STANDARD PREQUALIFICATION DOCUMENT

Prequalification of Firms for Procurement of Contraceptives

GOVERNMENT OF PUNJAB
POPULATION WELFRE DEPARTMENT
LAHORE

POPULATION WELFARE DEPARTMENT
GOVERNMENT OF THE PUNJAB

Invitation for Prequalification of Firms
For Population Welfare Department Punjab
For Procurement of Contraceptives (2017-18)

Population welfare Department, Government of the Punjab intends to procure contraceptives during FY 2017-18, for following contraceptive items: -

Sr #	Contraceptives
1.	Condoms
2.	IUCD (Cu-T 380A)
3.	COC (Oral Pills)
4.	POP (Exulton Tablets)
5.	ECP (Oral Pills)
6.	Inj. Megestron (DMPA/ Depo-Provera) (3 months Injectable)
7.	Implanon NXT

Population Welfare Department, Government of the Punjab invites sealed bids from manufacturers & their authorized agents of above items for pre-qualification. Pre-qualification is open to National / International manufacturers & their sole authorized agents. Interested eligible manufacturers may apply directly or through their sole authorized agents for prequalification.

A complete set of the prequalification document in *English* may be purchased by interested applicants on the submission of a written application to the Secretary, Population Welfare Department, Punjab at the address given below and upon payment of a non-refundable fee of *PKR 1000/- (Rupees one thousand only).* ***The last date for purchase of Pre-qualification Document is 27-11-2017 during office hours.***

The prequalification document can be downloaded at **www.ppra.punjab.gov.pk & www.pwd.punjab.gov.pk** and may obtain fee receipt and further information from office of the Section Officer (Procurement), PWD, *Punjab.*

Applications for prequalification should be submitted along with necessary documents and samples of quoted items in sealed envelopes, delivered to the address given below by **28-11-2017 till 11:00 hours**, and be clearly marked "Application to Prequalify for Procurement of Contraceptives, PWD/SO(P)/Contraceptives/17-18." The opening of the Applications shall be at **11:30 hours on 28-11-2017,** in the Committee Room, Office of the Director General, Population Welfare Department, **14-Babar Block, New Garden Town, Lahore**. Prequalification will be governed under the Punjab Procurement Rules 2014(amended). Provision of false, fabricated or materially incorrect information, if found at any stage will lead to disqualification.

SECTION OFFICER (PROCUREMENT)
Population Welfare Department, Government of Punjab,
58- Abu Bakar Block, New Garden Town, Lahore, Pakistan
Phone: +92-42-99232440

Acronyms & Abbreviations

FIDIC	Federation Internationale des Ingénieurs-Conseils; an association based in Switzerland that produces Conditions of Contract for different classes of works construction.
ICB	International Competitive Bidding
IFB	Invitation for Bids
IFP	Invitation for Prequalification
ITA	Instructions to Applicants
JV	Joint Venture
NCB	National Competitive Bidding
PDS	Prequalification Data Sheet
PQ	Prequalification
PQD	Prequalification Document
PDS	Prequalification Data Sheet
SBD	Standard Bidding Documents
SPD	Standard Prequalification Document

Contents

Section I: Instructions to Applicants (ITA)

A. General

1. Scope of Application

1.1 In connection with the Invitation for Prequalification indicated in Section II, Prequalification Data Sheet (PDS), the Procuring Agency, as defined in the **PDS,** issues this Prequalification Document (PQD) to applicants interested in bidding for the supply of contraceptives described in Section V**.**

2. Source of Funds

2.1 Government of the Punjab, Pakistan

3. Fraud and Corruption

3.1 It is the Government of the Punjab's {Rule 2(1) (p) of PPR 2014} policy to require that bidders, suppliers and manufacturers and their agents observe the highest standard of ethics during the procurement and execution of such contracts.

(a) 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; or

(b) the Procuring Agency will reject a proposal for award if it determines that the bidder recommended for award has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the contract in question;

(c) 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

(d) the Procuring Agency will have the right to require that a provision be included in bidding documents requiring bidders, suppliers and manufacturers and their agents 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 Purchaser;

4. Eligible Applicants

4.1 An Applicant can be a private, or public entity, or any combination of public or private entities including Joint Venture (JV), consortium with the formal intent, (substantiated with a letter of intent), to enter into an agreement or under an existing agreement.

4.2 Firms of a country may be excluded from bidding if as a matter of law or official regulation, the Government of Pakistan prohibits commercial relations with that country;

4.3 A firm declared disqualified / blacklisted by any of the public sector organization in Pakistan shall be ineligible to bid for a contract during the period of embargo.

4.4 Applicants and all parties constituting the Applicant shall not have a conflict of interest. Applicants shall be considered to have a conflict of interest, if they participated as a consultant in the preparation of the technical specifications of the goods that are the subject of this prequalification. Where a firm, or a firm from the same economic or financial group, in addition to consulting, also has the capability to manufacture or supply goods or to construct works, that firm, or a firm from the same economic or financial group, cannot normally be a supplier of goods or works, if it provided consulting services for the contract corresponding to this prequalification, unless it can be demonstrated that there is not a significant degree of common ownership, influence or control.

4.5 Applicants shall not be under execution of a Bid–Securing Declaration in the Procuring Agency's Country

5. Eligible Goods

5.1 All goods to be supplied under the Contract to be financed by the Government of Punjab shall have as their origin in any country not restricted by the Government of Pakistan (Notified from time to time)

5.2 All goods to be supplied by international manufacturers must be WHO prequalified. National manufacturers will be exempted from WHO prequalification. However, all batches/ lots of local manufactured contraceptives should be tested from the Central Drug Testing Laboratory, Karachi, as per DRAP sampling procedure. In case of doubt/complaint on quality assurance of the locally manufactured contraceptives, the Procuring Agency reserved the rights that they may get any of the supplied batches/lots tested (upto the maximum number of five batches) from WHO accredited Lab from the whole consignment on the risk & cost of the supplier.

B. Contents of the Prequalification Document

6. Sections of Prequalification Document

6.1 The document for the prequalification of Applicants (hereinafter **-** "prequalification document") consists all the sections indicated below, and should be read in conjunction with any Addendum if issued.

- Section I. Instructions to Applicants (ITA)
- Section II. Prequalification Data Sheet (PDS)
- Section III Qualification Criteria and Requirements
- Section IV. Application Forms
- Section V. Scope of Products

6.2 The "Invitation for Prequalification Applications" (IPA) issued by the Procuring Agency is not part of the prequalification document. A sample form is provided as an attachment to this Prequalification Document for information only.

6.3 The Procuring Agency accepts no responsibility for the completeness of the prequalification document and its addenda unless they were obtained directly from the Procuring Agency.

6.4 The Applicant is expected to examine all instructions, forms, and terms in the Prequalification Document and to furnish all information or documentation required by the Prequalification Document.

7. Clarification of Prequalification Document

7.1 A prospective Applicant requiring any clarification of the Prequalification Document shall contact the Procuring Agency in writing at the Procuring Agency's address indicated in the **PDS.** The Procuring Agency will respond in writing to any request for clarification provided that such request is received no later than ten (10) days prior to the deadline for submission of applications. The Procuring Agency shall forward copies of its response to all applicants who have acquired the prequalification document directly from the Procuring Agency including a description of the inquiry but without identifying its source. Should the Procuring Agency deem it necessary to amend the prequalification document as a result of a clarification it shall do under intimation to all the applicants who have obtained the prequalification documents.

8. Amendment of Prequalification Document

8.1 At any time prior to the deadline for submission of applications, the Procuring Agency may amend the Prequalification Document by issuing addenda.

8.2 Any addendum issued shall be part of the Prequalification Document and shall be communicated in writing to all who have obtained the prequalification document from the Procuring Agency.

8.3 To give prospective Applicants reasonable time to take an addendum into account in preparing their applications, the Procuring Agency may, at its discretion, extend the deadline for the submission of applications.

C. Preparation of Applications

9. Cost of Applications

9.1 The Applicant shall bear all costs associated with the preparation and submission of its application. The Procuring Agency will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the prequalification process.

10. Language of Application

10.1 The application as well as all correspondence and documents relating to the prequalification exchanged by the Applicant and the Procuring Agency, shall be written in the language specified in the **PDS.** Supporting documents and printed literature that are part of the application may be in another language, provided they are accompanied by an accurate translation of the relevant passages in the language specified in the **PDS,** in which case, for purposes of interpretation of the application, the translation shall govern.

