  |  |  |
| **1.2.** | Vaccines shall be supplied in flacon, ampoule or ready-to-use syringe (injector), with minimum of 100 IU/mL potency value and at least 200 IU/unit package. |  |  |  |
| **1.3.** | The combination vaccine shall maintain its stability to its expiration date at temperatures between (+2) - (+8) OC. |  |  |  |
| **2.** | **DOCUMENTS TO BE INCLUDED IN THE FILE TO BE REVIEWED BY THE TENDER COMMITTEE** |  |  |  |
| **2.1.** | The product in question;   * + 1. shall have a license issued by the Turkish Ministry of Health,     2. If it does not have a license issued by the Turkish Ministry of Health;   + It shall be included in the latest pre-qualification list published by the World Health Organization (<https://extranet.whoint/prequal/vaccines/prequalified-vaccines)> or,   + It shall have a license from the European Medicines Agency (EMA) and be manufactured in European Union countries, or   + It shall have a license from the US-FDA and be manufactured in the United States, **or**   + It shall be licensed by the Pharmaceuticals and Medical Devices Agency (PMDA) and manufactured in Japan, or   + It shall be licensed by the South Korean Food and Drug Administration and manufactured in South Korea, **or**   + It shall be licensed by the Canadian Food and Drugs Act and Regulations and manufactured in Canada, **or**   + The product shall be licensed by the Australian Department of Health Therapeutic Goods Administration and manufactured in Australia. |  |  |  |
| **2.2.** | The product shall be accompanied by a certificate (GMP certificate) showing that the factory producing it complies with the **Good Manufacturing Practices (**GMP) standards approved by the State Control Agency of the country where the product is manufactured. If the product is filled or manufactured in our country, there shall be a document showing that the factory where the production/filling is carried out, approved by the Turkish Ministry of Health, Turkish Medicines and Medical Devices Agency, manufactures in accordance with good manufacturing practices (GMP) rules. |  |  |  |
| **2.3.** | **Batch Release Certificate**, which pertains to any batch number generated within the past two years and is issued by the National Regulatory Authority or National Controlling Laboratory listed by WHO, shall be available. If the product is manufactured in our country, a batch release certificate or pharmaceutical product certificate issued by the Turkish Medicines and Medical Devices Agency shall be available. |  |  |  |
| **2.4.** | The product shall be accompanied by an **analysis certificate** that pertains to any series produced by the manufacturer within the past two years. |  |  |  |
| **2.5.** | Originals or notarized copies of the documents requested shall be submitted to the Tender Evaluation Commission. Original documents shall be submitted during the inspection stage. |  |  |  |
| **3.** | **DELIVERY OF PRODUCTS** |  |  |  |
| **3.1.** | If the products are imported, the tenderer's representative shall be present when the products are collected from customs and shall ensure that the goods are collected in accordance with the required specifications and delivered to the location deemed appropriate by GDPB without delay. |  |  |  |
| **3.2.** | The contractor shall provide the Department with the shipment details 3 days prior to the delivery date of the product. |  |  |  |
| **3.3.** | Product delivery shall be made in such a way that it does not coincide with holidays, official holidays, or the end of working hours in Türkiye. |  |  |  |
| **3.4.** | To clear products purchased by GDPB through customs, the Contractor shall enter the product information (serial release certificate and quantity for the lot/serial number for which import permission is requested) via the Single Window Portal System (<https://uygulama.gtb.gov.tr/TekPencere>). The Single Window approval request shall be submitted to the Department electronically (to the Department's official e-mail address) or in writing at least 3 days in advance. Products purchased by the General Directorate of Public Health shall be delivered to the GDPB Vaccine and Drug Warehouse within 48 hours after being cleared through customs (except for products filled in Türkiye) if they are imported. Any changes required after the initial inspection (packaging, barcode, etc.) may also be made at the Central Vaccine and Drug Warehouse with the approval of the GDPB. If storage exceeds 48 hours, it is mandatory to submit temperature records approved by the Contractor's quality manager from the production site until the Ministry of Health Vaccine Storage arrives, to use a warehouse licensed by the Turkish Ministry of Health, and, if "temperature monitoring cards" are installed at the production facility, not to change them. |  |  |  |
| **3.5.** | If the packaging of the imported product (including barcoding) is to be changed at a different location after the contract is signed, this situation shall be reported to the Department. The temporary storage location shall be licensed by the Turkish Ministry of Health, the initial opening of the packaging of the product withdrawn from customs shall be carried out under the supervision of GDPB or its authorized personnel, and the shipment and temporary storage temperature records shall also be submitted during the inspection phase. GDPB may inspect this entire process at any time and on any day after customs clearance. Intermediate storage shall be possible if the application made to GDPB and the storage period are found to be appropriate. |  |  |  |
| **3.6.** | Products filled in our country shall be delivered to the GDPB Vaccine and Drug Warehouse within 24 hours of leaving the filling facility. If the product is not delivered to the GDPB Vaccine and Drug Warehouse within 24 hours after leaving the filling facility and is to be stored in another warehouse, the organization performing the intermediate storage shall be licensed by the Turkish Ministry of Health, temperature records from the production site to the warehouse and within the warehouse shall be kept, and certified copies from the product quality representative shall be delivered to GDPB upon product delivery. These stages shall be open to inspection by GDPB if required. The Department shall be notified if temporary storage is required. Products shall not be accepted if the specified conditions cannot be met. |  |  |  |
| **3.7.** | If the products are filled/manufactured in Türkiye, the time limit specified in Article 3, except for 3.2 and 3.3, and the restrictions at shall not apply. |  |  |  |
| **4.** | **DOCUMENTS REQUIRED DURING INSPECTION AND PRODUCT CHARACTERISTICS** |  |  |  |
| **4.1.** | Products shall have **a shelf life of at least 18 (eighteen) months** from the date of delivery to our warehouse. |  |  |  |
| **4.2.** | **Documents required during the product inspection phase:** |  |  |  |
| **4.2.1.** | If the product is manufactured in a European Union member state, the Batch Release Certificate or Pharmaceutical Product Certificate (CPP) for the imported batch shall be issued by the National Regulatory Authority (NRA) listed in the WHO list, or by the US FDA or the relevant national authority, as specified in the annex to European Union Directive 89/342/EEC. a Batch Release Certificate or Pharmaceutical Product Certificate (CPP) for the imported batch shall be submitted. This document will be requested at the final acceptance stage if the product's labelling, packaging and/or filling or production has been carried out in our country and will be issued by the Turkish Medicines and Medical Devices Agency of the Ministry of Health or its authorised institutions. |  |  |  |
| **4.2.2.** | An Analysis Certificate (document containing the composition, analysis results, production/expiry dates) will be provided for each series organised by the manufacturing company. |  |  |  |
| **4.2.3.** | Stability studies and results proving the actual shelf life of the product in question shall be provided. If the product is filled or manufactured in our country, stability studies will not be required for preliminary approval; however, as stability studies are completed, they shall be submitted to the Directorate of Vaccine-Preventable Diseases. |  |  |  |
| **4.2.4.** | Products shall have a ‘Summary of Product Characteristics’ (SPC) or package leaflet or ‘Patient Information Leaflet’ (PIL) and their Turkish translations. |  |  |  |
| **4.2.5.** | If the product is used outside the country of manufacture, a document listing the countries where the product is used and containing the usage permits (import authorisations) or licence numbers for these products shall be provided. |  |  |  |
| **4.2.6.** | At every stage of the product's manufacture, there shall be a manufacturer-approved document demonstrating that the risk of diseases transmissible via blood/serum, such as TSE (Transmissible Spongiform Encephalopathy), HIV, Hepatitis, etc., has been minimised. |  |  |  |
| **4.2.7.** | The list of work to be carried out by the subcontractor and the Trade Register Gazette pertaining to the subcontractor shall be included. |  |  |  |
| **4.2.8.** | All technical documents required for the product in the tender (Good Manufacturing Practices, analysis report, KÜB, certificates, etc.) along with detailed SOPs, stability results (showing real-time and accelerated stability shelf life), product photographs, and technical information about the packaging (dimensions, volume, etc.) shall be submitted in duplicate on CD/DVD/flash drive to the inspection committee and the warehouse manager. Each heading shall be indicated with a separate folder name, and the relevant documents shall be located under the relevant folder. If deemed necessary, other documents and information related to the product may be requested in physical or digital form. |  |  |  |
| **4.2.9.** | The documents required in 4.2 shall be in Turkish and, if the documents submitted are not originals, they shall be certified as true copies either by the GDPB or by a notary public. |  |  |  |
| **4.3.** | The original or notarised copies of the licence, Market Release Certificate and analysis results shall also be submitted to the Department on CD/DVD/flash drive and in physical form during the final acceptance stage. |  |  |  |
| **4.4.** | Tenderers acknowledge that if the manufacturer or another country where this product is used suspends the use of the product for any reason, or if they receive any news in this regard, they will inform our Ministry within 24 hours (product name, serial number, reason for discontinuation of use, etc.) and that if such information is not provided within 24 hours, the administration has the right to unilaterally terminate the contract. In this case, the tenderer shall provide a commitment letter stating that they will take back all unused products stored in the administration's and Provincial Health Directorates' warehouses. |  |  |  |
| **4.5.** | **Required Packaging Characteristics** |  |  |  |
| **4.5.1.** | The products shall be packaged in ampoule, flacons or ready-to-use syringe (injector) containing a single dose. Those ready-to-use syringe (injector)s shall be single packed or provided in ten packs. If the products are packaged in packs of ten, the packs shall contain foam or cardboard separators to prevent the vials or ampoules from breaking due to contact. If the product is packaged individually, the packages shall then be bundled in packs of ten. If diluents are separate, 5 additional diluents shall be delivered with every 1000 doses of vaccine. |  |  |  |
| **4.5.2.** | The inner packaging of the ready-to-use syringe (injector), ampoule, or vial shall bear, at a minimum, the manufacturer's and product name, dosage, amount of content per dose, method of administration (IM/IV/SC/ID, etc.), lot (batch) number, and expiration date, printed in indelible ink. The package shall also contain storage temperature information in addition to the inner packaging. The product package shall bear the statement **"Property of the Turkish Ministry of Health, NOT FOR SALE**." |  |  |  |
| **4.5.3.** | Each product package shall contain at least one "Summary of Product Characteristics" (SPC) or Turkish package insert or "Patient Information Leaflet" (PIL) prepared in accordance with the "Regulation on the Packaging and Labelling of Human Medicinal Products" dated 25.04.2017 and numbered 30048. Additionally, the following text shall be added to the beginning of the “"Summary of Product Characteristics" (SPC)” or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention:  When administering tetanus immunoglobulin, the regulations concerning tetanus prophylaxis prepared by the Turkish Ministry of Health and currently in force should be taken into consideration.  For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates*."* |  |  |  |
| **4.5.4.** | The packages shall then be placed in boxes. The names and addresses of the manufacturer and representative company of the product, the name of the product, the lot number, the storage temperature, the expiration date, and the number of doses in the box shall be written on these boxes. If the products are packaged individually, ten packages shall be placed in each box. If the products are packaged in packs of ten, five packages shall be placed in each box. |  |  |  |
| **4.5.5.** | The packaging boxes shall be placed in styrofoam. The styrofoam shall then be placed inside cartons. The carton dimensions shall be 40X60X40 ±20 (Width, Length, Height) cm. A sufficient number of ice packs or gel packs, etc., shall be placed in the cartons. The ice packs or gel packs, etc.**,** placed in the cartons shall be **unfrozen and cooled**. The names and addresses of the manufacturer and representative company, the product name, serial number, storage temperature, expiration date, dose quantity in the carton, carton dimensions, and weight shall be written on these cartons. |  |  |  |
| **4.5.6.** | The boxes shall then be placed on pallets. The pallets shall be euro pallets (120cm±2cmx80cm±2cmx10-15cm). After the boxes are placed on the pallets, the height together with the pallet shall not exceed 2 (two) meters. The boxes may protrude from the pallet by a maximum of 5 cm. There shall be a maximum of 16 (sixteen) boxes on the pallet. |  |  |  |
| **4.5.7.** | There shall be a 2D barcode on the packages, boxes, cartons, and pallets. The barcode prepared for the ready-to-use syringe (injector) inside each individually packaged product (these barcodes shall also have HL7 and 97 breakdown values) shall be on the product's package. The packages shall then be tied in sets of ten, and the package label shall be affixed to a different area than the barcode affixed to each product. If the product is packaged in sets of ten, the barcode prepared for the ready-to-use syringe (injector) (these barcodes shall also have HL7 and 97 breakdown values) shall be placed inside the package, and the barcode corresponding to the package breakdown shall be on the package. For the information to be included in the barcode, the information specified in the Guide for Barcode Application to Vaccines, Antiserums, and Diluents published by the Turkish Ministry of Health shall be used as a basis, and any additional information required shall be determined by GDPB. If GDPB makes changes to the system instead of the barcode, the contractor shall be obliged to comply with the requirements of the newly created system without requesting a price difference. |  |  |  |
| **4.5.8.** | Even after acceptance, if any faulty operations related to the barcode system are detected later, the costs of changing the product packaging and, if deemed necessary, collecting the products from the field shall be borne by the Contractor. If this process exceeds one-month, new products with a new expiration date may be requested at the request of the Department to avoid any problems related to the expiration date. |  |  |  |
| **4.5.9.** | **Temperature monitoring during transportation:** |  |  |  |
| **4.5.9.1.** | Each box shall contain: one heat monitor card with a freezing indicator, and each pallet shall contain or have an electronic, temperature and freeze-sensitive digital monitor capable of long-term recording. |  |  |  |
| **4.5.9.2.** | The electronic, temperature and freeze-sensitive digital trackers installed on the pallet, capable of long-term recording, shall be delivered in a format readable during the inspection phase, such as printouts or on CD/DVD/Flash Drive. The monitors will be examined together with the company, and if deemed necessary, the outputs will be recorded in a report and signed together with the company. These devices will be returned to the company upon request. |  |  |  |
| **4.5.9.3.** | Products found not to have been transported under appropriate conditions (World Health Organisation WHO/IVB/05.23 publication Annex 1 Class C packaging temperature limits for Vaccines and Antiserums) as monitored by these temperature monitors shall be returned. The contractor shall deliver the same quantity of product from a different lot to the GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **4.5.10.** | The Contractor shall be responsible for fulfilling any other requirements arising from the applicable legislation concerning the transport, packaging or labelling of hazardous substances and/or for rectifying any deficiencies. |  |  |  |
| **4.5.11.** | The contractor's representative shall be present during the delivery or return of the products. The representative shall submit a letterhead, stamped and signed authorisation document belonging to the contractor, along with a photocopy of their photo ID, to the Department Warehouse Authorised Person. |  |  |  |
| **4.5.11.1.** | The contractor is responsible for unloading the products from the vehicle into the warehouse or for reloading them during return. A list containing the names, phone numbers, and address information of all employees and subcontractor personnel who will perform tasks related to the contractor shall be submitted to the Department Warehouse Authorised Person, signed by the contractor’s representative, prior to unloading. |  |  |  |
| **4.5.11.2.** | The contractor shall be liable for any damage that may be caused to the warehouse or equipment and for all responsibilities arising from the Occupational Health and Safety Law. The contractor shall submit a signed and stamped undertaking stating that it has assumed the SSK, occupational health and safety, and work accident liabilities of its employees for unloading products from the vehicle or loading them in the event of a return, and that it has assumed the obligation to pay compensation in the event of damage to the warehouse or any equipment inside the warehouse. Liability begins upon entry into the warehouse area after the security check. |  |  |  |
