ONLINE TENDER FOR PROCUREMENT OF CONTRACEPTIVES FOR FAMILY PLANNING (FP)

Tender No: CMSS/PROC/2023-24/FP/037
(National Competitive Bidding)
(FOR CLASS-1 and CLASS-2 LOCAL SUPPLIERS ONLY)

CENTRAL MEDICAL SERVICES SOCIETY
(An Autonomous Society Under Ministry of Health & Family Welfare, Govt. of India)
2nd Floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Marg, Teen Murti Marg,
Chanakyapuri, New Delhi-11002, Phone: 011-21410905, 21410906
Website: www.cmss.gov.in, **Email-** dgceocmss@cmss.gov.in,
gmproc1@cmss.gov.in, agmproc4@cmss.gov.in

This page is intentionally left blank

CENTRAL MEDICAL SERVICES SOCIETY

Ministry of Health & Family Welfare (Government of India)
2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Road,
Opposite Police Station Chanakya Puri,
New Delhi-110021
Telephones: 011-21410905, 21410906

Telephones: 011-21410906 Fax: 011-23730120
Email: gmproc1@cmss.gov.in
agmproc4@cmss.gov.in

ONLINE BIDS ARE INVITED IN TWO PACKET BID SYSTEM FOR PROCUREMENT OF CONTRACEPTIVES FOR FP (FAMILY PLANNING).

Manual bids shall not be accepted.

BID DOCUMENTS MAY BE DOWNLOADED FROM GeM WEBSITE: **gem.gov.in** AS PER THE SCHEDULE AS GIVEN IN CRITICAL DATE SHEET AS UNDER:

CRITICAL DATE SHEET

Published Date	10.08.2023
Pre-bid meeting	17.08.2023 at 11:00 AM, Venue- Conference Hall, CMSS HQ New Delhi
Last date & time to submit pre-bid queries	17.08.2023 till 05:00 PM
Bid Submission End Date and Time	31.08.2023 till 03:00 PM
Last date of submission of original documents	31.08.2023 till 03:00 PM
Bid Opening Date and Time	31.08.2023 at 03:30 PM

Note: Prospective bidders are requested to get their product registered on GEM to participate for the above-mentioned bids

For registration, please contact GeM authorities directly at the following e-mail ids:

1. Ms. Manju Sharma, Deputy CEO (email: Manju.sharma64@gem.gov.in, phone: 9810281603)
2. Shri Rajesh Jain, Deputy CEO (email: rajesh.jain072@gem.gov.in, phone: 9810632525)
3. Shri Deepak Kapoor, Joint Secretary & Addl. CEO (for escalation) (email: js-aceodk@gem.gov.in, phone 9971863571)

As per directives of GOI, the custom bid is published on GEM platform. In case of any contradiction in terms and conditions of GEM bid, the clauses of the tender document (uploaded in Technical Specifications- Buyer Specification Documents) shall prevail.

Not more than one bid shall be submitted by one contractor or contractors having business relationship.

CONTENTS

This page is intentionally left blank

LIST OF ANNEXURES

This page is intentionally left blank

Online Tender for Procurement & Supply of Contraceptives for FP (Family Planning)

The CMSS, an autonomous Society of Ministry of Health & Family Welfare (Govt. of India), is responsible for procuring quality drugs, vaccines, contraceptives, medical devices, diagnostic kits and other health sector goods.

Tender Inviting Authority: DG&CEO, Central Medical Services Society, Ministry of Health & Family Welfare (Government of India)2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Road, Opposite Police Station Chanakya Puri, New Delhi-110021(hereinafter referred as Tender Inviting Authority unless the context otherwise requires)

Tender Accepting Authority: Governing Body, Central Medical Services Society (hereinafter referred as **CMSS,** unless the context otherwise requires)

1. **As per directives of GOI, the custom bid is being published on GEM platform. In case of any contradiction in terms and conditions of GEM, the clauses of this tender document shall supersede all other terms & conditions.**

2. **BID VALIDITY:**
   i. The bid shall be valid for a period of 150 days from the date of opening of Packet 1 (Technical Bid).

   ii. In exceptional circumstances, the purchaser may request the consent of the bidder for an extension to the period of bid validity. The request and the responses thereto shall be made in writing. The bid security provided under clause 9 shall also be suitably extended. A bidder may refuse the request without forfeiting his bid security. A bidder accepting the request and granting extension will not be permitted to modify his bid.

3. **PRE-BID MEETING/CLARIFICATIONS:**

   i. A prospective bidder, requiring any clarification of the bid documents may notify the purchaser in writing or email at the purchaser's mailing address indicated in the Invitation of bid. The purchaser shall respond in writing to any request for clarification of bid documents, which it receives not later than date mentioned in critical date sheet and prior to the pre-bid meeting. **Queries received after the pre-bid date mentioned in the critical date sheet will not be entertained.**

   ii. The Tenderers or their Official Representatives are invited to attend a pre- bid meeting which will take place as specified in critical date sheet/GeM Portal.

iii. Any clarification issued by CMSS in response to query raised by prospective bidders shall form an integral part of bid documents and it may amount to an amendment of the relevant clauses of the bid documents.

4. ELIGIBILITY CRITERIA

a) For item Schedule no. II (IUCD 380A), III (IUCD 375) & IV (Tubal Rings), only Class- 1 local supplier and Class- II local supplier shall be eligible for participation. Bids from supplier (MSE/Non MSE) as defined in Department of Pharmaceuticals under Ministry of Chemicals and Fertilizers order no F.No 31026/36/2016-MD dated 16.02.2021 shall be accepted. **Bids from firms/vendors other than Class- 1 and Class- II local supplier (MSE/Non MSE) shall be summarily rejected.**

   For item Schedule no. I (Emergency Contraceptive Pills), only Class- 1 local supplier and Class- II local supplier shall be eligible for participation. Bids from supplier (MSE/Non MSE) as defined in Department of Pharmaceuticals under Ministry of Chemicals and Fertilizers order no F.No 31026/65/2020-MD dated 30.12.2020 shall be accepted. **Bids from firms/vendors other than Class- 1 and class- II local supplier (MSE/Non MSE) shall be summarily rejected.**

   For item Schedule no. V (Pregnancy Test Kits), Only Class- 1 local supplier, shall be eligible for participation. Bids from supplier (MSE/Non MSE) as defined in Department of Pharmaceuticals under Ministry of Chemicals and Fertilizers order no F.No 31026/36/2016-MD dated 16.02.2021 shall be accepted. **Bids from firms/vendors other than Class- 1 local supplier (MSE/Non MSE) shall be summarily rejected.**

b) The invitation to bid is open to domestic manufacturers (Indian Manufacturers) only.

c) Tenderer shall be a domestic primary manufacturer of the quoted item having valid own manufacturing license that should be valid on the date of tender opening packet 1. In case of failure to submit the same, the bid shall not be considered any further.

d) For all regulated products, the bidder should have at least two years i.e. 2020-21and 2021-22 OR 2021-22 and 2022-23 of manufacturing and marketing experience of the particular items as a manufacturer for each regulated product quoted in the tender. However, this would not apply to regulated products which have been licensed by DCG (I) in less than two years ago. A permission from DCG (I) shall be required for all new regulated products to this effect.

e) (i) Average Annual turnover for Tenderers in the last three years i.e. 2019-20, 2020-21 and 2021-22 OR 2020-21, 2021-22 and 2022-23 shall not be less than the following: -

Schedule	Amount (in Rs.) for 100% quantity quoted	Amount (in Rs.) for 50% Quantity quoted
I	56,05,200/-	28,02,600/-
II	2,39,76,000/-	1,19,88,000/-
III	1,58,59,800/-	79,29,900/-
IV	57,42,976/-	28,71,488/-
V	98,71,776/-	49,35,888/-

(ii) The turnover benchmark given in (e) above will not apply to Micro and Small Enterprises (MSE).

Note: MSE Traders will not get the benefits of MSE Firm

Note: The applicable turnover has been indicated in above table and is for 100% and 50% quantity of the schedule. If quoted quantity is anywhere between 50% to 100% of the quantity of schedule (as allowed under tender clause no. 4(h)), the applicable Turnover may be calculated by the tenderer proportionately.

f) Tender should not be submitted by the firm/company for the Product(s) for which the firm/ Company has been blacklisted/ banned/ debarred by CMSS/ State Governments/ Central Government/MOH&FW or any of the procurement agencies/Autonomous Bodies under the organisations stated above or if the Firm/Company is debarred as a whole by these organisations or any of its procurement agencies/Autonomous Bodies.

g) Department of Expenditure, Ministry of Finance, GOI vide OM No: F.1/20/2018/PPD dtd. 02.11.2021 has issued guidelines on debarment of firms from bidding. The bidders blacklisted by any firm/company/ CMSS /State Govt. /Central Govt./its drug procuring agencies prior to issuance of DOE OM No: F.1/20/2018/PPD dtd. 02.11.2021 are eligible to bid if:- The blacklisting order has been revised post facto with clearly mentioning of category (i) of OM No: F.1/20/2018/PPD dtd. 02.11.2021 and that the debarment is limited to the issuing ministry/department/ organization only. Such vendors should clearly mention the status of blacklisting in the undertaking to be submitted in compliance with clause 6.1 (t) of tender documents and also attach revised blacklisting order.

For blacklisting orders issued after 02.11.2021, the following shall be applicable: -

- If the blacklisting order is issued by DoE, the bid of blacklisted bidder shall be out rightly rejected.
- If the blacklisting order is issued by CPSUs, attached offices/autonomous bodies etc of MoHFW/ Other Ministries/ department and MoHFW/ Other

Ministries/ department by written approval has delegated powers under Sr. no. (8) of OM dated 02.11.2021 to such organizations /bodies that the blacklisting is applicable only for the Procurement made by such organization /bodies, the bid of such blacklisted bidders shall be accepted for further evaluation.

- In absence of such delegation extended by MoHFW/ Other Ministries/ department, the bid of the blacklisted bidder shall be rejected.

h) Tenderer should quote at least for 50% of the tender quantity of each items quoted and the tenderer shall have an annual production capacity not less than one and half times the quantity quoted for each schedule.

i) Tenderer should have supplied 40% of the quoted quantity of same or similar items during the last two financial years. Bidder should submit Purchase order copies and certificate duly issued by statutory auditor/practicing chartered accountant of the company on his letter head by certifying the quantities manufactured and marketed in trade, *export*, open market, sold to government institutions, private bodies etc. and the marketed quantities are not less than at least 40% of the quoted/ similar items.

Similar Items here relate to the following: -

Sch. No.	Tendered Item	Similar Item
I	Emergency Contraceptive Pills (ECP)	Any type of OCP or ECP
II	IUCD 380 A	Any type of IUCDs
III	IUCD 375	Any type of IUCDs
IV	Tubal Rings	Tubal Rings
V	Pregnancy Test Kits	Pregnancy Test Kits

Supply/Sale/Service order under loan license arrangement shall not be considered.

j) **For Schedule I (Emergency Contraceptive Pills): -**
Tenderer shall have a valid GMP Certificate as per Schedule M of Drugs & Cosmetics Act, 1940 & Rules made there under for the manufacturing facility.

5. GENERAL CONDITIONS

i. A complete set of tender documents may be downloaded by any interested eligible bidder from website: www.gem.gov.in as per the schedule given in Critical Date Sheet. No cost for the Tender document shall be charged for the Tender documents downloaded by the Tenderers.

ii. All tenders must be accompanied with Earnest Money Deposit as specified against each schedule in Annexure-III of the Tender document.

iii. Tenders will be opened online therefore, the presence of tenderers/authorized representatives of the Tenderers is not necessary.

iv. Bidders are advised to watch for amendments, if any, which may be issued prior date of submission of bids by tender inviting authority on the website: www.cmss.gov.in and www.gem.gov.in for which CMSS will not issue any separate communication to individual bidders.

v. All notices or communications relating to and arising out of this tender and any consequent agreement or any of the terms thereof shall be considered duly served on or given to the Tenderer if delivered to it or left at the premises, places of business or abode or sent at official email as provided by the Tenderer.

vi. FORGERY/FRAUD BY BIDDERS/SUPPLIER:

a) Genuineness of the papers/documents/certificates/ declaration submitted with bid is the responsibility of the bidder. Also, the bidder should take utmost care in submitting undertakings/self-declaration/certificates along with its bid. If at any stage it is found that the papers/ documents/certificates/declaration/undertaking/ self-certification submitted by the bidder are false/incorrect/suppressed/ misrepresented the actual fact or are not in order, are forged, manipulated, fabricated or altered, the bid or purchase order issued to the bidder is liable to be cancelled and further necessary action including forfeiture of its EMD/Security Deposit, debarring/blacklisting against the bidder will be taken. Purchaser may also initiate police/legal action and request concerned statutory authority for cancellation of license issued to supplier for tendered items.

(b)If any fraud, short supply of goods is detected on part of the bidder at any stage, the bid or work order/ Purchase order issued to the bidder is liable to be cancelled and further necessary action against the bidder including debarring/blacklisting will be taken.

(c) In any of above two cases, the CMSS is at liberty to make alternative purchase of the tendered items from other approved suppliers or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier.

vii. PATENT RIGHTS:

The supplier shall indemnify the purchaser against all third-party claims of infringement of patent, trademark or industrial design rights arising from use of the goods or any part thereof.

In event of any such claim in respect of alleged breach of patent, registered designs, trademarks etc. being made against TIA, the TIA shall notify the supplier of the same and the supplier shall at its own expenses take care of the same for settlement without any liability to the TIA.

viii. TERMINATION FOR DEFAULT:

1. The purchaser may, without prejudice to any other remedy for breach of contract, by written notice of default, sent to the supplier, terminate this contract in whole or in part.

   (a) If the supplier fails to deliver any or all of the goods within the time period(s) specified in the contract, or any extension thereof granted by the purchaser.

   (b) If the supplier fails to perform any other obligation(s) under the contract, and

   (c) If the supplier, in either of the above circumstances, does not remedy his failure within a period of 15 days (or such longer period as the purchaser may authorize in writing) after receipt of the default notice from the purchaser.

2. In the event the purchaser terminates the contract in whole or in part, pursuant to above the purchaser may procure; upon such terms and in such manner, as it deems appropriate, tendered goods undelivered and the supplier shall be liable to the purchaser for any excess cost for such similar goods. However, the supplier shall continue performance of the contract to the extent not terminated.

ix. TERMINATION FOR INSOLVENCY:

The purchaser may, at any time, terminate the contract by giving written notice to the supplier, without compensation to the supplier, if the supplier becomes bankrupt or otherwise insolvent, as declared by the competent court provided that such, termination will not prejudice or affect any right of action or remedy which has accrued or will accrue thereafter to the purchaser.

x. SET OFF:

Any sum of money due and payable to the supplier (including security deposit refundable to him) under this contract may be appropriated by the purchaser and set off the same against any claim of the purchaser for payment of a sum of money arising out of this contract or under any other contract made by the supplier with the Purchaser.

xi. Purchaser reserves the right to debar/ blacklist a bidder for a suitable period in case he fails to honour his bid/contract without sufficient grounds.

xii. BID SUBMISSION:

(a) Bidders are hereby cautioned that any attempt of cartel formation will be viewed seriously and may at the discretion of purchaser, lead to cancellation of tender. Purchaser in its discretion may decide to forfeit EMD of such bidders and black list or debar these bidders for suitable period besides taking other punitive measures. Decision of purchaser in this regard shall be final and binding.

(b) (i) Different firms or companies having any common partner(s) or Director(s) are not permitted to quote for more than one tender offer. In case more than

one offer is received from such bidders, then all such offers except with the lowest quote shall be rejected summarily.

(ii) In case more than one offer for any tendered item is received from the same bidder, then all such offers except with the lowest quote shall be rejected summarily.

xiii. NEAR RELATIVE CERTIFICATE:

The bidder should give a certificate that none of his/her near relative as defined below is working in CMSS where he is going to apply for the tender. In case of Proprietorship firm certificate will be given by the proprietor. For partnership firm certificate will be given by all the partners and in case of limited company by all the Directors of the company excluding Govt. of India/Financial Institutions nominees and independent non-official part time directors appointed by Govt. of India or the Governor of the state. Authorised signatory of bid may also sign this bid on behalf of the entire directors/ partners/ proprietor. Due to any breach of conditions by the company or firm or any other person the tender will be cancelled and bid security will be forfeited at any stage whenever it is noticed and CMSS will not pay any damage to the company or firm or the concerned person. The company or firm or the person will also be debarred for further participation for quoted item in the concerned unit.

The near relatives for this purpose are defined as:

(a) Members of a Hindu undivided family.

(b) They are husband and wife.

(c) The one is related to the other in the manner as father, mother, son(s) & son's wife (Daughter in law), daughter(s) and daughter's husband (son in law), brothers(s) and brother's wife, sister(s) and sister's husband (brother-in-law).

An undertaking as specified in Annexure-XVI to be submitted.

6. TECHNICAL BID – "PACKET 1"

(a) Those indenting to participate in the tender (herein called Tenderer) should first ensure that they fulfil all the eligibility criteria and All documents should be valid on the date of tender opening packet 1:

6.1 The Tenderer should electronically submit the soft copies of following documents in Technical Bid "Packet 1". (All the documents submitted should bear signature and stamp of the Tenderer)."

6.2 RTGS/NEFT e-receipt or Bank Guarantee (if applicable) in respect of EMD as per Clause 9 of this Tender document or in case of MSE, a copy of their valid registration certificate in support of their being an MSE and a notarised undertaking given in **Annexure-VIII**.

(b) Tender Forwarding letter as per **Annexure-II**.

(c) Tenderer should furnish the Manufacturing License valid on the date of tender opening for each items quoted been duly renewed up to date and the items quoted shall be clearly highlighted in the license. Original documents should be produced for verification when demanded. If the tendered drug is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only.

(d) Duly notarized general power of Attorney (on non-judicial stamp paper of worth Rs. 50/-) in favour of authorized signatory in case of partnership firm (to be signed by all partners) / proprietorship firm or board resolution in case of a company to sign the bid and bind the bidder. The signature of authorized signatory should be duly attested. In case of proprietorship on its letter head of firm declares himself as proprietor with specimen signature.

(e) Tenderer should have supplied 40% of the quoted quantity of same or similar items during the last two financial years. Bidder should submit Purchase order copies and certificate duly issued by statutory auditor/practicing chartered accountant of the company on his letter head by certifying the quantities manufactured and marketed in trade, *export*, open market, sold to government institutions, private bodies etc. and the marketed quantities are not less than at least 40% of the quoted/ similar items.

Similar Items here relate to the following: -

Sch. No.	Tendered Item	Similar Item
I	Emergency Contraceptive Pills (ECP)	Any type of OCP or ECP
II	IUCD 380 A	Any type of IUCDs
III	IUCD 375	Any type of IUCDs
IV	Tubal Rings	Tubal Rings
V	Pregnancy Test Kits	Pregnancy Test Kits

Supply/Sale/Service order under loan license arrangement shall not be considered.

(f) Manufacturing and Market Standing Certificate / Market Standing Certificate issued by the Licensing Authority as a manufacturer for each item quoted for the last 2 years i.e. 2020-21 & 2021-22 OR 2021-22 & 2022-23 for compliance of tender clause no. 4 (d).

Note:

1. Unless otherwise stipulated in the Market standing certificate, the said certificate issued on a particular date shall be treated valid certificate for the financial year in which it has been issued. For example, Market Standing Certificate issued on 15.07.2022 for the period 15.07.2022 to 14.07.2023 shall be treated as Market Standing Certificate for the FY 22-23 only.
2. Market standing certificate should be for the same manufacturing premises from which quoted goods have been offered for supply.
3. Only for the drugs introduced in Indian Pharmacopoeia in the recent past (last 2yrs), Market standing certificate for previously approved Pharmacopoeia or In-house Standards (Export/ Domestic) shall be accepted, as the case may be.

4. For the drugs recently introduced drugs in the county (introduced in the last two financial years), the requirement for Market standing certificate shall be waived off.

(g) Non-Conviction Certificate issued by the FDA/ Drugs Controller of the State certifying that the firm/company (as well as the manufacturer firm in case of non-manufacturer bidders) has not been convicted and the products quoted have not been cancelled during last two years i.e. 2020-21 and 2021-22 OR 2021-22 and 2022-23.

Note:

1. Unless otherwise stipulated in the Non-Conviction Certificate, the said certificate issued on a particular date shall be treated valid certificate for the financial year in which it is issued. For example, Non-Conviction Certificate issued on 15.07.2022 for the period 15.07.2022 to 14.07.2023 shall be treated as Non-Conviction Certificate for the FY 22-23 only.
2. Non-Conviction Certificate should be for the same manufacturing premises from which quoted goods have been offered for supply.

(h) **For Schedule II, III, IV & V: -**
Capacity certificate issued by Licensing authority/Chartered Accountant should be submitted.

For Schedule I: -
Capacity certificate issued by Licensing authority should be submitted.

(i) Draft Artwork, Product Catalogue, Literature, Data Sheet is to be submitted in technical bid.

(j) Performance Statement to establish 2 years market standing as per format given in Annexure-IV.

(k) Annual turnover statement for 3 years i.e. 2019-20, 2020-21 and 2021-22 OR 2020-21, 2021-22 and 2022-23 should be furnished in the format given in Annexure-V duly certified by the Chartered Accountant.

(l) Copies of the audited Annual reports including the Balance Sheet and Profit and Loss Account along with all the annexure for the last three years i.e. 2019-20, 2020-21 and 2021-22 OR 2020-21, 2021-22 and 2022-23 duly certified by a practicing Chartered Accountant.

(m) Certificate of Incorporation along with MOA (Memorandum of Association) & AOA (Articles of Association) in case of Companies or Copy of partnership deed in case of partnership firm or Declaration in case of being a proprietary firm.

(n) Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life and Certificate of Analysis of one batch/PER (Performance Evaluation Report) (As applicable) of the quoted product should be submitted.

(o) List of items quoted (the name and Model of the items quoted) and relevant annual production for the last 3 years as per the **Annexure-VI** and relevant quality standards certificates and Catalogue, Data Sheets and technical compliance statement clause by clause with Mentioned Model No & Make.

(p) A Checklist (**Annexure-VII**) indicating the documents submitted with the tender document and their respective page numbers shall be enclosed with the tender document. The documents should be serially arranged.

(q) Each page of submitted bid (along with tender document) be properly page numbered and shall be signed by the authorized signatory of the Tenderer with office seal.

(r) All the documents enclosed with the tender document should also be signed by the authorized signatory of the Tenderer.

(s) No Deviation Certificate as per **Annexure-XV**.

(t) Near Relative Certificate as per **Annexure-XVI.**

(u) Tenderer should submit a certificate from the statutory auditor or cost auditor of the company (in the case of companies) or from a practicing cost accountant or practicing chartered accountant (in respect of suppliers other than companies) giving the percentage of local content at the time of submission of bid as per **Annexure-XVII (A & B).**

All certificate issued by Chartered Accountant shall mandatory contain UDIN number.

(v) Vendors are requested to fulfil the requirements of Ministry of Finance, Department of Expenditure, Procurement Policy Division Office Memorandum No.- 6/9/2020-PPD dated 24.08.2020.

(w) Tenderer should submit an Undertaking on Letter head to Compliance to Ministry of Finance, DOE order No- 6/18/2019-PPD dated 23.07.2020 and No.F.7/10/2021-PPD (1), dated 23.02.2023 as per **Annexure-XVIII.**

(x) Tenderer should submit an undertaking that

"I/ We do hereby declare that our firm has not been blacklisted/ banned/debarred by CMSS/ State Governments/ Central Government/ MOH&FW or any of the procurement agencies/ Autonomous Bodies under the organizations stated above or the Firm/ Company (as whole) has not been debarred as a whole by these organizations or any of its procurement agencies/ Autonomous Bodies"

(y) Para wise compliance of technical specification of the quoted items.

