**BIDDING DOCUMENT**

**Procurement of Contraceptives**

**Competitive Bidding**

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**GOVERNMENT OF SINDH**

**Population Welfare Department**

**Population Welfare Department Government of Sindh, Pakistan**

**Notice Inviting Tender**

**for**

**Procurement of Contraceptives**

*(Contraceptive injections and oral pills, Emergency contraceptive pills & Syringes)*

The Population Welfare Department, Government of Sindh, Karachi, hereby invites sealed bids on single stage two envelops procedure from various Primary Manufacturers or their authorized representatives duly registered with Directorate of Sales Tax & Income Tax for the supply of Contraceptives & Misc. items for service delivery outlets.

Detailed description and quantities of above contraceptive are given in the bidding documents. Interested Manufacturers/Suppliers may get Bidding Documents from the office of the Deputy Director (W&D), Population Welfare Department, Sindh, Karachi, located at Z-39/1, Block-6, PECH Society, Karachi, from 13th December, 2016 Tuesday or date of publication on payment of tender fees Rs.2000/= (Non refundable) in the shape of Pay order in favour of Secretary, Population Welfare Department, Sindh, Karachi, till the date of closing i.e. 30th December, 2016 up to 11.00 AM. Tenders will be received upto 11.00 AM and opened same day i.e. 30th December, 2016 at 11.30 AM.

Manufactures/Suppliers can submit bid for single item or more than one items (separately) against full quantities given in the bidding documents, however evaluation of bids and award of contract shall be made on single item basis.

The bidders are required to furnish Bid Security @2.5% of the total bid value in the shape of Pay order/Bank Draft/Call Deposit/Bank Guarantee from any schedule bank of Pakistan or Foreign Country Schedule Bank alongwith financial bid. in favour of Secretary, Population Welfare Department, Government of Sindh, Karachi. In case of alternate offer separate tender documents should be purchased and offer should be submitted with the separate Bid Security. Any offer without 2.5% Bid Security will be rejected. The department may reject all bids or proposals at any time prior to the acceptance of bid or proposal. The Department shall upon request communicate to any supplier or contractor who submitted a bid or proposal, the grounds for its rejection of all bids or proposals, but is not required to justify those grounds.

##### Terms & Conditions:-

a) Offers are invited in Pakistani Currency (Pak Rupees).

b) Tenderers are requested to submit their quotations with sealed cover, failing which their quotations will not be entertained.

c) In case Government announces any Public Holiday then tenders will be submitted/opened on the next working day and the time & venue will remain the same.

d) The Firms must be registered with the Directorate of Sales Tax and Income Tax. The GST clearance for the year 2015-16 must be provided and the original registration documents must be shown at the time of opening of tenders.

f) Conditional Tenders will not be accepted.

g) Rates quoted in the Tender shall remain effective till 90 days from the date of opening or till extended bid validity period in terms of Rule 38 of SPP Rules 2010 (amended 2013).

h) Population Welfare Department reserve the rights to increase or decrease the quantity of any scheduled items as and when it is deemed necessary according to SPP Rules. The procuring Agency may reject all or any bid at any time prior to the acceptance of a bid or proposal, subject to the relevant provision of SPP Rules 2010 (amended 2013) .

**DEPUTY DIRECTOR (W&D)**

**POPULATION WELFARE DEPARTMENT, SINDH**

**PH: 34525675**

# SECTION I

Instructions to Bidders

(ITB)

**INSTRUCTIONS TO BIDDER**

1. Bids comprising single package, containing two separate envelops shall be submitted in sealed envelopes one for Technical Proposal and other for Financial Proposals (Rule 46 (2-a) of SPPRA 2010 (amended 2013). The envelops shall be marked as **FINANCIAL PROPOSALS & TECHNICAL PROPOSAL** in bold and legible letters.
2. The original bid shall be typed or written in indelible ink by the bidder or person duly authorized. The person or persons signing the bid shall initial all pages of the bid. The name and designation of each person signing must be mentioned below the signature.
3. The Interested bidders have to submit current price list (Trade Price & Market price) of the quoted item/s duly signed and stamped by the primary Manufacturer of quoted items.
4. The bidder shall drop their bids duly sealed in the tender box in the office of the Deputy Director (W&D), Population Welfare Department, Sindh, Karachi, upto 11.00 AM on 30th December, 2016.
5. The participant bidders have to submit samples of the quoted items alongwith Technical proposal on the day of opening of Technical proposal i.e. 30th December, 2016
6. The bid documents comprises the following ( as per rule, 21, of SPP Rules 2010 amended 2013)

a) Instruction to Bidder Annex-I

b) Form of Bid

i) Technical Proposal/Specification Annex-II

c) Form of Contract Annex-III

d) General/ special conditions of contract Annex-IV

e) Bid Evaluation Criteria Annex-V

f) Finance Proposal /Price Schedule

g) Integrity pact Annex-VI

1. The tenders will be received back upto ,**30th December, 2016** at 11.00 AM and will be opened on the same day i.e. on **30th December, 2016** at 11.30 AM in the presence of Tender Opening Committee and the bidders or their authorized representatives. In case of holiday the bids shall be opened on next day at same time.
2. Bid Security, amounting 2.5% of Bid price should be in shape of Pay order in favour of Secretary, Population Welfare Department, Sindh, Karachi, issued by any schedule Bank of Pakistan. A copy of de-faced bid security must be added with the Technical bid.
3. The bid security will be forfeited to the Government, if the bidder withdraws his bid after opening and before the expiry of the bid validity period or fails to sign the contract alongwith other forms. if the bid is accepted.
4. Conditional tender and tender without bid security shall not be considered.
5. Delivery time will be 45 days starting from the issuance of work order/signing the contract.
6. GST/Income Tax Certificates must be accompanied with tender.
7. The procuring Agency may reject all or any bid at any time prior to the acceptance of a bid or proposal, subject to the relevant provision of SPP Rules, 2010 (amended 2013). The payment will be made subject to availability of funds for the financial years 2016-17.
8. Supplier should submit the rate in the financial proposal which will be opened subject to the conditions that the bidder stand technically qualified.
9. Bids shall remain valid for 90 days after the date of bid opening and same may be extended in terms of Rule 38 (2) (3) (4) of SPPRA Rules.
10. If any extension in the bid validity period should be asked to extend the same. Such extension shall be for not more than the period of original bid validity.
11. Bidders who:
    1. Agree for extension of bid validity period shall also extend the validity of the bid security for the extended period of the bid validity.
    2. Agree to the procuring agency’s request for extension of bid validity period shall not be permitted to change the substances of their bids
    3. Do not agree to an extension of bid validity period shall be allowed to withdraw their bids without for feature of their bid security.
    4. The bidder name, unit as well as bid amount and bid security shall be announced.
12. Bids Submitted late due to any reason what so ever, shall not be considered and returned unopened to the bidder or his authorized representative.
13. The bids shall be quoted in Pak Rupees.
14. No bidder shall be allowed to alter or modify his bid after the bids have been opened.

However the procuring agency may seek and accept clarification to the bid that do not change substances of the bids.

1. Any request for clarification in the bid, made by the procuring agency shall invariably be in writing. The response to such request shall also be in writing.
2. The procuring agency may reject all bids or proposals at any time prior to the acceptance of a bid or proposal. The procuring agency upon request communicate to any supplier or contractor who submitted a bid or proposal, the grounds for its rejection of all bids or proposal, but is not required to justify those grounds.

**Deputy Director (W&D),**

**Population Welfare Department,**

**Government of Sindh,**

**Karachi**

# Bid Data Sheet (BDS)

The following specific data for the contraceptives to be procured shall complement,   
supplement or amend the provisions in the Instructions to Bidders (ITB). Whenever there   
is a conflict, the provisions in the Bid Data Sheet (BDS) shall prevail over those in the ITB.

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| **ITB Ref** | **Description** | **Detail** |
|  | Commencement of sale of Bidding Document | 13th  December, 2016 |
|  | Last Date of submission of Bidding Documents | 30th December, 2016 |
|  | Date of Opening of Bidding Documents | 30th December, 2016 at 11.30 AM |
| ITB Clause 1.1 | Bid title and reference number | Procurement of Contraceptives for Department of Population Welfare , Government of Sindh, Pakistan PWDS/W&D/CC/2016-17/08, Dated 8TH December,, 2016 |
| ITB Clause 4 | Documents Establishing Conformity to Bidding Documents | In addition to the list of documents stated in ITB 4.1 & 4.2; the following documents should be included with the Bid:   1. Certificate of analysis documenting product’s compliance with specification and performance requirements as given at section VI 2. For products manufactured outside of Pakistan and imported, a certificate documenting that the quoted product submitted is WHO prequalified. 3. For products manufactured in Pakistan, a certificate documenting acceptable quality of the product from WHO prequalified Laboratory or National DRA. |
| ITB Clause 5.1 | Qualifications of Bidder | In addition to Bid Forms 3(A) and 4, |
| ITB Clause 9.1 | Bidding procedure | Single stage – Two Envelop procedure |
| ITB Clause 11.1 | Clarification of Bidding Documents | Secretary  Population Welfare Department, Government of Sindh,  39 – Z/1, Block 6, PECHS  Karachi, Pakistan  Phone: +92-21-34525675 |
| ITB Clause 13.1 | Language of bid | English |
| ITB Clause 16.1,16.2.a.iii, 16.2.b.ii and | Bid Price: Final Destination | DAP at Central Warehouse Karachi |
| ITB Clause 16.5 | Bid Price | Price shall be fixed |
| ITB Clause 16.6 | Bid Price | Supplier must quote for the full quantities requested |
| ITB Clause 17.1 | Currencies of Bid | Pak Rupees |
| ITB Clause 18.1 | Bid validity period | 90 Days |
| ITB Clause 19.1 | Amount of bid security | 2.5% of the total bid value |
| ITB Clause 20.1 | Number of bid copies | One original set and *1* copy |
| ITB Clause 21.2.ii | Marking of Bids | Secretary  Population Welfare Department, Government of Sindh,  39 – Z/1, Block 6, PECHS  Karachi, Pakistan  Phone: +92-21-34525675 |
| ITB Clause 21.2.iv | Marking of the Bids | Procurement of Contraceptive for Secretary  Population Welfare Department, Government of Sindh,  39 – Z/1, Block 6, PECHS  Karachi, Pakistan  Phone: +92-21-34525675  PWDS/W&D/CC/2016-17/08, Dated 30th December, 2016 |
| ITB Clause 22.1 | Last date and time for the receipt of bidding document | 30th December, 2016 |
| ITB Clause 24.1 | Date, time and venue of opening of technical bids | **30th December, 2016 at 11.30 AM**  In the office of Secretary  Population Welfare Department, Government of Sindh,  39 – Z/1, Block 6, PECHS  Karachi, Pakistan  Phone: +92-21-34525675 |
| ITB Clause 36.1 | Right to Vary Quantities at Time of Award | As per SPPRA 2013 |

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**Opening and Evaluation of Bids**

