



POPULATION WELFARE DEPARTMENT
GOVERNMENT OF SINDH



ANNUAL PROCUREMENT PLAN FOR THE YEAR 2026-27 UNDER RULE 11 OF SPPRA

S. #	Description of Procurement	Quantity (where applicable)	Estimated unit cost (where applicable)	Estimate total Cost (Million)	Funds allocated	Sources of Funds (ADP/Non ADP)	Proposed Procurement Method	Timing of Procurement				Remarks
								1 st Qtr.	2 nd Qtr.	3 rd Qtr.	4 th Qtr.	
1.	Drugs/Medicines & others	-	-	229.867		Non ADP	Single Stage Two Envelope	1 st	-	-	-	
2.	Generic Consumables items			43.255		-do-	Single Stage Two Envelope	1 st	-	-	-	
3.	NCB Contraceptives	-	-	708.990		-do-	-do-	1 st	-	-	-	
4.	Liveries/Uniforms	-	-	3.096		-do-	Single Stage One envelope	1 st	-	-	-	
5.	Transportation of Goods	-	-	10.418		-do-	Single Stage Two Envelope	1 st	-	-	-	
6.	Stationery	-	-	13.623		-do-	-do-	1 st	-	-	-	
7.	Printing Material	-	-	18.191		-do-	-do-	1 st	-	-	-	
8.	ICB Contraceptives	-	-	281.010		-do-	Single Stage Two Envelope	-	2 nd	-	-	

Deputy Director (W&D)
Population Welfare Department
Government of Sindh Karachi

BIDDING DOCUMENT

Procurement of Contraceptives & Miscellaneous Items Competitive Bidding



GOVERNMENT OF SINDH

Population Welfare Department



SECTION I
Instructions to Bidders
(ITB)



Bid Data Sheet (BDS)

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

ITB Ref	Description	Detail
	Issuance of Bidding Document	From the date of Hoisting of Invitation to Bid on Website on SPPRA Web Site and after Publication of Tender in newspaper
	Last Date of submission of Bidding Documents	5TH August, 2026 at 11.00 AM
	Date of Opening of Bidding Documents	5TH August, 2026 at 11.30 AM
ITB Clause 1.1	Bid title and reference number	Procurement of Contraceptives by Department of Population Welfare, Government of Sindh, Karachi Pakistan No. PWDS/W&D/ NCB/CC/2026-27/01
ITB Clause 4	Documents Establishing Conformity to Bidding Documents	In addition to the list of documents stated in ITB 4.1 & 4.2; the following documents should be included with the Bid: (a) Certificate of analysis documenting product's compliance with specification and performance requirements. (b) For products manufactured outside of Pakistan and imported, a certificate documenting that the quoted product submitted is WHO/UNFPA prequalified and enlisted at DRAP with authorized dealer's name who participates in bidding process. (c) For products manufactured in Pakistan, a certificate documenting acceptable quality of the product from WHO prequalified Laboratory or National DRA.
ITB Clause 5.1	Qualifications of Bidder	In addition to Bid Forms 3(A) and 4,
ITB Clause 9.1	Bidding procedure	Single stage – Two Envelop procedure



ITB Clause 11.1	Clarification of Bidding Documents	Secretary Population Welfare Department, Government of Sindh, NICL Building 11 th Floor, Abbasi Shaheed Road Behind FTC Building Gora Qaburstan, Karachi, Pakistan Phone: +92-21-99225652
ITB Clause 13.1	Language of bid	English
ITB Clause 16.1, 16.2.a.iii, 16.2.b.ii and	Final Destination	DAP at Central Warehouse Karachi
ITB Clause 16.5	Bid Price	Price shall be fixed inclusive all applicable taxes and cost
ITB Clause 16.6	Bid Price	Supplier must quote for the full quantities requested
ITB Clause 17.1	Currencies of Bid	Pak Rupees
ITB Clause 18.1	Bid validity period	90 Days
ITB Clause 19.1	Amount of bid security	2.5% of bid price value
ITB Clause 19.2	Amount of Performance Security	3%
ITB Clause 20.1	Number of bid copies	One original set and 1copy
ITB Clause 21.2.ii	Marking of Bids	Secretary Population Welfare Department, Government of Sindh, NICL Building 11 th Floor, Abbasi Shaheed Road Behind FTC Building Gora Qaburstan, Karachi, Pakistan Phone: +92-21-99225652
ITB Clause 21.2.iv	Marking of the Bids	Procurement of Contraceptive for Secretary Population Welfare Department, Government of Sindh, NICL Building 11 th Floor, Abbasi Shaheed Road Behind FTC Building Gora Qaburstan, Karachi, Pakistan Phone: +92-21-99225652 No. PWDS/W&D/NCB/CC/2026-27/01
ITB Clause 22.1	Last date and time for the receipt of bidding document	5 TH August, 2026 at 11.00 AM
ITB Clause 24.1	Date, time and venue of opening of technical bids	Technical Bids shall be opened on dated 5 TH August, 2026 at 11.30 AM at Board Room of Secretary Population Welfare Department, Government of Sindh, NICL Building 11 th Floor, Abbasi Shaheed Road Behind FTC Building Gora Qaburstan, Karachi, Pakistan

Opening and Evaluation of Bids

- 1. Bid Opening**
- 1.1 All bids received, shall be opened by the Departmental Purchase Committee publically in the presence of the Bidders or their representatives who choose to be present on the date, time and venue stipulated in the Bid Data Sheet.
- 1.2 The bids shall be opened in accordance with the procedure specified in Bid Data Sheet
- 1.3 All Bidders in attendance shall sign an attendance sheet.
- 1.4 The Procuring Agency shall open one Bid at a time and read out aloud its contents which may include name of the Bidder and items bided for. The Procuring Agency may choose to announce any other details which it deems appropriate if not in conflict with the SPPR-2019, specifically Rule 41 (Opening of Bids)
- 1.5 Bids that are not opened and read out at bid opening shall not be considered further for bid evaluation irrespective of the circumstances.
- 1.6 The Procuring Agency shall have the minutes of the Bid opening (technical and when applicable financial) recorded.
- 1.7 The financial bid of the non-responsive bidder shall be returned unopened.
- 1.8 The financial bids without Bid Security being non-responsive shall be returned unannounced to the Bidders.
- 2. Clarification of Bids**
- 2.1 During evaluation of the bids, the Procuring Agency may, at its discretion, ask the Bidder for a clarification of its bid. The request for clarification and the response shall be in writing, and no change in the prices or substance of the bid shall be sought, offered, or permitted. Except to correct arithmetic errors identified by the Procuring Agency in the evaluation of the bids,
- 3. Confidentiality**
- 3.1 Information relating to the examination, clarification, evaluation and comparison of bids, and recommendations for the award of a Contract shall not be disclosed to bidders or any other persons not officially concerned with such process until the announcement of bid evaluation report.
- 3.2 Any effort by the bidder to influence the Procuring Agency in the bid evaluation, bid comparison or contract award decisions may result in the rejection of the Bidder's bid. Canvassing by any Bidder at any stage of the bid evaluation is strictly prohibited. Any infringement thereto shall lead to rejection of the bid
- 3.3 From the time of bid opening to the time of Contract award, if any Bidder wishes to contact the Procuring Agency on any matter related to its bid or intends to bring additional information to the notice of the Procuring Agency, it may do so in writing.



4. Examination of Bids and Determination of Responsiveness

4.1

The Procuring Agency shall examine the bids to ascertain as to whether they are complete, free of any computational errors, all required sureties have been attached, all documents have been properly signed, and the bids are generally in order. In the case the bidding process is conducted through prequalified bidders Procuring Agency shall ensure that bidding documents have been issued to the prequalified bidders only and each bid received is from a prequalified Bidder.

4.2

The Procuring Agency may waive any minor informality, nonconformity, or irregularity in a bid which does not impact the substance of the bid and constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any Bidder.

4.3

Prior to the detailed evaluation, the Procuring Agency shall determine whether each bid is of acceptable quality, is complete and is substantially responsive to the Bidding Documents. For purposes of this determination, a substantially responsive bid is one that conforms to all the terms, conditions, and specifications of the Bidding Documents without material deviations, exceptions, objections, conditionality, or reservations. A material deviation, exception, objection, conditionality, or reservation is one that:

changes the substance of the bid

limits in any substantial way the scope, quality or performance of the products and related Services;

limits, in any substantial way that is inconsistent with the Bidding Documents, the Procuring Agency's rights or the successful Bidder's obligations under the Contract; and the acceptance of which would unfairly affect the competitive position of other Bidders who have submitted substantially responsive bids.

4.4

If a bid is not substantially responsive, it shall be rejected by the Procuring Agency and may not subsequently be made responsive by the Bidder by correction of the nonconformity. The Procuring Agency's determination of a bid's responsiveness is to be based on the content of the bid itself.

5. Correction of Errors

5.1

In the financial bids the arithmetical errors shall be rectified on the following basis.

a) If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit price shall prevail, and the total price shall be corrected.

b) If the Bidder does not accept the correction of the errors, its bid shall be rejected, and its Bid Security shall be forfeited.

c) If there is a discrepancy between words and figures, the amount in words shall prevail.



- 6. Evaluation of Bids**
- 6.1 The Procuring Agency shall evaluate and compare the bids that have been determined to be substantially responsive in accordance with ITB Clause 27 above.
- 6.2 All bids shall be evaluated in accordance with the Evaluation Criteria and other terms and conditions set forth in the bidding documents
- 7. Qualification of Bidder**
- 7.1 The Procuring Agency, at any stage of the procurement proceedings, having credible reasons for or prima facie evidence of any defect in Bidder's capacities may require the Bidder to provide information concerning their professional, technical, financial, legal or managerial competence. Such clarification shall form part of the records of that procurement proceeding
- 7.2 The Procuring Agency shall disqualify a Bidder if it finds, at any time, that the information submitted by it concerning its qualification as Bidder is false, fake and materially incorrect.
- 7.3 The Local Manufacturer shall provide evidence that they are registered at DRAP
- 7.4 The quoted product manufactured abroad shall be mandatory WHO/UNICEF certified/registered as well as DRAP registered.
- 8. Announcement of Evaluation Report**
- 8.1 The Procuring Agency shall announce the results of the bid evaluation both technical and financial in the form of a report, as required by Rule 45 of the SPPR-2013 giving justification for acceptance or rejection of bids at least seven days prior to the award of procurement Contract. The unsuccessful bidder may file their grievance petition if any in accordance with rule 31 of SPPR (amended 2019).



BID/TENDER TECHNICAL EVALUATION CRITERIA
Contraceptives)

Failure to comply with any compulsory parameter will result in "Non Responsiveness of the bidder for quoted item". Bidders complying with Compulsory Parameters will be evaluated further for marking Criteria.