11. Documents Comprising the Application

11.1 The application shall comprise the following:

(a) Application Submission Form, in accordance with ITA 12;

(b) documentary evidence establishing the Applicant's eligibility to prequalify, in accordance with ITA 13;

(c) documentary evidence establishing the Applicant's qualifications, in accordance with ITA 14; and

(d) any other document required as specified in the PDS.

12.Application Submission Form

12.1 The Applicant shall prepare an Application Submission Sheet using the form provided in Section IV, Application Forms. This Form must be completed without any alteration to its format.

13. Documents Establishing the Eligibility of the Applicant

13.1 To establish its eligibility in accordance with ITA 4, the Applicant shall complete the eligibility declarations in the Application Submission Form and Forms ELI (eligibility) 1.1 and 1.2, included in Section IV, Application Forms.

14. Documents Establishing the Qualifications of the Applicant

14.1 To establish its qualifications to perform the contract(s) in accordance with Section III, Qualification Criteria and Requirements, the Applicant shall provide the information requested in the corresponding Information Sheets included in Section IV, Application Forms.

15. Signing of the Application and Number of Copies

15.1 The Applicant shall prepare one original of the documents comprising the application as described in ITA 11 and clearly mark it "ORIGINAL". The original of the application shall be typed or written in indelible ink and shall be signed by a person duly authorized to sign on behalf of the Applicant.

15.2 The Applicant shall submit copies of the signed original application, in the number specified in the **PDS,** and clearly mark them "COPY". In the event of any discrepancy between the original and the copies, the original shall prevail.

D. Submission of Applications and Samples

16. Sealing and Identification of Applications and samples

16.1 The Applicant shall enclose the original and the copies of the application in a sealed envelope that shall:

(a) bear the name and address of the Applicant;

(b) be addressed to the Procuring Agency, in accordance with ITA 17.1; and

(c) bear the specific identification of this prequalification process indicated in the PDS 1.1

(d) Sample of one box of quoted items should be attached with the application.

16.2 The Procuring Agency will accept no responsibility for not processing any envelope that was not identified as required.

17. Deadline for Submission of Applications

17.1 Applicants may always submit their applications by mail or by hand. Applications shall be received by the Procuring Agency at the address and no later than the deadline indicated in the **PDS.** A receipt will be given for all applications submitted.

17.2 The Procuring Agency may, at its discretion, extend the deadline for the submission of applications by amending the Prequalification Document in which case all rights and obligations of the Procuring Agency and the Applicants subject to the previous deadline shall thereafter be subject to the deadline as extended.

18. Late Applications

18.1 Any application received by the Procuring Agency after the deadline for submission of applications will not be entertained as indicated in the **PDS**.

19. Opening of Applications

19.1 The Procuring Agency shall open all Applications at the date, time and place specified in the **PDS**. Late Applications shall be treated in accordance with ITA 18.1.

19.2 Procuring Agency shall prepare a record of the opening of applications that shall include the name and other details of the Applicant. A copy of the record shall be distributed to all Applicants.

E. Procedures for Evaluation of Applications

20. Confidentiality

20.1 Information relating to the evaluation of applications, and recommendation for prequalification, shall not be disclosed to Applicants or any other persons not officially concerned with such process until the notification of prequalification is made to all Applicants.

20.2 From the deadline for submission of applications to the time of notification of the results of the prequalification, any Applicant that wishes to contact the Procuring Agency on any matter related to the prequalification process, may do so but only in writing.

21. Clarification of Applications	21.1	To assist in the evaluation of applications, the Procuring Agency may, at its discretion, ask any Applicant for a clarification of its application which shall be submitted within a stated reasonable period of time. Any request for clarification and all clarifications shall be in writing.
	21.2	If an Applicant does not provide clarifications of the information requested by the deadline, the application shall be evaluated based on the information and documents available at the time of evaluation of the application.
22. Responsiveness of Applications	22.1	All applications not responsive to the requirements of the prequalification document shall be rejected.
23. Domestic Bidder Price Preference	23.1	Unless otherwise specified in the **PDS,** a margin of preference for domestic bidders shall not apply in the bidding process resulting from this prequalification.
F. Evaluation of Applications and Prequalification of Applicants		
24. Evaluation of Applications	24.1	The Procuring Agency shall use the factors, methods, criteria, and requirements defined in Section III, Qualification Criteria and Requirements to evaluate the qualifications of the Applicants. The use of other methods, criteria, or requirements shall not be permitted.
	24.2	In case of more than one item, the Procuring Agency shall prequalify each Applicant for the maximum number and types of items for which the Applicant meets the appropriate aggregate requirements of such items, as specified in Section III, Qualification Criteria and Requirements.
25. Procuring Agency's Right to Accept or Reject Applications	25.1	The Procuring Agency reserves the right to accept or reject all the applications, and to annul the prequalification process, without thereby incurring any liability to Applicants.
26. Prequalification of Applicants	26.1	All Applicants whose applications have met the specified requirements will, to the exclusion of all others, be prequalified by the Procuring Agency.
27. Notification of Prequalification	27.1	Once the Procuring Agency has completed the evaluation of the applications it shall notify all Applicants in writing indicating their status as to qualified or ineligible.
28. Invitation to Bid	28.1	After the notification of the results of the prequalification the Procuring Agency shall initiate the procurement process which shall only be participated by the prequalified bidders.

Section II: Prequalification Data Sheet (PDS)	
A. General	
ITA 1.1	*Name of Procuring Agency: -* Population Welfare Department, Government of Punjab
ITA 1.1	*PQD name and number are: -* Pre-qualification of firms for Procurement of Contraceptives, PWD/SO(P)/Contraceptive/17-18
ITA 4.7	*Address for communication:* Secretary Population Welfare Department, Government of Punjab, 58-Abu Bakar Block, New Garden Town, Lahore, Pakistan Phone: +92-42-99232440 Email: pwdpunjab@gmail.com
B. Contents of the Prequalification Document	
ITA 7.1	For **clarification purposes,** the Procuring Agency's address is: *"same as in 4.7 above"*
C. Preparation of Applications	
ITA 10.1	The language of the application as well as of all correspondence is: **"English"**
ITA 11.1 (d)	The Applicant shall submit with its application, the following additional documents: 1. Articles of Incorporation or Documents of Constitution, and documents of registration of the legal entity named above. In case of JV, letter of intent to form JV or JV agreement. 2. Applicants signed affidavit on PKR 100.00 judicial paper confirming not having been declared ineligible by any of the public sector organization in Pakistan, as described in ITA Sub-Clause 4.3 3. Applicants signed affidavit on PKR 100.00 judicial paper confirming not having been involved in any litigation during last three years. 4. List of products manufactured / supplied 5. Copy of cGMP certification 6. Installed annual production capacity 7. Certification of WHO prequalification 8. Audited balance sheets, including all related notes, and income statements for the last 3 years 9. Copy of product registration with DRAP 10. Copy of latest Quality Assurance Certification 11. Proof of raw material product and facility registrations with manufacturer's country regulatory authority and international agencies
ITA 15.2	In addition to the original, the number of copies to be submitted with the application is: *[insert number of copies]*

D. Submission of Applications	
ITA 17.1	Applicants ***"shall not"*** have the option of submitting their applications electronically. For application submission purposes only, the Procuring Agency's address is: *"Procuring Agency's address is the same as that indicated in 4.7*
	The deadline for application submission is: Date: **28-11-2017** Time: **11*:00_ hours***
ITA 18.1	Late applications shall not be entertained.
ITA 19.1	The opening of the Applications shall be at **11:30 AM on 28-11-2017,** In Committee Room, Office of the Director General, Population Welfare Department, 14-Babar Block, New Garden Town, Lahore.

Section III: Qualification Criteria and Requirements

This Section contains all the methods, criteria, and requirements that the Procuring Agency shall use to evaluate applications. The information to be provided in relation to each requirement and the definitions of the corresponding terms are included in the respective Application Forms.