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| **1. Bid Opening** | 1.1 | All bids received, shall be opened by the Departmental Purchase Committee publically in the presence of the Bidders or their representatives who choose to be present on the date, time and venue stipulated in the Bid Data Sheet. |
|  | 1.2 | The bids shall be opened in accordance with the procedure specified in Bid Data Sheet |
|  | 1.3 | All Bidders in attendance shall sign an attendance sheet. |
|  | 1.4 | The Procuring Agency shall open one Bid at a time and read out aloud its contents which may include name of the Bidder and items bided for. The Procuring Agency may choose to announce any other details which it deems appropriate if not in conflict with the SPPR-2013, specifically Rule 41 (Opening of Bids) |
|  | 1.5 | Bids that are not opened and read out at bid opening shall not be considered further for bid evaluation irrespective of the circumstances. |
|  | 1.6 | The Procuring Agency shall have the minutes of the Bid opening (technical and when applicable financial) recorded. |
|  | 1.7 | The financial bid of the non-responsive bidder shall be returned unopened. |
|  | 1.8 | The financial bids without Bid Security being non-responsive shall be returned unannounced to the Bidders. |
| **2. Clarification of Bids** | 2.1 | During evaluation of the bids, the Procuring Agency may, at its discretion, ask the Bidder for a clarification of its bid. The request for clarification and the response shall be in writing, and no change in the prices or substance of the bid shall be sought, offered, or permitted. Except to correct arithmetic errors identified by the Procuring Agency in the evaluation of the bids, |
| **3. Confidentiality** | 3.1 | Information relating to the examination, clarification, evaluation and comparison of bids, and recommendations for the award of a Contract shall not be disclosed to bidders or any other persons not officially concerned with such process until the announcement of bid evaluation report. |
|  | 3.2 | Any effort by the bidder to influence the Procuring Agency in the bid evaluation, bid comparison or contract award decisions may result in the rejection of the Bidder’s bid. Canvassing by any Bidder at any stage of the bid evaluation is strictly prohibited. Any infringement thereto shall lead to rejection of the bid |
|  | 3.3 | From the time of bid opening to the time of Contract award, if any Bidder wishes to contact the Procuring Agency on any matter related to its bid or intends to bring additional information to the notice of the Procuring Agency, it may do so in writing. |
| **4. Examination of Bids and Determination of Responsiveness** | 4.1 | The Procuring Agency shall examine the bids to ascertain as to whether they are complete, free of any computational errors, all required sureties have been attached, all documents have been properly signed, and the bids are generally in order. In the case the bidding process is conducted through prequalified bidders Procuring Agency shall ensure that bidding documents have been issued to the prequalified bidders only and each bid received is from a prequalified Bidder. |
|  | 4.2 | The Procuring Agency may waive any minor informality, nonconformity, or irregularity in a bid which does not impact the substance of the bid and constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any Bidder. |
|  | 4.3 | Prior to the detailed evaluation, the Procuring Agency shall determine whether each bid is of acceptable quality, is complete and is substantially responsive to the Bidding Documents. For purposes of this determination, a substantially responsive bid is one that conforms to all the terms, conditions, and specifications of the Bidding Documents without material deviations, exceptions, objections, conditionality, or reservations. A material deviation, exception, objection, conditionality, or reservation is one that:  changes the substance of the bid  limits in any substantial way the scope, quality or performance of the products and related Services;  limits, in any substantial way that is inconsistent with the Bidding Documents, the Procuring Agency’s rights or the successful Bidder’s obligations under the Contract; and  the acceptance of which would unfairly affect the competitive position of other Bidders who have submitted substantially responsive bids. |
|  | 4.4 | If a bid is not substantially responsive, it shall be rejected by the Procuring Agency and may not subsequently be made responsive by the Bidder by correction of the nonconformity. The Procuring Agency’s determination of a bid’s responsiveness is to be based on the content of the bid itself. |
| **5. Correction of Errors** | 5.1 | In the financial bids the arithmetical errors shall be rectified on the following basis.  a) If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit price shall prevail, and the total price shall be corrected.  b) If the Bidder does not accept the correction of the errors, its bid shall be rejected, and its Bid Security shall be forfeited.  c) If there is a discrepancy between words and figures, the amount in words shall prevail. |
| **6. Evaluation of Bids** | 6.1 | The Procuring Agency shall evaluate and compare the bids that have been determined to be substantially responsive in accordance with ITB Clause 27 above. |
|  | 6.2 | All bids shall be evaluated in accordance with the Evaluation Criteria and other terms and conditions set forth in the bidding documents |
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| **7. Qualification of Bidder** | 7.1 | The Procuring Agency, at any stage of the procurement proceedings, having credible reasons for or prima facie evidence of any defect in Bidder’s capacities may require the Bidder to provide information concerning their professional, technical, financial, legal or managerial competence. Such clarification shall form part of the records of that procurement proceeding |
|  | 7.2 | The Procuring Agency shall disqualify a Bidder if it finds, at any time, that the information submitted by it concerning it’s qualification as Bidder is false, fake and materially incorrect. |
| **8 Announcement of Evaluation Report** | 8.1 | The Procuring Agency shall announce the results of the bid evaluation both technical and financial in the form of a report, as required by Rule 45 of the SPPR-2013 giving justification for acceptance or rejection of bids at least seven days prior to the award of procurement Contract. The unsuccessful bidder may file their grievance petition if any in accordance with rule 31 of SPPR 2013. |

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**TECHNICAL CRITERIA FOR BIDDERS**

1. Experience & Past performance (Government/Non Government)
2. No. of Major Institutions served in the past three years.

* 10…………….. 10
* 5-9………….. 06
* 1-5…………… 05

1. Financial Capability
2. Annual Sales turnover of the firm in the previous 3 years ( in millions)

* 2013
* 2014
* 2015

Average Annual turnover

* Rs.100 Million or above 08
* Rs.50 Million to 100 million 06
* Rs.10 Million to 50 million 04

Certificate from the Bank that Manufacturer is capable of doing business up to (indicate your capabilities)

1. Financial worth of the company.
2. Annual Audited Balance Sheet for 03 years.

* 3 years…………. 10
* 2 years………… 06
* 1 years………… 03

1. Packing and appearance of items.

Sample will be examined as per following parameters of Labeling and packing rules 1986

(Outer Packing, Inner packing)

* Physical appearance
* Excellent 10
* Good 08
* Satisfactory 06
* Not Satisfactory 00

1. LICENSING & REGISTRATION

* Valid Manufacturing License/Authorized dealer 05
* Copy of Registration Certificate from Ministry of DRA 05

1. TAX Registration

* Sales Tax Registration Number/NTN (Mandatory)
* (Attached of registration certificate and detail of sales 08

Tax paid in last 8 years (One mark of Each year)

1. QUALITY CERTIFICATION

* GMP Certification 06

1. Production Capacity

Per day production capacity of quoted items against the total advertised quantity

* Less than 1% 00
* 1% 06
* 1.1% - 1.5% 07
* 1.6% -2 % 08

All bidders qualifying the evaluation criteria shall be eligible to complete and the ranking shall be determined on the basis of their quoted cost.

# SECTION III

General Conditions of Contract

(GCC)

# General Conditions of Contract (GCC)

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| **1. Definitions** | 1.1 | In this Contract, the following terms shall be interpreted as indicated:  (a) “The Contract” means the agreement entered into between the Procuring Agency and the Supplier, as recorded in the Agreement signed by the Parties, including all attachments and appendices thereto and all documents incorporated by reference therein.  (b) “The Contract Price” means the price payable to the Supplier under the Contract for the full and proper performance of its Contractual obligations.  (c) “The Contraceptives” means all those supplies which the Supplier is required to supply to the Procuring Agency under the Contract.  (d) “The Services” means those services ancillary to the supply of above goods, such as printing of special instructions on the label and packing, design and logo of the government of Sindh, transportation of goods upto the desired destinations and other such obligations of the Supplier covered under the Contract.  (e) “GCC” means General Conditions of Contract contained in this section.  (f) “SCC” means Special Conditions of the Contract.  (g) “The Procuring Agency” means the Government of Sindh, (insert department name), Karachi.  (h) “The Supplier” means the individual or firm supplying the contraceptives under this Contract.  (i) “Day” means calendar day.  (j) “Effective Date” means the date on which this Contract becomes effective.  (k) “End User” means the organization(s) where the contraceptives will be used, as named in the SCC.  (l)“The Site,” where applicable, means the place or places named in the SCC |
| **2. Application** | 2.1 | These General Conditions shall apply to the extent that they are not superseded by provisions of other parts of the Contract. |
| **3. Source of Import** | 3.1 | All contraceptives and related services to be supplied under the contract that are required to be imported in Pakistan shall have their origin in eligible source coun­tries as prescribed by the commercial policies of the Government of Pakistan and all expenditures made under the contract shall be limited to such contraceptives and services. |
|  | 3.2 | For purposes of this clause, “origin” means the place where the contraceptives are produced, or the place from which the related services are supplied. Contraceptives are produced when, through manufacturing or processing. |
| **4. Standards** | 4.1 | The contraceptives supplied under this Contract shall conform to the standards mentioned in the Technical Specifications. |
|  | 4.2 | In consideration of the payments to be made by the Procuring Agency to the Supplier as hereinafter mentioned, the Supplier shall be required to provide the contraceptives and Services and to remedy defects therein in conformity in all respects with the provisions of this Contract. |
|  | 4.3 | If the Supplier provide substandard item and fail to provide the fresh supply, the procurement shall be made on the risk and cost of the supplier by the procuring agency. |
|  | 4.4 | In case of supply of substandard product the cost associated with disposal/destruction or handling cost shall be borne by the Supplier. |
| **5. Use of Contract Documents and Information** | 5.1 | The Supplier shall not, without the Procuring Agency’s prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the Procuring Agency in connection therewith, to any person other than a person authorized for this. Disclosure to any such employed person shall be made in confidence and shall extend only as far as may be necessary for purposes of such performance. |
|  | 5.2 | The Supplier shall not, without the Procuring Agency’s prior written consent, make use of any document or information enumerated in GCC except for purposes of performing the Contract. |
|  | 5.3 | Any document, other than the Contract itself, enumerated in GCC shall remain the property of the Procuring Agency and shall be returned (all copies) to the Procuring Agency on completion of the Supplier’s performance under the Contract if so required by the Procuring Agency. |
|  | 5.4 | The Supplier shall permit the Procuring Agency to inspect the Supplier’s accounts and records relating to the performance of the Supplier. |
| **6. Patent Rights** | 6.1 | The Supplier shall indemnify the Procuring Agency against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the contraceptives or any part thereof in the country. |
| **7. Submission of Samples** | 7.1 | Before commencing supplies, the Supplier shall provide samples free of cost, if and as specified in the Schedule of Requirements of the product to the designated office or staff, as the case may be. |
| **8. Ensuring storage arrangements** | 8.1 | To ensure storage arrangements for the intended supplies, the Supplier shall inform the Procuring Agency at least 7 working days in advance. However, in case no space is available at the Procuring Agency’s premises at the time of supply, the Procuring Agency shall, at least 02 working days prior to such situation, shall inform the Supplier, in writing, of the possible time frame of availability of space by which the supplies can be made. In case the Supplier abides by the given time frame it shall not be penalized for delay. |
| **9. Inspections and Tests** | 9.1 | The Procuring Agency or its representative shall have the right to inspect and / or to test the goods in accordance with the procedure given in the SCC to confirm their conformity to the Contract specifications at no extra cost to the Procuring Agency. |
|  | 9.2 | All costs associated with testing shall be borne by the Supplier. |
|  | 9.3 | The Procuring Agency’s right to inspect, test and, where necessary, reject the goods after the goods either at Supplier’s premises or upon arrival at Procuring Agency’s destinations shall in no way be limited or waived by reason of the goods having previously been inspected, tested, and passed by the Procuring Agency or its representative prior to the goods delivery from the point of Supply or manufacturing. |
|  | 94. | The Participants bidder in case participates with commodities manufactured outside Pakistan have to submit valid authorization certificate from the original manufacturer and also certificate that manufacturer is WHO/UNFPA qualified. Further the commodities supplied by such supplier would be tested in each batch from WHO prequalified Lab at the cost and expenses of supplier. |
|  | 9.5 | The local manufacturer which is not WHO prequalified is required to get each batch of the contraceptives tested from Central Drugs Testing Laboratory Karachi as per DRAP standard sampling procedure. However, in case of doubt for quality assurance of locally manufactured contraceptives, the procuring agency reserves the right that it may get any of the supplied batch, lots tested (up to maximum number of 05 batches from WHO accreted lab from the whole consignment on the risk and cost of supplier |
|  | 9.6 | Nothing in GCC Clause 9 shall in any way release the Supplier from any warranty or other obligations under this Contract. |
| **10. Packing** | 10.1 | The Supplier shall provide such packing of the contraceptives as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt and precipitation during transit and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the contraceptives’ final destination and the absence of heavy handling facilities at all points in transit. |
|  | 10.2 | The packing, marking and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the Contract, including additional requirements, if any, specified in the SCC or Technical Specifications, and in any subsequent instructions ordered by the Procuring Agency |
| **11. Delivery and Documents** | 11.1 | The Supplier in accordance with the terms and manner specified in the Schedule of Requirements shall make delivery of the goods. |
|  | 11.2 | The Supplier shall furnish all necessary documentation necessary for completion of the delivery, at the time of delivery and in the manner prescribed. |
|  | 11.3 | The goods supplied under the Contract shall be Delivered at Place (DAP) under which risk is transferred to the buyer and their insurance after the Goods having been delivered |
| **12. Insurance** | 12.1 | The supplier shall be responsible for supply of goods and their insurance at Central Warehouse, Karachi |
| **13. Transportation** | 13.1 | The Supplier shall arrange such transportation of the goods as is required to prevent their damage or deterioration during transit to their final destination and in accordance with the terms and manner prescribed in the Schedule of Requirement |
|  | 13.2 | All costs associated with the transportation of the goods subject to this contract shall be borne by the Supplier. |
| **14. Incidental** **Services** | 14.1 | The Supplier shall be required to provide the incidental services as specified in the SCC and the cost of which is included in the total bid price. |
| **15. Warranty** | 15.1 | All products must be of fresh manufacture and must bear the dates of manufacture and expiry.  The Supplier further warrants that all products supplied under the Contract that have shelf lives will have remaining a minimum of 75% of the specified shelf life upon delivery at port/airport of entry for products with a shelf life of more than two years and three-fourths (3/4) for products with a shelf life of two years or less, unless otherwise specified in the SCC or technical specifications; have “overages” within the ranges set forth in the Technical Specifications, where applicable; are not subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; and in every other respect will fully comply in all respects with the Technical Specifications and with the conditions laid down in the Contract. |
|  | 15.2 | The Procuring Agency shall have the right to make claims under the above warranty for three months after the products have been delivered to the final destination indicated in the Contract. Upon receipt of a written notice from the Procuring Agency, the Supplier shall, promptly, replace the defective products without cost to the Procuring Agency. The Supplier will be required to remove, at his own risk and cost, the defective products once the replacement contraceptives have been delivered |
|  | 15.3 | In case of supply of substandard quality, declared by the Testing Laboratory, the supplier shall be bound to replace the substandard goods. The procuring agency shall reserve the right to proceed against the supplier on account of supply of substandard goods, as per law. |
|  | 15.4 | In the event of a dispute by the Supplier, a counter analysis will be carried out on the manufacturer’s retained samples by an independent neutral laboratory agreed by both the Procuring Agency and the Supplier. If the counter analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective products. The procuring agency shall reserve the right to proceed against the supplier on account of supply of substandard goods, as per law. |
| **16. Payment** | 16.1 | The Respective Procuring Agency shall make payments to supplier in accordance with the conditions set forth in the Payment Schedule agreed and annexed to the contract. |
|  | 16.2 | The payment will be made to the supplier in Pak rupees through a cheque passed in favour of supplier by the office of Accountant General, Sindh. |
|  | 16.3 | All payments shall be made in the currency or currencies specified in the SCC pursuant to GCC 15.4 |
| **17. Prices** | 17.1 | Prices charged by the Supplier for goods delivered under the Contract shall not vary from the prices quoted by the Supplier in its bid and shall remain the same till the expiry of the contract. |
| **18. Contract Amendments** | 18.1 | No variation in or modification of the terms of the Contract shall be made unless supported by force majeure on either of the party. |
| **19. Assignment** | 19.1 | The Supplier shall not assign, in whole or in part, its obligations to perform under this Contract, |
| **20. Subcontracts** | 20.1 | The Supplier shall not be allowed to sublet and award subcontracts under this Contract. |
| **21. Delays in the Supplier’s Performance** | 21.1 | Delivery of the goods shall be made by the Supplier in accordance with the timeline prescribed by the Procuring Agency in the Schedule of Requirements. |
|  | 21.2 | If at any time during performance of the Contract, the Supplier encounters conditions impeding timely delivery of the goods, the Supplier shall promptly notify the Procuring Agency in writing of the fact of the delay, its likely duration and its cause(s). As soon as practicable after receipt of the Supplier’s notice, the Procuring Agency shall evaluate the situation and may at its discretion extend the Supplier’s time for performance, with or without liquidated damages, in which case the extension shall be ratified by the Parties by an amendment to the Contract. |
|  | 21.3 | Except as provided under GCC Clause 24, a delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to the imposition of liquidated damages as prescribed in the SCC, unless the parties to this contract mutually agree for extension of time. |
| **22. Termination for Default** | 22.1 | The Procuring Agency, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, shall terminate the Contract: in case:  if the Supplier fails to deliver any or all installments of the goods within the period(s) specified in the Contract and subsequent purchase order, or within any extension thereof granted by the Procuring Agency pursuant to GCC Clause 21; or  if the contraceptives do not meet the Technical Specifications stated in the Contract; or  if the Supplier fails to provide any registration or other certificates in respect of the contraceptives within the time specified in the Special Conditions.  if the Supplier fails to perform any other obligation(s) under the Contract.  if the Supplier, in the judgment of the Procuring Agency has engaged in corrupt, fraudulent or collusive practices in competing for or in executing the Contract.  For the purpose of this clause Corrupt, fraudulent and collusive practices means:  *the offering, giving, receiving, or soliciting of anything of value to influence the action of a public official or the supplier or contractor in the procurement process or in contract execution to the detriment of the Procuring agencies; or misrepresentation of facts in order to influence a procurement process or the execution of a contract, collusive practices among bidders (prior to or after bid submission) designed to establish bid prices at artificial, non-competitive levels and to deprive the Procuring agencies of the benefits of free and open competition and any request for, or solicitation of anything of value by any public official in the course of the exercise of his duty”*  The PA may also proceed against the supplier on account of its default which may result forfeiture of the performance guaranty and the blacklisting of the supplier |
| **23. Force Majeure** | 23.1 | Notwithstanding the provisions of GCC Clauses 21 and 22, the Supplier shall not be liable for forfeiture of its Performance Guaranty, or termination/ blacklisting for default if and to the extent that it’s delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure. |
|  | 23.2 | For the purposes of this clause Force Majeure means an act of God or an event beyond the control of the Supplier and not involving the Supplier’s fault or negligence directly or indirectly purporting to miss planning, mismanagement and/or lack of foresight to handle the situation. Such events may include but are not restricted to acts of the Procuring Agency in its sovereign capacity, wars or revolutions, fires, floods, earthquakes, strikes, epidemics, quarantine restrictions and freight embargoes. |
|  | 23.3 | If a Force Majeure situation arises, the Supplier shall promptly notify the Procuring Agency in writing with sufficient and valid evidence of such condition and the cause thereof. The Procuring Agency shall examine the merits of the case and all reasonable alternative means for completion of purchase order under the Contract and inform the Supplier of its findings promptly. |
|  | 23.4 | Unless Procuring Agency informs the Supplier in writing of its agreement on the application of force majeure, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably possible. |
| **24. Termination for Insolvency** | 24.1 | In case the Supplier becomes bankrupt or insolvent, the Procuring Agency may at any time terminate the Contract by giving written notice of reasonable time which will not be less than 15 days to the Supplier In this event, termination shall be without compensation to the Supplier, provided that such termination shall not prejudice or affect any right of action or remedy which has accrued or shall accrue thereafter to the Parties. |
| **25. Termination for Convenience** | 25.1 | The Procuring Agency, by written notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time on administrative grounds. The notice of termination shall specifically mention, the extent to which performance of the Supplier under the Contract is terminated and the date upon which such termination becomes effective. |
|  | 25.2 | The contraceptives that are complete and ready for shipment within thirty (30) days after the Supplier’s receipt of notice of termination shall be accepted by the Procuring Agency at the Contract terms and prices. For the remaining goods, the Procuring Agency may elect:  (a) to have any portion completed and delivered at the Contract terms and prices; and/or  (b) to cancel the remainder and pay to the Supplier an agreed amount for partially completed goods and Services and for materials and parts previously procured by the Supplier. |
| **26. Arbitration and Resolution of Disputes** | 26.1 | The Procuring Agency and the Supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the Contract. |
|  | 26.2 | If, after thirty (30) days from the commencement of such informal negotiations, the Procuring Agency and the Supplier have been unable to resolve amicably a Contract dispute, either party may require that the dispute be referred to the Arbitrator for resolution through arbitration |
|  | 26.3 | In case of any dispute concerning the interpretation and/or application of this Contract shall be settled through arbitration under the Arbitration Act of 1940 (As amended from time to time).  Administrative secretary of the PA shall act as an arbitrator. |
| **27. Limitation of Liability** | 27.1 | Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 7,  (a) the Supplier shall not be liable to the Procuring Agency, whether in contract, tort or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the Supplier to pay liquidated damages to the Procuring Agency; and  (b) the aggregate liability of the Supplier to the Procuring Agency, whether under the Contract, in tort or otherwise, shall not exceed the total Contract Price, provided that this limitation shall not apply to the cost of replacing defective goods. |
| **28. Governing** **Language** | 28.1 | The Contract shall be written in English language. Subject to GCC Clause 31, the version of the Contract written in the specified language shall govern its interpretation. All correspondence and other documents pertaining to the Contract, which are exchanged by the Parties, shall be written in English. |
| **29. Applicable** **Law** | 29.1 | This Contract shall be governed by the Laws of Pakistan and the courts of Pakistan shall have exclusive jurisdiction. |
| **30. Notices** | 30.1 | Any Notice given by one party to the other pursuant to the provision of the Contract shall be sent to the other party in writing and on the others address specified in SCC. |
|  | 30.2 | A notice shall be effective when delivered or on the notice’s effective date, whichever is later. |
| **31. Taxation** | 31.1 | All taxation, whether International, Federal, Provincial or Local, shall be borne by the Supplier. |