| **4.5.11.3.** | Except in emergencies, no contractor employees other than vehicle drivers and those declared shall enter the climate-controlled warehouse. |  |  |  |
| **4.5.11.4.** | If barcoding, packaging, and leaflet changes are to be carried out at the GDPB warehouse, the documents belonging to the subcontractors shall include:   * a contract demonstrating the provision of occupational safety expertise and workplace physician support services, as required by Law No. 6331 on Occupational Health and Safety. * The company structure shall include at least one coordinator, one operations manager, one quality control and GMP manager, and one warehouse manager. These personnel shall be present during the execution of the work. There shall be a document or documents showing that the personnel in the company structure have received GMP and Good Warehouse Practice Training organised by the Turkish Ministry of Health or an organisation that has received a GMP Certificate from the Turkish Ministry of Health. * Standard Operating Procedures (SOPs) prepared by a pharmacist and approved by the company representative, covering barcode printing and affixing procedures, as well as cold storage operating rules, will be in place |  |  |  |
| **5.** | **DOCUMENTS AND MATERIALS REQUIRED FOR LABORATORY ANALYSES AND METHODS TO BE FOLLOWED** |  |  |  |
| **5.1.** | As soon as the inspection is completed, a sample shall be taken from each batch using the random sampling method and delivered to the laboratory with a report signed by the Contractor's representative and one of the inspection members. |  |  |  |
| **5.2.** | Physical appearance of products European Pharmacopoeia 10.0 01/2020: As specified in monograph 20920 regarding visible particulate matter, this requires special equipment and expertise and will be carried out by specialist personnel at the National Reference Laboratory within the Turkish Medicines and Medical Devices Agency. Preliminary acceptance procedures will be completed once a positive result letter has been received from the laboratory. Products that are not suitable in terms of physical appearance will be returned. The contractor has no right to object to the physical appearance report. The contractor shall deliver the same quantity of product from a different lot to the GDPB free of charge and in accordance with the specifications within 90 calendar days from the date of notification to the contractor. Other tests will be performed after the physical tests of the products are found to be suitable. |  |  |  |
| **5.3.** | The product is licensed in Turkey and, if it has obtained a Batch Release Certificate approved by the Turkish Medicines and Medical Devices Agency (TİTCK), final acceptance will be granted following physical testing. For batches with a ‘bulk’ release certificate issued by TİTCK or OMCL (Official Medicines Control Laboratories) laboratories, the inspection and acceptance stage will be completed by performing final product analysis according to OCABR documents. |  |  |  |
| **5.4.** | These products are subject to the *"Regulations on Market Surveillance and Control Procedures and Principles to be Implemented by the Ministry of Health*." GDPB reserves the right to conduct analyses in case of possible suspicion or complaint. In the event of any analysis being carried out on any batch or batches, the Contractor shall, regardless of the outcome of the analysis, promptly deliver the same quantity of product to GDPB in accordance with the specifications. |  |  |  |
| **5.5.** | After the physical tests of the products have been deemed suitable, other tests will be carried out.. |  |  |  |
| **5.6.** | The biological product shall comply with the characteristics and conditions specified in Annex II of World Health Organisation (WHO) Technical Report Series 927, Annex III of Technical Report Series 977, and monograph 11.0 01/2015:0398 of the European Pharmacopoeia in terms of physical appearance and laboratory analyses. |  |  |  |
| **5.7.** | The Contractor shall submit the following free of charge; |  |  |  |
| **5.7.1.** | *For every 2 lots, 1 ampoule of International Reference Immunoglobulin (NIBSC Code TE-3 or 13/240) shall be supplied free of charge, along with 2 vials of lyophilised tetanus toxin product.* |  |  |  |
| **5.7.2.** | *In cases where the test needs to be repeated, the same quantities of International Reference Immunoglobulin and 2 vials of lyophilised tetanus toxin will be provided free of charge by the company within 15 calendar days.* |  |  |  |
| **5.8.** | Where necessary, the same quantities of **Standard Vaccine, Antigen, Antiserum, and other relevant standards and international standards** shall be provided free of charge and promptly by the Contractor |  |  |  |
| **5.8.1.** | Documents to be delivered to the laboratory with the product:  -Protocols related to production methods and processes, as well as quality control protocols,  -Standard Operating Procedure (SOP) documents related to the product's quality control tests, current validation reports, and validation procedure documents shall be provided with the product. |  |  |  |
| **5.8.2.** | If the reference antiserum and chemicals are sourced from abroad, customs clearance procedures shall be carried out by the applicants. |  |  |  |
| **5.8.3.** | For each batch of antiserum delivered, the company shall provide a sufficient number of samples free of charge for physical examination and laboratory analysis. |  |  |  |
| **5.8.4.** | If changes are made to the analysis methods, the standards and quantities requested from the company may be re-evaluated. |  |  |  |
| **5.8.5.** | In addition, official documents (official certificates) containing the unit values of the reference antiserum and/or references must also be submitted. The reagents, chemical materials, detailed test SOPs (latest updated version), current validation and validation procedure documents, and calculation documents shall be delivered complete with the antiserums to be tested. |  |  |  |
| **5.8.6.** | Documents to be delivered with the product: - Protocols related to production methods and processes, as well as protocols related to quality control. - Standard Operating Procedure (SOP) documents related to the product's quality control tests, along with the most recent validation and validation procedure documents, must be provided with the product. |  |  |  |
| **5.8.7.** | If the reference antiserum and chemicals are sourced from abroad, the import procedures shall be carried out by the applicants. |  |  |  |
| **5.8.8.** | For each batch delivered, the number of samples announced on the official website of the Turkish Medicines and Medical Devices Agency shall be delivered free of charge by the supplier for physical examination and laboratory analysis. |  |  |  |
| **5.8.9.** | In the event of changes in the analysis methods, the standards and quantities requested from the company shall be re-evaluated. |  |  |  |
| **5.9.** | If antiserums are prepared in vacuum-sealed ampoules/vials, and if the number of non-vacuum ampoules/vials exceeds 1% in the vacuum control performed on the lot samples taken for control purposes, the lot in question will be rejected and returned due to the number of non-vacuum ampoules/vials. If the number of non-vacuum ampoules/vials is less than 1%, the antiserum supplier shall deliver the equivalent number of non-vacuum ampoules/vials free of charge within 120 calendar days from the date of notification by the General Directorate of Public Health to the supplier. |  |  |  |
| **5.10.** | Biological controls of the products to be delivered will be carried out at the Turkish Medicines and Medical Devices Agency. however, in order to prevent any interruption in the application of vaccines and antiserum due to potential difficulties during the analysis process, they may also be carried out by a DSO-approved reference laboratory (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies), and the costs shall be borne by the company. The results in the control reports of the manufacturer must be consistent with the results in the control reports of the Turkish Medicines and Medical Devices Agency or the DSO-approved reference laboratory (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies). |  |  |  |
| **5.11.** | The contractor may object to the results within 15 days. Upon such objection, product samples shall be sent to a second laboratory from the DSO Reference Laboratories, either determined ex officio by GDPB or proposed by the contractor and deemed appropriate by GDPB, with the shipping and analysis costs borne by the company. If inconsistencies are detected following analyses conducted by DSO Reference Laboratories and the Turkish Medicines and Medical Devices Agency, the second report shall be accepted as the final report. |  |  |  |
| **5.12.** | Batches of products deemed unsuitable based on the inspection results shall be returned. The consignee shall collect these products from the GDPB warehouse where they are located, transport them to the country of origin, and deliver to GDPB, free of charge, the same quantity of products from a different batch that comply with the specifications, within 90 calendar days from the date of notification to the consignee. |  |  |  |
| **5.13.** | In the event that the products are returned to the company, the relevant official documents must be submitted to the administration within 60 calendar days after the products are delivered from the warehouse, indicating that the products have been removed from Turkey or destroyed. |  |  |  |

| **LOT 12 - HUMAN RABIES IMMUNOGLOBULIN (HRIG)** | | | | |
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| **Item No** | **Specifications** | **Specifications Offered** | **Notes, remarks,  ref to documentation** | **Evaluation Committee’s notes** |
| **1.** | **TECHNICAL SPECIFICATIONS OF PRODUCT** |  |  |  |
| **1.1.** | The product shall comply with the specifications and requirements set out in World Health Organization (WHO) Technical Report Series (TRS) No. 941 Annex II, (TRS) 941 Annex IV and monograph 11.0 01/2015:0723 and 01/2020:20920 of the European Pharmacopoeia. |  |  |  |
| **1.2.** | It shall possess the ability to neutralise all rabies virus strains and have a potency value of at least 150 TU/ml. |  |  |  |
| **1.3.** | Donor immunisation shall be carried out using inactivated rabies vaccines produced from cell cultures specified in the European Pharmacopoeia 11.0 01/2019:0216 monograph. |  |  |  |
| **1.4.** | Each vial/ampoule/pre-filled syringe shall contain at least 300 TU. |  |  |  |
| **1.5.** | The product shall maintain its stability for at least two years from the date of the manufacturer's last successful potency control at temperatures between (+2 °C) and (+8 °C). |  |  |  |
| **2.** | **DOCUMENTS TO BE INCLUDED IN THE FILE TO BE REVIEWED BY THE TENDER COMMITTEE** |  |  |  |
| **2.1.** | The product in question;   * + 1. shall have a license issued by the Turkish Ministry of Health,     2. If it does not have a license issued by the Turkish Ministry of Health;   + It shall be included in the latest pre-qualification list published by the World Health Organization (<https://extranet.whoint/prequal/vaccines/prequalified-vaccines)> or,   + It shall have a license from the European Medicines Agency (EMA) and be manufactured in European Union countries, or   + It shall have a license from the US-FDA and be manufactured in the United States, **or**   + It shall be licensed by the Pharmaceuticals and Medical Devices Agency (PMDA) and manufactured in Japan, or   + It shall be licensed by the South Korean Food and Drug Administration and manufactured in South Korea, **or**   + It shall be licensed by the Canadian Food and Drugs Act and Regulations and manufactured in Canada, **or**   + The product shall be licensed by the Australian Department of Health Therapeutic Goods Administration and manufactured in Australia. |  |  |  |
| **2.2.** | The product shall be accompanied by a certificate (GMP certificate) showing that the factory producing it complies with the **Good Manufacturing Practices (**GMP) standards approved by the State Control Agency of the country where the product is manufactured. If the product is filled or manufactured in our country, there shall be a document showing that the factory where the production/filling is carried out, approved by the Turkish Ministry of Health, Turkish Medicines and Medical Devices Agency, manufactures in accordance with good manufacturing practices (GMP) rules. |  |  |  |
| **2.3.** | **Batch Release Certificate**, which pertains to any batch number generated within the past two years and is issued by the National Regulatory Authority or National Controlling Laboratory listed by WHO, shall be available. If the product is manufactured in our country, a batch release certificate or pharmaceutical product certificate issued by the Turkish Medicines and Medical Devices Agency shall be available. |  |  |  |
| **2.4.** | A valid Pharmaceutical Product Certificate (CPP) approved by the manufacturer's country authority. |  |  |  |
| **2.5.** | A **manufacturer-approved** document showing that the risk of Transmissible Spongiform Encephalopathy (TSE) has been minimized at every stage of the product's production. |  |  |  |
| **2.6.** | If the product is licensed in Türkiye, it shall have a "Summary of Product Characteristics" (SPC) or package insert or "Patient Information Leaflet" (PIL) approved by the Turkish Medicines and Medical Devices Agency (TİTCK), or if it is not licensed in Türkiye, it shall have one approved by the relevant country's authority, along with Turkish translations. |  |  |  |
| **2.7.** | If applicable, a list of tasks to be performed by subcontractors shall be provided. |  |  |  |
| **2.8.** | The tenderer shall declare in writing how many batches of the product they can deliver. |  |  |  |
| **2.9.** | If the product is used outside the country of manufacture, a document shall be submitted containing the list of countries where the product is used, approved by the manufacturer, along with the usage permits (import permits) or license numbers for these products, and information on the total number of doses used in countries other than the country of manufacture for the last two calendar years prior to the year of the tender. |  |  |  |
| **2.10.** | The tenderer shall declare that if the manufacturer or another country where the product is used suspends the use of the product for any reason, or if they receive any news in this regard, they shall inform the Ministry within 24 hours (product name, serial number, reason for discontinuation, etc.) and that if the information is not provided within 24 hours, the administration has the right to unilaterally terminate the contract. It also indicates that in the event of discontinuation of the product, after the unused products are collected by the Ministry and sent to the Central Warehouse, the Tenderer undertakes to bring a new product from a different series that complies with the specifications within 90 (ninety) calendar days from the date the replacement request is notified. In addition, the Tenderer shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date of notification of the product replacement request after the unused products are collected by the Ministry to the Central Warehouse, without the requirement of manufacturer approval |  |  |  |
| **2.11.** | The Tenderer shall submit the original or notarized copies of the required documents, along with their certified Turkish translations, to the tender committee. |  |  |  |
| **3.** | **DELIVERY OF PRODUCTS** |  |  |  |
| **3.1.** | If the products are imported, the tenderer's representative shall be present when the products are collected from customs and shall ensure that the goods are collected in accordance with the required specifications and delivered to the location deemed appropriate by GDPB without delay. |  |  |  |
| **3.2.** | The contractor shall provide the Department with the shipment details 3 days prior to the delivery date of the product. |  |  |  |
| **3.3.** | Product delivery shall be made in such a way that it does not coincide with holidays, official holidays, or the end of working hours in Türkiye. |  |  |  |
| **3.4.** | To clear products purchased by GDPB through customs, the Contractor shall enter the product information (batch release certificate and quantity for the lot/serial number for which import permission is requested) via the Single Window Portal System (<https://uygulama.gtb.gov.tr/TekPencere>). The Single Window approval request shall be submitted to the Department electronically (to the Department's official e-mail address) or in writing at least 3 days in advance. Products purchased by the General Directorate of Public Health shall be delivered to the GDPB Vaccine and Drug Warehouse within 48 hours after being cleared through customs (except for products filled in Türkiye) if they are imported. Any changes required after the initial inspection (packaging, barcode, etc.) may also be made at the Central Vaccine and Drug Warehouse with the approval of the GDPB. If storage exceeds 48 hours, it is mandatory to submit temperature records approved by the Contractor's quality manager from the production site until the Ministry of Health Vaccine Storage arrives, to use a warehouse licensed by the Turkish Ministry of Health, and, if "temperature monitoring cards" are installed at the production facility, not to change them. |  |  |  |
| **3.5.** | If the packaging of the imported product (including barcoding) is to be changed at a different location after the contract is signed, this situation shall be reported to the Department. The temporary storage location shall be licensed by the Turkish Ministry of Health, the initial opening of the packaging of the product withdrawn from customs shall be carried out under the supervision of GDPB or its authorized personnel, and the shipment and temporary storage temperature records shall also be submitted during the inspection phase. GDPB may inspect this entire process at any time and on any day after customs clearance. Intermediate storage shall be possible if the application made to GDPB and the storage period are found to be appropriate. |  |  |  |