1.	Company Profile	Mandatory
2.	Valid Establishment License to Manufacture Medical Device/Contraceptives commodities locally issued under the Medical Rule 2017 (as applicable)	Mandatory
3.	Professional Tax Certificate	Mandatory
4.	Sales Tax Certificate	Mandatory
5.	NTN No. Certificate (should be active with FBR)	Mandatory
6.	Valid Drug License (DSL)	Mandatory
7.	Valid Drug Manufacturing License (In case applied for renewal than Bank Name Challan No. & date, and letter from DRAP regarding status of License) (where applicable)	Mandatory
8.	Valid Registration/Enlistment from DRAP of quoted Medical Device as mentioned in schedule D&E of Medical Device Rule 2017- (Class A, B & C Medical Devices are exempted as per S. R.O. 224(1)/2023, Dated 27 TH February, 2023)	Mandatory
9.	Licensed Warehouse as per their approved layout for storing the goods and logistic support. The Manufacturer should have proper valid/licensed Warehouse for storing the goods and logistic support the firm must have dedicated reefer of refrigerator container for delivery of Goods to procuring agency for temperature controlled drugs, the firm shall undertake notarized stamp paper Rs.200/- that they have reefer container (maintaining controlled temperature as per item specification with the temperature date logger) and the shall supply stock in the same container.	Mandatory
10.	Specification quoted in the technical offer will be verified from sample provided with the bid. Product that complies 100% with the required specification and fulfill the requirements as per prevailing rules shall be considered.	Mandatory
11.	Undertaking on Rs.200/- regarding Non	Mandatory



	declaration of any spurious/adulterated batch manufactured by firm by DTL of the same or any competent Lab established under the Drug Act 1976, DARAP Act 2012 and rules, framed there under	
12.	Valid notarize ISO 13485 from manufacture abroad of the quoted Medical Devices Original/true copy attached. Non Provision shall lead to disqualification of firm or item.	Mandatory
12.	Bidder must submit two packs of samples for evaluation by the Technical Standardization Committee	Mandatory
13.	Auto Disable Syringes should be WHO/FDA approved.	Mandatory
14.	Experience & Past Performance of supply Drugs/Medicine, Contraceptives. Medical Devices to institution (Government/Non Government) a) No. of Major Institutions served in the past three years. • 8-10..... 10 • 5-8.....08 • 1-4.....04	10
15.	Turnover each average for continues last three years (Financial soundness) a) 500 million and above.....10 b) 300 to 500 (million).....08 c) 100 to 200 (million)..... 06	10
16.	Experience of supply the quoted product since last three years (2023-24, 2024-25, 2025-26) to the closing date of Tender documents submission.	10
	Supply of the quoted product equivalent or higher than the advertised quantity in Private/Public Sector.	10
	Supply of the quoted product at least 70% or above of total advertised quantity in Private/Public Sector.	07
	Supply of the quoted product at least 50% to below 70% of advertised quantity in Private/Public Sector.	05
	Supply of the quoted product at least 25% to below 50% of advertised quantity in Private/Public Sector.	03
	Certificate from the Bank that Manufacturer is capable of doing business up to (indicate your capabilities)	



17.	Financial worth of the company	
	Annual Audited Balance Sheet for 03 years	
	03 years	
	02 years	10
	01 Year	06
		02
18.	Packing and appearance of items. Sample will be examined as per following parameters of Labeling and packing rules 1986 (Outer Packing, Inner Packing)	
	Excellent	10
	Good	08
	Satisfactory	06
19.	LICENSING & REGISTRATION	
	Valid Manufacturing License/Authorized dealer	05
	Copy of Registration Certificate from Ministry of DRAP	05
20.	TAX Registration	
	(Attached of registration certificate and detail of sales Tax paid in last 8 years (One mark of each year)	08
21.	QUALITY CERTIFICATION	
	GMP Certification	06
22.	Production Capacity	
	Per day production capacity of quoted items against the total advertised quantity	
	Less than 1%	00
	1%	06
	1.1.% - 1.5%	07
	1.6.% 2 %	08

Bidders securing 70% marks out of 80 i.e. 56 will qualify for further evaluation and Bidding process. All bidders qualifying the evaluation criteria shall be eligible to further competition and the ranking shall be determined on the basis of their quoted cost as the lowest rate shall be considered as most advantageous.

Note:

There are total 80 marks. Participant bidders who seeks 70% i.e. 56 marks, qualifies for further consideration of its quoted item in terms of technical specification/requirement.

- The participant bidder has to seek marks from all above areas.



BID/TENDER TECHNICAL EVALUATION CRITERIA (SYRINGE)
(Maximum Marks=100 Minimum qualifying Marks= 80)

Technical Criteria for Distributor (Mandatory)

If any distributor failed to submit any of the following documents, the distributor shall be disqualified and products of manufacture quoted by the disqualified shall be ignored.

1.	Tender Purchase Receipt in original
2.	Bid security (without showing amount)
3.	Sales Tax Certificated
4.	NTN Certificated (Should be active with FBR)
5.	FBR Tax Returns filed not less than 200 million averages yearly for last 3 years
6.	Valid Drug Sale License
7.	Valid Authority letter from manufacturer in reference to the particular tender.
8.	Undertaking on notarized stamp paper Rs.500/- bidder is not blacklisted/debarred by any procuring agency of Pakistan duly attested from Oath Commissioner.
9.	Technical Bid without showing rates.
10.	If distributor quoted the alternated offer of same generic, the distributor shall be disqualified.
11.	The bidder shall have 1 registered Pharmacist from Pharmacy Council Sindh as their bonafide employee.
12.	Bidder must submit two packs of samples for evaluation by the Technical Committee.
13.	Undertaking on notarized stamp paper Rs.500/- that all submit documents in the bid are genuine, certified and in case any variation/ forgery detected at any stage, the distributor will be responsible in person and legal action will be initiated under relevant rule duly attested by Oath Commissioner.
14.	The distributor (bidders) is responsible to fulfill mandatory technical criteria required for manufacturer/ importer (as quoted except Class 01 and 02 which will be considered of bidder/distributor.

Technical Criteria for Manufacturer (Mandatory)

1.	Tender Purchase Receipt in original
2.	Bid security (without showing amount)
3.	Sales Tax Certificate
4.	NTN No. Certificated (Should be active with FBR)
5.	Valid Drug Sale License
6.	Valid establishment license to manufacture medical device locally issued under the Medical Device Rule 2017
7.	Valid Registration /Enlistment from DRAP of quoted Medical Device as mentioned in Schedule-D and related SRO duly signed and stamped by the manufacturing firm.
8.	Licensed Warehouse as per their approved layout for Storing The Goods and Logistic Support. The Manufacturer should have proper valid/licensed Warehouse for storing the goods and logistic support the firm must have dedicated reefer or refrigerator container for delivery of Goods to procuring agency for temperature controlled drugs, the firm shall undertake notarized stamp paper Rs.500/- that they have reefer container (maintain controlled temperature as per item specifications with the temperature dated logger) and the shall supply stock in the same container.
9.	Valid Current Good Manufacturing Practices (cGMP) Certificate (60 days relaxation shall be accorded if certificate is expired on the day of opening the bid).
10.	Undertaking on Rs.500/- regarding Non-declaration of any spurious/adulterated batch manufactured by firm DTL of the same or any competent lab established under the Drug Act 1976, DRAP Act 2012 and rules framed there under.
11.	Bidder must submit two pack of sample for evaluation by the Technical Committee.
12.	Auto-disable Syringe should be WHO/FDA approved
13.	Undertaking on notarized stamp paper Rs.500/- that all submit documents in the bid are genuine, certified and in case any variation/ forgery detected at any stage, the distributor will be responsible in person and legal action will be initiated under relevant rule duly attested by Oath Commissioner.




QUALIFICATION CRITERIA FOR MANUFACTURER

		Max Marks
01.	Last Three years experience of 2 Public Sector of tertiary care multi-disciplinary hospital (04 marks for each)	08
02.	Last Three years experience of 2 private sector of tertiary care multi-disciplinary hospital (04 Marks for each)	08
03.	Turnover each year average for continuous last three years (financial soundness)	10
	a. More than 3 billion	10
	b. More than 2 billion to 3 billion	08
	c. More than 1 billion to 2 billion	06
	d. More than 500 million to 1 billion	04
04.	Financial worth each year average for continuous last three years (Assest-liabilities in FBR returns)	10
	a. More than 2 billion	10
	b. More than 1.5 billion to 2 billion	08
	c. More than 1 billion to 1.5 billion	06
	d. More than 500 million to 1 billion	04
05.	List of technical staff	06
	10 Pharmacists/biomedical Engineer minimum 6 have Master degree	06
	10 Pharmacists/biomedical Engineers	04
06.	Valid ISO-9001:2015 for Quality Management System	02
07.	Valid ISO-13485 for Occupational Health & Safety	02

For Individual products

		Max Marks
01.	Source of active pharmaceutical ingredient (AP) with certificate of analysis	10
	a. Source license original or accredited by US FDA WHO / EEU RRA countries (Firm should provide import documents i.e. airways bills/bill of lading/ GD from 01-01-2022 till 31-01-2025)	10
	b. In case of product contains more than one molecule than source of APIs from RRA Countries & from others.	08
	c. Other Sources of API	06
02.	Annual Product Quality Review (APQR)	10
	APQR for quoted drugs of 25 batches	10
	APQR for quoted drugs of 15 batches	07
	APQR for quoted drugs of 10 batches	04
03.	Valid ISO-10993 "OR" ISO-10555 certificate for biocompatibility of quoted medical device.	02
04.	Report of drug testing laboratory (DTLs) / central drug laboratory (CDL)	07
	a. If sample of quoted drug declare sub-standard by any DTL/CDL established under drug act 1976 / MDR Rules 2017 are less than 1% since January, 2023 to December, 2024	07



	b) . If sample of quoted drug declare sub-standard by any DTL/CDLINIH established under drug act 1976 // MDR Rules 2017 are less than 1-2 % since January, 2024 to June, 2026	05	
	c) If sample of quoted drug declare sub-standard by any DTLCDUNIH established under drug act 1976 / MDR Rules 2017 are less than 2-3 % since January, 2024 to June, 2026.	03	
05	ejected shall decide after expert opinion. Physical examination of the quoted items by the HPC Experts. Accepted or		10
06.	Test / analysis report from any competent lab report established under the Drug Act 1976, DRAP Act 2012, Medical Devices Rule 2017 and rules frame there under for schedule D&E specified Medical Devices Rules 2017 I SRO 224(1)/2023 dated: 27.02.2023, For other Medical Devices Test /Analysis report from DRAP approved or any ISO 9001 / ISO 17025 certified lab.		05
07.	Reports of WHO/FDA accredited International Labs performed on the product not older than 4 years		10



TECHNICAL CRITERIA FOR IMPORTER (MANDATORY)

1.	Tender Purchase Receipt in original.
2.	Bid Security (without showing rates).
3.	Sale Tax Certificate.
4.	NTN certificate (should be Active with FBR)
5.	Valid Drug Sale license (DSL)
6.	Valid establishment license as importer
7.	Valid Registration / Enlistment from DRAP of quoted Medical Device as mentioned in schedule -D&E and related SRO duly signed and stamped by the manufacturing firm.
8.	The Importer shall have Licensed Warehouse for Storing the Goods and Logistics Support. The firm must have dedicated reefer or refrigerator container for delivery of Goods to procuring agency for temperature controlled drugs, the firm shall undertake notarized stamp paper Rs.500/- that they have reefer container (maintaining controlled temperature as per item specifications with the temperature data logger) and they shall supply stock in the same container.
9.	Undertaking on notarized stamp paper Rs.500/- regarding "Non-Deceleration of any Spurious/Adulterated Batch manufactured by firm by DTL of the Sindh / any competent Lab" established under the Drug Act 1976, DRAP Act 2012 and rules framed there under.
10.	Valid letter of authorization of the manufacture of abroad (duly attested from embassy of Pakistan in country of origin or embassy of country of origin in Pakistan not older than one year) Original/ true copy attached. Non provision shall lead to disqualification of firm or item.
11.	Bidder shall submit the notarized ISO 13485.
12.	The bidder shall submit the notarize declaration of confirmative from manufacturer abroad or notarized production of fully quality assurance certificate (CE-marking Certificate) from Conformity Assessment Body (CAB). Or notarize free sales certificate from any of the reference country that is USA, Japan, Australia, Canada, Austria, Belgium, Denmark, France, Germany Ireland, Italy, Netherland, Norway, Spain, Sweden, UK, in case of schedule "D" and "E" Medical Devices as specified in Medical Device Rule 2017 or notarize free sale from country of origin along with WHO prequalification status in case of schedule "D" and "E" Medical Devices as specified in Medical Device Rule 2017.
13.	Valid notarize ISO 13485 from manufacture abroad of the quoted Medical Devices Original / true copy attached. Non provision shall lead to disqualification of firm or item
14.	Availability of minimum 10% inventory of the total import of the quoted item/s during last one year (certificate to the effect duly signed by the senior executive of the firm & can be verified evaluated by the HPC experts). Non availability of the 10% stock at the time of inspection shall lead to disqualification of the quoted item/(s).
15.	Bidder must submit two packs of samples for evaluation by the Technical Committee.
16.	Valid free sales certificate indicating that the "quoted brand" is freely available in the country of manufacturer. This certificate must be issued by relevant authority of country of origin duly legalized / notarized by Embassy of Pakistan / Country of manufacturer.
17.	Auto-disable Syringe should be WHO /FDA approved.
18.	Undertaking on notarized stamp paper Rs.500/- that all submitted documents in the bid are genuine, certified and in case any variation / forgery detected at any stage, the manufacturer will be responsible in person and legal action will be initiated under relevant rule duly attested by Oath Commissioner.