# SECTION IV

Special Conditions of Contract

(SCC)

# Special Conditions of Contract (SCC)

The following Special Conditions of Contract shall supplement the General Conditions of Contract. Whenever there is a conflict, the provisions herein shall prevail over those in the General Conditions of Contract. The corresponding clause number of the GCC is indicated in parentheses.

|  |  |  |
| --- | --- | --- |
| **1. The Contract** | 1.1 | The following documents shall be deemed to form and be read and construed as integral part of the Contract ,:-  the Schedule of Requirements.  the Technical Specifications.  the Price Schedule submitted by the Bidder.  the Procuring Agency’s Notification of Award.  the Purchase Order  the General Conditions of Contract  Special Conditions of Contract |
|  | 1.2 | Population Welfare Department, Sindh, will sign individual with a selected bidders separately against the indicated quantities. |
|  | 1.3 | The Contract words and expression shall have the same meaning as are respectively assigned to them in the General Conditions of Contract. |
|  |  |  |
|  | 1.4 | The contract is to be made on stamp paper worth of one hundred rupees |
| **2. Supplier’s declaration** | 2.1 | *The supplier shall provide integrity pact signed by the supplier and the PA.* |
|  | 2.2 | *[The Supplier]* certifies that it has made and shall make full disclosure of all agreements and arrangements with all persons in respect of or related to the transaction with Government of Sindh and has not taken any action or shall not take any action to circumvent the above declaration, representation or warranty |
|  | 2.3 | *[The Supplier]* accepts full responsibility and strict liability for making any false declaration, not making full disclosure, misrepresenting facts or taking any action likely to defeat the purpose of this declaration, representation and warranty. It agrees that any Contract, right, interest, privilege or other obligation or benefit obtained or procured as aforesaid shall, without prejudice to any other right and remedies available to Procuring Agency under any law, Contract or other instrument, be void able at the option of Procuring Agency. |
|  | 2.4 | Notwithstanding any rights and remedies exercised by Procuring Agency in this regard, *[The Supplier]* agrees to indemnify Procuring Agency for any loss or damage incurred by it on account of its corrupt business practices and further pay compensation to Procuring Agency in an amount equivalent to ten time the sum of any commission, gratification, bribe, finder’s fee or kickback given by *[The Supplier]* as aforesaid for the purpose of obtaining or inducing the procurement of any Contract, right, interest, privilege or other obligation or benefit in whatsoever form from Procuring Agency |
|  | 2.5 | In case of any dispute concerning the interpretation and/or application of this Contract shall be settled through arbitration. The Additional Chief Secretary or his nominee shall act as sole arbitrator. The decisions taken and/or award made by the sole arbitrator shall be final and binding on the Parties |
| **3. Price** | 3.1 | The Supplier shall provide to the Procuring Agency the items on the agreed cost more specifically described in the Price Schedule Submitted by the Bidder Bid form 5(A) |
|  | 3.2 | Each Items supplied shall strictly conform to the Schedule of Requirements (Section V) and to the Technical Specification (Section VI) prescribed by the Procuring Agency against each item |
|  | 3.3 | The Unit Cost agreed in the Price Schedule Bid form 5(A) , is inclusive of all taxation and costs associated with transportation and other agreed incidental costs |
| **4. Payments** | 4.1 | The Procuring Agency shall make the payment to the Supplier in consideration of the provision of the Goods and Services, as specified in the Schedule of Requirements and Technical Specification in accordance with the Price Schedule submitted by the Supplier, the amount against the delivered items or such other sum as may become payable under the provisions of this Contract at the time and in the manner prescribed by this Contract |
|  | 4.2 | i) In case of locally manufactured items 100% payment shall be made upon receipt of successful delivery after inspection .  All payments to the Supplier shall be made through Crossed Cheque issued in the name of *[supplier’s name]* |
|  | 4.3 | All payments to the Supplier shall be made in accordance with the agreed Payment Schedule upon satisfactory completion of delivery and fulfillment of documentary and Codal formalities highlighted in the Payment Schedule. |
| **5. Performance Guarantee** | 5.1 | The Supplier, 07 days prior to signing of this contract, shall provide to the Procuring Agency a Performance Guarantee equivalent to 5% of the Contract amount on the prescribed format and in prescribed manner. This Performance Guarantee shall be released to the Supplier upon successful completion of the Contract and within 30 days after the final payment |
|  | 5.2 | Supplier’s Bid Security already submitted with the Bid shall only be released upon satisfactory submission of a Performance Guarantee in accordance with sub-clause (i) above |
|  | 5.3 | Failure to submit a Performance Guarantee shall result into forfeiture of Bid Security and Cancellation of Contract and initiation of blacklisting procedure. |
| **6. Inspections & Tests** | 6.1 | Local manufacturers will provide acceptable quality test from Central Drugs Authority. |
| **7. Penalties/ Liquidated Damages** | 7.1 | In case the Supplier fails to make deliveries as per purchase order and within the time frame as stipulated in the Schedule of Requirement, proceedings shall be initiated against the defaulter which may result into forfeiture of the performance guarantee and blacklisting of the supplier. |
|  | 7.2 | In case of delay in delivery of goods beyond the periods specified in the Schedule of Requirements and subsequent purchase order, a penalty @ 0.067% per day of the cost of late delivered supply shall be imposed upon the Supplier. |
| **8. Notices** | 8.1 | Secretary  Population Welfare Department, Government of Sindh,  39 – Z/1, Block 6, PECHS  Karachi, Pakistan  Phone: +92-21-34525675  Fax: +92-21- 34522644 |
| **9. Packing** | 9.1 | Any necessary additional requirements with respect to packing and marking or state that additional requirements are indicated in the Technical Specifications.  All packing (which includes unit, master carton, and shipping carton) must have the following printed wording in appropriate size and at place.  “Not for Sale –Govt. of Sindh Property”.  (*printed in green color along with Sindh government logo as per sample approved by Procuring Agency*).  GS1 health commodities standard data matrix bar code must be included in primary as well as secondary packing.  Make table for all packing aligning with specifications |
| **10. Delivery and Documents** | 10.1 | Three originals and two copies of the Supplier’s invoice, showing Procuring Agency as Department of Health/Population Welfare Department, Government of Sindh, Pakistan; the Contract number, contraceptives description, quantity, unit price and total amount. Invoices must be signed in original, stamped, or sealed with the company stamp/seal; |
|  | 10.3 | In the event that the documents presented by the Supplier are not in accordance with the Contract, then payment will be made against issue of the Acceptance Certificate, to be issued in accordance with SCC 6 above |

# Section V

Schedule of Requirements

# SCHEDULE OF REQUIREMENTS

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **#** | **Products** | **Quantity** | **Total Delivery period** | **Shelf life minimum** | **Place of delivery** |
| 1 | COC (cycles) | 7,029,343 | 45 Day | 75% | CWH, Karachi |
| 2 | POP (cycles | 179,847 | -do- | 75% | CWH, Karachi |
| 3 | ECP  (Pack of 2 tabs) | 50,596 | -do- | 75% | CWH, Karachi |
| 4. | Injectable DMPA (3 month) with syringe | 2,217,574 | -do- | 75% | CWH, Karachi |
| 5 | Injectable  (2 month) with syringe | 7,631 | -do- | 75% | CWH, Karachi |
| 6. | Syringes 5 ml | 2,015,977 | -do- | -do- | -do- |

## Mode of Penalty

Late delivery charges/penalty @ 0.067 % per day after 30 days after each installment delivery period.