| **3.6.** | Products filled in our country shall be delivered to the GDPB Vaccine and Drug Warehouse within 24 hours of leaving the filling facility. If the product is not delivered to the GDPB Vaccine and Drug Warehouse within 24 hours after leaving the filling facility and is to be stored in another warehouse, the organization performing the intermediate storage shall be licensed by the Turkish Ministry of Health, temperature records from the production site to the warehouse and within the warehouse shall be kept, and certified copies from the product quality representative shall be delivered to GDPB upon product delivery. These stages shall be open to inspection by GDPB if required. The Department shall be notified if temporary storage is required. Products shall not be accepted if the specified conditions cannot be met. |  |  |  |
| **3.7.** | If the products are filled/manufactured in Türkiye, the time limit specified in Article 3, except for 3.2 and 3.3, and the restrictions at shall not apply. |  |  |  |
| **4.** | **DOCUMENTS REQUIRED DURING INSPECTION AND PRODUCT CHARACTERISTICS** |  |  |  |
| **4.1.** | Products shall have **a shelf life of at least 18 (eighteen) months** from the date of delivery to our warehouse. For products containing diluents, an additional amount of diluent equivalent to 0.2% (two per thousand) of the total number of diluents shall be delivered under the same conditions. |  |  |  |
| **4.1.1.** | **Documents required during the product inspection phase:**  The documents specified in Article 2 of the Technical Specifications and the documents specific to the delivered series/lot shall be submitted during the inspection stage. These documents are:   * Product License * Current GMP certificate for the production site, * Analysis report for the delivered batch (document containing information such as composition, analysis results, reference values, production/expiration dates, etc.), * BRC for the delivered batch, * Current Pharmaceutical Product Certificate (CPP) * TSE declaration (item 2.5), * List of tasks to be performed by subcontractors, * Package Insert or Prospectus or IFU (Article 2.6), * List of countries where the product is used and import permit/license number and the number of doses used in each country in the last two calendar years prior to the year of the offer (Article 2.9), * Commitment letter (Article 2.10). |  |  |  |
| **4.2.** | The Contractor, manufacturer or any other country where this product is used shall notify the Ministry within 24 hours if the use of the product is suspended for any reason or if they receive any information in this regard (product name, serial number, reason for discontinuation, etc.) and acknowledges that the administration has the right to unilaterally terminate the contract if such information is not provided within 24 hours. In the event of discontinuation of the product, the Contractor shall be required to bring a manufacturer-approved commitment letter to the Ministry within 90 (ninety) calendar days from the date the replacement request is notified to the Contractor. Additionally, the Contractor shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date the request for product replacement is notified, following the collection of unused products by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **4.3.** | Stability studies and results proving the actual shelf life of the product in question shall be submitted. If the product is filled or manufactured in our country and stability studies are still ongoing, the TİTCK-approved study results shall be submitted to the Department as they are completed. |  |  |  |
| **4.4.** | Along with the product, all technical documents required in the tender for the product (Good Manufacturing Practices, analysis report, SPC, certificates, etc.) and detailed SOP (may be provided in the original license), **stability results (showing real-time and accelerated stability shelf life)**, product photos, and all documents containing technical information about the packaging (dimensions, volume, etc.) shall be submitted to the inspection commission in duplicate on CD/DVD/flash drive. Each heading shall be indicated with a separate folder name, and the relevant documents shall be found under the relevant folder. If deemed necessary, other documents and information related to the product may be requested in physical or digital form. |  |  |  |
| **4.5.** | Documents that do not change with each shipment shall be submitted once, with the first shipment. If deemed necessary, documents may be requested again. |  |  |  |
| **4.6.** | **Required Packaging Characteristics** |  |  |  |
| **4.6.1.** | The products shall be packaged in vials, flacons or ready-to-use injector containing a single dose. Those ready-to-use syringes shall be single packed or provided in ten packs. If the products are packaged in packs of ten, the packs shall contain foam or cardboard separators to prevent the vials or ampoules from breaking due to contact. If the product is packaged individually, the packages shall then be bundled in packs of ten. If diluents are separate, 5 additional diluents shall be delivered with every 1000 doses of vaccine. |  |  |  |
| **4.6.2.** | The inner and outer packaging of licensed products in Türkiye shall comply with the current "Regulation on Packaging Information, Instructions for Use, and Tracking of Human Medicinal Products" published by the Turkish Ministry of Health. If the product is not licensed in our country, the inner packaging of the ready-to-use syringe, ampoule, or vial shall bear, at a minimum, the manufacturer's and product name, dosage, amount of content per dose, method of administration (IM/IV/SC/ID, etc.), lot (batch) number, and expiration date, printed in indelible ink. The package shall also contain storage temperature information in addition to the inner packaging. The product package shall bear the statement **"Property of the Turkish Ministry of Health, NOT FOR SALE**." |  |  |  |
| **4.6.3.** | Each product package shall contain at least one "Summary of Product Characteristics" (SPC) or Turkish package insert or "Patient Information Leaflet" (PIL) prepared in accordance with the "Regulation on the Packaging and Labelling of Human Medicinal Products" dated 25.04.2017 and numbered 30048. Additionally, the following text shall be added to the beginning of the “"Summary of Product Characteristics" (SPC)” or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention:  “The regulations concerning rabies prophylaxis prepared by the Turkish Ministry of Health and currently in force shall be considered when administering the rabies vaccine and immunoglobulin  For any questions or problems encountered in this regard, contact Department of Zoonotic and Vectoral Diseases of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates***."*** |  |  |  |
| **4.6.4.** | The packages shall then be placed in boxes. The names and addresses of the manufacturer and representative company of the product, the name of the product, the lot number, the storage temperature, the expiration date, and the number of doses in the box shall be written on these boxes. If the products are packaged individually, ten packages shall be placed in each box. If the products are packaged in packs of ten, five packages shall be placed in each box. |  |  |  |
| **4.6.5.** | The packaging boxes shall be placed in styrofoam. The styrofoam shall then be placed inside cartons. The carton dimensions shall be 40X60X40 ±2 (Width, Length, Height) cm. A sufficient number of ice packs or gel packs, etc., shall be placed in the cartons. The ice packs or gel packs, etc.**,** placed in the cartons shall be **unfrozen and cooled**. The names and addresses of the manufacturer and representative company, the product name, serial number, storage temperature, expiration date, dose quantity in the carton, carton dimensions, and weight shall be written on these cartons. |  |  |  |
| **4.6.6.** | The boxes shall then be placed on pallets. The pallets shall be euro pallets (120cm±2cmx80cm±2cmx10-15cm). After the boxes are placed on the pallets, the height together with the pallet shall not exceed 2 (two) meters. The boxes may protrude from the pallet by a maximum of 5 cm. There shall be a maximum of 16 (sixteen) boxes on the pallet. |  |  |  |
| **4.6.7.** | There shall be a 2D barcode on the packages, boxes, cartons, and pallets. The barcode prepared for the ready-to-use syringe inside each individually packaged product (these barcodes shall also have HL7 and 97 breakdown values) shall be on the product's package. The packages shall then be tied in sets of ten, and the package label shall be affixed to a different area than the barcode affixed to each product. If the product is packaged in sets of ten, the barcode prepared for the ready-to-use syringe (these barcodes shall also have HL7 and 97 breakdown values) shall be placed inside the package, and the barcode corresponding to the package breakdown shall be on the package. For the information to be included in the barcode, the information specified in the Guide for Barcode Application to Vaccines, Antiserums, and Diluents published by the Turkish Ministry of Health shall be used as a basis, and any additional information required shall be determined by GDPB. **The barcode area for the dose shall be at least 12X12 mm in accordance with the Guide**. If GDPB makes changes to the system instead of the barcode, the contractor shall be obliged to comply with the requirements of the newly created system without requesting a price difference. |  |  |  |
| **4.6.8.** | Even after acceptance, if any faulty operations related to the barcode system are detected later, the costs of changing the product packaging and, if deemed necessary, collecting the products from the field shall be borne by the Contractor. If this process exceeds one-month, new products with a new expiration date may be requested at the request of the Department to avoid any problems related to the expiration date. |  |  |  |
| **4.7.** | **Temperature monitoring during transportation:** |  |  |  |
| **4.7.1.** | The freeze indicator, temperature monitoring card, and digital temperature recording devices used **shall be listed in the WHO "E006: Temperature monitoring devices"** (<https://extranet.who.int/prequal/immunization-devices/prequalified/imd-products>)**.** |  |  |  |
| **4.7.2.** | If the product(s) are sensitive to freezing, each box shall contain a freeze indicator. |  |  |  |
| **4.7.3.** | If the product(s) are sensitive to high temperatures, each box shall contain a temperature monitoring card **with the date it was activated and the name/code of the activator written on it**. |  |  |  |
| **4.7.4.** | If the product(s) are sensitive to both freezing and high temperatures, or if they are packaged together, each box shall contain both a freeze indicator and a temperature monitor card with the date of activation and the name/code of the activator written on it. |  |  |  |
| **4.7.5.** | In addition, each pallet shall have an electronic, temperature, and freeze-sensitive digital monitor capable of long-term recording. The electronic, temperature, and freeze-sensitive digital monitors capable of long-term recording placed on the pallet shall be read during the inspection phase, the outputs shall be recorded in a report and signed by the company, and if there are no deviations, they can be filed electronically. If requested by the company, these devices shall be returned for storage without destruction for at least three months. Upon return, the pallet numbers and device serial numbers shall be recorded in a report. If the pallets consist of insulated boxes, each containing heat tracking material (such as a digital recording device, heat monitoring card, or freeze indicator), and conflicting results are found between the digital heat records on or inside the pallet and the heat records inside the box when evaluating the heat records, the temperature monitoring results inside the boxes shall be considered when processing. |  |  |  |
| **4.7.6.** | Products found not to have been transported under appropriate conditions (Guidelines for the international packaging and shipping of vaccines, sixth edition. Geneva: World Health Organization, 2020) as monitored by these heat trackers shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **4.8.** | Each product shall be delivered with a Material Safety Data Sheet (MSDS). The contractor is responsible for the “Transportation, packaging, and labelling of hazardous materials” and completing any shortfalls if there is any. |  |  |  |
| **4.9.** | The contractor's representative shall be present during the delivery or return of the products. The representative shall submit a letterhead, stamped, and signed authorization document belonging to the contractor and a photocopy of their photo ID to the Warehouse Manager. The contractor is responsible for unloading the products from the vehicle into the warehouse or loading them back onto the vehicle for return. A list of the names, telephone numbers, and addresses of all employees and subcontractor personnel who shall perform work on behalf of the contractor shall be submitted to the Warehouse Manager, signed by the contractor's representative, prior to unloading. The contractor shall be responsible for any damage that may be caused to the warehouse or equipment and for all liabilities arising from "Occupational Health and Safety Regulations." The contractor shall submit a stamped and signed commitment stating that it has assumed the SSI, occupational health and safety, and work accident liabilities of its employees for unloading the products from the vehicle or loading them in case of return, and that it has assumed the liability for compensation in case of damage to the warehouse or any equipment inside the warehouse. Responsibility begins upon entry into the Warehouse area after the security check. |  |  |  |
| **4.10.** | Except in emergencies, no contractor employees other than the vehicle drivers and those declared shall enter the climate-controlled warehouse. |  |  |  |
| **4.11.** | If barcoding, packaging, or prospectus changes are to be performed in the GDPB warehouse, the documents belonging to the subcontractors shall be as follows:   * + - * shall be a contract demonstrating the availability of occupational safety expertise and workplace physician support services as required by the "Occupational Health and Safety Law" No. 6331.       * The contractor's structure shall include at least one coordinator, one operations manager, one quality control and GMP manager, and one warehouse manager. These personnel shall be present during the execution of the work. There shall be a document or documents proving that the personnel included in the company structure have received GMP and Good Warehouse Practices Training organized by the Turkish Ministry of Health or an organization that has received a GMP Certificate from the Turkish Ministry of Health.       * There shall be standard operating procedures (SOPs) prepared by a pharmacist and approved by the company representative, covering barcode printing and affixing procedures and cold storage room operating rules. |  |  |  |
| **5.** | **DOCUMENTS AND MATERIALS REQUIRED FOR LABORATORY ANALYSES AND METHODS TO BE FOLLOWED** |  |  |  |
| **5.1.** | For each batch of antiserum delivered, the contractor shall provide, free of charge, the number of samples requested by the Turkish Medicines and Medical Devices Agency (TITCK) for physical examination and laboratory analysis. |  |  |  |
| **5.2.** | If the product does not comply with Article 5.1, after the inspection is completed, a sample shall be taken from each batch using the random sampling method and delivered to the laboratory with a report signed by the Contractor's representative and one of the inspection members. |  |  |  |
| **5.3.** | **Documents to be delivered to the laboratory with the product:**   * + Protocols related to production methods and processes, as well as quality control protocols,   + Standard Operating Procedure (SOP) documents related to the product's quality control tests, current validation reports, and validation procedure documents shall be provided with the product.   + In addition, official documents (official certificates) containing the reference vaccine and/or reference unit values shall also be submitted. The reagents, chemical materials, detailed test SOPs (latest updated version), current validation and validation procedure documents, and calculation documents sent shall be delivered complete with the vaccines to be tested |  |  |  |
| **5.4.** | The Contractor shall submit the following free of charge; |  |  |  |
| **5.4.1.** | One (ampoule) International Reference Immunoglobulin (RAI) free of charge for every 2 lots, 3 x 0.5 ml CVS or one (ampoule) (ampoule) International Reference Immunoglobulin (RAI) and 1 Plateia Rabies II Kit (ELISA) shall be delivered together with the antiserums to be tested. |  |  |  |
| **5.4.2.** | In cases where the test is repeated, the same quantities of International Reference Immunoglobulin and 2 vials of lyophilised tetanus toxin shall be provided free of charge by the company within 15 calendar days. |  |  |  |
| **5.4.3.** | Where necessary, the same quantities of Standard Vaccine, Antigen, Antiserum, and other relevant standards and international standards shall be provided free of charge and promptly by the Contractor. |  |  |  |
| **5.5.** | If changes are made to the analysis methods, the standards and quantities requested from the company may be re-evaluated. |  |  |  |
| **5.6.** | If the reference antiserum and chemicals are imported from abroad, the import procedures shall be carried out by the applicants. |  |  |  |
| **5.7.** | Physical appearance of products European Pharmacopoeia 11.0 01/2020: As stated in monograph 20920, since it requires special equipment and expertise, it shall be performed by specialist personnel at the National Reference Laboratory within the Turkish Medicines and Medical Devices Agency, and the preliminary acceptance procedures shall be completed after a positive result letter is received from the laboratory. |  |  |  |
| **5.8.** | Products that are not suitable in terms of physical appearance shall be returned. The supplier has no right to object to the physical appearance report. The supplier shall deliver the same quantity of products from a different lot to HSGM free of charge and in accordance with the specifications within 90 calendar days from the date of notification to the supplier. |  |  |  |
| **5.9.** | Other tests shall be performed after the physical tests of the products have been found to be suitable. |  |  |  |