Eligibility and Qualification Criteria			**Compliance Requirements**				**Documentation**
No.	**Subject**	**Requirement**	**Single Entity**	**Joint Venture / Consortium**			**Submission Requirements**
				All Parties Combined	**Each Partner**	**One Partner**	
1. Eligibility							
1.1	**Nationality**	Nationality in accordance with ITA Clause 4	Must meet requirement	Existing or intended JV/consortium must meet requirement	Must meet requirement	N/A	Forms ELI – 1.1 with attachments
1.2	**Conflict of Interest**	No conflicts of interest in accordance with ITA Sub-Clause 4.4	Must meet requirement	Existing or intended JV/consortium must meet requirement	Must meet requirement	N/A	Application Submission Form
1.3	**Ineligibility**	a)Not having been declared ineligible by any of the public sector organization in Pakistan, as described in ITA Sub-Clause 4.3 b) not having been involved in any litigation during last three years. In case yes, provide details	Must meet requirement	Existing JV/consortium must meet requirement	Must meet requirement	N/A	Form ELI – 1.2 (a) Affidavit (b) Affidavit
1.4	**Applicant's Production Capacity**	cGMP certification, Installed production capacity three times the contract order quantity	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Form ELI – 1.3
1.5	**WHO Prequalification**	Only for products not manufactured in Pakistan, as per ITA Sub-Clause 5.2	Must meet requirement	Must meet requirement	Must meet requirement	N/A	Form ELI – 1.3

Eligibility and Qualification Criteria			**Compliance Requirements**				**Documentation**
No.	**Subject**	**Requirement**	**Single Entity**	**Joint Venture / Consortium**			**Submission Requirements**
				All Parties Combined	**Each Partner**	**One Partner**	
2. Financial Situation							
2.1	**Financial Performance**	Submission of audited balance sheets, for the last 3 years to ascertain :	Must meet requirement	N/A	Must meet requirement	N/A	Form FIN – 2.1 (a) with attachments
		(a) the financial soundness and stability of the applicant's position and its prospective long term profitability, and	(a) Must meet requirement	(a) N/A	(a) Must meet requirement	(a) N/A	
		(b) capacity to have a cash flow amount of two times the estimated contract value in (PKR/US$)	(b) Must meet requirement	(b) Must meet requirement	(b) N/A	(b) N/A	
		c) Average annual turnover/sales value (PKR/US$) should be at least five times the estimated contract value during the last 3 years (three years)	(c) Must meet requirement	(c) Must meet requirement	(c) N/A	(c) Must meet requirement	Form FIN – 2.1 (b)
		d) An undertaking by locally manufacturer that the Procuring Agency reserved the right to send maximum upto the five batches from the total supplied batches to WHO prequalified Labs.					

	Eligibility and Qualification Criteria			**Compliance Requirements**			**Documentation**
No.	**Subject**	**Requirement**	**Single Entity**	**Joint Venture / Consortium**			**Submission Requirements**
				All Parties Combined	**Each Partner**	**One Partner**	
		for quality assurance purposes on the risk & cost of the locally manufacturer.					

Eligibility and Qualification Criteria			**Compliance Requirements**				**Documentation**
No.	**Subject**	**Requirement**	**Single Entity**	**Joint Venture / Consortium**			**Submission Requirements**
				All Parties Combined	**Each Partner**	**One Partner**	
3. Experience							
3.1	**General Supplies Experience**	Experience under supplies contracts in the role of supplier/manufacturer or agent for at least the last five years prior to the application submission deadline.	Supporting information	Supporting information	Supporting information	Supporting information	Form EXP – 3.1
3.2	**Specific Supplies Experience**	Participation as supplier/manufacturer or agent in at least one or more contracts within the last two years, each with a value of at least equal or more than the estimated contract value, that have been successfully and substantially completed and that are similar to the proposed goods.	Must meet requirement	Must meet requirement	N/A	Must meet requirement	Form EXP 3.2
3.3	**Manufacturing Experience**	The applicant should have manufactured and marketed (a) the specific goods subject of bidding specified in the PDS for at least *3* years, and Applicants wishing to prequalify for products that they do not manufacture must	Must meet requirement	Must meet requirement	N/A	Must meet requirement	Form EXP 3.3

	Eligibility and Qualification Criteria			**Compliance Requirements**			**Documentation**
No.	**Subject**	**Requirement**	**Single Entity**	**Joint Venture / Consortium**			**Submission Requirements**
				All Parties Combined	**Each Partner**	**One Partner**	
		submit the information corresponding to the primary manufacturer of the goods who shall comply with the above manufacturing requirements					
3.4	**Production Capacity**	The Annual Production capacity should be at least three times the quantities specified under the contract	Must meet requirement	Must meet requirement	N/A	Must meet requirement	Form EXP 3.3
3.5	**Sample of quoted Item**	04 sample of the quoted item should be provide with the bids	Must meet requirement	Must meet requirement	N/A	Must meet requirement	N/A

Section IV: Application Forms

Application Submission Form

Date: _ _/_ _/2017

PQD No. and title: PWD/SO(P)/Contraceptive/17-18

Procurement of Contraceptives

To: Population Welfare Department, Government of Punjab

I/we, the undersigned, apply to be prequalified for the referenced procurement and declare that:

(a) I/we have examined and have no reservations to the Prequalification Documents, including Addendum(s) No(s).,(if any) issued in accordance with Instructions to Applicants (ITA) Clause 8: *[insert the number and issuing date of each addendum]*.

(b) I/we, have nationalities from eligible countries, in accordance with ITA Sub-Clause 4.2: *[insert the nationality of the Applicant, including that of all partners in case of a Joint Venture /Consortium if applicable];*

(c) I/we, for any part of the contract resulting from this prequalification, do not have any conflict of interest;

(d) I/we for any part of the contract resulting from this prequalification, have not been declared disqualified / blacklisted by any of the public organization of the Procuring Agency's country

(e) I/we understand that you may cancel the prequalification process at any time, the prequalification does not bound the procuring agency to call for the bids from the prequalified firms.

(f) all information, statements and description contained in the Application are in all respect true, correct and complete to the best of our knowledge and belief.

Signed *[insert signature(s) of an authorized representative(s) of the Applicant]*

Name [insert full name of person signing the application]

In the Capacity of *[insert capacity of person signing the application]*

Duly authorized to sign the application for and on behalf of:
Applicant's Name *[insert full name of Applicant]*

Address *[insert street number/town or city/country address]*

Dated on _ _/_ _/2017

Form ELI -1.1
Applicant Information Form

Date: _ _/_ _/2017
PQD No. and title: PWD/SO(P)/Contraceptive/17-18, Procurement of Contraceptives

Applicant's legal name *[insert full legal name]*
In case of Joint Venture (JV), and consortium legal name of each partner: *[insert full legal name of each partner in JV]*
Applicant's Actual or Intended country of constitution: *[indicate country of Constitution]*
Applicant's actual or Intended year of constitution: *[indicate year of Constitution]*
Applicant's legal address in country of constitution: *[insert street/ number/ town or city/ country]*
Applicant's authorized representative information Name: *[insert full legal name]* Address: *[insert street/ number/ town or city/ country]* Telephone/Fax numbers: *[insert telephone/fax numbers, including country and city codes]* E-mail address: *[indicate e-mail address]*
Attached are copies of original documents of ☐ Articles of Incorporation or Documents of Constitution, and documents of registration of the legal entity named above. ☐ In case of JV, letter of intent to form JV or JV agreement.

Form ELI -1.2
Applicant Affidavit

a) Applicants signed affidavit on PKR 100.00 judicial paper confirming not having been declared ineligible by any of the public sector organization in Pakistan, as described in ITA Sub-Clause 4.3

b) Applicants signed affidavit on PKR 100.00 judicial paper confirming not having been involved in any litigation during last three years.

c) An undertaking by locally manufacturer that the Procuring Agency reserved the right to send maximum upto the five batches from the total supplied batches to WHO prequalified Labs. for quality assurance purposes on the risk & cost of the locally manufacturer.

Form ELI -1.3
Applicant's Information Form[1]

Date: *[insert day, month, year]*
PQD No. and title: PWD/SO(P)/Contraceptive/17-18, Procurement of Contraceptives
Page *[insert page number]* of *[insert total number]* pages

1	Applicant's Primary Business Details	1	
		2	
		3	
		4	
2	List of Products / Services	1	
		2	
		3	
		4	
3	List of Authorization from the principals	1	
		2	
		3	
		4	
5	Warranty Details		
6	Return/Replacement Policy		
7	cGMP certification		
8	Installed annual production capacity		
9	Certification of WHO prequalification[2]		
10	Any Other Information that supplier may like to provide		

[1] For local manufacturers, the Procuring Agency reserves the right to physically verify the information provided by the applicant in the prequalification documents.
[2] For international manufacturers only.

