# Section IV. Bidding Forms

##  Notes on the Bidding Forms

The Bidding Forms provided in this SSBD provide standard formats for a number of the key documents that the Contracting Entity and Bidders will exchange in the process of bidding.

{The Contracting Entity shall fill in the Forms with the needed information relevant to each procurement before launching the Bidding Process. The required place for writing this information is under the paragraphs written in Italic style and shaded in grey. Any notes provided to the Contracting Entity which is underlined and shaded in yellow is for information only and shall be deleted before releasing the Bidding Documents.}

The Bidder will fill in his part of the form where it is designated between brackets or\_\_\_\_\_\_\_\_\_.

The Bidders must complete the Forms as indicated on the form, and submit them to the Contracting Entity.

 Price Schedules: The price breakdown given in the sample Price Schedules generally follows the usual breakdown requested for procurement of Goods in order for the domestic preference procedure to be applied. It is essential that Bidders submit their prices in the manner prescribed by the Price Schedules. Failure to do so may result in loss of the preference, if applicable.

 Manufacturer’s Authorization Form: In accordance with ITB Sub-Clause 8.1 (b), Bidders must submit, as part of their bids, Manufacturer’s Authorization Form(s) in the format provided in the SSBD for all items specified in the Bid Data Sheet.

 Bid Security Form: Regarding ITB Clause 17, the Contracting Entity should include the Bid Security form provided in the SSBD in the Bidding Documents. The Contracting Entity must ensure that the submitted form substantially complies with the features of the form included here in respect to its degree of protection and clarity of conditions under which it can be made effective in accordance with the applicable Iraqi Laws.

**1. Bid Submission Form**

 Date: [insert: **date of bid**]

 {ContractingEntity to insert: Tender Number: [Med/16/2019”}

IFB Number:{16 }

To: {Contracting Entity to insert: [**Name and address of Contracting Entity**]}

Dear Sir or Madam:

 Having examined the Bidding Documents,including Addenda Nos. [ insert **numbers** ], the receipt of which is hereby acknowledged, we, the undersigned, offer to supply and deliver the Goods under the above-named Contract in full conformity with the said Bidding Documents for the sum of:

|  |  |
| --- | --- |
| [ insert: **amount of “Iraqi Dinar” in words** ] | ([ insert: **amount of “Iraqi Dinar” in figures** ]) |
| **plus** | [ insert: **amount of “US Dollar” in words**] | ([ insert: **amount of “US Dollar” in figures**]) |
| **plus** | [ insert: **amount of “Euro” in words**] | ([ insert: **amount of “Euro” in figures**]) |

(hereinafter called “the Total Bid Price”) or such other sums as may be determined in accordance with the terms and conditions of the Contract. The above amounts are in accordance with the Price Schedules attached herewith and are made part of this bid.

2. We undertake, if our bid is accepted, to deliver the Goods in accordance with the delivery schedule specified in the [ insert “Schedule of Requirements in Section-VI”**or**“as quoted in Price Schedule in Section-IV”] (the Bidder may select as appropriate clause).

3. We agree to all General Conditions of Contract in Section-VII read in conjunction with the Special Conditions of Contract in Section-VIII.

4. If our bid is accepted, we undertake to provide an advance payment security and a performance security in the form, in the amounts, and within the times specified in the Bidding Documents.

5. We agree to abide by this bid, for the Bid Validity Period specified in Sub-Clause 16.1 of the Bid Data Sheet in Section II and it shall remain binding upon us and may be accepted by you at any time before the expiration of that period.

6. Until the formal final Contract is prepared and executed between us, this bid, together with your written acceptance of the bid and your notification of award, shall constitute a binding Contract between us.

7. We understand that you are not bound to accept the lowest evaluated bid or any other bid that you may receive.

8. We agree to the following Eligibility Criteria:

(a) We have nationality from Eligible countries as per ITB Sub-Clause-6.1 of Section-I.

(b) We do not have conflict of interest in accordance with ITB Sub-Clause-6.1 (a) of Section-I.

(c) We are not a Government-owned Entity in Republic of Iraq./ We are a Government-owned Entity in the Republic of Iraq and meet the requirement as per Sub-Clause 6.1(b) of Section - I.