# Section VI

# Technical Specifications

## Technical Specification - Oral Contraceptive

### (Combined oral contraceptive pill)

Information for submission of samples

The sample oral contraceptives submitted by the Bidder in response to this Invitation for Bids must be exactly the same[[1]](#footnote-1) as would be supplied if a contract were awarded to the Bidder. The packets containing the product need not have a printed logo as stipulated under Clause 1.12 of this specification; however, other information as stipulated under the aforementioned clause must be furnished. For sample submission only, this information (logo optional) may be printed on a sticker and affixed to the packets containing the product. The Procuring Agency should replace italics with the actual requirements of the contraceptive to be procured.

1. Requirements

Oral contraceptive tablets in accordance with the following specifications:

* Twenty-eight (28)-day cycle package consisting of twenty-one (21) oral contraceptive norgestrel and ethinyl estradiol tablets and seven (7) ferrous fumarate tablets.
* Contraceptive tablets: 21
  + Each tablet shall contain 0.03 mg of ethinyl estradiol and 0.3 mg of norgestrel.
* Spacing tablets: 7
  + Each tablet shall contain 75 mg ferrous fumarate.

1.1 Product and Brand Names

Product name: ………………………………………………………………………

Brand names: ……………………………………………………………………….

Registration Number: ……………………………………………………………….

1.2 Raw Materials

Oral contraceptives offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor.[[2]](#footnote-2)

1.3 Registration Requirements

Oral contraceptives offered under this purchase description shall be currently registered in Pakistan and approved by the Ministry of Health under the Drugs Act, 1976.

1.4 Certificate of Registration Status in Country of Origin (in case of imported drugs)

Oral contraceptives offered under this purchase description shall be licensed for marketing   
by the drug regulatory authority of the country of origin. Prior to award of the Contract,   
the successful offeror(s) may be required to submit a “statement of licensing status of   
pharmaceutical product(s)” as provided under the World Health Organization (WHO)   
Certification Scheme on the Quality of Pharmaceutical Products Moving in International   
Commerce.[[3]](#footnote-3)

1.5 Compliance with Current Good Manufacturing Practices

The Supplier must be able to provide certification that the oral contraceptives are manufactured according to WHO current good manufacturing practices (cGMPs). Such certification can be found in the WHO Certification Scheme “Certificate of Pharmaceutical Product.” Supplier also must be able to provide copies of its annual cGMP audit reports conducted by the local Drug Regulatory Authority.

1.6 WHO Certification—Movement in International Commerce (For imported products)

The Supplier must be able to provide documentation indicating that the manufacturer of the product has received confirmation from the Ministry of Health of the country of manufacture that the pharmaceutical meets the requirements in the WHO Certification Scheme.

1.7 Shape and Dimensions

Tablets shall be of the shape and dimensions of the Bidder’s normal, standard commercial tablets which are available in the local market.

1.8 Colors

Contraceptive and ferrous fumarate (or inert, if applicable) tablets shall be similar to Bidder’s normal, standard commercial tablets.

1.9 Tablet Markings

Each tablet shall bear the identifying imprint of its manufacturer.

1.10 Packaging

1.10.1 Monthly Cycle Presentation

Each individual tablet shall be enclosed in a transparent blister pack of thermoformed polymer, with a minimum thickness of 0.1905 mm (.0075 inch) backed with aluminum foil, minimum thickness 0.0178 mm (0.0007 inch). Variations must be proven scientifically comparable by means of stability data.

The size of the package shall not be less than 57.15 mm (2.25 inches) x 82.55 mm (3.25 inches). Thicker polymer or foil or the addition of a card to either the front or the back of the package (in addition to the minimum polymer or foil) is acceptable.

1.10.2 Mounting

Tablets shall be mounted on four (4) rows of seven (7) tablets per row. Contraceptive tablets shall precede the ferrous fumarate tablets (or inert tablets, if applicable).

1.11 Identification Markings on Individual Blister Packs

Each individual blister pack shall have the following information:

* Product/brand name
* Lot/batch number
* Expiration date (day, month and year)
* Date of manufacture
* Manufacturer’s name and address
* Arrow indicating sequence of tablets
* Contents and quantity, including tablet formulation (amounts of active ingredients per tablet)
* Drug registration number (if applicable)
* Family planning logo (if applicable)
* Drug Manufacturing License Number
* Product use and storage instructions (accompanying the blister pack).

1.11.1 Printing and Layout

On the front of each monthly cycle above the first row of tablets and in the left-hand corner, the trade or brand name of the product shall be printed in full. In parentheses, in reduced lettering (smallest type no less than 1 mm high) and below the product or brand name, shall be printed “Family Planning Pills.” Sequence of administration shall be clearly indicated by an arrow/line pathway on the unit.

The day, month and year of expiration shall be shown in the following format DD/MM/YY. The lot/control number shall be shown in English numerals. Debossing is acceptable for these numbers.

The tablet formulation and a “copy control code” (evidence that artwork/packaging has been approved by all parties) shall be printed on the individual packet and may be printed on the reverse side (smallest type no less than 1 mm high).

1.11.2 Colour

Background colour shall be the natural colour of the aluminum foil on the face, with a   
dark blue (PMS Blue 301) stripe across the top and the “Blue Lady” symbol depicted to the right but within the blue stripe. The reverse of the individual packet will not be inked except for necessary printing.

1.12 Workmanship

Products and packaging shall be free of defects that impair their serviceability, affect their durability, or detract from their appearance.

1.13 Lots per Order

The Supplier shall fill the order using the fewest number of manufacturing lots possible.

1.14 Shelf Life

The shelf life of the product provided under this solicitation shall be five (5) years from the date of manufacture when stored under tropical conditions such as those prevailing in the local environment. The Supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer’s stability test data substantiating this five (5) year shelf life at ambient temperatures at or greater than 32 degrees Celsius and at a relative humidity of 85% in the proposed blister package.

At the time of inspection or acceptance for delivery to the country of destination, no more than nine (9) months shall have expired since the date of manufacture shown on the batch release or Certificate of Analysis.

1.16 Test Data

Chemical and physical test data for raw materials, components in-process and finished product testing must be on record for each lot manufactured and must be available to Procuring Agency’s representatives when requested.

2. Quality Assurance Provisions

2.1 Compliance

The Supplier shall guarantee that the products as packed for supply comply with all provisions of the specifications and related documents.

2.2 Documentation

2.2.1 The Supplier shall provide evidence[[4]](#footnote-4) of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided.

2.2.2 The Supplier shall provide a copy of the manufacturing record and procedures to the Procuring Agency for each lot intended for supply.

2.2.3 The Supplier shall provide a copy of the Certificate of Analysis to the Procuring Agency for each lot intended for supply.

2.2.4 The Supplier shall provide to the Procuring Agency a copy of the approval of each component for each lot intended for supply.

2.3 Inspection by the Procuring Agency

The Procuring Agency reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Technical Specifications and Special Conditions of Contract to ensure that the goods conform to prescribed requirements. The Procuring Agency reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to supply of the goods and to draw samples from the Supplier’s factory and/ or warehouse for test analysis. Except as otherwise specified in the Contract or purchase order, prior to supply, the Procuring Agency will sample, or cause to be sampled, the product as packed in inner boxes preparatory to packing in exterior shipping cartons. The sampling shall be according to recognized standards.[[5]](#footnote-5)

The Procuring Agency may have some or all of the tests specified in the Technical Specifications   
(Dossier) of the Contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on pharmaceutical products according to the Pharmacopoeia   
specification.

2.4 Sampling Procedures

The Procuring Agency, or the Procuring Agency’s representative, shall select the required samples from the lot according to the Special Conditions of Contract. If the order is to be filled using more than one production lot, each production lot shall be separately sampled and tested.

The normal, tightened and reduced inspection provisions of ISO 2859 (Inspection by Attributes) may be used for visual inspection. Sampling for analytical testing shall be done in accordance with pharmacopoeial requirements.

All sampled boxes and supply cartons shall be so marked and shall include the date and initials of the sampler.

2.5 Sample Retention

The Supplier shall retain a sample of ten (10) cycles, or the equivalent required to perform three (3) complete chemical assays, from each lot shipped, for a period of one (1) year after the printed expiration date.

3. Packing

3.1 Inner Boxes

3.1.1 Products sealed in individual packets as specified in Section 1.11 shall be packed in inner boxes of one hundred (100) cycles.[[6]](#footnote-6)

Inner boxes shall be made of light fiberboard (white) of a size sufficient to contain the specified number of cycles. The overall dimensions should be such that the product does not get damaged during transportation and storage.

3.1.2 For inner boxes, the Bidder shall fill in the blanks provided below:

Each inner box will contain one hundred (100) cycles. The overall dimensions of a box will be cm x cm x cm.

3.2 Exterior Shipping Cartons

3.2.1 Product and printed materials, packaged and packed as specified above, shall be   
contained in triple-wall corrugated fiberboard cartons made from weather-resistant   
fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall   
be secured with water-resistant adhesive applied to not less than 75% of the area of contact   
between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the   
center seams and extending over the ends not less than 75 mm[[7]](#footnote-7). Plastic strapping shall be   
placed around the carton, with a minimum of two crossing bands. Cartons exceeding 760   
mm (30 inches) in length shall have additional bands placed around the carton.

3.2.2 The Bidder shall fill in the following blanks:

The exterior shipping carton will contain inner boxes. The overall dimensions of a carton will be cm x cm x cm, and the gross weight of one shipping carton will be kg.

A standard 6.096-meter (20-foot) container will accommodate exterior shipping cartons.

3.3 Markings

3.3.1 Inner Boxes

The inner boxes shall be marked with the following information in a clearly legible manner that is acceptable to the Procuring Agency[[8]](#footnote-8):

* Product/brand name
* Drug Manufacturing License Number
* Lot/batch number
* Expiration date (day, month and year)
* Date of manufacture
* Manufacturer’s name and address
* Contents and quantity
* Drug registration numbers (if applicable)
* Instructions for storage and handing

3.3.2 Exterior Supply Cartons

The following information shall be stenciled or labeled on the exterior supply cartons on two opposing sides in bold letters at least ………..mm high with waterproof ink in a clearly legible manner that is acceptable to the Procuring Agency.[[9]](#footnote-9)

Regulatory information (on two opposing sides of carton)

* Product/brand name
* Drug Manufacturing License Number
* Lot/batch number
* Expiration date (day, month and year)
* Date of manufacture
* Manufacturer’s name and address
* Contents and quantity
* Drug registration numbers (if applicable)
* Instructions and symbols for storage and handling, such as KEEP DRY or DO NOT FREEZE

3.4 Printed Materials—Product Information Sheets

3.4.1 Consumer information and directions for use shall be printed in English and/or in and provided as package inserts, one copy for each consumer unit. All copies are to be accumulated, fastened together and included in each exterior supply carton.

3.4.2 Information for physicians’ use shall be printed in English and/or in Urdu. Two copies of such information shall be provided for each one thousand two hundred (1,200) monthly cycles and shall be placed in each exterior supply carton.

Inspection Sampling and Testing—Oral Contraceptives

Prior to shipment, the Procuring Agency or its appointed representative has the right to sample and inspect each consignment of oral contraceptives at the factory or Supplier’s warehouse in accordance with ISO 2859 Inspection by Attributes (or WHO specifications) and Technical Specification of this Contract.

1.1 Packaging, Packing and Markings

1. One hundred percent (100%) of the exterior supply cartons will be examined for:

* General physical characteristics and condition.
* Markings per Technical Specification

1. A representative sample of the inner boxes and individual packages will be drawn from the exterior supply cartons at General Inspection Level II, or, at the discretion of the Procuring Agency, General Inspection Level III, and Single Sampling Plan for Normal Inspection.
2. The sample will be examined for:

* General physical characteristics per Technical Specification, Section
* Markings per Technical Specification, Section

1. Inspection criteria and classification of defects shall follow the inspection guidelines outlined in Section 1.4 below. For critical defects, the acceptable quality limit (AQL) shall be 0%; for major defects, the AQL shall be 1%; for minor defects, the AQL shall be 4%.

1.2 Tablet

At the discretion of the Procuring Agency, part of the selected sample may be sent to a qualified government drug testing laboratory for physical and chemical testing as follows.

Pharmacopoeial tests:

* Identification
* Assay of active ingredient(s)
* Content uniformity
* Disintegration and/or dissolution
* Uniformity of mass (not required if content uniformity test performed)

Non-pharmacopoeial tests:

* Package seal integrity test.[[10]](#footnote-10)

A Certificate of Analysis for production lot(s) shall be made available to the inspector and/ or Procuring Agency upon request. The certificate shall state all tests performed, their specifications, and actual test results obtained. All pharmacopoeial test results shall meet applicable pharmacopoeial limits.

1.3 Resolution of Defects

1. Packaging, Packing, and Markings
   * Defects in exterior shipping carton markings must be corrected by the Supplier prior to supply.
   * All goods from corresponding production lots with inspection lot defect in excess of the AQLs listed in Section 1.4 of this specification must be corrected and re-inspected at Supplier’s expense or rejected.
2. Tablet

* Any deviation from the manufacturer’s Certificate of Analysis, product specifications,

Or   
relevant pharmacopoeial limits shall result in rejection of goods from the entire production lot.