(z) **For Schedule II, III, IV & V: -**
Tenderer should submit a valid ISO 13485 certificate issued by an independent recognized certification body for the factory where the specific goods are manufactured and are being offered for supply. Certificate should be valid on the date of tender opening.

For Schedule I (Emergency Contraceptive Pills): - Tenderer shall have a valid GMP Certificate as per Schedule M of Drugs & Cosmetics Act, 1940 & Rules made there under for the manufacturing facility.

(aa) The bidders are requested to submit an undertaking on their letterhead for compliance to the Artwork enclosed for the items quoted by them. No further approval for Artwork would be provided by CMSS to any bidder.

6.3 (a) The above-mentioned documents are to be submitted in soft copy electronically on the GeM portal www.gem.gov.in Technical Bid "Packet 1" as per date prescribed in critical date sheet.

(b) **All original documents in lieu of EMD / Notarised undertaking by MSE companies Annexure-VIII** for exemption of EMD in physical form is to be deposited with the Tender Inviting Authority up to bid submission end date and time as per prescribed in the critical date sheet. If the last date of deposit of original documents in lieu of EMD / Notarised undertaking by MSE companies Annexure-VIII happens to be a central government holiday for offices located in New Delhi, next working day shall be treated as the last date of deposit. The original documents in lieu of EMD / Notarised undertaking by MSE companies Annexure-VIII may be either deposited in person or by courier. If sent by courier, the tenderer has to send it in advance so as to make sure that the original documents in lieu of EMD / Notarised undertaking by MSE companies Annexure-VIII is delivered to the Tender Inviting Authority by the date specified in critical date sheet. Failure to deposit the original documents in lieu of EMD / Notarised undertaking by MSE companies Annexure-VIII by the specified last date shall result in rejection of bid summarily.

(c) Conditional Bids shall be summarily rejected

7. PRICE BID- "Packet 2"

i. The price quoted shall be the landed price per unit at the specified locations on DDP basis and shall include all taxes and duties including transportation and other incidental expenditure for delivery at CMSS warehouses.

ii. The rate quoted in Price Schedule should be for a unit as given in specifications as detailed in the tender document. The bidder is not permitted to change / alter specification or unit size in the box.

7.1 GST (Goods and Service Tax)/other statutory Taxes/Levies

i. The bidder may quote for GST as per applicability in accordance with relevant Government notification.

ii. Any variation upwards/downwards as a result of statutory variation in GST/ other taxes/duties/levies for supplies during original *specified delivery schedule* of goods shall be allowed.

iii. Any upward/downward revision (only during scheduled delivery period) in statutory taxes, levies will be allowed and benefit will pass on to supplier/purchaser.

iv. Any increase in taxes and other statutory duties/levies after the expiry of the delivery date shall be to the supplier's accounts. However, the benefit of any decrease in these taxes/duties shall be passed on to the purchaser by the supplier.

The basic unit price quoted by the bidder shall remain fixed during the entire period of contract and shall not be subject to variation on any account. A bid submitted with an adjustable price quotation will be treated as non-responsive and rejected.

Breakup of the quoted price indicating the various components like Ex Work, GST, Transportation cost etc. has to be submitted, if desired by the TIA before placing the order

8. OPENING OF "PACKET 1" i.e. 'TECHNICAL BID AND "PACKET 2" i.e. FINANCIAL BID' OF TENDER:

8.1 To assist in the examination, evaluation and comparison of bids, the purchaser may, at his discretion ask the bidder for the clarification in its bid. The request for the clarification and response shall be in writing. However, no post bid clarification at the initiative of the bidder shall be entertained. Documents issued after the date of Tender Opening will not be accepted.

8.2 Tenderers are advised to submit all the required documents as per tender terms and conditions. Failure to submit shall result in rejection of bids. Clarification (if required) to assist in the evaluation of bids will be asked by the purchaser only once. The tenderer is requested to reply in the given time by the purchaser.

8.3 The purchaser shall evaluate the bids to determine whether they are complete, whether any computational errors have been made, whether required sureties have been furnished, whether the documents have been properly signed and whether the bids are generally in order.

8.4 Prior to the detailed evaluation, pursuant to clause above, the purchaser will determine the substantial responsiveness of each bid to the bid documents for purposes of these clauses. A substantially responsive bid is one, which confirms to all the terms and conditions of the bid documents without material deviations. The purchaser's determination of bid's responsiveness shall be based on the contents of the bid itself without recourse to extrinsic evidence.

8.5 A bid determined as substantially non-responsive will be rejected by the purchaser and shall not subsequent to the bid opening be made responsive by the bidder by correction of the non-conformity.

8.6 The purchaser may waive any minor infirmity or non-conformity or irregularity in a bid, which does not constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any bidder. Such minor infirmity will be identified by the TEC and clarification in this regard may be called for.

8.7 Technical Evaluation Summary will be uploaded on CPP/ GeM Portal. The bidders are intimated that representations, if any, may be sent before price bid opening as per schedule indicated in uploaded- summary. Any representations received after the indicated date and time would not be entertained under any circumstances. No new document would be allowed to be submitted at this stage.

8.8 "Packet 2" will be opened only for tenderers, who are found techno-commercially eligible on satisfying the criteria for technical evaluation and plant inspection (wherever necessary) based on the documents submitted in "Packet 1". Presence of authorized official of Tenderers is not necessary in opening of "Packet 2" as opening is online.

8.9 Arithmetical errors shall be rectified on the following basis. If there is a discrepancy between the unit price and total price that is obtained multiplying the unit price and quantity, the unit price shall prevail and total price shall be corrected by the purchaser. If there is a discrepancy between words and figures, the amount in words shall prevail.

9. EARNEST MONEY DEPOSIT

9.1. (a) The Earnest Money Deposit (EMD) is payable by all Tenderers, for an amount indicated in **Annexure-III** UNLESS EXEMPTED under clause 9.2. In case a Tenderer is quoting for more than one item, the Earnest Money Deposit payable by such Tenderer shall be the aggregate total of the Earnest Money Deposit for all the items quoted by such Tenderer. The Tenderers are required to furnish the breakup of the Earnest Money Deposit for the items quoted in the format as per Annexure-III. The Earnest Money Deposit shall be paid by Account payee/ Demand Draft/ Fixed Deposit Receipt/ Banker's Cheque /Bank Guarantee or RTGS/NEFT/Insurance Surety Bonds in the following Bank Account:

Beneficiary Name: Central Medical Services Society
A/C No. : 32719062216
Bank Name: SBI Bank
Branch: Nirman Bhawan, Maulana Azad Road, New Delhi
IFSC Code: SBIN0000583

(b) Bank Guarantee (**as per Annexure-XIV)** can also be accepted as a mode of payment and the named beneficiary shall be Central Medical Services Society. The Bank guarantee shall be issued by a bank (Nationalized or Scheduled Bank) in

India to make it enforceable and acceptable to the purchaser. The Bank Guarantee shall be in the format as per **Annexure-XIV** provided in the tender document. EMD shall remain valid for 45 days beyond the validity period for the bid and will be extended accordingly beyond any extension subsequently requested by purchaser.

(c) The applicable EMD amount has been indicated in **Annexure-III** and is for 100% and 50% quantity of the schedule. If quoted quantity is anywhere between 50% to 100% of the quantity of schedule, the applicable EMD may be calculated by the tenderer by proportionately reducing the amount applicable to 100% quantity.

9.2 EXEMPTION FROM PAYMENT OF EARNEST MONEY DEPOSIT TO MSME (MICRO & SMALL ENTERPRISES)

(i) (The MSE Units will be required to furnish a notarized undertaking (as per **Annexure-VIII**) to the effect that in the event of non-fulfillment or non-observance of any of the conditions stipulated in the tender, the MSE Unit shall pay a penalty, equivalent to the Earnest Money Deposit to offset the loss incurred by the Tender Inviting Authority consequent on such breach of any bid condition.

(ii) Vide Gazette no. CG-DL-E-26062020-220191 dt. 26.06.2020, Ministry of MSME have revised criteria for classifying the enterprises as Micro, small and medium enterprises with effect from Ist July 2020 therefore following firms will be exempted from submission of EMD.

a) Micro and Small Enterprises as per classification given in MSME Notification dtd. 26.06.2020 registered under "Udyam Registration" w.e.f 01.07.2020 will be granted exemption from payment of Earnest Money Deposit. Udyam Registration Certificate has to be produced in support of above.

b) In accordance with M/o MSME Gazette Notification No S.O. 2119 (E) dt. 26th June 2020, " In case of reverse-graduation of an enterprise, whether as a result of re-classification or due to actual changes in investment in plant and machinery or equipment or turnover or both, and whether the enterprise is registered under the Act or not, the enterprise will continue in its present category till the closure of the financial year and it will be given the benefit of the changed status only with effect from 1st April of the financial year following the year in which such change took place."

c) In accordance with M/o MSME Gazette Notification No S.O. 4926 (E) dt. 18th October 2022, "In case of an upward change in terms of investment in plant and machinery or equipment or turnover or both, and consequent re-classification, an enterprise shall continue to avail of all non - tax benefits of the category (micro or small or medium) it

was in before the re-classification, for a period of three years from the date of such upward change."

Note: **Traders will not get benefit of MSE Firms**

9.3. (i) Offers of the firms submitted without EMD / for a shorter period/lesser amount as demanded will summarily rejected. (if applicable)

(ii) The Earnest Money Deposit will be refunded to the lowest responsive bidder/s within 30 days from the date of signing the contract agreement and on the deposit of Security Deposit.

(iii) The Earnest Money Deposit (EMD) furnished by all unsuccessful tenderers will be returned as early as possible after the expiration of the period of tender validity but not later than 30 days of the award of the contract.

9.4 FORFEITURE OF EMD (if applicable)

(i) The Earnest Money Deposit (EMD) will be forfeited/vendor would be required to deposit the equivalent EMD amount as per Notarised Undertaking by MSE bidder, if the Tenderer withdraws or amends, impairs or derogates from the tender in any respect within the period of validity of his Tender.

(ii) The Earnest Money Deposit (EMD) will be forfeited/ vendor would be required to deposit the equivalent EMD amount as per Notarised Undertaking by MSE bidder, in case of the lowest/ matched bidder, fails to execute the contract agreement and / or deposit the Security Deposit within the stipulated time. Additionally, actions as stipulated in clause no. 18.1 will also be taken.

(ii) In both the above cases, the bidder will not be eligible to participate in the tender for same item for two years from the date of issue of letter of acceptance. The bidder will not approach the court against the decision of the CMSS in this regard.

10. OTHER CONDITIONS:

10.1 The details of the annual required quantity of ***items*** are shown in **Annexure-I**

(i) Central Medical Services Society (CMSS) will have the right to increase or decrease up to 50% for Schedule II, III, IV & V and 25% for Schedule I of the quantity of goods and/or services specified in the schedule of requirements without any change in the unit price or other terms and conditions at the time of award of contract.

(ii) In exceptional situation where the requirement is of an emergent nature and/ or it is necessary to ensure continued supplies from the existing vendors, the purchaser reserves the right to place repeat order up to 50% of the quantity of the goods and/or services contained in the running tender/contract up to a period of twelve months from the earliest date of Long Term agreement (LTA) at the same rate or a rate negotiated (downwardly) with the existing vendors considering the reasonability

of rates based on prevailing market conditions and the impact of reduction in duties and taxes etc.

(iii) The delivery of the additional quantity (as per ii above) shall be scheduled after the completion of the delivery of the original tendered quantity or on mutual consent between the supplier and CMSS.

10.2 (i) The rates quoted and accepted will be binding on the Tenderer for the full contract period of ONE year and any increase in the price will not be entertained till the completion of this contract period.

(ii) Any upward/downward revision (only during scheduled delivery period) in statutory taxes, levies will be allowed and benefit will pass on to supplier/purchaser.

(iii) Any increase in taxes and other statutory duties/levies after the expiry of the delivery date shall be to the supplier's accounts. However, the benefit of any decrease in these taxes/duties shall be passed on to the purchaser by the supplier.

(iv) The delivery of the additional quantity shall be scheduled after the completion of the delivery of the original tendered quantity.

10.3 In accordance to the notification the participating Micro and Small Enterprises (MSEs) in a tender, quoting price within the band of L 1 + 15% would be allowed to supply a portion of the requirement by bringing down their price to the L 1 price, in a situation where L 1 price is from someone other than an MSE. In exercising of the powers conferred in Section 11 of the Micro, Small and Medium Enterprises Development (MSMED) Act 2006, the Government has notified a new Public Procurement Policy for Micro & Small Enterprises effective from 9th November 2018. The policy mandates that 25% of procurement of annual requirement of goods and services by all Central Ministries / Public Sector Undertakings will be from the Micro and Small Enterprises. Government has also earmarked a sub target of 4% procurement of goods & services out of 25% from MSEs owned by SC/ST entrepreneurs and 3% to micro and small enterprises owned by women.

10.4 The Department of Pharmaceuticals under Ministry of Chemicals and Fertilizers has issued guidelines for implementation of the provisions of public procurement (Preference to Make in India) order (PPO) 2017 as desired by DPIIT on 16.09.2020 w.r.t public procurement of goods and services in medical devices vide order no F.No 31026/36/2016-MD dated 16.02.2021. The relevant provisions of DoP order dt. 16.02.2021 and DPIIT order dt. 16.09.2020 and all subsequent orders from time to time will apply in the instant case. Bidders are requested to submit a declaration indicating percentage of local content as per **Annexure-XVII**.

11. ACCEPTANCE OF TENDER

11.1 Technically responsive tenders will be evaluated based only on the "landed price" (all-inclusive price), i.e. Rate per Unit inclusive of all taxes, duties, transportation& other charges.

11.2 The evaluation for ranking shall be carried out on the basis of "all inclusive" prices of the goods offered for each schedule separately.

11.3 The purchaser reserves the right to accept or reject any bid, and to annul the bidding process and reject all bids, at any time prior to award of contract without assigning any reason whatsoever and without thereby incurring any liability to the affected bidder or bidders on the grounds of purchaser's action.

11.4 (i) CMSS or its authorized representative(s) has the right to inspect the factories of Tenderers, before accepting the rate quoted by them or before releasing any purchase order(s) or at any point of time during the continuance of tender and also has the right to reject the tender or terminate/ cancel the purchase orders issued and/or not to place further order, based on adverse reports brought out during such inspections. In such situation CMSS reserves the right to take other actions against the tenderer including forfeit of security deposit, debarring/blacklisting for appropriate period.

(ii) The Tenderer shall allow inspection of the factory at any time by a team of Experts/ Officials nominated by the Tender Inviting Authority for the purpose. The Tenderer shall extend necessary cooperation to such team in inspection of the manufacturing process, quality control measures adopted etc., in the manufacture of the items quoted. If Company/ Firm does not allow for any such inspection, their tenders will be rejected during the currency of the contract.

11.5 The acceptance of the tenders will be communicated to the lowest / matched tenderers in writing (through email), as per format of the Acceptance Letter given in **Annexure-IX.**

The Contract shall be issued from GEM as per their format. In addition to contract through GEM, the LOA, LTA and PO would be issued from CMSS e-Aushadhi platform and details mentioned in these documents will be considered for all purposes i.e. tender obligations, delivery completion and payment purposes irrespective of GEM contract whenever issued.

12. SECURITY DEPOSIT AND AGREEMENT

12.1 Security Deposit:

In accordance with Department of Expenditure Ministry of Finance notification dated 12.11.2020, the clause may be read as:

On being intimated about the acceptance of the tender the L1/Matched tenderer shall pay a Security Deposit at the rate of 3% of the total value of goods to be awarded. The Security Deposit amount, is to be deposited in the form of NEFT/RTGS/Fixed Deposit Receipt/Demand Draft (payable at New Delhi)/Bank Guarantee in favor of Central Medical Service Society.

Beneficiary Name: Central Medical Services Society
A/C No. 32719062216
Bank Name: SBIBank
Branch: Nirman Bhawan, Maulana Azad Road, New Delhi
IFSC Code: SBIN0000583

12.2 The Performance Bank Guarantee shall be valid for **....** days from the date of commencement.

LOA Submission	-15 days
Rate Valid	-365 days
Delivery period	-90 days
Shelf life	-365 x 2 Years
B.G. Extension	-60 days
	……. days

12.3 The lowest/ matched tenderer shall execute an Agreement on a non-judicial stamp paper of value of Rs.100/- (stamp duty to be paid by the Tenderer) within 15 days from the date of the intimation from CMSS informing that his tender has been accepted. The Specimen form of Agreement is available in **Annexure-X.**

12.4 The proceeds of the performance security shall be payable to the purchaser as compensation for any loss resulting from the supplier's failure to complete its obligations under the contract.

12.5 The performance security bond will be discharged by the purchaser after completion of the supplier's performance obligations including any warranty obligations under the contract.

12.6 Failure to deposit the performance security will attract clause 9.4.

13. METHODOLOGY FOR PLACING ORDERS

For placing orders the following procedures will be adopted:

13.1 After the Price Bid opening, the lowest offer will be declared as the L1 tenderer. CMSS reserves right to negotiate prices with L1 bidder in justified cases.

13.2 The Tenderer, who has been declared as Lowest Tenderer for certain item(s), shall within the tender issue of LOA (letter of acceptance) execute necessary Agreement for the supply of the allocated quantity of such items as specified in the Tender Document after depositing the required amount as Security Deposit and on execution of the agreement

such Tenderer shall supply goods on receipt of Purchase Orders. The format of LOA, agreement, Purchase Order is attached at **Annexure –IX, X, XI** respectively. Generally speaking, the draft art work should be given in technical specifications however, in those cases where draft artwork not given in tender specifications, the vendor must need to coordinate with respective programme division of ministry to freeze (get approval) for the art work. No extension would be given on this pretext.

13.3 If two or more than two Tenderers are declared as lowest suppliers for the same item(s)(i.e. emerge L1),such Tenderers shall execute necessary agreement as specified in the Tender Document on depositing the required amount as Security Deposit and on execution of the agreement such Tenderer will be eligible for placement of Purchase Orders for equal proportion of tendered quantities (50:50 or 33.33:33.33:33.33) for such item(s) for which they are declared as lowest (L1).

13.4 CMSS will counter offer the lowest rate (L1 rate) to other Tenderers in the order of their ranking i.e. L2, L3 and so on will be asked to match the L1 price.

13.5 CMSS will counter offer the lowest rate (L1 rate) to other Tenderers in the order of their ranking i.e. L2, L3 and so on will be asked to match the L1 price.

i. In order to maintain uninterrupted supplies, the CMSS will place orders with minimum of two suppliers for tendered product with 70% of the orders given to L1 and the balance 30% to the next Matched Lowest Tenderer.

ii. In case there is no L2 /matched bidder, balance quantity up to extent of quoted quantity or at most for balance 50% quantity can be offered to L1 bidder. Quantity beyond quoted quantity will be ordered on mutual consent.

iii. In case, L2 bidder/matched bidder refuses to accept the offered quantity, balance quantity up to extent of quoted quantity or at most for balance 50% quantity can be offered to L1 bidder. Quantity beyond quoted quantity (and including quantity in consideration in Clause No. 10.1 (i)) will be ordered on mutual consent.

iv. In case L1 bidder has quoted for 50% quantity, the balance quantity will be offered to L2 and L3 bidders for 30% and 20% quantity respectively.

v. In case there is no L3/matched bidder at 3rd position (i) above may be followed or balance 50% quantity may be offered to L2/matched bidder in case L1 does not agree to supply 70% of tendered quantity.

vi. In case of requirement of large quantities, CMSS may place orders with 3 suppliers in the ratio of 50:30:20, which will be indicated in the tender document at **Annexure-I**.

13.6 If the lowest supplier has failed to supply the required items within the stipulated time or within the extended time, as the case may be, CMSS may cancel such purchase orders

and on cancellation, CMSS *may* place Purchase Orders with the Matched Lowest Tenderer or to the other tenderers at the risk and cost of the defaulted supplier.

13.7 The supplier shall complete the supply of the items required by CMSS at the consignee destination mentioned in the schedule, within minimum required period as stipulated in order from the date of the orders.

13.8 The supplier shall supply the items at the specified destination and submit a copy of the Purchase Order, Delivery Challan and other relevant documents at the same destinations.

13.9 After supply of items at the specified destinations, the supplier shall submit Invoice (Original), Certificate of analysis (Batch Wise) and other relevant documents etc., at the Head Office, CMSS for claiming payment.

13.10 Subject to para (13.6) to para (13.9) above, CMSS will process the invoices submitted by the supplier and the payments against supply will be made within 60 days from the date of submission of all relevant documents to the CMSS provided the items supplied has been declared of STANDARD QUALITY, by the Empanelled Laboratory of CMSS.

13.11 Provision of Department of Expenditure, Ministry of Finance (No.F.1/4/2021-PPD, dated 18.05.2023) in respect of Concurrent application of Public Procurement Policy for Micro and Small Enterprises Order, 2012 and Public Procurement (Preference to Make in India) Order, 2017 shall be applicable.

14 SUPPLY / DELIVERYCONDITIONS

14.1 The supplier should acknowledge the receipt of the Purchase Order within 3 days of its receipt.

14.2 The supplies will be made in staggered quantities (if applicable) as detailed in **Annexure-I.**

14.3(a) The supplier shall supply the ordered quantity within minimum required period of 60 days (or as mentioned in LOA/PO) from the date of award at the destinations mentioned. If the above day happened to be a holiday for CMSS, the supply should be completed by 5.00 PM on the next working day. In case of non-execution of the order either partially or fully, CMSS reserves the right to cancel the purchase order or place fresh purchase orders on alternative source at the risk and cost of the default supplier. In such cases the CMSS, has every right to recover the cost and impose penalty including blacklisting of the supplier and the product.

(b) With the prior approval of CMSS, the supplier may continue to supply the unexecuted quantity after 60th day or after the delivery dates/schedule as mentioned in order with Liquidated Damages as specified in Clause 18 of the tender conditions on the delayed supplies.

(c) Supplies should be made directly by the tenderer and not through any other Agency/Dealer/Distributor.

(d) The Tenderer shall not, at any time, assign, or make over the contract or the benefit there of or any part thereof to any person or persons whatsoever.

14.4All goods must be of fresh manufacturing and must bear the dates of manufacturing and expiry. The bidder further warrants that all goods supplied will have, at least 5/6th of the minimum shelf life must remain at the time of delivery to the consignee. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the offered package.

14.5 For both items delivered to direct consignees & CMSS warehouses, the supplier should ensure that the items are delivered with the minimum shelf-life as mentioned in the tender document/Purchase Order failing which the consignees/CMSS WHs shall not accept the items. Further, the bidder's attention is invited that if they supply/deliver the items with short shelf-life as per tender/Purchase Order and even if direct consignees receive such items, the invoices shall not be processed by CMSS for payments. It is the sole responsibility of the bidder/vendor to deliver the items with minimum residual shelf-life as mentioned in the tender/Purchase Order.

14.6A Certificate of Analysis/ Performance Evaluation Report from manufacturer's own Quality Control Lab covering each batch delivered is to be submitted along with shipping documents.

The Certificate of Analysis shall include:
a) Generic name of the product
b) Batch No.
c) Pharmacopoeia Reference and/ or In-house method
d) Batch quantity
e) Date of manufacture
f) Expiry date
g) Date of test
h) Description
i)All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia and/or In-house method. Both the actual results and the limits for the individual tests should be given
j) Conclusion
k) Qualified signatures
as applicable
OR/And

The Performance Evaluation Report shall include:
a) Product name
b) Lot/Batch Number
c) Date of manufacture
d) Date of Expiry
e) Manufacturer's name
f) Number of samples tested
g) Testing principle

Information about reference used

h) TESTING PROCEDURE- Sensitivity, Specificity etc

i) Results
j) report number
k) Date of Analysis
l) Designation and signature of analyst
m) Authorized signatory of lab

The above-mentioned batch shall be manufactured in accordance with the applicable GMP/QMS regulations.