(d) We including any of our subcontractors or manufacturers for any part of the contract, have not been declared ineligible by the Contracting Entity, under the Contracting Entity’s country laws or official regulations or by an act of compliance with a decision of the United Nations Security Council.

(e) We have not been Black listed or Suspended by Republic of Iraq and declared ineligible to bid during the period of time determined as per ITB Clause 6.3 of Section-I.

9. We confirm that our website address is insert web side\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and our mail address is: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and that Mr. /Ms.\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_of Job Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and e-mail address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ will be following up all matters relevant to any Clarifications.

Dated this [insert: **number**] day of [insert: **month**], [insert: **year**].

**Signed:**

**Date**:

**In the capacity of** [insert: **title or position**]

Duly authorized to sign this bid for and on behalf of [insert: **name of Bidder**]

2. A. Price Schedule for Domestic Goods or Goods of Foreign Origin Located In Iraq

|  |
| --- |
| **1** |
| **Brief Description of Goods** |
| **No. of bid tpreciept committee** | **Code of manufactur company** | **Offers submission** | **National code** | **Generic name** | **Generic name related to company that submit the bid** | **Trade name** | **Active item** | **Pharmaceutical from** | **volume** | **weight** | **Registration item no.** | **Registration item date** | **Quality certificate** | **Sample submission** | **sodium meta bisulfate) existance in this compand or not)** | **Raw material** | **Registration product no.** | **Registration product date** | **Per unite of package** | **Per unite of sheet** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

Grand Total of Bid price in Iraqi Dinar: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (In figures) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (In words)

Delivery Period: \_\_\_\_\_\_\_\_\_\_\_ [Bidder may insert quoted delivery period] as per INCOTERMS® current edition \_\_\_\_\_\_\_\_ [Insert Incoterms].

|  |  |  |
| --- | --- | --- |
|  |  | Signature of Bidder\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name & Designation\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Seal of the Bidder \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

2. B. Price Schedule for Domestic Goods or Goods of Foreign Origin Located In Iraq

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **2** | **3** | **4** | **5** | **6** |
| **Quantity offered**  | **Country of origin** | **Price per physical unit Iraq currency (NO. , Write)** | **Price & the transport way**  | **Total Price** |
| **Quantity of bid submitted** | **Free goods** | **The name of producting company** | **The origin of producting company** | **Package price** | **Per unit price** | **Currency type** | **Ex-factory/ex-warehouse/ex-show room/off-the shelf including packing and forwarding charges****(a)** | **Sales and other taxes and duties payable if contract is awarded****(b)** | **Inland transportation insurance loading/unloading and incidental costs till end-users site****(c)** | **Incidental services as defincal in schedule of requirement****(d)** | **Price on DDP/free delivery at end-users****e=(a+b+c+d)** | **Total Price on DDP/Free Delivery at End-users’ site.****(Iraqi Dinar)****quantityX 5 (e)** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

Grand Total of Bid price in Iraqi Dinar: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (In figures) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (In words)

Delivery Period: \_\_\_\_\_\_\_\_\_\_\_ [Bidder may insert quoted delivery period] as per INCOTERMS® current edition \_\_\_\_\_\_\_\_ [Insert Incoterms].

|  |  |  |
| --- | --- | --- |
|  |  | Signature of Bidder\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name & Designation\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Seal of the Bidder \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

3.A. Price Schedule for Goods to be imported from Abroad

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Serial no.** | **1** | **2** | **3****Description item of manufactur company** | **4****Country origin……** |
| **National code** | **National description** | **Unit** | **Qty.** |  |  |
| **No. Of item** | **no. of tander receipt committee** | **Manufacturing comp. Code (K-code)** | **National item code** | **Generic name** | **Pharmasutical from** | **Unit per blister** | **Unit per pack** | **Offer Quantity**  | **Desicription item of manufactur co.** | **Generic name of company item** | **Active ingredient**  | **(sodium meta bisulfate) existance in this compand or not** | **Trade Name** | **volume** | **weight** | **Arrival way** | **Entry point to country** | **Shelf life of item** | **Supplying periocl**  |  **Item Registration Date & No.** | **Submission of Samples**  | **Origin of Raw material** | **Goods origin** | **Country origin** | **Registration No. Of Offer submitting company**  |
| 1 |   |   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

Grand Total of Bid price: [Bidders may insert permissible Currency] \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (In figures) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (In words)

Delivery Period: \_\_\_\_\_\_\_\_\_\_\_ [Bidder may insert quoted delivery period] as per INCOTERMS® current edition \_\_\_\_\_\_\_\_ [Insert Incoterms].