QUALIFICATION CRITERIA FOR IMPORTER

			Max Marks
01.	Last Three years experience of 2 public sector of tertiary care multi- disciplinary hospital (04 marks for each)		08
02.	Last Three years experience of 2 Private sector of tertiary care multi - disciplinary hospital (04 marks for each)		08
03.	Turnover each year average for continuous last three years (financial soundness)		10
	a. More than 3 billion	10	
	b. More than 2 billion to 3 billion	08	
	c. More than 1 billion to 2 billion	06	
	d. More than 500 million to 1 billion	04	
04.	Financial worth each year average for continuous last three years (Assets - liabilities in FBR returns).		10
	a) More than 2 billion	10	
	b) More than 1.5 billion to 2 billion	08	
	c) More than 1 billion to 1.5 billion	06	
	d) More than 500 million to 1 billion	04	
05.	Valid ISO-9001:2015 certified (for principal manufacturer		03
06.	Valid ISO-13485 (for principal manufacturer)		03

For Individual Product

			Max Marks
01	Source of active pharmaceutical ingredient (AP) with certificate of analysis		10
	a. Source license original or accredited by US FDA/WHO / EEU/RRA countries (Firm should provide import documents i.e. airways bills/bill of lading/ GD from 01-01-2022 till 31-01-2025)	10	
	b) In case of product contains more than one molecule than source of APIs from RRA Countries & from others.	08	
	c) Other source of API	06	
02.	Annual Product Quality Review (APQR)		10
	APQR for quoted drugs of 25 batches	10	
	APQR for quoted drugs of 15 batches	07	
	APQR for quoted drugs of 10 batches	04	
03	Report of drug testing laboratory (DTLs) / central drug laboratory (CDL)		07
	a) If sample of quoted drug declare sub-standard by any DTL/CDL established under drug act 1976 / MDR Rules 2017 are less than 1% since January, 2023 to December, 2024	07	
	b) If sample of quoted drug declare sub-standard by any DTL/CDL established under drug act 1976 / MDR Rules 2017 are less than 1-2 % since January, 2023 to December, 2024.	05	



	c) If sample of quoted drug declare sub-standard by any DTLCDUNI established under drug act 1976 / MDR Rules 2017 are less than 2-3 % since January, 2024 to June, 2026	03	
4.	Importer and manufacturer relationship (Importer experience)		02
	a) Above five years	02	
	b) 2 to 5 years	01	
5.	Availability of quoted Medical Device since last two years EE/RRA counties (LIKE USA/EUROPE/JAPAN or other RRA countries, one mark of each country.		02
06.	Physical examination of the quoted items by the HPC Experts. Accepted or rejected shall decide after expert opinion.		10
07.	Test/analysis report from any competent lab report established under the Drug Act 1976, DRAP Act 2012, Medical Devices Rule 2017 and rules frame there under for schedule D & D specified Medical Devices Rules 2017 /SRO 224(1)/2023 DATED 27.2.2023. For other Medical Devices Test/Analysis report from DRAP approved or any ISO 9001/ISO17025 certified lab.		05
08.	Valid ISO-10993 Certificates for bio compatibility of quoted Medical Devices		02
09.	Reports of WHO/FDA/EEU accredited International Labs performed on the product not older than 4 years		10



SECTION III

General Conditions of Contract (GCC)



General Conditions of Contract (GCC)

- 1. Definitions**
- 1.1 In this Contract, the following terms shall be interpreted as indicated:
- (a) "The Contract" means the agreement entered into between the Procuring Agency and the Supplier, as recorded in the Agreement signed by the Parties, including all attachments and appendices thereto and all documents incorporated by reference therein.
 - (b) "The Contract Price" means the price payable to the Supplier under the Contract for the full and proper performance of its Contractual obligations.
 - (c) "The Contraceptives" means all those supplies which the Supplier is required to supply to the Procuring Agency under the Contract.
 - (d) "The Services" means those services ancillary to the supply of above goods, such as printing of special instructions on the label and packing, design and logo of the government of Sindh, transportation of goods upto the desired destinations and other such obligations of the Supplier covered under the Contract.
 - (e) "GCC" means General Conditions of Contract contained in this section.
 - (f) "SCC" means Special Conditions of the Contract.
 - (g) "The Procuring Agency" means the Government of Sindh, (insert department name), Karachi.
 - (h) "The Supplier" means the individual or firm supplying the contraceptives under this Contract.
 - (i) "Day" means calendar day.
 - (j) "Effective Date" means the date on which this Contract becomes effective.
 - (k) "End User" means the organization(s) where the contraceptives will be used, as named in the SCC.
 - (l) "The Site," where applicable, means the place or places named in the SCC
- 2. Application**
- 2.1 These General Conditions shall apply to the extent that they are not superseded by provisions of other parts of the Contract.
- 3. Source of Import**
- 3.1 All contraceptives and related services to be supplied under the contract that are required to be imported in Pakistan shall have their origin in eligible source countries as prescribed by the commercial policies of the Government of Pakistan and all expenditures made under the contract shall be limited to such contraceptives and services.
- 3.2 For purposes of this clause, "origin" means the place where the contraceptives are produced, or the place from which the related services are supplied. Contraceptives are produced



- when, through manufacturing or processing.
- 4. Standards**
- 4.1 The contraceptives supplied under this Contract shall conform to the standards mentioned in the Technical Specifications.
- 4.2 In consideration of the payments to be made by the Procuring Agency to the Supplier as hereinafter mentioned, the Supplier shall be required to provide the contraceptives and Services and to remedy defects therein in conformity in all respects with the provisions of this Contract.
- 4.3 If the Supplier provide substandard item and fail to provide the fresh supply, the procurement shall be made on the risk and cost of the supplier by the procuring agency.
- 4.4 In case of supply of substandard product the cost associated with disposal/destruction or handling cost shall be borne by the Supplier.
- 5. Use of Contract Documents and Information**
- 5.1 The Supplier shall not, without the Procuring Agency's prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the Procuring Agency in connection therewith, to any person other than a person authorized for this. Disclosure to any such employed person shall be made in confidence and shall extend only as far as may be necessary for purposes of such performance.
- 5.2 The Supplier shall not, without the Procuring Agency's prior written consent, make use of any document or information enumerated in GCC except for purposes of performing the Contract.
- 5.3 Any document, other than the Contract itself, enumerated in GCC shall remain the property of the Procuring Agency and shall be returned (all copies) to the Procuring Agency on completion of the Supplier's performance under the Contract if so required by the Procuring Agency.
- 5.4 The Supplier shall permit the Procuring Agency to inspect the Supplier's accounts and records relating to the performance of the Supplier.
- 6. Patent Rights**
- 6.1 The Supplier shall indemnify the Procuring Agency against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the contraceptives or any part thereof in the country.
- 7. Submission of Samples**
- 7.1 Before commencing supplies, the Supplier shall provide samples free of cost, if and as specified in the Schedule of Requirements of the product to the designated office or staff, as the case may be.



8. Ensuring storage arrangements

- 8.1 To ensure storage arrangements for the intended supplies, the Supplier shall inform the Procuring Agency at least 7 working days in advance. However, in case no space is available at the Procuring Agency's premises at the time of supply, the Procuring Agency shall, at least 02 working days prior to such situation, shall inform the Supplier, in writing, of the possible time frame of availability of space by which the supplies can be made. In case the Supplier abides by the given time frame it shall not be penalized for delay.

9. Inspections and Tests

- 9.1 The Procuring Agency or its representative shall have the right to inspect and / or to test the goods in accordance with the procedure given in the SCC to confirm their conformity to the Contract specifications at no extra cost to the Procuring Agency.
- 9.2 All costs associated with testing shall be borne by the Supplier.
- 9.3 The Procuring Agency's right to inspect, test and, where necessary, reject the goods after the goods either at Supplier's premises or upon arrival at Procuring Agency's destinations shall in no way be limited or waived by reason of the goods having previously been inspected, tested, and passed by the Procuring Agency or its representative prior to the goods delivery from the point of Supply or manufacturing.
94. The Participants bidder in case participates with commodities manufactured outside Pakistan have to submit valid authorization certificate from the original manufacturer and also certificate that manufacturer is WHO/UNFPA qualified. Further the commodities supplied by such supplier would be tested in each batch from WHO prequalified Lab at the cost and expenses of supplier.
- 9.5 The local manufacturer which is not WHO prequalified is required to get each batch of the contraceptives tested from Central Drugs Testing Laboratory Karachi as per DRAP standard sampling procedure. However, in case of doubt for quality assurance of locally manufactured contraceptives, the procuring agency reserves the right that it may get any of the supplied batch, lots tested (up to maximum number of 05 batches from WHO accreted lab from the whole consignment on the risk and cost of supplier
- 9.6 Nothing in GCC Clause 9 shall in any way release the Supplier from any warranty or other obligations under this Contract.



- 10. Packing**
- 10.1 The Supplier shall provide such packing of the contraceptives as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt and precipitation during transit and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the contraceptives' final destination and the absence of heavy handling facilities at all points in transit.
- 10.2 The packing, marking and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the Contract, including additional requirements, if any, specified in the SCC or Technical Specifications, and in any subsequent instructions ordered by the Procuring Agency
- 11. Delivery and Documents**
- 11.1 The Supplier in accordance with the terms and manner specified in the Schedule of Requirements shall make delivery of the goods.
- 11.2 The Supplier shall furnish all necessary documentation necessary for completion of the delivery, at the time of delivery and in the manner prescribed.
- 11.3 The goods supplied under the Contract shall be Delivered at Place (DAP) under which risk is transferred to the buyer and their insurance after the Goods having been delivered
- 12. Insurance**
- 12.1 The supplier shall be responsible for supply of goods and their insurance at Central Warehouse, Karachi
- 13. Transportation**
- 13.1 The Supplier shall arrange such transportation of the goods as is required to prevent their damage or deterioration during transit to their final destination and in accordance with the terms and manner prescribed in the Schedule of Requirement
- 13.2 All costs associated with the transportation of the goods subject to this contract shall be borne by the Supplier.
- 14. Incidental Services**
- 14.1 The Supplier shall be required to provide the incidental services as specified in the SCC and the cost of which is included in the total bid price.
- 15. Warranty**
- 15.1 All products must be of fresh manufacture and must bear the dates of manufacture and expiry.
The Supplier further warrants that all products supplied under the Contract that have shelf lives will have remaining a minimum of 60% to 75% of the specified shelf life upon delivery at port/airport of entry for products with a shelf life of more than two years and three-fourths (3/4) for products with a shelf life of two years or less, unless otherwise specified in the SCC or technical specifications; have "overages" within the ranges set forth in the Technical



Specifications, where applicable; are not subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; and in every other respect will fully comply in all respects with the Technical Specifications and with the conditions laid down in the Contract.

15.2 The Procuring Agency shall have the right to make claims under the above warranty for three months after the products have been delivered to the final destination indicated in the Contract. Upon receipt of a written notice from the Procuring Agency, the Supplier shall, promptly, replace the defective products without cost to the Procuring Agency. The Supplier will be required to remove, at his own risk and cost, the defective products once the replacement contraceptives have been delivered

15.3 In case of supply of substandard quality, declared by the Testing Laboratory, the supplier shall be bound to replace the substandard goods. The procuring agency shall reserve the right to proceed against the supplier on account of supply of substandard goods, as per law.

15.4 In the event of a dispute by the Supplier, a counter analysis will be carried out on the manufacturer's retained samples by an independent neutral laboratory agreed by both the Procuring Agency and the Supplier. If the counter analysis confirms the defect, the cost of such analysis will be borne by the Supplier as well as the replacement and disposal of the defective products. The procuring agency shall reserve the right to proceed against the supplier on account of supply of substandard goods, as per law.

16. Payment

16.1 The Respective Procuring Agency shall make payments to supplier in accordance with the conditions set forth in the Payment Schedule agreed and annexed to the contract.

16.2 The payment will be made to the supplier in Pak rupees through a cheque passed in favour of supplier by the office of Accountant General, Sindh.