14.7 All the Tenderers are required to supply the product(s) with printed text "FP SUPPLIES – NOT FOR SALE" in red-colour on the strips, blisters, vials, ampoules & bottles and also on the external packings. The type/thickness of packing materials used in Blister packs may also be specified. Goods received without this print will not be accepted by CMSS/Consignee. Affixing of rubber stamp shall not be accepted. However, the approved art work will prevail.

14.9 If at any time the Tenderer has, in the opinion of the CMSS, delayed the supply of items due to one or more reasons related to Force Majeure events such as riots, mutinies, wars, fire, storm, tempest or other exceptional events at the manufacturing premises, the time for supplying the items may be extended by the CMSS at its discretion for such period as may be considered reasonable. However, such extension shall be considered only if a specific written request is made by the Tenderer within 10 days from the date of occurrence of such event. The exceptional events do not include scarcity of raw material, increase in the cost of raw material, electricity failure, labour disputes/ strikes, insolvency, and closure of the factory/ manufacturing unit on any grounds etc.

14.10 The supplier shall not be liable to pay LD/ penalty and forfeiture of security deposit for the delay in executing the contract on account of the extension of supply period on the ground of force majeure events.

15. PACKING

15.1 The items shall be supplied in the package specified in the Technical Specifications in **Annexure-I.**

15.2 The Weight, Volume & Dimensions of shipping cartons & intermediate packaging carton may be mentioned.

15.3 The packing shall be of a sturdy quality to provide adequate protection of the product for carriage to final destination, ***PAN INDIA*** including remote locations under adverse climatic and storage conditions and high humidity. Used cartons should never be used.

15.4 Products with specific temperature requirements will be packed and stored and delivered in appropriate conditions.

15.5 The packaging unit should be strong, able to be stacked to a height of 4 pallets as static storage and 2 pallets during transport, and resistant to puncturing.

15.6 Special attention of suppliers is invited to ensure the material is of good quality and is free from development of fungus/termites. In case fungus/termites develops within 15 days of delivery at specified locations, suppliers at their own cost would lift the entire batch from various locations and supply fresh replaced batches. For LD purposes the date of receipt of replaced batches would count. In addition, the expenses on pest control to be undertaken by CMSS would be borne by the tenderer.

16. QUALITY CONTROL

16.1 Quality Control is an essential part of the current procurement and it is the responsibility of the supplier to ensure quality assurance as per specifications/bid document. The products should conform to the standards as specified in **Annexure-I** of the Tender document.

16.2 The bidder/ supplier understand that the tendered item/items is/are critical health goods and the quality parameters of supplied goods are to be ensured during complete specified shelf life as indicated in technical specification/bid document/ official compendium. Bidder/Supplier also appreciate that failure in quality checks is serious default as it may derail entire programme and can also risk the life of users of supplied health goods.

16.3 CMSS will embark on stringent quality checks to ensure that tendered goods meet required standards throughout specified shelf life. For this purpose, CMSS reserves the right to carry necessary inspections/tests at any of, or any combination of or/ all of following stages:

(a) At Pre-Dispatch stage.
Pre-dispatch inspection for passing the quality of the goods, would be done before direct shipment to the consignees from supplier Warehouses (in India).

(b) At Delivery Stage: inspection done once the goods reach at consignee location and before taking over supplied goods in inventory.

(c) Post Delivery Surveillance: The Drugs/goods shall have the active ingredients and all other parameters at the prescribed level as indicated in official compendiums or technical specifications throughout the shelf-life period of the drugs/ goods. Quality Monitoring Activities may also be organized by CMSS post-delivery.

16.4 CMSS may engage the services of a Quality Control Agent & Quality Control Testing Laboratories for the purpose of Inspection & Quality Control.

16.5 **Inspection Methodology:**
PDI (Pre-Dispatch Inspection) as mentioned in **Annexure-I** means, the QA inspection/testing shall be completed prior dispatch of supplies direct to

consignees/CMSS warehouses. After completion of manufacturing process, the supplier should offer goods for PDI inspection in writing to Quality Assurance department of CMSS at least 10 days before proposed inspection date. The samples of each batch will be collected and sent to designated laboratories (Government/ Private Drugs Testing Laboratories) for testing as decided by the CMSS. Sample quantities will be borne by the supplier. However, handling and testing charges will be borne by CMSS. After the dispatch clearance of Quality Assurance department of CMSS, the supplier will deliver the items to the consignee or CMSS warehouses as per the schedule mentioned in the Purchase Order. If the supplier delivers/dispatches goods without completing the QA inspection, sample testing, dispatch clearance etc., CMSS shall not be processing the payments of such goods and the supplier will be solemnly responsible for the supply of such goods.

Non-PDI (Post Delivery Inspection) as mentioned in **Annexure-I** means, the supplier will deliver/dispatch the manufactured items (as per the technical specifications) directly to CMSS warehouses. The samples will be collected from the warehouse of CMSS and sent to designate Quality Control Labs in respect of supplied goods at any point during specified shelf life as per decision of CMSS. Sample quantities will be borne by Purchaser. Also, handling and testing charges will be borne by CMSS

In case of failure of batches during or at any stage (indicated at 16.5), the testing charges would be claimed for the defaulting vendor.

16.6 The supplies will be deemed to be completed only upon receipt of the quality certificates from the laboratories.
"Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be deemed to be rejected goods.

16.7 **At any of Inspection/testing stage,** samples which do not meet quality requirement/specifications shall render the relevant batches liable to be rejected. If the sample is declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be deemed to be rejected goods and the cost of entire batch paid will be recovered whether consumed fully/ partially. Besides action may also be initiated for debarring/blacklisting against supplier for suitable period.

16.8 In the event of the samples of Drugs/goods supplied fails in quality tests or found to be not as per specifications at any of testing stages (as mentioned in clause no. 16.3), depending upon the type, nature and seriousness of failure, consequences resulting from such default, availability of alternate sources, the CMSS is at liberty to either:

(i) Ask the supplier to replace the entire quantity of relevant batches, in addition to imposition of penalty @ 25% of batch supply cost or

(ii) To make alternative purchase of the items of Drugs from other approved suppliers or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier.

(iii) In addition to (i) or (ii) above, action to debar/blacklist the supplier for suitable period, as decided by CMSS may also be initiated. In addition to forfeiture of Performance Security Deposit.

(iv) In addition, the FDA/ Drugs Control Authority of concerned State will be informed for initiating necessary action on the Tenderer in their state. Security deposit will also be forfeited without any intimation.

(v) The decision of the CMSS or any officer authorized by CMSS, as to the quality of the supplied drugs, medicines, vaccines etc., shall be final and binding.

16.9 In case of supply of "NOT OF STANDARD QUALITY" goods to CMSS, the supplier shall make replace the rejected quantity by replacement within 2 months. If replaced batch is also found "NOT OF STANDARD QUALITY", the supplier shall be blacklisted for the product and no further supplies shall be accepted for the particular product category. In addition, the licensing authority will be informed for initiating necessary action on the supplier in their state. The security deposit will also be forfeited without any intimation. The warranty shall apply to replacement batches also. The decision of CMSS, as to the quality of the supplied goods shall be final and binding.

16.10 If the product is non-Pharmacopoeia, then the supplier must provide the in-house test method along with the required reference standards if asked for. The Master Formula of the products shall be provided whenever asked for.

17. PAYMENT PROVISIONS

17.1 No advance payments towards costs of items will be made to the Tenderer.

17.2 The payment towards supply of items to CMSS will be made either by means of Cheque or through RTGS (Real Time Gross Settlement System)/ Core Banking/ NEFT. The Tenderer shall furnish the relevant details in original **(Annexure-XII)** to make the payment through RTGS/Core Banking/NEFT. The payment will be in INR only.

17.3 All bills/ Invoices should be raised in duplicate and the bills should be drawn in the name of Central Medical Services Society, 2nd Floor, Vishwa Yuvak Kendra, Pandit Uma Shankar Dikshit Road, Chanakyapuri, New Delhi-110021or in the name of any other authority as may be designated. Supplier have to mention e- aushadhi PO No. and tranche/ lot on the invoice.

17.4 Payments for supply will be made only after completion of supply of Items ordered in the individual Purchase Order PROVIDED quality reports are acceptable. The CMSS shall endeavour to make payment within 75 days in respect of items requiring sterility tests and within 60 days in respect of items requiring non- sterility test from the date of submission of invoice or from the date of receipt of material, whichever is later along with all the relevant documents of tender.

17.5 Lot/Tranche/PO vise Part payments for supply will be considered only after completion of supply of at least 50% quantity ordered in the individual Purchase Order/Lot/Tranche PROVIDED original consignee receipts (or on GeM by consignee for the receipt, with original CRC to be submitted before next payment is released) are produced and the quality pass reports of Standard Quality on samples testing are received from approved laboratories of CMSS.

17.6 (i) Variations in prices will be admitted on account of increase or decrease in the Statutory taxes levies, such as customs duty, GST etc., on production of relevant government notification, but during scheduled delivery period only.

(ii) Any increase in taxes and other statutory duties/levies after the expiry of the delivery date shall be to the supplier's accounts. However, the benefit of any decrease in these taxes/duties shall be passed on to the purchaser by the supplier.

17.7 The supplier shall submit the following documents while claiming payments for supplies:

(a) Delivery challan along with the supplies (POD)
(b) Packing list
(c) Certificate of analysis along with the supplies (for each batch supplied).
(d) Itemized Invoice/ Bill in duplicate to CMSS Head Office.
(e) Such other documents as required by CMSS.
(f) Bidders are requested to submit their Original Invoice along with copies of Lorry Receipt/ Delivery challans and original Consignee Receipt Certificate (CRC) or such CRC to be uploaded on GeM by the consignee (if applicable) (with originals to be submitted before next payment is processed) as per format given in the tender document Annexure duly signed & stamped with other necessary documents for smooth processing of payment

17.8 Supplier will integrate with e- aushdhi system of CMSS and Supplier Interface Module in which selected bidders shall be required to enter/upload batch no, qty, mfg & expiry date, tranche no, invoice/challan copy etc. against PO no. Bidders are requested to submit their Original Invoice along with copies of Lorry Receipt/ Delivery challans or original Consignee Receipt Certificate (CRC) duly signed & stamped with other necessary documents for smooth processing of payment.

18. LIQUIDATED DAMAGES AND OTHER PENALTIES:

18.1 DELAYS IN SUPPLIER'S PERFORMANCE:

(a) Delivery of the goods and performance of services shall be made by the supplier in accordance with the time schedule specified by the purchaser in its LOA/purchase order. In case the supply is not completed in the stipulated delivery period, as indicated in the LOA/purchase order or in case of non-submission of Security Deposit within the stipulated time, purchaser reserves the right either to short-close/cancel this LOA/purchase order and/or recover liquidated damage charges. The cancellation/short-closing of the LOA/Purchase order shall be at the risk and responsibility of the supplier and purchaser reserves the right to purchase balance-unsupplied quantity at the risk and cost of the defaulting vendor. This purchase at the

risk and cost of the defaulting vendor can be at the same L1 cost of the tender or at higher cost and can be met through other vendors available in the present tender/contract or through any vendor from the open market. Any additional cost towards this risk purchase will be entirely borne/adjusted from running bills/demanded from the defaulting vendor.

(b) Repeated/habitual delays by the supplier in the performance of its delivery obligations shall render the supplier liable to any or all of the following sanctions; imposition of liquidated damages, forfeiture of its performance security, and/or termination of the contract for default and purchaser reserves the right to purchase balance-unsupplied quantity at the risk and cost of the defaulting vendor.

(c) If the suppliers are not completed in the extended delivery period, the purchase order may be short closed without any compensation to supplier and the performance security shall be forfeited.

(d) Quantum of liquidated damages assessed and levied by the purchaser shall be final and not challengeable by the supplier.

(e) Purchaser reserves the right to debar/blacklist the supplier for a suitable period who habitually failed to supply the goods/services in time. The decision of purchaser will be final and binding.

18.2 If the supply reaches the designated consignee places or CMSS Warehouse after scheduled delivery date mentioned in LOA/P.O, liquidated damages will be levied @ 2.5% per week to be applied proportionately on per day basis up to a maximum of 10% of P.O. Cost, irrespective of the fact that whether the CMSS has suffered any damage/ loss or not, on account of delay in effecting supply. If the last scheduled delivery day happens to be a holiday the supply will be accepted on the next working day without any penalty.

18.3 If the supply is received in damaged condition, it shall not be accepted. In case of damage in the packing only, the supply may be accepted subject to purchaser's decision and after levying a penalty which may be up to 5% of cost of package received with damaged packing.

18.4 Timely supply is the essence of contract/ Purchase order. The drugs/medicines/items ordered are meant for key National programmes & delay in supply can have the adverse impact on patients can derail the critical National level Disease Control Programme.

For each lot/tranche, the delivery schedule (dates) are mentioned in the LOA/PO. The vendors are to make every effort to complete the delivery of each Lot/Tranche as per delivery schedule mentioned in the LoA/PO.

In continuation to provisions of liquidated damages clause no. 18, it may be noted that:

If the vendor is not able to supply the total qty. of each lot/tranche within the scheduled delivery dates, the following may be noted:

a. The supplier will not dispatch/supply stocks/goods after the last date of scheduled delivery of the Lot/Tranche without PO amendment issued by procurement wing.

b. CMSS Warehouses/Direct consignees would not accept any stock/goods of any Lot/tranche beyond scheduled delivery period in absence of delivery extension PO amendment. E-Aushadhi software functionality has been made that CMSS WHs would not be able to receive the goods (GRN creation barred). These consignees will accept the stocks beyond scheduled delivery date only if Procurement wing has issued PO Amendment for delivery extension.

c. No extension of the delivery date would be granted suo motu unless the supplier specifically asks for it. However, in a few cases, it may be necessary to grant an extension of the delivery period suo motu in the interest of the administration. In such cases, the supplier should mandatorily submit clear acceptance of the extension letter.

d. If at any time during the currency of the contract, the supplier encounters conditions hindering delivery of goods, he shall promptly inform the concerned officer in writing. The supplier/vendor should raise request for delivery time extension well in advance i.e. at least 15 days before scheduled delivery date, should mention the likely duration within which it intends to complete the supplies and request for extension of delivery schedule accordingly. On receiving the supplier's communication, CMSS shall examine the proposal and on approval from the CA, may consider issuing delivery extension with/without LD provided: -

    i. That there are sufficient grounds for acceptance of such requests.
    ii. That there is no falling trend in prices for this item as evidenced from the fact that, in the intervening period, neither orders have been placed at rates lower than this contract nor any tender been opened where such rates have been received even though the tender is not yet decided.

e. In such cases, for delivery extension, PO amendment would be issued and the supplier should mandatorily supply the goods in extended time period.

f. Vendors are strictly advised not to deliver/transport any consignment reaching beyond scheduled delivery date without proper PO amendment issued by Procurement wing of CMSS, as it would not be received by consignees. CMSS shall not process any bills of such supplies if made beyond LOA/PO delivery schedule and without any PO amendment. For such actions, vendor would be solely responsible.

g. If the supplier again fails to deliver the balance quantity within extended time, CMSS reserves the rights/options to procure the undelivered quantity from other

approved supplier available in the contract at the same rates (with no financial implication and without regular tender to save time) or from open market at the risk & cost of the defaulting supplier (which may be with financial implication) or grant further extension if deemed fit.

Note- Vendors may note that it may not be necessary that each request for extension in delivery dates is accepted and scheduled delivery date is extended by CMSS.

h. After completion of complete LD period, if the supplier/vendor still fails to deliver goods (or a part of it) within extended timelines, actions against the supplier/vendor may be initiated for default in supplies as per terms & conditions stipulated in the tender including: -

i. CMSS reserves the rights/options to short close the delayed lot/tranche undelivered without going for purchase of balance quantity or

ii. Short close the delayed lot/tranche and go for procurement of the undelivered quantity from other approved supplier available in the contract at the same rates (with no financial implication) or from open market at the risk & cost of the defaulting supplier (which may be with financial implication).

For repeated defaults in delivery in same or various POs, to debar such habitual defaulting vendor for suitable period.

Note: - In event of Force majeure reasons/ situations as explained herein at clause no. 18, this clause would not be operated.

19. *WARRANTY*

19.1 The supplier shall warrant that goods/items to be supplied shall be new and free from all defects and faults in material, workmanship and manufacturing and shall be of the highest grade and consistent with the established and generally accepted standards for materials of the type ordered and shall perform in full conformity with the specifications. Supplier shall warrant that goods supplied will meet and maintain the technical specification throughout specified shelf life. The supplier shall be responsible for any defects that may develop under proper storage/ use, arising because of improper quality of API, Excipients in packaging material etc. manufacturing /packaging details from faulty materials, manufacturing or workmanship or otherwise and shall remedy such defects at his own cost when called upon to do so by the purchaser who shall state in writing in what respect stores is faulty.

19.2 The portion of clause 16.8 (i) to (v) would also apply in case the goods/items supplied doesn't match to shelf life.

19.3 Replacement under warranty clause shall be made by the Supplier within 60 days period, free of all charges at site including freight, insurance and other incidental charges.

19.4 If any defect is not remedied within a reasonable time the purchaser may proceed to procure such defective quantities at the Supplier's risk and cost from other tenderer or open market, but without prejudice to may other rights which the purchaser may have against the contract in respect of such defects.

20. DEDUCTION & OTHER PENALTIES ON ACCOUNT OF DELAYS/ DEFAULT/ TERMINATION/ PART CANCELLATION/SHORT CLOSURE:

20.1 If the samples do not conform to tender specifications, the Tenderer will be liable for relevant action under the existing laws and the entire stock in such batch has to be taken back by the Tenderer within a period of 30 days of the receipt of the letter from the CMSS. Such stock shall be taken back at the expense of the Tenderer. The CMSS has the right to destroy such "NOT OF STANDARD QUALITY DRUGS" if the Tenderer does not take back the goods within the stipulated time. The CMSS will arrange to destroy the "NOT OF STANDARD QUALITY DRUGS" after the expiry of 30 days mentioned above without further notice, and shall also collect demurrage charges calculated at the rate of 0.5% per week on the value of the drugs rejected till such time stipulated.

20.2 The CMSS will be at liberty to terminate, without assigning any reasons thereof, the contract either wholly or in part or short closed on 30 days' notice. The Tenderer will not be entitled for any compensation whatsoever in respect of such termination besides forfeiture of Security Deposit and purchaser reserves the right to purchase balance- unsupplied item at the risk and cost of the defaulting vendor.

20.3 For infringement of the stipulations of the contract, for non-performance/ compliance of contractual terms or for other justifiable reasons, the contract may be terminated either wholly, or in part or short closed. by the CMSS and the Tenderer shall be liable to pay for all losses sustained by the CMSS in consequence of the termination which may be recovered personally from the Tenderer or from his properties, as per rules besides forfeiture of Security Deposit.

20.4 In the event of making Alternative Purchase, as specified in in Clause 13(f), Clause 14.2(a), Clause 16.8 and other clauses herein, penalty will be imposed on the supplier. The excess expenditure over and above contracted prices incurred by the CMSS, in making such purchases from any other sources or in the open market or from any other Tenderer who has quoted higher rates and other losses sustained in the process, shall be recovered from the Security Deposit or from any other money due and become due to the supplier and in the event of such amount being insufficient, the balance will be recovered personally from the supplier as per rules.

20.5 In all the above conditions, the decision of the CMSS shall be final and binding.

21. SAVING CLAUSE

No suit, prosecution or any legal proceedings shall lie against the Tender Inviting Authority or any person for anything that is done in good faith or intended to be done in pursuance of the tender.

22. PROHIBITION OF INFLUENCING CMSS BY THE BIDDER:

(i) No bidder shall contact or influence the CMSS or its employees on any matter relating to its bid from the time of bid opening to the time the contract is awarded.

(ii) Any effort by a bidder to influence the CMSS in the bid evaluation, bid comparison or contract award decisions may result in rejection of the bidder's bid.

(iii) The bidder shall not make any attempt to establish unsolicited and unauthorized contact with the Tender Accepting Authority, Tender Inviting Authority or Tender Evaluation Committee after opening of the bids and prior to the notification of award and any attempt by any bidder to bring to bear extraneous pressures on the Tender Accepting Authority, Inviting Authority or Tender Evaluation Committee, shall be sufficient reason to disqualify the bidder.

(iv) Not withstanding anything contained in clause (iii) above the Tender Inviting Authority or the Tender Accepting Authority, may seek bonafide clarifications from bidders relating to the bids submitted by them during the evaluation of bids.

23. RESOLUTION OF DISPUTES

(i) The CMSS 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.

(ii) In case of a dispute or difference arising between the CMSS and a supplier relating to any matter arising out of or connected with this agreement, such dispute or difference shall be settled in accordance with the Arbitration and Conciliation Act, 1996. The venue of arbitration shall be New Delhi.

24. JURISDICTION

In the event of any dispute arising out of the tender such dispute would subject to the jurisdiction of the Civil Court within the city of New Delhi only.

Annexure -I

CENTRAL MEDICAL SERVICES SOCIETY
NEW DELHI- 110021

Online Tender of Procurement of Contraceptives for FP (Family Planning)

LIST OF PRODUCT & THEIR TECHNICAL SPECIFICATIONS

Sch. No.	Item Name	Total Tentative Quantity	Unit	Detailed Technical Specifications of the Goods/Drugs	Order Distribution Criteria	Inspection Methodology (PDI/Non-PDI)	Consignee Location
I	Emergency Contraceptive Pills (ECP)	40,50,000	Pack of 1 Pill	Annexure-IA	70:30 as per clause no. 13	Non-PDI Items (Inspection at Delivery Stage)	CMSS Warehouses
II	IUCD 380 A	18,00,000	Pieces				
III	IUCD 375	13,21,650	Pieces				
IV	Tubal Rings	7,64,100	Pairs				
V	Pregnancy Test Kits	81,72,000	Kits				

(Please refer technical specifications attached in Annexure-IA)

Delivery Terms:

(a) The delivery shall be on DDP (Destination basis).
Dummy consignee as CMSS Delhi is created to enter the quantity. However, vendors may please note that exact consignee wise allocation will be intimated along with Purchase Order.

(b) Delivery Schedule

Sch. No.	Item Name	LOT No.	Delivery Schedule
I	Emergency Contraceptive Pills (ECP)	I	27,49,668 Pack of 1 Pill to be delivered between 90 days from the date of issue of LOA
		II	13,00,332 Pack of 1 Pill to be delivered between 91-180 days from the date of issue of LOA
II	IUCD 380 A	I	11,25,500 Pieces to be delivered between 90 days from the date of issue of LOA
		II	6,74,500 Pieces to be delivered between 91-180 days from the date of issue of LOA
III	IUCD 375	I	8,73,771 Pieces to be delivered between 90 days from the date of issue of LOA

Sch. No.	Item Name	LOT No.	Delivery Schedule
		II	4,47,879 Pieces to be delivered between 91-180 days from the date of issue of LOA
IV	Tubal Rings	I	4,64,100 Pairs to be delivered between 90 days from the date of issue of LOA
		II	3,00,000 Pairs to be delivered between 91-180 days from the date of issue of LOA
V	Pregnancy Test Kits	I	47,12,500 Kits to be delivered between 90 days from the date of issue of LOA
		II	34,59,500 Kits to be delivered between 91-180 days from the date of issue of LOA

Annexure 1A – Technical Specification & Artwork
Annexure 1B – Consignee Location
Annexure 1C- CMSS Warehouses

Note: -

1) All the consignees receiving supplies should issue Consignee Receipt Certificate as per Annexure-XX (Copy attached) to supplier for payment.