Agent Name & Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [Bidder may insert, if applicable]

Agency Commission: \_\_\_\_\_\_\_\_\_\_\_\_ [Bidder may insert, if applicable]

|  |  |  |
| --- | --- | --- |
| Place: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | Signature of Bidder\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name& Designation \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Business address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Seal of the Bidder\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

3.B. Price Schedule for Goods to be imported from Abroad

|  |  |  |
| --- | --- | --- |
| **4** | **5** | **6** |
| **……..Country origin** | **Unit price (CIP)** | **Total Price****(CIP)** |
| **Date of registration of offer submitting company**  | **Name of offer submitting company**  | **Origin of offer submitting company** | **Manufacture company name** | **Certificates obtained** | **Registration no of manufacture company**  | **Registration date of manufacture company** | **Company address** | **Company phone no** | **Company email** | **Company website** | **Name of scientific bureau in Iraq that representive the company** | **Beneficiary name** | **Bank name** | **Bank address** | **Bank phone no** | **Account no** | **Price per pack** | **Price per unit** **(CIP) (A)** | **Currency type** | **Secondary services as defined in table (B)** | **Free goods** | **Payment method** | **Price CIP {C=(A+B)}** | **Total price CIP of the offered Qty.****( C x Qty.)** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

Grand Total of Bid price: [Bidders may insert permissible Currency] \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (In figures) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (In words)

Delivery Period: \_\_\_\_\_\_\_\_\_\_\_ [Bidder may insert quoted delivery period] as per INCOTERMS® current edition \_\_\_\_\_\_\_\_ [Insert Incoterms].

Agent Name & Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [Bidder may insert, if applicable]

Agency Commission: \_\_\_\_\_\_\_\_\_\_\_\_ [Bidder may insert, if applicable]

|  |  |  |
| --- | --- | --- |
| Place: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | Signature of Bidder\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name& Designation \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Business address \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Seal of the Bidder\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

5. Bid Security Form (Bank Guarantee)

 [The Bank shall fill in this Bank Guarantee Form in accordance with the instructions indicated.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
[insert **Bank’s Name**, and **Address** of Issuing Branch or Office]

**Beneficiary:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [insert **Name and Address of Contracting Entity**]

**Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**BID GUARANTEE No.:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

We have been informed that [insert **name of the Bidder**] (hereinafter called "the Bidder") has submitted to you its bid dated (hereinafter called "the Bid") for the execution of [insert **name of tender/project**] under Invitation for Bids No. [insert**IFB number**] (“the IFB”).

Furthermore, we understand that, according to your conditions, bids must be supported by a bid guarantee.

At the request of the Bidder, we [insert **name of Bank**] hereby irrevocably undertake to pay you any sum or sums not exceeding in total an amount of [insert **amount in figures**] ([insert **amount in words**]) upon receipt by us of your first demand in writing accompanied by a written statement stating that the Bidder is in breach of its obligation(s) under the bid conditions, because the Bidder:

(a) has withdrawn its Bid during the period of bid validity specified by the Bidder in the Form of Bid; or

(b) having been notified of the acceptance of its Bid by the Contracting Entity during the period of bid validity, (i) fails or refuses to execute the Contract Form, if required, or (ii) fails or refuses to furnish the performance security, in accordance with the Instructions to Bidders.

(c) has complained or appealed as per ITB clause 36 and it is decided by the competent authorities for this Bidder to compensate all damages resulting from delaying the contract signature for false or unjustified reasons.

 This guarantee will expire: (a) if the Bidder is the successful bidder, upon our receipt of copies of the contract signed by the Bidder and the performance security issued to you upon the instruction of the Bidder; or (b) if the Bidder is not the successful bidder, upon the earlier of (i) our receipt of a copy of your notification to the Bidder of the name of the successful bidder and the bidder has not complaint or appeals to the Contracting Entity; or (ii) twenty-eight days after the expiration of the Bidder’s Bid and the bidder has not complaint or appeals to the Contracting Entity.

Consequently, any demand for payment under this guarantee must be received by us at the office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 458.