16.3 All payments shall be made in the currency or currencies specified in the SCC pursuant to GCC 15.4

17. Prices

17.1 Prices charged by the Supplier for goods delivered under the Contract shall not vary from the prices quoted by the Supplier in its bid and shall remain the same till the expiry of the contract.

18. Contract Amendments

18.1 No variation in or modification of the terms of the Contract shall be made unless supported by force majeure on either of the party.

19. Assignment

19.1 The Supplier shall not assign, in whole or in part, its obligations to perform under this Contract,

20. Subcontracts

20.1 The Supplier shall not be allowed to sublet and award subcontracts under this Contract.

21. Delays in the Supplier's Performance

21.1 Delivery of the goods shall be made by the Supplier in accordance with the timeline prescribed by the Procuring Agency in the Schedule of Requirements.

21.2 If at any time during performance of the Contract, the Supplier encounters conditions impeding timely delivery of the goods, the Supplier shall promptly notify the Procuring Agency in writing of the fact of the delay, its likely duration and its cause(s). As soon as practicable after receipt of the Supplier's notice, the Procuring Agency shall evaluate the situation and may at its discretion extend the Supplier's time for performance, with or without liquidated damages, in which case the extension shall be ratified by the Parties by an amendment to the



22. Termination for Default

- Contract.
- 21.3 Except as provided under GCC Clause 24, a delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to the imposition of liquidated damages as prescribed in the SCC, unless the parties to this contract mutually agree for extension of time.
- 22.1 The Procuring Agency, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, shall terminate the Contract: in case:
- if the Supplier fails to deliver any or all installments of the goods within the period(s) specified in the Contract and subsequent purchase order, or within any extension thereof granted by the Procuring Agency pursuant to GCC Clause 21; or
 - if the contraceptives do not meet the Technical Specifications stated in the Contract; or
 - if the Supplier fails to provide any registration or other certificates in respect of the contraceptives within the time specified in the Special Conditions.
 - if the Supplier fails to perform any other obligation(s) under the Contract.
 - if the Supplier, in the judgment of the Procuring Agency has engaged in corrupt, fraudulent or collusive practices in competing for or in executing the Contract.
- For the purpose of this clause Corrupt, fraudulent and collusive practices means:
- the offering, giving, receiving, or soliciting of anything of value to influence the action of a public official or the supplier or contractor in the procurement process or in contract execution to the detriment of the Procuring agencies; or misrepresentation of facts in order to influence a procurement process or the execution of a contract, collusive practices among bidders (prior to or after bid submission) designed to establish bid prices at artificial, non-competitive levels and to deprive the Procuring agencies of the benefits of free and open competition and any request for, or solicitation of anything of value by any public official in the course of the exercise of his duty"*

23. Force Majeure

- 23.1 Notwithstanding the provisions of GCC Clauses 21 and 22, the Supplier shall not be liable for forfeiture of its Performance Guaranty, or termination/ blacklisting for default if and to the extent that it's delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure.
- 23.2 For the purposes of this clause Force Majeure means an act of God or an event beyond the control of the Supplier and not involving the Supplier's fault or negligence directly or indirectly purporting to miss planning, mismanagement and/or lack of foresight to handle the situation. Such events may include but are not restricted to acts of the Procuring Agency in its sovereign capacity, wars or revolutions, fires, floods, earthquakes, strikes, epidemics, quarantine restrictions and freight embargoes.



- 23.3 If a Force Majeure situation arises, the Supplier shall promptly notify the Procuring Agency in writing with sufficient and valid evidence of such condition and the cause thereof. The Procuring Agency shall examine the merits of the case and all reasonable alternative means for completion of purchase order under the Contract and inform the Supplier of its findings promptly.
- 23.4 Unless Procuring Agency informs the Supplier in writing of its agreement on the application of force majeure, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably possible.
- 24. Termination for Insolvency** 24.1 In case the Supplier becomes bankrupt or insolvent, the Procuring Agency may at any time terminate the Contract by giving written notice of reasonable time which will not be less than 15 days to the Supplier. In this event, termination shall be without compensation to the Supplier, provided that such termination shall not prejudice or affect any right of action or remedy which has accrued or shall accrue thereafter to the Parties.
- 25. Termination for Convenience** 25.1 The Procuring Agency, by written notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time on administrative grounds. The notice of termination shall specifically mention, the extent to which performance of the Supplier under the Contract is terminated and the date upon which such termination becomes effective.
- 25.2 The contraceptives that are complete and ready for shipment within thirty (30) days after the Supplier's receipt of notice of termination shall be accepted by the Procuring Agency at the Contract terms and prices. For the remaining goods, the Procuring Agency may elect:
- (a) to have any portion completed and delivered at the Contract terms and prices; and/or
- (b) to cancel the remainder and pay to the Supplier an agreed amount for partially completed goods and Services and for materials and parts previously procured by the Supplier.
- 26. Arbitration and Resolution of Disputes** 26.1 The Procuring Agency and the Supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the Contract.
- 26.2 If, after thirty (30) days from the commencement of such informal negotiations, the Procuring Agency and the Supplier have been unable to resolve amicably a Contract dispute, either party may require that the dispute be referred to the Arbitrator for resolution through arbitration.
- 26.3 In case of any dispute concerning the interpretation and/or application of this Contract shall be settled through arbitration under the Arbitration Act of 1940 (As amended from time to time). Administrative secretary of the PA shall act as an arbitrator.

[Handwritten signature] 24/11/20



- 27. Limitation of Liability** 27.1 Except in cases of criminal negligence or willful misconduct, and in the case of infringement pursuant to Clause 7,
(a) the Supplier shall not be liable to the Procuring Agency, whether in contract, tort or otherwise, for any indirect or consequential loss or damage, loss of use, loss of production or loss of profits or interest costs, provided that this exclusion shall not apply to any obligation of the Supplier to pay liquidated damages to the Procuring Agency; and
(b) the aggregate liability of the Supplier to the Procuring Agency, whether under the Contract, in tort or otherwise, shall not exceed the total Contract Price, provided that this limitation shall not apply to the cost of replacing defective goods.
- 28. Governing Language** 28.1 The Contract shall be written in English language. Subject to GCC Clause 31, the version of the Contract written in the specified language shall govern its interpretation. All correspondence and other documents pertaining to the Contract, which are exchanged by the Parties, shall be written in English.
- 29. Applicable Law** 29.1 This Contract shall be governed by the Laws of Pakistan and the courts of Pakistan shall have exclusive jurisdiction.
- 30. Notices** 30.1 Any Notice given by one party to the other pursuant to the provision of the Contract shall be sent to the other party in writing and on the others address specified in SCC.
30.2 A notice shall be effective when delivered or on the notice's effective date, whichever is later.
- 31. Taxation** 31.1 All taxation, whether International, Federal, Provincial or Local, shall be borne by the Supplier.

SECTION IV
Special Conditions of
Contract
(SCC)



Special Conditions of Contract (SCC)

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

1. The Contract

- 1.1 The following documents shall be deemed to form and be read and construed as integral part of the Contract ,:-
the Schedule of Requirements.
the Technical Specifications.
the Price Schedule submitted by the Bidder.
the Procuring Agency's Notification of Award.
the Purchase Order
the General Conditions of Contract
Special Conditions of Contract
- 1.2 Population Welfare Department, Sindh, will sign individual with a selected bidders separately against the indicated quantities.
- 1.3 The Contract words and expression shall have the same meaning as are respectively assigned to them in the General Conditions of Contract.

2. Supplier's declaration

- 1.4 The contract is to be made on E-stamp paper.
- 2.1 *The supplier shall provide integrity pact signed by the supplier and the PA.*
- 2.2 *[The Supplier]* certifies that it has made and shall make full disclosure of all agreements and arrangements with all persons in respect of or related to the transaction with Government of Sindh and has not taken any action or shall not take any action to circumvent the above declaration, representation or warranty
- 2.3 *[The Supplier]* accepts full responsibility and strict liability for making any false declaration, not making full disclosure, misrepresenting facts or taking any action likely to defeat the purpose of this declaration, representation and warranty. It agrees that any Contract, right, interest, privilege or other obligation or benefit obtained or procured as aforesaid shall, without prejudice to any other right and remedies available to Procuring Agency under any law, Contract or other instrument, be voidable at the option of Procuring Agency.
- 2.4 Notwithstanding any rights and remedies exercised by Procuring Agency in this regard, *[The Supplier]* agrees to indemnify Procuring Agency for any loss or damage incurred by it on account of its corrupt business practices and further pay compensation to Procuring Agency in an amount equivalent to ten times the sum of any commission, gratification, bribe, finder's fee or kickback given by *[The Supplier]* as aforesaid for the purpose of obtaining or



inducing the procurement of any Contract, right, interest, privilege or other obligation or benefit in whatsoever form from Procuring Agency

2.5 In case of any dispute concerning the interpretation and/or application of this Contract shall be settled through arbitration. The Additional Chief Secretary or his nominee shall act as sole arbitrator. The decisions taken and/or award made by the sole arbitrator shall be final and binding on the Parties

3. Price

3.1 The Supplier shall provide to the Procuring Agency the items on the agreed cost more specifically described in the Price Schedule Submitted by the Bidder Bid form 5(A)

3.2 Each Items supplied shall strictly conform to the Schedule of Requirements (Section V) and to the Technical Specification (Section VI) prescribed by the Procuring Agency against each item

3.3 The Unit Cost agreed in the Price Schedule Bid form 5(A) , is inclusive of all taxation and costs associated with transportation and other agreed incidental costs

4. Payments

4.1 The Procuring Agency shall make the payment to the Supplier in consideration of the provision of the Goods and Services, as specified in the Schedule of Requirements and Technical Specification in accordance with the Price Schedule submitted by the Supplier, the amount against the delivered items or such other sum as may become payable under the provisions of this Contract at the time and in the manner prescribed by this Contract

4.2 i) In case of locally manufactured items 100% payment shall be made upon receipt of successful delivery after inspection.

All payments to the Supplier shall be made through Crossed Cheque issued in the name of *[supplier's name]*

4.3 All payments to the Supplier shall be made in accordance with the agreed Payment Schedule upon satisfactory completion of delivery and fulfillment of documentary and Codal formalities highlighted in the Payment Schedule.

5. Performance Guarantee

5.1 The Supplier, 07 days prior to signing of this contract, shall provide to the Procuring Agency a Performance Guarantee equivalent to 3% of the Contract amount on the prescribed format and in prescribed manner. This Performance Guarantee shall be released to the Supplier upon successful completion of the Contract and within 120 days after the final payment

5.2 Supplier's Bid Security already submitted with the Bid shall only be released upon satisfactory submission of a Performance Guarantee in accordance with sub-clause (i) above

5.3 Failure to submit a Performance Guarantee shall result into forfeiture of Bid Security and Cancellation of Contract and initiation of blacklisting procedure.