Technical Specification - Oral Contraceptive

### (Progestogen only oral contraceptive pill)

Information for submission of samples

The sample oral contraceptives submitted by the Bidder in response to this Invitation for Bids must be exactly the same[[11]](#footnote-11) as would be supplied if a contract were awarded to the Bidder. The packets containing the product need not have a printed logo as stipulated under Clause 1.12 of this specification; however, other information as stipulated under the aforementioned clause must be furnished. For sample submission only, this information (logo optional) may be printed on a sticker and affixed to the packets containing the product. The Procuring Agency should replace italics with the actual requirements of the contraceptive to be procured.

1. Requirements

Oral contraceptive tablets in accordance with the following specifications:

* Twenty-eight (28)-day cycle package consisting of twenty-eight (28) oral contraceptive progestogen only tablets (insert active ingredient).
* Contraceptive tablets: 28
  + Each tablet shall contain (insert quantity of active ingredient).

.

1.1 Product and Brand Names

Product name: ………………………………………………………………………

Brand names: ……………………………………………………………………….

Registration Number: ……………………………………………………………….

1.2 Raw Materials

Oral contraceptives offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor.[[12]](#footnote-12)

1.3 Registration Requirements

Oral contraceptives offered under this purchase description shall be currently registered in Pakistan and approved by the Ministry of Health under the Drugs Act, 1976.

1.4 Certificate of Registration Status in Country of Origin (in case of imported drugs)

Oral contraceptives offered under this purchase description shall be licensed for marketing   
by the drug regulatory authority of the country of origin. Prior to award of the Contract,   
the successful offeror(s) may be required to submit a “statement of licensing status of   
pharmaceutical product(s)” as provided under the World Health Organization (WHO)   
Certification Scheme on the Quality of Pharmaceutical Products Moving in International   
Commerce.[[13]](#footnote-13)

1.5 Compliance with Current Good Manufacturing Practices

The Supplier must be able to provide certification that the oral contraceptives are manufactured according to WHO current good manufacturing practices (cGMPs). Such certification can be found in the WHO Certification Scheme “Certificate of Pharmaceutical Product.” Supplier also must be able to provide copies of its annual cGMP audit reports conducted by the local Drug Regulatory Authority.

1.6 WHO Certification—Movement in International Commerce (For imported products)

The Supplier must be able to provide documentation indicating that the manufacturer of the product has received confirmation from the Ministry of Health of the country of manufacture that the pharmaceutical meets the requirements in the WHO Certification Scheme.

1.7 Shape and Dimensions

Tablets shall be of the shape and dimensions of the Bidder’s normal, standard commercial tablets which are available in the local market.

1.8 Colors

Contraceptive and ferrous fumarate (or inert, if applicable) tablets shall be similar to Bidder’s normal, standard commercial tablets.

1.9 Tablet Markings

Each tablet shall bear the identifying imprint of its manufacturer.

1.10 Packaging

1.10.1 Monthly Cycle Presentation

Each individual tablet shall be enclosed in a transparent blister pack of thermoformed polymer, with a minimum thickness of 0.1905 mm (.0075 inch) backed with aluminum foil, minimum thickness 0.0178 mm (0.0007 inch). Variations must be proven scientifically comparable by means of stability data.

The size of the package shall not be less than 57.15 mm (2.25 inches) x 82.55 mm (3.25 inches). Thicker polymer or foil or the addition of a card to either the front or the back of the package (in addition to the minimum polymer or foil) is acceptable.

1.10.2 Mounting

Tablets shall be mounted on four (4) rows of seven (7) tablets per row. Contraceptive tablets shall precede the ferrous fumarate tablets (or inert tablets, if applicable).

1.11 Identification Markings on Individual Blister Packs

Each individual blister pack shall have the following information:

* Product/brand name
* Lot/batch number
* Expiration date (day, month and year)
* Date of manufacture
* Manufacturer’s name and address
* Arrow indicating sequence of tablets
* Contents and quantity, including tablet formulation (amounts of active ingredients per tablet)
* Drug registration number (if applicable)
* Family planning logo (if applicable)
* Drug Manufacturing License Number
* Product use and storage instructions (accompanying the blister pack).

1.11.1 Printing and Layout

On the front of each monthly cycle above the first row of tablets and in the left-hand corner, the trade or brand name of the product shall be printed in full. In parentheses, in reduced lettering (smallest type no less than 1 mm high) and below the product or brand name, shall be printed “Family Planning Pills.” Sequence of administration shall be clearly indicated by an arrow/line pathway on the unit.

The day, month and year of expiration shall be shown in the following format DD/MM/YY. The lot/control number shall be shown in English numerals. Debossing is acceptable for these numbers.

The tablet formulation and a “copy control code” (evidence that artwork/packaging has been approved by all parties) shall be printed on the individual packet and may be printed on the reverse side (smallest type no less than 1 mm high).

1.11.2 Colour

Background colour shall be the natural colour of the aluminum foil on the face, with a   
dark blue (PMS Blue 301) stripe across the top and the “Blue Lady” symbol depicted to the right but within the blue stripe. The reverse of the individual packet will not be inked except for necessary printing.

1.12 Workmanship

Products and packaging shall be free of defects that impair their serviceability, affect their durability, or detract from their appearance.

1.13 Lots per Order

The Supplier shall fill the order using the fewest number of manufacturing lots possible.

1.14 Shelf Life

The shelf life of the product provided under this solicitation shall be five (5) years from the date of manufacture when stored under tropical conditions such as those prevailing in the local environment. The Supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer’s stability test data substantiating this five (5) year shelf life at ambient temperatures at or greater than 32 degrees Celsius and at a relative humidity of 85% in the proposed blister package.

At the time of inspection or acceptance for delivery to the country of destination, no more than nine (9) months shall have expired since the date of manufacture shown on the batch release or Certificate of Analysis.

1.16 Test Data

Chemical and physical test data for raw materials, components in-process and finished product testing must be on record for each lot manufactured and must be available to Procuring Agency’s representatives when requested.

2. Quality Assurance Provisions

2.1 Compliance

The Supplier shall guarantee that the products as packed for supply comply with all provisions of the specifications and related documents.

2.2 Documentation

2.2.1 The Supplier shall provide evidence[[14]](#footnote-14) of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided.

2.2.2 The Supplier shall provide a copy of the manufacturing record and procedures to the Procuring Agency for each lot intended for supply.

2.2.3 The Supplier shall provide a copy of the Certificate of Analysis to the Procuring Agency for each lot intended for supply.

2.2.4 The Supplier shall provide to the Procuring Agency a copy of the approval of each component for each lot intended for supply.

2.3 Inspection by the Procuring Agency

The Procuring Agency reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Technical Specifications and Special Conditions of Contract to ensure that the goods conform to prescribed requirements. The Procuring Agency reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to supply of the goods and to draw samples from the Supplier’s factory and/ or warehouse for test analysis. Except as otherwise specified in the Contract or purchase order, prior to supply, the Procuring Agency will sample, or cause to be sampled, the product as packed in inner boxes preparatory to packing in exterior shipping cartons. The sampling shall be according to recognized standards.[[15]](#footnote-15)

The Procuring Agency may have some or all of the tests specified in the Technical Specifications   
(Dossier) of the Contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on pharmaceutical products according to the Pharmacopoeia   
specification.

2.4 Sampling Procedures

The Procuring Agency, or the Procuring Agency’s representative, shall select the required samples from the lot according to the Special Conditions of Contract. If the order is to be filled using more than one production lot, each production lot shall be separately sampled and tested.

The normal, tightened and reduced inspection provisions of ISO 2859 (Inspection by Attributes) may be used for visual inspection. Sampling for analytical testing shall be done in accordance with pharmacopoeial requirements.

All sampled boxes and supply cartons shall be so marked and shall include the date and initials of the sampler.

2.5 Sample Retention

The Supplier shall retain a sample of ten (10) cycles, or the equivalent required to perform three (3) complete chemical assays, from each lot shipped, for a period of one (1) year after the printed expiration date.

3. Packing

3.1 Inner Boxes

3.1.1 Products sealed in individual packets as specified in Section 1.11 shall be packed in inner boxes of one hundred (100) cycles.[[16]](#footnote-16)

Inner boxes shall be made of light fiberboard (white) of a size sufficient to contain the specified number of cycles. The overall dimensions should be such that the product does not get damaged during transportation and storage.

3.1.2 For inner boxes, the Bidder shall fill in the blanks provided below:

Each inner box will contain one hundred (100) cycles. The overall dimensions of a box will be cm x cm x cm.

3.2 Exterior Shipping Cartons

3.2.1 Product and printed materials, packaged and packed as specified above, shall be   
contained in triple-wall corrugated fiberboard cartons made from weather-resistant   
fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall   
be secured with water-resistant adhesive applied to not less than 75% of the area of contact   
between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the   
center seams and extending over the ends not less than 75 mm[[17]](#footnote-17). Plastic strapping shall be   
placed around the carton, with a minimum of two crossing bands. Cartons exceeding 760   
mm (30 inches) in length shall have additional bands placed around the carton.

3.2.2 The Bidder shall fill in the following blanks:

The exterior shipping carton will contain inner boxes. The overall dimensions of a carton will be cm x cm x cm, and the gross weight of one shipping carton will be kg.

A standard 6.096-meter (20-foot) container will accommodate exterior shipping cartons.

3.3 Markings

3.3.1 Inner Boxes

The inner boxes shall be marked with the following information in a clearly legible manner that is acceptable to the Procuring Agency[[18]](#footnote-18):

* Product/brand name
* Drug Manufacturing License Number
* Lot/batch number
* Expiration date (day, month and year)
* Date of manufacture
* Manufacturer’s name and address
* Contents and quantity
* Drug registration numbers (if applicable)
* Instructions for storage and handing

3.3.2 Exterior Supply Cartons

The following information shall be stenciled or labeled on the exterior supply cartons on two opposing sides in bold letters at least ………..mm high with waterproof ink in a clearly legible manner that is acceptable to the Procuring Agency.[[19]](#footnote-19)

Regulatory information (on two opposing sides of carton)

* Product/brand name
* Drug Manufacturing License Number
* Lot/batch number
* Expiration date (day, month and year)
* Date of manufacture
* Manufacturer’s name and address
* Contents and quantity
* Drug registration numbers (if applicable)
* Instructions and symbols for storage and handling, such as KEEP DRY or DO NOT FREEZE

3.4 Printed Materials—Product Information Sheets

3.4.1 Consumer information and directions for use shall be printed in English and/or in and provided as package inserts, one copy for each consumer unit. All copies are to be accumulated, fastened together and included in each exterior supply carton.

3.4.2 Information for physicians’ use shall be printed in English and/or in Urdu. Two copies of such information shall be provided for each one thousand two hundred (1,200) monthly cycles and shall be placed in each exterior supply carton.

Inspection Sampling and Testing—Oral Contraceptives

Prior to shipment, the Procuring Agency or its appointed representative has the right to sample and inspect each consignment of oral contraceptives at the factory or Supplier’s warehouse in accordance with ISO 2859 Inspection by Attributes (or WHO specifications) and Technical Specification of this Contract.

1.1 Packaging, Packing and Markings

1. One hundred percent (100%) of the exterior supply cartons will be examined for:

* General physical characteristics and condition.
* Markings per Technical Specification

1. A representative sample of the inner boxes and individual packages will be drawn from the exterior supply cartons at General Inspection Level II, or, at the discretion of the Procuring Agency, General Inspection Level III, and Single Sampling Plan for Normal Inspection.
2. The sample will be examined for:

* General physical characteristics per Technical Specification, Section
* Markings per Technical Specification, Section

1. Inspection criteria and classification of defects shall follow the inspection guidelines outlined in Section 1.4 below. For critical defects, the acceptable quality limit (AQL) shall be 0%; for major defects, the AQL shall be 1%; for minor defects, the AQL shall be 4%.

1.2 Tablet

At the discretion of the Procuring Agency, part of the selected sample may be sent to a qualified government drug testing laboratory for physical and chemical testing as follows.

Pharmacopoeial tests:

* Identification
* Assay of active ingredient(s)
* Content uniformity
* Disintegration and/or dissolution
* Uniformity of mass (not required if content uniformity test performed)

Non-pharmacopoeial tests:

* Package seal integrity test.[[20]](#footnote-20)

A Certificate of Analysis for production lot(s) shall be made available to the inspector and/ or Procuring Agency upon request. The certificate shall state all tests performed, their specifications, and actual test results obtained. All pharmacopoeial test results shall meet applicable pharmacopoeial limits.

1.3 Resolution of Defects

1. Packaging, Packing, and Markings
   * Defects in exterior shipping carton markings must be corrected by the Supplier prior to supply.
   * All goods from corresponding production lots with inspection lot defect in excess of the AQLs listed in Section 1.4 of this specification must be corrected and re-inspected at Supplier’s expense or rejected.
2. Tablet

* Any deviation from the manufacturer’s Certificate of Analysis, product specifications,

Or   
relevant pharmacopoeial limits shall result in rejection of goods from the entire production lot.