| **5.10.** | If the product is licensed in Turkey and has obtained a Batch Release Certificate approved by TITCK, final acceptance shall be made after the physical test. For batches with a ‘bulk’ release certificate issued by TITCK or OMCL (Official Medicines Control Laboratories) laboratories, the final product analysis shall be performed according to OCABR documents, and the inspection acceptance stage shall be completed. |  |  |  |
| **5.11.** | The analysis reports for the product are part of the batch release certificate, and both documents shall be considered together in the evaluations. |  |  |  |
| **5.12.** | Biological products, in terms of physical appearance and laboratory analyses, shall comply with the World Health Organisation (WHO) Technical Report Series 941 Annex II, Technical Report Series 941 Annex IV, European Pharmacopoeia 11.0 01/2015:0723 and 01/2020:20920 monograph. |  |  |  |
| **5.13.** | Biological controls of products to be delivered shall be carried out at the Turkish Medicines and Medical Devices Agency, but in order to prevent interruption of vaccine and antiserum administration due to potential difficulties in the analysis process, a WHO-approved reference laboratory (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies) ([https://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)](http://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)) may also be conducted, and the costs shall be borne by the Contractor. The results of the control reports of the producer country shall be consistent with the results of the control reports of the Turkish Medicines and Medical Devices Agency or WHO-approved reference laboratories (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies). |  |  |  |
| **5.14.** | Batches of products deemed unsuitable based on control results shall be returned. The contractor shall collect these products from the GDPB warehouse where they are located, transport them to the country of origin, and deliver the same quantity of products from a different batch that comply with the specifications to GDPB free of charge within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **5.15** | The Contractor may object to the results within 15 days. Upon such objection, product samples shall be sent to a second laboratory from among the WHO Reference Laboratories designated ex officio by GDPB or deemed appropriate by GDPB upon the Contractor's recommendation, with the shipping and analysis costs borne by the Contractor. If inconsistencies are detected following analyses conducted by WHO Reference Laboratories and the Turkish Medicines and Medical Devices Agency, the second report shall be accepted as the final report. |  |  |  |
| **5.16.** | These products are subject to the *"Regulations on Market Surveillance and Control Procedures and Principles to be Implemented by the Ministry of Health*." GDPB reserves the right to conduct analyses in case of possible suspicion or complaint. The Contractor shall provide the required number of product doses for analysis and the materials required for the analysis specified in Article 5 free of charge. If the analysis result is found to be unsatisfactory, even if the product in question has been accepted, the Contractor shall deliver the same quantity from different series within 90 calendar days. |  |  |  |
| **5.17.** | In the event that products are returned to the company, the relevant official documents shall be submitted to the administration within 60 calendar days after the products are removed from Turkey or destroyed, following their collection from the warehouse. |  |  |  |
| **6** | **OTHER PROVISIONS** |  |  |  |
| **6.1.** | Due to delays caused by incorrect or incomplete materials and documents specified in Article 5, such as references, standards, and SOPs required for analysis, which are the responsibility of the contractor to deliver, the product's shelf life shall be shortened by the duration of the delay. The shelf life suitability specified in Article 4 shall be reduced by the duration of the delay. If the shelf life falls below the specified duration, return and exchange processes shall be initiated. For example, if the specification requires a minimum shelf life of 18 months upon delivery to the warehouse, but the product has a shelf life of 20 months at the time of delivery, and the SOP, references, etc. are delivered 70 days later due to a reason attributable to the contractor that prevented the completion of the analyses, the products shall be subject to processing due to shelf life non-compliance and shall be returned. |  |  |  |
| **6.2.** | Batches of products deemed unsuitable based on biological or chemical control results shall be returned. The contractor shall collect these products from the GDPB warehouse where they are located, transport them to the country of origin, and deliver the same quantity of products from a different batch that comply with the specifications to GDPB free of charge within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **6.3.** | In the event of product return (rejection or lot change), the products shall be collected from the warehouse within 30 calendar days after the notification date, during official working hours and days. If not collected, the contractor shall bear the storage and/or disposal costs for the delayed period. |  |  |  |
| **6.4.** | In the event that the products are returned to the Contractor, the relevant official documents proving that the products have been removed from Türkiye or destroyed shall be submitted to the administration within 120 calendar days after the products are collected from the warehouse. If no notification is made, the procedures shall be carried out in accordance with customs regulations. |  |  |  |
| **6.5.** | After acceptance of the products, if any physical deficiencies (barcode errors, packaging, labels, etc.) are detected, the contractor shall remedy the deficiency free of charge. |  |  |  |

| **LOT 13 - HORSE RABIES ANTISERUM** | | | | |
| --- | --- | --- | --- | --- |
| **Item No** | **Specifications** | **Specifications Offered** | **Notes, remarks,  ref to documentation** | **Evaluation Committee’s notes** |
| **1.** | **TECHNICAL SPECIFICATIONS OF PRODUCT** |  |  |  |
| **1.1.** | The product shall comply with the conditions specified in the monograph of the World Health Organisation (WHO) 413 Annex II, European Pharmacopoeia 11.0 04/2021:0084 and 01/2020:20920, and Turkish Pharmacopoeia 01/2023:90010. |  |  |  |
| **1.2.** | Rabies vaccines used for the immunisation of horses shall be produced from virus strains and cell cultures specified in WHO TRS 941,2007 Annex II and EP 10.0 01/2019:0216 monograph, and from cell culture medium. |  |  |  |
| **1.3.** | It shall contain sufficient immunoglobulin to neutralise all rabies virus strains. |  |  |  |
| **1.4.** | Equine Rabies Antiserum shall be purified and concentrated. |  |  |  |
| **1.5.** | The antiserum shall be lyophilised or in liquid form. |  |  |  |
| **1.6.** | Each millilitre of the antiserum shall contain a protective titre of at least 200 [U/ml]. |  |  |  |
| **1.7.** | Products shall be supplied in 5 ml single-dose ampoules, vials, flacons or ready-to-use syringes. |  |  |  |
| **1.8.** | Products shall maintain their stability from the date of the manufacturer's last successful potency test until the expiry date at temperatures between (+) 2 °C and (+) 8 °C. |  |  |  |
| **2.** | **DOCUMENTS TO BE INCLUDED IN THE FILE TO BE REVIEWED BY THE TENDER COMMITTEE** |  |  |  |
| **2.1.** | The product in question;   * + 1. shall have a license issued by the Turkish Ministry of Health,     2. If it does not have a license issued by the Turkish Ministry of Health;   + It shall be included in the latest pre-qualification list published by the World Health Organization (<https://extranet.whoint/prequal/vaccines/prequalified-vaccines)> or,   + It shall have a license from the European Medicines Agency (EMA) and be manufactured in European Union countries, or   + It shall have a license from the US-FDA and be manufactured in the United States, **or**   + It shall be licensed by the Pharmaceuticals and Medical Devices Agency (PMDA) and manufactured in Japan, or   + It shall be licensed by the South Korean Food and Drug Administration and manufactured in South Korea, **or**   + It shall be licensed by the Canadian Food and Drugs Act and Regulations and manufactured in Canada, **or**   + The product shall be licensed by the Australian Department of Health Therapeutic Goods Administration and manufactured in Australia. |  |  |  |
| **2.2.** | The product shall be accompanied by a certificate (GMP certificate) showing that the factory producing it complies with the **Good Manufacturing Practices (**GMP) standards approved by the State Control Agency of the country where the product is manufactured. If the product is filled or manufactured in our country, there shall be a document showing that the factory where the production/filling is carried out, approved by the Turkish Ministry of Health, Turkish Medicines and Medical Devices Agency, manufactures in accordance with good manufacturing practices (GMP) rules. |  |  |  |
| **2.3.** | **Batch Release Certificate**, which pertains to any batch number generated within the past two years and is issued by the National Regulatory Authority or National Controlling Laboratory listed by WHO, shall be available. If the product is manufactured in our country, a batch release certificate or pharmaceutical product certificate issued by the Turkish Medicines and Medical Devices Agency shall be available. |  |  |  |
| **2.4.** | A valid Pharmaceutical Product Certificate (CPP) approved by the manufacturer's country authority. |  |  |  |
| **2.5.** | A **manufacturer-approved** document showing that the risk of Transmissible Spongiform Encephalopathy (TSE) has been minimized at every stage of the product's production. |  |  |  |
| **2.6.** | If the product is licensed in Türkiye, it shall have a "Summary of Product Characteristics" (SPC) or package insert or "Patient Information Leaflet" (PIL) approved by the Turkish Medicines and Medical Devices Agency (TİTCK), or if it is not licensed in Türkiye, it shall have one approved by the relevant country's authority, along with Turkish translations. |  |  |  |
| **2.7.** | If applicable, a list of tasks to be performed by subcontractors shall be provided. |  |  |  |
| **2.8.** | Within the last two years, there shall be an analysis certificate for any series produced by the manufacturer. |  |  |  |
| **2.9.** | The tenderer shall declare in writing how many batches of the product they can deliver. |  |  |  |
| **2.10.** | If the product is used outside the country of manufacture, a document shall be submitted containing the list of countries where the product is used, approved by the manufacturer, along with the usage permits (import permits) or license numbers for these products, and information on the total number of doses used in countries other than the country of manufacture for the last two calendar years prior to the year of the tender. |  |  |  |
| **2.11.** | The tenderer shall declare that if the manufacturer or another country where the product is used suspends the use of the product for any reason, or if they receive any news in this regard, they shall inform the Ministry within 24 hours (product name, serial number, reason for discontinuation, etc.) and that if the information is not provided within 24 hours, the administration has the right to unilaterally terminate the contract. It also indicates that in the event of discontinuation of the product, after the unused products are collected by the Ministry and sent to the Central Warehouse, the Tenderer undertakes to bring a new product from a different series that complies with the specifications within 90 (ninety) calendar days from the date the replacement request is notified. In addition, the Tenderer shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date of notification of the product replacement request after the unused products are collected by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **2.12.** | The Tenderer shall submit the original or notarized copies of the required documents, along with their certified Turkish translations, to the tender committee. |  |  |  |
| **3.** | **DELIVERY OF PRODUCTS** |  |  |  |
| **3.1.** | If the products are imported, the tenderer's representative shall be present when the products are collected from customs and shall ensure that the goods are collected in accordance with the required specifications and delivered to the location deemed appropriate by GDPB without delay. |  |  |  |
| **3.2.** | The contractor shall provide the Department with the shipment details 3 days prior to the delivery date of the product. |  |  |  |
| **3.3.** | Product delivery shall be made in such a way that it does not coincide with holidays, official holidays, or the end of working hours in Türkiye. |  |  |  |
| **3.4.** | To clear products purchased by GDPB through customs, the Contractor shall enter the product information (batch release certificate and quantity for the lot/serial number for which import permission is requested) via the Single Window Portal System (<https://uygulama.gtb.gov.tr/TekPencere>). The Single Window approval request shall be submitted to the Department electronically (to the Department's official e-mail address) or in writing at least 3 days in advance. Products purchased by the General Directorate of Public Health shall be delivered to the GDPB Vaccine and Drug Warehouse within 48 hours after being cleared through customs (except for products filled in Türkiye) if they are imported. Any changes required after the initial inspection (packaging, barcode, etc.) may also be made at the Central Vaccine and Drug Warehouse with the approval of the GDPB. If storage exceeds 48 hours, it is mandatory to submit temperature records approved by the Contractor's quality manager from the production site until the Ministry of Health Vaccine Storage arrives, to use a warehouse licensed by the Turkish Ministry of Health, and, if "temperature monitoring cards" are installed at the production facility, not to change them. |  |  |  |
| **3.5.** | If the packaging of the imported product (including barcoding) is to be changed at a different location after the contract is signed, this situation shall be reported to the Department. The temporary storage location shall be licensed by the Turkish Ministry of Health, the initial opening of the packaging of the product withdrawn from customs shall be carried out under the supervision of GDPB or its authorized personnel, and the shipment and temporary storage temperature records shall also be submitted during the inspection phase. GDPB may inspect this entire process at any time and on any day after customs clearance. Intermediate storage shall be possible if the application made to GDPB and the storage period are found to be appropriate. |  |  |  |
| **3.6.** | Products filled in our country shall be delivered to the GDPB Vaccine and Drug Warehouse within 24 hours of leaving the filling facility. If the product is not delivered to the GDPB Vaccine and Drug Warehouse within 24 hours after leaving the filling facility and is to be stored in another warehouse, the organization performing the intermediate storage shall be licensed by the Turkish Ministry of Health, temperature records from the production site to the warehouse and within the warehouse shall be kept, and certified copies from the product quality representative shall be delivered to GDPB upon product delivery. These stages shall be open to inspection by GDPB if required. The Department shall be notified if temporary storage is required. Products shall not be accepted if the specified conditions cannot be met. |  |  |  |
| **3.7.** | If the products are filled/manufactured in Türkiye, the time limit specified in Article 3, except for 3.2 and 3.3, and the restrictions at shall not apply. |  |  |  |
| **4.** | **DOCUMENTS REQUIRED DURING INSPECTION AND PRODUCT CHARACTERISTICS** |  |  |  |
| **4.1.** | Products shall have **a shelf life of at least 18 (eighteen) months** from the date of delivery to our warehouse. For products containing diluents, an additional amount of diluent equivalent to 0.2% (two per thousand) of the total number of diluents shall be delivered under the same conditions. |  |  |  |
| **4.1.1.** | **Documents required during the product inspection phase:**  The documents specified in Article 2 of the Technical Specifications and the documents specific to the delivered series/lot shall be submitted during the inspection stage. These documents are:   * Product License * Current GMP certificate for the production site, * Analysis report for the delivered batch (document containing information such as composition, analysis results, reference values, production/expiration dates, etc.), * BRC for the delivered batch, * Current Pharmaceutical Product Certificate (CPP) * TSE declaration (item 2.5), * List of tasks to be performed by subcontractors, * Package Insert or Prospectus or IFU (Article 2.6), * List of countries where the product is used and import permit/license number and the number of doses used in each country in the last two calendar years prior to the year of the offer (Article 2.9), * Commitment letter (Article 2.10). |  |  |  |
| **4.2.** | The Contractor, manufacturer or any other country where this product is used shall notify the Ministry within 24 hours if the use of the product is suspended for any reason or if they receive any information in this regard (product name, serial number, reason for discontinuation, etc.) and acknowledges that the administration has the right to unilaterally terminate the contract if such information is not provided within 24 hours. In the event of discontinuation of the product, the Contractor shall be required to bring a manufacturer-approved commitment letter to the Ministry within 90 (ninety) calendar days from the date the replacement request is notified to the Contractor. Additionally, the Contractor shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date the request for product replacement is notified, following the collection of unused products by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **4.3.** | Stability studies and results proving the actual shelf life of the product in question shall be submitted. If the product is filled or manufactured in our country and stability studies are still ongoing, the TİTCK-approved study results shall be submitted to the Department as they are completed. |  |  |  |