- 6. Inspections & Tests**
- 6.1 Local manufacturers will provide acceptable quality test from Central Drugs Authority.
- 6.2 The non local manufacturer shall supply WHO/UNFPA approve Lab. Certificate.
- 7. Penalties/ Liquidated Damages**
- 7.1 In case the Supplier fails to make deliveries as per purchase order and within the time frame as stipulated in the Schedule of Requirement, proceedings shall be initiated against the defaulter which may result into forfeiture of the performance guarantee and blacklisting of the supplier.
- 7.2 In case of delay in delivery of goods beyond the periods specified in the Schedule of Requirements and subsequent purchase order, a penalty @ 0.067% per day of the cost of late delivered supply shall be imposed upon the Supplier.
- 8. Notices**
- 8.1 Secretary
Population Welfare Department, Government of Sindh,
NICL Building 11th Floor, Abbasi Shaheed Road Behind
FTC Building Gora Qaburstan, Karachi, Pakistan
- 9. Packing**
- 9.1 Any necessary additional requirements with respect to packing and marking or state that additional requirements are indicated in the Technical Specifications.
All packing (which includes unit, master carton, and shipping carton) must have the following printed wording in appropriate size and at place.
"Not for Sale –Govt. of Sindh Property".
(Printed in green color along with Sindh government logo as per sample approved by Procuring Agency).
GS1 health commodities standard data matrix bar code must be included in primary as well as secondary packing.
Make table for all packing aligning with specifications
- 10. Delivery and Documents**
- 10.1 Three originals and two copies of the Supplier's invoice, showing Procuring Agency as Department of Health/Population Welfare Department, Government of Sindh, Pakistan; the Contract number, contraceptives description, quantity, unit price and total amount. Invoices must be signed in original, stamped, or sealed with the company stamp/seal;
- 10.3 In the event that the documents presented by the Supplier are not in accordance with the Contract, then payment will be made against issue of the Acceptance Certificate, to be issued in accordance with SCC 6 above



Section V Schedule of Requirements



SCHEDULE OF REQUIREMENTS

S #	Products	Quantity	Total Delivery period	Shelf life minimum	Place of delivery
1.	COC (cycles)	1,600,000	120 Days	75%	CWH, Karachi
2	POP (cycles)	170,000	-do-	75%	CWH, Karachi
3	ECP (Pack of 2 tabs)	100,000	-do-	75%	CWH, Karachi
4	Injectable DMPA (3 month)	3,100,000	-do-	75%	CWH, Karachi
5.	Auto Disable Syringes 23Gx1" 0.2ml Detachable must be WHO/FDA approved.	3,100,000	-do-	75%	CWH, Karachi
6.	Condom	10,000,000	-do-	75%	CWH, Karachi
7.	IUCD T380	125,000	-do-	75%	CWH, Karachi
8.	Two-Rod Levonorgestrel Contraceptive Implant	10,000	-do-	75%	CWH, Karachi

Mode of Penalty

Late delivery charges/penalty @ 0.067 % per day after 120 days after each installment delivery period.



Section VI

Technical Specifications



Technical Specification - Oral Contraceptive

(Combined oral contraceptive pill)

Information for submission of samples

The sample oral contraceptives submitted by the Bidder in response to this Invitation for Bids must be exactly the same¹ as would be supplied if a contract were awarded to the Bidder. The packets containing the product need not have a printed logo as stipulated under Clause 1.12 of this specification; however, other information as stipulated under the aforementioned clause must be furnished. For sample submission only, this information (logo optional) may be printed on a sticker and affixed to the packets containing the product. The Procuring Agency should replace italics with the actual requirements of the contraceptive to be procured.

1. Requirements

Oral contraceptive tablets in accordance with the following specifications:

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

1.1 Product and Brand Names

Product name:

Brand names:

Registration Number:

1.2 Raw Materials

Oral contraceptives offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor.²

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 offer or(s) may be required to submit a "statement of licensing status of pharmaceutical product(s)" as provided under the World Health Organization (WHO)

¹ Records demonstrating raw materials with the required physical and chemical characteristics.



Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.³

1.5 Compliance with Current Good Manufacturing Practices

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

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

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

1.7 Shape and Dimensions

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

1.8 Colors

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

1.9 Tablet Markings

Each tablet shall bear the identifying imprint of its manufacturer.

1.10 Packaging

1.10.1 Monthly Cycle Presentation

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

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

1.10.2 Mounting

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

1.11 Identification Markings on Individual Blister Packs

Each individual blister pack shall have the following information:

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



- Arrow indicating sequence of tablets
- Contents and quantity, including tablet formulation (amounts of active ingredients per tablet)
- Drug registration number (if applicable)
- Family planning logo (if applicable)
- Drug Manufacturing License Number
- Product use and storage instructions (accompanying the blister pack).

1.11.1 Printing and Layout

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

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

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

1.11.2 Colour

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

1.12 Workmanship

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

1.13 Lots per Order

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

1.14 Shelf Life

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

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

1.16 Test Data

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

2. Quality Assurance Provisions

2.1 Compliance

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

2.2 Documentation

2.2.1 The Supplier shall provide evidence⁴ of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided.

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

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

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

2.3 Inspection by the Procuring Agency

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

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

(Dossier) of the Contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on pharmaceutical products according to the Pharmacopoeia specification.

2.4 Sampling Procedures

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

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

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

2.5 Sample Retention

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

the printed expiration date.

3. Packing

3.1 Inner Boxes

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

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 mm⁷. 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 Agency⁸:

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

3.3.2 Exterior Supply Cartons

The following information shall be stenciled or labeled on the exterior supply cartons on two



opposing sides in bold letters at leastmm high with waterproof ink in a clearly legible manner that is acceptable to the Procuring Agency.⁹

Regulatory information (on two opposing sides of carton)

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

3.4 Printed Materials—Product Information Sheets

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

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

Inspection Sampling and Testing—Oral Contraceptives

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

1.1 Packaging, Packing and Markings

- a. One hundred percent (100%) of the exterior supply cartons will be examined for:
 - General physical characteristics and condition.
 - Markings per Technical Specification
- b. A representative sample of the inner boxes and individual packages will be drawn from the exterior supply cartons at General Inspection Level II, or, at the discretion of the Procuring Agency, General Inspection Level III, and Single Sampling Plan for Normal Inspection.
- c. The sample will be examined for:
 - General physical characteristics per Technical Specification, Section
 - Markings per Technical Specification, Section
- d. Inspection criteria and classification of defects shall follow the inspection guidelines outlined in Section 1.4 below. For critical defects, the acceptable quality limit (AQL) shall be 0%; for major defects, the AQL shall be 1%; for minor defects, the AQL shall be 4%.

1.2 Tablet

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



Pharmacopoeial tests:

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

Non-pharmacopoeial tests:

- Package seal integrity test.¹⁰

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

1.3 Resolution of Defects

- 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.



Technical Specification - Oral Contraceptive

(Progestogen only oral contraceptive pill)

Information for submission of samples

The sample oral contraceptives submitted by the Bidder in response to this Invitation for Bids must be exactly the same¹¹ as would be supplied if a contract were awarded to the Bidder. The packets containing the product need not have a printed logo as stipulated under Clause 1.12 of this specification; however, other information as stipulated under the aforementioned clause must be furnished. For sample submission only, this information (logo optional) may be printed on a sticker and affixed to the packets containing the product. The Procuring Agency should replace italics with the actual requirements of the contraceptive to be procured.

1. Requirements

Oral contraceptive tablets in accordance with the following specifications:

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

1.1 Product and Brand Names

Product name:

Brand names:

Registration Number:

1.2 Raw Materials

Oral contraceptives offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor.¹²

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 offer or(s) may be required to submit a "statement of licensing status of pharmaceutical product(s)" as provided under the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.¹³

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

- *Records demonstrating raw materials with the required physical and chemical characteristics.*



certification can be found in the WHO Certification Scheme "Certificate of Pharmaceutical Product." Supplier also must be able to provide copies of its annual cGMP audit reports conducted by the local Drug Regulatory Authority.

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

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

1.7 Shape and Dimensions

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

1.8 Colors

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

1.9 Tablet Markings

Each tablet shall bear the identifying imprint of its manufacturer.

1.10 Packaging

1.10.1 Monthly Cycle Presentation

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

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

1.10.2 Mounting

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

1.11 Identification Markings on Individual Blister Packs

Each individual blister pack shall have the following information:

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



1.11.1 Printing and Layout

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

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

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

1.11.2 Colour

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

1.12 Workmanship

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

1.13 Lots per Order

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

1.14 Shelf Life

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

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

1.16 Test Data

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

2. Quality Assurance Provisions

2.1 Compliance

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

2.2 Documentation

- 2.2.1 The Supplier shall provide evidence¹⁴ of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided.
- 2.2.2 The Supplier shall provide a copy of the manufacturing record and procedures to the Procuring Agency for each lot intended for supply.
- 2.2.3 The Supplier shall provide a copy of the Certificate of Analysis to the Procuring Agency for each lot intended for supply.
- 2.2.4 The Supplier shall provide to the Procuring Agency a copy of the approval of each component for each lot intended for supply.

2.3 Inspection by the Procuring Agency

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

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

2.4 Sampling Procedures

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

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

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

2.5 Sample Retention

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



3. Packing

3.1 Inner Boxes

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

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

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

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

3.2 Exterior Shipping Cartons

3.2.1 *Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fiberboard cartons made from weather-resistant fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm*¹⁷. 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 Agency¹⁸:

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

3.3.2 Exterior Supply Cartons

The following information shall be stenciled or labeled on the exterior supply cartons on two opposing sides in bold letters at leastmm high with waterproof ink in a clearly

legible manner that is acceptable to the Procuring Agency.¹⁹

Regulatory information (on two opposing sides of carton)

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

3.4 Printed Materials—Product Information Sheets

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

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

Inspection Sampling and Testing—Oral Contraceptives

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

1.1 Packaging, Packing and Markings

- e. One hundred percent (100%) of the exterior supply cartons will be examined for:
 - General physical characteristics and condition.
 - Markings per Technical Specification
- f. A representative sample of the inner boxes and individual packages will be drawn from the exterior supply cartons at General Inspection Level II, or, at the discretion of the Procuring Agency, General Inspection Level III, and Single Sampling Plan for Normal Inspection.
- g. The sample will be examined for:
 - General physical characteristics per Technical Specification, Section
 - Markings per Technical Specification, Section
- h. Inspection criteria and classification of defects shall follow the inspection guidelines outlined in Section 1.4 below. For critical defects, the acceptable quality limit (AQL) shall be 0%; for major defects, the AQL shall be 1%; for minor defects, the AQL shall be 4%.

1.2 Tablet

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

Pharmacopoeial tests:

- Identification

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

Non-pharmacopoeial tests:

- Package seal integrity test.²⁰

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

1.3 Resolution of Defects

- c. Packaging, Packing, and Markings
 - Defects in exterior shipping carton markings must be corrected by the Supplier prior to supply.
 - *All goods from corresponding production lots with inspection lot defect in excess of the AQLs listed in Section 1.4 of this specification must be corrected and re-inspected at Supplier's expense or rejected.*
- d. Tablet
 - Any deviation from the manufacturer's Certificate of Analysis, product specifications,
Or
relevant pharmacopoeial limits shall result in rejection of goods from the entire production lot.



Technical 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.²¹

The antiprogestin mifepristone has also been extensively studied for use as an emergency contraceptive pill. Mifepristone is a first generation progesterone receptor modulator. A second generation antiprogestin, ulipristal acetate (30mg in a single dose), has been studied for use as emergency contraception and has been found to be highly effective and well tolerated.²² However both these products are not registered in Pakistan

1. Requirements

Emergency contraceptive tablets in accordance with the following specifications:

- Each tablet shall contain 0.753 mg of Levonorgestrel

1.1 Product and Brand Names

Product name:

Brand names:

Registration Number:

1.2 Raw Materials

Emergency contraceptive tablets offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor.²³

1.3 Registration Requirements

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

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

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

- Records demonstrating raw materials with the required physical and chemical characteristics.



(WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.²⁴

1.5 Compliance with Current Good Manufacturing Practices

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

1.7 Shape and Dimensions

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

1.8 Colors

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

1.9 Tablet Markings

Each tablet shall bear the identifying imprint of its manufacturer.

1.10 Packaging

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

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

1.11 Identification Markings on Individual Blister Packs

Each individual blister pack shall have the following information:

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

1.12 Workmanship

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

1.13 Lots per Order

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

1.14 Shelf Life

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

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

1.16 Test Data

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

2. Quality Assurance Provisions

Same as Oral Contraceptive Pills

3. Packing

Same as Oral Contraceptive Pills

Inspection Sampling and Testing

Same as Oral Contraceptive Pill



Technical Specifications - Injectable Contraceptives (3 months)

Information for Submission of Samples

The sample injectable contraceptives submitted by the Bidder in response to this Invitation for Bids must be exactly the same as would be supplied if a contract were awarded to the Bidder.²⁵ 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.²⁶

1.3 Primary Packaging Requirements

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

1.4 Registration Requirements

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

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

Injectable contraceptives offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the Contract, the successful offeror(s) may be required to submit a "statement of licensing status of pharmaceutical product(s)" as provided under the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.²⁷

1.6 Compliance with Current Good Manufacturing Practices

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

1.7 Appearance

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

1.8 Filling Volume

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

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

1.9 Identification Markings on Individual Vials or Ampoules

Each individual vial or ampoule shall have the following information:

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

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

- Recommended storage conditions.
- Drug Manufacturing License Number.