2) Suppliers may note that supplies meeting the required residual shelf-life criteria (5/6 of the shelf life) will only be accepted by CMSS/Consignees.

Annexure-1A

Sch. I Emergency Contraceptive Pills (ECP)

EC PILLS

Annexure-9

Specification for Emergency Contraceptives Pills (ECP)

Specifications : I.P. 2014 (Indian Pharmacopoeia)

Against this enquiry, the procurement decision as well as the subsequent supply in pursuance to such decision shall be on the condition that Emergency Contraceptive Pills are manufactured out of the material of Levonorgestrel as specified in the IP. 2014. The supplier shall furnish a certification from the Drug Authority in the country of origin that the material offered by him meets the requisite standard of quality. Such certificate shall also be furnished with each batch supply for inspection by successful tenderer.

Note:-These quantity will be supplied to States/ UTs against Asha and Free Supply Scheme.

*** (As per specifications attached in Annex 1A)**

iii. The **identification mark** like manufacturer's name (initials), year of production and scheme Free Supply/ Asha supply/ Social Marketing (F/S), as the case may be, would be printed/ embossed on the tablet itself.

iv. The Batch No. would also be indicated in bar-code on the outer packaging in addition to it's indication in the alpha numeric form.

Packing and Marking:

c) The store should be packed as per details given in the relevant specifications. Each pack will have the following printed in indelible ink across each label. For Free Supply: "Free Central Government Supply Not for Sale and not for Export outside India" and for ASHA Supply: "Government of India supply, home delivery by ASHA, Rs. 2/- for a pack of EC Pills". The packing will also be marked as under

i) Nomenclature of the stores.

ii) Manufacturers name , Address and Licence No.

iii) Date of Manufacture, Expiry and Batch No.

iv) Quantity contained therein.

v) Inspection Note No. and Date.

vi) Any other particulars required under the Drugs and Cosmetics Act of India and the Rules framed there under.

vii) Artwork of the EC Pills for ASHA Supply and Free Supply should be approved by the Ministry before manufacturing the tablets.

Special Note:

i	The identification mark "initial" for Emergency Contraceptive Pills should be embossed on the tablet itself.
ii	The packing of the outer cases of Emergency Contraceptive Pills should bear batch numbers indicated prominently both in "Alphanumeric characters" and in Bar-code.

IUCD-380A

Annexure-10

Technical Specifications of Intra-Uterine Contraceptive Devices (IUCDs) – 380A

Appendix –A

STANDARDS FOR COPPER - T 380A

Definition: Copper-T 380A is a T shaped intrauterine device having a copper collar on each of the horizontal arms and a copper wire wound on to the vertical arm with dimensions as shown in figure I, with a plastic mono filament tied to the ball end of the vertical arm of the T. The T shall be dispensed with a plastic insertion tube and a solid rod having dimensions as shown in figure I, to facilitate insertion of the device in to the uterine cavity.

1.1 This standards, cover the shape dimensions, manufacturing specification and the finished product specifications required for intra uterine contraceptive device Copper-T 380A and its components.

2. References:

2.1 The following standards contain provisions which through reference in this text, constitute provisions of this standards. At the time of publications, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

IS No.		Title
3395:1997	:	Low density. Poly Ethylene (LDPE) and Linear Low Density Poly Ethylene (LLDPE) – materials for moulding & extrusion (2nd Version)
13360(part4/SecI): 1995	:	Plastics-methods of testing : part 4 Rheological properties: Section 1 determination of the melt mass flow rate (MFR) and the melt volume flow rate (MVR) of thermo plastics.

3. Procedure/specification for testing during manufacture:

3.1 Shape and dimensions

3.1.a The shape and dimensions of Copper-T 380A components are shown in Figure I.

3.1.b The flange as shown in figure shall be positioned so as to be at 70±5mm from T end on the insertion tube. The dimension of the flange given in the figure I are for guidance only.

3.2 Mass of Copper wire and collar

3.2a Mass of Copper wire:

The mass of the copper wire wound on the vertical frame of the T shall be 176±11mgs – Sampling Plan: Single Plan General Inspections level II – AQL 1%

3.2.b Mass of Copper Collar-

The mass of each copper collar fitted on the horizontal arm shall be 68.7±3mgs - Sampling Plan: Single Plan General Inspections level II – AQL 1%

3.3 Materials for Copper-T components

3.3.a The T shall be made of a compound obtained by blending low density poly ethylene (see IS 3395) and barium sulphate (20-24%) quality of $BaSO_4$ shall be as per IP /USP/BP/EP. The low density poly ethylene shall pass the extractable test as per Method A given in IS 12418(Part-4) and shall have melt mass flow rates between 1.8 to 2.2 g—per 10 minutes when tested according to the method in IS 13360 (part 4/Sec. 1). The blend of LDPE and $BaSO_4$ shall meet the requirements of the implantation test as per method B given in IS 12418(Part-4).

3.3.a.1 The lower end of the vertical arm of the T shall not deviate by more than 3mm from the central axis.

3.3.b. Solid Rod

The solid rod shall be made of polypropylene with approximately 0.5% pharmaceuticals grade titanium dioxide.

3.3.b.1 The solid rods with following shape structures shall be accepted:

a. Rod without having ball or fin
b. Rod with ball
c. Rod with fin

3.3.c Insertion tube

The insertion tube shall made of high density poly ethylene which shall pass the extractable tests as per pharmacopoeia requirements. The polyethylene shall be tested at the manufacturing stage. It shall have a melt mass flow rate between 0.6 to 0.8 g/10 minute when tested according to the method given in IS 13360(part4/Sec.1).

3.3.c.1 It is optional to have the marking on scale in cm on the insertion tube with a pharmaceutical grade material so that it does not produce any toxic effects when in contact with the body fluids.

3.3.d. Flange

The flange shall be made of ply vinyl chloride containing approx. 1% titanium di oxide and pharmacopeial grade "blue" or "yellow" (IP grade).

3.3.e. Tie (Thread)

The tie shall be made of high density polyethylene with approx. 1% titanium di oxide (IP

grade) or iron oxide to give white or dark colour respectively. The material shall pass implantation test when tested as per Method B. The tie shall be monofilament.

3.3.f. Copper wire/Copper Collar

The material of copper wire and copper collar shall be 99.99% pure and no other individual element shall be more than 50ppm. The manufacturer shall ascertain the purity of copper wire and copper collar used.

3.4 Dimensions

		Specification	AQL	Sampling Plan
3.4.a	**T frame**			
	Horizontal arm length	31.6mm-32.3mm	4%	**Single plan General inspection Level II**
	Horizontal arm diameter	1.5mm-1.7mm	1.5%	**-do-**
	Vertical arm length	35.7mm-36.2mm	4%	**-do-**
	Vertical arm diameter	1.4mm-1.6mm	1.5%	**-do-**
3.4.b	**Suture**			
	Diameter	0.25± 0.05mm	4%	**-do-**
3.4.c	**Copper Wire**			
	Diameter of Copper Wire	0.25± 0.005mm	2.5%	**-do-**
3.4.d	**Copper Collar**			
	Length	4.9 – 5.15mm	4%	**-do-**
	Outer diameter	2.17 – 2.22mm	1.5%	**-do-**
	Inner diameter	1.65-1.7mm	2.5%	**-do-**
3.4.e	**Insertion Tube**			
	Length	203-208mm	1%	**-do-**
	Inner diameter	3.6-3.8mm	1%	**-do-**
	Outer diameter	4.3-4.5mm	1%	**-do-**
3.4.f	**Solid Road**			
	Length of the stem	188-193mm	1%	**-do-**
	Tip diameter	2.5-2.8mm	1%	**-do-**
	Stem diameter	2.3-2.6mm	1%	**-do-**
3.4.g	**Flange**			
	Hole diameter	Approx. 4.14mm		

3.5 Flange Displacement force

Moulded flanges selected at random after 24hours of moulding when assembled on insertion tubes selected at random and allowed to age for 24 hours shall show a displacement force between 180-630 gms. This test should not be carried out in the finished product - Sampling Plan: Single Plan General Inspections level II – AQL 2.5%.

3.6 Flexibility

The standard flexibility test measures the deflection in mm when a 20gm weight is applied to the cross arm of the T for 30 seconds at a distance of 12mm from the stem of the T. T units are subjected to the test between 24 and 96 hours after moulding. Before measurements are made the Ts are equilibrated for atleast 6 hours at within $\pm 1.5^0$C of the temperatures they will encounter during measurements. Measurements made at other than 24^0C, but within the range 20^0C - 29^0C, may be corrected by subtracting 0.125 units for each degree above 24^0C and adding a similar amount for each degree below. Sample 50 units of moulded Ts from each batch. Not more than 5 of the 50 samples shall show a flexibility of less than 4.8mm or more than 6.5mm. None shall show a flexibility above 7.0mm. A batch shall be defined a units made with a single moulding mixture and in an uninterrupted manner except for momentary turn off.

3.7 Memory

Memory is measured in terms of recovery after acute flexation. The horizontal arms are folded and inserted to a depth of 6.35mm in a hole of 4mm diameter. They are allowed to remain in this position for 5 minutes and then removed and allowed to recover their shape under zero load for 1 Minute. The recovery of the arms must be such that the tips of
the arms are not displaced by more than 5mm from the horizontal. Test shall be conducted on 10 pcs. from a batch and if the average recovery is greater than 5.5mm then reject. If between 5 and 5.5mm then sample another 10 units and the average of the 20 tested shall be below 5mm.

4. Standards for the finished product

4.a Amount of Copper wire

The weight of the wire on the T arm shall be between 165-187mg. Sampling plan Single Plan General Inspections level II – AQL 1%.

4.a.1 The ends of the copper wire shall be round and shall not have any sharp point at the edges and the end of the wire shall not protrude out more than 0.25mm from the outer surface of the copper wire winding on T-Sampling Plan: Single Plan General Inspections level II – AQL 0.65%.

4.b Dimension and position of the copper collar

The outer diameter of the copper collar on the finished product shall be smooth and shall be between 2.05 – 2.11mm and shall be positioned at a distance of 5.4 ± 0.4mm from the ends of the horizontal arm of the T - Sampling Plan: Single Plan General Inspections level II – AQL 1.5%.

4.c Length of the Tie

The length of the Tie attached to the T arm shall be 100mm minimum from the ball end of the T - Sampling Plan: Single Plan General Inspections level II – AQL 2.5%.

4.d Strength of the Tie

Place the IUD in the tensile machine. The upper part of the IUD in the upper clamp and thread at a distance of 5cm from the attachment of the lower clamp. Apply the force steadily at a separation speed of 3.3 ± 0.3mm/sec (200 ± mm/min.). The thread shall not come out of the T or break a load of less than 9.5N - Sampling Plan: Single Plan General Inspections level II – AQL 0.65%.

4.e Pouch Burst Strength

Select one pouch at random from each 800 units of finished goods or at least a total of 32 units. Apply 60 mm Hg or equivalent air pressure inside the pouch section extending approximately 20cm beyond the added seal. The pouch shall hold the pressure for 30 seconds. No seal may open. If one opens repeat the sampling procedure. Not more than total of one seal may open in the combined sampling.

4.f Copper Collar Pull force

The Copper Collar on the finished product shall withstand a minimum pull force of 5N or 500 gm when a force is steadily applied at the rate of 200 ± 20mm/min. Sampling Plan: Single Plan General Inspections level II – AQL 4%.

4.g Sterility

The device shall meet the requirements of the sterility test as specified in the latest Indian Pharmacopoeia.

5. Batch size of Copper-T 380A shall not exceed 10,000nos.

The sampling shall be as per IS 2500 (Part 1) and the samples size shall be as per single normal plan general inspection level 1.

Hence when the batch size is between 3201 to 10000, then 120 pcs shall be sampled and if the batch size is between 10001 to 35000 then 165 pcs shall be sampled. The above said samples will be tested as follows;

	120 pcs.	**165 pcs.**
Amount of Copper Wire	80	125
Dimensions and position of Copper Collar	80	125
Length of Tie	80	125
Strength of Tie	80	125
Pouch Burst Strength	32	44
Copper Collar Pull Force	80	125
Sterility	20	20

In addition to the tests to be conducted on the finished product as above, the following tests are to be added-

Visual Inspection for (80/125)

(i) Package integrity
(ii) Pouch contents & integrity of components

6. In the case of supply and field samples, the sample packed in each inner carton shall not exceed 50 Nos.

Appendix – II

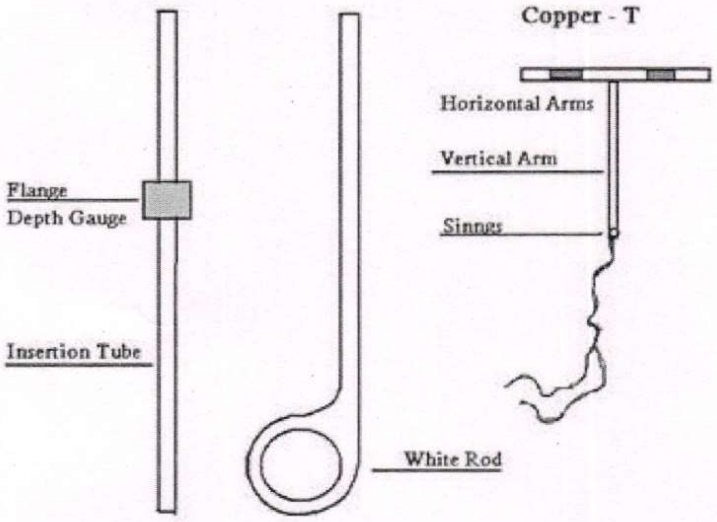
Inspection

a) The mode of offering supply and procedure adopted for sampling will be governed by specification No.IS:12418(Part-4) 2000.

b) A packing slip indicating the quantity of the contents in the box should invariably be kept in each box by the manufacturer/supplier. Quantities withdrawn from the boxes as samples for test should be indicated in the packing slip contained therein.

i) ISI specification is meant to be a reference to the latest issue of the said specification.

ISI specifications are priced publication and can be procured on payments from the Bureau Standards Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi-2 or from any of the regional offices.



IUCD - 375

Annexure-11

Specifications for
Copper Intra Uterine Contraceptive Device 375

1. Scope

1.1 The standard covers the shape, dimensions and other requirements for Copper intra-uterine contraceptive device, 375 and its components.

2. Normative references

The following Indian and international standards are necessary adjunct to this standard. However subsequent amendments have been made to the contents of the following references as per the requirements of this standard.

- *IS 3395:1984, Low density polyethylene materials for moulding and extrusion (First Revision)*
- *IS 12418 (Part 3): 1987, Intra Contraceptive device: Part 3 Packaging and labeling*
- *The Cu 375 Intra Uterine Contraceptive Device (IUD) WHO/UNFPA specification, 2011 (UNFPA/CPH/09/31)*
- *ASTM D638: 2010, 10 Standard Test Method for Tensile Properties of Plastics*
- *ASTM D790 – 10 Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials*
- *ISO 10993: Standards for evaluating the biocompatibility of a medical device prior to a clinical study. Special reference to ISO 10993:1; ISO:10993:5;*

3. Shapes and Dimensions

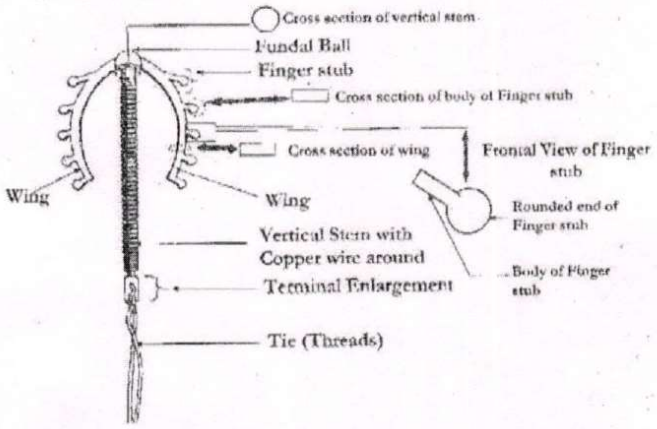
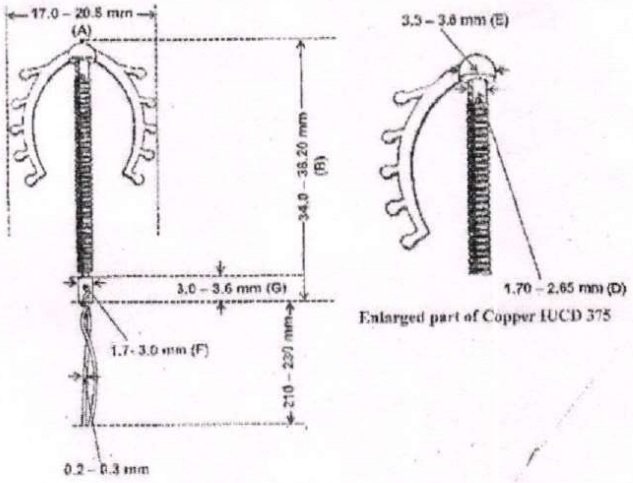


Figure1 Copper IUCD 375 (FRONTAL VIEW)



Enlarged part of Copper IUCD 375

Figure2 Copper IUCD 375 with dimensions

2

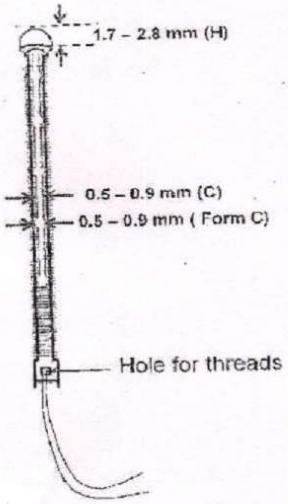
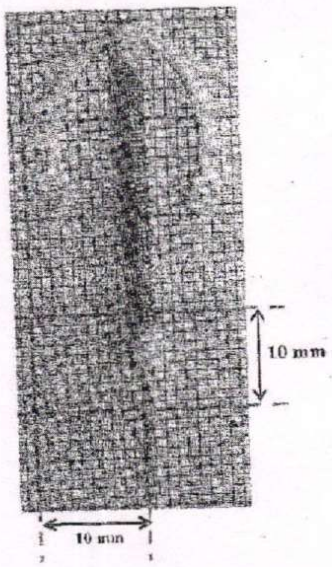
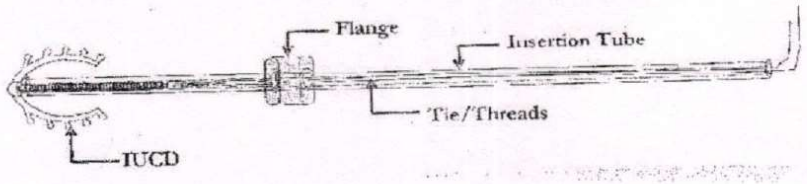


Figure3 Copper IUCD 375
(CORONAL VIEW)



Copper IUCD 375 (FRONTAL VIEW)



3.1 General Description

The IUCD as shown in Figure 1 represents the IUCD in the "Frontal plane" and IUCD as shown in Figure 3 is in the "Coronal plane".

The Copper IUCD 375 consists of a ∩ shaped frame comprising of two 'Wings' joined to an enlargement of the Vertical Stem termed the "Fundal Ball". The shape is loosely described as inverted 'U' shape. The shape shall be as shown in Figure1. The vertical stem has a terminal enlargement at the bottom to guard against cervical penetration. A small hole is located on the vertical stem to act as an anchor for the copper wire which over vertical stem. A filament is tied in a knot through a small hole in the terminal enlargement to provide two equal length marker threads (termed as "Tie"), as a means to locate and remove the device. There will be 5 'Finger stubs' on both wings.

The device is supplied with a tubular insertion as shown in Figure 4. A movable plastic flange is positioned on the insertion tube to assist in positioning the IUCD correctly in relation to the uterine fundus during insertion thus minimizing of perforation of the uterus.

The IUCD device with the insertion instrument is pre-positioned ready for insertion as shown in Figure 5 is supplied sterile within a sealed primary pack. The IUCD and associated components are made up of:

- **Frame –** Low-density polyethylene(LDPE) or High Density Polyethylene or High Density Polyethylene (HDPE) + ethylene vinyl acetate copolymer
- **Wire wound around Vertical stem –** Copper
- **Tie –** Nylon
- **Insertion Tube –** HDPE (high Density Polyethylene) or gamma radiation resistant Polypropylene
- **Flange –** Polyvinyl chloride
- **Package** - Polyester and polyethylene

FRAME

Material

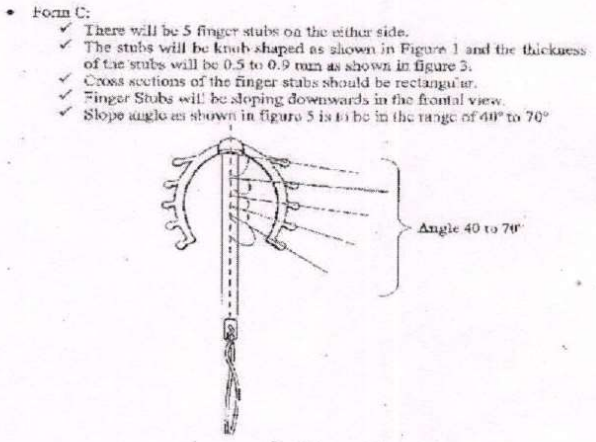
The Frame shall be made from Low-Density polyethylene (LDPE) or Gamma Radiation resistant high Density Polyethylene (HDPE) + ethylene vinyl acetate copolymer free of stabilizers having a minimum tensile strength of 15 MPa and 2% secant flexural modules in the range 133.5 MPa to 180.6 MPa.
The material shall be blended with 20% to 24% barium sulphate with a particle

size of 95% less than 10 micron. The implant shall pass the cytotoxicity tests, implantation test and extractable test as per the international standards.
The finger stubs shall be moulded together with the wings and have the same material as that of the frame.

Dimensions and Form

- Dimension A: Width of horizontal wings shall lie between 17.00 to 20.5 mm
- Dimension B: Vertical stem length shall lie between 34.00 to 36.20 mm
- Dimension C: Thickness of wings shall lie between 0.5 to 0.9 mm
- Dimension D: Diameter of vertical stem (before winding) shall lie between 1.70 o 2.65 mm, a uniform over the length of the stem between fundal ball and terminal enlargement.
- Dimension E: Fundal ball should be solid hemisphere with diameter 3.3 to 3.6 mm
- The size of the terminal enlargement should be in the range of:
  Dimension F: Lateral- 1.7 to 3.0 mm
  Dimension G: Vertical – 3.0 to 3.6 mm
- Dimension H: Height of the fundal ball shall lie between 1.7 to 2.8 mm
- Form A: Hole for anchoring an end of the copper wire may be provided.
- Form B: Cross section of the wings should be rectangular.

Figure 5: Measurement of slope angle of finger stubs



Requirements and Tests

The material of the frame to meet the ISO 10993 standards for chronic biomedical implants specifically the ISO 10993:5 Cytotoxicity test, 10993:18 Implantation and extractable test must give comparable biocompatibility as USP grade negative control.