## Technical Specifications - Injectable Contraceptives with Syringe (3 months)

Information for Submission of Samples

The sample injectable contraceptives submitted by the Bidder in response to this Invitation for Bids must be exactly the same as would be supplied if a contract were awarded to the Bidder.[[21]](#footnote-21)The vial or ampoule containing the product need not have a printed logo; however, other information as stipulated under Clause 1.11 of this specification must be furnished. For sample submission only, this information (logo optional) may be printed on a sticker and affixed to the vials or ampoules containing the product. The Procuring Agency should replace italics with the actual requirements of the contraceptive to be procured.

1. Requirements

Injectable contraceptives in accordance with the following specifications:

* Long-acting progestin in sterile aqueous suspension for intramuscular injection once every three (3) months.
* Each 1-ml vial or ampoule should contain a minimum of 1.1 ml of sterile aqueous suspension containing 150 mg/ml medroxy progesterone acetate.

1.1 Product and Brand Names

Product name: ………………………………………………………………………

Brand names: ……………………………………………………………………….

Registration Number: ……………………………………………………………….

Drug Manufacturing License Number: ……………………………………………..

1.2 Raw Materials

Injectable contraceptives offered under this purchase description shall be produced from   
validated raw materials obtained from a licensed manufacturer or its authorized distributor.[[22]](#footnote-22)

1.3 Primary Packaging Requirements

Injectable contraceptives offered under this purchase description shall be packaged in vials or ampoules that meet quality standards as specified in ISO 8362-1. Closures for injection vials shall meet quality standards as specified in ISO 8362-2.

1.4 Registration Requirements

Injectable contraceptives offered under this purchase description shall be currently registered in Pakistan and approved by the Ministry of Health under the Drugs control Act 1976. (local regulatory authority).

1.5 Certificate of Registration Status in Country of Origin (in case of imported contraceptives)

Injectable contraceptives offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the   
Contract, the successful offeror(s) may be required to submit a “statement of licensing status   
of pharmaceutical product(s)” as provided under the World Health Organization (WHO)   
Certification Scheme on the Quality of Pharmaceutical Products Moving in International   
Commerce.[[23]](#footnote-23)

1.6 Compliance with Current Good Manufacturing Practices

The Supplier must be able to provide certification that the injectable contraceptives are manufactured according to WHO current good manufacturing practices (cGMPs). Such certification can be found in the WHO Certification Scheme “Certificate of Pharmaceutical Product”. Supplier also must be able to provide copies of its annual cGMP audit reports conducted by the local Drug Regulatory Authority.

1.7 Appearance

Injectable contraceptives shall appear as an aqueous white suspension contained in 1-ml or 10-ml glass vials or 1-ml glass ampoules.

1.8 Filling Volume

Each 1-ml glass vial or ampoule shall contain a minimum of 1.1 ml of sterile aqueous suspension.

Each 10-ml glass vial shall contain a minimum of 10.5 ml of sterile aqueous suspension.

1.9 Identification Markings on Individual Vials or Ampoules

Each individual vial or ampoule shall have the following information:

* Product/brand name
* Lot/batch number
* Expiration date (day, month and year)
* Date of manufacture
* Manufacturer’s name and address
* Presentation (e.g., sterile aqueous suspension)
* Formulation (amounts of active ingredients per vial or ampoule)
* Drug registration number (if applicable)
* Family planning logo (if applicable)

If space allows, the following information shall also appear on each individual vial or ampoule:

* Recommended storage conditions.
* Drug Manufacturing License Number.

1.10 Workmanship

Products and packaging shall be free of defects that impair their serviceability, affect their durability or detract from their appearance.

1.11 Lots per Order

The Supplier shall fill the order using the fewest number of manufacturing lots possible.

1.12 Shelf Life

The shelf life of the product provided under this solicitation shall be at least three (3) years from the date of manufacture when stored under tropical conditions such as those prevailing in the local environment. The Supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer’s stability test data substantiating this three (3) year shelf life at ambient temperatures at or greater than 32 degrees Celsius and at a relative humidity of 85% in the proposed vial or ampoule.

At the time of inspection or acceptance for delivery to the country of destination, no more than nine (9) months shall have expired since the date of manufacture shown on the batch release or Certificate of Analysis.

1.13 Test Data

Chemical, physical and microbiological test data for raw materials, components in-process and finished product testing must be on record for each lot manufactured and must be available to Procuring Agency’s representatives when requested.

2. Quality Assurance Provisions

2.1 Compliance

The Supplier shall guarantee that the products as packed for supply comply with all provisions of the specifications and related documents.

2.2 Documentation

2.2.1 The Supplier shall provide evidence[[24]](#footnote-24) of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided. Such evidence is contained in the “Manufacturer’s Batch Certificate” under the WHO Certification Scheme.

2.2.2 The Supplier shall provide a copy of the manufacturing record and procedures to the Procuring Agency for each lot intended for supply.

2.2.3 The Supplier shall provide a copy of the Certificate of Analysis to the Procuring Agency for each lot intended for supply.

2.2.4 The Supplier shall provide to the Procuring Agency a copy of the approval of each component for each lot intended for supply.

2.3 Inspection by the Procuring Agency

The Procuring Agency reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Technical Specifications and Special Conditions of Contract to ensure that the goods conform to prescribed requirements. The Procuring Agency reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to supply of the goods and to draw samples from the Supplier’s factory and/or warehouse for test analysis. Except as otherwise specified in the Contract or purchase order, prior to shipment, the Procuring Agency will sample, or cause to be sampled, the product as packed in inner boxes preparatory to packing in exterior shipping cartons. The sampling shall be according to recognized standards.[[25]](#footnote-25)

The Procuring Agency may have some or all of the tests specified in the Technical Specifications of   
the Contract performed by a laboratory suitably equipped and qualified to conduct quality   
assurance tests on pharmaceutical products according to Pharmacopoeia specifications.

2.4 Sampling Procedures

The Procuring Agency or the Procuring Agency’s representative shall select the required samples from the lot according to the Special Conditions of Contract. If the order is to be filled using more than one production lot, each production lot shall be separately sampled and tested.

The normal, tightened and reduced inspection provisions of ISO 2859 (Inspection by Attributes) may be used for visual inspection. Sampling for analytical testing shall be done in accordance with pharmacopoeial requirements.

All sampled boxes and supply cartons shall be so marked and shall include the date and initials of the sampler.

2.5 Sample Retention

The Supplier shall retain a sample of ten (10) vials or ampoules, or the equivalent required to perform three (3) complete chemical assays, from each lot shipped, for a period of one (1) year after the printed expiration date.

3. Packing

3.1 Inner Boxes

3.1.1 One hundred (100) individual glass vials or ampoules will be contained in sturdy white cardboard boxes outfitted with individual segments for protecting and separating each vial or ampoule.

Inner boxes shall be made of sturdy white cardboard of a size sufficient to contain the specified number of vials or ampoules. The overall dimensions should be such that the product does not get damaged during transportation and storage.

3.1.2 For inner boxes, the Bidder shall fill in the blanks provided below:

Each inner box will contain one hundred (100) units. The overall dimensions of a box will be cm x cm x cm.

3.2 Exterior Shipping Cartons

3.2.1 Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fiberboard cartons made from weather-resistant   
fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm[[26]](#footnote-26). Plastic strapping shall be placed around the carton, with a minimum of two crossing bands. Cartons exceeding 760 mm (30 inches) in length shall have additional bands placed around the carton.

3.2.2 Additional cushioning shall be provided as needed to protect the vials or ampoules from breakage during transit and handling.

3.2.3 The Bidder shall fill in the following blanks:

The exterior shipping carton will contain inner boxes. The overall dimensions of a carton will be cm x cm x cm, and the gross weight of one shipping carton will be kg.

A standard 6.096-meter (20-foot) container will accommodate exterior shipping cartons.

3.3 Markings

3.3.1 Inner Boxes

The inner boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Procuring Agency[[27]](#footnote-27):

* Product/brand name
* Drug manufacturing License number
* Lot/batch number
* Expiration date (day, month and year)
* Date of manufacture
* Manufacturer’s name and address
* Contents and quantity
* Drug registration number (if applicable)
* Instructions for storage and handing
* Formulation and presentation

3.3.2 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 mm high with waterproof ink in a clearly legible manner that is acceptable to the Procuring Agency.[[28]](#footnote-28)

Regulatory information (on two opposing sides of carton)

* Product/brand name
* Drug manufacturing License Number
* Lot/batch number
* Expiration date (day, month and year)
* Date of manufacture
* Manufacturer’s name and address
* Contents and quantity
* Drug registration numbers (if applicable)
* Instructions and symbols for storage and handling, such as KEEP DRY or DO NOT FREEZE.

3.4 Printed Materials—Product Information Sheets

Twenty (20) patient information sheets and one (1) prescribing information sheet, printed in English and/or in, shall be included in each intermediate container.

Inspection Sampling and Testing—Injectable Contraceptives

Prior to shipment, the Procuring Agency or its appointed representative has the right to sample and inspect each consignment of injectable contraceptives at the factory or Supplier’s warehouse in accordance with ISO 2859 Inspection by Attributes (or WHO specifications) and Technical Specification of this Contract.

1.1 Packaging, Packing and Markings

1. One hundred percent (100%) of the exterior shipping cartons will be examined for:

* General physical characteristics and condition
* Markings per Technical Specification ...

1. A representative sample of the inner boxes and individual vials or ampoules will be drawn from the exterior shipping cartons at General Inspection Level II, or, at the discretion of the Procuring Agency, General Inspection Level III, and Single Sampling Plan for Normal Inspection.

The sample will be examined for:

* General physical characteristics per Technical Specification Section
* Markings per Technical Specification, Section c. Inspection criteria and classification of defects shall follow the inspection guidelines outlined in Section 1.4 below. For critical defects, the acceptable quality limit (AQL) shall be 0%; for major defects, the AQL shall be 1%; for minor defects, the AQL shall be 4%.

1.2 Injectable

At the discretion of the Procuring Agency, part of the selected sample may be sent to a qualified government drug testing laboratory for physical, chemical or microbiological testing as follows.

Pharmacopoeial tests

* Active ingredient(s) identification and assay
* Appearance (colour, turbidity, visible particles)
* Filling volume
* pH
* Preservative identification
* Pyrogens
* Sterility

Non-pharmacopoeial tests

* Package seal integrity test
* Particle size (for suspensions only)

A Certificate of Analysis for production lot(s) represented by test samples shall be made available to the inspector and/or Procuring Agency upon request. The certificate shall state all tests performed their specifications and actual test results obtained. All pharmacopoeial test results shall meet applicable pharmacopoeial limits.

1.3 Resolution of Defects

1. Packaging, Packing and Markings

* Defects in exterior shipping carton markings must be corrected by the Supplier prior to shipment.
* All goods from corresponding production lots with inspection lot defect in excess of the AQLs listed in Section 1.4 of this specification must be corrected and re-inspected at Supplier’s expense or rejected.

1. Injectable

* Any deviation from the manufacturer’s Certificate of Analysis, product specifications or   
  relevant pharmacopoeial limits shall result in rejection of goods from the entire production lot.

**1.4 Syringe Specification**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Size** | **Needle Gauge** | **Needle Diameter** | **Needle length** | **Shelf Life (years)** | **Sterilization** | **Unit Box** |
| 1 ml | 22 | 0.7 mm | 30 mm | 5 | EtO | 100 |
| 2 ml | 22 | 0.7 mm | 40 mm | 5 | EtO | 100 |

## Technical Specifications - Injectable Contraceptives with Syringe (2 months)

Information for Submission of Samples

The sample injectable contraceptives submitted by the Bidder in response to this Invitation for Bids must be exactly the same as would be supplied if a contract were awarded to the Bidder.[[29]](#footnote-29)The vial or ampoule containing the product need not have a printed logo; however, other information as stipulated under Clause 1.11 of this specification must be furnished. For sample submission only, this information (logo optional) may be printed on a sticker and affixed to the vials or ampoules containing the product. The Procuring Agency should replace italics with the actual requirements of the contraceptive to be procured.

1. Requirements

Injectable contraceptives in accordance with the following specifications:

* Long-acting progestin in sterile aqueous suspension for intramuscular injection once every two (2) months.
* Each 1-ml vial or ampoule should contain a minimum of 1.1 ml of sterile aqueous suspension containing 200 mg/ml norethisterone enanthate.

1.1 Product and Brand Names

Product name: ………………………………………………………………………

Brand names: ……………………………………………………………………….

Registration Number: ……………………………………………………………….

Drug Manufacturing License Number: ……………………………………………..

1.2 Raw Materials

Injectable contraceptives offered under this purchase description shall be produced from   
validated raw materials obtained from a licensed manufacturer or its authorized distributor.[[30]](#footnote-30)

1.3 Primary Packaging Requirements

Injectable contraceptives offered under this purchase description shall be packaged in vials or ampoules that meet quality standards as specified in ISO 8362-1. Closures for injection vials shall meet quality standards as specified in ISO 8362-2.

1.4 Registration Requirements

Injectable contraceptives offered under this purchase description shall be currently registered in Pakistan and approved by the Ministry of Health under the Drugs control Act 1976. (local regulatory authority).

1.5 Certificate of Registration Status in Country of Origin (in case of imported contraceptives)

Injectable contraceptives offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the   
Contract, the successful offeror(s) may be required to submit a “statement of licensing status   
of pharmaceutical product(s)” as provided under the World Health Organization (WHO)   
Certification Scheme on the Quality of Pharmaceutical Products Moving in International   
Commerce.[[31]](#footnote-31)

1.6 Compliance with Current Good Manufacturing Practices

The Supplier must be able to provide certification that the injectable contraceptives are manufactured according to WHO current good manufacturing practices (cGMPs). Such certification can be found in the WHO Certification Scheme “Certificate of Pharmaceutical Product”. Supplier also must be able to provide copies of its annual cGMP audit reports conducted by the local Drug Regulatory Authority.