Form FIN – 2.1 (a)
Financial Situation

[The following table shall be filled in for the Applicant and for each partner of a Joint Venture / Consortium]

Applicant's Legal Name: *[insert full name]*
Date: *[insert day, month, year]*
Applicant's Party Legal Name*:[insert full name]*
PQD No. and title: PWD/SO(P)/Contraceptive/17-18, Procurement of Contraceptives
Page *[insert page number]* of *[insert total number]* pages

1. Financial data

Financial information in (PKR/US$ equivalent in 000s)	**previous** *_[insert number] years, years information [insert in words]* **(PKR/US$ equivalent in 000s)**				
	Year 1	Year 2	Year 3	Year …	Year n
Information from Balance Sheet					
Total Assets (TA)					
Total Liabilities (TL)					
Net Worth (NW)[3] (TA – TL)					
Current Assets (CA)					
Current Liabilities (CL)					
Working Capital[4] (CA – CL)					
Information from Income Statement					
Total Revenue (TR)					
Profits Before Taxes (PBT)					

[3] **Net worth** is the difference between total assets and total liabilities. The **net worth** measures a firm's ability to produce profits over the long run as well as its ability to sustain losses.
[4] **Working capital** is the difference between current assets and current liabilities, and measures the firm's ability to generate cash in the short term.

2. Financial documents

The Applicant and its parties shall provide copies of the balance sheets and/or financial statements for *[number]* years pursuant Section III, Qualifications Criteria and Requirements, Sub-factor 3.1. The financial statements shall:

(a) reflect the financial situation of the Applicant or partner to a JV/Consortium, and not sister or parent companies.

(b) be audited by a certified chartered accountant.

(c) be complete, including all notes to the financial statements.

(d) correspond to accounting periods already completed and audited (no statements for partial periods shall be requested or accepted).

☐ Attached are copies of financial statements (balance sheets, including all related notes, and income statements) for the *[number]* years required above; and complying with the requirements

Form FIN - 2.1 (b)
Average Annual Turnover/Sales

[The following table shall be filled in for the Applicant]

Applicant's/Joint Venture Partner's Legal Name: *[insert full name]*
Date: *[insert day, month, year]*
Applicant's Party Legal Name: *[insert full name]*
PQD No. and title: *[insert PQD number and title]*
Page *[insert page number]* of *[insert total number]* pages

Annual turnover/sales data		
Year	**Amount and Currency**	**PKR/US$ equivalent**
[indicate year]	*[insert amount and indicate currency]*	*[insert amount in PKR/US$ equiv.]*
Average Annual Turnover *		

* Average annual turnover calculated as total certified payments received for supplies in progress or completed, divided by the number of years specified in Section III, Qualification Criteria and Requirements, Sub-Factor 2.1.

Form EXP - 3.1
General Experience

[The following table shall be filled in for the Applicant]

Applicant's Legal Name: *[insert full name]*
Date: *[insert day, month, year]*
Applicant Party Legal Name: *[insert full name]*
PQD No. and title: *[insert PQD number]*
Page *[insert page number]* of *[insert total number]* pages

[Identify contracts that demonstrate continuous supplies over the past [number] years pursuant to Section III, Qualification Criteria and Requirements, Sub-Factor 4.1.List contracts chronologically, according to their commencement (starting) dates. Attach documentary proof with proper reference for the companies / organizations mentioned above.*]*

Starting Month / Year	Ending Month / Year	Contract Identification	Role of Applicant
[indicate month/ year]	*[indicate month/ year]*	Contract name: *[insert full name]* Brief Description of the supplies by the Applicant: *[describe goods supplied briefly]* Amount of contract: *[insert amount in PKR equivalent]* Name of Procuring Agency: *[indicate full name]* Address: *[indicate street/number/town or city/country]*	*[insert "Supplier/Manufacturer or Agent"]*
		Contract name: *[insert full name]* Brief Description of the supplies by the Applicant: *[describe goods supplied briefly]* Amount of contract: *[insert amount in PKR equivalent]* Name of Procuring Agency: *[indicate full name]* Address: *[indicate street/number/town or city/country]*	*[insert Supplier/Manufacturer or Agent"]]*
		Contract name: *[insert full name]* Brief Description of the supplies by the Applicant: *[describe goods supplied briefly]* Amount of contract: *[insert amount in PKR equivalent]* Name of Procuring Agency: *[indicate full name]* Address: *[indicate street/number/town or city/country]*	*[insert " Supplier/Manufacturer or Agent"]"]*

Form EXP - 3.2
Specific Experience

[The following table shall be filled in for contracts performed by the Applicant. Attach documentary proof with proper reference for the companies / organizations mentioned.*]*

Applicant's Legal Name: *[insert full name]*
Date: *[insert day, month, year]*
Party Name: *[insert full name]*
PQD No. and title: *[insert PQD number and title]*
Page *[insert page number]* of *[insert total number]* pages

Similar Contract No. *[insert number]* of *[insert number of similar contracts required]*	**Information**		
Contract Identification	*[insert contract name and number, if applicable]*		
Award date	*[insert day, month, year, i. e., _ _ / -/, 201_]*		
Completion date	*[insert day, month, year, i.e., / - /, 201_]*		
Role in Contract			
Total Contract Amount	*[insert total contract amount in local currency]*		PKR/US$ *[insert total contract amount in PKR/US$ equivalent]*
If partner in a JV/Consortium, or subcontractor, specify participation in total contract amount	*[insert a percentage amount]*	*[insert total contract amount in local currency]*	*[insert total contract amount in PKR/US$ equivalent]*
Procuring Agency's Name:	*[insert full name]*		
Address: Telephone/fax number E-mail:	*[indicate street / number / town or city / country]* *[insert telephone/fax numbers, including country and city area codes]* *[insert e-mail address, if available]*		

Form EXP - 3.2 (cont.)
Specific Experience (cont.)

Similar Contract No. *[insert number]* of *[insert number of similar contracts required]*	**Information**
Description of the similarity in accordance with Sub-Factor 4.2of Section III:	
1. Amount	*[insert amount in PKR/US$ in words and in Figures]*
2. Products	*[insert type and description of product]*

Similar Contract No. *[insert number]* of *[insert number of similar contracts required]*	**Information**
Description of the similarity in accordance with Sub-Factor 4.2of Section III:	
1. Amount	*[insert amount in PKR/US$ in words and in Figures]*
2. Products	*[insert type and description of product]*

Similar Contract No. *[insert number]* of *[insert number of similar contracts required]*	**Information**
Description of the similarity in accordance with Sub-Factor 4.2of Section III:	
1. Amount	*[insert amount in PKR/US$ in words and in Figures]*
2. Products	*[insert type and description of product]*

Form EXP - 3.3
Manufacturing Experience & Production Capacity

[The following table shall be filled in for contracts performed by the Applicant. Attach documentary proof with proper reference for the companies / organizations mentioned.*]*

Applicant's Legal Name: *[insert full name]*
Date: *[insert day, month, year]*
Party Name: *[insert full name]*
PQD No. and title: *[insert PQD number and title]*
Page *[insert page number]* of *[insert total number]* pages

1. Year Established:		
2. Key Personnel: [include name of candidate, position, professional qualifications, and experience] Technical	Production	Management
3. Products: Brand Name	Generic Name	Batch size
4. Dates, Numbers, and Expiration Dates of Current Licenses and Permits:		
5. Proof of product and facility registrations with purchaser's country regulatory authority and international agencies.		
6. Name of government agency(ies) responsible for inspecting and licensing of facilities in the country of origin of the raw material and or processing of the goods: Date of last inspection:		
7. Quality Assurance Certification (Please include a copy of your latest certificate with the PQ application):		
8. Production capacity for the requested product: *[insert peak and average production capacity over the last three years in units/day or units/month, etc.]*		
9. List of names and addresses of sources of raw material used for the requested product.		

10. Proof of raw material product and facility registrations with manufacturer's country regulatory authority and international agencies.
11. Raw materials tested prior to use:
12. Presence and characteristics of in-house quality control laboratory
13. Names and addresses of external quality control laboratories used:
14. Are all finished products tested and released by quality control prior to release for sale? Yes No If not, why?
15. Are control tests of the requested product done during production? If so list.
16. Procedures for dealing with rejected batches:
17. List tests conducted after production and prior to release of product on market:
18. List product recalls linked to defects of the requested product during the last 36 months. Include reason and date of recall.