 [signature(s)]

6. Manufacturer’s Authorization

[The Bidder shall require the Manufacturer to fill in this Form in accordance with the instructions indicated. Thisletter of authorization should be on the letterhead of the Manufacturer and should be signed by a person with the proper authority to sign documents that are binding on the Manufacturer. The Bidder shall include it in its bid, if so indicated in the BDS.]

Date: [insert: **date** (as day, month and year) **of Bid Submission**]

IFB No.: [insert: **number of bidding process**]

To: [insert: complete name of Contracting Entity]

WHEREAS

We [insert: **complete name of Manufacturer**], who are official manufacturers of[insert: **type of goods manufactured**], having factories at [insert: **full address of Manufacturer’s factories**], do hereby authorize [insert: **complete name of Bidder**] to submit a bid the purpose of which is to provide the following Goods, manufactured by us [insert: **name and or brief description of the Goods**], and to subsequently negotiate and sign the Contract.

We hereby extend our full guarantee and warranty in accordance with Clause 15 of the General Conditions of Contract, with respect to the Goods offered by the above firm.

Signed: [**insert: signature(s) of authorized representative(s) of the Manufacturer**]

Name: [insert: **complete name(s) of authorized representative(s) of the Manufacturer**]

Title: [insert: **title**

Duly authorized to sign this Authorization on behalf of: [insert: **complete name of Bidder**]

Dated on \_\_\_\_\_\_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, \_\_\_\_\_\_\_ [insert: **date of signing**]

7. Sample Form for Performance Statement

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Contract placed by** | **Order No and date** | **Order placed on** | **Description of Goods** | **Quantity** | **Date if completion of Contract** | **Reasons of delay, if any** | **Are the goods supplied satisfactory?** |
| **As per Contract** | **Actual** |  |  |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|  |  |  |  |  |  |  |  |  |

PART 2

PROCUREMENT REQUIREMEN

# Section VI Schedule of Requirements

## Notes on the Schedule of Requirements

The Schedule of Requirements provides a concise description of each product and the quantity required, along with any technical specifications unique to that item.

##

**Schedule of Requirements**

Schedule: I List of Goods, Delivery Schedule and Terms of Delivery:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **1** | **2** | **3** | **4** | **5** | **6** |
| **Schedule No.****(a)** | **Item No.****(b)** | **Brief Description of Goods****[Insert for Pharmaceuticals, Product, Strength, Dosage form, Pharmacopoeia Standard and Unit pack size. For Medical Equipment only Brief Description of goods may be mentioned]** | **Quantity and physical unit** | **Bid security amount in Iraqi Dinar****[Note Insert Bid Security amount Schedule wise as one percent of Estimated Value ]** | **Final Destination****[Note Insert End-users’’ address ]** | **Required Delivery period as per \_\_\_****[ insert Incoterms® current edition]** |
| **Product****(a)** | **Strength****(b)** | **Dosages form****(c)** | **Pharmacopeia Standard****(d)** | **Unit pack size****(e)** |
| **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** |
| **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** |
| **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** | **[Insert]** |

**Terms of Delivery:** The Bidders are required to quote prices as per the terms of delivery stipulated in Price Schedule in Section -IV

ScheduleII: Scope of Incidental Services:

[Insert:“**Nil**” for Health Sector Goods

OR “Required Installation, Demonstration and onsite Training” for Medical Equipment]

ScheduleIV. Technical Specifications

The purpose of the Technical Specifications (TS) is to define the technical characteristics of the Goods and Related Services required by the Contracting Entity

|  |  |
| --- | --- |
| **Technical Specifications****1-**the items offer should be stated by it’s commercial name if it offer in it’s scientific name should be stated in pharmacopoeia standards.2-stat the shelf life.3-stat the origin of a material.  | **Pharmaceuticals**  |