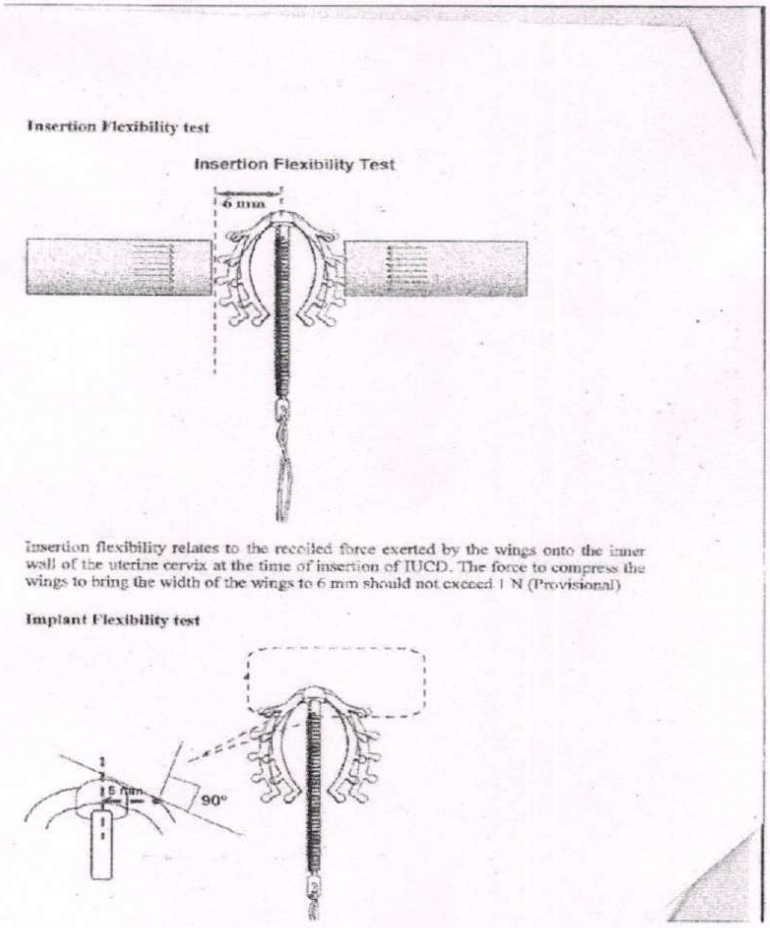
Memory test

Memory is measured in terms of recovery after acute flexion quantified by restoration of width of the horizontal wings (Dimension A). On removal and

observation after 1 minute of the frame following an insertion into 6 mm internal diameter tubing for 2 minutes. Dimension A to be no less than 25% less than the original pre stressed width of the wings (Provisional).

Insertion Flexibility Test

Insertion Flexibility Test



Implant flexibility relates to the recoiled force when the wings are compressed by uterine contractions under normal placement of the IUCD within the uterus. The force is quantified by the bending of the wings on application of the bilateral force perpendicular to the wings at a point where a horizontal line of length 6 mm is calculated from the base of the first finger stub to the centre of the fundal ball. The force required to displace the point towards the vertical stem by 1.5 mm is to be in the range of 7-12 N (Provisional).

Frame shall be ratio-opaque and shall have two ties for easy removal

Ash Content

Ash Content (as barium sulphate) of moulded frame shall be between 20-24 percent when tested in accordance with the method specified in latest Indian Pharmacopoeia.

Sterility Test
When Copper 375 is distributed as sterile, it shall be capable of meeting the requirements of any suitable sterility test specified in latest Indian Pharmacopoeia.

WIRE
The Copper wire should be wounded tightly around the vertical stem with the loops even spaced. "Single" or "Double" wounding format may be used. The two ends of the copper wire are so closely positioned on the vertical stem surface that there are no projections of the wire end.

Material
The wire shall be made from 99.99% pure copper.

Dimensions
Copper wire of should be of 349 – 392 mm2 surface area and of diameter 0.38 to 0.41 mm
The mass of copper wire wound shall be 310 mg.

TIE (THREADS)

Material
The thread shall be made from Polyamide Nylon 6 or polyamide nylon 66 monofilament thread. The material shall pass ISO 10993 test as applicable for chronic implantation.

Dimension
Thread Length
Thread length shall be 210 to 230 mm.
Colour of the thread should be medical grade green.

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

Thread dimension
The thread shall be made of Nylon of diameter 0.20 to 0.30mm.
Tensile strength of the thread shall be more than 9.5 N for a force applied for 30 S.

Extractables test
The thread shall pass currently applicable USP extractable test class II and shall be evaluated for biological safety in accordance with ISO 10993-1: 2003 requirements for mucosal membrane contact devices intended for permanent contact.

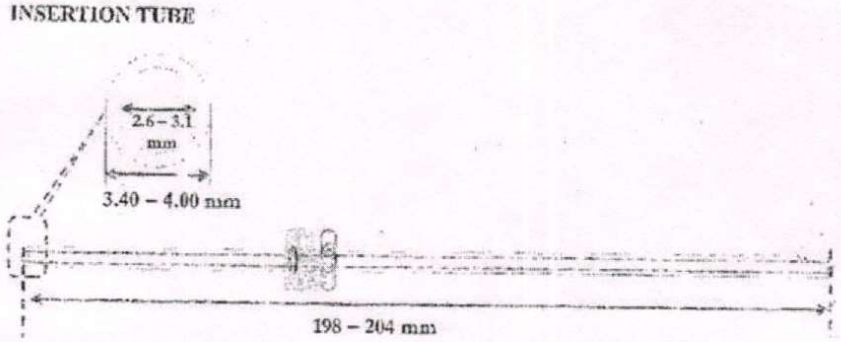


Figure 6: Insertion Tube Dimensions

Material
The insertion tube shall be made of HDPE (High Density Polyethylene) or gamma radiation resistant Polypropylene. The material shall pass the 10993:18 Implementation and extractable test and must give comparable biocompatibility as USP grade negative control

Dimension
Length must lie between 198 to 204 mm.
Internal Diameter must lie within 2.6 to 3.1mm.
Outside Diameter must lie within 3.40 to 4.00 mm (As shown in Figure 6)

Requirement
The insertion tube must slip out of the tie and vertical stem without exerting excessive drag force on the frame when insertion tube is pulled in a direction axial to the vertical stem and away from the fundal ball.

Test
When gripping the fundal ball, the frame and insertion tube assembly is held in a position with the vertical stem being vertical and the fundal ball being topmost the insertion tube should slip out virtue of its own weight.

FLANGE

FLANGE

Material
The flange shall be made of polyvinyl chloride containing titanium dioxide.

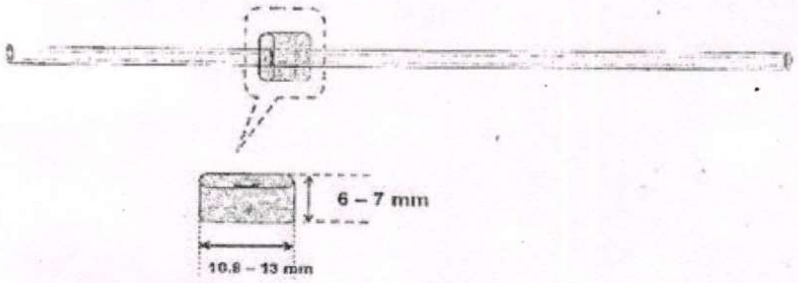


Figure 7: Insertion Tube with Flange and Flange Dimensions

Dimension
The lateral length of the flange shall be in the range of 10.9 to 13 mm (as shown in Figure 7).
The vertical length of the flange shall be in the range of 6 7 mm.
Diameter of central hole shall be chosen and specified with a tolerance to achieve the flange displacement force. The shape and dimensions of the central hole may be changed to facilitate meeting the specified flange displacement force.

Flange Displacement Force
Flange selected at random is placed on the insertion tube selected at random and allowed to age in place for minimum of 24 hours. The resistance to displace the flange by a steadily applied force shall be between 1.8-10 N.

PACKAGING AND LABELING
The packaging shall be done in film pouch. Double cover packaging preferred for withstanding adverse storage conditions.
Continuous pin hole free Gamma radiation resistant polymer films shall be used. Manufacturers shall select films that reduce the risk of tarnishing the copper & withstand extremes of storage conditions. For optimum protection against tarnishing continuous pin hole free polyester-polyethylene laminate or other material giving equivalent or better protection may be used.

Sealed Pouch
IUCD shall be packed in individual sealed pouches.

Sealed Pouch Integrity
Sealed pouch integrity shall be tested according to ASTM D3078:1994 (standard test method

for determination of leaks in flexible packaging by bubble emission).
The integrity is to be maintained under test exposure to an environment of temperature 60 deg. and 80% relative humidity for a period of 12 hrs.

Sealed Pouch Peel Strength
When tested according to ASTM F 88: 2000 (Standard test method for seal strength of flexible barrier materials) the peel force shall be not less than 4 N and not greater than 17 N. when a double cover packaging is used & the pealable inner cover is not the primary barrier the peeling force of the inner packaging will be in the range of 4N-17 N. The outer cover of a double layer pouch is to be "tear open".

Labelling and Inserts
Information required in accordance with ISO 7439: 2002 including information intended for the women shall be provided in accordance with the contractual requirements agreed with the purchaser.
The Expiry Date is the date after which the product cannot be inserted.
The Expiry shall be printed on the sealed pouch/ID card 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 5 years from the date of insertion.

Printing
All printing shall be clear and readily legible.

Cleanliness
The device, insertion tube, flange and any insert such as instructions included in the pack shall be free of visible particulate matter and cutting should be non-adherent.

Pouch Peeling Force
The packing pouch shall peel off when a force of 4 to 17 N is applied on both the edges of the pouch.

Product Shelf Life before Insertion
The maximum permitted shelf life for storage of the device prior to insertion is 4 years.

General Requirements
The materials of which the frame, insertion tube, flange and tie are made shall be sufficiently resistant to the unintended influence by body fluids and tissues, and shall be biologically compatible without causing undue/ unacceptable allergic, toxic or inflammatory reaction.

The tie or thread attached to the frame shall be monofilament which is easily feelable after the insertion of the Copper IUCD375.

Copper IUCD 375 shall be free from sharp edges, rough surfaces and shall be finished smooth.

Copper IUCD 375 when inserted shall produce an acceptable level of efficacy and minimal incidence of adverse reactions.

Sch. IV Tubal Rings

Tubal Ring

Annexure-12

Specification for Tubal Rings

(Undertaking should be given by the manufacturers that Implantation Test will be done by the manufacturers)

Technical Specifications of Tubal Rings under Family Welfare Programme:

Specifications: IS 13009:2000 (relevant IS enclosed).
Units: Pair
Life: 4 Years

Packing and Marking :

The store should be packed as per details given in Specifications IS-13009:2000. The pouch should be made of tyvek on one side and Transparent Polyester Polyethylene film on other side, as per past practice. Each will have to following printed in indelible ink across each label '**CENTRAL GOVERNMENT SUPPLY: NOT FOR SALE'.**

The packing will also be marked as under

i) Nomenclature of the stores.

ii) Manufacturers name, Address and License No.

iii) Date of Manufacture, Expiry and Batch No.

iv) Quantity contained therein.

v) Inspection Note No. and Date.

vi) Any other particulars required under the Drugs and Cosmetics Act of India and the Rules framed there under.

Indian Standard

CONTRACEPTIVE DEVICES — TUBAL RING — SPECIFICATION

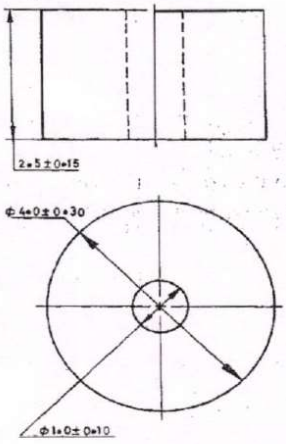
(First Revision)

1 SCOPE

1.1 This standard specifies the dimensions and other requirements of tubal ring, a tubal ligation device.

2 SHAPE AND DIMENSIONS

The shape and dimensions of tubal ring shall be as shown in Fig. 1.



All dimensions in millimetres.

FIG. 1 TUBAL RING

3 MATERIAL

The tubal rings shall be made from silicone rubber of medical grade which shall pass the extractables test according to the method given in Annex A and implantation test as given in Annex B.

4 REQUIREMENTS

4.1 The tubal rings shall be cut at right angle (maximum 5° angulation allowed) and shall be round without any fibrous protrusions at the outer and inner surfaces.

4.2 The silicone rubber tube of which the tubal ring is made shall not degrade by prolonged exposure to the biological environment or by procedure of sterilization, shall be sufficiently resistant to unintended influence by the body fluids and tissues and shall be biologically compatible without causing allergic, toxic or inflammatory reaction.

4.3 Tubal ring when loaded on the fallopian tube shall produce an acceptable level of efficacy and minimal incidence of adverse reactions.

4.4 The tubal ring shall be radio-opaque.

4.5 The tubal ring shall meet the requirements for stress properties as given in 5.1 and 5.2. When loaded on the fallopian tube the tubal ring shall have necessary memory for its inner diameter as per requirement given in 5.3 to compress the fallopian tube.

4.6 The tubal ring shall be stored at a temperature ranging from 0 to 50°C.

5 TESTS

5.0 All the tests on the tubal ring shall be carried out on the final product after sterilization.

5.1 Fracture Test

5.1.0 This test is used to determine the load at fracture (maximum load) during fracture test and elongation at maximum load. From the value of elongation at maximum load strain capacity is also calculated. This test shall be done very stringently.

5.1.1 The test is performed on a tensile testing machine with special adapters to hold two 'U' shaped steel clips of 1.35 ± .01 mm diameter. The crosshead separation speed is kept at 100 mm per minute.

5.1.2 To test the ring, position the tubal ring on two 'U' shaped steel grips and insert these grips into two adapter tubes, one attached to the fixed crosshead and other to the moving crosshead. The jaws are now separated and the load is measured with the help of a load cell and the values for load and displacement are recorded on a chart recorder. The strain capacity is calculated as follows;

$$\text{Strain capacity (percent)} = \frac{ED - 5.5}{5.5} \times 100$$

where *ED* is equivalent diameter which can be calculated as follows:

$$ED = \frac{2 \times DSPL + 6.94}{3.14}$$

where *DSPL* is the separation of jaws at break.

5.1.3 The test shall be carried out on 40 pieces of tubal rings drawn as sample for a batch size up to IO 000.

5.1.4 The load required to break the ring shall be 2. 1 kg, minimum. The displacement at peak load shall be 560 percent, minimum. The strain capacity shall range between 20 and 80 percent. For each parameter, out of 40 rings tested, not more than one ring shall have values outside the range.

5.2 Friction Force Test

5.2.0 This test is used to determine the force required to load the tubal ring on a standard laparocator.

5.2.1 This test shall be performed on a compression testing machine. A metal disc with a tube like projection of 5.5 mm outer diameter in the centre which can hold the dilator cone is placed on the compression plate whereas an adapter which can hold the guide is attached to the moving head. The crossheads are brought closer with a speed of 100 mm/min. To test the force, the tubal ring is loaded on the dilator cone using water as lubricant and the guide is brought right at the top of the dilator cone. The jaws are now moved closer and the load is measured with the help of a compression cell.

5.2.2 The test shall be carried out on 40 pieces of tubal rings drawn as sample from a batch size up to 10 000.

5.2.3 Out of 40 rings tested, the force required to load a tubal ring shall not exceed 3.5 kgf in more than one ring.

5.3 Memory Test

5.3.0 This test determines the capacity of the tubal ring to recover the inner diameter after stretching to 5.5 mm for an extended period.

5.3.1 For this purpose, the tubal ring shall be kept loaded on a standard laparocator for a period of 30 minutes and then removed and allowed to recover its inner diameter under unstretched condition for one minute. The test shall be carried out on 40 pieces of tubal rings drawn as sample from a batch size up to IO 000.

5.3.2 The recovery of the inner diameter shall be such that the increase in the inner diameter does not exceed 25 percent of the original diameter.

5.4 Fatigue Test

5.4.0 This test determines the ability of the tubal ring to maintain its mechanical structure even after repeated loading and unloading on the tubal ring/band applicator or equivalent jig fixture.

5.4.1 For this purpose, the ring shall be loaded on a tubal ring/band applicator or equivalent jig fixture and after keeping it loaded for 20 minutes, it is unloaded. The process of loading and unloading is repeated on the same ring for four times after a gap of one minute between each cycle. The ring is observed for cracks and breakage.

5.4.2 The test shall be carried out on ten pieces of tubal rings drawn as sample from a batch size up to IO 000.

5.4.3 The tubal ring shall neither break nor develop any crack.

5.5 Sterility

When tubal ring is supplied as sterile, it shall be capable of meeting the requirements of any suitable sterility test method specified in Indian Pharmacopoeia.

6 LABELLING AND MARKING

6.1 Printing and illustrations shall be clear, neat, legible and indelible. The label shall be free from gross particulate matter and cuttings shall be non-adherent.

6.2 Each package shall be marked with the following:

a) Identity of the source of manufacture;
b) The batch number;
c) The method, month and year of sterilization;
d) Storage directives;
e) Use before (specify month and year); and
f) Each individual package shall carry the following text:
   i) *Warning* — Sterile unless package is opened or damaged.
   ii) The tubal ring should be held on the applicator preferably for 5 minutes but in any case not more than 15 minutes.

7 SAMPLING

7.1 Lot

All the tubal rings of the same material and produced under similar conditions of manufacture shall be grouped together to constitute a lot which shall not exceed 10 000.

7.1.1 Unless otherwise agreed to between the purchaser and the supplier, the procedure given in

IS 2500 (Part I) 'Sampling inspection procedures: Part I Attribute sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection (second *revision)* shall be followed for sampling inspection.

8 PACKAGING

8.1 One pair of tubal ring shall be packed in peel open pouch/blister pack with seal width 2 mm, minimum. The pouch/ blister pack, once opened, shall not reseal.

8.2 Each -pouch/blister pack shall ensure:

a) adequate protection of the contents during normal handling, transit and storage for a period of four years;

b) maintenance of sterility of the contents under dry, clean and adequately ventilated storage conditions at temperature ranging from 0 to 50°C;

c) minimal risk for contamination of the contents during removal from the pouch/ blister pack; and

d) that the pouch/blister pack once opened cannot-be resealed.

8.3 Each pouch/blister pack shall have a suitable sterilization indicator affixed on it to ensure its sterilization.

ANNEX A

(*Clause* 3.1)

EXTBACTABLES TEST

A-I To find the suitability of the tubal ring material intended for use inside the human body, the ring material has to be tested for its extractables from systemic injection test (intraperitoneal and intravenous) and intracutaneous test. The procedure provides for testing the reaction of living animal tissue and of normal animals to the presence of extract of the material.

A-2 APPARATUS

A-2.1 **Autoclave**

Capable of maintaining a temperature of 121° ± 0.5°C equipped with a thermometer, a pressure gauge, a vent cock, a rack adequate to accommodate the test containers above the water level and water cooling system that will allow for cooling of the test containers to about, but not below 22°C immediately following the heating cycle.

A-2.2 **Oven**

Preferably a forced circulation model that maintains operating temperatures of 50°C or 70°C within ± 1°C.

A-2.3 **Extraction Containers**

Use containers, such as ampules or screw-cap culture test tubes, of borosilicate glass. If culture test tubes are used, they shall be closed with screw caps having suitable rubber liners. The exposed surface of the rubber liner is completely protected with an inert solid disk 0.05 to 0.075 mm in thickness. A suitable disk may be fabricated from a polytetrafluoro-ethylene resin.

A-3 PREPARATION OF APPARATUS

A-3.1 Clean all glassware thoroughly with chromic acid cleansing mixture, or if necessary with hot nitric acid, followed by prolonged rinsing with water. Clean cutting devices by an appropriate method (for example successive cleaning with acetone and methylene chloride) prior to use in subdividing a specimen. Clean all other equipment by thorough scrubbing with a suitable detergent and prolonged rinsing with water.

Render the containers and devices used for extraction, and in transfer and administration of test material, sterile and dry by a suitable process.

NOTE — If ethylene oxide is used as the sterilizing agent, allow adequate time for complete degassing.

A-3.2 Procedure

A-3.2.1 *Preparation of Sample*

From a sample of silicone rubber tube, use a portion equivalent to a total surface area of 60 cm^2 or 4 g by mass; subdivide into pieces of approximately 5 cm in length. Remove particulate matter, such as lint and

free particles by treating each subdivided sample as follows:

Transfer the subdivided sample to a clean, glass-stoppered, 100 ml graduated cylinder of Type I glass (highly resistant borosilicate glass) and add about 70 ml of water for injection. Agitate for about 30 seconds, and drain off the water, repeat this step, and dry those pieces prepared for extraction with vegetable oil in an oven at a temperature not exceeding 50°C.

NOTE — Do not clean the sample pieces with a dry or wet cloth or by rinsing or washing with an organic solvent, surfactant, etc.

A-3.2.2 *Extracts*

A-3.2.2.1 Place two properly prepared samples of the silicone rubber tube to be tested in separate extraction flasks, and add to each flask 20 ml of the appropriate extracting medium. Repeat these directions for each extracting medium required for testing. Also prepare one 20 ml blank of each medium for parallel injections and comparisons. Extract by heating in an oven at 70°C for 24 hours. Allow adequate time for the liquid within the container to reach the extraction temperature.

A-3.2.2.2 Cool to about room temperature but not below 22°C, shake vigorously and decant each extract, using aseptic precautions, into a dry, sterile vessel. Store the extracts at a temperature between 22°C and 30°C and do not use for tests after 24 hours. Of importance are the contact of the tube and the time and temperature during extraction, the proper cooling, agitation, and decanting process, and the aseptic handling and storage of the extract following extraction.

NOTE — No extract should be stored at any time at a temperature below 22°C.

A-4 SYSTEMIC INJECTION TEST

A-4.1 Test Animal

Use healthy, not previously used albino mice weighing between 17 g and 23 g. For each test group use only mice of the same source. Offer water and food commonly used for laboratory animals and known with respect to composition, ad *libitum*.

A-4.2 Procedure

Inject each extract of the sample and the corresponding blank, into groups of 5 mice each in the amount and by the route set forth in Table 1. Observe the animals immediately after injection, again 4 hours after injection and not earlier than 24, 48 and 72 hours, respectively, after injection. If during the observation period none of the animals treated with the extract of the sample show a significantly greater reaction than the animals treated with the blank, the sample meets the requirements of this test.

Table 1 Amounts and Routes and Systemic Injection of Extracts and Blanks

Extract or Blank	Dose (per kg)	Injection	
		Route	Rate (ml/second)
Sodium chloride injection	50 ml	Intravenous	0.1
1 in 20 solution of alcohol in sodium chloride injection	50 ml	Intravenous	0.1
Polyethylene glycol, 400	10 g	Intraperitoneal	
Vegetable oil	50 ml	Intraperitoneal	—

NOTES

1 Agitate each extract vigorously prior to withdrawal of each injection dose, to ensure even distribution of the extracted matter.

2 If any animal treated with the sample shows slight signs of toxicity, and not more than 1 animal shows gross symptoms of toxicity or dies, repeat the test using groups of 10 mice each. On the repeat test, the requirements of the test are met, if none of the animals treated with the sample shows a significantly greater reaction than that observed in the animals treated with the blank.

3 The extract prepared with polyethylene glycol and blank are diluted with sodium chloride injection in ratios 1:4.1 *w/v* and 1:7.4 *w/v* for systemic and intracutaneous tests respectively.

A-S INTRACUTANEOUS TEST

A-S.0 This test is designed for the evaluation of extracts of a plastic material in rabbits.

A-5.1 Test Animal

Select healthy, thin-skinned albino rabbits not previously used for any test, whose fur can be clipped closely and whose skin is free from mechanical irritation or trauma. In handling the animals, avoid touching the injection sites during observation period.

A-S.2 Procedure

On the day of the test, closely clip the fur on the animal's back on both sides of the spinal column over a sufficiently large test area. Avoid mechanical irritation and trauma. Remove loose hair by means of vacuum. If necessary, swab the skin slightly with diluted alcohol, and dry the skin prior to injection.