| **4.4.** | Along with the product, all technical documents required in the tender for the product (Good Manufacturing Practices, analysis report, SPC, certificates, etc.) and detailed SOP (may be provided in the original license), **stability results (showing real-time and accelerated stability shelf life)**, product photos, and all documents containing technical information about the packaging (dimensions, volume, etc.) shall be submitted to the inspection commission in duplicate on CD/DVD/flash drive. Each heading shall be indicated with a separate folder name, and the relevant documents shall be found under the relevant folder. If deemed necessary, other documents and information related to the product may be requested in physical or digital form. |  |  |  |
| **4.5.** | Documents that do not change with each shipment shall be submitted once, with the first shipment. If deemed necessary, documents may be requested again. |  |  |  |
| **4.6.** | **Required Packaging Characteristics** |  |  |  |
| **4.6.1.** | The products shall be packaged in ampoules, vials, flacons or ready-to-use syringe containing a single dose. Those ready-to-use ampoules, vials, flacons or ready-to-use syringes shall be single packed or provided in ten packs. If the products are packaged in packs of ten, the packs shall contain foam or cardboard separators to prevent the vials or ampoules from breaking due to contact. If the product is packaged individually, the packages shall then be bundled in packs of ten. |  |  |  |
| **4.6.2.** | The inner and outer packaging of licensed products in Türkiye shall comply with the current "Regulation on Packaging Information, Instructions for Use, and Tracking of Human Medicinal Products" published by the Turkish Ministry of Health. If the product is not licensed in our country, the inner packaging of the ready-to-use syringe, ampoule, or vial shall bear, at a minimum, the manufacturer's and product name, dosage, amount of content per dose, method of administration (IM/IV/SC/ID, etc.), lot (batch) number, and expiration date, printed in indelible ink. The package shall also contain storage temperature information in addition to the inner packaging. The product package shall bear the statement **"Property of the Turkish Ministry of Health, NOT FOR SALE**." |  |  |  |
| **4.6.3.** | Each product package shall contain at least one "Summary of Product Characteristics" (SPC) or Turkish package insert or "Patient Information Leaflet" (PIL) prepared in accordance with the "Regulation on the Packaging and Labelling of Human Medicinal Products" dated 25.04.2017 and numbered 30048. Additionally, the following text shall be added to the beginning of the “"Summary of Product Characteristics" (SPC)” or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention:  ***"***In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration.  For any questions or problems encountered in this regard, contact and Department of Zoonotic and Vectoral Diseases and the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates***."*** |  |  |  |
| **4.6.4.** | The packages shall then be placed in boxes. The names and addresses of the manufacturer and representative company of the product, the name of the product, the lot number, the storage temperature, the expiration date, and the number of doses in the box shall be written on these boxes. If the products are packaged individually, ten packages shall be placed in each box. If the products are packaged in packs of ten, five packages shall be placed in each box. |  |  |  |
| **4.6.5.** | The packaging boxes shall be placed in styrofoam. The styrofoam shall then be placed inside cartons. The carton dimensions shall be 40X60X40 ±2 (Width, Length, Height) cm. A sufficient number of ice packs or gel packs, etc., shall be placed in the cartons. The ice packs or gel packs, etc.**,** placed in the cartons shall be **unfrozen and cooled**. The names and addresses of the manufacturer and representative company, the product name, serial number, storage temperature, expiration date, dose quantity in the carton, carton dimensions, and weight shall be written on these cartons. |  |  |  |
| **4.6.6.** | The boxes shall then be placed on pallets. The pallets shall be euro pallets (120cm±2cmx80cm±2cmx10-15cm). After the boxes are placed on the pallets, the height together with the pallet shall not exceed 2 (two) meters. The boxes may protrude from the pallet by a maximum of 5 cm. There shall be a maximum of 16 (sixteen) boxes on the pallet |  |  |  |
| **4.6.7.** | There shall be a 2D barcode on the packages, boxes, cartons, and pallets. The barcode prepared for the ready-to-use syringe inside each individually packaged product (these barcodes shall also have HL7 and 97 breakdown values) shall be on the product's package. The packages shall then be tied in sets of ten, and the package label shall be affixed to a different area than the barcode affixed to each product. If the product is packaged in sets of ten, the barcode prepared for the ready-to-use syringe (these barcodes shall also have HL7 and 97 breakdown values) shall be placed inside the package, and the barcode corresponding to the package breakdown shall be on the package. For the information to be included in the barcode, the information specified in the Guide for Barcode Application to Vaccines, Antiserums, and Diluents published by the Turkish Ministry of Health shall be used as a basis, and any additional information required shall be determined by GDPB. **The barcode area for the dose shall be at least 12X12 mm in accordance with the Guide**. If GDPB makes changes to the system instead of the barcode, the contractor shall be obliged to comply with the requirements of the newly created system without requesting a price difference. |  |  |  |
| **6.8.** | Even after acceptance, if any faulty operations related to the barcode system are detected later, the costs of changing the product packaging and, if deemed necessary, collecting the products from the field shall be borne by the Contractor. If this process exceeds one-month, new products with a new expiration date may be requested at the request of the Department to avoid any problems related to the expiration date. |  |  |  |
| **4.7.** | **Temperature monitoring during transportation:** |  |  |  |
| **4.7.1.** | The freeze indicator, temperature monitoring card, and digital temperature recording devices used **shall be listed in the WHO "E006: Temperature monitoring devices"** (<https://extranet.who.int/prequal/immunization-devices/prequalified/imd-products>)**.** |  |  |  |
| **4.7.2.** | If the product(s) are sensitive to freezing, each box shall contain a freeze indicator. |  |  |  |
| **4.7.3.** | If the product(s) are sensitive to high temperatures, each box shall contain a temperature monitoring card **with the date it was activated and the name/code of the activator written on it**. |  |  |  |
| **4.7.4.** | If the product(s) are sensitive to both freezing and high temperatures, or if they are packaged together, each box shall contain both a freeze indicator and a temperature monitor card with the date of activation and the name/code of the activator written on it. |  |  |  |
| **4.7.5.** | In addition, each pallet shall have an electronic, temperature, and freeze-sensitive digital monitor capable of long-term recording. The electronic, temperature, and freeze-sensitive digital monitors capable of long-term recording placed on the pallet shall be read during the inspection phase, the outputs shall be recorded in a report and signed by the company, and if there are no deviations, they can be filed electronically. If requested by the company, these devices shall be returned for storage without destruction for at least three months. Upon return, the pallet numbers and device serial numbers shall be recorded in a report. If the pallets consist of insulated boxes, each containing heat tracking material (such as a digital recording device, heat monitoring card, or freeze indicator), and conflicting results are found between the digital heat records on or inside the pallet and the heat records inside the box when evaluating the heat records, the temperature monitoring results inside the boxes shall be considered when processing. |  |  |  |
| **4.7.6.** | Products found not to have been transported under appropriate conditions (Guidelines for the international packaging and shipping of vaccines, sixth edition. Geneva: World Health Organization, 2020) as monitored by these heat trackers shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **4.8.** | Each product shall be delivered with a Material Safety Data Sheet (MSDS). The contractor is responsible for the “Transportation, packaging, and labelling of hazardous materials” and completing any shortfalls if there is any. |  |  |  |
| **4.9.** | The contractor's representative shall be present during the delivery or return of the products. The representative shall submit a letterhead, stamped, and signed authorization document belonging to the contractor and a photocopy of their photo ID to the Warehouse Manager. The contractor is responsible for unloading the products from the vehicle into the warehouse or loading them back onto the vehicle for return. A list of the names, telephone numbers, and addresses of all employees and subcontractor personnel who shall perform work on behalf of the contractor shall be submitted to the Warehouse Manager, signed by the contractor's representative, prior to unloading. The contractor shall be responsible for any damage that may be caused to the warehouse or equipment and for all liabilities arising from "Occupational Health and Safety Regulations." The contractor shall submit a stamped and signed commitment stating that it has assumed the SSI, occupational health and safety, and work accident liabilities of its employees for unloading the products from the vehicle or loading them in case of return, and that it has assumed the liability for compensation in case of damage to the warehouse or any equipment inside the warehouse. Responsibility begins upon entry into the Warehouse area after the security check. |  |  |  |
| **4.10.** | Except in emergencies, no contractor employees other than the vehicle drivers and those declared shall enter the climate-controlled warehouse. |  |  |  |
| **4.11.** | If barcoding, packaging, or prospectus changes are to be performed in the GDPB warehouse, the documents belonging to the subcontractors shall be as follows:   * + - * shall be a contract demonstrating the availability of occupational safety expertise and workplace physician support services as required by the "Occupational Health and Safety Law" No. 6331.       * The contractor's structure shall include at least one coordinator, one operations manager, one quality control and GMP manager, and one warehouse manager. These personnel shall be present during the execution of the work. There shall be a document or documents proving that the personnel included in the company structure have received GMP and Good Warehouse Practices Training organized by the Turkish Ministry of Health or an organization that has received a GMP Certificate from the Turkish Ministry of Health.       * There shall be standard operating procedures (SOPs) prepared by a pharmacist and approved by the company representative, covering barcode printing and affixing procedures and cold storage room operating rules. |  |  |  |
| **5.** | **DOCUMENTS AND MATERIALS REQUIRED FOR LABORATORY ANALYSES AND METHODS TO BE FOLLOWED** |  |  |  |
| **5.1.** | For each batch of antiserum delivered, the contractor shall provide, free of charge, the number of samples requested by the Turkish Medicines and Medical Devices Agency for physical examination and laboratory analysis. |  |  |  |
| **5.2.** | As soon as the inspection is completed, a sample shall be taken from each batch using the random sampling method and delivered to the laboratory with a report signed by the Contractor's representative and one of the inspection members. |  |  |  |
| **5.3.** | **Documents to be delivered to the laboratory with the product:**   * + Protocols related to production methods and processes, as well as quality control protocols,   + Standard Operating Procedure (SOP) documents related to the product's quality control tests, current validation reports, and validation procedure documents shall be provided with the product.   + In addition, official documents (official certificates) containing the reference vaccine and/or reference unit values shall also be submitted. The reagents, chemical materials, detailed test SOPs (latest updated version), current validation and validation procedure documents, and calculation documents sent shall be delivered complete with the vaccines to be tested |  |  |  |
| **5.4.** | The Contractor shall submit the following free of charge; |  |  |  |
| **5.4.1.** | For each lot, three in-house reference antisera (antiserums) and three 0.5 ml CVS samples or three in-house reference antiserums and one Rabies Antiserum Potency Test Kit (Platelia Rabies II, Bio-Rad, France) shall be supplied free of charge along with the antiserums to be tested. |  |  |  |
| **5.4.2.** | In cases where the test needs to be repeated, the same quantities of International Reference Immunoglobulin and two vials of lyophilized rabies toxin shall be provided free of charge by the company within 15 calendar days. |  |  |  |
| **5.4.3.** | Where necessary, the same quantities of Standard Antiserum, CVS or Rabies Antiserum Potency Test Kit (Platelia Rabies 11, Bio-Rad, France) shall be provided free of charge and urgently by the company. |  |  |  |
| **5.5.** | In case of any changes to be made to the analysis methods, the standards and quantities requested from the company may be reassessed. |  |  |  |
| **5.6.** | If the reference antiserum and chemicals are sourced from abroad, the import procedures shall be carried out by the applicants. |  |  |  |
| **5.7.** | Physical appearance of products European Pharmacopoeia 11.0 01/2020: As stated in monograph 20920 regarding visible particles, this requires special equipment and expertise. It shall be carried out by specialist personnel at the National Reference Laboratory within the Turkish Medicines and Medical Devices Agency, and preliminary acceptance procedures shall be completed once a positive result letter is received from the laboratory. |  |  |  |
| **5.8.** | Products that are unsuitable in terms of physical appearance shall be returned. The Contractor has no right to object to the physical appearance description. The Contractor shall deliver the product of the same quantity from a different lot to HSGM free of charge and in accordance with the terms and conditions within 90 calendar days from the date of notification to the Contractor. |  |  |  |
| **5.9.** | If antiserums are prepared in vacuum-sealed ampoules/vials, and if the number of non-vacuum ampoules/vials exceeds 1% during the vacuum check performed on the antiserum lot samples taken for control purposes, the antiserum lot in question shall be rejected and returned due to the number of non-vacuum ampoules/vials. If the number of ampoules/vials without vacuum is less than Yo1, the supplier shall deliver the number of antiserums corresponding to the number of ampoules/vials without vacuum free of charge within 120 calendar days from the date of notification by the General Directorate of Public Health to the supplier. |  |  |  |
| **5.10.** | Other tests shall be conducted after the physical tests of the products have been found to be satisfactory. |  |  |  |
| **5.11.** | If the product is licensed in Türkiye and has obtained a Batch Release Certificate approved by TITCK, final acceptance shall be made after the physical tests. For batches with a ‘bulk’ release certificate issued by TITCK or OMCL (Official Medicines Control Laboratories) laboratories, the inspection and acceptance phase shall be completed by performing a final product analysis according to OCABR documents. |  |  |  |
| **5.12.** | The analysis reports for the product are part of the batch release certificate, and both documents shall be considered together in the evaluations. |  |  |  |
| **5.13.** | Biological products, in terms of physical appearance and laboratory analyses, shall comply with the World Health Organisation (WHO) Technical Report Series 941 Annex II, Technical Report Series 941 Annex IV, European Pharmacopoeia 11.0 01/2015:0723 and 01/2020:20920 monograph. |  |  |  |
| **5.14.** | Biological controls of products to be delivered shall be carried out at the Turkish Medicines and Medical Devices Agency, but in order to prevent interruption of vaccine and antiserum administration due to potential difficulties in the analysis process, a WHO-approved reference laboratory (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies) ([https://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)](http://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)) may also be conducted, and the costs shall be borne by the Contractor. The results of the control reports of the producer country shall be consistent with the results of the control reports of the Turkish Medicines and Medical Devices Agency or WHO-approved reference laboratories (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies). |  |  |  |
| **5.15** | Batches of products deemed unsuitable based on control results shall be returned. The contractor shall collect these products from the GDPB warehouse where they are located, transport them to the country of origin, and deliver the same quantity of products from a different batch that comply with the specifications to GDPB free of charge within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **5.16.** | The Contractor may object to the results within 15 days. Upon such objection, product samples shall be sent to a second laboratory from among the WHO Reference Laboratories designated ex officio by GDPB or deemed appropriate by GDPB upon the Contractor's recommendation, with the shipping and analysis costs borne by the Contractor. If inconsistencies are detected following analyses conducted by WHO Reference Laboratories and the Turkish Medicines and Medical Devices Agency, the second report shall be accepted as the final report. |  |  |  |