**Technical Specifications**

Pharmaceuticals

|  |  |
| --- | --- |
| **1. Product and Package Specifications** | 1.1 The Goods to be purchased by the Contracting Entity under this Invitation for Bids are included in Iraq’s current national essential drugs list or national formulary. The required packing standards and labeling must meet the latest requirements of the World Health Organization (WHO) good manufacturing practices (GMP) standards in all respects. (These standards are contained in “Good Practices in the Manufacture and Quality Control of Drugs.”) |
|  | 1.2 Product specifications indicate dosage form (e.g., tablet, capsules, dry syrup, liquid, ointment, injectable, emulsion, suspension, etc.) and the drug content (exact number of mg or international units [IU] or % v/v, w/w or v/w acceptable range). The Goods should conform to standards specified in the following compendia: [The Contracting Entity should specify an acceptable pharmacopoeia standard from one of the following: the British Pharmacopoeia, the United States Pharmacopoeia, the French Pharmacopoeia, the International Pharmacopoeia, or the European Pharmacopoeia, the latter particularly for raw materials.] The standards will be the latest edition unless otherwise stated by the Contracting Entity or other if applicable. In case the pharmaceutical product is not included in the specified compendium, but included in the Iraq’s national essential drug list, the Contracting Entity should clearly indicate acceptable limitsand the Bidder (Supplier), upon award of the Contract, must provide the reference standards and testing protocols to allow for quality control testing. |
|  | 1.3 Not only the pharmaceutical item, but also the packaging and labeling components (e.g., bottles, closures, and labeling) should also meet specifications suitable for distribution,storage, and use in a climate similar to that prevailing in Iraq. All packaging must be properly sealed and tamper-proofand packaging components must meet the latest compendium standards and be approved for pharmaceutical packaging by the manufacturer’s national regulatory authority (RA). The Contracting Entity should specify any additional special requirements. |
|  | 1.4 All labeling and packaging inserts shall be in the language requested by the Contracting Entity or English if not otherwise stated. |
|  | 1.5 Goods requiring refrigeration or freezing or those that should not fall below a certain minimum temperaturefor stability must specifically indicate storage requirements on labels and containers and be shipped in special containers to ensure stability in transit from point of shipment to port of entry. |
|  | 1.6 Upon award, the successful Bidder(Supplier) shall, on demand, provide a translated version in the language of the bid of the prescriber’s information for any specific goods the Contracting Entity may request. |
| **2. Labeling Instructions** | 2.1 The label of the primary container for each pharmaceutical and vaccine products shall meet the W210 GMP standard and include:1. The international nonproprietary name (INN) or generic name prominently displayed and above the brand name, where a brand name has been given. Brand names should not be bolder or larger than the generic name;
2. dosage form, e.g., tablet, ampoule, syrup, etc.;
3. the active ingredient “per unit, dose, tablet or capsule, etc.;
4. the applicable pharmacopoeia standard;
5. the Purchaser’s logo and code number and any specific color coding if required;
6. content per pack;
7. instructions for use;
8. special storage requirements;
9. batch number;
10. date of manufacture and date of expiry (in clear language, not code);
11. name and address of manufacture;
12. any additional cautionary statement.
 |
|  | 2.2 The outer case or carton should also display the above information. |
| **3. Case Identification** | 3.1 All cases should prominently indicate the following:1. Purchaser’s line and code numbers;
2. the generic name of the product;
3. the dosage form (tablet, ampoule, syrup);
4. date of manufacture and expiry (in clear language not code);
5. batch number;
6. quantity per case;
7. special instructions for storage;
8. name and address of manufacture;
9. any additional cautionary statements.
 |
|  | 3.2 No case should contain pharmaceutical products from more than one batch. |
| **4. Unique Identifiers** | 4.1 The Contracting Entity(Purchaser) shall have the right to request the Supplierto imprint a logo, if the quantity so justifies it, on thelabels of the containers used for packaging and in certain dosage forms, such as tablets, and ampoules and this will be in the Technical Specifications. The designand detail will be clearly indicated at the time of bidding, and confirmation of the design of such logoshall be provided to the Bidder(Supplier) at the time of contract award. |
| **5. Standards of Quality Control for Supply** | 5.1 The successful Bidder (Supplier) will be required to furnish to the Contracting Entity:1. With each consignment, and for each item a WHO certificate of quality control test results concerning quantitative assay, chemical analysis, sterility, pyrogen content uniformity, microbial limit, and other tests, as applicable to the Goods being supplied and the manufacturer’s certificate of analysis.
2. Assay methodology of any or all tests if requested.
3. Evidence of bio-availability and/or bio-equivalence for certain critical Goods upon request. This information would be supplied on a strictly confidential basis only.
4. Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.