Section V: Scope of Products

1. Description of the Contraceptives

S#	Products	Remarks
1	Condoms (Male latex)	WHO Pre-qualified firms
2	IUD (Cu-T380A)	
3	Implanon NXT	
4	COC (Cycles)	Each batch to be tested from Central Drug Testing Laboratory, Karachi, as per DRAP sampling procedure. In case of doubt/complaint on quality assurance of the locally manufactured contraceptives, the Procuring Agency reserved the rights that they may get any of the supplied batches/lots tested (upto the maximum number of five batches) from WHO accredited Lab from the whole consignment on the risk & cost of the supplier.
5	POP (Cycles)	
6	Injections DMPA (3 month)	
7	ECP (Cycles)	

Technical Specification - Male Latex Condom

(from WHO document "The Male Latex Condom. Specifications and Guidelines for Condom Procurement :2010")

General Requirements (to be verified during prequalification)	
Materials	
General Requirements	The condoms shall be made of natural rubber latex. The condoms shall not liberate toxic or otherwise harmful substances in amounts that can be irritating, sensitizing or otherwise harmful to the user of the condom under normal conditions of use.
Bioburden levels	
Biocompatibility	Biocompatibility assessments shall be conducted in accordance with ***ISO 10993–1.*** Specifically, tests shall be conducted for cytotoxicity according to *ISO 10993–5* and for irritation and sensitization according to ***ISO 10993–10.*** Manufacturers should choose accredited laboratories for these tests, and the results should be interpreted by an accredited toxicologist or other suitably qualified expert. Expert reports should be available for review. *Manufacturers and/or the Procuring Agencys are advised to confirm local requirements for safety testing with appropriate regulatory authorities in the countries in which the condoms are to be distributed.* In accordance with *ISO 10993–1,* manufacturers may provide data on equivalent products.
water-extractable protein levels	***It is recommended*** **that manufacturers determine the water-extractable levels of proteins in their products.** The recommended levels for soluble protein, as determined by the modified Lowry method, should be less than **200 µg/g.** Manufacturers should take steps not to exceed this level and should monitor production periodically. There is no specific standard for determining the protein levels in condoms. The methods described in *ISO 12243, EN 455–3* and *ASTM D5172* for determining the protein levels in medical gloves can be modified for condoms[1]. Documentation recording protein levels should be available for review.

1 Tinkler J et al. Risk assessment of dithiocarbamate accelerator residues in latex-based medical devices: genotoxicity considerations.
Journal of Food Chemistry and Toxicology, 1998, 36(9–10):849–866. For further details regarding nitrosamines, refer to Annex I.

2 That is, in the temperature range of 28 °C to 35 °C.

3 As described in *ISO 4074.*

General Requirements (to be verified during prequalification)	
Provisional shelf-life	Pending the outcome of the real-time studies, manufacturers may estimate a provisional shelf-life using an accelerated ageing study[5].
Sampling	Sample condoms from three manufacturing LOTS in accordance with Annex B of *ISO 4074.*
conditioning	Condition condoms at (50 ± 2) °C for 120 days or 180 days in accordance with the relevant annex of *ISO 4074.*
testing requirement	Assess compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of *ISO 4074.* If all three LOTS of condoms remain in compliance with the requirements for bursting properties, free- dom from holes and package integrity specified in the relevant clauses of *ISO 4074* for a period of **120 days** at (50 ± 2) °C, *a provisional shelf-life of* ***three years*** *may be assigned.* If all three LOTS of condoms remain in compliance with the requirements for bursting properties, free- dom from holes and package integrity specified in the relevant clauses of *ISO 4074* for a period of **180 days** at (50 ± 2) °C, *a provisional shelf-life of* ***five years*** *may be assigned.*
Minimum stability requirements	Condoms shall comply with the minimum stability requirements defined in the relevant clause of *ISO 4074.* Condoms meeting these minimum stability requirements can be assumed to have a provisional shelf-life of two years.
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:* • One set for 168 ± 2 hours at (70 ± 2) °C, and another set for (90 ± 1) days at (50 ± 2) °C. • At the end of the incubation periods, withdraw the condoms and test for airburst properties, freedom from holes and package seal. • 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: AQL 1.5** **Volume:** 16.0 dm^3 for condoms with widths less than 50.0 mm 18.0 dm^3 for condoms with widths from 50.0 mm up to 55.5 mm 22.0 dm^3 for condoms with widths greater than or equal to 56.0 mm **Pressure:** 1.0 kPa (for all widths) 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 (75 ± 5) mm from the closed end, rounded to the nearest 0.5 mm.

5 As described in *ISO 4074.*

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: AQL 1.5** **Volume:** 16.0 dm^3 for condoms with widths less than 50.0 mm 18.0 dm^3 for condoms with widths from 50.0 mm up to 55.5 mm 22.0 dm^3 for condoms with widths greater than or equal to 56.0 mm **Pressure:** 1.0 kPa (for all widths) 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 (75 ± 5) mm from the closed end, rounded to the nearest 0.5 mm.
Freedom from holes and visible defects	
Sampling	*ISO 2859–1* General Inspection Level I, but at least Code Letter M. For prequalification testing at least Code Letter N as specified in Annex B of *ISO 4074* shall be used.
Testing	In accordance with the relevant annex of *ISO 4074*.
requirement	In accordance with test method in the relevant annex of *ISO 4074*. Freedom from holes: **AQL 0.25** Critical visible defects: **AQL 0.4** Non-critical visible defects: **AQL 2.5** *ISO 4074* describes a limited number of critical visible defects. WHO specifies an extended list of critical visible defects and a list of non-critical visible defects in Chapter 3, Clauses 2.1 and 2.2. **exact definitions of critical and non-critical defects should be reviewed and agreed upon during the contractual process.**
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. Condoms may be of any shape consistent with normal commercial practice and client requirements. *If the condom is not parallel-sided and smooth, attach a dimensioned drawing with detailed description, and check here:*
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 coloured. **Pigments used with coloured condoms shall be suitable for use in medical devices.** If a pigment is required, indicate the colour here and provide full details of the pigment, including a Material Safety Data Sheet (MSDS).
odour, fragrance and flavor	
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.) 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. 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. If a fragrance is desired, describe here (specify fragrance and amount added) and provide full details of the fragrance, including a Material Safety Data Sheet (MSDS).

Design Requirements	
	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. **AQL 1.0** 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. 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. A minimum of 180 mm for condoms with widths from 50.0 mm up to 55.5 mm. A minimum of 190 mm for condoms with widths equal to or greater than 56.0 mm. **AQL 1.0** Length may be specified based on the best available data on the target population. Indicate the length here: 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. 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. 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. **AQL 1.0** The mean single-wall thickness (calculated from the three individual measurements) for each condom shall be 0.065 + 0.015 mm – 0.020 mm. *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	
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. *Other lubricants such as glycols and water-based lubricants may be used. Oil-based lubricants* ***should NOT*** *be used.* If an alternative lubricant is required, specify the type here and provide full details of the lubricant including a Material Safety Data Sheet (MSDS). The quantity of lubricant, including powder, in the package should be (550 ± 150) mg. **AQL 4.0** *If user preferences indicate that it is desirable, lower lubricant levels may be used, but the minimum recommended quantity is 250 mg.* If the lubricant quantity is less than (550 ± 150) mg, indicate here:
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. The individual package shall have the following markings: • manufacturer's name; • LOT number or LOT identification code (printed at the time of packaging, not pre-printed); • expiry date: month and year labelled expiry date; • date in a language to be specified by the Procuring Agency. *Manufacturing date: Month-and-year manufacturing date can be added if required by Procuring Agency.* **AQL 2.5**
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.

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.* If an alternative material is required, append the full specification and mark here: ☐ The LOT numbers on packages must be printed at the time of packaging. In addition, the following shall apply: • There shall be no evidence of leakage. • The outside surface of the package shall be clean. • There shall be no separation of the layers of laminate. • If the sealed packages are in strips, the individual packages are separated by perforations or other means that allow the packages to be separated by hand without interfering with the seals. • The package must be easy to open without damaging the condom.