| **5.17.** | These products are subject to the *"Regulations on Market Surveillance and Control Procedures and Principles to be Implemented by the Ministry of Health*." GDPB reserves the right to conduct analyses in case of possible suspicion or complaint. The Contractor shall provide the required number of product doses for analysis and the materials required for the analysis specified in Article 5 free of charge. If the analysis result is found to be unsatisfactory, even if the product in question has been accepted, the Contractor shall deliver the same quantity from different series within 90 calendar days. |  |  |  |
| **5.18.** | In the event that products are returned to the company, the relevant official documents shall be submitted to the administration within 60 calendar days after the products are collected from the warehouse, indicating that the products have been removed from Türkiye or destroyed. |  |  |  |
| **6** | **OTHER PROVISIONS** |  |  |  |
| **6.1.** | Due to delays caused by incorrect or incomplete materials and documents specified in Article 5, such as references, standards, and SOPs required for analysis, which are the responsibility of the contractor to deliver, the product's shelf life shall be shortened by the duration of the delay. The shelf life suitability specified in Article 4 shall be reduced by the duration of the delay. If the shelf life falls below the specified duration, return and exchange processes shall be initiated. For example, if the specification requires a minimum shelf life of 18 months upon delivery to the warehouse, but the product has a shelf life of 20 months at the time of delivery, and the SOP, references, etc. are delivered 70 days later due to a reason attributable to the contractor that prevented the completion of the analyses, the products shall be subject to processing due to shelf life non-compliance and shall be returned. |  |  |  |
| **6.2.** | Batches of products deemed unsuitable based on biological or chemical control results shall be returned. The contractor shall collect these products from the GDPB warehouse where they are located, transport them to the country of origin, and deliver the same quantity of products from a different batch that comply with the specifications to GDPB free of charge within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **6.3.** | In the event of product return (rejection or lot change), the products shall be collected from the warehouse within 30 calendar days after the notification date, during official working hours and days. If not collected, the contractor shall bear the storage and/or disposal costs for the delayed period. |  |  |  |
| **6.4.** | In the event that the products are returned to the Contractor, the relevant official documents proving that the products have been removed from Türkiye or destroyed shall be submitted to the administration within 120 calendar days after the products are collected from the warehouse. If no notification is made, the procedures shall be carried out in accordance with customs regulations. |  |  |  |
| **6.5.** | After acceptance of the products, if any physical deficiencies (barcode errors, packaging, labels, etc.) are detected, the contractor shall remedy the deficiency free of charge. |  |  |  |

| **LOT 14 - 13-VALENT PNEUMOCOCCAL CONJUGATE VACCINE (PCV13)** | | | | |
| --- | --- | --- | --- | --- |
| **Item No** | **Specifications** | **Specifications Offered** | **Notes, remarks,  ref to documentation** | **Evaluation Committee’s notes** |
| **1.** | **VACCINE TECHNICAL SPECIFICATIONS** |  |  |  |
| **1.1.** | The product shall comply with the quality and safety requirements specified in WHO Technical Report Series No. 977, Annex 3; it shall also comply with monograph No. 01/2150 and the provisions of general text 2.9.20 in the European Pharmacopoeia 11.0/2023. |  |  |  |
| **1.2.** | The vaccine shall be produced as a conjugate vaccine. |  |  |  |
| **1.3.** | Each dose of the vaccine shall contain pneumococcal serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F. |  |  |  |
| **1.4.** | The vaccine shall be packaged in a single-dose, ready-to-use syringe (injector) containing, vial or ampule. |  |  |  |
| **1.5.** | The vaccine shall maintain its stability at least 2 (two) years at temperatures between (+2) - (+8) OC from the last successful potency test. |  |  |  |
| **2.** | **DOCUMENTS TO BE INCLUDED IN THE FILE TO BE REVIEWED BY THE TENDER COMMITTEE** |  |  |  |
| **2.1** | The product in question;   * + 1. shall have a license issued by the Turkish Ministry of Health,     2. If it does not have a license issued by the Turkish Ministry of Health;  1. It shall be included in the latest pre-qualification list published by the World Health Organization (<https://extranet.whoint/prequal/vaccines/prequalified-vaccines)> or, 2. It shall have a license from the European Medicines Agency (EMA) and be manufactured in European Union countries, or 3. It shall have a license from the US-FDA and be manufactured in the United States, **or** 4. It shall be licensed by the Pharmaceuticals and Medical Devices Agency (PMDA) and manufactured in Japan, or 5. It shall be licensed by the South Korean Food and Drug Administration and manufactured in South Korea, **or** 6. It shall be licensed by the Canadian Food and Drugs Act and Regulations and manufactured in Canada, **or** 7. The product shall be licensed by the Australian Department of Health Therapeutic Goods Administration and manufactured in Australia. |  |  |  |
| **2.2.** | The product shall be accompanied by a certificate (GMP certificate) showing that the factory producing it complies with the **good manufacturing practices (**GMP) standards approved by the State Control Agency of the country where the product is manufactured. If the product is filled or manufactured in our country, there shall be a document showing that the factory where the production/filling is carried out, approved by the Turkish Ministry of Health, Turkish Medicines and Medical Devices Agency, manufactures in accordance with good manufacturing practices (GMP) rules. |  |  |  |
| **2.3.** | A **manufacturer-approved** document showing that the risk of Transmissible Spongiform Encephalopathy (TSE) has been minimized at every stage of the product's production |  |  |  |
| **2.4.** | For any batch produced within the last two years, the 'National Regulatory Authority' (NRA) or the Batch Release Certificate issued by the EMA (from the locations specified in the annex to the European Union's 2001/83/EC directive), US-FDA, Japan, South Korea, Canada, and Australian state authorities, as specified in 2.1. If the product is manufactured in Türkiye, it shall be a marketing authorization certificate issued by the Turkish Medicines and Medical Devices Agency of the Ministry of Health of the Republic of Türkiye. The analysis report for the same series shall also be included in the BRC annex. |  |  |  |
| **2.5.** | A valid Pharmaceutical Product Certificate (CPP) approved by the manufacturer's country authority. |  |  |  |
| **2.6.** | If the product is licensed in Türkiye, it shall have a "Summary of Product Characteristics" (SPC) or package insert or "Patient Information Leaflet" (PIL) approved by the Turkish Medicines and Medical Devices Agency (TİTCK), or if it is not licensed in Türkiye, it shall have one approved by the relevant country's authority, along with Turkish translations. For companies in the process of transitioning to the 13-valent vaccine, a commitment letter must be included stating that they will submit documentation to the Turkish Medicines and Medical Devices Agency (TİTCK) confirming the submission of the KÜB-HKT presentation, along with TİTCK-approved documents, and that approved HKT will be placed in the boxes of the doses to be delivered. |  |  |  |
| **2.7.** | If applicable, a list of tasks to be performed by subcontractors shall be provided. |  |  |  |
| **2.8.** | The tenderer shall declare in writing how many batches of the product they can deliver. |  |  |  |
| **2.9.** | If the product is used outside the country of manufacture, a document shall be submitted containing the list of countries where the product is used, approved by the manufacturer, along with the usage permits (import permits) or license numbers for these products, and information on the total number of doses used in countries other than the country of manufacture for the last two calendar years prior to the year of the tender. |  |  |  |
| **2.10.** | The tenderer shall declare that if the manufacturer or another country where the product is used suspends the use of the product for any reason, or if they receive any news in this regard, they shall inform the Ministry within 24 hours (product name, serial number, reason for discontinuation, etc.) and that if the information is not provided within 24 hours, the administration has the right to unilaterally terminate the contract. It also indicates that in the event of discontinuation of the product, after the unused products are collected by the Ministry and sent to the Central Warehouse, the Tenderer undertakes to bring a new product from a different series that complies with the specifications within 90 (ninety) calendar days from the date the replacement request is notified. In addition, the Tenderer shall undertake to collect the products to be returned from the Ministry Central Warehouse within 30 (thirty) calendar days starting from the date of notification of the product replacement request after the unused products are collected by the Ministry to the Central Warehouse, without the requirement of manufacturer approval. |  |  |  |
| **2.11.** | The Tenderer shall submit the original or notarized copies of the required documents, along with their certified Turkish translations, to the tender committee. |  |  |  |
| **2.12.** | Manufacturers must include in the tender file a notarized copy of the official website address where the document was published, along with a statement indicating that the document is only available in digital format, for documents that are not issued as physical certificates by national authorities and are only published electronically. In this case, the requirement to submit a digital copy of the relevant document in the file does not apply. The statement regarding the electronic document and the access address must be verifiable by the administration. |  |  |  |
| **3.** | **DELIVERY OF PRODUCTS** |  |  |  |
| **3.1.** | If the products are imported, the tenderer's representative shall be present when the products are collected from customs and shall ensure that the goods are collected in accordance with the required specifications and delivered to the location deemed appropriate by GDPB without delay. |  |  |  |
| **3.2.** | The contractor shall provide the Department with the shipment details 3 days prior to the delivery date of the product. |  |  |  |
| **3.3.** | Product delivery shall be made in such a way that it does not coincide with holidays, official holidays, or the end of working hours in Türkiye. |  |  |  |
| **3.4.** | To clear products purchased by GDPB through customs, the Contractor shall enter the product information (batch release certificate and quantity for the lot/serial number for which import permission is requested) via the Single Window Portal System (<https://uygulama.gtb.gov.tr/TekPencere>). The Single Window approval request shall be submitted to the Department electronically (to the Department's official e-mail address) or in writing at least 3 days in advance. Products purchased by the General Directorate of Public Health shall be delivered to the GDPB Vaccine and Drug Warehouse within 48 hours after being cleared through customs (except for products filled in Türkiye) if they are imported. Any changes required after the initial inspection (packaging, barcode, etc.) may also be made at the Central Vaccine and Drug Warehouse with the approval of the GDPB. If storage exceeds 48 hours, it is mandatory to submit temperature records approved by the Contractor's quality manager from the production site until the Ministry of Health Vaccine Storage arrives, to use a warehouse licensed by the Turkish Ministry of Health, and, if "temperature monitoring cards" are installed at the production facility, not to change them. |  |  |  |
| **3.5.** | If the packaging of the imported product (including barcoding) is to be changed at a different location after the contract is signed, this situation shall be reported to the Department. The temporary storage location shall be licensed by the Turkish Ministry of Health, the initial opening of the packaging of the product withdrawn from customs shall be carried out under the supervision of GDPB or its authorized personnel, and the shipment and temporary storage temperature records shall also be submitted during the inspection phase. GDPB may inspect this entire process at any time and on any day after customs clearance. Intermediate storage shall be possible if the application made to GDPB and the storage period are found to be appropriate. For products imported prior to the signing of the contract, it is sufficient to submit approved storage temperature records documenting all processes and to document that the product has been kept in storage facilities licensed by the Ministry of Health until the delivery stage. |  |  |  |
| **3.6.** | Products filled in our country shall be delivered to the GDPB Vaccine and Drug Warehouse within 24 hours of leaving the filling facility. If the product is not delivered to the GDPB Vaccine and Drug Warehouse within 24 hours after leaving the filling facility and is to be stored in another warehouse, the organization performing the intermediate storage shall be licensed by the Turkish Ministry of Health, temperature records from the production site to the warehouse and within the warehouse shall be kept, and certified copies from the product quality representative shall be delivered to GDPB upon product delivery. These stages shall be open to inspection by GDPB if required. The Department shall be notified if temporary storage is required. Products shall not be accepted if the specified conditions cannot be met. |  |  |  |
| **3.7.** | If the products are filled/manufactured in Türkiye, the time limit specified in Article 3, except for 3.2 and 3.3, and the restrictions at shall not apply. |  |  |  |
| **4.** | **DOCUMENTS REQUIRED DURING INSPECTION AND PRODUCT CHARACTERISTICS** |  |  |  |
| **4.1.** | Products shall have **a shelf life of at least 18 (eighteen) months** from the date of delivery to our warehouse. |  |  |  |
| **4.2.** | **Documents required during the product inspection phase:**  The documents specified in Article 2 of the Technical Specifications and the documents specific to the delivered series/lot shall be submitted during the inspection stage. These documents are:   * Product License * Current GMP certificate for the production site, * Analysis report for the delivered batch (document containing information such as composition, analysis results, reference values, production/expiration dates, etc.), * BRC for the delivered batch, * Current Pharmaceutical Product Certificate (CPP) * TSE declaration (item 2.5), * List of tasks to be performed by subcontractors, * Package Insert or Prospectus or IFU (Article 2.6), * List of countries where the product is used and import permit/license number and the number of doses used in each country in the last two calendar years prior to the year of the offer (Article 2.9), * Commitment letter (Article 2.10). |  |  |  |
| **4.3.** | Stability studies and results proving the actual shelf life of the product in question shall be submitted. If the product is filled or manufactured in our country and stability studies are still ongoing, the TİTCK-approved study results shall be submitted to the Department as they are completed. |  |  |  |
| **4.4.** | Along with the product, all technical documents required in the tender for the product (Good Manufacturing Practices, analysis report, SPC, certificates, etc.) and detailed SOP (may be provided in the original license), **stability results (showing real-time and accelerated stability shelf life),** product photos, and all documents containing technical information about the packaging (dimensions, volume, etc.) shall be submitted to the inspection commission in duplicate on CD/DVD/flash drive. Each heading shall be indicated with a separate folder name, and the relevant documents shall be found under the relevant folder. If deemed necessary, other documents and information related to the product may be requested in physical or digital form. |  |  |  |
| **4.5.** | Documents that do not change with each shipment shall be submitted once, with the first shipment. If deemed necessary, documents may be requested again. |  |  |  |
| **4.6.** | For documents issued by national authorities to manufacturers that are not issued as physical certificates but are only published electronically, the Contractor shall submit a notarized copy of the official web address where the document is published, along with a statement indicating that the document is only available in digital format and its Turkish translation. In this case, the requirement to submit a physical copy of the relevant document does not apply. The statement regarding the electronic document and the access address must be verifiable by the Administration. |  |  |  |
| **4.7.** | **Required Packaging Characteristics** |  |  |  |
| **4.7.1.** | The product shall be packaged in vials or tubes containing a single dose, 10 doses, or a maximum of 20 doses. If the products are packaged in packs of ten, the packs shall contain foam or cardboard separators to prevent the vials or ampoules from breaking due to contact. If the product is packaged individually, the packages shall then be bundled in packs of ten. If diluents are separate, 5 additional diluents shall be delivered with every 1,000 doses of vaccine. |  |  |  |
| **4.7.2.** | The inner and outer packaging of licensed products in Türkiye shall comply with the current "Regulation on Packaging Information, Instructions for Use, and Tracking of Human Medicinal Products" published by the Turkish Ministry of Health. If the product is not licensed in our country, the inner packaging of the ready-to-use syringe (injector), ampoule, or vial shall bear, at a minimum, the manufacturer's and product name, dosage, amount of content per dose, method of administration (IM/IV/SC/ID, etc.), lot (batch) number, and expiration date, printed in indelible ink. The package shall also contain storage temperature information in addition to the inner packaging. The product package shall bear the statement "Property of the Turkish Ministry of Health, NOT FOR SALE." |  |  |  |