5.2 The Supplier (Bidder) will also be required to provide the Contracting Entity(Purchaser) with access to its manufacturing facilities to inspect the compliance with the GMP requirements and quality control mechanisms.] |

**[Sample:**

**Technical Specification**

Vaccines

|  |  |
| --- | --- |
| **1. Product Qualification Requirements** | Option A1.1 The Goods to be purchased by the Contracting Entity under this Invitation for Bids must be produced under the control of a recognized, well-functioning National Control Authority (NCA) for biologicals, which performs all six critical functions as defined by the World Health Organization (WHO): |
|  | 1. licensing based on published set of requirements
2. surveillance of vaccine field performance
3. system of lot release for vaccines
4. use of laboratory when needed
5. regular inspections for Good Manufacturing Practices (GMP)
6. evaluation of clinical performance

Or state the following:Option B1.1 The Goods under this Invitation for Bids should be purchased from WHO-approved sources only. |
|  | 1.2 The Goods to be purchased by the Contracting Entity under this Invitation for Bids must be produced in accordance with the GMP recommendations of WHO for biological products. |
|  | 1.3 The Goods to be purchased by the Contracting Entity under this Invitation for Bids must be registered by the National Control Authority (NCA) of Iraq. |
| **2. Product Specifications** | 2.1 Dosage form (e.g.: oral or injectable; liquid or freeze dried with sterile diluents packed separately, etc.). |
|  | 2.2 Type (e.g.: “live attenuated,” “manufactured from purified inactivated (...) obtained from human plasma or manufactured using recombinant DNA technology,” etc.). |
|  | 2.3 Administration (e.g.: “intended for intramuscular injection,” etc.). |
|  | 2.4 Description of intended use (e.g.: “immunization of newborn infants,” etc.). |
|  | 2.5 Dosage size (if not restrictive), or expected immunogenic reaction (e.g.: each dose shall contain that amount of Hbsag protein with micrograms/ml specified by the manufacturer for newborn dosage, that when given as part of a primary immunization series [3 doses] is capable of producing specific humoral antibody [anti HBs] at a level of at least 10 milli international units in >-90 percent of recipients,” etc.). |
|  | 2.6 Dose package (e.g.: “5 infant dose sterile glass vials,” etc.). |
|  | 2.7 Filling volume (e.g.: “final product should contain 15% overfill,” etc.). |
|  | 2.8 Closures (e.g.: “vaccine vials shall be fitted with closures that conform to ISO standard 8362-2”). |
|  | 2.9 Storage temperature (e.g.: “2–8 degrees C. Do not freeze,” or as appropriate, etc.). |
|  | 2.10 The product should remain stable up to the indicated test expiry date if kept according to the required storage temperature. |
|  | 2.11 Standards (e.g.: “The vaccine should conform to standards established by Iraq or, where no standard has been adopted, meet current requirements published by the WHO Expert Committee on Biological Standardization, or requirements of an established body of equivalent stature such as the U.S. Pharmacopoeia, the British Pharmacopoeia, the French Pharmacopoeia, or the International Pharmacopoeia”). |
| **3. Labeling Requirements** | 3.1 Each vial or ampoule shall carry the manufacturer’s standard label in Iraqi language, if available at no extra charge; otherwise, the label shall be in English. |
|  | 3.2 Each vial or ampoule label shall state the following:1. name of the vaccine;
2. name of the manufacturer;
3. place of manufacture;
4. lot number;
5. composition;
6. concentration;
7. dose mode for administration;
8. expiration date;
9. storage temperature;
10. any other information that is appropriate.
 |
|  | 3.3 All labeling shall withstand immersion in water and remain intact. |
| **4. Packing Requirements** | 4.1 Inner boxes: Inner Boxes shall contain not more than (number) individual vials/ampoules and shall be constructed of sturdy white cardboard outfitted with individual segments for protecting and separating each vial/ampoules. |
|  | 4.2 Printed materials: Each inner box shall contain at least (number) manufacturer’s standard package inserts in the Iraqi language if available at no extra charge; otherwise, package insert shall be in English. |