1.7 Appearance

Injectable contraceptives shall appear as an aqueous white suspension contained in 1-ml glass vials or 1-ml glass ampoules.

1.8 Filling Volume

Each 1-ml glass vial or ampoule shall contain a minimum of 1.1 ml of sterile aqueous suspension.

1.9 Identification Markings on Individual Vials or Ampoules

Each individual vial or ampoule shall have the following information:

* Product/brand name
* Lot/batch number
* Expiration date (day, month and year)
* Date of manufacture
* Manufacturer’s name and address
* Presentation (e.g., sterile aqueous suspension)
* Formulation (amounts of active ingredients per vial or ampoule)
* Drug registration number (if applicable)
* Family planning logo (if applicable)

If space allows, the following information shall also appear on each individual vial or ampoule:

* Recommended storage conditions.
* Drug Manufacturing License Number.

1.10 Workmanship

Products and packaging shall be free of defects that impair their serviceability, affect their durability or detract from their appearance.

1.11 Lots per Order

The Supplier shall fill the order using the fewest number of manufacturing lots possible.

1.12 Shelf Life

The shelf life of the product provided under this solicitation shall be at least three (3) years from the date of manufacture when stored under tropical conditions such as those prevailing in the local environment. The Supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer’s stability test data substantiating this three (3) year shelf life at ambient temperatures at or greater than 32 degrees Celsius and at a relative humidity of 85% in the proposed vial or ampoule.

At the time of inspection or acceptance for delivery to the country of destination, no more than nine (9) months shall have expired since the date of manufacture shown on the batch release or Certificate of Analysis.

1.13 Test Data

Chemical, physical and microbiological test data for raw materials, components in-process and finished product testing must be on record for each lot manufactured and must be available to Procuring Agency’s representatives when requested.

2. Quality Assurance Provisions

2.1 Compliance

The Supplier shall guarantee that the products as packed for supply comply with all provisions of the specifications and related documents.

2.2 Documentation

2.2.1 The Supplier shall provide evidence[[32]](#footnote-32) of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided. Such evidence is contained in the “Manufacturer’s Batch Certificate” under the WHO Certification Scheme.

2.2.2 The Supplier shall provide a copy of the manufacturing record and procedures to the Procuring Agency for each lot intended for supply.

2.2.3 The Supplier shall provide a copy of the Certificate of Analysis to the Procuring Agency for each lot intended for supply.

2.2.4 The Supplier shall provide to the Procuring Agency a copy of the approval of each component for each lot intended for supply.

2.3 Inspection by the Procuring Agency

The Procuring Agency reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Technical Specifications and Special Conditions of Contract to ensure that the goods conform to prescribed requirements. The Procuring Agency reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to supply of the goods and to draw samples from the Supplier’s factory and/or warehouse for test analysis. Except as otherwise specified in the Contract or purchase order, prior to shipment, the Procuring Agency will sample, or cause to be sampled, the product as packed in inner boxes preparatory to packing in exterior shipping cartons. The sampling shall be according to recognized standards.[[33]](#footnote-33)

The Procuring Agency may have some or all of the tests specified in the Technical Specifications of   
the Contract performed by a laboratory suitably equipped and qualified to conduct quality   
assurance tests on pharmaceutical products according to Pharmacopoeia specifications.

2.4 Sampling Procedures

The Procuring Agency or the Procuring Agency’s representative shall select the required samples from the lot according to the Special Conditions of Contract. If the order is to be filled using more than one production lot, each production lot shall be separately sampled and tested.

The normal, tightened and reduced inspection provisions of ISO 2859 (Inspection by Attributes) may be used for visual inspection. Sampling for analytical testing shall be done in accordance with pharmacopoeial requirements.

All sampled boxes and supply cartons shall be so marked and shall include the date and initials of the sampler.

2.5 Sample Retention

The Supplier shall retain a sample of ten (10) vials or ampoules, or the equivalent required to perform three (3) complete chemical assays, from each lot shipped, for a period of one (1) year after the printed expiration date.

3. Packing

3.1 Inner Boxes

3.1.1 One hundred (100) individual glass vials or ampoules will be contained in sturdy white cardboard boxes outfitted with individual segments for protecting and separating each vial or ampoule.

Inner boxes shall be made of sturdy white cardboard of a size sufficient to contain the specified number of vials or ampoules. The overall dimensions should be such that the product does not get damaged during transportation and storage.

3.1.2 For inner boxes, the Bidder shall fill in the blanks provided below:

Each inner box will contain one hundred (100) units. The overall dimensions of a box will be cm x cm x cm.

3.2 Exterior Shipping Cartons

3.2.1 Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fiberboard cartons made from weather-resistant   
fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm[[34]](#footnote-34). Plastic strapping shall be placed around the carton, with a minimum of two crossing bands. Cartons exceeding 760 mm (30 inches) in length shall have additional bands placed around the carton.

3.2.2 Additional cushioning shall be provided as needed to protect the vials or ampoules from breakage during transit and handling.

3.2.3 The Bidder shall fill in the following blanks:

The exterior shipping carton will contain inner boxes. The overall dimensions of a carton will be cm x cm x cm, and the gross weight of one shipping carton will be kg.

A standard 6.096-meter (20-foot) container will accommodate exterior shipping cartons.

3.3 Markings

3.3.1 Inner Boxes

The inner boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Procuring Agency[[35]](#footnote-35):

* Product/brand name
* Drug manufacturing License number
* Lot/batch number
* Expiration date (day, month and year)
* Date of manufacture
* Manufacturer’s name and address
* Contents and quantity
* Drug registration number (if applicable)
* Instructions for storage and handing
* Formulation and presentation

3.3.2 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 mm high with waterproof ink in a clearly legible manner that is acceptable to the Procuring Agency.[[36]](#footnote-36)

Regulatory information (on two opposing sides of carton)

* Product/brand name
* Drug manufacturing License Number
* Lot/batch number
* Expiration date (day, month and year)
* Date of manufacture
* Manufacturer’s name and address
* Contents and quantity
* Drug registration numbers (if applicable)
* Instructions and symbols for storage and handling, such as KEEP DRY or DO NOT FREEZE.

3.4 Printed Materials—Product Information Sheets

Twenty (20) patient information sheets and one (1) prescribing information sheet, printed in English and/or in, shall be included in each intermediate container.

Inspection Sampling and Testing—Injectable Contraceptives

Prior to shipment, the Procuring Agency or its appointed representative has the right to sample and inspect each consignment of injectable contraceptives at the factory or Supplier’s warehouse in accordance with ISO 2859 Inspection by Attributes (or WHO specifications) and Technical Specification of this Contract.

1.1 Packaging, Packing and Markings

1. One hundred percent (100%) of the exterior shipping cartons will be examined for:

* General physical characteristics and condition
* Markings per Technical Specification ...

1. A representative sample of the inner boxes and individual vials or ampoules will be drawn from the exterior shipping cartons at General Inspection Level II, or, at the discretion of the Procuring Agency, General Inspection Level III, and Single Sampling Plan for Normal Inspection.

The sample will be examined for:

* General physical characteristics per Technical Specification Section
* Markings per Technical Specification, Section c. Inspection criteria and classification of defects shall follow the inspection guidelines outlined in Section 1.4 below. For critical defects, the acceptable quality limit (AQL) shall be 0%; for major defects, the AQL shall be 1%; for minor defects, the AQL shall be 4%.

1.2 Injectable

At the discretion of the Procuring Agency, part of the selected sample may be sent to a qualified government drug testing laboratory for physical, chemical or microbiological testing as follows.

Pharmacopoeial tests

* Active ingredient(s) identification and assay
* Appearance (colour, turbidity, visible particles)
* Filling volume
* pH
* Preservative identification
* Pyrogens
* Sterility

Non-pharmacopoeial tests

* Package seal integrity test
* Particle size (for suspensions only)

A Certificate of Analysis for production lot(s) represented by test samples shall be made available to the inspector and/or Procuring Agency upon request. The certificate shall state all tests performed their specifications and actual test results obtained. All pharmacopoeial test results shall meet applicable pharmacopoeial limits.

1.3 Resolution of Defects

1. Packaging, Packing and Markings

* Defects in exterior shipping carton markings must be corrected by the Supplier prior to shipment.
* All goods from corresponding production lots with inspection lot defect in excess of the AQLs listed in Section 1.4 of this specification must be corrected and re-inspected at Supplier’s expense or rejected.

1. Injectable

* Any deviation from the manufacturer’s Certificate of Analysis, product specifications or   
  relevant pharmacopoeial limits shall result in rejection of goods from the entire production lot.

**1.4 Syringe Specification**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Size** | **Needle Gauge** | **Needle Diameter** | **Needle length** | **Shelf Life (years)** | **Sterilization** | **Unit Bod** |
| 1 ml | 22 | 0.7 mm | 30 mm | 5 | EtO | 100 |
| 2 ml | 22 | 0.7 mm | 40 mm | 5 | EtO | 100 |

## Technical Specification: Emergency contraceptive Pills

**General Description**

There are three types of ECPs: combined ECPs containing both, estrogen and progestin, progestin-only ECPs, and ECPs containing an anti-progestin. Progestin-only ECPs have now largely replaced the older combined ECPs because they are more effective and cause fewer side effects. Although this therapy is commonly known as the morning-after pill, the term is misleading; ECPs may be initiated sooner than the morning after—immediately after unprotected intercourse—or later—for at least 120 hours after unprotected intercourse.

Progestin-only ECPs contain no estrogen. Only the progestin levonorgestrel has been studied for freestanding use as an emergency contraceptive. The original treatment schedule was one 0.75 mg dose within 72 hours after unprotected intercourse, and a second 0.75 mg dose 12 hours after the first dose. However, recent studies have shown that a single dose of 1.5 mg is as effective as two 0.75 mg doses 12 hours apart.[[37]](#footnote-37)

The antiprogestin mifepristone has also been extensively studied for use as an emergency contraceptive pill. Mifepristone is a first generation progesterone receptor modulator. A second generation antiprogestin, ulipristal acetate (30mg in a single dose), has been studied for use as emergency contraception and has been found to be highly effective and well tolerated.[[38]](#footnote-38) However both these products are not registered in Pakistan

1. Requirements

Emergency contraceptive tablets in accordance with the following specifications:

* Each tablet shall contain 0.753 mg of Levonorgestrel

1.1 Product and Brand Names

Product name: ………………………………………………………………………

Brand names: ……………………………………………………………………….

Registration Number: ……………………………………………………………….

1.2 Raw Materials

Emergency contraceptive tablets offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor.[[39]](#footnote-39)

1.3 Registration Requirements

Emergency contraceptives offered under this purchase description shall be currently registered in Pakistan and approved by the Ministry of Health under the Drugs Act, 1976.

1.4 Certificate of Registration Status in Country of Origin (in case of imported contraceptives)

Emergency contraceptives offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the Contract, the successful offeror(s) may be required to submit a “statement of licensing status of pharmaceutical product(s)” as provided under the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.[[40]](#footnote-40)

1.5 Compliance with Current Good Manufacturing Practices

The Supplier must be able to provide certification that the oral contraceptives are manufactured according to WHO current good manufacturing practices (cGMPs). Such certification can be found in the WHO Certification Scheme “Certificate of Pharmaceutical Product.” Supplier also must be able to provide copies of its annual cGMP audit reports conducted by the local Drug Regulatory Authority.

1.7 Shape and Dimensions

Tablets shall be of the shape and dimensions of the Bidder’s normal, standard commercial tablets which are available in the local market.

1.8 Colors

Emergency contraceptives tablets shall be similar to Bidder’s normal, standard commercial tablets.

1.9 Tablet Markings

Each tablet shall bear the identifying imprint of its manufacturer.

1.10 Packaging

Each individual tablet shall be enclosed in a transparent blister pack of thermoformed polymer, with a minimum thickness of 0.1905 mm (.0075 inch) backed with aluminum foil, minimum thickness 0.0178 mm (0.0007 inch). Variations must be proven scientifically comparable by means of stability data.

The size of the package shall not be less than 57.15 mm (2.25 inches) x 82.55 mm (3.25 inches). Thicker polymer or foil or the addition of a card to either the front or the back of the package (in addition to the minimum polymer or foil) is acceptable.

1.11 Identification Markings on Individual Blister Packs

Each individual blister pack shall have the following information:

* Product/brand name
* Lot/batch number
* Expiration date (day, month and year)
* Date of manufacture
* Manufacturer’s name and address
* Contents and quantity, including tablet formulation (amounts of active ingredients per tablet)
* Drug registration number (if applicable)
* Family planning logo (if applicable)
* Drug Manufacturing License Number
* Product use and storage instructions (accompanying the blister pack).

1.12 Workmanship

Products and packaging shall be free of defects that impair their serviceability, affect their durability, or detract from their appearance.

1.13 Lots per Order

The Supplier shall fill the order using the fewest number of manufacturing lots possible.

1.14 Shelf Life

The shelf life of the product provided under this solicitation shall be five (5) years from the date of manufacture when stored under tropical conditions such as those prevailing in the local environment. The Supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer’s stability test data substantiating this five (5) year shelf life at ambient temperatures at or greater than 32 degrees Celsius and at a relative humidity of 85% in the proposed blister package.

At the time of inspection or acceptance for delivery to the country of destination, no more than nine (9) months shall have expired since the date of manufacture shown on the batch release or Certificate of Analysis.