1.10 Workmanship

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

1.11 Lots per Order

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

1.12 Shelf Life

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

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

1.13 Test Data

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

2. Quality Assurance Provisions

2.1 Compliance

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

2.2 Documentation

2.2.1 The Supplier shall provide evidence²⁸ 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.²⁹

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

2.4 Sampling Procedures

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

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

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

2.5 Sample Retention

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

3. Packing

3.1 Inner Boxes

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

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

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

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

3.2 Exterior Shipping Cartons

3.2.1 *Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fiberboard cartons made from weather-resistant fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm³⁰. 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 Agency³¹:

- 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 handling
- 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.³²

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, and Single Sampling Plan for Normal Inspection.*

The sample will be examined for:

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

1.2 Injectable

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

Pharmacopoeial tests

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

Non-pharmacopoeial tests

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

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

1.3 Resolution of Defects

- a. Packaging, Packing and Markings
 - Defects in exterior shipping carton markings must be corrected by the Supplier prior to shipment.
 - *All goods from corresponding production lots with inspection lot defect in excess of the AQLs listed in Section 1.4 of this specification must be corrected and re-inspected at Supplier's expense or rejected.*
- b. Injectable
 - Any deviation from the manufacturer's Certificate of Analysis, product specifications or relevant pharmacopoeial limits shall result in rejection of goods from the entire production lot.



Technical Specification - Male Latex Condom

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

General Requirements	
Materials	
General Requirements	The condoms shall be made of natural rubber latex.
Bio burden levels	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.
Bio compatibility	Bio compatibility assessments shall be conducted in accordance with <i>ISO10993-1</i> . Specifically, tests shall be conducted for cytotoxicity according to <i>ISO10993-5</i> and for irritation and sensitization according to <i>ISO10993-10</i> . 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.
water-extractable protein levels	<i>It is recommended that manufacturers determine the water-extractable levels of proteins in their products.</i> 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 <i>ISO12243</i> , <i>EN455-3</i> and <i>ASTM D5172</i> for determining the protein levels in medical gloves can be modified for condoms ¹ .

1 Tinkler Jetal. Risk assessment of dithiocarbamate accelerator resin dyes 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 of 28°C to 35°C. As described in *ISO4074*.

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 <i>ISO4074</i> .
Conditioning	Condition condoms at (50±2)°C for 120 days or 180 days in accordance with the relevant annex of <i>ISO4074</i> .
testing requirement	Assess compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of <i>ISO4074</i> . If all three LOTS of condoms remain in compliance with the requirements for bursting properties, freedom from holes and package integrity specified in the relevant clauses of <i>ISO4074</i> for a period of 120 days at (50±2)°C, a provisional shelf-life of three years may be assigned.
Minimum stability requirements	Condoms shall comply with the minimum stability requirements defined in the relevant clause of <i>ISO4074</i> . 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 <i>ISO2859-1</i> and Annex B of <i>ISO4074</i> .
Conditioning	Incubatesamplesintheirindividualsealedcontainersaccordingtotherelevantannexof <i>ISO4074</i> : • Onesetfor168±2hoursat(70±2)°C, andanother setfor(90±1)daysat(50±2)°C. • At the end of the incubation periods, with draw the condoms and test for airburst properties, freedom from holes and packages al. • 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 <i>ISO4074</i> .
Conditioning	Incubate samples in their individual sealed containers according to the relevant annex of <i>ISO 4074</i> : • One set or 168±2 hours at(70±2)°C, and another set for(90±1) days at(50±2)°C.
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 <i>ISO 4074</i> .

Performance Requirements

The performance requirements specified here are based on the requirements of *ISO4074*. 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 *ISO4074* shall be used. For LOT-by-LOT Pre-shipment compliance testing the sampling plans specified in Annex A of *ISO4074* shall be used.

Performance Requirements	
Bursting volume and pressure	
Sampling	In accordance with <i>ISO2859-1</i> General Inspection Level. For prequalification testing at least Code Letter as specified in Annex B of <i>ISO4074</i> shall be used.
Testing	In accordance with test method in the relevant annex of <i>ISO4074</i> and the relevant clause in <i>ISO4074</i> .
Requirement	Minimum bursting requirements as listed below: AQL 1.5 Volume: 16.0dm ³ for condoms with widths less than 50.0mm 18.0dm ³ for condoms with widths from 50.0mm up to 55.5mm 22.0dm ³ for condoms with widths greater than or equal to 56.0mm

Performance Requirements	
Bursting volume and pressure after oven conditioning (optional: see Annex I ⁶)	
Sampling	In accordance with <i>ISO2859-1</i> General Inspection Level. For prequalification testing at least Code Letter Ma s specified in Annex B of <i>ISO4074</i> shall be used.
Testing	Condition the samples in accordance with the relevant annex of <i>ISO4074</i> 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 <i>ISO4074</i> and the relevant clause in <i>ISO4074</i> .



Requirement	Minimum bursting requirements as listed below: AQL1.5 Volume: 16.0dm³for condoms with widths less than50.0mm 18.0dm³for condoms with widths from 50.0mmupto55.5mm 22.0dm³for condoms with widths greater than or equalto56.0mm
Freedom from holes and visible effects	
Sampling	ISO 2859-1General Inspection Level, but at least Code Letter M.
Testing	In accordance with the relevant annex of ISO4074.
Requirement	In accordance with test method in the relevant annex of ISO4074.Freedom from holes: AQL0.25 Critical visible effects: AQL0.4 Non-critical visible effects: AQL2.5 ISO4074 describes a limited number of critical visible effects. WHO specifies an extended list of critical visible effects and a list of non-critical visible defects in Chapter 3, Clauses 2.1 and 2.2?
Packages integrity	
Sampling	ISO2859-1InspectionLevelS-3.
Testing	In accordance with the package integrity test method in the relevant annex of ISO4074.
Requirement	AQL2.5

- 5 A sanitarium measure pending the production of definitive evidence supporting the benefit soft sting 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 Agency may wish to include this requirement in specific contracts depending upon the level of confidence in the supplier.

6 Design Requirements

- 7 The design proper ties listed below may be adapted, where appropriately indicated, to reflect the specific needs of the program 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.
8. If specified sign 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 air burst properties and, in some circumstances, freedom from holes.
9. *It is recommended* that, where changes to the specification are made, dimensional requirements and design features should be subject to ISO2859-1 Inspection LevelS-2 with an **AQLof1.0**.



10. 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 on to the surface of the condom. Condoms may be of any shape consistent with normal commercial practice and client requirements.
Integral bead	
Verify by visual inspection	The open end of the condom shall have a rolled ring of latex, called an integral bead.
Colour	
Verify by visual inspection	Condoms can be translucent or colored. Pigments used with colored condoms shall be suitable for use in medical devices.
odour, fragrance and flavor	
Verify by visual inspection and smell	The condoms shall not give off an un pleasant odor when the package is opened at any time after manufacture and for the shelf-life of the product. (Condoms have a character is ticod our 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 references amples be retained by the testing laboratory to helper solve disputes over odour. It is recommended that the retained samples be kept for the duration of the shelf-life of the condom. Procuring Agency may specify the addition of a suitable fragrance and/ or flavour. Such fragrances and flavours must be non-toxic, non-irritant and noted grade the rubber.
Design Requirements	
	If a flavour is desired, describe here (specify fla vour and amount added)and provide full details of the flavour including 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. our testing should be included in ageing studies.
Width	
sampling	In accordance with /ISO2859-1 Inspection LevelS-2.
Testing	In accordance with the test method in the relevant annex of ISO4074.



requirement	Standard widths within the public sector are 49mm and 53mm, with a tolerance of ± 2 mm. AQL1.0 Other widths are available and may be more appropriate for specific target populations described in Annex. 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 ISO2859-1 Inspection Level S-2.
Testing	In accordance with the test method in there Levant annex of ISO4074.
requirement	A minimum of 165mm for condoms with widths less than 50.0mm. A minimum of 180mm for condoms with widths from 50.0mm upto 55.5mm. A minimum of 190mm for condoms with widths equal to or greater than 56.0mm. AQL1.0 Length may be specified based on the best available at a 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 ISO4074 at a point (35 $\pm$ 15)mm from the opened, rounded to the nearest 0.5mm.
Thickness	
sampling	In accordance with ISO2859-1 Inspection Level S-2.
testing	In accordance with the test method in the relevant annex of ISO4074.
requirement	The thickness measurements are taken at three points: 30 $\pm$ 5mm from the open end, 30 $\pm$ 5mm from the closed end (excluding the reserve tip), and at their 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. AQL1.0 The mean single-wall thickness (calculated from the three individual measurements) for each condom shall be 0.065 $\pm$ 0.015mm–0.020mm. <i>Condoms thicker than 0.080mm are usually considered to be extra thick, where as condoms that are thinner than 0.060mm are usually considered to be thin. There is no evidence that extra thick condoms (sometimes called extra strong) provide additional protection.</i>

Design Requirements	
Quantity of lubricant including powder	
sampling	In accordance with ISO2859-1 Inspection Level S-2.
testing	In accordance with the test method in the relevant annex of ISO4074.



requirement	The condom shall be lubricated with a quantity of silicone fluid having a viscosity between 200 and 350centistokes. <i>Other lubricants such as glycols and water-based lubricants may be used. Oil-based lubricants should NOT</i> <i>Be used.</i> If an alternative lubricant is required, specify the type here and provide full details of the lubricant including Material Safety Data Sheet (MSDS). The quantity of lubricant, including powder, in the package should be(550±150)mg. AQL4.0 <i>If user preferences indicate that it is desirable, lower lubricant levels may be used, but the minimum recommended quantity is 250mg.</i>
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Individual package materials and markings

sampling	In accordance with/SO2859InspectionLevelS-3.
testing	The sample of condom packages is visually inspected to verify the required aspects of package equality.
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 labeled expiry date; • date in a language to be specified by the Procuring Agency.
Verified by visual inspection	Individual packages shall be square or circular and shall not distort the rolled condom. The packages shall be hermetically sealed and shall protect the product from oxygen, ozone, water vapour, ultra violet let and visible light.
Verified by supplier's data or independent test	The recommended packages should be constructed of a laminate, which include slayer of suitable impermeable flexible aluminum foil (recommended minimum thickness of 8micrometers)and layers of plastic materials suitable for the mechanical protection of the metal foil and for printing and sealing.

Design Requirements

Alternate package materials	<i>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.</i> 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 followings shall apply: • There shall be no evidence of leak age. • The outside surface of the packages shall be clean. • There shall be no separation of the layers of laminate.
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Packaging for shipment

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

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

Packaging Requirements	
Consumer packs	The consumer packs should contain 144 pieces per packet of condom.
Inner boxes	The inner boxes shall be constructed of card board. 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 eligible manner to describe the contents and to facilitate identification 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 <i>Date of Manufacture, Month, Year</i>) in language(s) to be specified by the Procuring Agency. They shall be written as a four-digit number and the month as a two-digit number; • month and year of expiry (including the words <i>Expiry Date, Month, Year</i>) in language(s) to be specified by the Procuring Agency. They shall 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.



