# BIDDING DOCUMENTS

## Procurement of Contraceptives

## Open Competitive Bidding

## GOVERNMENT OF SINDH

**Population Welfare Department**

**And**

**Department of Health**

# Contents





POPULATION WELFARE DEPARTMENT GOVERNMENT OF SINDH

POPULATION WELFARE DEPARTMENT GOVERNMENT OF SINDH

# Population Welfare Department
# Government of Sindh, Pakistan

## Invitation for Bids (IFB)
### for
### Procurement of Contraceptives

*(Condoms, IUCDs, Sub-dermal Implants, Contraceptive injections and oral pills, Emergency contraceptive pills)*

The Population Welfare Department, Government of Sindh, Karachi, hereby invites sealed bids on single stage two envelops procedure from Primary Manufacturers or their authorized representatives/suppliers duly registered with Directorate of Sales Tax & Income Tax for the supply of above items. Tenders will be received upto 11.00 AM and opened at 11.30 AM on the date shown below in presence of such tenderers who may wish to attend.

The interested bidder can purchase set of blank Tender documents from office of the Deputy Secretary (W&D), Population Welfare Department, Sindh, Karachi, located at Z-39/1, Block-6, PECH Society, Karachi, from 10th April, 2015 Friday or date of publication on payment of tender fees Rs.2000/= (Non refundable) in the shape of Pay order in favour Secretary, Population Welfare Department, Sindh, Karachi, till the date of closing i.e. 24th April, 2015 up to 11.00 AM.

The tender documents duly filled and supported with required documents should be dropped in the tender box at office of the Deputy Secretary (W&D), Population Welfare Department, Sindh, Karachi on 24th April, 2015 at 11.00 AM which shall be opened on same day at 11.30 AM in the presence of participant bidder(s) or their authorized representatives before Tender Opening Committee

The bidders are required to furnish Bid Security @2.5% of the total bid value in the shape of Pay order in favour of Secretary, Population Welfare Department, Government of Sindh, Karachi. In case of alternate offer separate tender documents



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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 wax 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 2013-2014 must be provided and the original registration documents must be shown at the time of opening of tenders.

e) Conditional Tenders will not be accepted.

f) 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 SECRETARY (W&D)**

**POPULATION WELFARE DEPARTMENT, SINDH**

**PH: 34525675**

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# SECTION I
# Instructions to Bidders (ITB)



POPULATION WELFARE DEPARTMENT
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## Instructions to Bidders (ITB)

### A. Introduction

**1. Scope of Bid**

1.1 The Department of Health and Population Welfare Department, Government of Sindh, Pakistan, invites bids from the bidders for the supply of contraceptives (as specified in the Bid Data Sheet) described in the Schedule of Requirements. The name and identification number of the procurement has been provided in the Bid Data Sheet and in the SCC.

1.2 The terms "writing" and "days" wherever appearing in the bidding documents shall mean any type written, or printed communication, including e-mail, telex, cable and facsimile transmission, and "day" means calendar day. Singular also means plural.

**2. Fraud and Corruption**

2.1 The Government of Sindh requires that bidders, suppliers and contractors and their sub-contractors observe the highest standard of ethics during the procurement and execution of such contracts. In pursuance of this policy, the following terms are defined:

(i) "corrupt practice" is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;

(ii) "fraudulent practice" is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation;

(iii) "collusive practice" is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;

(iv) "coercive practice" is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;

(v) "obstructive practice" is:

deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Bank investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation;

2.2 the Procuring Agency will reject a proposal for award if it determines that the bidder recommended for award has,



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directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the contract in question

2.3 the Procuring Agency will sanction a firm or individual, including declaring ineligible, either indefinitely or for a stated period of time, to be awarded a contract if it, at any time, determines that the firm has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for, or in executing, the contract; and

2.4 the Procuring Agency will have the right to require that a provision be included in bidding documents requiring bidders, suppliers and contractors and their sub-contractors to permit the Procuring Agency to inspect their accounts and records and other documents relating to the bid submission and contract performance and to have them audited by auditors appointed by the Procuring Agency

2.5 Furthermore, bidders shall be aware of the provision stated in Sub-Clauses 5.4 and 23.1 (d) of the General Conditions of Contract

2.6 Indulgence in corruption and fraudulent practices is liable to result in rejection of Bids, cancellation of contracts, debarring and blacklisting of the Bidder, for a stated or indefinite period of time

**3. Eligibility**

3.1 This Invitation for Bids is open to all Local manufacturers and authorized suppliers of International firms for supply of Goods described in the Schedule of Requirement (Section-III.)

3.2 Firms of a country may be excluded from bidding if:
(a) as a matter of law or official regulation, the Government of Pakistan prohibits commercial relations with that country;
(b) government-owned enterprises in Pakistan may participate only if they can establish that they
(i) are legally and financially autonomous and
(ii) operate under commercial law.

3.3 Any qualified firm if disqualified or blacklisted by any public sector organization or is involved in litigation on account of disqualification/blacklisting at the time of submission of bid shall be ineligible to bid for the instant procurement.

**4. Documents Establishing Conformity to Bidding Documents**

4.1 The documentary evidence of conformity of the contraceptives to the Bidding Documents may be in the form of literature, drawings and data and shall consist of:
a detailed description of the essential technical and performance characteristics of the contraceptives;
an item-by-item commentary on the Procuring Agency's Technical Specifications demonstrating substantial responsiveness of the contraceptives to those



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specifications, or a statement of deviations and exceptions to the provisions of the Technical Specifications;
any other procurement-specific documentation requirement if mentioned in the Bid Data Sheet.

4.2 The contraceptives to be supplied under the Contract shall be registered if applicable with the Drug Regulatory Authority of Pakistan. A Bidder who has already registered its contraceptives by the time of bidding should submit a copy of the Registration Certificate with its bid.
In case the successful bidder fails to provide the requisite certificate of registration by the date of contract stipulated in the offer letter of contract execution, the bid shall stand rejected automatically without forfeiting the bid security. No justification will thereupon be accepted.

4.3 For the purpose of obtaining additional information about the requirements for registration, Bidders may contact Drugs Regulatory Authority of Pakistan (DRAP):
Tel: +92-51-9202566
Fax: +92-51-9205216
Email: contact@dra.gov.pk
http://www.dra.gov.pk

4.4 For purposes of the commentary to be furnished pursuant to ITB Clause 4.1 (ii) above, the Bidder shall note that standards as well as references to brand names designated by the Procuring Agency in its Technical Specifications are intended to be descriptive only and not restrictive. The Bidder may substitute alternative standards, brand names, and/or catalogue numbers in its bid, provided that it demonstrates to the Procuring Agency's satisfaction that the substitutions ensure substantial equivalence to those designated in the Technical Specifications

**5. Qualifications of the Bidder**

5.1 The Bidder shall provide documentary evidence to establish to the Procuring Agency's satisfaction that:
The Bidder has the financial, technical, and production capability necessary to perform the Contract, meets the qualification criteria specified in the Bid Data Sheet, and has a successful performance history in accordance with criteria specified in the Bid Data Sheet.
In case the bidder is not manufacturer, a certificate from the manufacturer of its being valid authorized agent of the manufacturer up to the finalization of the contract would be submitted along with the bid

**6. Bidding for Selective Items**

6.1 A Bidder is authorized to bid for all the items mentioned in the Schedule of Requirements provided it fulfills the prerequisite for that particular item/items.



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However, bid for partial quantities of an item in the Schedule of requirement is not allowed. THE BID FOR MORE THAN ONE ITEM SHALL BE FOR THE WHOLE QUANTITY OF THAT ITEM.

**7. One Bid per Bidder**

7.1 An individual firm, bidder or joint venture shall be authorized to submit only one bid for one item. More than one bid for an item by any one of the above mentioned shall disqualify either of the one for that particular item bidding competition.

**8. Cost of Bidding**

8.1 The Bidder shall bear all costs associated with the preparation and submission of its bid, and the Procuring Agency will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the bidding process.

**9. Applicable Bidding Procedure**

9.1 The open bidding procedure shall be single stage two envelop as provided under Rule 46 (2) of Sindh Public Procurement Rules, Amended 2013 as mentioned in ITB 9.2. Bidders are advised also to refer to the Bid Data Sheet to confirm the Bidding procedure applicable in the instant bidding process.

9.2 The "Single stage – Two Envelop bidding procedure" is explained below:

*The bid shall comprise a single package containing two separate envelopes. Each envelope shall contain separately the financial proposal and the technical proposal;*

*the envelopes shall be marked as "FINANCIAL PROPOSAL" and "TECHNICAL PROPOSAL" in bold and legible letters to avoid confusion;*

*initially, only the envelope marked "TECHNICAL PROPOSAL" shall be opened;*

*the envelope marked as "FINANCIAL PROPOSAL" shall be retained in the custody of Procuring Agency without being opened;*

*the Procuring Agency shall evaluate the technical proposal, without reference to the price and reject any proposal which do not conform to the specified requirements;*

*during the technical evaluation no amendments in the technical proposal shall be permitted;*

*the financial proposals of bids shall be opened publicly at a time, date and venue to be announced and communicated to the Bidders in advance;*

*After the evaluation and approval of the technical proposal the Procuring Agency shall at a time within the bid validity period, publicly open the financial proposals of the technically accepted bids only. The financial proposal of bids found technically non-responsive shall be returned un-opened to the respective Bidders; and*

*The bid found to be the lowest or best evaluated bid shall be accepted.*

## B. The Bidding Documents

**10. Content of Bidding Documents**

10.1 The Bidding Documents are those stated below and should be read in conjunction with any addendum issued in accordance with ITB Clause 12.
Invitation for bid (IFB)
Instructions to Bidders (ITB)
Bid Data Sheet (BDS)
General Conditions of Contract (GCC)
Special Conditions of Contract (SCC)
Schedule of Requirements (including list of goods with quantities and delivery time)
Technical Specifications
Bid Forms (including Contract Agreement and sample format of all securities)

10.2 The "Invitation for Bids" is not a formal part of the Bidding Documents and is included as a reference only. In case of discrepancies between the Invitation for Bid and the Bidding Documents listed in 10.1 above, the Bidding Documents shall take precedence.

10.3 The Bidder is expected to examine all instructions, forms, terms, and specifications in the Bidding Documents. Failure to furnish all information required by the Bidding Documents or any bid not substantially responsive to the Bidding Documents requirement shall be at the Bidder's risk and may result in the rejection of its bid.

**11. Clarification of Bidding Documents**

11.1 A prospective Bidder requiring any clarification of the Bidding Documents shall contact the Procuring Agency shall request the procuring agency for clarification of the contest of the bidding document in writing and the procuring agency shall response to shall quarries in writing within 3 calendar days, provided they are receipt at least 5 calendar days prior to the day of opening of the bids. The procuring agency in such case shall communicate the response to all parties who have obtain bidding documents.

**12. Amendment of Bidding Documents**

12.1 At any time prior to the deadline for submission of bids, the Procuring Agency may amend the Bidding Documents by issuing Addenda.

12.2 Any addendum so issued shall be part of the Bidding Documents and shall be communicated in writing to all the purchasers of the bidding documents along with change in

submission time if necessitate. All prospective Bidders so conveyed the change shall be required to immediately acknowledge receipt of the information and shall be presumed to have included the amendment while formulating the bid or have modified their bids accordingly.

12.3 To give prospective Bidders reasonable time in which to take the amendment into account in preparing their bids, the Procuring Agency may extend, at its discretion, the deadline for submission of bids, in which case, the Procuring Agency will notify all Bidders by cable confirmed in writing of the extended deadline

## C. Preparation of Bids

**13. Language of Bids** 13.1 All correspondences, communications, associated with preparation of Bids, clarifications, amendments, submissions shall be written in English. Supporting documents and printed literature furnished by the Bidder may be in another language provided they are accompanied by an accurate translation of the relevant passages in English, in which case, for purposes of interpretation of the Bid, the said translation shall take precedence.

**14. Documents Constituting the Bid** 14.1 The Bid shall constitute the following documents:
Filled-in Form of Bid and Price Schedule, in accordance with the forms indicated in Section VII;
Original form of bid security in accordance with the provisions of ITB Sub-Clause 19 (Bid Security);
Written power of attorney authorizing the signatory of the bid to commit the Bidder;
Documentary evidence establishing to the Procuring Agency's satisfaction, and in accordance with ITB Clause 3.1 that the Bidder is qualified to perform the Contract if its bid is accepted. In the case where prequalification of Bidders has been undertaken, and pursuant to ITB Clause 3.1, the Bidder must provide evidence on any changes in the information submitted as the basis for prequalification, or if there has been no change at all in said information, a statement to this effect;
Any other documentation as requested in the Bid Data Sheet.

**15. Bid Form** 15.1 The Bidder shall complete the Bid Form and the Price Schedule provided in the Bidding Documents.

**16. Bid Price** 16.1 Prices shall be quoted in Pak Rupee.

16.2 Prices shall also be quoted as specified in each Price Schedule included in Section VII, Sample Forms. The disaggregation of price components is required solely for the purpose of facilitating the comparison of bids by the



Procuring Agency. This shall not in any way limit the Procuring Agency's right to contract on any of the terms offered.