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	No consumer packs are included in the *WHO/UNFPA Specification.* If required, the full design of the consumer pack should be specified in accordance with the require- ments of the programme.
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. The inner boxes will be marked in a legible manner to describe the contents and to facilitate identifica- tion in case of subsequent query. **the following information shall be included in the inner box marking:** • LOT identification number; • 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; • 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; • manufacturer's name and registered address; • nominal width of the condom, expressed in millimeters; • number of condoms in box; • instructions for storage. **note: All markings must be legible.** Inner box markings can be specified in accordance with programme requirements.

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: • to handle the condom carefully, including removal from the package so as to avoid damage to the condom by fingernails, jewellery, etc.; • 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; • to stop and check if the user feels the condom slipping, as it may fall off the penis; • to stop and check if the user feels the condom tightening excessively on the penis, as this may lead to breakage; • to withdraw the penis soon after ejaculation, while holding the condom firmly in place at the base of the penis; • 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; • to consult a doctor or pharmacist about the compatibility of topical medicines that might come in contact with the condom; • to seek medical assistance at soon as possible within five days, should a condom leak or burst during use; • if the individual container is obviously damaged, to discard that condom and use a new one from an undamaged package; • instructions on how to dispose of the used condom; • a statement that the condom is for single use; • the number of the International Standard, i.e. *ISO 4074*. ***It is recommended*** **that the following statement relating to the safety and effectiveness of the condom be included:** **"When used correctly every time you have sex, condoms greatly reduce the risk of unin- tended pregnancy, HIV/AIDs and some other sexually transmitted infections. Use a new condom every time you have sex and follow the instructions carefully."**
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 fiberboard with a bursting test strength of not less than 1900 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 centre seams and extending over the ends by not less than 75 mm. The cartons may be secured by plastic strapping at not less than two positions. Alternatively, wire-bound, cleated plywood or nailed wood boxes are acceptable when lined with a waterproof barrier material. The barrier material must be sealed at the edges with waterproof tape or adhesive, and there must be no sharp protrusions inside the boxes. In some countries the three-wall corrugated fiberboard available is not of sufficient strength and rigid- ity to meet stacking requirements or to resist being cut at the corners when the plastic strapping is applied. In such cases an inner carton of two-walled corrugated fiberboard shall be inserted into the shipping carton before packing the condoms.

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: • LOT identification number; • 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; • 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; • name and address of supplier; • nominal width; • number contained in the carton; • instructions for storage and handling. To facilitate monitoring of LOT quality during shipping and storage, all exterior shipping cartons for each
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. 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 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 pack- age 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 Minimum Code Letter M	Minimum volumes: 1. **16.0** dm^3 for condoms with widths less than 50 mm 2. **18.0** dm^3 for condoms with widths from 50 mm to 55.5 mm 3. **22** dm^3 for condoms with widths greater than 56 mm AQL 1.5
Bursting pressure (before and after oven conditioning)	Level G-I Minimum Code Letter M	Minimum pressure: 1.0 kPa AQL 1.5
Freedom from holes (before and after oven conditioning for (168 ± 5) h at (70 ± 2) °C)	Level G-I 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 Minimum Code Letter N	Critical defects: AQL 0.4 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 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 AQL 1.0
Length	Level S-2	1. **165** mm for widths less than 50 mm 2. **180** mm for widths between 50 mm and 55.5 mm 3. **190** mm for widths of 56.0 and above AQL 1.0
Thickness	Level S-2	0.045–0.080 mm AQL 1.0
Lubricant quantity (including powder)	Level S-2	Viscosity: 200–350 centistokes Qty: 400–700 mg/condom 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		
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: 1. **16.0** dm^3 for condoms with widths less than 50 mm 2. **18.0** dm^3 for condoms with widths from 50 mm to 55.5 mm 3. **22** dm^3 for condoms with widths greater than 56 mm AQL 1.5
Bursting pressure (before and after oven conditioning)	Level G-I	Minimum pressure: 1.0 kPa AQL 1.5
Freedom from holes	Level G-I Minimum Code Letter M	AQL 0.25
Visible defects	Level G-I 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 AQL 1.0
Length	Level S-2	1. **165** mm for widths less than 50 mm 2. **180** mm for widths between 50 mm and 55.5 mm 3. **190** mm for widths of 56.0 and above AQL 1.0
Thickness	Level S-2	0.045–0.080 mm AQL 1.0
Lubricant quantity (including powder)	Level S-2	Viscosity: 200–350 centistokes Qty: 400–700 mg/condom 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 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[5], 33 ISWG[6]).

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

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

[5] *American Wire Gauge*
[6] *Imperial Standard Wire Gauge*

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.

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 radiused 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 90^0 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 180^0).

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. 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).

Technical Specification - Oral Contraceptive (COC)

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[7] 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.[8]

1.3 Registration Requirements

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

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

Oral contraceptives offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the Contract, the successful offeror(s) may be required to submit a "statement of licensing status of pharmaceutical product(s)" as provided under the World Health Organization (WHO)

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[7] *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.*

[8] *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, 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.*

Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.[9]

1.5 Compliance With Current Good Manufacturing Practices

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

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

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

1.7 Shape and Dimensions

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

1.8 Colors

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

1.9 Tablet Markings

Each tablet shall bear the identifying imprint of its manufacturer.

1.10 Packaging

1.10.1 Monthly Cycle Presentation

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

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

1.10.2 Mounting

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

1.11 Identification Markings on Individual Blister Packs

Each individual blister pack shall have the following information:

- Product/brand name
- Lot/batch number
- Expiration date (day, month and year)
- Date of manufacture

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

- 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 as per registration and approved by the Drug Registration Authority of Pakistan. The Supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer's stability test data substantiating the 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[10] 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.[11]

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

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

[11] *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.*

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.[12]

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

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

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

3.2 Exterior Shipping Cartons

3.2.1 Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fiberboard cartons made from weather-resistant fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm[13]. 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[14]:

- Product/brand name
- Drug Manufacturing License Number
- Lot/batch number
- Expiration date (day, month and year)
- Date of manufacture

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[12] *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.*

[13] *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.*

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

- 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.[15]

Regulatory information (on two opposing sides of carton)

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

3.4 Printed Materials—Product Information Sheets

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

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

Inspection Sampling and Testing—Oral Contraceptives

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

1.1 Packaging, Packing and Markings

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, 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

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

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:

- Package seal integrity test.[16]

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.

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

Technical Specification - Progestogen only oral contraceptive pill (POP)

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[17] 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(levonorgestrel 30 micrograms).
- Contraceptive tablets: 28
    - Each tablet shall contain levonorgestrel 30 micrograms.

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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.[18]

1.3 Registration Requirements

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

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

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

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[17] *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.*

[18] *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, 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.*

Commerce.[19]

1.5 Compliance With Current Good Manufacturing Practices

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

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

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

1.7 Shape and Dimensions

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

1.8 Colors

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

1.9 Tablet Markings

Each tablet shall bear the identifying imprint of its manufacturer.

1.10 Packaging

1.10.1 Monthly Cycle Presentation

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

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

1.10.2 Mounting

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

1.11 Identification Markings on Individual Blister Packs

Each individual blister pack shall have the following information:

- Product/brand name
- Lot/batch number
- Expiration date (day, month and year)
- Date of manufacture
- Manufacturer's name and address

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

- 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 as per registration and approved by the Drug Registration Authority of Pakistan. The Supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer's stability test data substantiating the 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[20] 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.[21]

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

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

[21] *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.*

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.[22]

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

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

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

3.2 Exterior Shipping Cartons

3.2.1 Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fiberboard cartons made from weather-resistant fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm[23]. 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[24]:

- Product/brand name
- Drug Manufacturing License Number
- Lot/batch number
- Expiration date (day, month and year)
- Date of manufacture

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[22] *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.*

[23] *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.*

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

- 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.[25]

Regulatory information (on two opposing sides of carton)

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

3.4 Printed Materials—Product Information Sheets

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

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

Inspection Sampling and Testing—Oral Contraceptives

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

1.1 Packaging, Packing and Markings

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, 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

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

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.[26]

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.

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

Technical Specifications - Injectable Contraceptives (Three month)

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.[27] 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.[28]

1.3 Primary Packaging Requirements

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

1.4 Registration Requirements

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

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

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[27] *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.*

[28] *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, 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.*

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.[29]

1.6 Compliance with Current Good Manufacturing Practices

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

1.7 Appearance

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

1.8 Filling Volume

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

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

1.9 Identification Markings on Individual Vials or Ampoules

Each individual vial or ampoule shall have the following information:

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

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

- Recommended storage conditions.
- Drug Manufacturing License Number.