| **4.7.3.** | Each product package shall contain at least one "Summary of Product Characteristics" (SPC) or Turkish package insert or "Patient Information Leaflet" (PIL) prepared in accordance with the "Regulation on the Packaging and Labelling of Human Medicinal Products" dated 25.04.2017 and numbered 30048. Additionally, the following text shall be added to the beginning of the “"Summary of Product Characteristics" (SPC)” or Turkish prospectus or "Patient Information Leaflet" (PIL) in bold and coloured font to draw attention.  "In vaccine and serum applications, the EXPANDED IMMUNIZATION PROGRAM CIRCULAR shall be taken into consideration.  For any questions or problems encountered in this regard, contact Vaccine-Preventable Diseases and Department of the Public Health Directorate of the Ministry of Health or the Provincial Health Directorates***."*** |  |  |  |
| **4.7.4.** | The packages shall then be placed in boxes. The names and addresses of the manufacturer and representative company of the product, the name of the product, the lot number, the storage temperature, the expiration date, and the number of doses in the box shall be written on these boxes. If the products are packaged individually, ten packages shall be placed in each box. If the products are packaged in packs of ten, five packages shall be placed in each box. |  |  |  |
| **4.7.5.** | The packaging boxes shall be placed in styrofoam. The styrofoam shall then be placed inside cartons. The carton dimensions shall be 40X60X40 ±20 (Width, Length, Height) cm. A sufficient number of ice packs or gel packs, etc., shall be placed in the cartons. The ice packs or gel packs, etc.**,** placed in the cartons shall be **unfrozen and cooled**. If the products are not sensitive to freezing (lyophilized), dry ice or frozen ice packs or gel may be used during transport. The names and addresses of the manufacturer and representative company, the product name, serial number, storage temperature, expiration date, dose quantity in the carton, carton dimensions, and weight shall be written on these cartons. |  |  |  |
| **4.7.6.** | The boxes shall then be placed on pallets. The pallets shall be euro pallets (120cm±2cmx80cm±2cmx10-15cm). After the boxes are placed on the pallets, the height together with the pallet shall not exceed 2 (two) meters. The boxes may protrude from the pallet by a maximum of 5 cm. There shall be a maximum of 16 (sixteen) boxes on the pallet. |  |  |  |
| **4.7.7.** | There shall be a 2D barcode on the packages, boxes, cartons, and pallets. The barcode prepared for the ready-to-use syringe (injector) inside each individually packaged product (these barcodes shall also have HL7 and 97 breakdown values) shall be on the product's package. The packages shall then be tied in sets of ten, and the package label shall be affixed to a different area than the barcode affixed to each product. If the product is packaged in sets of ten, the barcode prepared for the ready-to-use syringe (injector) (these barcodes shall also have HL7 and 97 breakdown values) shall be placed inside the package, and the barcode corresponding to the package breakdown shall be on the package. For the information to be included in the barcode, the information specified in the Guide for Barcode Application to Vaccines, Antiserums, and Diluents published by the Turkish Ministry of Health shall be used as a basis, and any additional information required shall be determined by GDPB. **The barcode area for the dose shall be at least 12X12 mm in accordance with the Guide**. If GDPB makes changes to the system instead of the barcode, the contractor shall be obliged to comply with the requirements of the newly created system without requesting a price difference. |  |  |  |
| **4.7.8.** | Even after acceptance, if any faulty operations related to the barcode system are detected later, the costs of changing the product packaging and, if deemed necessary, collecting the products from the field shall be borne by the Contractor. If this process exceeds one-month, new products with a new expiration date may be requested at the request of the Department to avoid any problems related to the expiration date. |  |  |  |
| **4.7.9.** | **Temperature monitoring during transportation:** |  |  |  |
| **4.7.9.1.** | The freeze indicator, temperature monitoring card, and digital temperature recording devices used **shall be listed in the WHO "E006: Temperature monitoring devices"** (https://extranet.who.int/prequal/immunization-devices/prequalified/imd-products)**.** |  |  |  |
| **4.7.9.2.** | If the product(s) are sensitive to freezing, each box shall contain a freeze indicator. |  |  |  |
| **4.7.9.3.** | If the product(s) are sensitive to high temperatures, each box shall contain a temperature monitoring card **with the date it was activated and the name/code of the activator written on it**. |  |  |  |
| **4.7.9.4.** | If the product(s) are sensitive to both freezing and high temperatures, or if they are packaged together, each box shall contain both a freeze indicator and a temperature monitor card with the date of activation and the name/code of the activator written on it. |  |  |  |
| **4.7.9.5.** | In addition, each pallet shall have an electronic, temperature, and freeze-sensitive digital monitor capable of long-term recording. The electronic, temperature, and freeze-sensitive digital monitors capable of long-term recording placed on the pallet shall be read during the inspection phase, the outputs shall be recorded in a report and signed by the company, and if there are no deviations, they can be filed electronically. If requested by the company, these devices shall be returned for storage without destruction for at least three months. Upon return, the pallet numbers and device serial numbers shall be recorded in a report.  If the pallets consist of insulated boxes, each containing heat tracking material (such as a digital recording device, heat monitoring card, or freeze indicator), and conflicting results are found between the digital heat records on or inside the pallet and the heat records inside the box when evaluating the heat records, the temperature monitoring results inside the boxes shall be considered when processing. |  |  |  |
| **4.7.9.6.** | Products found not to have been transported under appropriate conditions (Guidelines for th international packaging and shipping of vaccines, sixth edition. Geneva: World Health Organization; 2020. Licence: BY-NC-SA 3.0 IGO) as monitored by these heat trackers shall be returned. The evaluation of temperature monitoring equipment shall be carried out in accordance with the operating instructions for the relevant equipment. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **4.7.10.** | Each product shall be delivered with a Material Safety Data Sheet (MSDS). The contractor is responsible for the “Transportation, packaging, and labelling of hazardous materials” and completing any shortfalls if there is any. |  |  |  |
| **4.7.11.** | The contractor's representative shall be present during the delivery or return of the products. The representative shall submit a letterhead, stamped, and signed authorization document belonging to the contractor and a photocopy of their photo ID to the Warehouse Manager. The contractor is responsible for unloading the products from the vehicle into the warehouse or loading them back onto the vehicle for return. A list of the names, telephone numbers, and addresses of all employees and subcontractor personnel who shall perform work on behalf of the contractor shall be submitted to the Warehouse Manager, signed by the contractor's representative, prior to unloading. The contractor shall be responsible for any damage that may be caused to the warehouse or equipment and for all liabilities arising from "Occupational Health and Safety Regulations." The contractor shall submit a stamped and signed commitment stating that it has assumed the SSI, occupational health and safety, and work accident liabilities of its employees for unloading the products from the vehicle or loading them in case of return, and that it has assumed the liability for compensation in case of damage to the warehouse or any equipment inside the warehouse. Responsibility begins upon entry into the Warehouse area after the security check. |  |  |  |
| **4.7.12.** | Except in emergencies, no contractor employees other than the vehicle drivers and those declared shall enter the climate-controlled warehouse. |  |  |  |
| **4.7.13.** | If barcoding, packaging, or prospectus changes are to be performed in the GDPB warehouse, the documents belonging to the subcontractors shall be as follows:   * + - * shall be a contract demonstrating the availability of occupational safety expertise and workplace physician support services as required by the "Occupational Health and Safety Law" No. 6331.       * The contractor's structure shall include at least one coordinator, one operations manager, one quality control and GMP manager, and one warehouse manager. These personnel shall be present during the execution of the work. There shall be a document or documents proving that the personnel included in the company structure have received GMP and Good Warehouse Practices Training organized by the Turkish Ministry of Health or an organization that has received a GMP Certificate from the Turkish Ministry of Health.       * There shall be standard operating procedures (SOPs) prepared by a pharmacist and approved by the company representative, covering barcode printing and affixing procedures and cold storage room operating rules. |  |  |  |
| **5.** | **DOCUMENTS AND MATERIALS REQUIRED FOR LABORATORY ANALYSES AND METHODS TO BE FOLLOWED** |  |  |  |
| **5.1.** | **General principles of product safety;** |  |  |  |
| **5.1.1.** | The analysis reports for the product are part of the batch release certificate, and both documents shall be considered together in the evaluations. |  |  |  |
| **5.1.2.** | The product shall be manufactured in our country, have a manufacturing license from the Turkish Medicines and Medical Devices Agency (TİTCK), and present the SBB certificate for the delivered batch obtained from the TİTCK/Analysis and Control Laboratories Department. In addition, if there is no break in the cold chain during product transfer, the physical examination is appropriate, and the commission grants approval, the inspection acceptance process can be completed. |  |  |  |
| **5.1.3.** | If the product is manufactured outside our country and has an import license from TİTCK or is on the WHO's prequalification list (Prequalified vaccines), the Series Release Certificate for the delivered series shall be obtained from WHO/ Reference Laboratories/institutions, provided that the analyses are performed in accordance with the OCABR guidelines at the TİTCK/Analysis and Control Laboratories Directorate. The inspection acceptance process for products found to be suitable through analysis can be completed. |  |  |  |
| **5.1.4.** | If the product is not licensed in our country, but is licensed by the authorities in EMA, US-FDA, Japan, Canada, South Korea, and Australia as specified in Article 2.1 of the technical specifications, tests may be performed in accordance with the OCABR guidelines by the TİTCK/Analysis and Control Laboratories Department. The inspection and acceptance process for products with suitable analyses can be completed. |  |  |  |
| **5.2.** | If there are any doubts regarding product safety within the scope of the cold chain or other matters specified in the technical specifications, new samples may be taken if necessary, and analyses may be performed as required, including analyses based on batch release. |  |  |  |
| **5.3.** | These products are subject to the *"Regulations on Market Surveillance and Control Procedures and Principles to be Implemented by the Ministry of Health*." GDPB reserves the right to conduct analyses in case of possible suspicion or complaint. The Contractor shall provide the required number of product doses for analysis and the materials required for the analysis specified in Article 5 free of charge. If the analysis result is found to be unsatisfactory, even if the product in question has been accepted, the Contractor shall deliver the same quantity from different series within 90 calendar days. |  |  |  |
| **5.4.** | If the product does not comply with Article 5.1, after the inspection is completed, a sample shall be taken from each batch using the random sampling method and delivered to the laboratory with a report signed by the Contractor's representative and one of the inspection members. |  |  |  |
| **5.5.** | Since the physical appearance of the products requires expertise, it shall be assessed by specialized personnel at the National Reference Laboratory within the TİTCK in accordance with the current Turkish/European Pharmacopoeia. Products that are not suitable in terms of physical appearance shall be returned. The contractor shall deliver the same quantity of product from a different lot to GDPB free of charge and in accordance with the specifications within **30 calendar days** from the date of notification to the contractor. After the physical tests of the products are found to be suitable, other tests shall be performed in accordance with Article 5. |  |  |  |
| **5.6.** | The vaccine shall comply with the characteristics and conditions specified in **World Health Organization** **(WHO) Technical Report Series** 977 Annex 3, and **European Pharmacopoeia** **11.0/2023:01/2150 monograph** in terms of physical appearance and laboratory analyses. |  |  |  |
| **5.7.** | The manufacturer shall provide three (3) standard reference antiserums for each lot (batch) of vaccine, to be used in potency (efficacy) and identity tests for each pneumococcal polysaccharide serotype (1, 3, 4, 5, 6A, 68, 7F, 9V, 14, 18C, 19A, 19F, and 23F) contained in the vaccine, free of charge, along with the vaccines to be tested. |  |  |  |
| **5.8.** | Considering the total number of batches to be delivered under the tender, one set of WHO International Reference Materials or international reference antigen/antiserum sets defined by the European Directorate for the Quality of Medicines (EDQM) shall be delivered with the products for every 5 (five) batches of KPA vaccine. Upon request, the manufacturer shall submit documentation regarding the source of the reference antigens and antisera used for each lot to the inspection commission. Where necessary, additional reference materials shall be provided free of charge by the manufacturer. |  |  |  |
| **5.9.** | Certified standard antigens, antiserums, and control reagents approved by the manufacturer shall be delivered along with the tests. |  |  |  |
| **5.10.** | When necessary, the same quantities of standard vaccines, antigens, antiserums, and other relevant standards and international standards shall be promptly provided free of charge by the Contractor. |  |  |  |
| **5.11.** | Documents to be delivered to the laboratory with the product:  -Protocols related to production methods and processes, as well as quality control protocols,  -Standard Operating Procedure (SOP) documents related to the product's quality control tests, current validation reports, and validation procedure documents shall be provided with the product. |  |  |  |
| **5.12.** | If the reference vaccine and chemicals are imported from abroad, customs clearance procedures shall be carried out by the contractors. |  |  |  |
| **5.13.** | For each batch of vaccine delivered, the Contractor shall provide a sufficient number of samples free of charge for physical examination and laboratory analysis. |  |  |  |
| **5.14.** | If changes are made to the analysis methods, the standards and quantities requested from the Contractor may be re-evaluated. |  |  |  |
| **5.15.** | In addition, official documents (official certificates) containing the reference vaccine and/or reference unit values shall also be submitted. The reagents, chemical materials, detailed test SOPs (latest updated version), current validation and validation procedure documents, and calculation documents sent shall be delivered complete with the vaccines to be tested. |  |  |  |
| **5.16.** | If vaccines are prepared in vacuum-sealed ampoules/vials, and if the number of non-vacuum ampoules/vials exceeds 1% in the vacuum control performed on vaccine lot samples taken for inspection, the vaccine lot in question shall be rejected and returned due to the number of non-vacuum ampoules/vials. If the number of non-vacuum ampoules/vials is less than 1%, the vaccine supplier shall deliver the equivalent number of non-vacuum ampoules/vials free of charge within 120 calendar days from the date of notification by the General Directorate of Public Health to the supplier. |  |  |  |
| **5.17.** | Biological controls of products to be delivered shall be carried out at the Turkish Medicines and Medical Devices Agency, but in order to prevent interruption of vaccine and antiserum administration due to potential difficulties in the analysis process, a WHO-approved reference laboratory (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies) ([https://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)](http://www.who.int/publications/m/iteın/list-of-nras-operatinc-at-ml3-and-ml4)) may also be conducted, and the costs shall be borne by the Contractor. The results of the control reports of the producer country shall be consistent with the results of the control reports of the Turkish Medicines and Medical Devices Agency or WHO-approved reference laboratories (National regulatory authorities of countries exporting vaccines through United Nations purchasing agencies). |  |  |  |
| **5.18.** | The Contractor may object to the results within 15 days. Upon such objection, product samples shall be sent to a second laboratory from among the WHO Reference Laboratories designated ex officio by GDPB or deemed appropriate by GDPB upon the Contractor's recommendation, with the shipping and analysis costs borne by the Contractor. If inconsistencies are detected following analyses conducted by WHO Reference Laboratories and the Turkish Medicines and Medical Devices Agency, the second report shall be accepted as the final report. |  |  |  |
| **6.** | **OTHER PROVISIONS** |  |  |  |