16.3 The Bidder's separation of price components in accordance with ITB Clause 16.2 above will be solely for the purpose of facilitating the comparison of bids by the Procuring Agency and will not in any way limit the Procuring Agency's right to contract on any of the terms offered.

16.4 Unless otherwise specified in the Bid Data Sheet, prices quoted by the Bidder shall be fixed during the Bidder's performance of the Contract and not subject to variation on any account. A bid submitted with an adjustable price quotation will be treated as non-responsive and will be rejected. Pursuant to Sub-Clause 14.1 above, and if so indicated in the Bid Data Sheet, bids are being invited for one or more items, or for individual Contracts (lots). Each item offered must comprise the full quantity required under that item. Bidders wishing to offer any price reduction for the award of more than one Contract shall specify in their bid the price reductions applicable to each package or, alternatively, to individual Contracts within the package. Price reductions may be submitted as an amount or a percentage to be applied to the bid prices.

16.5 Form prescribed for quoting of prices is to be filled in very carefully, preferably typed. Any alteration/ correction must be initialed. Every page is to be signed and stamped at the bottom. Serial number of the quoted item may be marked with red/yellow marker.

16.6 The Bidder should quote the prices of goods according to the technical specifications as provided in Section VI of this document. The technical specifications of goods, different from the required specifications, shall straightway be rejected.

16.7 The Bidder is required to offer a competitive price. All prices must include the taxes and duties, where applicable. If there is no mention of taxes, the offered/ quoted price shall be considered as inclusive of all prevailing taxes/ duties.

16.8 The benefit of exemption from or reduction in the taxes and duties shall be passed on to the Procuring Agency

16.9 Prices offered should be for the entire quantity of an item demanded in the Schedule of Requirement; partial quantity offers shall straightaway be rejected. Conditional offer shall also be considered as non-responsive Bid

16.10 While making a price quote, trend/ inflation in the rate of goods and services in the market should be kept in mind. No request for increase in price due to market fluctuation in the

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| | | cost of goods and services shall be entertained. |
| | 16.11 | Unless otherwise specified in the Bid Data Sheet, prices quoted by the Bidder shall be fixed during the Bidder's performance of the Contract and not subject to variation on any account. |
| **17. Currencies of Bids** | 17.1 | Prices shall be quoted in currency as stipulated in the Bid Data Sheet |
| **18. Period of Validity of Bids** | 18.1 | Bids shall remain valid for the period stipulated in the Bid Data Sheet which will commence from the date of bid opening. Any bid valid for a shorter period shall be rejected |
| | 18.2 | In exceptional circumstances, prior to expiry of the original bid validity period, the Procuring Agency may request that the Bidders to extend the period of validity for a specified additional period. The request and the responses thereto shall be made in writing. A Bidder may refuse the request without forfeiture of its bid security. A Bidder agreeing to the request will not be required or permitted to modify its bid except to the extent of bid validity and bid security only, |
| **19. Bid Security** | 19.1 | The Bidder shall furnish, as part of its bid, a bid security as specified in the Bid Data Sheet. The amount of the Bid Security shall be as stipulated in the Bid Data Sheet in Pak Rupees. |
| | 19.2 | The bid security shall remain valid for a period of 30 days beyond the validity period for the bid, and beyond any extension subsequently requested. |
| | 19.3 | The bid security shall, at the Bidder's option, be in the form of either a bank guarantee, CDR (Call Deposit Receipt) or banker's cheque from a scheduled bank in Pakistan., The format of the bank guarantee shall be in accordance with the forms included in the bidding documents.; |
| | 19.4 | Any bid not accompanied by an acceptable bid security shall be rejected by the Procuring Agency being non-responsive. The bid security of a joint venture must be in the name of the principal partner of the joint venture |
| | 19.5 | The bid securities of technically non-responsive Bidders will be returned as promptly as possible |
| | 19.6 | The bid security of the successful Bidder will be returned when the Bidder has signed the Contract and furnished the required performance security |
| | 19.7 | The bid security may be forfeited:<br>if the Bidder withdraws its bid after opening of the bids, except as provided in ITB Sub-Clauses 18.2 or<br>in the case of a successful bidder, if the Bidder fails within the specified time limit to:<br>sign the contract; or |

furnish the required performance security.

**20. Format and Signing of Bid**

20.1 The Bidder shall prepare an original and the number of copies/sets of the bid indicated in the Bid Data Sheet, clearly marking each one as "ORIGINAL BID" and "COPY OF BID," as appropriate. In the event of any discrepancy between them, the original shall govern

20.2 The original and all copies of the bid, each consisting of the documents listed in ITB Sub-Clause 14.1, shall be typed or written in indelible ink and shall be signed by the Bidder or a person or persons duly authorized to sign the Bid. The later authorization shall be indicated by written power of attorney, which pursuant to ITB Sub-Clause 14.1 shall accompany the bid

20.3 Any interlineations, erasures, or overwriting to correct errors made by the Bidder should be initialed by the person or persons signing the bid.

20.4 The Bid shall be accompanied by the original receipt for payment made for the purchase of the bidding document. In an event where the Bidder has downloaded the bidding document from the web site, he will be required to submit /exhibit the original payment receipt at the time of opening of the bids failing which his bid will not be opened.

20.5 The Bidder shall furnish in the Bid Form (a sample of which is provided in the Sample Forms Section of the Bidding Documents) information regarding commissions or gratuities, if any, paid or to be paid to agents relating to this bid and to the execution of the Contract if the Bidder is awarded the Contract

## D. Submission of Bids

21. Sealing and Marking of Bids

21.1 Bidders may submit their bids by hand or through registered post which should reach to the Procuring Agency within the given time. The bid received after the stipulated time shall stand rejected without any legal liability on the Procuring Agency.

The Bidder shall enclose the original and each copy of the bid, in separate sealed envelopes, duly marking the envelopes as "ORIGINAL" and "COPY". The envelopes containing the original and copies shall then be enclosed in another envelope.

The envelopes shall be marked as "FINANCIAL PROPOSAL" and "TECHNICAL PROPOSAL" in bold and legible letters to avoid confusion. Similarly, the Bidder shall seal the proposals/ bids in separate envelopes. The envelopes shall then be sealed in an outer envelope.

21.2 The inner and outer envelopes shall:

bear the name and address of the Bidder;
be addressed to the Procuring Agency at the address given in the Bid Data Sheet;
Clearly mark inner envelopes separately as Financial and Technical Bids
bear the specific identification of this bidding process indicated in the Bid Data Sheet, the Invitation for Bids (IFB) title and number indicated in the Bid Data Sheet; and
bear a statement "DO NOT OPEN BEFORE [date and time]" to be completed with the time and date specified in the Bid Data Sheet in accordance with ITB Sub-clause 22.1.

21.3 If the outer envelope is not sealed and marked as required by ITB Sub-Clause 21.1 the Procuring Agency will assume no responsibility for the misplacement or premature opening of the bid

21.4 In case the Bidder is bidding for more than one item, they will have to prepare separate price schedule for each item, seal them in separate envelops with naming of items. Envelops of each individual items will further be sealed in one envelope marked as "Financial Proposal". This arrangement will enable the Procuring Agency to return bid related to any item of any Bidder unopened in case the bid is declared as ineligible or non-responsive

**22. Deadline for Submission of Bids**

22.1 Bids must be received by the Procuring Agency at the address, date and time as specified in the Bid Data Sheet

22.2 The Procuring Agency may, at its discretion, extend the deadline for the submission of bids by amending the Bidding Documents in accordance with ITB Sub-Clause 10.3, in which case all rights and obligations of the Procuring Agency and Bidders previously subject to the deadline will thereafter be subject to the deadline as extended

**23. Modification and Withdrawal of Bids**

23.1 Modification or withdrawal of bids is not allowed after opening of bids

## E. Opening and Evaluation of Bids

**24. Bid Opening**

24.1 All bids received, shall be opened by the Procuring Agency 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.

24.2 The bids shall be opened in accordance with the procedure specified in Bid Data Sheet

24.3 All Bidders in attendance shall sign an attendance sheet.



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24.4 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)

24.5 Bids that are not opened and read out at bid opening shall not be considered further for bid evaluation irrespective of the circumstances.

24.6 The Procuring Agency shall have the minutes of the Bid opening (technical and when applicable financial) recorded.

24.7 The financial bid of the non-responsive bidder shall be returned unopened.

24.8 The financial bids without Bid Security being non-responsive shall be returned unannounced to the Bidders.

**25. Clarification of Bids**

25.1 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, in accordance with ITB Sub-Clause 28.1

**26. Confidentiality**

26.1 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.

26.2 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

26.3 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.



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**27 Examination of Bids and Determination of Responsiveness**

27.1 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.

27.2 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.

27.3 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.

27.4 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.

**28. Correction of Errors**

28.1 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.

**29. Evaluation of Bids**

29.1 The Procuring Agency shall evaluate and compare the bids that have been determined to be substantially responsive in accordance with ITB Clause 27 above.

29.2 All bids shall be evaluated in accordance with the Evaluation Criteria and other terms and conditions set forth in the bidding documents

**30. Qualification of Bidder**

30.1 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

30.2 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.

**31 Announcement of Evaluation Report**

31.1 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.

## F. Award of Contract

**32 Post Qualification**

In the absence of pre-qualification, the Procuring Agency will determine to its satisfaction whether the Bidder that is selected as having submitted the lowest evaluated responsive bid is qualified to perform the Contract satisfactorily, in accordance with the criteria listed in ITB Sub-Clause 5.1 and any additional post-qualification criteria stated in the Bid Data Sheet. If a pre-qualification process was undertaken for the Contract(s) for which these Bidding Documents were issued, the Procuring Agency will determine in the manner described above that no material changes have occurred after the pre-qualification that negatively affect the ability of the Bidder that has submitted the lowest evaluated bid to perform the Contract.
The determination will evaluate the Bidder's financial, technical and production capabilities. It will be based on an

examination of the documentary evidence of the Bidder's qualifications submitted by the Bidder, pursuant to ITB Sub-Clause 5.1, as well as other information and clarification the Procuring Agency deems necessary and appropriate.

An affirmative post-qualification determination will be a pre-requisite for award of the contract to the lowest evaluated Bidder. A negative determination will result in rejection of the Bidder's bid, in which event the Procuring Agency will proceed to the next-lowest evaluated Bidder to make a similar determination of that Bidder's capabilities to perform satisfactorily.

**33 Award Criteria** 32.1 The Procuring Agency will award the Contract to the Bidder whose bid has been determined to be substantially responsive and has been determined to be the lowest evaluated bid, provided further that the Bidder is determined to be qualified to perform the Contract satisfactorily, pursuant to ITB Clause 34, within the original or extended period of bid validity

**34. Procuring Agency's Right to Accept or Reject any or all bids** 34.1 The Procuring Agency reserves the right under Rule 25 of Sindh Public Procurement Rules, 2010 (Amended 2013) to accept or reject any bid, or to annul the bidding process and reject all bids at any time prior to acceptance of bid , without thereby incurring any liability to the affected Bidder or Bidders

**35. Procuring Agency's Right to Vary Quantities at Time of Award** 35.1 The Procuring Agency reserves the right to increase or decrease the quantities of the goods being procured to the extent as specified in the Bid Data Sheet at the time of Contract award. The qualified bidder shall be bound to supply the requisite quantity as per approved evaluated rate and without any change in terms and conditions of the bidding document

**36. Notification of Award** 36.1 Prior to the expiration of the period of bid validity, the Procuring Agency will notify the successful Bidder in writing by registered letter, , that its bid has been accepted.

36.2 The notification of award will constitute the formation of the Contract between the Procuring Agency and the successful Bidder

36.3 The enforcement of the Contract shall be governed by Rule 50 of the SPPR-2013

36.4 Upon the successful Bidder's furnishing of the signed Contract Form and performance security pursuant to ITB Clause 40, the Procuring Agency will immediately execute the contract.