Packaging Requirements

information	If, in accordance with local regulations or program 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 finger nails, 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 as 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. <i>It is recommended that the following statement relating to the safety and effectiveness of the condom be included:</i>
Exterior shipping cartons	The inner boxes shall be packed in to plastic or other water proof lining bags, which will be placed in three-wall cartons made from weather-resistant corrugated fiber board with a bursting test strength of not less than 1900k Pa. 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 75mm wide water-resistant tape applied to the full length of the centre seams and extending over the ends by not less than 75mm. 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 water proof 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 fiber board available is not of sufficient strength and rigidity to meet stacking requirements or to resist being cut at the corners when the plastic strapping is applied. In such cases an inner carton of two-walled corrugated fiber board shall be inserted in to 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 <i>Date of Manufacture, Month, Year</i>) 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 <i>Expiry Date, Month, Year</i>) in language(s) to be specified by the Procuring Agency. They ear 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 discrete LOT shall be assembled and shipped together.
lot traceability	Best efforts shall be made to ensure that shipments remain as discrete LOT Sand 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.

table1.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, damage dornon-serviceable.
workmanship	Shipping cartons in adequately 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 *ISO4074:2002 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 *ISO17025* 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 labeling, but may apply to the 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 *ISO4074:2002*. UNFPA includes testing condoms that have been oven conditioning for (168 ± 5) hours at $(70 \pm 2)^\circ\text{C}$ 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 *ISO4074:2002*. In anticipation of changes in then expedition of *ISO4074* (which is expected to be



published later in 2013) UNFPA also requires testing for freedom from holes and visible effects, and package integrity after oven conditioning for (168 ± 5) hours at $(70 \pm 2)^{\circ}\text{C}$ for prequalification testing.

table2. summary of prequalification tests and requirements		
Sample according to Annex B of ISO4074 for "isolated Lots" and ISO2859-1		
test	Sampling	Requirements
Verification of constituent materials	NA	Manufacturer's documentation
Verification of shelf-life	NA	Manufacturer's documentation
Minimum stability(if required)	As listed below for burst volume, burst pressure, freedom from holes and package integrity	As listed below for burst volume, burst pressure, freedom from holes and package integrity
Bursting volume(before and after oven conditioning)	Level G-I Minimum Code Letter M	Minimum volumes: 1. 16.0 dm ³ for condoms with widths less than 50mm 2. 18.0 dm ³ for condoms with widths from 50mm to 55.5mm 3. 22 dm ³ for condoms with widths greater than 56mm AQL1.5
Bursting pressure(before and after oven conditioning)	Level G-I Minimum Code Letter M	Minimum pressure:1.0kPaA QL1.5
Freedom from holes (before and after oven conditioning for (168 ± 5) hat $(70 \pm 2)^{\circ}\text{C}$)	Level G-I Minimum Code Letter N	AQL0.25
Visible defects(before and after oven conditioning for (168 ± 5) hat $(70 \pm 2)^{\circ}\text{C}$)	Level G-I Minimum Code Letter N	Critical defects:AQL0.4Non-critical defects:AQL2.5
Shape and texture	Agreed between manufacturer and buyer	Visual inspection
Package integrity(before and after oven conditioning for (168 ± 5) hat $(70 \pm 2)^{\circ}\text{C}$)	LevelS-3 Minimum Code Letter H	AQL2.5
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	LevelS-2	± 2 mm of claimed widthAQ L1.0
Length	LevelS-2	1. 165 mm for widths less than 50mm 2. 180 mm for widths between 50mm and 55.5 mm 3. 190 mm for widths of 56.0 and above AQL1.0
Thickness	LevelS-2	0.045–0.080mm AQL1.0
Lubricant quantity (including powder)	LevelS-2	Viscosity:200–350centistokes Qty:400–700mg/condom AQL4.0
Odour(if necessary)	Agreed between manufacturer and buyer	Sensory inspection
Inner box	LevelS-3	Compliant with procurement specifications
Exterior shipping cartons	LevelS-2	Compliant with procurement specifications



table3.summaryofLot-by-LotPre-shipmentcompliancetestingandrequirements

Sample according to Annex A in ISO4074 for "continuous Lots" and ISO2859-1

Test	Sampling	Requirements
Bursting volume (before and after oven conditioning)	Level G-I	Minimum volumes: 1. 16.0dm³ for condoms with widths less than 50mm 2. 18.0dm³ for condoms with widths from 50mm to 55.5mm 3. 22dm³ for condoms with widths greater than 56mm AQL1.5
Bursting pressure (before and after oven)	Level G-I	Minimum pressure: 1.0kPa AQL1.5
Freedom from holes	Level G-I Minimum Code Letter M	AQL0.25
Visible defects	Level G-I Minimum Code Letter M	Critical defects: AQL0.4 Non-critical defects: AQL2.5
Shape and texture	Agreed between manufacturer and buyer	Visual inspection
Package integrity	Level S-3	AQL2.5
Integral bead	Agreed between manufacturer and buyer	Visual inspection
Colour	Agreed between manufacturer and buyer	Visual inspection
Fragrance and flavoring	Agreed between manufacturer and buyer	Sensory inspection
Width	Level S-2	±2mm of claimed width AQL1.0
Length	Level S-2	1. 165mm for widths less than 50mm 2. 180mm for widths between 50mm and 55.5 mm 3. 190mm for widths of 56.0 and above AQL1.0
Thickness	Level S-2	0.045–0.080mm AQL1.0
Lubricant quantity (including powder)	Level S-2	Viscosity: 200–350 centistokes Qty: 400–700mg/condom AQL4.0
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	Level S-3	Compliant with procurement specifications AQL2.5



Technical Specification: TCU380A Intrauterine Device (IUD)

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 AWG³³, 33 ISWG³⁴).

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 C10100³. 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 de burred, 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 food contact grade radiation stabilized polypropylene (PP) with a tip diameter of $(2.6 \pm$

³³ American Wire Gauge

³⁴ Imperial Standard Wire Gauge



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: $(3.0 \text{ mm} \pm 0.7 \text{ mm})$. The junction between the ball and the vertical stem shall preferably be radiused.

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

The junctions between the horizontal arms and the vertical stem may be radiused to prevent stress concentrations. If the junction is radiused the radius shall be between 0.25 - 0.40 mm. Manufacturers shall confirm that introducing the radius does not lead to an increase in crush damage at the junction when the T is deformed as it is loaded into the insertion tube. This can be done by comparing the strength of radiussed and non radiussed 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. Manufacturers 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 $380 \text{ mm}^2 \pm 10\%$.

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. Manufacturers 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 $23 \pm 2^\circ\text{C}$.

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 $(23 \pm 2)^\circ\text{C}$. Before testing the T frames shall be stored for at least 6 hours at the test temperature.

A suitable test rig may be used to clamp the T frame and measure the amplitude of the deflection. 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



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

Compliance shall be with an AQL of 0.65

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

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

8.4 Labeling and inserts

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

The following information shall be supplied:

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

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

SUBDERMAL CONTRACEPTIVE IMPLANT

2*75 levonorgestrel, 2 rod implant

The offered contraceptive implant shall be a two-rod levonorgestrel sub dermal implant containing a total of 150 mg levonorgestrel (75 mg per rod), intended for long-acting reversible contraception with a minimum approved duration of effectiveness of three (3) years. The product shall be WHO Prequalified and approved by DRAP and shall comply with WHO GMP and applicable international quality standards.

Mandatory Requirement: World Health Organization (WHO) Prequalified and DRAP Registered

Composition: Implant

Product Category: Medical devices

Efficacy to provide birth spacing: must be effective for up to 3 years. More than 99% effective in a 3-year period.

Composition and structure: must be composed of two thin and flexible silicone rods, containing 75 mg of levonorgestrel in each rod (150 mg total)

Mechanism of action: must Prevent the release of the egg and thickens mucus in the cervical canal to prevent sperm reaching and fertilizing the egg.

Shelf life of the product: 5 years

Removal mechanism/ Reversible contraception: The implant must be removable at any time at the woman's request and there must be no delay in return to fertility

Insertion timings:/ Broad eligibility: should be almost for all women of any age, including those who have just given birth, are breastfeeding, or women who have had an abortion can use this-provided they meet the medical eligibility criteria.

Pack size: 10 x 2 pieces per pack



Technical Specifications

Two-Rod Levonorgestrel Contraceptive Implant

1. Product Description

A long-acting, reversible, sub dermal hormonal contraceptive implant consisting of **two sterile, flexible, non-biodegradable silicone elastomer rods**, each containing **Levonorgestrel USP/BP/Ph. Eur.** as the active pharmaceutical ingredient.

2. Active Pharmaceutical Ingredient

- Pharmacological Class: Progestogen-only contraceptive
- Strength:
 - 75 mg Levonorgestrel per rod
 - 150 mg total per implant set

3. Implant Characteristics

- Number of rods: **Two (2)**
- Rod colour: White or off-white
- Rod material: Medical-grade silicone elastomer
- Rod length: Approximately **44 mm**
- Rod diameter: Approximately **2.4 mm**
- Each rod shall be hermetically sealed.

4. Duration of Effectiveness

The implant shall provide **highly effective contraception for at least three (3) years** following insertion.

5. Mechanism of Action

The implant shall provide contraceptive efficacy through:

- Suppression/inhibition of ovulation;
- Thickening of cervical mucus;
- Endometrial changes that reduce the likelihood of implantation.

6. Clinical Performance

- Contraceptive effectiveness exceeding **99%** during the approved duration of use.
- Rapid return to fertility following implant removal.
- Suitable for women seeking long-acting reversible contraception (LARC).



7. Sterility

- Sterile product.
- Sterilized using a validated method.
- Intended for **single patient use only**.
- Shall remain sterile until the package is opened or damaged.

8. Packaging

Each unit pack shall contain:

- One sterile pouch containing:
 - Two contraceptive implant rods
 - One sterile disposable insertion trocar (or approved insertion device)
- Instructions for insertion and removal.
- Patient information leaflet.
- Product identification label with batch number and expiry date.

9. Shelf Life

- Minimum remaining shelf life upon delivery: **80% of total shelf life or at least 24 months**, whichever is greater.

10. Storage Conditions

- Protect from excessive heat, moisture and direct sunlight.
- No cold-chain storage required.

11. Quality Standards

The product shall comply with:

- WHO recommendations for contraceptive implants;
- Current Good Manufacturing Practice (cGMP);
- ISO 13485 certified ;

12. Regulatory Requirements

The offered product should meet following requirement:

- WHO Prequalified Product;
- DRAP Pakistan registered.

13. Manufacturer Requirements

The manufacturer shall:



- Operate under WHO GMP or equivalent GMP certification.
- Maintain an effective quality management system.
- Provide Certificate of Analysis (CoA) for each batch supplied.
- Provide Batch Release Certificate.

14. Labeling

Each package shall clearly display:

- Generic name
- Strength
- Batch/Lot Number
- Manufacturing Date
- Expiry Date
- Storage Conditions
- Manufacturer's Name and Address
- Sterility indication
- Single-use symbol
- Instructions not to use if package is damaged.

15. Documentation Required with Bid

The bidder shall submit:

- Product dossier/specifications
- Valid GMP Certificate
- Free Sale Certificate (where applicable)
- Certificate of Pharmaceutical Product (CPP)
- WHO Prequalification certificate and DRAP Registration
- Certificate of Analysis for supplied batches
- Package insert and Instructions for Use (IFU)



SECTION VII

Bid Forms



24/7/2017

7/2

BID COVER SHEET

Bid Ref. No. _____

Date_____

Name of the Supplier/Firm Contractor: _____

Address:_____

E-mail: _____

Phone: _____

Facsimile: _____

Bid Security.

Bid Security attached with Financial Bid YES NO

Bid for:

: All Items mentioned in the Schedule of Requirements.

: Selected Items from the Schedule of Requirements³⁵.

List of Selected Items: (In case the Bidder has opted to bid for Selected Items, please type the Serial No³⁶. and the name of the Items selected for Bidding. Use additional Sheets if Required)

S. No.	Name of the Item	Batch Capacity of the Drug/Medicine/Product	Trade Price	MRP



Signed:

Dated:

Official Stamp:

Attachment³⁷: Original receipt for the purchase of the bidding documents.



[Handwritten signatures and marks in blue ink]

BID FORM 1

Letter of Intention

Bid Ref No.

Date of the Opening of Bids

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

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

Dear Sir/Madam,

Having examined the bidding documents including Addenda Nos. *[insert numbers & Date of individual Addendum]*, the receipt of which is hereby acknowledged, we, the undersigned, offer to supply and deliver the Goods under the above-named Contract in full conformity with the said bidding documents and at the rates/unit prices described in the price schedule or such other sums as may be determined in accordance with the terms and conditions of the Contract. The above amounts are in accordance with the Price Schedules attached herewith and are made part of this bid.

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

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

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

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

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



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

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

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

Signed:

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

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



AFFIDAVIT

On Rs. 500/- Judicial Paper

I/We, the undersigned solemnly state that:

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

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

Signed



BID FORM 3(A)

Name of the Firm

Bid Reference No:

Date of opening of Bid.