Inject intracutaneously 0.2 ml of each extract of the sample at 10 sites on one side of each of two rabbits. Similarly, at five other sites on the other sides of each rabbit inject 0.2 ml of the corresponding blank. Examine the injected sites 24, 18 and 72 hours after the injection for gross evidence of tissue reaction such as erythema, edema, and eschar. To facilitate the examination, swab the skin lightly with diluted alcohol, and clip the fur, if necessary. Rate the

observation on a numerical scale for the extract of the sample and for the blank, respectively using Table 2.

A-5.2.1 The requirements of the test are met if the average for the sample is not significantly greater than that for the blank.

NOTE Agitate each extract vigorously prior to withdrawal of each injection dose, to ensure even distribution of the extracted matter.

A-5.3 If the result is doubtful, repeat the test using fresh extract in three more rabbits. The requirements of the test are met if on the repeat test the average for the extract of the sample is not significantly greater than that for the blank.

Table 2 Evaluation of Skin Reaction
(Clause A-5.2)

Erythema and Eschar Formation	Value
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythma (beet-redness) to slight eschar formulation (injuries in depth)	4
Edema Formation	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (raised approx 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond the area of exposure)	4

ANNEX B

(Clause 3.1)

IMPLANTATION TEST

B-1 This method of test is designed to provide information on the effects of direct contact of a test material with living tissues when implanted into the paravertebral muscle of the rat/rabbit for a period of 14 days.

B-1.1 This method of test is employed for plastic materials which are intended for long term use - covering a period from a few months to permanent use - within the body tissue.

B-2 DEFINITIONS

B-2.0 For the purpose of this test the following definitions shall apply.

B-2.1 **Final Product**

Medical device in its ready-for-use state.

B-2.2 **Test Material**

The final product or sample of final product that is to be tested.

B-2.3 **Test Specimen**

The piece of test material that is implanted.

B-2.4 **Implant**

The test specimen or negative control specimen that has been implanted.

B-2.5 **Implant Site**

The implant shall be planted into the paravertebral muscle on one side of the spine and not less than 2 mm and not more than 5 mm of tissue surrounding it measured from the centre of the implant.

B-2.6 Negative **Control Specimen**

A piece of material, which when implanted by the procedure described in B-4.5 produces a negative reaction (see B-4.7.1.4).

NOTE — Negative control standards available from USP-NF Reference Standards 12601, Twinbrook Parkway, Rockville, Maryland 20852 USA **or equivalent** may be used.

B-2.7 Medical Device

Any item used in medical treatment, diagnosis or contraception, not intended to have a pharmacological reaction on the **body.**

B-3 ANIMALS AND HUSBANDRY

B-3.1 Two healthy adult rats/rabbits should be selected, whose paravertebral muscles are sufficiently large in size to allow for implantation of the test and negative control specimens, as described in B-4.5.

B-3.2 The animals shall be housed individually and have free access to food and water.

B-4 TEST AND CONTROL SPECIMENS

B-4.1 Number of Specimens Required

The minimum number of specimens for implantation in each rat/rabbit shall be:

a) not less than two negative control specimens; and

b) not less than six test specimens

NOTE — It may be necessary to implant more specimens than the minimum required because of loss, for example by extrusion of implants during the 14 days test period.

B-4.2 **Sterilization and Handling of Specimens**

B-4.2.1 Test specimens for pre-sterilized devices and pre-sterilized controls shall be aseptically handled.

B-4.2.2 All other test specimens shall be sterilized and thereafter shall be aseptically handled.

B-4.2.3 All other items used for the test shall be pre-sterilized and shall be eseptically handled.

B-4.3 **Preparation of Specimen**

B-4.3.1 The ring may be implanted as it is, and the negative control material is cut into specimen of 10 mm in length.

B-4.3.2 These cut or shaped specimens shall have smooth sides to minimize mechanical trauma during implantation.

B-4.3.3 After preparing and before implanting, place each specimen in a sterile solution containing 9 g/l of sodium chloride.

B-4.4 **Test Procedure**

B-4.4.1 On the day of the test or up to 20 hours before testing, clip the fur on the back of the rat/rabbit on both sides of the spinal column close to the skin and swab the clipped area with an antiseptic solution. Remove loose hair by means of vacuum, if necessary.

B-4.4.2 Perform the test in a clean area.

B-4.4.3 Anaesthetize the rat/rabbit with a commonly used anaesthetic agent adequate enough to prevent muscular movements, such as twitching.

B-4.5 **Implanatation of Specimens**

B-4.5.1 Implant in one of the rats/rabbits four test specimens and two negative control specimens.

B-4.5.2 Each implant shall be at least 10 mm away from any other implant.

B-4.6 **Recovery of the Implant Sites**

B-4.6.1 After the implants have been in position for 14 days, sacrifice the rats/rabbits with an overdose of anaesthetic.

B-4.6.2 Place these rats/rabbits in the prone position with the legs splayed.

B-4.6.3 Carefully excise the implant sites, leaving the implant in position.

B-4.7 **Examination of Implant Sites**

B-4.7.1 Perform the microscopic examination.

B-4.7.1.1 Examine each excised implant site under normal vision or with the aid of a low magnification lens. Record the nature, extent and distribution of any tissue reaction observed.

B-4.7.1.2 If any negative control specimen evokes a reaction other than that described in B-4.7.1.4; the results for the test specimens in the rat/rabbit shall be rejected and the test repeated in another rat/rabbit.

B-4.7.1.3 If any test specimen implant site shows a negative reaction (see B-4.7.1.4) all the test specimen implant sites and the negative control implant sites shall be removed for histological examination to confirm the response.

B-4.7.1.4 A reaction shall be considered a negative reaction if there is no reaction, or there is reaction that can be attributed to experimental trauma, typically asymmetrical, non-nectrotic and non-inflammatory.

B-4.7.1.5 If more than the minimum number of test specimens or negative control specimens are implanted, all of them shall be recovered.

B-4.7.1.6 All recovered specimens shall be considered as part of the test.

B-4.7.2 Perform the histological examination.

B-4.7.2.1 Preserve the excised implant sites in formal saline.

B-4.7.2.2 Prepare sections transverse to the excised implants.

NOTES

1 Ideally, the implant should remain in place during preparation for sectioning to ensure correct orientation of the surrounding tissue, unless adverse reaction with dehydrating or defatting solvents is likely to occur.

2 Hard implants may be removed before cutting of sections, if cutting would otherwise be difficult.

B-4.7.2.3 Stain the section with haemotoxylin and eosin.

B-4.7.2.4 Examine the histological sections microscopically and record the findings.

B-5 TEST RESULTS

B-5.1 The tissues surrounding negative control should appear normal and entirely free from haemorrhage, film or encapsulation (see B-4.7.1.4).

B-5.2 The requirements of the test are met if, in each rat/rabbit, the reaction to not more than one of the four test specimens is significantly greater than that of the negative control implant.

Sch. V Pregnancy Test Kits

PTK

Annexure-13

APPROVED SPECIFICATIONS FOR ONE STEP PREGNANCY TEST KIT (Card/Cassette Format)

1	TEST SPECIMEN	:	URINE
2	TEST PRINCIPLE	:	SINGLE STEP, SELF PERFORMING SANDWICHED IMMUNOSSAY USING COULLOINDAL GOLD & ANTI hCG ANTIBODIES IN LATERAL FLOWIMMUNOCHROMATOGRAPY FORMAT
3	SENSITIVITY	:	NOT LESS THAN 25 MILLI I.U PER ML. OF URINE
4	SPECIFICITY	:	100% (NO CROSS REACTIVITY WITH OTHER GONADOTROPIN HORMONES LIKE LH, FSH ETC.)
5	BUILT IN CONTROL	:	SHOULD HAVE BUILD IN CONTROL FOR CORRECTNESS OF THE TESTING PROCEDURE
6	NITROCELLULOSE PAPER	:	NITROCELLULOSE PAPER COATED WITH ANTI HCG ANITBODIES FOR TEST BAND & APPROPRIATE REAGENTS FOR CONTROL BAND
7	CASSESTTE	:	CASSETTE MADE OF ABS OR PP
8	POUCH	:	TRIPPLE LAYERED LAMINATED POUCH HAVING ALUMIMIUM FOIL IN THE MIDDLE LAYER
9	SILICA GEL	:	EVERY TEST PACK SHOULD HAVE MOISTURE INDICATING SLIICA GEL POUCH
10	DROPER	:	EVERY TEST POUCH SHOULD HAVE DISPOSABLE DROPER FOR URINE SPECIMEN ADDITION
11	SHELF LIFE	:	18-24 MONTH FROM THE DATE OF MANUFACTURING
12	PACK SIZE	:	10 TESTS PER BOX
13	STORAGE CONDITION	:	THE KIT SHOULD BE STABLE AT ROOM TEMPERATURE
14	PACKING	:	LAMINATED PRINTED CARTON, THE CARTONS SHOULD BE PACKED IN SUITABLE CORRUGATED SHIPPER BOX FOR DISPATCH.

Annexure-1B

CONSIGNEE LIST

Consignee list will be provided with the Purchase Order.

CMSS reserve to right the change the consignee at any time if required.

Annexure-1C

The details of CMSS warehouses are given below: -

CMSS Warehouse & Mapped States			
Sr No	**Warehouse Location**	**States/UT's covered by the Warehouse**	**Address**
1	Agartala	Tripura	Near ONGC Complex, PO-Hapania , Agartala-799014
2	Ahmadabad	Gujarat	Opp. P&T Colony, Shahalam, Ahmedabad-380028
3	Bangalore	Karnataka	APMC Yard, Yeswanthpur, Bangalore - 560022
4	Bhopal	Madhya Pradesh	Chhola Road, Near Nishatpura Cabin, Bhopal, M.P.
5	Chandigarh	Chandigarh Punjab Haryana Himanchal Pradesh Jammu & Kashmir, Leh Ladakh Uttarakhand	Central Medical Services Society Godown no. B014/3433, Near Vivekanand School, Godown area, Village Bhabat, Thana-Zirakpur, Dist: SAS Nagar-140603(Punjab)
6	Chennai	Tamil Nadu Pondicherry Andaman & Nicobar Islands	Chitalapakkam(P.O), Chennai - 600064, T.N.
7	Jajpur	Odisha	Dhawalgiri, Post-Jajpur Road, Dist-Jajpur, Odisha
8	Delhi	Delhi	Ware Housing Scheme Block No 2. Kirti Nagar, New Delhi-110015.
9	Guwahati	Assam Arunachal Pradesh Meghalaya Nagaland Sikkim Manipur Mizoram	EPIP Complex, Amingaon, Guwahati-781031
10	Hyderabad	Telangana Andhra Pradesh	Behind Gandhibhavan, Nampally, Hyderabad-500001
11	Jaipur	Rajasthan	Plot no SPL-1296, EPIP Sitapura, Ind Area, Jaipur-302002
12	Kolkata	West Bengal	Rehabilitation Industries Corporation Estate, Bonhooghly, Kolkatta - 700 108
13	Lucknow	Uttar Pradesh	New Mandi Complex, Sitapur Road Lucknow-226020
14	Navi Mumbai	Maharastra Goa Dadra and Nagar Haveli Daman and Diu	Sector-20 Near APMC Fruit Market, Vashi Navi Mumbai-400613
15	Patna	Bihar	Bazar Sammittee , Katra Bazar, Patna city-800008
16	Raipur	Chattisgarh	Rawabhata, Raipur -493221
17	Ranchi	Jharkhand	Po-Hehal, Ratu Road, Dist-Ranchi-834005
18	Trivandrum	Kerala Lakshadweep	Kinfra Apparel Park, Thumba, Palliphura(PO), Trivandrum-695586

CMSS reserve to right the change the consignee at any time if required.

Annexure-II

TENDER FORWARDING LETTER

Date:

To,
DG&CEO,
Central Medical Services Society
2nd Floor, Vishwa Yuvak Kendra,
Pandit Uma Shaker Dixit Marg,
Chanakyapuri, New Delhi- 110021

Sub: Acceptance of Terms & Conditions of Tender.

Tender No: CMSS/PROC/2023-24/FP/037
Name of Tender: - Online tender for Procurement of Contraceptives for FP (Family Planning).

Dear Sir,

I/ We have downloaded / obtained the tender document(s) for the above mentioned 'Tender/Work' from the web site(s) namely:

_____

_____

as per your advertisement, given in the above-mentioned website(s).

2. I / We hereby certify that I / we have read the entire terms and conditions of the tender documents (Including all document like annexure(s), schedule(s), etc .,), which form part of the contract agreement and I / we shall abide hereby by the terms / conditions / clauses contained therein.

3. The corrigendum(s) issued from time to time by your department/ organization too has also been taken into consideration, while submitting this acceptance letter.

4. I / We hereby unconditionally and unequivocally accept the tender conditions of above-mentioned tender document(s) / corrigendum(s) in its totality / entirety.

5. I / We do hereby declare that our Firm has not been blacklisted/ debarred by any Govt. Department/Public sector undertaking for the quoted product from any procurement agency or as a whole.

6. I/We hereby declare that bid will remain valid for a period of 150 days after opening of Tender bid/packet1.

7. I / We certify that all information furnished by our Firm is true & correct and in the event that the information is found to be incorrect/untrue or found violated, then your department/ organization shall without giving any notice or reason therefore or summarily reject the bid or terminate the contract, without prejudice to any other rights or remedy including the forfeiture of the full said earnest money deposit absolutely.

Yours Faithfully,
(Signature of the Tenderer, with Official Seal)

Annexure-III

DETAILS OF E.M.D. SUBMITTED

We herewith submit the EMD (**Annexure-XIV**) in favour of Central Medical Services Society for the following items.

Sch. No.	Item Name	UOM	Quantity in Bid	Quantity Quoted	% of the Bid Quantity	Amount of EMD Payable (in INR) for 100% quantity	Amount of EMD Payable (in INR) for 50% quantity	Amount of Bid Security
I	Emergency Contraceptive Pills (ECP)	Pack of 1 Pill	40,50,000			2,80,260	1,40,130	
II	IUCD 380 A	Pieces	18,00,000			11,98,800	5,99,400	
III	IUCD 375	Pieces	13,21,650			7,92,990	3,96,495	
IV	Tubal Rings	Pairs	7,64,100			2,87,149	1,43,574	
V	Pregnancy Test Kits	Kits	81,72,000			4,93,589	2,46,794	

Annexure-IV

PROFORMA FOR PERFORMANCE STATEMENT

(FOR A PERIOD OF LAST 2 YEARS)

Name of Bidder with Address_____
Manufacturer with Address_____
Tender No _____
Sr. No. of the Product _____
Name of the Product _____

Sl.	Name of Product	Year 2021-22	Year 2022-23	Quantity manufactured and marketed	UOM	Name and full address of the Purchaser
1	2	3	4	5	6	7
1.						
2.						
3.						

Note:

1. Proof for the manufacturing (BMR) / importing of the items quoted to be produced, if demanded.
2. Copies of purchase orders in support of performance statement may be uploaded along with this **Annexure-IV.**

Signature of Tenderer
Name in Capitals
Date:
Seal:

Signature of Statutory Auditor/Practicing Chartered Accountant
Name in Capitals
Date
Seal

Annexure-V

ANNUAL TURN OVER STATEMENT

The Annual Turnover (Sales) of M/s._____ for the past three years are given below and certified that the statement is true and correct.

Sl. No.	Financial Year	Turnover in Lakhs (Rs)
1.	2020-2021	-
2.	2021-2022	-
3.	2022-2023	-

Total - Rs. _____ Lakhs.

Average Turnover Per Annum in the last three years mentioned above - Rs._____ Lakhs.

Date:
Seal:

Signature of Auditor/Chartered Accountant
(Name in Capital)

Annexure-VI

LIST OF ITEMS QUOTED & THEIR PRODUCTION CAPACITY

1. Name of the firm :

2. Address of the firm as given in Drug license/Manufacturing License :

3. Details of Endorsement for all products quoted :

Sch No	Item Code	Drug/Goods Name	UOM	Quantity Tendered	Quantity quoted	Manufacturing Capacity	Quantity Manufactured **8**		Average Quantity Manufactured
							2021-22	2022-23	
1	**2**	**3**	**4**	**5**	**6**	**7**	**8A**	**8B**	**9**
I		Emergency Contraceptive Pills (ECP)	Pack of 1 Pill	40,50,000					
II		IUCD 380 A	Pieces	18,00,000					
III		IUCD 375	Pieces	13,21,650					
IV		Tubal Rings	Pairs	7,64,100					
V		Pregnancy Test Kits	Kits	81,72,000					
				TOTAL					

Date: Authorized Signatory:

Annexure-VII

CHECK LIST

Packet 1

		Pg. No. in bid	
1.	Checklist – Annexure-VII- (Clause 6.2 p)	Yes	No
2.	EMD (as per Annexure-XIII) (Clause 6.2 a)	Yes	No
3.	Certificate by MSME/ SSI units in support of being a MSE/ SSI unit. (Clause 6.2 a)	Yes	No
4.	Tender Forwarding Letter (Annexure-II) (Clause 6.2 b)	Yes	No
5.	Duly attested photocopy of Manufacturing License (valid on the date of tender opening) for the product duly approved by the Licensing Authority for each and every product quoted. (Clause 6.2 c)	Yes	No
6.	Power of Attorney duly signed & Authorization letter nominating a responsible person of the tenderer to transact the business with the Tender inviting Authority. (Clause 6.2 d)	Yes	No
7.	Purchase Order Copy (Clause 6.2 e)	Yes	No
8.	Market Standing Certificate (Clause 6.2 f)	Yes	No
9.	Non-Conviction Certificate (Clause 6.2 g)	Yes	No
10.	Manufacturing Capacity Certificate (Clause 6.2 h)	Yes	No
11.	Performance Statement (Annexure-IV) (Clause 6.2 j)	Yes	No
12.	Annual Turnover Statement for 3 Years (Annexure-V) (Clause 6.2 k)	Yes	No
13.	Copies of Annual Audit Reports including Balance Sheet & Profit & Loss Account for last three years (Clause 6.2 l)	Yes	No
14.	Certificate of Incorporation along with MOA & AOA in case of companies/copy of partnership deed in case of partnership firm/ Declaration in case being a proprietary firm. (Clause 6.2 m)	Yes	No
15.	Long term stability data (Clause 6.2 n)	Yes	No
16.	List of items quoted and their production capacity –	Yes	No

Annexure-VI (Clause 6.2 o)

17.	No Deviation Certificate (Annexure-XV) (Clause 6.2 s)	Yes	No
18.	Near Relative Certificate (Annexure-XVI) (Clause 6.2 t)	Yes	No
19.	Certificate for local content (Clause 6.2 u)	Yes	No
20.	Undertaking to compliance i.r.o Ministry of Finance, Department of Expenditure, Procurement Policy Division No- 6/18/2019-PPD dated 23.07.2020 (Annexure-XIX) (Clause 6.2 v & w)	Yes	No
21.	Undertaking that Firm is not being blacklisted or debarred from any Govt. Agency (Clause 6.2 x)	Yes	No
22.	Para-wise compliance of technical specification of the quoted item (Clause 6.2 y)	Yes	No
23.	Annexure-XII (Mandate Form)	Yes	No
24.	The bidders are requested to submit an undertaking on their letterhead for compliance to the Artwork enclosed for the items quoted by them. No further approval for Artwork would be provided by CMSS to any bidder.	Yes	No

NOTE: Bidders are requested to submit all documents with the bid as shown as checklist (Annexure-VII). NO CLARIFICATIONS may be sought from bidders and incomplete bid may be summarily rejected at sole responsibility of bidder(s). CMSS decision in this regard will be final and binding.

M/s _____

For Self and Firm / Company Ltd.

Signature and Seal

Annexure-VIII

NOTARISED UNDERTAKING BY MSE COMPANIES

(In 20- Rupees stamp paper)

I _____, S/o _____, Proprietor / Partner / Managing Director of _____ (Proprietary Concern / Firm / Company Ltd.) execute this Undertaking for myself and on behalf of _____ (Proprietary Concern / Firm / Company Ltd.).

2. Whereas, CMSS (Tender Inviting Authority) has invited Tender for supply of Drugs and medicines, goods for the year 2022-23 and in pursuant to the conditions in the tender documents. M/s _____ (Proprietary Concern/ Firm / Company Ltd.), having its Office at _____ _____ is exempted from payment of Earnest Money Deposit as indicated in the Clause 9.2 of tender document.

3. And whereas, in pursuant to the conditions in Clause Nos. 9.2, 9.3 & 9.4 of the tender, the Earnest Money Deposit can be forfeited by the Tender Inviting Authority in case of violation of any of the conditions and for non-performance of the obligation under tender document.

4. In consideration of exempting M/s._____ (Proprietary Concern/ Firm / Company Ltd.) from payment of Earnest Money Deposit as indicated in the clause 9.2 of tender document, I undertake to pay the said sum without any demur on receipt of demand issued by the tender inviting authority.

M/s _____

For Self and Firm / Company Ltd.

Signature and Seal

Witness:-

(1)

(2)

Annexure-IX

Central Medical Services Society

2nd Floor, Vishwa Yuvak Kendra, Pandit Uma Shankar Dixit Marg, Teen Murti Road, Opp. Police Station, Chanakyapuri, New Delhi- 110021, Tel: 011-214109005 011-21410906

Email: gmproc1@cmss.gov.in

LETTER OF ACCEPTANCE

No: CMSS/PROC/2023-24/FP/037 Date _____

To,

M/s _____

Address: _____

Attn: _____

Phone: _____

Email _____

(Kind Attn: _____(Name), _____ Designation)

Sub: Acceptance of Tender for supply of to CMSS

Ref: 1) CMSS Tender No. **CMSS/PROC/2023-24/FP/037,** opened on _____

2) Your Ref. No. _____ dated _____ in response to above mentioned tender.

Dear Sir,

I am pleased to inform you that your offer in response to above mentioned tender for supply of Contraceptives for FP (Family Planning) has been accepted for following items:

Sch No.	Items Description	Quantity	Unit	Ex-Works per Unit (Rs.)	GST (%)	GST (Rs)	Transport & any other charges (Rs.)	Total unit price (all incl) (Rs.)	Grand Total (Rs.)
1									
2									
								Grand Total	

2. You are requested to deposit Security Deposit @ 3% of the total value by NEFT/ RTGS/ Bank Guarantee/Demand Draft/ Banker's Cheque and enter into an Agreement, as per the format given in **Annexure-X** of the Tender document, within 15 days from the date of receipt of this letter. The Security Deposit shall be valid for 1260 days from the date of commencement.

3. Please convey your acceptance to this LOA within 03 days of issue, else it will be presumed that you are not keen to accept the LOA and CMSS may proceed for allocation of quantity to other bidder and with other actions stipulated in referred Tender document.

4. All other terms and conditions will be applicable as per Tender document no. CMSS/PROC/2023-24/FP/037 and subsequent amendments to it.

Anjana
GM/Procurement

Annexure A to LOA No:
Supplier: M/s _____

Annexure-A

LIST OF MANUFACTURING LICENSES & SITE ADDRESSES					
Sr. No.	**Item Code**	**Item Description**	**Manufacturing Site Address**	**Manufacturing License No.**	**Remarks**
1					
2					
3					

Annexure-X

LONG TERM AGREEMENT (LTA) NO.: CMSS/PROC/2023-24/FP/LTA/037

E- STAMP CERTIFICATE NO.:

LTA Validity: From _____ to _____

TERMS OF AGREEMENT

THIS AGREEMENT made the..... day of ....., year between **Central Medical Services Society, 2nd Floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Marg, Opposite Police Station Chanakya Puri, New Delhi-110021** (here in after "the Purchaser") of the one part and ..... (Name of Supplier) of..... (Address and Country of Supplier) (Here in after called "the Supplier") of the other part:

WHEREAS the Purchaser is desirous that certain Goods and ancillary services viz; **Procurement of Contraceptives for FP (Family Planning)** in the Tender Reference No. **CMSS/PROC/2023-24/FP/037, Dt**_____(Brief Description of Goods and Services) and has accepted a bid by the Supplier for the supply of those goods and services for the sum of..... (Contract Price in Words and Figures) (Hereinafter called "the Contract Price").