36.5 If, after notification of award, a Bidder wishes to ascertain the grounds on which its bid was not selected, it should

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| | | address its request to the Procuring Agency. The Procuring Agency will promptly respond in writing to the unsuccessful Bidder |
| | 36.6 | After publication of the award, unsuccessful bidders may request in writing to the Procuring Agency for a debriefing under Rule 51 of SPPR 2013 seeking explanations on the grounds on which their bids were not selected. The Procuring Agency shall promptly respond in writing to any unsuccessful Bidder who, after Publication of contract award, requests a debriefing<br>The requesting bidder shall bear all the costs of attending such a debriefing. |
| **37. Limitation on Negotiations** | 37.1 | There shall be no negotiation on price. Rule 52 of the SPPR-2013 |
| **38. Performance Guarantee** | 38.1 | Within ten(10) working days of the receipt of notification of award from the Procuring Agency, the successful Bidder shall furnish a Performance Guarantee, in the form and manner prescribed by the Procuring Agency as specified in the bidding document |
| | 38.2 | The Bid Security submitted by the bidder at the time of submitting its bid shall be returned to the successful Bidder upon submission of Performance Guarantee |
| | 38.3 | Failure to provide a Performance Guarantee by the Bidder is a sufficient ground for annulment of the award and forfeiture of Bid Security. In such event the Procuring Agency may award the contract to the next lowest evaluated bidder or call for new bid |
| **39. Signing of Contract** | 39.1 | The contract with the successful bidder shall be executed as per call letter for contract execution within ten days. |
| | 39.2 | The Contract shall become effective from the date of affixation of signature by the Procuring Agency and the successful Bidder on the Contract document, |



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# SECTION II
# Bid Data Sheet
# (BDS)



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## 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.

| ITB Ref | Description | Detail |
|---|---|---|
| | Commencement of sale of Bidding Document | 10-04- 2015 |
| ITB Clause 1.1 | Bid title and reference number | Procurement of Contraceptives for Department of Population Welfare and Department of Health, Government of Sindh, Pakistan PWDS/W&D/CC/2014-15/07, Dated 8th April, 2015 |
| 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:<br>(a) Certificate of analysis, documenting product's compliance with specification and performance requirements as given at section VI<br>(b) For products manufactured outside of Pakistan and imported, a certificate documenting that the quoted product submitted is WHO prequalified.<br>(c) 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, see list below |
| ITB Clause 9.1 | Bidding procedure | Single stage – Two Envelop procedure |
| ITB Clause 11.1 | Clarification of Bidding Documents | Secretary<br>Population Welfare Department,<br>Government of Sindh,<br>39 – Z/1, Block 6, PECHS<br>Karachi, Pakistan<br>Phone: +92-21-34525675<br><br>Email:proc_pwd@pwdsindh.gov.pk, |



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| 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 | DDP 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 | Prices shall be quoted in Pakistan Rupees. For products manufactured outside of Pakistan to be imported prices shall also be quoted in Pakistan Rupees by the Authorized Agents/Primary manufacturer |
| 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<br>Population Welfare Department,<br>Government of Sindh,<br>39 – Z/1, Block 6, PECHS<br>Karachi, Pakistan<br>Phone: +92-21-34525675 |
| ITB Clause 21.2.iv | Marking of the Bids | Procurement of Contraceptive for<br>Secretary<br>Population Welfare Department,<br>Government of Sindh,<br>39 – Z/1, Block 6, PECHS<br>Karachi, Pakistan<br>Phone: +92-21-34525675<br>PWDS/W&D/CC/2014-15/07,<br>Dated 08th April, 2015 |
| ITB Clause 22.1 | Last date and time for the receipt of bidding document | April 24, 2015 11:00 PST |
| ITB Clause 24.1 | Date, time and venue of opening of technical bids | April 24, 2015 11:30 PST<br>In the office of Secretary<br>Population Welfare Department,<br>Government of Sindh,<br>39 – Z/1, Block 6, PECHS<br>Karachi, Pakistan<br>Phone: +92-21-34525675 |



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| ITB Clause 36.1 | Right to Vary Quantities at Time of Award | As per SPPRA 2013 |

**ITB 5.1 Qualifications of the Bidder**

Qualification requirements for Bidders, following documents must be included with the bid:

1. Documentary evidence of the Bidder's qualifications to perform the Contract if its bid is accepted:
   (i) that, in the case of a Bidder offering to supply contraceptives under the Contract that the Bidder manufactures or otherwise produces (using ingredients supplied by primary manufacturers), evidence that the Bidder:
      a) is incorporated in the country of manufacture of the contraceptives;
      b) has been licensed by the regulatory authority in the country of manufacture to supply the contraceptives;
      c) has manufactured and marketed the specific contraceptives covered by this Bidding Document.
      d) has received a satisfactory cGMP inspection certificate in line with the WHO certification scheme on pharmaceuticals moving in International Commerce from the regulatory authority (RA) in the country of manufacture of the contraceptives or has been certified by the competent authority of a member country of the Pharmaceuticals Inspection Convention (PIC), and has demonstrated compliance with the quality standards during the past two years prior to bid submission;
   (ii) that, in the case of a Bidder offering to supply contraceptives under the Contract, the Bidder does not manufacture or otherwise produce:
      (a) that the Bidder has been duly authorized by a manufacturer of the contraceptives that meets the criteria under (i) above to supply the contraceptives in the Procuring Agency's country.
2. The Bidder shall also submit the following additional information:
   a. documentary evidence of installed manufacturing capacity
   b. Documentary evidence indicating average annual production capacity
   c. Documentary evidence of the batch size of the quoted items
   d. copies of its audited financial statements for the past three fiscal years;
   e. details of on-site quality control laboratory facilities and services and range of tests conducted;
   f. list of major supply contracts for similar products conducted within the last five years.
   g. child free labor certificate documenting that their firm is free from child labor and has a standard child free labor policy.
   h. valid import license (where applicable)
   i. Certificate for National Tax number
   j. Certificate for General Sales Tax
   k. Certificate of registration with Sindh Revenue Board (where applicable)

**ITB 14.1 Documents Constituting the Bid**

In addition to the documents stated in ITB 14.1, the following documents must be included with the Bid

1. Valid cGMP
2. WHO Prequalification Certificate for quoted items manufactured outside of Pakistan
3. Manufacturer / Principal's authorization certificate
4. Valid Registration by DRAP (if already obtained), where applicable

5. Documentary evidence for obtaining registration (if not previously obtained), where applicable
6. Copy of Agreement in case of joint venture / consortium of two or more bidders
7. Undertaking that the bidder is NOT blacklisted or debarred at local and international level
8. The Bidder will also provide representative samples of the products quoted.
   a. The sample quantities of pharmaceutical products such as injectables and hormonal contraceptives, to be provided not less than twenty units from most recent batch/lot.
   b. The sample quantities of non pharmaceuticals, such as condoms and IUDs, should not be less than ten from most recent batch/lot.
   c. All samples to be provided by the bidder's representative in person at the time of opening of technical bids.

      Note: For any products requiring testing at a WHO prequalified laboratory per the requirements of this bid, all related expenses including laboratory tests and costs to ship products to the laboratory for testing will be at the bidder's expense.



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## Evaluation and Comparison of Bids

The evaluation will take into account WHO prequalification, cGMP certification, specific product experience, financial status, production capacity and samples verification. The evaluation criteria will be scored according to the following table.

### Evaluation Criteria Table

| S. No. | Parameters | Detail | Total Marks | Remarks |
|---|---|---|---|---|
| 1 | General experience of the bidder in supplying FP products | i Less than 2 years 0<br>ii 2 to 5years 5<br>iii Above 5years 8 | 08 | Documentary evidence will have to be provided |
| 2 | Specific experience of the bidder in supplying quoted items | i Less than 1 year 1<br>ii 1 to 2 years 8<br>iii Above 2 years 12 | 12 | Documentary evidence will have to be provided |
| 3 | Manufacturing experience of Principal Manufacturer in quoted products | i Less than 1 year 0<br>ii 1 to 3years 5<br>iii) 3 to 5 years 10<br>iv) Above 5 years 15 | 15 | Documentary evidence will have to be provided |
| 4 | Financial status of the bidders<br>a) Average annual turnover / sales value in PKR in last three years | i If less than Half of the estimated contract value 3<br>ii) If greater than Half of the estimated contract value 8<br>iii) If greater than the estimated contract value 15 | 15 | Bidder to provide audited financial statements for the last 3 years |



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<table>
<tr>
<td>5</td>
<td>Production Capacity of Primary Manufacturer</td>
<td>Per day production capacity of quoted items against the total advertised quantity:
<table>
<tr><td>i</td><td>Less than 1%</td><td>0</td></tr>
<tr><td>ii)</td><td>1%</td><td>05</td></tr>
<tr><td>iii)</td><td>1.1%-1.5%</td><td>07</td></tr>
<tr><td>iv)</td><td>1.6%-2%</td><td>10</td></tr>
<tr><td>v)</td><td>Above 3%</td><td>15</td></tr>
</table>
</td>
<td>15</td>
<td>Provide documentary evidence</td>
</tr>
<tr>
<td>6</td>
<td>Product Sample</td>
<td>Samples will be examined per following parameters:<br>a. Labeling and Packing Rules 1986<br>b. Outer packing<br>c. Inner packing<br>d. Physical appearance
<table>
<tr><td>i</td><td>Excellent</td><td>5</td></tr>
<tr><td>ii</td><td>Good</td><td>3</td></tr>
<tr><td>iii</td><td>Satisfactory</td><td>2</td></tr>
<tr><td>iv</td><td>Unsatisfactory</td><td>0</td></tr>
</table>
</td>
<td>5</td>
<td>Product that 100% comply with the advertised specifications will be considered for evaluation. Products registered with DRAP should follow specific as registered with DRAP</td>
</tr>
</table>

**Total Marks: 70**

Qualifying marks: 70% (49) and above

# SECTION III
# General Conditions of Contract (GCC)

## General Conditions of Contract (GCC)

**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 (provincial and district Health department) 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 pursuant to GCC Clause 6.2.

(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

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| | | 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. |



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**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.

9.4 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

9.5 Nothing in GCC Clause 9 shall in any way release the Supplier from any warranty or other obligations under this Contract.



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| **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.<br>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 |



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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 Procuring Agency shall make payments to the Supplier in accordance with the conditions set forth in the Payment Schedule agreed and annexed to this contract.

16.3 All payments shall be made in the Pak Rupees .

**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.**

20.1 The Supplier shall not be allowed to sublet and award



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**Subcontracts**

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*



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*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.



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**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.



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| **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,<br>(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<br>(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. |



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# SECTION IV
# Special Conditions of Contract (SCC)



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## 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 The Contract words and expressions shall have the same meanings as are respectively assigned to them in the General Conditions of Contract

1.3 The contract shall remain valid for one year from the date of signing, unless amended by mutual consent

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 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 | The Supplier shall test batches of contraceptives ready for shipment in accordance with the WHO specification. The size of the sample for testing will be calculated by reference to ISO2859-1. With each consignment, the Supplier must provide a certificate of quality control test results in conformity with the standards laid down in ISO 2859-1 and in accordance with the general sampling levels appropriate to each feature as necessary. The Supplier will bear the cost of such tests |
| | 6.2 | For imported contraceptives, copies of WHO prequalification certificate to be provided |
| | 6.3 | 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<br>Population Welfare Department, Government of Sindh,<br>39 – Z/1, Block 6, PECHS<br>Karachi, Pakistan<br>Phone: +92-21-34525675<br>Fax: +92-21- 34522644<br>Email: proc_sindh@pwdsindh.gov.pk |
| **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.<br>All packing (which includes unit, master carton, and shipping carton) must have the following printed wording in appropriate size and at place.<br>"Not for Sale –Govt. of Sindh Property".<br>(*printed in green color along with Sindh government logo as per sample approved by Procuring Agency*).<br>GS1 health commodities standard data matrix bar code must be included in primary as well as secondary packing.<br>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 |



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## SCHEDULE OF REQUIREMENTS

| # | Products | Quantity | Total Delivery period | Shelf life minimum | Place of delivery |
|---|---|---|---|---|---|
| 1 | Male Latex Condoms | 57,209,899 | 45 days of issuance of Work order. The delivery period may vary as per operational exigency of the Government | 75% | CWH, Karachi |
| 2 | IUD (Cu-T380A) | 114,714 | -do- | 75% | CWH, Karachi |
| 3 | Implant (Double Rod) | 27169 | -do- | 75% | CWH, Karachi |
| 4. | Implant (Single Rod) | 63393 | -do- | 75% | CWH, Karachi |
| 5 | COC (cycles) | 5,286,530 | -do- | 75% | CWH, Karachi |
| 6 | PCP (cycles | 135,257 | | 75% | CWH, Karachi |
| 7 | ECP (Pack of 2 tabs) | 38,052 | -do- | 75% | CWH, Karachi |
| 8 | Injectable DMPA (3 month) with syringe | 1,667,762 | -do- | 75% | CWH, Karachi |
| 9 | Injectable (2 month) with syringe | 5,739 | -do- | 75% | CWH, Karachi |

Mode of Penalty

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

# Section VI

# Technical Specifications



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| | |
|---|---|
| **sampling** | Three LOTS sampled in accordance with *ISO 2859–1* and Annex B of *ISO 4074*. |
| **conditioning** | Incubate samples in their individual sealed containers according to the relevant annex of *ISO 4074*:<br>• One set for 168 ± 2 hours at (70 ± 2) °C, and another set for (90 ± 1) days at (50 ± 2) °C.<br>• At the end of the incubation periods, withdraw the condoms and test for airburst properties, freedom from holes and package seal.<br>• The incubation period at (50 ± 2) °C can be extended to 120 or 180 days in order to estimate a provisional shelf life by accelerated ageing, in which case testing at 90 days is not necessary. |
| **testing requirement** | All three LOTS of condoms shall remain in compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of *ISO 4074*. |