1.16 Test Data

Chemical and physical test data for raw materials, components in-process and finished product testing must be on record for each lot manufactured and must be available to Procuring Agency’s representatives when requested.

2. Quality Assurance Provisions

Same as Oral Contraceptive Pills

3. Packing

Same as Oral Contraceptive Pills

Inspection Sampling and Testing

Same as Oral Contraceptive Pill

# SECTION VII

# Bid Forms

## **BID COVER SHEET**

Bid Ref. No. ------------------------ Date----------------------------

Name of the Supplier/Firm Contractor: --------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Address:------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

E-mail:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Facsimile: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Bid Security.

Bid Security attached with Financial Bid YES NO

Bid for:

⁯: All Items mentioned in the Schedule of Requirements.

⁯: Selected Items from the Schedule of Requirements[[41]](#footnote-41).

List of Selected Items: *(In case the Bidder has opted to bid for Selected Items, please type the Serial No[[42]](#footnote-42). and the name of the Items selected for Bidding. Use additional Sheets if Required)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *S. No.* | *Name of the Item* | *Batch Capacity of the Drug/Medicine/Product* | *Trade Price* | *MRP* |
|  |  |  |  |  |
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Signed:

Dated:

Official Stamp:

Attachment[[43]](#footnote-43): ⁯ Original receipt for the purchase of the bidding documents.

## **BID FORM 1** **Letter of Intention**

*Bid Ref No.*

*Date of the Opening of Bids*

*Name of the Contract :{ Add name e.g. Supply of Dugs and Medicines etc}*

To: *[Name* ***and address of Procuring Agency]***

Dear Sir/Madam,

Having examined the bidding documents including Addenda Nos. *[insert* ***numbers& Date of individual Addendum]***, 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 and at the rates/unit prices described in the price schedule 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.

We undertake, if our bid is accepted, to deliver the Goods in accordance with the delivery schedule specified in the schedule of requirements.

If our bid is accepted, we undertake to provide a performance security/guaranty in the form, in the amounts, and within the times specified in the bidding documents.

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

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.

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

We undertake that, in competing for (and, if the award is made to us, in executing) the above contract, we will strictly observe the laws against fraud and corruption in force in Pakistan.

We confirm that we comply with the eligibility requirements as per ITB clauses 18 &19 of the bidding documents.

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

Signed:

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

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

## **AFFIDAVIT**

**On Rs. 100/- Judicial Paper**

I/We, the undersigned solemnly state that:

1. We have read the contents of the Bidding Document and have fully understood it.
2. The Bid being submitted by the undersigned complies with the requirements enunciated in the bidding documents.
3. The Goods that we propose to supply under this contract are eligible goods within the meaning of Clause 2 of the ITB.
4. The undersigned are also eligible Bidders within the meaning of Clause 2of the ITB.
5. The undersigned are solvent and competent to undertake the subject contract under the Laws of Pakistan.
6. The undersigned have not paid nor have agreed to pay, any Commissions or Gratuities to any official or agent related to this bid or award or contract.
7. The undersigned are not blacklisted or facing debarment from any Government, or its organization or project.
8. That the prices offered are not more than trade price.
9. I / We, further undertake that the prices given are reasonable and not given more than in any Government/Autonomous/District Government institutions during the current financial year. If any difference detected, the firm is bound to refund the difference in price.

I/We affirm that the contents of this affidavit are correct to the best of our knowledge and belief.

Signed

## **BID FORM 3(A)**

Name of the Firm

Bid Reference No:

Date of opening of Bid.

Documentary Evidence: Eligibility of the Bidders and Goods

|  |  |  |  |
| --- | --- | --- | --- |
| Required Documentation  (*To Be Filled by the Procuring Agency*) | Checklist[[44]](#footnote-44)  *(To be initialed by the Bidder against each document)* | Relevant Page Number[[45]](#footnote-45) in the Bid *(To be filled by the Bidder)* | Supporting Documents[[46]](#footnote-46)  *(To be filled by the Bidder with name of the documents that are submitted to meet the requirement)* |
| **Column:1** | **Column:2** | **Column:3** | **Column:4** |
| Valid Manufacturing License |  |  |  |
| Valid Registration(s) of quoted items |  |  |  |
| Valid Drugs Sale License[[47]](#footnote-47) |  |  |  |
| WHO prequalification certification[[48]](#footnote-48) |  |  |  |
| Valid Import License (where applicable) |  |  |  |
| Letter of Manufacturer's authorization |  |  |  |
| Partnership Deed (where applicable) |  |  |  |
| NTN Certificate |  |  |  |
| GST Certificate |  |  |  |
| Letter of Intention |  |  |  |
| **Affidavit** |  |  |  |
| Three years experience evidence |  |  |  |
| Child Labor Free Certificate[[49]](#footnote-49) |  |  |  |
| Original Receipt of purchase of Bidding Documents |  |  |  |

## **BID FORM 3(B) MANUFACTURER’S AUTHORIZATION[[50]](#footnote-50)**

##### **To: *[Name & Address of the Procuring Agency]***

WHEREAS *[name of the Manufacturer]* who are established and reputable Manufacturers of *[name and/or description of the goods]* having factories at *[address of factory]* do hereby authorize *[name and address of Supplier/ Agent]* to submit a bid, and subsequently negotiate and sign the Contract with you against the Invitation for Bids (IFB) No. *[Reference of the Invitation to Bid] for* the goods manufactured by us.

We hereby extend our full guarantee and warranty as per Clause 15 of the General Conditions of Contract for the goods offered for supply by the above firm against this Invitation for Bids.

Signature: --------------------------------------.

Designation: --------------------------------------

Official Stamp: -----------------------------------

## **BID FORM 4 Firm’s Past Performance[[51]](#footnote-51).**

Name of the Firm:

Bid Reference No:

Date of opening of Bid: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**2014**

Assessment Period: (One Year as per Evaluation Criteria)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name of the Procuring Agency/Institution | Purchase Order No. | Description Of Order | Value of Order | Date of Completion | Procuring Agency’s[[52]](#footnote-52)  Certificate |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
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## **BID FORM Price Schedule**

*User Note: This form is to be filled by the Bidder for each individual item and shall submit with Financial Proposal.*

Name of the Firm:

Bid.Ref. No:

Date of opening of Bid.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| S. No. | Name of the Item | Unit Price (inclusive all applicable taxes) | No. of Units | Total Price | Discounts *(if any)* | Final Total Price (Inclusive of all taxes) |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 3\*4 | 5-6 |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  | TOTAL | | | | |  |

A) FINAL TOTAL PRICE: --------------------------------------------------

B) DISCOUNT[[53]](#footnote-53): --------------------------------------------------

C) FINAL QOUTED PRICE: --------------------------------------------------

(C=A-B)

Signature: -------------------------------------------------

Designation: ------------------------------------------------

Date: ------------------------------------------------

Official Stamp

## **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 of Procuring Agency)*

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 Procurement of Contraceptives, under Invitation for Bids No. *(Insert 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 Procuring Agency 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.

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; or (ii) twenty-eight days after the expiration of the Bidder’s Bid.

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]

## **Form of Contract Agreement**

THIS CONTRACT AGREEMENT is made on the [insert: number] day of [insert: month], [insert: year].

BETWEEN

(1) *(Insert name and address of Procuring Agency*) (hereinafter called “the Procuring Agency”), and

(2) [insert: name of Supplier], a corporation incorporated under the laws of [insert: country of Supplier] and having its principal place of business at [insert: address of Supplier] (hereinafter called “the Supplier”).

WHEREAS the Procuring Agency invited bids for certain contraceptives and ancillary services, viz., Male Condoms, IUCD (Cu-T-380A), Implant (single rod and 2 rods) and has accepted a bid by the Supplier for the supply of those contraceptives and services in the sum of [ insert: contract price in words and figures ] (hereinafter called “the Contract Price”).

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to.

2. The following documents shall constitute the Contract between the Procuring Agency and the Supplier, and each shall be read and construed as an integral part of the Contract:

This Contract Agreement

Special Conditions of Contract

General Conditions of Contract

Technical Requirements (including Technical Specifications) The Supplier’s bid and original Price Schedules

The Procuring Agency’s Notification of Award

[Add here: any other documents]

3. In consideration of the payments to be made by the Procuring Agency to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the Procuring Agency to provide the contraceptives and Services and to remedy defects therein in conformity in all respects with the provisions of the Contract.

4. The Procuring Agency hereby covenants to pay the Supplier in consideration of the provision of the contraceptives and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.

For and on behalf of the Procuring Agency

Signed:

In the capacity of [insert: title or other appropriate designation]

In the presence of

For and on behalf of the Supplier

Signed:

In the capacity of [insert: title or other appropriate designation]

In the presence of

CONTRACT AGREEMENT dated the \_\_\_ day of \_\_\_\_\_\_\_\_\_, 2014

BETWEEN

Directorate General Health Services, “the Procuring Agency”

And

[Insert: name of Supplier], “the Supplier”

## **Performance Guarantee**

To: *[Name & Address of the Procuring Agency]*

Whereas *[Name of Supplier]* (hereinafter called “the Supplier”) has undertaken, in pursuance of Contract No. *[Number]* dated *[date]* to supply *[description of goods]* (hereinafter called “the Contract”).

And whereas it has been stipulated by you in the said Contract that the Supplier shall furnish you with a Bank Guarantee by a scheduled bank for the sum of **5%** of the total Contract amount as a Security for compliance with the Supplier’s performance obligations in accordance with the Contract.

And whereas we have agreed to give the Supplier a Guarantee:

Therefore we hereby affirm that we are Guarantors and responsible to you, on behalf of the Supplier, up to a total of *[Amount of the Guarantee in Words and Figures]* and we undertake to pay you, upon your first written demand declaring the Supplier to be in default under the Contract and without cavil or argument, any sum or sums within the limits of *[Amount of Guarantee]* as aforesaid, without your needing to prove or to show grounds or reasons for your demand or the sum specified therein.

This guarantee is valid until the\_\_\_\_\_\_\_\_\_\_\_\_ day of\_\_\_\_\_\_\_\_\_, 2016

Signature and Seal of the Guarantors/ Bank

Address

Date

## **Integrity Pact**

**DECLARATION OF FEES, COMMISSION AND BROKERAGE ETC**

**PAYABLE BY THE SUPPLIERS/CONTRACTORS/CONSULTANTS**

Contract Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Dated: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contract Value: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contract Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[*Name of Supplier/Contractor*] hereby declares that it has not obtained or induced the procurement of any contract, right, interest, privilege or other obligation or benefit from Government of Sindh or any administrative subdivision or agency thereof or any other entity owned or controlled by it through any corrupt business practice.

Without limiting the generality of the foregoing, [*Name of Supplier/Contractor*] represents and warrants that it has fully declared the brokerage, commission, fees etc. paid or payable to anyone and not given or agreed to give and shall not give or agree to give to anyone within or outside Pakistan either directly or indirectly through any natural or juridical person, including its affiliate, agent, associate, broker, consultant, director, promoter, shareholder, sponsor or subsidiary, any commission, gratification, bribe, finder’s fee or kickback, whether described as consultation fee or otherwise, with the object of obtaining or inducing the procurement of a contract, right, interest, privilege or other obligation or benefit, in whatsoever form, from Procuring Agency, except that which has been expressly declared pursuant hereto.

[Name of Supplier/Contractor] certifies that it has made and will make full disclosure of all agreements and arrangements with all persons in respect of or related to the transaction with Procuring Agency and has not taken any action or will not take any action to circumvent the above declaration, representation or warranty.

[*Name of Supplier/Contractor*] accepts full responsibility and strict liability for making any false declaration, not making full disclosure, misrepresenting facts or taking any action likely to defeat the purpose of this declaration, representation and warranty. It agrees that any contract, right, interest , privilege or other obligation or benefit obtained or procured as aforesaid shall, without prejudice to any other right and remedies available to Procuring Agency under any law, contract or other instrument, be voidable at the option of Procuring Agency.

Notwithstanding any rights and remedies exercised by Procuring Agency in this regard, [*Name of Supplier/Contractor*] agrees to indemnify Procuring Agency for any loss or damage incurred by it on account of its corrupt business practices and further pay compensation to Procuring Agency in an amount equivalent to ten time the sum of any commission, gratification, bribe, finder’s fee or kickback given by [*Name of Supplier/Contractor*] as aforesaid for the purpose of obtaining or inducing the procurement of any contract, right, interest, privilege or other obligation or benefit, in whatsoever form, from Procuring Agency.

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[*Procuring Agency*] [*Supplier /Contractor*]

## **CHECK LIST OF DOCUMENTS PROVIDED WITH PAGE MARKING**

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| **No** | **Description** | **Documents Attached** | | |
|  |  | **Yes** | **No** | **Page No.** |
|  | Receipt of the bidding document Purchase |  |  |  |
|  | Name of the signatory of the firm with CNIC copy |  |  |  |
|  | 2 ½ % bid security attached with the Financial bid (in original) |  |  |  |
|  | Name & pack size of the Product offered are clearly mentioned in the technical bid |  |  |  |
|  | Drug Registration bearing latest price of the contraceptive enclosed (specific items) |  |  |  |
|  | Undertaking on judicial stamp paper regarding potency of the contraceptive and fit for human use/consumption. |  |  |  |
|  | Undertaking on judicial stamp paper that the firm participating in the tender has not been black listed/suspended the license by any Government/Institution/organization etc... |  |  |  |
|  | Undertaking on judicial stamp paper that no violation of child labor in the firm |  |  |  |
|  | For repacking item the bidder has enclosed the valid License/Excise license & relevant documents etc. |  |  |  |
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