1.10 Workmanship

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

1.11 Lots Per Order

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

1.12 Shelf Life

The shelf life of the product provided under this solicitation shall be at least three (3) years from the date of manufacture when stored under tropical conditions such as those

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

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[30] of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided. Such evidence is contained in the "Manufacturer's Batch Certificate" under the WHO Certification Scheme.

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

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

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

2.3 Inspection by the Procuring Agency

The Procuring Agency reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Technical Specifications and Special Conditions of Contract to ensure that the goods conform to prescribed requirements. The Procuring Agency reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to supply of the goods and to draw samples from the Supplier's factory and/or warehouse for test analysis. Except as otherwise specified in the Contract or purchase order, prior to shipment, the Procuring Agency will sample, or cause to be sampled, the product as packed in inner boxes preparatory to packing in exterior shipping cartons. The sampling shall be according to recognized standards.[31]

The Procuring Agency may have some or all of the tests specified in the Technical

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

[31] *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.*

Specifications of the Contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on pharmaceutical products according to Pharmacopoeia specifications.

2.4 Sampling Procedures

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

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

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

2.5 Sample Retention

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

3. Packing

3.1 Inner Boxes

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

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

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

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

3.2 Exterior Shipping Cartons

3.2.1 Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fiberboard cartons made from weather-resistant fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm[32]. 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:

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[32] *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.*

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[33]:

- 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.[34]

Regulatory information (on two opposing sides of carton)

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

3.4 Printed Materials—Product Information Sheets

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

Inspection Sampling and Testing—Injectable Contraceptives

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

1.1 Packaging, Packing and Markings

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

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

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, 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.

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.[35]

1. **Requirements**

Emergency contraceptive tablets in accordance with the following specifications:

- Each tablet shall contain 0.753 mg of Levonorgestrel

1.1 **Product and Brand Names**

Product name: ……

Brand names: …….

Registration Number: …….

1.2 **Raw Materials**

Emergency contraceptive tablets offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor.[36]

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)**

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[35] *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.

[36] *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, 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.*

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.[37]

1.5 **Compliance with Current Good Manufacturing Practices**

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

1.7 **Shape and Dimensions**

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

1.8 **Colors**

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

1.9 **Tablet Markings**

Each tablet shall bear the identifying imprint of its manufacturer.

1.10 **Packaging**

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

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

1.11 **Identification Markings on Individual Blister Packs**

Each individual blister pack shall have the following information:

- Product/brand name
- Lot/batch number
- Expiration date (day, month and year)
- Date of manufacture
- Manufacturer's name and address
- Contents and quantity, including tablet formulation (amounts of active ingredients per tablet)
- Drug registration number (if applicable)
- Family planning logo (if applicable)
- Drug Manufacturing License Number

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

- Product use and storage instructions (accompanying the blister pack).

1.12 Workmanship

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

1.13 **Lots per Order**

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

1.14 **Shelf Life**

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

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

1.16 **Test Data**

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

2. **Quality Assurance Provisions**

Same as Oral Contraceptive Pills

3. **Packing**

Same as Oral Contraceptive Pills

Inspection Sampling and Testing

Same as Oral Contraceptive Pill

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.[38]

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

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

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

3.2 **Exterior Shipping Cartons**

3.2.1 Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fiberboard cartons made from weather-resistant fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm[39]. 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[40]:

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

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[38] *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.*

[39] *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.*

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

opposing sides in bold letters at least ……..mm high with waterproof ink in a clearly legible manner that is acceptable to the Procuring Agency.[41]
Regulatory information (on two opposing sides of carton)
Product/brand name
Drug Manufacturing License Number
Lot/batch number
Expiration date (day, month and year)
Date of manufacture
Manufacturer's name and address
Contents and quantity
Drug registration numbers (if applicable)
Instructions and symbols for storage and handling, such as KEEP DRY or DO NOT FREEZE

3.4 **Printed Materials—Product Information Sheets**

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

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

Inspection Sampling and Testing—Oral Contraceptives

Markings per Technical Specification 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, Single Sampling Plan for Normal Inspection.
The sample will be examined for:
General physical characteristics per Technical Specification, Section
Markings per Technical Specification, Section
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.[42]
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

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

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

applicable pharmacopoeial limits.

1.3 **Resolution of Defects**

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.

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[43] (Three month)

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.[44]

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.[45]

1.3 **Primary Packaging Requirements**

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

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[43] Evaluation criteria (1) WHO prequalification certificate for international bidders / imported items and Evaluation criteria (2) Batch Inspection certificate from any of the WHO prequalified labs for locally manufactured products

[44] *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.*

[45] *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, 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.[46]

1.6 **Compliance with Current Good Manufacturing Practices**

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

1.7 **Appearance**

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

1.8 **Filling Volume**

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

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

1.9 **Identification Markings on Individual Vials or Ampoules**

Each individual vial or ampoule shall have the following information:

Product/brand name

Lot/batch number

Expiration date (day, month and year)

Date of manufacture

Manufacturer's name and address

Presentation (e.g., sterile aqueous suspension)

Formulation (amounts of active ingredients per vial or ampoule)

Drug registration number (if applicable)

Family planning logo (if applicable)

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

Recommended storage conditions.

Drug Manufacturing License Number.

1.10 **Workmanship**

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

1.11 **Lots Per Order**

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

1.12 **Shelf Life**

The shelf life of the product provided under this solicitation shall be at least three (3) years from the date of manufacture when stored under tropical conditions such as those prevailing in the local environment. The Supplier shall be able to provide to the satisfaction of the

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

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[47] of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided. Such evidence is contained in the "Manufacturer's Batch Certificate" under the WHO Certification Scheme.

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

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

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

2.3 **Inspection by the Procuring Agency**

The Procuring Agency reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Technical Specifications and Special Conditions of Contract to ensure that the goods conform to prescribed requirements. The Procuring Agency reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to supply of the goods and to draw samples from the Supplier's factory and/or warehouse for test analysis. Except as otherwise specified in the Contract or purchase order, prior to shipment, the Procuring Agency will sample, or cause to be sampled, the product as packed in inner boxes preparatory to packing in exterior shipping cartons. The sampling shall be according to recognized standards.[48]

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)

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

[48] *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.*

may be used for visual inspection. Sampling for analytical testing shall be done in accordance with pharmacopoeial requirements.
All sampled boxes and supply cartons shall be so marked and shall include the date and initials of the sampler.

2.5 **Sample Retention**

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

3. **Packing**

3.1 Inner Boxes

3.1.1 One hundred (100) individual glass vials or ampoules will be contained in sturdy white cardboard boxes outfitted with individual segments for protecting and separating each vial or ampoule.
Inner boxes shall be made of sturdy white cardboard of a size sufficient to contain the specified number of vials or ampoules. The overall dimensions should be such that the product does not get damaged during transportation and storage.

3.1.2 For inner boxes, the Bidder shall fill in the blanks provided below:
Each inner box will contain one hundred (100) units. The overall dimensions of a box will be cm x cm x cm.

3.2 **Exterior Shipping Cartons**

3.2.1 Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fiberboard cartons made from weather-resistant fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm[49]. 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[50]:
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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[49] *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.*

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

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.[51]

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

3.4 **Printed Materials—Product Information Sheets**

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

Inspection Sampling and Testing—Injectable Contraceptives

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

1.1 **Packaging, Packing and Markings**

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

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, 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

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

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**

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.

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

Technical Specification: 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 less time to insert and remove, and produce fewer bleeding disturbances for users.

Types of implants:

- A single-rod system that contains etonogestrel a progestin and provides contraception for five years.

Implanon NXT:

X-*ray visible Implanon (Org 3236 Implants 68 mg) is a subdermal contraceptive, consisting of a coaxial implant (i.e. the implant core surrounded by a skin), contained in an applicator. The implant core consists of a mixture of ethylene vinyl acetate copolymer containing 28% vinyl acetate (EVA 28) with etonogestrel (Org 3236) as the drug substance, barium sulfate as a radio-opacifying agent and magnesium stearate as a lubricant. The implant skin consists of ethylene vinyl acetate copolymer containing 15% vinyl acetate (EVA 15). Each implant contains 68 mg of etonogestrel a progestin and provides contraception for three years.*

Materials

The single sterile rod implant is 4 cm in length with a diameter of 2 mm. It **c**onsists 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 combination of Polycarbonate (PC) and acrylonitrile-butadiene-styrene (ABS) body with a stainless steel needle and a copolymer of Methacrylate, Butadiene and Styrene (MBS) needle protection camp.