**Performance Requirements**

The performance requirements specified here are based on the requirements of *ISO 4074*. These requirements cannot be altered. Verification of compliance with these requirements must be done as part of prequalification and the LOT-by-LOT Pre-shipment compliance testing of the product. For prequalification purposes the sampling plans specified in Annex B of *ISO 4074* shall be used. For LOT-by-LOT Pre-shipment compliance testing the sampling plans specified in Annex A of *ISO 4074* shall be used.

| **Performance Requirements** | |
|---|---|
| **Bursting volume and pressure** | |
| **sampling** | In accordance with *ISO 2859–1* General Inspection Level I. For prequalification testing at least Code Letter M as specified in Annex B of *ISO 4074* shall be used. |
| **testing** | In accordance with test method in the relevant annex of *ISO 4074* and the relevant clause in *ISO 4074*. |
| **requirement** | **Minimum bursting requirements as listed below:**<br>**AQL 1.5**<br>**Volume:**<br>16.0 $dm^3$ for condoms with widths less than 50.0 mm<br>18.0 $dm^3$ for condoms with widths from 50.0 mm up to 55.5 mm<br>22.0 $dm^3$ for condoms with widths greater than or equal to 56.0 mm |

5 As described in *ISO 4074*.



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| Performance Requirements | |
|---|---|
| **Bursting volume and pressure after oven conditioning (optional: see Annex I[6])** | |
| **sampling** | In accordance with *ISO 2859–1* General Inspection Level I. For prequalification testing at least Code Letter M as specified in Annex B of *ISO 4074* shall be used. |
| **testing** | Condition the samples in accordance with the relevant annex of *ISO 4074* for (168 ± 2) hours at 70 °C. Remove from oven and keep the packages at (25 ± 5) °C until tested. Within 96 hours but no sooner than 12 hours after removal from the oven, determine the bursting volume and pressure in accordance with the test method in the relevant annex of *ISO 4074* and the relevant clause in *ISO 4074*. |
| **requirement** | **Minimum bursting requirements as listed below:**<br>**AQL 1.5**<br>**Volume:**<br>16.0 $dm^3$ for condoms with widths less than 50.0 mm<br>18.0 $dm^3$ for condoms with widths from 50.0 mm up to 55.5 mm<br>22.0 $dm^3$ for condoms with widths greater than or equal to 56.0 mm |
| **Freedom from holes and visible defects** | |
| **sampling** | *ISO 2859–1* General Inspection Level I, but at least Code Letter M. |
| **testing** | In accordance with the relevant annex of *ISO 4074*. |
| **requirement** | In accordance with test method in the relevant annex of *ISO 4074*.<br>Freedom from holes: **AQL 0.25**<br>Critical visible defects: **AQL 0.4**<br>Non-critical visible defects: **AQL 2.5**<br>*ISO 4074* describes a limited number of critical visible defects. WHO specifies an extended list of critical |
| **Package seal integrity** | |
| **sampling** | *ISO 2859–1* Inspection Level S-3. |
| **testing** | In accordance with the package integrity test method in the relevant annex of *ISO 4074*. |
| **requirement** | **AQL 2.5** |

6 As an interim measure pending the production of definitive evidence supporting the benefits of testing oven-conditioned condoms on a LOT-by-LOT basis, it has been decided to make this an optional requirement within the *WHO/UNFPA Specification*. Procuring Agencys may wish to include this requirement in specific contracts depending upon the level of confidence in the supplier.

### Design Requirements

The design properties listed below may be adapted, where appropriately indicated, to reflect the specific needs of the programme and population of intended users. Modification should be based on information about the target population. Verification of

compliance with these requirements is to be done as part of the LOT-by-LOT compliance testing of the product.

If specific design changes are agreed between manufacturer and Procuring Agency, then any appropriate testing procedures, sampling plans and compliance levels (AQLs) should also be agreed. Changes in condom design, such as different shapes or the inclusion of pigments, can affect airburst properties and, in some circumstances, freedom from holes.

*It is recommended* that, where changes to the specification are made, dimensional requirements and design features should be subject to *ISO 2859-1* Inspection Level S-2 with an **AQL of 1.0.**

Appropriate reference samples should be maintained by the manufacturer and testing laboratory. The Procuring Agency and/or national regulatory authority may also retain reference samples.

| Design Requirements | |
|---|---|
| **shape and texture** | |
| Verify by visual inspection | The surface of the condoms can be textured or non-textured. Texturing typically consists of a number of ribs or dots formed onto the surface of the condom.<br><br>Condoms may be of any shape consistent with normal commercial practice and client requirements. |
| **Integral bead** | |
| Verify by visual inspection | The open end of the condom shall have a rolled ring of latex, called an integral bead. |
| **Colour** | |
| Verify by visual inspection | Condoms can be translucent or colored.<br><br>**Pigments used with colored condoms shall be suitable for use in medical devices.** |
| **odour, fragrance and flavour** | |
| Verify by visual inspection and smell | The condoms shall not give off an unpleasant odour when the package is opened at any time after manufacture and for the shelf-life of the product. (Condoms have a characteristic odour of rubber, which tends to dissipate quickly once the package is opened. A mild odour that dissipates quickly is acceptable.)<br><br>It is suggested that appropriate reference samples be retained by the testing laboratory to help resolve disputes over odour. It is recommended that the retained samples be kept for the duration of the shelf-life of the condom.<br><br>Procuring Agencys may specify the addition of a suitable fragrance and/or flavour. Such fragrances and flavours must be non-toxic, non-irritant and not degrade the rubber. |
| **Design Requirements** | |



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| | |
|---|---|
| | If a flavour is desired, describe here (specify flavour and amount added) and provide full details of the flavour including a Material Safety Data Sheet (MSDS). |
| testing | See Annex III for guidance on odour testing. If a masking agent or flavour is used, odour testing should become part of the LOT-by-LOT Pre-shipment compliance testing. Odour testing should be included in ageing studies. |
| **Width** | |
| **sampling** | In accordance with *ISO 2859–1* Inspection Level S-2. |
| **testing** | In accordance with the test method in the relevant annex of *ISO 4074*. |
| **requirement** | Standard widths within the public sector are 49 mm and 53 mm, with a tolerance of ± 2 mm.<br>**AQL 1.0**<br>Other widths are available and may be more appropriate for specific target populations described in Annex I. Users should select the appropriate width based on the best available data on the target population.<br>Indicate the width here: |
| **Length** | |
| **sampling** | In accordance with *ISO 2859–1* Inspection Level S-2. |
| **testing** | In accordance with the test method in the relevant annex of *ISO 4074*. |
| **requirement** | A minimum of 165 mm for condoms with widths less than 50.0 mm.<br>A minimum of 180 mm for condoms with widths from 50.0 mm up to 55.5 mm.<br>A minimum of 190 mm for condoms with widths equal to or greater than 56.0 mm.<br>**AQL 1.0**<br>Length may be specified based on the best available data on the target population.<br>Indicate the length here:<br>The width is defined as the mean lay-flat width of 13 condoms measured in accordance with the relevant annex of *ISO 4074* at a point (35 ± 15) mm from the open end, rounded to the nearest 0.5 mm. |
| **thickness** | |
| **sampling** | In accordance with *ISO 2859–1* Inspection Level S-2. |
| **testing** | In accordance with the test method in the relevant annex of *ISO 4074*. |
| **requirement** | The thickness measurements are taken at three points: 30 ± 5 mm from the open end, 30 ± 5 mm from the closed end (excluding the reservoir tip), and at the mid-distance between those two points.<br>For partially textured condoms the thickness shall be measured at points closest to those specified above where the surface is smooth. The locations of the points of measurement shall be noted.<br>If it is not possible to locate a smooth region on the condom where thickness can be measured, then thickness shall be measured at the points specified above and the specification should be adjusted to allow for the effect of the texturing—for example, by reference to the manufacturer's specification.<br>**AQL 1.0**<br>The mean single-wall thickness (calculated from the three individual measurements) for each condom shall be 0.065 + 0.015 mm – 0.020 mm.<br>*Condoms thicker than 0.080 mm are usually considered to be extra thick, whereas condoms that are thinner than 0.060 mm are usually considered to be thin.* There is no evidence that extra thick condoms (sometimes called extra strong) provide additional protection. |

## Design Requirements



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| Quantity of lubricant including powder | |
|---|---|
| sampling | In accordance with *ISO 2859–1* Inspection Level S-2. |
| testing | In accordance with the test method in the relevant annex of *ISO 4074*. |
| requirement | The condom shall be lubricated with a quantity of silicone fluid having a viscosity between 200 and 350 centistokes.<br><br>*Other lubricants such as glycols and water-based lubricants may be used. Oil-based lubricants* ***should NOT*** *be used.*<br><br>If an alternative lubricant is required, specify the type here and provide full details of the lubricant including a Material Safety Data Sheet (MSDS). |

| Individual package materials and markings | |
|---|---|
| sampling | In accordance with *ISO 2859* Inspection Level S-3. |
| testing | The sample of condom packages is visually inspected to verify the required aspects of package quality. |
| requirement | The colour, print design and identification markings, including Pantone references and font sizes, shall be as specified by the buyer and annexed to this specification.<br><br>The individual package shall have the following markings:<br>• manufacturer's name;<br>• LOT number or LOT identification code (printed at the time of packaging, not pre-printed);<br>• expiry date: month and year labelled expiry date;<br>• date in a language to be specified by the Procuring Agency. |
| Verified by visual inspection | Individual packages shall be square or circular and shall not distort the rolled condom. The package shall be hermetically sealed and shall protect the product from oxygen, ozone, water vapour, ultraviolet let and visible light. |
| Verified by supplier's data or independent test | The recommended packages should be constructed of a laminate, which includes a layer of suitable impermeable flexible aluminum foil (recommended minimum thickness of 8 micrometers) and layers of plastic materials suitable for the mechanical protection of the metal foil and for printing and sealing. |



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| Design Requirements | |
|---|---|
| Alternate package materials | *Alternative package materials can be accepted if they have barrier and strength properties comparable to those of the packaging recommended above or if there are real-time stability data to show that the condom in its pack has adequate shelf-life.*<br><br>If an alternative material is required, append the full specification and mark here;<br>The LOT numbers on packages must be printed at the time of packaging.<br><br>In addition, the following shall apply:<br><br>• There shall be no evidence of leakage. ☐ |

**Packaging for shipment**

Inspections or verifications in this section will generally be carried out during LOT-by-LOT Pre-shipment compliance testing and periodic inspections.

Information included on all packaging shall be in accordance with the language specified by the Procuring Agency.

| Packaging Requirements | |
|---|---|
| consumer packs | The consumer packs should contain 10 (ten) individual pieces of condom. |
| inner boxes | The inner boxes shall be constructed of cardboard. A suitable moisture-resistant barrier on its inner or outer surfaces may be specified by the Procuring Agency. The boxes shall be of sufficient strength and rigidity to retain their shape through every stage of the distribution chain.<br><br>The inner boxes will be marked in a legible manner to describe the contents and to facilitate identification in case of subsequent query.<br><br>**the following information shall be included in the inner box marking:**<br><br>• LOT identification number;<br>• month and year of manufacture (including the words *Date of Manufacture, Month, Year*) in language(s) to be specified by the Procuring Agency. The year will be written as a four-digit number and the month as a two-digit number;<br>• month and year of expiry (including the words *Expiry Date, Month, Year*) in language(s) to be specified by the Procuring Agency. The year will be written as a four-digit number and the month as a two-digit number;<br>• manufacturer's name and registered address;<br>• nominal width of the condom, expressed in millimetres;<br>• number of condoms in box; |