WHEREAS the Supplier confirms that it is qualified, ready, willing and able to supply/services the **Procurement of Contraceptives for FP (Family Planning)**, in accordance with the terms and conditions of this Agreement.

1. DEFINITIONS

Commencement Date means _____

Expiry Date means _____

Products, in singular form Product, means the item(s), as described and detailed above, provided by the Supplier to CMSS from time to time pursuant to this agreement.

Tender means Tender No. Tender No: **CMSS/PROC/2023-24/FP/037** from CMSS to the Supplier, to quote for the cost of supply of the Products to CMSS.

Long Term Agreement, as abbreviated to Agreement or LTA, means this Agreement between the Parties, to provide Products, including its Annexure, however with due consideration of the order of precedence among the LTA and individual Annexure.

Parties means CMSS and the Supplier, their successors and assigns and where not repugnant to the context, their servants or agents.

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. **LTA DOCUMENTS:**

The following documents shall be deemed to form and be read and construed as part of this Agreement, viz.:

(a) This LTA
(b) The Notice Inviting Tender
(c) Terms and Conditions of Tender Document as given in Tender No: **CMSS/PROC/2023-24/FP/037** dt. _____
(d) The Minutes of Pre-Bid meeting and corrigendum issued.
(e) Schedule of Requirement.
(f) The Technical Specification
(g) The Supplier's Offer including Enclosures, Annexure etc.
(h) Any other document listed in the supplier's bid and replies to queries, clarifications issued by the purchaser, such confirmations given by the tenderer which are acceptable to the purchaser and the entire Addendum issued as forming part of the contract.
(i) The Letter of Acceptance issued by the purchaser.

2. **PURPOSE OF LTA:**

2.1 The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the goods, the Contract Price at the times and in the manner prescribed by this Agreement.

2.2 Brief particulars of the Products or goods which shall be supplied / provided by the Supplier are as under.

Sch No.	Items Description	Quantity	Unit	Ex-Works per Unit (Rs.)	GST (%)	GST (Rs)	Transport & any other charges (Rs.)	Total unit price (all incl) (Rs.)	Grand Total (Rs.)
1									
2									
								Grand Total	

2.3 The supplier agrees that his supplies are subject to terms and conditions details

contained in LTA documents mentioned above. The supplier appreciates that the supplies are meant for public health system in the country and hence will agree to supply the goods of good quality as per standards in a timely manner as specified as per tender terms and conditions. The supplier has already given its no deviation (clause-by-clause compliance) for the subject terms and conditions.

3 . Manufacturing License and Site

License and Site Address: As per Annexure A.

IN WITNESS where of the parties here to have caused this Agreement to be executed in accordance with their respective laws the day and year first above written.

Signed, Sealed and Delivered by the said..... (For the Purchaser)

in the presence of .....

Signature

Name

Address

Signed, Sealed and Delivered by the Said ..... (For the Supplier)

in the presence of .....

Signature

Name

Address

Annexure A to LTA No:

Supplier: M/s

Annexure-A

Annexure A to LTA No:
Supplier: M/s

LIST OF MANUFACTURING LICENSES & SITE ADDRESSES					
Sr. No.	**Item Code**	**Item Description**	**Manufacturing Site Address**	**Manufacturing License No.**	**Remarks**
1					
2					
3					

Annexure-XI

CENTRAL MEDICAL SERVICES SOCIETY
Ministry of Health & Family Welfare
(Government of India)
2nd Floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Marg,
Opposite Police Station Chanakya Puri, New Delhi-110021, India

PURCHASE ORDER

PO No: CMSS/PROC/2023-24/FP/037 **Dated:** _____

To,

M/s _____
Address: _____
Attn: _____
Phone: _____
Email _____

Subject: **Purchase Order for supply of Contraceptives for FP (Family Planning).**
Ref : Long Term Agreement No: CMSS/PROC/2023-24/FP/037 /LTA/..... dated_____

Dear Sir,

Please supply following quantities for the items specified as per the technical specifications and terms & conditions of the Long-Term Agreement referred above:

Sr. No.	Item Code	Item Description	Quantity Accepted by the Purchaser	Unit	Ex Works Price per Unit (Rs)	GST (%)	GST (Rs)	Transportation Charges (Rs)	Rate Per Unit (Landed Price) (Rs)	Total Value (Rs)	Destination
1											As per Annex 1
2											As per Annex -1

1. All the Terms & Conditions of the Agreement signed by you on acceptance of your tender are applicable.
2. Delivery Period: As per Annexure A of the tender document
3. Manufacturing license as per Annexure A and site address as per Annexure B.

4. Payment Terms: Within 75 days of supplies in respect of items requiring sterility tests and within 60 days of supplies for other items.

(Anjana)
General Manager (Procurement)

Copy to :

1. General Manager (LSC), CMSS
2. General Manager (QA), CMSS
3. General Manager (Finance), CMSS
4. All Consignees (CMSS Warehouses) concerned.

Annexure-A

Annexure A to PO No:
Supplier: M/s

CONSIGNEE-LIST						
Sr. No.	**Item Description**	**Consignee Location**	**Consignee Address**	**Quantity**	**UOM**	**Remarks**
1						
2						
3						

Annexure-B

Annexure B to PO No:
Supplier: M/s

LIST OF MANUFACTURING LICENSES & SITE ADDRESSES					
Sr. No.	**Item Code**	**Item Description**	**Manufacturing Site Address**	**Manufacturing License No.**	**Remarks**
1					
2					
3					

Annexure-XII

MANDATE FORM

01	Company Name	
02	Postal Address of the company with Telephone No., Fax No. and Mail ID.	
03	Name of the Managing Director / Director / Manager Mobile No. / Phone No. E-mail ID.	
04	Name and Designation of the authorized company official Mobile No. E-mail ID	

Date: Company Seal Signature
Place: (Name of the person signing & designation)

Mandate Form contd..

01	Name of the Bank. Branch Name& address. Branch Code No. Branch Manager Mobile No. Branch Telephone no. Branch E-mail ID	
02	9 digit MICR code number of the bank and branch appearing on the MICR cheque issued by the bank.	
03	IFSC code of the Branch	
04	Type of Account (Current / Savings)	
05	Account Number (as appear in Cheque book)	

(in lieu of the bank certificate to be obtained , please **attach the original cancelled cheque** issued by your bank for verification of the above particulars).

I /We hereby declare that the particulars given above are correct and complete. If the transaction is delayed or not effected at all for reasons of incomplete or incorrect information, I would not hold M/s. Central Medical Services Society (CMSS) responsible. I have read the conditions of the tender/agreement entered and agree to discharge the responsibility expected of me / from the company as a tenderer /successful tenderer.

Date: Company Seal Signature
Place: (Name of the person signing& designation)

CERTIFIED THAT THE PARTICULARS FURNISHED ABOVE BY THE COMPANY ARE CORRECT AS PER OUR RECORDS.

Bank Seal with address. Signature of the authorized official of the bank

Annexure-XIII

Bank Guarantee for EMD (Format)

(if applicable)

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

_____

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

Beneficiary: *[insert **Name and Address of Purchaser**]*

Date: _____

BIDGUARANTEE No.: _____

We have been informed that *[insert **name of the Tenderer**]* (hereinafter called "the Tenderer ") has submitted to you its bid dated (hereinafter called "the Bid")for the execution of *[insert **name of contract**]*under Tender No……
Furthermore, we understand that, according to your conditions, bids must be supported by an EMD.

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

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

(b) having been notified of the acceptance of its Bid by the Purchaser 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 security deposit, in accordance with the Instructions to Tenderer s.

(c)does not accept the correction of the Bid Price

(d)This guarantee will expire: (a) if the Tenderer is the successful tenderer ,upon our receipt to copies of the contract signed by the Tenderer and the performance security issued to you upon the instruction of the Tenderer ; or(b) if the Tenderer is not the successful tenderer ,upon the earlier of (i) our receipt of a copy of your notification to the Tenderer of the name of the successful tenderer ;or (ii) Twenty Eight days after the expiration of the Tenderer '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. 758.

_____

[signature(s)]

Annexure-XIV

Security Bank Guarantee (Format)

_____ *[insert:* ***Bank's Name, and Address of Issuing Branch or Office****]*

Beneficiary:_____ *[insert:* ***Name and Address of Purchaser****]*
Date:_____

PERFORMANCE GUARANTEE No.:_____

We have been informed that *[insert:* ***name of Supplier****]* (hereinafter called "the Supplier") has received a Letter of Acceptance No. *[insert:* ***reference number of the Letter of Acceptance****]* dated _____ for entering into a Rate Agreement with you, for the supply of *[insert:* ***description of goods****]*

Furthermore, we understand that, according to the conditions of the Tender, a performance guarantee is required post acceptance of letter of Acceptance.
At the request of the Supplier, 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****]*[1] upon receipt by us of your first demand in writing accompanied by a written statement stating that the Supplier is in breach of its obligation(s) under the Tender , without your needing to prove or to show grounds for your demand or the sum specified therein.

This guarantee shall expire no later than the ____ day of _____, 2_____,[2] and any demand for payment under it must be received by us at this office on or before that date.

This guarantee is subject to the Uniform Rules for Demand Guarantees, ICC Publication No. 758, except that subparagraph (ii) of Sub-article 20(a) is hereby excluded._____
[signature(s)]

The Guarantor shall insert an amount representing the percentage of the Price specified in the letter of Acceptance and denominated in the currency of the Contract.

Established in accordance with tender conditions taking into account any warranty obligations of the Supplier as per tender conditions The Purchaser should note that in the event of an extension of the time to perform the Contract, the Purchaser would need to request an extension of this guarantee from the Guarantor. Such request must be in writing and must be made prior to the expiration date established in the guarantee. In preparing this guarantee, the Purchaser might consider adding the following text to the form, at the end of the penultimate paragraph: "The Guarantor agrees to a one-time extension of this guarantee for a period not to exceed [six months] [one year], in response to the Purchaser's written request for such extension, such request to be presented to the Guarantor before the expiry of the guarantee."

Annexure-XV

No Deviation Certificate

This is to certify that the product(s) quoted_____ by our firm, M/s. _____ is as per the given technical specifications in the tender document & there is no deviation in relation to any conditions/requirements specified in the tender document.

Signature (with Stamp)

Annexure-XVI

Near Relative Certificate

(In case of Proprietorship firm certificate will be given by the proprietor. For partnership firm certificate will be given by all the partners and in case of limited company by all the Directors of the company excluding Govt. of India/Financial Institutions nominees and independent non-official part time directors appointed by Govt. of India or the Governor of the state. Authorised signatory of bid may also sign this bid on behalf of the entire directors/ partners/ proprietor).

This is to certify that none of my/our Company Directors' near relative as defined below currently works in CMSS where I am/we are going to apply for the tender. I/We also agree to the condition that due to any breach of conditions by the company or firm or any other related person the bid submitted on behalf of the company or firm will be cancelled and bid security will be forfeited at any stage whenever it is noticed and CMSS will not pay any damage to the company or firm or the concerned person. The company or firm will also be debarred for further participation for the quoted item in CMSS for a period of one year.

The near relatives for this purpose are defined as:

(a) Members of a Hindu undivided family.

(b) They are husband and wife.

(c) The one is related to the other in the manner as father, mother, son(s) & son's wife (Daughter in law), daughter(s) and daughter's husband (son in law), brothers(s) and brother's wife, sister(s) and sister's husband (brother in law).

Signature/Signatures (with Stamp)

Annexure-XVII (A)

Format of Local Content Declaration for Schedule II, III, IV & V

Tender Reference No: Date:

I _____, S/o, D/o, W/o _____,

Resident of _____do hereby solemnly affirm and declare as under:-

The local content is _____% for the _____ (quoted item of M/s _____.

That I on behalf of M/s _____will agree to abide by the terms and conditions of the Ministry of Chemicals & Fertilizers, DOP, Government of India issued vide notification no. 31026/36/2016- policy dated 16.02.2021 and DPIIT order no. P-45021/2/2017- PPBE- II dated 16.09.2020 and calculations for local content have been done in accordance with Sr. No. 1 of DOP order no. 31026/36/2016- policy dated 16.02.2021.

That the information furnished hereinafter is correct to best of my knowledge and belief and I on behalf of M/s _____undertake to produce relevant records before the procuring entity or any authority so nominated by the Department of Pharmaceuticals. Government of India for the purpose of assessing the local content.

(Name of Firm/ Entity)

Authorized Signatory/ Statutory Auditor/ Chartered Accountant/Cost Auditor

(with Company Seal/Stamp)

(Refer Clause 9 of DPIIT Order dtd. 16.09.2020)

Annexure-XVII (B)

Format of Local Content Declaration for the item Schedule no. I

Tender Reference No: Date:

I _____, S/o, D/o, W/o _____, Resident of _____do hereby solemnly affirms and declares as under:-

The local content is _____% for the _____ (quoted item of M/s _____.

That I on behalf of M/s _____will agree to abide by the terms and conditions of the Ministry of Chemicals & Fertilizers, DOP, Government of India issued vide notification no. **31026/65/2020-MD dated 30.12.2020** and DPIIT order no. P- 45021/2/2017- PPBE- II dated 16.09.2020 and calculations for local content have been done in accordance with Sr. No. 1 of DOP order no. **31026/65/2020-MD dated 30.12.2020**.

That the information furnished hereinafter is correct to best of my knowledge and belief and I on behalf of M/s _____undertake to produce relevant records before the procuring entity or any authority so nominated by the Department of Pharmaceuticals, Government of India for the purpose of assessing the local content.

(Name of Firm/ Entity)

Authorized Signatory/ Statutory Auditor/ Chartered Accountant

(with Company Seal/Stamp)

(Refer Clause **9 of DPIIT** Order dtd. **16.09.2020**)

Annexure-XVIII

UNDERTAKING

(On Company's Letter Head)

We,.....(name of bidder), having offices at

……..are participating in Bid No.

…… Dated.....

We equivocally and irrevocably undertake that,

i) Compliance of DOE, MOF order No. 6/18/2019 – PPD dated: - 23.07.2020 and No.F.7/10/2021-PPD (1), dated 23.02.2023 or any other subsequent revised order in said matter.

ii) Compliance of Public Procurement Order 2017- revision, issued vide No. P-45021/2017-PP (BE-II) Dated: - 16/9/2020 or any other subsequent revised order in said matter.

If at any stage of tendering process, non-compliance of above orders - observed/found we will be liable for stringent actions as per the tender terms and condition including suspension/debarment from any bidding in CMSS/MoHFW tenders for twoyears.

M/s_____

Witness

For Self and Firm/Company Limited

1.

Signature & Seal of company

Annexure-XIX

CONSIGNEE RECEIPT CERTIFICATE

(To be given by consignee's authorized representative)

The following store(s) has/have been received in good condition:

1) P.O No. & date:_____
2) Supplier's Name:_____
3) Consignee's Name & Address with telephone No. & Fax No. : _____

   _____

   _____
4) Name of the items/equipment supplied:_____
5) Quantity of items/equipment Supplied:_____
6) Date of Receipt of items/equipment by the Consignee:_____
7) Name and designation of Authorized Representative of Consignee :_____
8) Signature of Authorized Representative of Consignee with date:_____
9) Counter Signed by Director/MS/Dean of the concerned Hospital/Institute:_____
10) Seal of the Consignee:_____

Artwork

Schedule I

ARTWORK OF EZY PILL (LEVONORGESTREL 1.5 MG TABLETS I.P.) LEAFLET

160 mm

110 mm

INSTRUCTIONS FOR EZY-PILL USE

What is EZY-PILL ?
EZY-PILL is an Oral Emergency Contraceptive for women. It is a hormonal which can prevent pregnancy if used within 72 hours of unprotected intercourse.

When to use EZY-PILL ?
EZY-PILL should be used only in Emergency situations like:

- Any unprotected sex
- Contraceptive mistakes (Failure to use regular contraceptive method in a correct and consistent manner)
- Sex was forced (rape) or coerced.

Dosage
One Pill of Levonorgestrel 1.5 mg.

How to take?
The Pill must be taken within 72 hours of unprotected intercourse, preferably within 12 hours. If vomiting occurs within 2 hours after taking EZY-PILL, the dose should be repeated with anti-nausea medication (As per the direction of Health Care Provider)
If vomiting occurs after two hours of taking EZY-PILL, she need not take any extra Pill.

Effectiveness.
EZY-PILL reduces the risk of pregnancy from a single act of unprotected sexual intercourse by 85 percent.

Pregnancy and Lactation.
There is no evidence of harmful effects of EZY-PILL on pregnancy or lactation.

Side effects:
Nausea, pain in abdomen and vomiting may occur in some cases. Less common side effects are headache, breast tenderness, dizziness, irregular bleeding and effect on skin due to over sensitivity.

Contraindications:

- Hypersensitivity to Levonorgestrel.
- Known or suspected pregnancy.

Important:

- EZY-PILLs are not a substitute for regular contraception. Hence, after taking EZY-PILL it is advised to visit nearest health centre/health worker for regular contraception as soon as possible.
- EZY -PILLs neither prevent nor increase the chance of anectopic pregnancy.
- It is not an abortion Pill.

Manufactured by:
HLL Lifecare Limited
(A Govt. of India Enterprise)
Kanagala - 591 225, Dist. Belagavi Karnataka State. INDIA

For Ministry of Health & Family Welfare, New Delhi

Contact our consumer cell assistant manager at +919341806085

ARTWORK NO. : AL-A2A-00
ITEM CODE : 1110310161
EFFECTIVE DATE : MAY 2019
REFERENCE : OCP ARTWORK
REVISION HISTORY:
00 - New Artwork

REMARKS:

PREPARED BY:	CHECKED BY:	VERIFIED BY:	APPROVED BY:
(RA)	(QA)	(Production)	(Head of QA)

ARTWORK OF EZY PILL (LEVONORGESTREL 1.5 MG TABLETS I.P.) LEAFLET

160 mm

110 mm

ईजी - पिल लेने के लिए सूचनाएँ

ईजी - पिल महिलाओं के लिए मौखिक आकस्मिक गर्भनिरोधक है. यह एक हार्मोनल दवा है जो असुरक्षित संभोग के 72 घंटो के अंदर लेने से गर्भधारण को रोकती है.

ईजी - पिल का प्रयोग कब किया जाता है ?

- ईजी - पिल का इस्तेमाल केवल आकस्मिक परिस्थितियों में किया जाना चाहिए, जैसे असुरक्षित संभोग
- दंपति द्वारा अपनाए गर्भनिरोधक के इस्तेमाल में गलती होने पर (जिससे उसके विफल हो जाने की संभावना हो)
- बलात्कार या जबरदस्ती किए गए संभोग में

ईजी - पिल खुराक

1.5 मि. ग्रा. लिओनार्जेस्ट्रल की एक गोली

कैसी लेनी है ?

यह गोली असरक्षित संभोग के 72 घंटों के अंदर लेनी है (बेहतर है 12 घंटों के अंदर). अगर गोली लेने के 2 घंटे के अंदर महिला को उल्टी होतीं है तो दूसरी गोली, उल्टी रोकने की दवा के साथ लेनी चाहिए (स्वास्थ्य कार्यकर्ता / डाक्टर की सलाह लें). अगर उल्टी, गोली लेने के 2-घंटे पश्चात होती है, तो दूसरी गोली लेने की आवश्यकता नहीं है.

प्रभावशीलता

ईजी - पिल असुरक्षित लैंगिक संबंध से होनेवाली गर्भधारणा की जोखिम को 85 प्रतिशत से कम करती हैं.

गर्भधारणा एवं दुग्धस्त्रवण

ईजी - पिल लेने पर गर्भधारण अथवा दुग्धस्त्रवण पर कोई हानिकर परिणाम के कोई प्रमाण प्राप्त नहीं है.

साईड इफेक्ट्स

कुछ मामलों में उबकाई, पेट में दर्द एवं उल्टी संभावित है. कम सामान्य साईड इफेक्ट्स - सिरदर्द, स्तन में नरमी एवं चक्कर आना.

विपक्ष / प्रतिकलत:

- लिओनार्जेस्ट्रल अतिसंवेदनशील
- ज्ञात अथवा संदिग्ध गर्भधारणा

महत्वपूर्ण :

- ईजी - पिल नियमित गर्भनिरोध का विकल्प नहीं है, इसलिये ईजी - पिल लेने के बाद जितनी जल्दी हो सके अपने निकटतम स्वास्थ्य केन्द्र से परिवार नियोजन के नियमित तरीकों की सलाह लें.
- ईजी - पिल बाह्य गर्भधारणा (गर्भाशय के बाहर - या तो ट्युब में या अन्य कहीं) को न तो रोकती है और न ही उसके होने की संभावना बढाती है.
- यह गर्भपात गोली नहीं है.