| **6.1.** | Due to delays caused by incorrect or incomplete materials and documents specified in Article 5, such as references, standards, and SOPs required for analysis, which are the responsibility of the contractor to deliver, the product's shelf life shall be shortened by the duration of the delay. The shelf life suitability specified in Article 4 shall be reduced by the duration of the delay. If the shelf life falls below the specified duration, return and exchange processes shall be initiated. For example, if the specification requires a minimum shelf life of 18 months upon delivery to the warehouse, but the product has a shelf life of 20 months at the time of delivery, and the SOP, references, etc. are delivered 70 days later due to a reason attributable to the contractor that prevented the completion of the analyses, the products shall be subject to processing due to shelf life non-compliance and shall be returned. |  |  |  |
| **6.2.** | 6.3 Batches of products deemed unsuitable based on biological or chemical control results shall be returned. The contractor shall collect these products from the GDPB warehouse where they are located, transport them to the country of origin, and deliver the same quantity of products from a different batch that comply with the specifications to GDPB free of charge within **90 calendar days** from the date of notification to the contractor. |  |  |  |
| **6.3.** | In the event of product return (rejection or lot change), the products shall be collected from the warehouse within 30 calendar days after the notification date, during official working hours and days. If not collected, the contractor shall bear the storage and/or disposal costs for the delayed period. |  |  |  |
| **6.4.** | In the event that the products are returned to the Contractor, the relevant official documents proving that the products have been removed from Türkiye or destroyed shall be submitted to the administration within 120 calendar days after the products are collected from the warehouse. If no notification is made, the procedures shall be carried out in accordance with customs regulations.After acceptance of the products, if any physical deficiencies (barcode errors, packaging, labels, etc.) are detected, the contractor shall remedy the deficiency free of charge. |  |  |  |

| **LOT 15 - STERILE DISPOSABLE VACCINE SYRINGE (INJECTOR) 1 ML** | | | | |
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| **Item No** | **Specifications** | **Specifications Offered** | **Notes, remarks,  ref to documentation** | **Evaluation Committee’s notes** |
| **1.** | **TECHNICAL SPECIFICATIONS** |  |  |  |
| **1.1.** | It shall be approved by the Turkish Ministry of Health. |  |  |  |
| **1.2.** | It shall be a single-use, sterile syringe with a maximum scale of 1 millilitre. |  |  |  |
| **1.3.** | The pointed tip of the syringe shall be centred and have a 6% slope, screwless/lockless (Luer) type. |  |  |  |
| **1.4.** | The syringe needle shall be 26G or 27G, with a needle length of no more than 12 mm and a needle tube outer diameter of no more than 0.45 mm. This information shall be documented in the analysis report. |  |  |  |
| **1.5.** | The capped needle tip shall be fixed to the syringe. |  |  |  |
| **1.6.** | The calibration lines and numbers on the barrel shall be clear and legible, and the normal standard scale range shall be marked to show 0.1 ml and 0.05 ml (with the numbers 0.1 ml and 0.05 ml also written). |  |  |  |
| **1.7.** | The dead space caused by the conical part of the syringe shall be minimised or eliminated. |  |  |  |
| **1.8.** | Syringe needles shall comply with TS EN ISO 7864:2016 or ISO 7864:2016. |  |  |  |
| **1.9.** | Syringes shall comply with the TS EN ISO 7886-1 or ISO 7886-1 standard text in terms of size and characteristics. |  |  |  |
| **2.** | **PACKAGING TYPE** |  |  |  |
| **2.1.** | The syringes shall be packaged individually in packs. Boxes shall contain 100, 200 or 250 packaged syringes. The boxes shall be placed in cartons suitable for transport and shipping. Each carton shall contain 1000, 2000 or 4000 syringes. |  |  |  |
| **2.2.** | Boxes and/or cartons shall be placed on pallets. Pallets shall be euro pallets (120cm±2cmx80cm±2cmx10-15cm). After the cartons are placed on the pallets, the height together with the pallet shall not exceed 2 (two) metres. Cartons may protrude from the pallet by a maximum of 5 cm. |  |  |  |
| **2.3.** | The following information, at a minimum, shall be provided in Turkish on the single syringe packaging. |  |  |  |
| **2.3.1.** | The name or abbreviated name of the manufacturer, its address, and its registered trademark, if any |  |  |  |
| **2.3.2.** | The capacity of the syringe (ml or cc), |  |  |  |
| **2.3.3.** | The dimensions of the syringe needle |  |  |  |
| **2.3.4.** | Expiry date (MONTH/YEAR), |  |  |  |
| **2.3.5.** | Batch/lot number, |  |  |  |
| **2.3.6.** | Indication that it is sterile, a pyrogenic, and non-toxic, |  |  |  |
| **2.3.7.** | Type of sterilisation, |  |  |  |
| **2.3.8.** | A mark indicating the direction for easy opening of the packaging, |  |  |  |
| **2.3.9.** | Text indicating that it is for single use only, |  |  |  |
| **2.3.10.** | Warning stating that syringes with torn packaging shall not be used, |  |  |  |
| **2.3.11.** | The inner and outer packaging shall contain at least the information specified in sections 3.3.1, 3.3.2, 3.3.4, and 3.3.5, as well as the number of syringes contained. |  |  |  |
| **3.** | **PREPARATION AND EVALUATION OF TENDERS** |  |  |  |
| **3.1.** | Tenderers participating in the tender shall submit 10 syringe samples together with their tenders to the Tender Commission Chair. |  |  |  |
| **3.2.** | Documents and/or commitments demonstrating the matters specified in Article 2. |  |  |  |
| **3.3.** | Documents to be submitted to the Tender Commission: |  |  |  |
| **3.3.1.** | A document proving that the syringes are registered with the Turkish Medicines and Medical Devices Agency's ‘Product Tracking System’. |  |  |  |
| **3.3.2.** | Documents certified by the manufacturer's Production and Quality Control Director; |  |  |  |
| **3.3.2.1.** | Analysis certificates for the last two years produced by the manufacturer. The analysis certificates shall specify the maximum dead space volume control value and the needle length, inner and outer diameter control values. |  |  |  |
| **3.3.2.2.** | A document explaining the sterilisation method. |  |  |  |
| **3.3.3.** | A document defining how the syringe serial numbers are determined, the approximate number of batches to be delivered, and the quantity of each batch. |  |  |  |
| **4.** | **ACCEPTANCE AND INSPECTION** |  |  |  |
| **4.1.** | If the product is imported from abroad, all customs procedures, permits and expenses related to the importation of the product shall be carried out by the contractor. |  |  |  |
| **4.2.** | During the provisional acceptance of the product, after counting the packages, the physical characteristics shall be checked for compliance with the specifications and the characteristics specified in the specifications shall be sought. |  |  |  |
| **4.3.** | Documents to be submitted during the inspection and acceptance phase shall include: |  |  |  |
| **4.3.1.** | A list showing the serial numbers of the delivered syringes and the quantity of each series. |  |  |  |
| **4.3.2.** | Analysis certificates for the delivered series. |  |  |  |
| **4.4.** | One hundred samples from each batch of products found to be acceptable during acceptance shall be sent to the Turkish Medicines and Medical Devices Agency analysis laboratory, together with one copy of the analysis certificates. If the analyses have been carried out at the Turkish Medicines and Medical Devices Agency analysis laboratory, the products shall not be re-analysed. Any additional samples that may be requested and other materials required for analysis shall be provided by the contractor. |  |  |  |
| **4.5.** | Analyses of the syringes' compliance with the relevant standards shall be carried out at the Turkish Medicines and Medical Devices Agency, and the costs shall be borne by the contractor. All products deemed unsuitable based on the control results or unsuitable series shall be returned to the applicant. In their place, the contractor shall deliver the same quantity of products from a different series that comply with the specifications free of charge to the Vaccine and Medicines Depot of the General Directorate of Public Health of the Ministry of Health of the Republic of Türkiye within 90 days from the date of notification to the contractor. The contractor may object to the results within 15 days. Upon such objection, product samples shall be sent to a different centre jointly determined by the requester and the General Directorate of Public Health of the Ministry of Health of the Republic of Türkiye for re-evaluation, with all expenses borne by the contractor. |  |  |  |
| **4.6.** | Final acceptance of the syringes shall be made by the Inspection and Preliminary Acceptance Commission based on a report confirming that the 100-piece samples taken are suitable as a result of the analyses performed and the inspection and acceptance commission report. If the analyses were performed at the Turkish Medicines and Medical Devices Agency analysis laboratory, the products shall not be re-analysed. In this case, the final acceptance of the syringes shall be made with the inspection and acceptance commission report and the analysis certificates issued by the Turkish Medicines and Medical Devices Agency, delivered by the contractor. |  |  |  |
| **4.7.** | All permits and procedures related to the import of the product shall be carried out by the contractor. |  |  |  |
| **4.8.** | The syringes shall have a shelf life of at least 36 months from the date of delivery. |  |  |  |
| **5.** | **DELIVERY OF SYRINGES** |  |  |  |
| **5.1.** | The applicant shall notify the General Directorate of Public Health, Department of Vaccine-Preventable Diseases, Ministry of Health of the Republic of Türkiye, of the arrival of the syringes 5 days prior to the delivery date by email (department email) or official letter. |  |  |  |
| **5.2.** | Delivery of the syringes shall be made in such a way as to avoid coinciding with public holidays, official holidays, and non-working hours in Türkiye. The Company Representative shall be present during the delivery of the syringes and shall ensure that the goods are delivered in accordance with the specifications and that there are no delays in their delivery to the Vaccine and Drug Depot of the General Directorate of Public Health, Ministry of Health of the Republic of Türkiye. |  |  |  |

| **LOT 16 - STERILE DISPOSABLE VACCINE SYRINGE (INJECTOR) 2 ML** | | | | |
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| **Item No** | **Specifications** | **Specifications Offered** | **Notes, remarks,  ref to documentation** | **Evaluation Committee’s notes** |
| **1.** | **TECHNICAL SPECIFICATIONS** |  |  |  |
| **1.1.** | It shall be approved by the Turkish Ministry of Health. |  |  |  |
| **1.2.** | It shall be a single-use, sterile syringe with a 2-millilitre body. |  |  |  |
| **1.3.** | The pointed tip of the syringe shall be centred and have a 6% slope, screwless/lockless (Luer) type. |  |  |  |
| **1.4.** | The syringe needle shall be 24G or 25G, with a needle length of 25mm, and shall be packaged together with the syringe. This information shall be documented in the analysis report. |  |  |  |
| **1.5.** | The calibration lines and numbers on the reservoir shall be clear and legible, and shall be marked (with numbers) to indicate the standard scale range of 0.5 ml, 1 ml, 1.5 ml and 2 ml. |  |  |  |
| **1.6.** | The dead space caused by the conical part of the syringe shall be minimised or eliminated. |  |  |  |
| **1.7.** | Syringes shall comply with the TS EN ISO 7886-1 or ISO 7886-1 standard text in terms of size and characteristics. |  |  |  |
| **1.8.** | Syringe needles shall comply with TS EN ISO 7864:2016 or ISO 7864:2016. |  |  |  |
| **2.** | **PACKAGING TYPE** |  |  |  |
| **2.1.** | The syringes shall be packaged individually in packs. Boxes shall contain 100, 200 or 250 packaged syringes. The boxes shall be placed in cartons suitable for transport and shipping. Each carton shall contain 1000, 2000 or 4000 syringes. |  |  |  |
| **2.2.** | Boxes and/or cartons shall be placed on pallets. Pallets shall be euro pallets (120cm±2cmx80cm±2cmx10-15cm). After the cartons are placed on the pallets, the height together with the pallet shall not exceed 2 (two) metres. Cartons may protrude from the pallet by a maximum of 5 cm. |  |  |  |
| **2.3.** | The following information, at a minimum, shall be provided in Turkish on the single syringe packaging. |  |  |  |
| **2.3.1.** | The name or abbreviated name of the manufacturer, its address, and its registered trademark, if any, |  |  |  |
| **2.3.2.** | The capacity of the syringe (ml or cc), |  |  |  |
| **2.3.3.** | The dimensions of the syringe needle |  |  |  |
| **2.3.4.** | Expiry date (MONTH/YEAR), |  |  |  |
| **2.3.5.** | Batch/lot number, |  |  |  |
| **2.3.6.** | Indication that it is sterile, a pyrogenic, and non-toxic, |  |  |  |
| **2.3.7.** | Type of sterilisation, |  |  |  |
| **2.3.8.** | A mark indicating the direction for easy opening of the packaging, |  |  |  |
| **2.3.9.** | Text indicating that it is for single use only, |  |  |  |
| **2.3.10.** | Warning stating that syringes with torn packaging shall not be used, |  |  |  |
| **2.3.11.** | The inner and outer packaging shall contain at least the information specified in sections 3.3.1, 3.3.2, 3.3.4, and 3.3.5, as well as the number of syringes contained. |  |  |  |
| **3.** | **PREPARATION AND EVALUATION OF TENDERS** |  |  |  |
| **3.1.** | Tenderers participating in the tender shall submit 10 syringe samples together with their tenders to the Tender Commission Chair. |  |  |  |
| **3.2.** | Documents and/or commitments demonstrating the matters specified in Article 2. |  |  |  |
| **3.3.** | Documents to be submitted to the Tender Commission: |  |  |  |
| **3.3.1.** | A document proving that the syringes are registered with the Turkish Medicines and Medical Devices Agency's ‘Product Tracking System’. |  |  |  |
| **3.3.2.** | Documents certified by the manufacturer's Production and Quality Control Director; |  |  |  |
| **3.3.2.1.** | Analysis certificates for the last two years produced by the manufacturer. The analysis certificates shall specify the maximum dead space volume control value and the needle length, inner and outer diameter control values. |  |  |  |
| **3.3.2.2.** | A document explaining the sterilisation method. |  |  |  |
| **3.3.3.** | A document defining how the syringe serial numbers are determined, the approximate number of batches to be delivered, and the quantity of each batch. |  |  |  |
| **4.** | **ACCEPTANCE AND INSPECTION** |  |  |  |
| **4.1.** | If the product is imported from abroad, all customs procedures, permits and expenses related to the importation of the product shall be carried out by the contractor. |  |  |  |
| **4.2.** | During the provisional acceptance of the product, after counting the packages, the physical characteristics shall be checked for compliance with the specifications and the characteristics specified in the specifications shall be sought. |  |  |  |
| **4.3.** | Documents to be submitted during the inspection and acceptance phase shall include: |  |  |  |
| **4.3.1.** | A list showing the serial numbers of the delivered syringes and the quantity of each series. |  |  |  |
| **4.3.2.** | Analysis certificates for the delivered series. |  |  |  |
| **4.4.** | One hundred samples from each batch of products found to be acceptable during acceptance shall be sent to the Turkish Medicines and Medical Devices Agency analysis laboratory, together with one copy of the analysis certificates. If the analyses have been carried out at the Turkish Medicines and Medical Devices Agency analysis laboratory, the products shall not be re-analysed. Any additional samples that may be requested and other materials required for analysis shall be provided by the contractor. |  |  |  |
| **4.5.** | Analyses of the syringes' compliance with the relevant standards shall be carried out at the Turkish Medicines and Medical Devices Agency, and the costs shall be borne by the contractor. All products deemed unsuitable based on the control results or unsuitable series shall be returned to the applicant. In their place, the contractor shall deliver the same quantity of products from a different series that comply with the specifications free of charge to the Vaccine and Medicines Depot of the General Directorate of Public Health of the Ministry of Health of the Republic of Türkiye within 90 days from the date of notification to the contractor. The contractor may object to the results within 15 days. Upon such objection, product samples shall be sent to a different centre jointly determined by the requester and the General Directorate of Public Health of the Ministry of Health of the Republic of Türkiye for re-evaluation, with all expenses borne by the contractor. |  |  |  |
| **4.6.** | Final acceptance of the syringes shall be made by the Inspection and Preliminary Acceptance Commission based on a report confirming that the 100-piece samples taken are suitable as a result of the analyses performed and the inspection and acceptance commission report. If the analyses were performed at the Turkish Medicines and Medical Devices Agency analysis laboratory, the products shall not be re-analysed. In this case, the final acceptance of the syringes shall be made with the inspection and acceptance commission report and the analysis certificates issued by the Turkish Medicines and Medical Devices Agency, delivered by the contractor. |  |  |  |
| **4.7.** | All permits and procedures related to the import of the product shall be carried out by the contractor. |  |  |  |
| **4.8.** | The syringes shall have a shelf life of at least 36 months from the date of delivery. |  |  |  |
| **5.** | **DELIVERY OF SYRINGES** |  |  |  |
| **5.1.** | The applicant shall notify the General Directorate of Public Health, Department of Vaccine-Preventable Diseases, Ministry of Health of the Republic of Türkiye, of the arrival of the syringes 5 days prior to the delivery date by email (department email) or official letter. |  |  |  |
| **5.2.** | Delivery of the syringes shall be made in such a way as to avoid coinciding with public holidays, official holidays, and non-working hours in Türkiye. The Company Representative shall be present during the delivery of the syringes and shall ensure that the goods are delivered in accordance with the specifications and that there are no delays in their delivery to the Vaccine and Drug Depot of the General Directorate of Public Health, Ministry of Health of the Republic of Türkiye. |  |  |  |