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| Packaging Requirements | |
|---|---|
| information | If, in accordance with local regulations or programme requirements, information is to be provided with the condom, then the following instructions should be considered for inclusion:<br>• to handle the condom carefully, including removal from the package so as to avoid damage to the condom by fingernails, jewellery, etc.;<br>• how and when to put on the condom; mention should be made that the condom should be placed on the erect penis before any contact occurs between the penis and the partner's body, to assist in the prevention of sexually transmitted infections and pregnancy;<br>• to stop and check if the user feels the condom slipping, as it may fall off the penis;<br>• to stop and check if the user feels the condom tightening excessively on the penis, as this may lead to breakage;<br>• to withdraw the penis soon after ejaculation, while holding the condom firmly in place at the base of the penis;<br>• if an additional lubricant is desired, to use the correct type of lubricant, one that is recommended for use with condoms, and the need to avoid the use of oil-based lubricants, such as petroleum jelly, baby oil, body lotions, massage oils, butter, margarine, etc., as these are deleterious to the integrity of the condom;<br>• to consult a doctor or pharmacist about the compatibility of topical medicines that might come in contact with the condom;<br>• to seek medical assistance at soon as possible within five days, should a condom leak or burst during use;<br>• if the individual container is obviously damaged, to discard that condom and use a new one from an undamaged package;<br>• instructions on how to dispose of the used condom;<br>• a statement that the condom is for single use;<br>• the number of the International Standard, i.e. *ISO 4074*.<br><br>***It is recommended*** **that the following statement relating to the safety and effectiveness of the condom be included:** |
| exterior shipping cartons | The inner boxes shall be packed into plastic or other waterproof lining bags, which will be placed in three-wall cartons made from weather-resistant corrugated fibreboard with a bursting test strength of not less than 1900 kPa.<br><br>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 centre seams and extending over the ends by not less than 75 mm.<br><br>The cartons may be secured by plastic strapping at not less than two positions.<br><br>Alternatively, wire-bound, cleated plywood or nailed wood boxes are acceptable when lined with a waterproof barrier material.<br><br>The barrier material must be sealed at the edges with waterproof tape or adhesive, and there must be no sharp protrusions inside the boxes.<br><br>In some countries the three-wall corrugated fibreboard available is not of sufficient strength and rigidity to meet stacking requirements or to resist being cut at the corners when the plastic strapping is |



| Packaging Requirements | |
|---|---|
| | The exterior shipping carton, like the inner box, shall be marked with information about the contents in a clearly legible manner. The information shall include:<br>• LOT identification number;<br>• month and year of manufacture (including the words *Date of Manufacture, Month, Year*) in language(s) to be specified by the Procuring Agency. The year shall be written as a four-digit number and the month as a two-digit number;<br>• month and year of expiry (including the words *Expiry Date, Month, Year*) in language(s) to be specified by the Procuring Agency. The year shall be written as a four-digit number and the month as a two- digit number;<br>• name and address of supplier;<br>• nominal width;<br>• number contained in the carton;<br>• instructions for storage and handling.<br>To facilitate monitoring of LOT quality during shipping and storage, all exterior shipping cartons for each discrete LOT shall be assembled and shipped together. |
| **lot traceability** | Best efforts shall be made to ensure that shipments remain as discrete LOTS and that these LOTS remain intact as far down the distribution system as possible.<br><br>These efforts may include the use of very large lettering for LOT codes on the exterior shipping cartons; colour coding; using one pallet per LOT; physically linking all exterior shipping cartons from discrete LOTS; and issuing instructions to this effect to shippers and warehouse personnel. |

**Summary tables**

The following tables summarize the testing methods and requirements for packaging defects, general requirements, performance requirements and design requirements for prequalification and LOT-by-LOT compliance testing.

| table 1 Classification of defects in packaging and marking of packaging for delivery | |
|---|---|
| **examine** | **Defects** |
| **contents** | Number of condoms not as specified; packages or strips not as specified. |
| **marking** | Omitted; incorrect; illegible; of an improper size (exterior, interior), incorrect location, sequences, or method of application. |
| **materials** | Packaging/packing materials not as specified, missing, damaged or non-serviceable. |
| **workmanship** | Shipping cartons inadequately closed and secured; poor application of internal packaging and packing material; distorted intermediate packages. |

The following tables summarize the different requirements for prequalification and pre-shipment testing. For pre-shipment testing, which is required prior to the consignment of condoms, samples sizes will be selected in accordance with *ISO 4074: 2002* Annex A and will be inspected and tested against technical specifications that govern the respective agreement or purchase orders. All testing activities will be conducted under *ISO 17025* accreditation.

For prequalification testing, UNFPA requires that three lots of condoms be randomly selected for testing. At the time of the prequalification inspection, the inspected factory may not be producing condoms against the *WHO/ UNFPA Male Latex Condom Specification, 2010*. Thus, the manufacturer may not be producing condoms that comply with the full requirements of the *WHO/UNFPA Male Latex Condom Specification, 2010*. This applies in particular to requirements for package marking and labelling, but may apply to other properties such as dimensions. Inspectors and/or inspection companies shall select condom lots for testing that comply as closely



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as possible with the requirements of the *WHO/UNFPA Male Latex Condom Specification 2010*. The selected sample must comply with and will be tested against the requirements of *ISO 4074: 2002*.UNFPA includes testing condoms that have been oven conditioning for (168 ± 5) hours at (70 ± 2) °C for bursting pressure and volume during prequalification testing to confirm that the condoms comply with the minimum stability requirements specified in Clause 7.2 of *ISO 4074: 2002*. In anticipation of changes in the next edition of *ISO 4074* (which is expected to be published later in 2013) UNFPA also requires testing for freedom from holes and visible defects, and package integrity after oven conditioning for (168 ± 5) hours at (70 ± 2) °C for prequalification testing.

**table 2. summary of prequalification tests and requirements**

**sample according to Annex B of *ISO 4074* for "isolated Lots" and *ISO 2859–1***

| test | sampling | requirements |
|---|---|---|
| Verification of constituent materials | NA | Manufacturer's documentation |
| Verification of shelf-life | NA | Manufacturer's documentation |
| Minimum stability (if required) | As listed below for burst volume, burst pressure, freedom from holes and package integrity | As listed below for burst volume, burst pressure, freedom from holes and package integrity |
| Bursting volume (before and after oven conditioning) | Level G-I<br>Minimum Code Letter M | Minimum volumes:<br>1. **16.0** $dm^3$ for condoms with widths less than 50 mm<br>2. **18.0** $dm^3$ for condoms with widths from 50 mm to 55.5 mm<br>3. **22** $dm^3$ for condoms with widths greater than 56 mm<br>AQL 1.5 |
| Bursting pressure (before and after oven conditioning) | Level G-I<br>Minimum Code Letter M | Minimum pressure: 1.0 kPa<br>AQL 1.5 |
| Freedom from holes (before and after over conditioning for (168 ± 5) h at (70±2) °C) | Level G-I<br>Minimum Code Letter N | AQL 0.25 |
| Visible defects (before and after oven conditioning for (168 ± 5) h at (70±2)°C) | Level G-I<br>Minimum Code Letter N | Critical defects: AQL 0.4<br>Non-critical defects: AQL 2.5 |
| Shape and texture | Agreed between manufacturer and buyer | Visual inspection |
| Package integrity (before and after oven conditioning for (168 ± 5) h at (70±2)°C | Level S-3<br>Minimum Code Letter H | AQL 2.5 |
| Integral bead | Agreed between manufacturer and buyer | Visual inspection |
| Colour | Agreed between manufacturer and buyer | Visual inspection |
| Fragrance and flavouring | Agreed between manufacturer and buyer | Sensory inspection |
| Width | Level S-2 | ± 2 mm of claimed width<br>AQL 1.0 |
| Length | Level S-2 | 1. **165** mm for widths less than 50 mm<br>2. **180** mm for widths between 50 mm and 55.5 mm<br>3. **190** mm for widths of 56.0 and above<br>AQL 1.0 |
| Thickness | Level S-2 | 0.045–0.080mm<br>AQL 1.0 |

| | | |
|---|---|---|
| Lubricant quantity (including powder) | Level S-2 | Viscosity: 200–350 centistokes<br>Qty: 400–700 mg/condom<br>AQL 4.0 |
| Odour (if necessary) | Agreed between manufacturer and buyer | Sensory inspection |
| Inner box | Level S-3 | Compliant with procurement specifications |
| Exterior shipping cartons | Level S-2 | Compliant with procurement specifications |

**table 3. summary of Lot-by-Lot Pre-shipment compliance testing and requirements**

**sample according to Annex A in *ISO 4074* for "continuous Lots" and *ISO 2859–1***

| test | sampling | requirements |
|---|---|---|
| Bursting volume (before and after oven conditioning) | Level G-I | Minimum volumes:<br>1. **16.0** $dm^3$ for condoms with widths less than 50 mm<br>2. **18.0** $dm^3$ for condoms with widths from 50 mm to 55.5 mm<br>3. **22** $dm^3$ for condoms with widths greater than 56 mm<br>AQL 1.5 |
| Bursting pressure (before and after oven conditioning) | Level G-I | Minimum pressure: 1.0 kPa<br>AQL 1.5 |
| Freedom from holes | Level G-I<br>Minimum Code Letter M | AQL 0.25 |
| Visible defects | Level G-I<br>Minimum Code Letter M | Critical defects: AQL 0.4 Non-critical defects: AQL 2.5 |
| Shape and texture | Agreed between manufacturer and buyer | Visual inspection |
| Package integrity | Level S-3 | AQL 2.5 |
| Integral bead | Agreed between manufacturer and buyer | Visual inspection |
| Colour | Agreed between manufacturer and buyer | Visual inspection |
| Fragrance and flavouring | Agreed between manufacturer and buyer | Sensory inspection |
| Width | Level S-2 | ± 2 mm of claimed width<br>AQL 1.0 |
| Length | Level S-2 | 1. **165** mm for widths less than 50 mm<br>2. **180** mm for widths between 50 mm and 55.5 mm<br>3. **190** mm for widths of 56.0 and above<br>AQL 1.0 |
| Thickness | Level S-2 | 0.045–0.080 mm<br>AQL 1.0 |
| Lubricant quantity (including powder) | Level S-2 | Viscosity: 200–350 centistokes<br>Qty: 400–700 mg/condom<br>AQL 4.0 |
| Odour (if necessary) | Agreed between manufacturer and buyer | Sensory inspection |
| Inner box | Level S-3 | Compliant with procurement specifications |
| Exterior shipping cartons | Level S-2 | Compliant with procurement specifications |
| Individual package materials and markings | Level S-3 | Compliant with procurement specifications<br>AQL 2.5 |

# Technical Specification: TCu380A Intrauterine Device (IUD)

(From WHO draft TCU380A IUD Specification Document May 2010)

## 1. General Description

The TCu380A IUD consists of a T shaped frame made from low density polyethylene with barium sulphate added for x-ray opacity. The device is 32 mm wide and 36 mm long with a plastic ball at the bottom of the vertical stem to guard against cervical penetration. A small hole may be located on the vertical stem near to its junction with the horizontal arms to act as an anchor for the copper wire. The IUD has solid copper collars on each of its two horizontal arms, each of which has a surface area of 35 mm2 and copper wire of 310 mm2 surface area wound tightly around the vertical stem, giving a total surface area of 380 mm2, as indicated in the name of the device A pigmented polyethylene filament is tied in a knot through a small hole in the ball to provide two equal length threads, as a means to locate and remove the device.

The device is supplied sterile in a sealed primary pack together with an insertion instrument consisting of a high-density polyethylene tube and a rod to hold the device correctly positioned within the uterus while the introducer is removed. A moveable plastic flange is positioned on the insertion tube to control the depth of insertion to locate the IUD correctly within the uterus during insertion.

*It is recommended that all biological safety in accordance with ISO 10993 parts 1, 3, 5, 10 and 11 is conducted by accredited laboratories.*

## 2. Materials

The following materials shall be used.

### 2.1 T frame

The T Frame shall be made from low density polyethylene (LDPE) free of stabilizers having a minimum tensile strength of 13 MPa (ASTM D638 – ISO 527–2, using a crosshead speed of 50 mm/min and a type 1 specimen bar) and a 2% secant flexural modulus in the range 133.5 MPa to 180.6 MPa (ASTM D790).

The LDPE shall be blended with 15% to 24% USP precipitated barium sulphate with a particle size of 95% less than 10 micron. The compounded polymer (LDPE plus barium sulphate) shall be evaluated for biological safety in accordance with ISO 10993-1 requirements for mucosal membrane contact devices intended for permanent contact. Specifically the following testing is required:

- Testing for geno-toxicity according to ISO 10993-3
- Testing for cyto-toxicity testing according to ISO 10993-5
- Testing for irritation and delayed-type hypersensitivity according to ISO 10993-10
- Testing for sub acute and sub chronic toxicity according to ISO 10993-11

For a specific material, it is only necessary to carry out the assessment of biological safety once. The evaluation shall be repeated if there is a significant change to the materials, for example, if the grade or supplier is changed.

It has been agreed that manufacturers using the original grade of LDPE specified by the

Population Council may continue to use this material for a period of two years from the date of publication of this specification before completing this testing.

**2.2 Copper wire**

The wire shall be made from Oxygen Free Electronic (OFE) 99.99% pure copper meeting the National Bureau of Standards designation UNS C10100. The diameter of the wire shall be (0.255 ± 0.005) mm (30 AWG[1], 33 ISWG[2]).

**2.3 Copper collars**

The copper collars shall be made from Oxygen Free Electronic (OFE), 99.99% pure copper meeting the National Bureau of Standards designation UNS C10100[3]. The collars shall be manufactured from copper tube half hard temper with internal diameter (1.68 ± 0.025) mm and external diameter: (2.2 ± 0.025) mm. The collars shall be (5 ± 0.15) mm in length.

The collars shall be deburred, polished and free from sharp edges, for example by barrel tumbling.

**2.4 Thread**

The thread shall be monofilament made from high density polyethylene, (HDPE) free of stabilizers having a sufficient minimum tensile strength to produce a thread meeting the specified strength requirement (9.5 Newton). A material with a minimum tensile strength (ASTM D6380, ISO 527-2) of 28 MPa is recommended.