|  | 4.3 Over packing: Inner boxes shall be over packed so that the vaccine remains refrigerated as designated in Sub-Clause 2.9. The over packing must be suitable for export handling and be in accordance with WHO Expanded Program of Immunization (EPI) Guidelines on International Packaging and Shipping of Vaccines including all measures needed to maintain required temperatures for seventy-two (72) hours. It must have adequate insulation and sufficient refrigerant to ensure that the warmest storage temperature of the vaccine does not rise above that designated in Sub-Clause 2.9 when exposed to continuous outside temperature of +43 degrees C, nor fall below that specified of -20 degrees C during transit and for a period of at least twenty-four (24) hours after arrival at the airport destination. Additional cushioning shall be provided sufficient to protect the vials/ampoules from breakage during transit and handling. |
|  | 4.4 Exterior shipping cartons: Product and printed materials, packaged as described above, shall be packed in weather-resistant, triple-wall corrugated fiberboard cartons with a bursting test strength of not less than 1,900 kPa. The overall dimensions of the exterior shipping cartons should be such that the product does not become damaged during transportation and storage.  No shipping carton should contain vaccine from more than one lot. |
|  | 4.5 Cold chain monitor cards: Each insulated shipping container must include appropriate temperature-monitoring devices designated by the Contracting Entity. |
|  | 1. At least two suitable cold chain monitor cards, as approved by the Contracting Entity, shall be packed in each transport case of vaccine.
2. Freeze watch indicators shall be included in each transport case at the direction of Contracting Entity.
 |
| **5. Marking Requirements** | 5.1 All containers and invoices must bear the following information:1. the name of the vaccine;
2. expiration date of the vaccine;
3. appropriate storage temperature.
 |
|  | 5.2 Inner boxes: The inner boxes containing vaccine vials or ampoules shall be marked with the following information in a clearly legible manner that is acceptable to the Contracting Entity: |
|  | 1. Generic name and trade name of the vaccine;
2. Manufacturer’s name and trade registered address;
3. Manufacturer’s national registration number;
4. Lot or batch number;
5. Composition and concentration;
6. Number of vials contained in box;
7. Expiration date (month and year in clear language, not code);
8. Instructions for storage and handling;
9. Place of manufacture (Made in \_\_\_\_\_\_).
 |
|  | 5.3 Exterior Shipping Cartons: The following information shall be stenciled or labeled on the exterior shipping cartons on two opposing sides in bold letters at least 30mm high with waterproof ink in a clearly legible manner that is acceptable to the Contracting Entity. |
|  | 1. Generic name and trade name of the vaccine;
2. Lot or batch number;
3. Expiration date (month and year in clear language, not code);
4. Manufacturer’s name and registered address;
5. Manufacturer’s national registration number;
6. Destination airport and routing;
7. Consignee’s name and address in full;
8. Consignee contact name and telephone number;
9. Number of vials or ampoules contained in the carton;
10. Gross weight of each carton (in kg);
11. Carton #\_\_\_\_ of \_\_\_\_\_;
12. Instructions for storage and handling;
13. Contract number;
14. Place of manufacture (Made in\_\_\_\_\_\_).
 |
| **6. Quality Control for Supply** | 6.1 All goods must:1. meet the requirements of manufacturing legislation and regulation of vaccines in the country of origin;
2. meet internationally recognized standards for safety, efficacy, and quality;
3. conform to all the specifications and related documents contain herein;
4. be fit for the purposes expressly made known to the Bidderby the Contracting Entity;
5. be free from defects in workmanship and materials; and
6. be certified by a competent authority in the manufacturer’s country according to resolution WHA 28-65(2), of the WHO release certificate.
 |
|  | 6.2 The Supplier will be required to furnish to the Contracting Entity with each consignment; |
|  | 1. A certificate of quality control and test results in conformity with the WHO release certificate.
2. Assay methodology of any or all tests if required.
3. Evidence of basis for expiration dating and other stability data concerning the commercial final package upon request.
 |
|  | 6.3 Pre-shipment inspection and testing: The Supplier will be required to provide the Purchaser or his representative with access to the product as packed for shipment at the sellers’ factory and/or warehouse at a mutually agreeable time prior to shipment of the product. |
|  | 1. The Purchaser may inspect and sample, or cause to be sampled, such product.
2. The Purchaser may cause independent laboratory testing to be performed as deemed necessary to ensure that the Goods conform to prescribed requirements. The testing laboratory shall be of the Purchaser’s choice and suitably equipped and qualified to conduct quality control test on biological products.
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