Documentary Evidence: Eligibility of the Bidders and Goods

Required Documentation (To Be Filled by the Procuring Agency)	Checklist ³⁸ (To be initialed by the Bidder against each document)	Relevant Page Number ³⁹ in the Bid (To be filled by the Bidder)	Supporting Documents ⁴⁰ (To be filled by the Bidder with name of the documents that are submitted to meet the requirement)
Column:1	Column:2	Column:3	Column:4
Valid Manufacturing License			
Valid Registration(s) of quoted items			
Valid Drugs Sale License ⁴¹			
WHO prequalification certification ⁴²			
Valid Import License (where applicable)			
Letter of Manufacturer's authorization			
Partnership Deed (where applicable)			
NTN Certificate			
GST Certificate			
Letter of Intention			
Affidavit			
Three years experience evidence			
Child Labor Free Certificate ⁴³			
Original Receipt of purchase of Bidding Documents			



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

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

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

Signature: -----

Designation: -----

Official Stamp: -----



[Handwritten signature]

[Handwritten signature]

BID FORM 4**Firm's Past Performance⁴⁵**

Name of the Firm:

Bid Reference No:

Date of opening of Bid: _____

Assessment Period: (One Year as per Evaluation Criteria)

Name of the Procuring Agency/Institution	Purchase Order No.	Description Of Order	Value of Order	Date of Completion	Procuring Agency's ⁴⁶ Certificate



BID FORM Price Schedule

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

Name of the Firm:

Bid.Ref. No:

Date of opening of Bid.

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

A) FINAL TOTAL PRICE:

B) DISCOUNT⁴⁷:

C) FINAL QOUTED PRICE:

(C=A-B)

Signature:

Designation:

Date:

Official Stamp



Bid Security Form (Bank Guarantee)

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

[Insert Bank's Name, and Address of Issuing Branch or Office]

Beneficiary (Insert name of Procuring Agency)

Date: _____

BID GUARANTEE No.: _____

We have been informed that [insert name of the Bidder] (hereinafter called "the Bidder") has submitted to you its bid dated (hereinafter called "the Bid") for the execution of Procurement of Contraceptives, under Invitation for Bids No. (Insert number) ("the IFB").

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

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

- (a) has withdrawn its Bid during the period of bid validity specified by the Bidder in the Form of Bid; or
- (b) having been notified of the acceptance of its Bid by the Procuring Agency during the period of bid validity, (i) fails or refuses to execute the Contract Form, if required, or (ii) fails or refuses to furnish the performance security, in accordance with the Instructions to Bidders.

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

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

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

[Signature]



Form of Contract Agreement

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

BETWEEN

- (1) (Insert name and address of Procuring Agency) (hereinafter called "the Procuring Agency"), and
(2) [insert: name of Supplier], a corporation incorporated under the laws of [insert: country of Supplier] and having its principal place of business at [insert: address of Supplier] (hereinafter called "the Supplier").

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

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Conditions of Contract referred to.
2. The following documents shall constitute the Contract between the Procuring Agency and the Supplier, and each shall be read and construed as an integral part of the Contract:

This Contract Agreement

Special Conditions of Contract

General Conditions of Contract

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

The Procuring Agency's Notification of Award

[Add here: any other documents]

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

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

For and on behalf of the Procuring Agency

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

In the presence of _____

For and on behalf of the Supplier

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

In the presence of _____

CONTRACT AGREEMENT dated the ____ day of _____, 2026

BETWEEN

Directorate General Health Services, "the Procuring Agency"

And

[Insert: name of Supplier], "the Supplier"



Performance Guarantee

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

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

And whereas it has been stipulated by you in the said Contract that the Supplier shall furnish you with a Bank Guarantee by a scheduled bank for the sum of 3% of the total Contract amount as a Security for compliance with the Supplier's performance obligations in accordance with the Contract.

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

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

This guarantee is valid until the _____ day of _____, 2026

Signature and Seal of the Guarantors/ Bank

Address

Date



Integrity Pact

DECLARATION OF FEES, COMMISSION AND BROKERAGE ETC PAYABLE BY THE SUPPLIERS/CONTRACTORS/CONSULTANTS

Contract Number: _____ Dated: _____

Contract Value: _____

Contract Title: _____

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

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

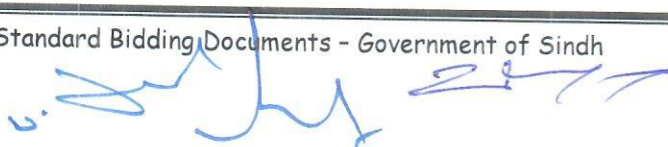
[Name of Supplier/Contractor] certifies that it has made and will make full disclosure of all agreements and arrangements with all persons in respect of or related to the transaction with Procuring Agency and has not taken any action or will not take any action to circumvent the above declaration, representation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

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

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

[Procuring Agency]

[Supplier /Contractor]



CHECK LIST OF DOCUMENTS PROVIDED WITH PAGE MARKING

No	Description	Documents Attached		
		Yes	No	Page No.
1)	Receipt of the bidding document Purchase			
2)	Name of the signatory of the firm with CNIC copy			
3)	2 ½ % bid security attached with the Financial bid (in original)			
4)	Name & pack size of the Product offered are clearly mentioned in the technical bid			
5)	Drug Registration bearing latest price of the contraceptive enclosed (specific items)			
6)	Undertaking on judicial stamp paper regarding potency of the contraceptive and fit for human use/consumption.			
7)	Undertaking on judicial stamp paper that the firm participating in the tender has not been black listed/suspended the license by any Government/Institution/organization etc...			
8)	Undertaking on judicial stamp paper that no violation of child labor in the firm			
9)	For repacking item the bidder has enclosed the valid License/Excise license & relevant documents etc.			
10)				
11)				
12)				



[Handwritten signature in blue ink]

[Handwritten mark]



POPULATION WELFARE DEPARTMENT
GOVERNMENT OF SINDH
NICL BUILDING 11TH FLOOR ABBASI SHAHEED ROAD BEHIND FTC
BUILDING GORA QABURSTAN, KARACHI.



NOTIFICATION

In terms of Rule-31 of SPPRA Rules 2010 (Amended 2019) Complaint Redressal Committee comprising of the following officers is constituted for procurement of Drugs/Medicines, ICB/NCB Contraceptives, Liveries/Uniforms, Printing Material, Stationery etc for the office of Secretary, Director General, Population Welfare Department, Sindh, Karachi for the year 2026-27.

1.	Additional Secretary (A&F)	Chairman
2.	Representative of A.G, Sindh, Karachi Not below BS-18	Member
3.	Representative of Industries Department, Sindh, Not below BS-18	Member

(Hafeezullah Abbasi)
Secretary to Govt. of Sindh

No. PWDS/W&D/CRC/2026-27/338

Dated: 11th June, 2026

Copy to: -

1. P.S. to Minister of Population Welfare, Sindh, Karachi.
2. P.S. to Secretary, PWDS, Karachi.
3. P.A. to Director General, PWDS, Karachi.
4. Director (CTL & S)/(Medical), PWDS Karachi.
5. _____ (all the members of the Committee)
6. Notification File.
7. Master File.

(ALLAH RAKHIO KHASKHELI)
DEPUTY DIRECTOR (W&D)



**POPULATION WELFARE DEPARTMENT
GOVERNMENT OF SINDH**

**NICL BUILDING 11TH FLOOR ABBASI SHAHEED ROAD BEHIND FTC
BUILDING GORA QABURSTAN, KARACHI.**



NOTIFICATION

In terms of Rule-7 of SPPRA Rules 2010 (Amended 2019) Departmental Purchase Committee comprising of following officers is hereby constituted for procurement of Drugs/Medicines & Others, ICB/NCB Contraceptives, Stationery, Printing Material, Liveries/Uniforms, Transportation of Contraceptives & Medicines etc for the office of Secretary, Director General Population Welfare Department, Sindh, Karachi for the year 2026-27.

1.	Director (CTL & S)	Chairman
2.	Director (Admn)	Member
3.	Director (Medical)	Member
4.	Representative of Health Department, Government of Sindh, Karachi	Member
5.	Representative of Industries Department, Government of Sindh, Karachi	Member
6.	Budget Officer	Member
7.	Deputy Director (W&D)	Member/Secretary

Procurement Committee shall be responsible for:

- (1) Preparing bidding documents.
- (2) Carrying out technical as well as financial evaluation of the bid;
- (3) Preparing evaluation report as provided in Rule 45;
- (4) Marking recommendations for the award of contract to the competent authority; and
- 5) Perform any other function ancillary and incidental to the above

**(Hafeezullah Abbasi)
Secretary to Govt. of Sindh**

No: PWDS/W&D/DPC/2026-27/335

Dated: 11th June, 2026

Copy to: -

1. P.S. to Minister of Population Welfare, Sindh, Karachi.
2. P.S. to Secretary, PWDS, Karachi.
3. P.A. to Director General, PWDS, Karachi.
4. Director (CTL & S)/(Medical), PWDS Karachi.
5. _____ (all the members of the Committee)
6. Notification File.
7. Master File.

**(ALLAH RAKHIO KHASKHELI)
DEPUTY DIRECTOR (W&D)**



POPULATION WELFARE DEPARTMENT
GOVERNMENT OF SINDH
NICL BUILDING 11TH FLOOR ABBASI SHAHEED ROAD BEHIND FTC BUILDING
GORA QABURSTAN KARACHI



Dated: 20th July, 2026

TENDER NOTICE

The Population Welfare Department, Government of Sindh, Karachi, hereby invites online bids on SPPRA EPADS (only) from various Primary Manufacturers or their authorized representatives/Distributors duly registered with Directorate of Sales Tax & Income Tax/SRB for the supply of following store items for service delivery outlets.

S.#	Invitation of Tender	Stores	Estimated Value	Tender Fee/Cost Rs.
1.	No. PWDS/W&D/CC/NCB/2026-27/01	Contraceptives	Various	Rs.2000/-
2.	No. PWDS/W&D/Med/2026-27/02	Drugs/Medicines	Various	Rs.2000/=

Tender Fees & Date

Tender Document Fee	Rs.2000/-
Issuance start date	21 ST July, 2026
Issuance end date & time	5 TH August, 2026 at 11.00 PM
Submission date & time	21 ST July, 2026 to 5 TH August, 2026 at 11.00 PM
Opening date and time	5 TH August, 2026 at 11.30 PM

The tender documents can be downloaded from the SPPRA EPADS websites. Tender Document/Bid (with a copy of Bid Security/Earnest Money and supporting documents) should be submitted/uploaded on SPPRA EPADS <https://portalsindh.eprocure.gov.pk/>. The original Bid Security along with the Original Bid (duly signed and stamped) can be delivered in the office of the Deputy Director (W&D), Population Welfare Department, Sindh, Karachi, 11th Floor, NICL Building, Abbasi Shaheed Road behind FTC Building Gora Qaburstan, Karachi before bid opening schedule. Bids will be opened on the same date and venue in the presence of the bidders' representatives who may wish to attend.

The bidders are required to furnish Bid Security @2.5% of the total bid value in the shape of Pay order in favour of Secretary, Population Welfare Department, Government of Sindh, Karachi. Any offer without 2.5% Bid Security will be rejected. The department may reject all bids or proposals at any time prior to the acceptance of bid or proposal. The Department shall upon request communicate to any supplier or contractor who submitted a bid or proposal, the grounds for its rejection of all bids or proposals, but is not required to justify those grounds.

Terms & Conditions:-

- Offers are invited in Pakistani Currency (Pak Rupees).
- Only uploaded bid alongwith supporting documents will be accepted. In case there is a contradiction between bidders's EPADS submitted bid and manually submitted bid, bid submitted on EPADS will be considered valid for evaluation purposes
- In case Government announces any Public Holiday then tenders will be submitted/opened on the next working day and the time & venue will remain the same.
- Rates quoted in the Tender shall remain effective till 90 days from the date of opening or till extended bid validity period in terms of Rule 38 of SPP Rules 2010 (amended 2019).
- Population Welfare Department reserve the rights to increase or decrease the quantity of any scheduled items as and when it is deemed necessary according to SPP Rules. The procuring Agency may reject all or any bid at any time prior to the acceptance of a bid or proposal, subject to the relevant provision of SPP Rules 2010 (amended 2019).

DEPUTY DIRECTOR (W&D)
POPULATION WELFARE DEPARTMENT, SINDH
PH: 021-99225652