The thread polymer shall be compounded with 0.4% up to 1.0% by weight of USP (EP) rutile titanium dioxide.

The compounded polymer (HDPE plus titanium dioxide) shall be evaluated for biological safety in accordance with ISO 10993-1 requirements for mucosal membrane contact devices intended for permanent contact. Specifically the following testing is required:

- Testing for geno-toxicity according to ISO 10993-3
- Testing for cyto-toxicity testing according to ISO 10993-5
- Testing for irritation and delayed-type hypersensitivity according to ISO 10993-10
- Testing for sub acute and sub chronic toxicity according to ISO 10993-11

For a specific material, it is only necessary to carry out the assessment of biological safety once. The evaluation shall be repeated if there is a significant change to the materials, for example, if the grade or supplier is changed.

Manufacturers using the original grade of HDPE specified by the Population Council or an equivalent grade that has been used for more than 5 years may continue to use the current material for a period of two years from the date of publication of this specification before completing this testing.

The thread diameter shall be (0.25 ± 0.05) mm. When tested according to ISO 7439: 2002 clause 7 (clamping the thread only) the peak load at break of the thread shall be greater than 9.5 Newton.

**2.5 Insertion tube**

[1] *American Wire Gauge*
[2] *Imperial Standard Wire Gauge*



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HDPE (High Density Polyethylene) Food Contact grade of internal diameter (3.7 ± 0.1) mm and outside diameter of (4.4 ± 0.1) mm.

**2.6 Insertion rod**

Food contact grade radiation stable ABS (Acrylonitrile-Butadiene-Styrene polymer) or food contact grade radiation stabilized polypropylene (PP) with a tip diameter of (2.6 ± 0.2) mm.

Optionally the insertion rod may be pigmented.

**2.7 Positioning flange**

Polymer with adequate radiation stability to function mechanically post-sterilization. Optionally the flange may be pigmented.

**2.8 Packaging**

Packaging materials shall comply with ISO 11607-1.

Polymer films shall be used, preferably continuous, to reduce the risk of tarnishing the copper.

Tarnishing is a natural phenomenon for copper and does not affect the performance of the IUD. However, significant tarnishing of copper during shelf life may not be aesthetically acceptable. The use of continuous film packaging, where possible, can reduce the risk of tarnishing

## 3. Materials Testing

Every new batch (lot) of compounded frame material (LDPE plus barium sulphate) and thread material (HDPE plus titanium dioxide) shall be subjected to *in vitro* cyto-toxicity testing in accordance with ISO 10993 - 5 (Biological evaluation of medical devices — Part 5: Tests for in vitro cyto-toxicity).

The cytotoxic response shall not be worse than that recorded for the compounded material when originally evaluated for biological safety according to the requirements of ISO 10993-1.

The barium sulphate content of the frame material shall be determined according to ISO 7439: 2002 clause 7.5.

## 4. Materials Storage

The maximum storage period for the frame polymer and the thread is 3 years from the date of manufacture when stored at temperatures under 30 °C and 2 years when stored at temperatures between 30 °C and 35 °C. The maximum storage period for the frame polymer and the thread is 3 years from the date of manufacture when stored at temperatures under 30 °C and 2 years when stored at temperatures between 30 °C and 35 °C.

Provided the tensile strength of the frame material exceeds 13 MPa (which may be determined by testing moulded frames) and the breaking force of the thread exceeds 9.5 Newton, then the materials may be used for a further 3 years when stored at temperatures under 30 °C and 2 years when stored at temperatures between 30 °C and 35 °C.

## 5. Materials processing

The recycling of injection molded reclaim material for the T frame and the thread is not permitted.



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## 6. Dimensions and Requirements for Finished Product

When tested according to ISO 7439: 2002 clause 7.2, the dimensions of the finished product after sterilization shall comply with the requirements as individually specified below.

- Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4 unless otherwise indicated. Compliance shall be with an AQL of 0.65 unless otherwise indicated.
- Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same Inspection level and AQL. In cases of dispute sampling according to ISO 2859-1 shall be used.
- In order to use the tables in ISO 2859-1 it is necessary for the manufacturer to specify the batch (lot) size.
- The manufacturer is responsible for defining the batch size (lot) and ensuring traceability and the use of appropriate sampling in process and product validation.

### 6.1 T frame dimensions

- Length of horizontal arms (total length of both arms): (32 ± 0.5) mm
- Length of vertical stem: (36 ± 0.5) mm
- Diameter of horizontal arm: (1.6 ± 0.1) mm
- Diameter of vertical stem: (1.5 ± 0.1) mm

Optionally a hole for anchoring an end of the copper wire may be provided. The hole must not reduce the breaking strength of the vertical stem that is specified below in Performance Requirements 7.4.

### 6.3 Breaking strength

The hole may be tapered or dumbbell shaped with a maximum diameter: 0.55 mm and placed (2.8 ± 0.14) mm from the intersection of the horizontal arm and vertical stem centerlines.

T Piece Ball (at end of vertical stem) diameter: (3.0 mm ± 0.7 mm). The junction between the ball and the vertical stem shall preferably be radiused.

T Piece Ball (at end of vertical stem) shall have a hole of maximum diameter 0.79 mm for securing the thread. The hole may be tapered or dumbbell shaped.

The junctions between the horizontal arms and the vertical stem may be radiused to prevent stress concentrations. If the junction is radiused the radius shall be between 0.25 - 0.40 mm. Manufacturers shall confirm that introducing the radius does not lead to an increase in crush damage at the junction when the T is deformed as it is loaded into the insertion tube. This can be done by comparing the strength of radiussed and non radiused T frames after loading in the insertion tube. Microscopic examination should be used alongside strength testing to monitor the extent of any damage.

### 6.3 Thread dimension

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same Inspection level and AQL. In cases of dispute sampling according to ISO 2859-1 shall be used.

- Compliance shall be with an AQL 1.5 for thread length.



- Thread Length: The length of each tail shall be 105 to 125 mm.

### 6.4 Copper collars

- Collar length: (5.0 ± 0.15) mm
- Collar weight: (68.7 ± 3.0) mg
- Collar Position: 5.4 ± 0.4 mm from the ends of the T horizontal arm.

### 6.5 Copper wire

The weight of wire on the frame shall be not less than 165 mg and not more than 187 mg.

### 6.6 Insertion tube

Length: (206 ± 2) mm

Internal Diameter: (3.7 ± 0.1) mm Outside Diameter: (4.4 ± 0.1) mm

### 6.7 Insertion rod

Length: (190 ± 5) mm from handle brace to tip. Diameter at tip: (2.6 ± 0.2) mm

### 6.8 Insertion tube flange

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same Inspection level and AQL. In cases of dispute, sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 1.5. Diameter of central hole: (4.1 ± 0.1) mm

The shape and dimensions of the central hole may be changed to facilitate meeting the specified flange displacement force.

### 6.9 Other assist components

These are other optional components which the manufacturer may evaluate and choose to include. When considering design and choice of materials for these components, manufacturers shall take into account the function of the devices, the type and duration of exposure to the body and the effect of sterilization by gamma radiation.

## 7. Performance Requirements

### 7.1 Copper surface area

The total nominal active copper surface area, wire and collars shall be 380 mm2 ± 10%.

### 7.2 Copper wire winding

The wire shall be wound so that it is in contact with the frame and is uniform. The proximal and distal end of the wire must lie smoothly on the T surface and not protrude beyond the wire profile to prevent any chance abrasion of uterine tissue during insertion or *in situ.* The length of wire protruding from the anchoring hole ('the tag') shall not exceed 10mm. It shall be bent down to run parallel with the vertical stem and not interfere with the position of the arms when the IUD is placed in the insertion device.

Single and double wound configurations are acceptable.

### 7.3 Thread knot



The knot shall be secure and not promote breakage under normal use.

**7.4 Breaking strength**

Sampling shall be in accordance with ISO 2859-1, Inspection Level G I. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same Inspection level and AQL. In cases of dispute, sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 1.0.

When pulled at 200 mm/minute, according to ISO 7439: 2002 clause 7.3 with the arms bent upwards and clamped parallel (8 ± 2) mm and a single thread clamped, the breaking force of the finished product after sterilization shall be greater than 9.5 Newton.

Temperature during testing shall be 23± 2C°.

Conditioning as specified in ISO 7439: 2002 needs to be carried out only in the case of disputes.

When conducting the tensile test, the T frame shall be clamped by the copper collars (only) on the horizontal arms, using a gripping fixture that deforms the arms simultaneously parallel to each other and to the vertical stem, with horizontal arms (8 ± 2) mm apart, centre-line to centre-line. The tee junction must be unconstrained by the clamp.

In use, the toggle clamp should be sufficiently tightened to prevent slippage but not so tight that it fully crushes the collars.

One of the threads shall be gripped in the opposing grip at a distance of 5 cm from its point of attachment to the IUD. A grip with parallel flat rubber faces has been found satisfactory if well-tightened. Force is then applied and the IUD is stretched until either it or the thread breaks or detaches. The force at break or detachment is measured and recorded. Any tensile test should be rejected if breakage of the thread occurs at the entry to the grip.

The location of failure for any device failing the minimum strength requirement shall be noted (thread, thread/ball junction, wire insertion hole in vertical stem, or the junction between the vertical and horizontal arms).

**7.5. Flexibility test**

Sampling shall be in accordance with ISO 2859-1, Special Inspection Level S-4.

Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same Inspection level and AQL. In cases of dispute sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 4.0.

When a 20g weight is applied to one of the horizontal arms of the T frame for a period of 20 seconds at a distance 12 mm from the vertical arm, the deflection of the horizontal arm measured at the end of the arm shall be as follows:

For freshly manufactured T frames that are greater than 24 hours but less than 96 hours from time of molding: within the range 4.8 mm to 6.5 mm.

For T frames that are older than 96 hours: greater than 4.0 mm.

The test shall be carried out at a temperature of (23 ± 2) °C. Before testing the T frames shall be stored for at last 6 hours at the test temperature.

A suitable test rig may be used to clamp the T frame and measure the amplitude of the defection. A pivoted needle or lever may be used to amplify the deflection of the horizontal arm: Flexibility Apparatus. If such a test rig is used the T frame arm deflection may be converted into a scale reading using the appropriate amplification factor for the rig.

**7.6 Copper collar retention force**

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1, using the same Inspection level and AQL. In cases of dispute sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 4.0.

The minimum force required to displace a collar on the arm shall be 6.86 Newton (700 g -force).

When conducting the copper collar retention force, test the T frame shall be clamped by the collar on one of the arms using a suitable jig if necessary and the opposing arm shall be gripped in the opposite clamp.

Optionally one collar may be clamped in one jaw and the other collar clamped in the opposing jaw. The clamp(s) gripping the copper collar shall have a groove milled with a 1.59 mm (1/16 inch) ball end mill to a depth of 1.38 mm, or about 65% of the collar diameter, to prevent crushing the collar.

**7.7 Memory**

When the finished product after sterilization is tested according to ISO 7439: 2002 clause 7.4, the maximum displacement from the horizontal of the horizontal arms shall be not greater than 5.0 mm.

Sampling shall be 20 units per lot irrespective of lot size.

**7.8 Insertion instrument**

The insertion rod shall be a snug fit but slide smoothly within the insertion tube and shall not trap the thread.

**7.9 Flange displacement force**

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1 using the same Inspection level and AQL. In cases of dispute, sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 0.65.

Use a steadily applied displacement. The required force should fall between 2.0 and 9.0 Newton.

## 8. Packaging

- Packaging shall comply with ISO 11607 Part 1.

- Continuous polymer films shall be used to reduce the risk of tarnishing unless ethylene oxide is used for sterilization.
- Continuous polymer films cannot be used with ethylene oxide sterilization. A suitable Ethylene Oxide permeable microbiological barrier shall be used in accordance with ISO 11607 Part 1.

**8.1 Sealed pouch**

IUDs shall be packed in individual sealed pouches.

**8.2 Sealed pouch integrity**

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4.

Compliance shall be an AQL of 0.65.

Sealed pouch integrity shall be tested according to ASTM D3078 (Standard test method for determination of leaks in flexible packaging by bubble emission).

If permeable packaging material is used, sealed pouch integrity shall be tested by ASTM F 1929 (Standard test method for detecting seal leaks in porous medical packaging by dye penetration).

**8.3 Sealed pouch peel strength**

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1, using the same Inspection level and AQL. In cases of dispute sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 0.65

When tested according to ASTM F 88 (standard test method for seal strength of flexible barrier materials) the peel force shall be not less than 4.4 N/2.54 cm and not greater than 19 N/2.54 cm.

- If the packaging is made from two equally flexible materials Technique B of ASTM F 88 shall be used (sample supported at 90° by hand).
- If a rigid material is used as part of the pack, for example a molded tray then Technique C of ASTM F 88 shall be used (sample supported at 180°).