Implanon NXT:

The implant consists of a non-biodegradable single-rod implant, pre-filled in the stainless steel needle of a ready-for use disposable applicator. The implant has a length of 4 cm and a diameter of 2 mm and contains a synthetic progestagen, etonogestrel (3-ketodesogestrel, Org 3236). After subdermal insertion of the implant in the upper-arm, a continuous, slowly decreasing release of etonogestrel occurs, providing contraceptive protection for three years.

The product consists of an implant, placed inside an applicator. The implant consists of a core containing a mixture of the drug substance etonogestrel (Org 3236), barium sulfate and ethylene vinylacetate copolymer with a vinylacetate content of 28% and a skin consisting of ethylene vinylacetate copolymer with a vinylacetate content of 14%. Each implant contains 68 mg of etonogestrel.

Evaluation criteria (1) WHO prequalification certificate for international bidders / imported items and Evaluation criteria (2) Batch Inspection certificate from any of the WHO prequalified labs for locally manufactured products.

Packaging

The single rod implant containing 68 mg etonogestrel is preloaded in the stainless steel needle of the disposable applicator. The sterile applicator containing implant is packed in a blister pack consisting of Polyethylene Terephtalate Glycolate (PETG) from film that is heat sealed with a non-wovan (spunbonded) High Density Polyethylene (HDPE) lidding film with an Ethylene Vinylacetate co-polymer (EVA) coating layer.

- The PETG shall comply with EU Directive 10/2011/EC
- The HDPE is ISO 11607 – complaint

Closure integrity of the blisters

After cyclic temperature treatment was tested using the dye penetration test, according to ASTM F1929-98

The performance of the proposed bulk blister shipping system was measure by means of

(1) Drop testing Standard Test Method for Drop Test of Loaded Containers by Free Fall (ASTM D 5276)
(2) Transport simulation testing Standard Practice for Performance Testing of Shipping Containers and Systems (ASTM D4169) and test methods D880. D4728 and D6179

Printing

All printing shall be clear and readily legible.

Sterility

The LRV for EVA coated, spunbonded HDPE lidding film was determined superior according to ASTM F 1608-00 sterilization method
Sterilization shall be by Gamma irradiation
Irradiated blisters were used for a stability study conform ASTM F1980-02 under real time/long term (20^{o}C/55% RH) and accelerated 50^{o}C/ambient RH) conditions.

Sterility assurance level

The sterilization assuance level shall be 10-6

Storage and shelf life

Shelf life
The shelf life of Implanon NXT is 5 years when stored as indicated under Section 6.4 "Special precautions for storage".
Implanon NXT should not be inserted after the expiry date as indicated on the primary package.

Special precautions for storage
Store in the original package at 2^{o} to 30^{o}C.

Effective life

If inserted anytime before the expiration date (shelf life), single rod is effective for 3 years. The rod should be removed by the end of the fifth year. If desired, a new rod may be 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.

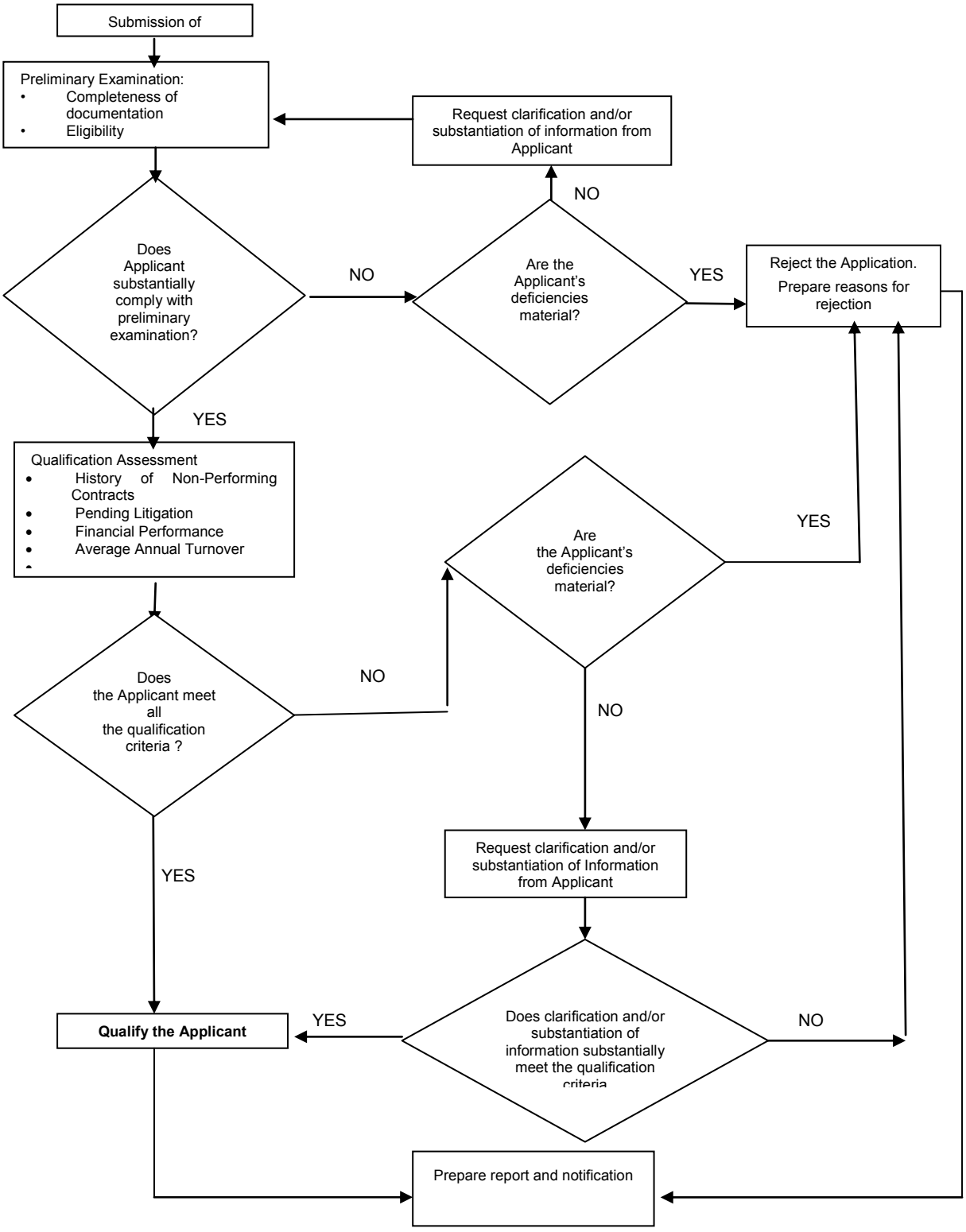
Sampling Procedures

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).

Prequalification Evaluation Flow Chart

The attached flow chart indicates the successive steps of the evaluation process. The process is consistent with (i) Sections I and II, Instructions to Applicants and Prequalification Data Sheet and (ii) Section III, Qualification Criteria and Requirements. The flow chart should be reviewed by the evaluation team prior to the evaluation, and used as a Guide during the evaluation, concurrently with Section III



Glossary

Bid Securing Declaration	An undertaking by a prospective bidder, committing to pay the corresponding fine and be suspended for a period of time from being qualified to participate in any government procurement activity in the event it violates any of the conditions stated in the bidding documents.
Procuring Agency	One of the two parties to a supplies contract, the other party being the "Supplier."
Supplier	The legal entity that is party to and performs a supplies contract, the other party to the contract being the "Procuring Agency."
Post-qualification	An assessment made by the Procuring Agency after the evaluation of bids and immediately prior to award of contract, to ensure that the lowest-evaluated, responsive, eligible Bidder is qualified to perform the contract in accordance with previously specified prequalification requirements.
Pre-qualification	An assessment made by the Procuring Agency before inviting bids, of the appropriate level of experience and capacity of firms expressing interest in undertaking a particular contract, before inviting them to bid.
turnover	The gross earnings of a firm, defined as the billings for supplies in progress and/or completed, normally expressed on an annual basis, and excluding income from other sources.
In writing	For the purpose of this document, means authenticated handwritten, typed, or printed; a document prepared in writing can be transmitted by telex, electronic mail, facsimile, with proof of receipt; and in the form requested by the sender.