**8.4 Labeling and inserts**

Information required in accordance with ISO 7439 including information intended for the women shall be provided in accordance with the contractual requirements agreed with the Procuring Agency. Up-to-date information on IUDs can be obtained from WHO publications already referenced in this document.

The following information shall be supplied:

- The Latest Insertion Date (LID) is the date after which the product cannot be inserted in utero.
- The Latest Insertion Date shall be printed on the sealed pouch and shall be based on the maximum product shelf life from the date of sterilization.

The sterilization shall be completed within 30 days of sealing the finished device in the pouch.



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In addition, the duration of the maximum period the device can remain in utero shall be printed on the primary container. This period shall not exceed 12 years from the date of insertion.

### 8.5 Printing

All printing shall be clear and readily legible.

### 8.6 Cleanliness

The device, insertion tube, insertion rod, flange and any insert such as instructions included in the pack shall be free of visible particulate matter.

## 9. Sterility

### 9.1 Sterilization method

Sterilization shall be by radiation according to ISO 11137 series or by Ethylene Oxide according to ISO 11135 series and standards normatively referenced therein. Radiation sterilization is preferred to allow the use of continuous polymer film packaging materials.

### 9.2 Sterility assurance level

The sterilization assurance level shall be 10-6.

### 9.3 Residual Ethylene Oxide levels

If ethylene oxide sterilization is used, then residual ethylene oxide levels shall not exceed 10 ppm and ethylene chlorohydrin levels shall not exceed 20 ppm on any individual sample when measured using a method that complies with the requirements of ISO 10993-7.

Average residual levels across all samples tested shall not exceed 5 ppm for ethylene oxide and 10 ppm for ethylene chlorohydrin.

## 10. Latest insertion date (LID)

The maximum permitted shelf life for storage of the device prior to insertion is 5 years and this defines the 'Latest Insertion Date' (LID).

A two year transition period from the date of publication of the specification to implement this requirement has been agreed with the manufacturers.

Shelf life claims shall be supported by appropriate stability data.

Guidance on conducting stability studies is given in Annex 5 - Accelerated Ageing Testing. When conducting stability studies, manufacturers shall include products assembled from components that have been stored for the maximum component storage periods, specified by the manufacturer.

## 11. Materials Procurement - Good Manufacturing Practice (GMP)

Manufacturers shall take appropriate steps to ensure that batches of compounded materials (T and thread materials) are not contaminated by any extraneous impurities during compounding operations.

Where lubricants are used in molding, the grades shall be 'Food Grade' and/ or suitable for medical device manufacture. Manufacturers shall introduce procedures to monitor and control the degree of tarnish and rough edges on the copper component. If appropriate the copper components should be cleaned prior to assembly.

## 12. Dimensional Tolerances and Manufacturing Tolerance Specifications

The nominal specified dimensions and tolerances may not provide the correct clearance for components such as the insertion rod which must slide smoothly and the flange which has to have the correct displacement force. It remains the responsibility of the manufacturer to produce a fully functioning, safe and effective product within the dimensional tolerance limits provided.

## 13. Workmanship

Finished IUDs should be inspected visually for evidence of visible defects and poor workmanship. Defects are divided into two categories depending upon the level of impact they may have on the safety, effectiveness and acceptability of the product. Defects that might be expected to affect the safety and or effectiveness of the product are classified as critical defects and an AQL of 0.65 is applied. Defects that might affect the acceptability of the product, causing the device to be rejected at the time of insertion, are classified as minor defects and an AQL of 2.5 applies. Manufacturers and testing laboratories should maintain a list of these defects with clear definitions and diagrams or photographs to assist both in the assessment of workmanship and in the resolution of any disputes.

## 14. Critical Visible defects

0.65 AQL - assessed by visual examination not measurement

a) Tarnishing
b) Missing components
c) Flash on the mould lines of the T Frame
d) Sharp protruding edges and burrs
e) Unsecured thread
f) Incomplete/deformed ball
g) Deformed collars
h) Improperly sealed pouches
i) Empty pouches
j) Embedded/surface/foreign particles

## Non-critical visible defects

2.5 AQL- all assessed by visual examination not measurement

a) Insertion rod bent or distorted
b) Discoloration of plungers
c) Damaged packing cartons - depending on severity

## 15. Certificate of Registration Status in Country of Origin

IUDs 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 products(s)" as provided under the World Health Organization (WHO) Certification Scheme, if applicable.

## 16. Compliance with Good Manufacturing Practices

The Supplier must be able to provide certification that the IUDs are manufactured according to WHO



good manufacturing practices (GMP). Supplier also must be able to provide copies of its annual GMP audit reports.

## 17. Quality Assurance Provisions

### 17.1 Compliance

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

### 17.2 Documentation

The Supplier shall provide evidence 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.

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

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

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

### 17.3 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 Specification and Special Conditions of Contract to ensure that the contraceptives 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 contraceptives and to draw samples from the Supplier's factory and/ or warehouse. 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.

The Procuring Agency may have some or all of the tests specified in the contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on IUDs.

### 17.4 Sampling Procedures

The Procuring Agency or the Procuring Agency's representative shall select the required samples from the lot according to the Technical specification of 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.

Where an inspection lot is smaller than 10,001 units, it will be deemed to be 10,001 for determination of sample sizes. The normal, tightened, and reduced inspection provisions of ISO 2859 (Inspec).



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# Technical Specification: Sub-dermal Implants

## General Description

Hormonal implants are small flexible matchstick-sized rods which release progestin when inserted under the skin of the upper arm to prevent pregnancy. Contraceptive Implants are effective for 3 to 5 years, depending on the type and are immediately reversible. First introduced in the mid-1980s as Norplant, a six-capsule product, newer generations of products are smaller, require ess time to insert and remove, and produce fewer bleeding disturbances for users.

Types of implants:

- A two-rod product contains levonorgestrel a progestin and offers contraception for up to five years.
- A single-rod system that contains etonogestrel a progestin and provides contraception for three years.

## Materials

The two rods Levonorgestrel implants are a progestin-only product; they contain noestrogen. A set consists of two small, flexible rodsthat have a core consisting of anequal mixture of levonorgestrel andsilicone elastomer. The rods are covered with thin-walled silicone tubing and are sealed at the ends with Silastic medical grade adhesive. Each rod is 43 millimeters (mm) long, 2.5 mm in diameter and contains75 mg Levonorgestrel (LNG).

The single sterile rod implant is 4 cm in length with a diameter of2 mm. **It** consists of an ethylene vinyl acetate (EVA) copolymer core, containing 68 mg of the synthetic progestin etonogestrel (ENG), surrounded by an EVA copolymer skin. The applicator consists of acrylonitrile-butadienestyrenebody with a stainless steel needle and a polypropylene shield.

## Packaging

The two rod implant is supplied as a set. One sealed, sterile plastic pouch contains two rods, each filled with 75 mg of levonorgestrel, for use in one woman.

The single rod implant containing68mg etonogestrel is preloaded in the needle of a disposable applicator. The sterile applicator containing implant is packed in a blister pack.

- Packaging shall comply with ISO 11607 Part 1.
- Continuous polymer films shall be used to reduce the risk of tarnishing unless ethylene oxide is used for sterilization.
- Continuous polymer films cannot be used with ethylene oxide sterilization. A suitable Ethylene Oxide permeable microbiological barrier shall be used in accordance with ISO 11607 Part 1.

**Sealed pouch**

Implants shall be packed in individual sealed pouches.

**Sealed pouch integrity**

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4.

Sealed pouch integrity shall be tested according to ASTM F2096 (Standard test method for determination of leaks in flexible packaging by bubble emission).



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**Package Impurities**

The package material evaluation should meet requirements for the package impurities test specifications of 'USP 661 Containers: Physicochemical tests- plastics'.

**Sealed pouch peel strength**

Sampling shall be in accordance with ISO 2859-1, Inspection Level S-4. Manufactures and testing laboratories may opt to sample in accordance with ISO 3951-1, using the same Inspection level and AQL. In cases of dispute sampling according to ISO 2859-1 shall be used.

Compliance shall be with an AQL of 0.65

When tested according to ASTM F 88 (standard test method for seal strength of flexible barrier materials) the peel force shall be not less than 4.4 N/2.54 cm and not greater than 19 N/2.54 cm.

- If the packaging is made from two equally flexible materials Technique B of ASTM F 88 shall be used (sample supported at 90° by hand).
- If a rigid material is used as part of the pack, for example a molded tray then Technique C of ASTM F 88 shall be used (sample supported at 180°).

**Labeling and inserts**

Information required in accordance with ISO 7439 including information intended for the women shall be provided in accordance with the contractual requirements agreed with the Procuring Agency.

The following information shall be supplied:

- The Latest Insertion Date (LID) is the date after which the product cannot be inserted.
- The Latest Insertion Date shall be printed on the sealed pouch and shall be based on the maximum product shelf life from the date of sterilization.

**Printing**

All printing shall be clear and readily legible.

## Sterility

**Sterilization method**

Sterilization shall be by Ethylene Oxide according to ISO 11135 series and standards normatively referenced therein.

**9.2 Sterility assurance level**

The sterilization assurance level shall be 10-6.

**9.3 Residual Ethylene Oxide levels**

Standard ISO-10993-7: Ethylene Oxide Residuals

## Storage and shelf life

The sterile packs of **two** rods Levonorgestrel implant should be stored away from excessive heat (temperatures higher than 30°C) and moisture. An unopened, undamaged sterile pack of **two**



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rods, if properly stored, has a shelf life of 5 years. The last date for insertion (expiration date) is stamped on each box.

Store etonogestrel implant at 25°C (77°F); excursions permitted to 15°-30°C(59°-86°F). Protect from light. Avoid storing in direct sunlight or at temperatures above 30°C (86°F).

Shelf life claims shall be supported by appropriate stability data.

Guidance on conducting stability studies is given in Annex 5 - Accelerated Ageing Testing. When conducting stability studies, manufacturers shall include products assembled from components that have been stored for the maximum component storage periods, specified by the manufacturer.

### Effective life

If inserted any time before the expiration date (shelf life), a setoff **two** rods is effective for5 years. The rods should be removed by the end of the fifth year. If desired, a new set of rods maybe inserted in the same location immediately following removal.

## Certificate of Registration Status in Country of Origin

Implants 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 products(s)" as provided under the World Health Organization (WHO) Certification Scheme, if applicable.

## Compliance with Good Manufacturing Practices

The Supplier must be able to provide certification that the Implants are manufactured according to WHO good manufacturing practices (GMP). Supplier also must be able to provide copies of its annual GMP audit reports.

## Quality Assurance Provisions

**Compliance**

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

**Documentation**

The Supplier shall provide evidence 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.

- Verification that each lot meets the requirements specified by the regulatory authority.
- Specifications for Active Ingredient content
- Evaluation of residuals remaining after the sterilization process
- Evaluation of levels of metal elements (Based on USP <231>USP General Chapter on Inorganic Impurities: Heavy Metals)
- Evaluation of residual levels of solvents utilized during the manufacturing process



(Standard: Based on USP <467> Organic Volatile Impurities)

- Tests to evaluate the presence of bacterial endotoxins and evaluate biological reactivity
- Tests to predict how the body will react to product contact
- Tests to ensure that the package is sealed appropriately
- Tests to show that the package can be used in contact with the product

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

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

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

**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 Specification and Special Conditions of Contract to ensure that the contraceptives 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 contraceptives and to draw samples from the Supplier's factory and/ or warehouse. 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.

The Procuring Agency may have some or all of the tests specified in the contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on Implants.

**Sampling Procedures**

The Procuring Agency or the Procuring Agency's representative shall select the required samples from the lot according to the Technical specification of 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.

Where an inspection lot is smaller than 10,001 units, it will be deemed to be 10,001 for determination of sample sizes. The normal, tightened, and reduced inspection provisions of ISO 2859 (Inspec).



# 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[3] 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.[4]

### 1.3 Registration Requirements

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[3] *For example, same tablet shape, colour, weight, ingredients and identification imprint; same blister pack size, material, text and identification markings; same inner box size, material, text and identification markings.*

[4] *Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, current good manufacturing practices require that manufacturers validate vendors for all raw materials. A typical validation includes, but is not limited to, these areas:*

- *Manufacturing records and procedures for raw materials synthesis, processing, packing and storage.*
- *Quality control records and procedures for the raw materials, in-process and final product.*
- *Plant certification by local regulatory authorities (such as commerce, industry, health, labour, and environment) as required.*
- *Certification of workers' training in current good manufacturing practices and safety protection.*
- *Records demonstrating raw materials with the required physical and chemical characteristics.*

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.[5]

**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*

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[5] *Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/index.html.*



### 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[6] 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

[6] *Evidence includes quality control and manufacturing records, in-process control records and final product Certificate of Analysis.*



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shall be according to recognized standards.[7]

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.*[8]

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*

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[7] *Depending on the tests required, sampling may be conducted according to the standards of the International Organization for Standardization (ISO 2859: Inspection by Attributes) (included as Appendix IVI.H), the report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (included as Appendix IVI.I), or as dictated by local or international pharmacopoeia. Following recognized sampling procedures helps to ensure that the products tested are representative of the whole.*

[8] *Sometimes oral contraceptives are packaged to contain three (3) cycles per inner box. If this is the preferred configuration a three (3)-cycle-per-box packaging description should be detailed in the specification.*

*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[9]. 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[10]:

- 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.[11]

**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

[9] *The use of additional tape along the joint of the outer lids and around the top and bottom corners will greatly increase each carton's resistance to damage during shipment and storage. Tape can be made of plastic film, Kraft paper, or fabric, either plain or reinforced with plastic threads.*

[10] *The smallest type shall be no less than 1 mm high, unless otherwise specified by the commercial laws of the country of importation.*

[11] *The smallest type shall be no less than 10 mm high, unless otherwise specified by the commercial laws of the country of importation.*

- 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**

a. One hundred percent (100%) of the exterior supply cartons will be examined for:
   - General physical characteristics and condition.
   - Markings per Technical Specification

b. *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.*

c. The sample will be examined for:
   - General physical characteristics per Technical Specification, Section
   - Markings per Technical Specification, Section

d. 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:



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- Package seal integrity test.[12]

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**

a. 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.*

b. 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.

[12] *Immerse package in 0.05 percent methylene blue solution under 15 vacuum gauge for two minutes. Observe for leakage. AQL 2.5%.*

# 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[13] 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.[14]

**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.

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[13] *For example, same tablet shape, colour, weight, ingredients and identification imprint; same blister pack size, material, text and identification markings; same inner box size, material, text and identification markings.*

[14] *Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, current good manufacturing practices require that manufacturers validate vendors for all raw materials. A typical validation includes, but is not limited to, these areas:*

- *Manufacturing records and procedures for raw materials synthesis, processing, packing and storage.*
- *Quality control records and procedures for the raw materials, in-process and final product.*
- *Plant certification by local regulatory authorities (such as commerce, industry, health, labour, and environment) as required.*
- *Certification of workers' training in current good manufacturing practices and safety protection.*
- *Records demonstrating raw materials with the required physical and chemical characteristics.*

*Taolets 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



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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[16] 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.[17]

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[16] *Evidence includes quality control and manufacturing records, in-process control records and final product Certificate of Analysis.*

[17] *Depending on the tests required, sampling may be conducted according to the standards of the International Organization for Standardization (ISO 2859: Inspection by Attributes) (included as Appendix IVI.H), the report of the WHO Expert Committee on*

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.*[18]

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*

*Specifications for Pharmaceutical Preparations (included as Appendix IVI.I), or as dictated by local or international pharmacopoeia. Following recognized sampling procedures helps to ensure that the products tested are representative of the whole.*

[18] *Sometimes oral contraceptives are packaged to contain three (3) cycles per inner box. If this is the preferred configuration, a three (3)-cycle-per-box packaging description should be detailed in the specification.*

*center seams and extending over the ends not less than 75 mm[19]. 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[20]:

- 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.[21]

**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

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[19] *The use of additional tape along the joint of the outer lids and around the top and bottom corners will greatly increase each carton's resistance to damage during shipment and storage. Tape can be made of plastic film, Kraft paper, or fabric, either plain or reinforced with plastic threads.*

[20] *The smallest type shall be no less than 1 mm high, unless otherwise specified by the commercial laws of the country of importation.*

[21] *The smallest type shall be no less than 10 mm high, unless otherwise specified by the commercial laws of the country of importation.*

- 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**

e. One hundred percent (100%) of the exterior supply cartons will be examined for:
   - General physical characteristics and condition.
   - Markings per Technical Specification

*f. 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.*

g. The sample will be examined for:
   - General physical characteristics per Technical Specification, Section
   - Markings per Technical Specification, Section

h. 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.[22]

[22] *Immerse package in 0.05 percent methylene blue solution under 15 vacuum gauge for two minutes. Observe for leakage. AQL 2.5%.*



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**

c. 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.*

d. 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.[23] 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.[24]

### 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

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[23] *For example, vials or ampoules must be of the same glass type, closure type, colour, size, text and identification markings; contents must have same ingredients, colour and weight; same inner box size, material, text and identification markings.*

[24] *Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, current good manufacturing practices require that manufacturers validate vendors for all raw materials. A typical validation includes, but is not limited to, these areas:*

- *Manufacturing records and procedures for raw materials synthesis, processing, packing and storage.*
- *Quality control records and procedures for the raw materials, in-process and final product.*
- *Plant certification by local regulatory authorities (such as commerce, industry, health, labour, and environment) as required.*
- *Certification of workers' training in current good manufacturing practices and safety protection.*
- *Records demonstrating raw materials with the required physical and chemical characteristics.*

**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.[25]

**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:

[25] *Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/index.html.*

- 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[26] 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**

[26] *Evidence includes quality control and manufacturing records, in-process control records and final product Certificate of Analysis.*

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.[27]

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.

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[27] *Depending on the tests required, sampling may be conducted according to the standards of the International Organization for Standardization (ISO 2859: Inspection by Attributes) (included as Appendix IVI.H), the report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (included as Appendix IVI.I), or as dictated by local or international pharmacopoeia. Following recognized sampling procedures helps to ensure that the products tested are representative of the whole.*

### 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*[28]*. 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[29]:

- 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.[30]

**Regulatory information (on two opposing sides of carton)**

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[28] *The use of additional tape along the joint of the outer lids and around the top and bottom corners will greatly increase each carton's resistance to damage during shipment and storage. Tape can be made of plastic film, Kraft paper, or fabric, either plain or reinforced with plastic threads.*

[29] *The smallest type shall be no less than 1 mm high, unless otherwise specified by the commercial laws of the country of importation.*

[30] *The smallest type shall be no less than 10 mm high, unless otherwise specified by the commercial laws of the country of importation.*

- 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**

a. One hundred percent (100%) of the exterior shipping cartons will be examined for:
   - General physical characteristics and condition
   - Markings per Technical Specification ...

b. *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

a. 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.*

b. 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 |



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# 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.[31] 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.[32]

**1.3 Primary Packaging Requirements**

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[31] *For example, vials or ampoules must be of the same glass type, closure type, colour, size, text and identification markings; contents must have same ingredients, colour and weight; same inner box size, material, text and identification markings.*

[32] *Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, current good manufacturing practices require that manufacturers validate vendors for all raw materials. A typical validation includes, but is not limited to, these areas:*

- *Manufacturing records and procedures for raw materials synthesis, processing, packing and storage.*
- *Quality control records and procedures for the raw materials, in-process and final product.*
- *Plant certification by local regulatory authorities (such as commerce, industry, health, labour, and environment) as required.*
- *Certification of workers' training in current good manufacturing practices and safety protection.*
- *Records demonstrating raw materials with the required physical and chemical characteristics.*



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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.[33]

### 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:

[33] *Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/index.html.*

- 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[34] 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**

[34] *Evidence includes quality control and manufacturing records, in-process control records and final product Certificate of Analysis.*

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.[35]

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.

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[35] *Depending on the tests required, sampling may be conducted according to the standards of the International Organization for Standardization (ISO 2859: Inspection by Attributes) (included as Appendix IVI.H), the report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (included as Appendix IVI.I), or as dictated by local or international pharmacopoeia. Following recognized sampling procedures helps to ensure that the products tested are representative of the whole.*

### 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*[36]*. 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[37]:

- 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.[38]

**Regulatory information (on two opposing sides of carton)**

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[36] *The use of additional tape along the joint of the outer lids and around the top and bottom corners will greatly increase each carton's resistance to damage during shipment and storage. Tape can be made of plastic film, Kraft paper, or fabric, either plain or reinforced with plastic threads.*

[37] *The smallest type shall be no less than 1 mm high, unless otherwise specified by the commercial laws of the country of importation.*

[38] *The smallest type shall be no less than 10 mm high, unless otherwise specified by the commercial laws of the country of importation.*

- 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**

c. One hundred percent (100%) of the exterior shipping cartons will be examined for:
   - General physical characteristics and condition
   - Markings per Technical Specification ...

d. *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**

c. 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.*

d. 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 |



POPULATION WELFARE DEPARTMENT GOVERNMENT OF SINDH

# 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.[39]

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.[40] 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: .....

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[39] *Von Hertzen H, Piaggio G, Ding J, Chen J, Song S, Bártfai G, Ng E, Gemzell-Danielsson K, Oyunbileg A, Wu S, Cheng W, Lüdicke F, Pretnar-Darovec A, Kirkman R, Mittal S, Khomassuridze A, Apter D, Peregoudov A. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomised trial. Lancet. 2002; 360:1803-10.*

*Arowojolu AO, Okewole IA, Adekunle AO. Comparative evaluation of the effectiveness and safety of two regimens of levonorgestrel for emergency contraception in Nigerians. Contraception. 2002; 66:269-73.*

[40] *Creinin MD, Schlaff W, Archer DF, Wan L, Frezieres R, Thomas M, Rosenberg M, Higgins J. Progesterone receptor modulator for emergency contraception: a randomized controlled trial. Obstet Gynecol. 2006; 108:1089□97.*

*Fine P, Mathé H, Ginde S, Cullins V, Morfesis J, Gainer E. Ulipristal acetate taken 48□120 hours after intercourse for emergency contraception. Obstet Gynecol. 2010; 115:257□63.*

*Glasier AF, Cameron ST, Fine PM, Logan SJ, Casale W, Van Horn J, Sogor L, Blithe DL, Scherrer B, Mathe H, Jaspart A, Ulmann A, Gainer E. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non□inferiority trial and meta□analysis. Lancet. 2010; 375:555□62.*



POPULATION WELFARE DEPARTMENT GOVERNMENT OF SINDH

### 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.[41]

### 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.[42]

### 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

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41 *Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, current good manufacturing practices require that manufacturers validate vendors for all raw materials. A typical validation includes, but is not limited to, these areas:*

- *Manufacturing records and procedures for raw materials synthesis, processing, packing and storage.*
- *Quality control records and procedures for the raw materials, in-process and final product.*
- *Plant certification by local regulatory authorities (such as commerce, industry, health, labour, and environment) as required.*
- *Certification of workers' training in current good manufacturing practices and safety protection.*
- *Records demonstrating raw materials with the required physical and chemical characteristics.*

42 *Available at:*

*http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/index.html.*



POPULATION WELFARE DEPARTMENT GOVERNMENT OF SINDH

# 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[43].

List of Selected Items: *(In case the Bidder has opted to bid for Selected Items, please type the Serial No[44]. 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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[43] In case a bidder is bidding for only some of the items mentioned in the list Technical Specifications , he is advised to take note of ITB Clauses 7 & 15.6

[44] The Serial No. of the item as mentioned in the Technical Specifications.

| | | | | |
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Signed:

Dated:

Official Stamp:

Attachment[45]: † Original receipt for the purchase of the bidding documents.

[45] The Attachment must be made with the Bid Cover Sheet.

**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 this *[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



POPULATION WELFARE DEPARTMENT

## 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[46] *(To be initialed by the Bidder against each document)* | Relevant Page Number[47] in the Bid *(To be filled by the Bidder)* | Supporting Documents[48] *(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[49] | | | |
| WHO prequalification certification[50] | | | |
| 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[51] | | | |
| Original Receipt of purchase of Bidding Documents | | | |

[46] Bidders should only initial against those requirements that they are attaching with the form 3(a). In case they do not have any document to attach the corresponding cell in column 2 should be left blank.

[47] Bidders are required to mention the exact page number of relevant document placed in the Bid.

[48] Bidders are advised to attach all Supporting documents with this form in the order of the requirement as mentioned in column 1.

[49] In case of Sole Agent

[50] WHO prequalification certification required for imported products.

[51] Bidders are required to furnish a certificate to the effect that their firm is free from child labor and having standard child labor free policy

**BID FORM 3(B)** **MANUFACTURER'S AUTHORIZATION**[52]

**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: ----------

[52] This letter of authority should be on the letterhead of the Manufacturer and should be signed by a person competent and having the power of attorney to bind the Manufacturer. It should be included by the Bidder in its bid.

**BID FORM 4** **Firm's Past Performance[53].**

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[54] Certificate |
|---|---|---|---|---|---|
| | | | | | |
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[53] Bidders may use additional Sheets if required.
[54] All certificates are to be attached with this form.

**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<br>3*4 | 6 | 7<br>5-6 |
| | | | | | | |
| | | | | | | |
| | TOTAL | | | | | |

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

B) DISCOUNT[55]: ----------

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

(C=A-B)

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

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

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

Official Stamp

[55] If a Bidder does not wish to offer an item wise discount but intends to offer an overall discount to its quoted price that should be mentioned here.

## Bid Security Form (Bank Guarantee)

*[The Bank shall fill in this Bank Guarantee Form in accordance with the instructions indicated.]*

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*[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]*

# 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.

_____ _____

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