विनिर्माणकर्ता :
एचएलएल लाइफकेयर लिमिटेड
(भारत सरकार का उद्यम)
कणगला - 591 225, जिला - बेलगावि, कर्नाटक राज्य
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, नई दिल्ली के लिए
हमारे उपभोक्ता कक्ष सहा. प्रबंधक से संपर्क करें - 919341806085

ARTWORK NO.	: AL-A2A-00
ITEM CODE	: 1110310161
EFFECTIVE DATE	: MAY 2019
REFERENCE	: OCP ARTWORK

REVISION HISTORY:
00 - New Artwork

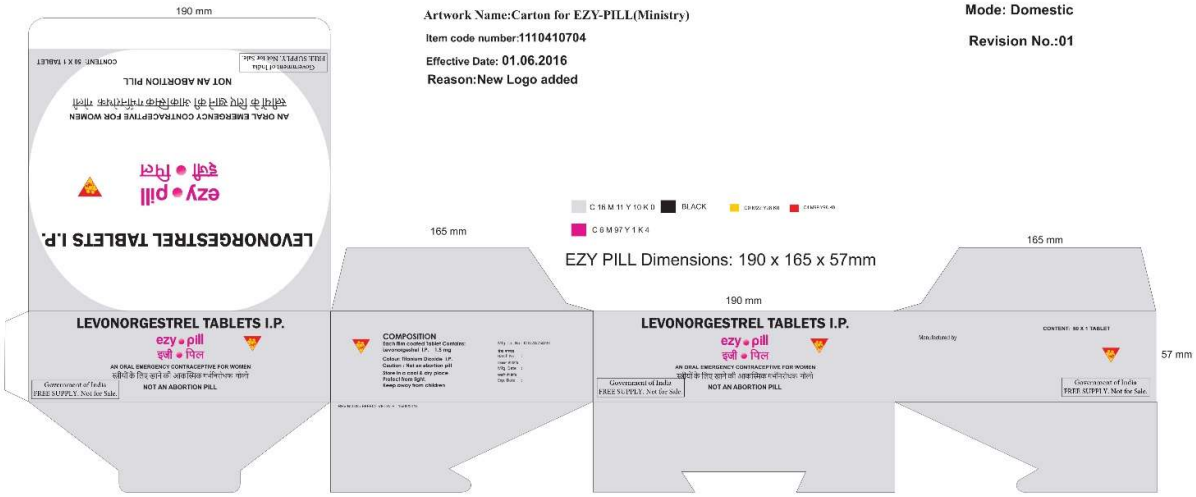
REMARKS:

PREPARED BY:	CHECKED BY:	VERIFIED BY:	APPROVED BY:
(RA)	(QA)	(Production)	(Head of QA)

HLL LIFECARE LIMITED
KANAGALA, BELGAUM- DIST. KARNATAKA

Annexure- 9 a

FINAL APPROVED ARTWORK FORMAT
(HLL/KFB/QA-022R 01)



Artwork Name:Carton for EZY-PILL(Ministry)

Item code number:1110410704

Effective Date: 01.06.2016

Reason:New Logo added

Mode: Domestic

Revision No.:01

Prepared By:
(Lab Dept.)
Date:

Checked By:
(Lab Dept.)
Date:

Reviewed By:
Executive (QA)
Date:

Approved by:
Head of QA
Date:

HLL LIFECARE LIMITED
KANAGALA, BELGAUM- DIST. KARNATAKA

FINAL APPROVED ARTWORK FORMAT
(HLL/KFB/QA-022R 01)

Artwork Name:Wallet for EZY-PILL(Ministry)

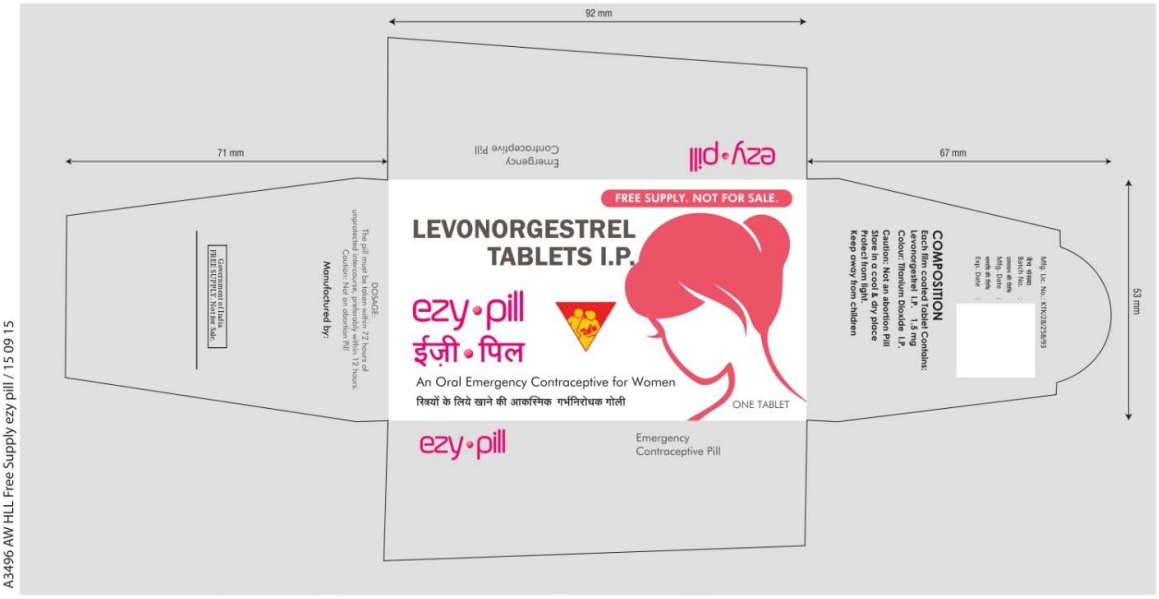
Item code number:1110210748

Effective Date: 01.06.2016

Reason:New Logo added

Mode: Domestic

Revision No.:01



A3496 AW HLL Free Supply ezy pill / 15 09 15

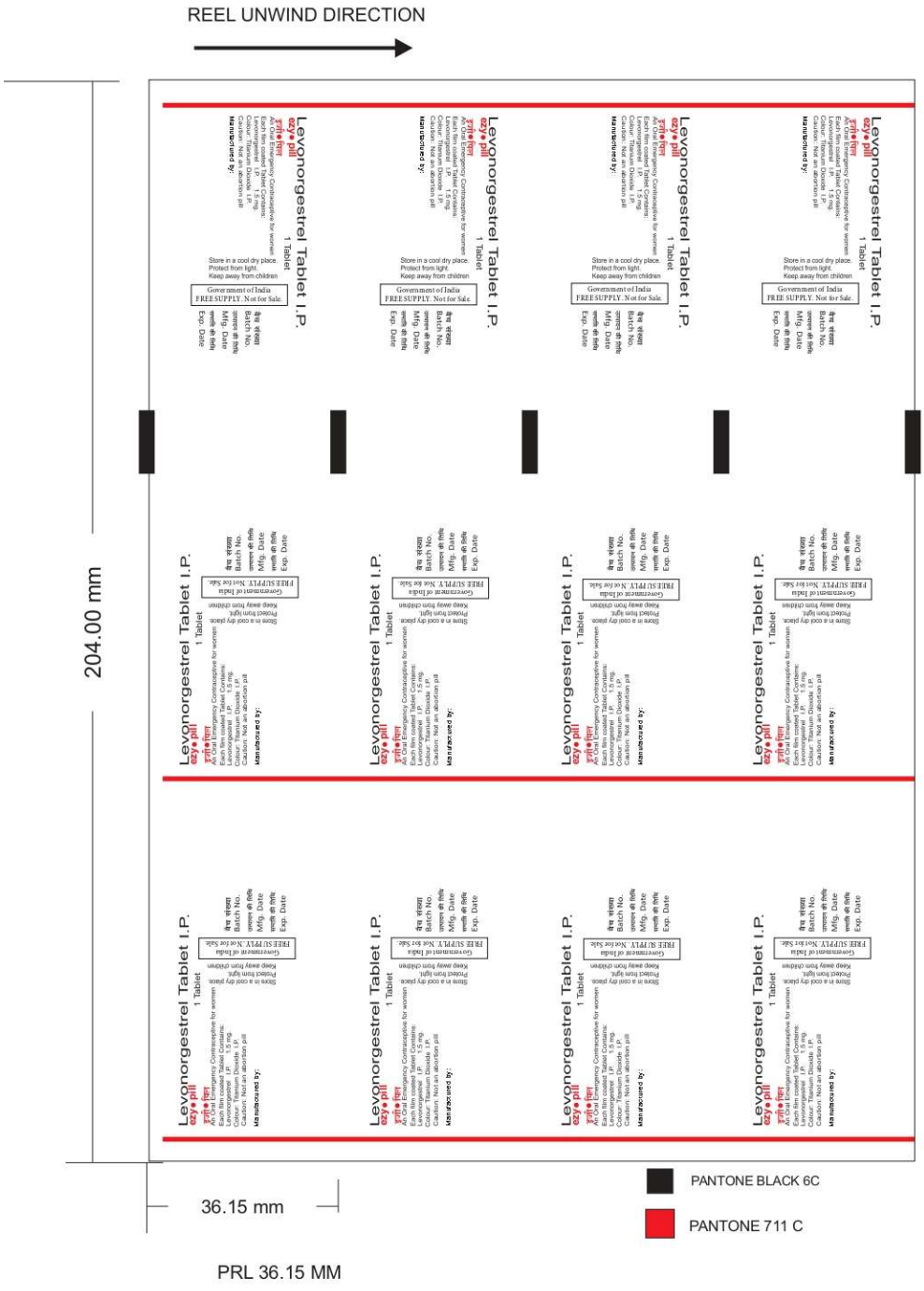
C 16 M 11 Y 10 K 0 BLACK C 6 M 97 Y 1 K 4 C0 M22 Y98 K0 C4 M99 Y98 K0

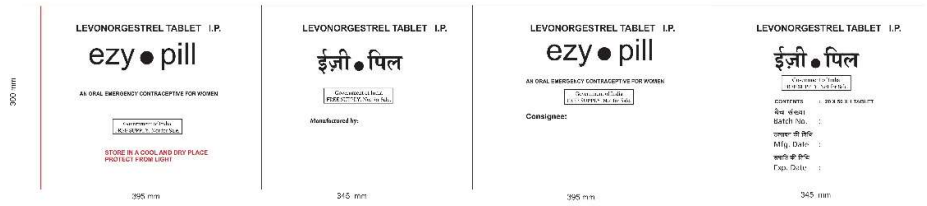
Prepared By:
(Lab Dept.)
Date:

Checked By:
(Lab Dept.)
Date:

Reviewed By:
Executive (QA)
Date:

Approved by:
Head of QA
Date:


REEL UNWIND DIRECTION
204.00 mm
36.15 mm
PRL 36.15 MM
PANTONE BLACK 6C
PANTONE 711 C
Levonorgestrel Tablet I.P.
ezy pill
1 Tablet
Store in a cool dry place. Protect from light. Keep away from children
Government of India FREE SUPPLY. Not for Sale.
Batch No.
Mfg. Date
Exp. Date
Manufactured by:


LEVONORGESTREL TABLET I.P.
ezy • pill
AN ORAL EMERGENCY CONTRACEPTIVE FOR WOMEN
STORE IN A COOL AND DRY PLACE
PROTECT FROM LIGHT
300 mm
395 mm
LEVONORGESTREL TABLET I.P.
ईज़ी • पिल
Manufactured by:
345 mm
LEVONORGESTREL TABLET I.P.
ezy • pill
AN ORAL EMERGENCY CONTRACEPTIVE FOR WOMEN
Consignee:
395 mm
LEVONORGESTREL TABLET I.P.
ईज़ी • पिल
Batch No.
Mfg. Date
Exp. Date
345 mm

Schedule II

SPECIAL RISK FACTORS

Special Risk Factors for Infection (Pelvic Inflammatory Disease)

Studies suggest that Copper T users are more likely than other women to suffer a serious infection called pelvic inflammatory disease (PID), particularly in women with multiple sexual partners. PID is the medical term for infection in the upper pelvic area. This area includes the uterus (womb), fallopian tubes, ovaries, and surrounding tissues . (Vaginitis, a local infection of the vagina, is not PID, but may lead to it). Studies indicate that the highest rate of PID occurs shortly after insertion and up to 4 months thereafter. PID can cause permanent blockage of the tubes; sterility; ectopic pregnancy; or, in infrequent cases, death. If you now have PID or have ever had episodes of PID, you must not use the Copper T. PID is an infection caused by gonorrhea, Chlamydia, or other microscopic organisms. PID is frequently a sexually transmitted disease (STD or VD), and your chances of getting PID increases greatly if you have more than one sexual partner. Your risk of getting PID also increases if you have a sexual partner who has sexual intercourse with others. If you are exposed to such situations, you have an increased risk of getting PID and must not use the Copper T. You should consider the use of a barrier method which may provide partial protection against sexually transmitted diseases. Treatment of PID may require surgical removal of your uterus (hysterectomy), tubes, and ovaries. Such surgery may have to be done on an emergency basis, and may result in death. Removing the ovaries may result in a lifelong need for hormonal treatments. Symptoms of PID include pelvic or lower abdominal pain, chills, fever, abnormal vaginal discharge, abnormal menstrual bleeding, or painful sexual intercourse. PID can occur even without these symptoms. If you are using the Copper T and develop any of these symptoms, see your clinician as soon as possible. If you have PID, you should receive appropriate antibiotics promptly, and the IUD should be removed at the appropriate time. Failure to seek and receive prompt and adequate treatment will greatly increase the chances that you will become sterile, require surgery, or have life-threatening or fatal PID. Even prompt and adequate treatment cannot guarantee that these events will not occur.

Special Risk Factors for Ectopic Pregnancy

Ectopic pregnancy is an infrequent, but dangerous type of pregnancy that develops outside the uterus. Although current data indicate that the rate of ectopic pregnancy in patients using the Copper T Model TCu 380A is no higher, and some data suggest a lower rate than among women of fertile age group not using contraception, a pregnancy which occurs with the Copper T in place is more likely to be ectopic than a pregnancy occurring without the Copper T. If you have ever had an ectopic pregnancy, you have an increased risk of having another one. You also have increased risk of an ectopic pregnancy if you have ever had certain types of infections. These infections include pelvic inflammatory disease (PID) or any venereal disease (VD) or sexually transmitted disease (STD) caused by, for example, gonorrhea or Chlamydia. If you have ever had an ectopic pregnancy or these kinds of infections, you must not use the Copper T. Other contraceptive methods may be more suitable for you, Discuss this matter with your clinician.

Other Conditions that Increase Risk of Infection

Some conditions make you more susceptible to infection during Copper T use or following insertion. These conditions include leukemia and acquired immune deficiency syndrome (AIDS). In addition, certain defects or diseases of the heart valves, such as rheumatic heart disease, and diabetes and long-term steroid therapy, make you more likely than other Copper T users to develop an infection which may involve the heart. If you have any of these conditions you should probably not use the Copper T.

SIDE EFFECTS

The following may occur while the Copper T is being inserted and while it is in place:

1. Pain, usually uterine cramps or low backache, may occur at the time of insertion and may persist (Pain and cramping may also occur at removal). If pain is severe, becomes worse, or persists, contact your clinician.
2. Fainting may occur at the time of insertion or removal of the Copper T.
3. Some bleeding occurs following insertion in most women.
4. Partial or total perforation by the Copper T through the wall of the uterus may occur at the time of, or after, insertion. If you think the Copper T is displaced, check with your clinician (See Warning – tail or thread disappearance). Perforation could result in abdominal adhesions (scars), intestinal obstruction or penetration, inflammation, and loss of contraceptive protection. Perforation and its complications may require surgery and, in infrequent cases, may result in serious illness or death.
5. Bleeding between menstrual periods may occur during the first 2 or 3 months after insertion. The first few menstrual periods after insertions may be heavier and longer than usual. If these conditions continue for longer than 2 or 3 months, consult your clinician.
6. Occasionally, you may miss a menstrual period while using the Copper T. It is important to determine if you are pregnant, report this without delay to your clinician.
7. The Copper T may come out of your uterus through the cervical opening. This is called expulsion, and is most likely to occur during the first 2 or 3 menstrual cycles following insertion. Expulsion leaves you unprotected against pregnancy. Refer to the section called Directions for Use for information on how to check to see if your Copper T has been expelled. If you think the Copper T has come out or has been displaced, use another birth control method, such as contraceptive vaginal foam, cream, or jelly, or condoms (rubbers), until you can be checked by your clinician. (These alternative methods are usually not as effective is preventing uterine pregnancy as the Copper T Model TCu 380A). Contact Your clinician for an examination.

WHAT YOU SHOULD TELL YOUR CLINICIAN

Before you have a Copper T inserted, it is your responsibility to inform your clinician fully of your past medical history. Tell your clinician if you now have, or have had, or suspect that you had, any of the following conditions which might make the Copper T unsuitable as a method of contraception for you.

CONDITIONS LISTED ARE NOT NECESSARILY CONTRAINDICATIONS.

- Heart Disease
- Heart Murmur
- Hepatitis or severe liver disease
- Wilson's disease
- Diabetes
- Leukemia
- Fainting attacks
- Steroid therapy
- Anemia or blood clotting problems
- Current suspected or possible pregnancy
- Ectopic pregnancy (pregnancy outside of the uterus)
- Recent pregnancy
- Genital sores or lesions
- Sexually transmitted disease (venereal disease), such as herpes, gonorrhea, chlamydia, or acquired immune deficiency syndrome (AIDS)
- Recent abortion or miscarriage
- Abnormalities of the uterus
- Bleeding between periods
- Cancer of the uterus (womb) or cervix
- Suspicious or abnormal Pap smear
- Prior IUD use
- IUD in place now
- Heavy menstrual flow
- Severe menstrual cramps
- Multiple sexual partners
- A sexual partner who has multiple sexual partners
- Pelvic infection (including pus in fallopian tubes)
- Infection of the uterus (womb) or cervix
- Unexplained genital bleeding
- Uterine or pelvic surgery
- Vaginal discharge or infection

Make certain you discuss any items you are not sure about.

ADVERSE REACTIONS

The following adverse reactions have been reported and maybe caused by the Copper T

- Abdominal infection or adhesions (scar tissue)
- Anemia
- Backache
- Blood poisoning
- Bowel obstruction
- Cervical infection or erosion
- Cysts on ovaries and tubes
- Death
- Delayed menstruation
- Difficult removal
- Ectopic pregnancy
- Embedment (IUD surrounded by uterine tissue)
- Expulsion (IUD comes completely or partially out of the uterus)
- Fainting and pain at the time of Insertion or removal
- Fragmentation of the copper wire
- Breakage of the T
- Infertility
- Spotting between periods
- Miscarriage
- Pain and cramps
- Painful intercourse
- Pelvic infection (PID), which may result in surgical removal of your reproductive organs including hysterectomy
- Perforation of the uterus (womb) or cervix (IUD) passes through uterine tissue)
- Pregnancy
- Prolonged or heavy menstrual flow
- Infected miscarriage followed, in some cases, by blood poisoning, which can lead to death
- Vaginal discharge
- Allergy to copper

WARNINGS

This product is intended to prevent pregnancy. It does not protect against transmission of HIV (AIDS) and other sexually transmitted diseases such as Chlamydia, genital herpes, genital warts, gonorrhea, hepatitles B. and syphilis.

If you have the Copper T inserted, contact your clinician immediately for any of the following reasons.

1. A missed period. This may mean you are pregnant and the Copper T should be removed.
2. Unexplained or abnormal vaginal bleeding or discharge. This could indicate a serious complication, such as an infection or ectopic pregnancy.
3. A delayed period following by scanty or irregular bleeding. This could indicate an ectopic pregnancy.
4. Pelvic or lower abdominal pain or cramps or unexplained fever. Such symptoms could mean that an ectopic pregnancy or infection has developed, requiring immediate treatment.
5. Exposure to venereal disease (VD), also called sexually transmitted disease (STD). The use of the Copper T does not prevent venereal disease. If exposure to venereal disease is suspected, report for examination and treatment promptly. Failure to do so could result in serious pelvic infection.
6. Genital sores or lesions or fever with vaginal discharge. These may indicate an infection.
7. Severe or prolonged menstrual bleeding. If the flow is heavier and lasts much longer than your usual menstrual flow, you may need to have the Copper T removed to prevent anemia.
8. Tail or thread disappearance or pain during sex. If you cannot feel the threads coming through the cervix, or have pain during sex, the Copper T may have been expelled or displaced, or may have perforated the uterus. If any of these has occurred, you are no longer protected from pregnancy. Use another birth control method, such as contraceptive vaginal foam, cream, or jelly, or condoms (rubbers) until you can be checked. (These alternative methods are not as effective against uterine pregnancy as the Copper T Model TCu 380A).If perforation has occurred, removal of the Copper T is necessary, usually by surgery.
9. Risk of death. Available data from a variety of sources have been analyzed to estimate the risk of death associated with various methods of contraception. The estimates of risk of death include the combined risk of the contraceptive method plus the risk of death associated with pregnancy or abortion in the event of method failure. The findings of the analysis are shown in Table 2.

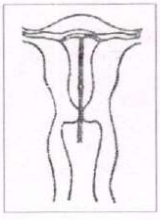
Table 2

Annual Number of Birth – Related or Method – Related Deaths Associated with Control of Fertility per 100,000 Non-sterile Women, by Fertility Control Method, According to Age.

Method of control/age	15-19	20-24	25-29	30-34	35-39	40-44
No fertility control method*	7.0	7.4	9.1	14.8	25.7	28.2
Oral contraceptives non-smokers**	0.3	0.5	0.9	1.9	13.8	31.6
Oral contraceptives smokers**	2.2	3.4	6.6	13.5	51.1	117.2
IUD**	0.8	0.8	1.0	1.0	1.4	1.4
Condom*	1.1	1.6	0.7	0.2	0.3	0.4
Diaphragm/spermicide*	1.9	1.2	1.2	1.3	2.2	2.8
Periodic abstinence*	2.5	1.6	1.6	1.7	2.9	3.6

*Deaths are birth-related **Deaths are primarily method-related

HOW THE COPPER T IS INSERTED AND REMOVED



Before insertion, your clinician will perform a pelvic examination. Its purpose is to determine the size, shape, and position of the uterus. An instrument called a speculum will hold your vagina open so that the cervix (the entrance to the uterus) can be seen.(You will probably feel pressure from the speculum throughout the insertion procedure.)

The cervix is then cleaned with an antiseptic solution and an instrument called a tenaculum is attached to it. This instrument assists in holding the uterus steady during insertion You may feel pain or a pinching sensation as the tenaculum is attached. Then the clinician will guide a narrow instrument called a sound through to opening of the cervix into the uterus. The sound measures the depth and position of the uterus. You can expect to feel cramping similar to menstrual cramps as the sound is inserted and withdrawn.

Then your clinician will guide the Copper T (with the cross arms of the T folded down) through the vagina and the cervix into the uterus.

As the Copper T is inserted, the arms of the T will unfold. During insertion, you will have some pain or cramping. You may feel nauseated, weak or faint. After the inserter is removed, the threads attached to the end of the Copper T will be clipped. The threads will extend into the vagina from the cervical opening. The tenaculum and speculum will then be removed. You may feel pain or pinching when the tenaculum is removed. You should remain lying down for a while and rise slowly to prevent fainting. During intercourse, neither you nor your partner should be aware of the threads. You should also not be aware of any other part of the Copper T. If you are, promptly following the instructions under the heading, Checking Your Copper T, in the section Directions for

नूतन तोपनो
(NUTAN TOPNO)
अवर सचिव/Under Secretary
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & F.W.
भारत सरकार/Govt. of India

When it is time to remove the Copper T, your clinician must remove it. Its removal may cause pain or cramping. The arms of the Copper T should fold upward as it is withdrawn from the uterus.

DIRECTION FOR USE

Please read the following information and instructions carefully. Keep a copy of this brochure so that you may refer to it. If you have any questions, consult your clinician.

CHECKING YOUR COPPER T

The Copper T can come out of the uterus (womb) without your knowing it. When this occurs, it is most often during or right after a menstrual period. Therefore, at least after each menstrual period, check to make sure the threads can be felt at the cervix. You may check more often, and especially if you have some concern, or think you have an expulsion.

Follow these steps to make sure that the Copper T has not been expelled without your knowing it:

1. Wash your hands
2. Squat down or seat yourself on the toilet.
3. Insert the index or middle finger high into your vagina and locate your cervix. The cervix is the mouth of the uterus (womb). It feels firm, like the tip of your nose.
4. Feel for the threads of the Copper T. The threads should extend from the cervix and be high in your vagina. The threads may be difficult to feel.
5. If you can feel the threads, the Copper T is probably, but not always, in place. You should not pull on the threads. Doing so may displace the Copper T.
6. If you cannot feel the threads, or if you can feel the Copper T itself, it has probably been displaced from the uterus. Also, if you or your partner can feel the Copper T during intercourse, it is displaced. If so, you are not being protected against pregnancy. Until you can be examined, use another birth control method, such as a contraceptive vaginal foam, cream or jelly, or condoms (rubber). (These alternative methods are not as effective against uterine pregnancy as the Copper T Model TCu 380A). Contact your clinician for an examination.

Follow-up visit to the Clinician

1. You should return to see your clinician as soon as possible after your first menstrual period following insertion of your IUD, but no later than 3 months after insertion. This will allow the clinician to check on the location of the Copper T.
2. The Copper T Model TCu380A requires replacement every 10 years. Check with you clinician concerning an appointment to have the Copper T replaced or removed.
3. The Copper T should not interfere with the proper use of tampons and douches. You may want to discuss this with your clinician.

SPECIAL WARNING ABOUT UTERINE PREGNANCY WITH THE COPPER T IN PLACE

Some women become pregnant while using the Copper T. If you miss your menstrual period or if you suspect you are pregnant, see your clinician right away. When a pregnancy continues with the Copper T in place, serious complications may occur, including severe blood infection, spontaneous miscarriage, infected miscarriage, and death. These may occur at any time during the pregnancy.

When the Copper T remains in the uterus during conception or pregnancy, the long-term effects on the child (or fetus) are not known. Under such conditions some birth defects have occurred. There relationship to the Copper T has not been established but has been suggested.

If your clinician confirms that you are pregnant, the Copper T should be removed. Removal of the Copper T may cause a miscarriage. However, successful Copper T removal in pregnancy decreases the likelihood of subsequent complications.

In some cases removal of the Copper T may prove to be difficult. If you and your clinician should discuss at that time the question of continuing the pregnancy in view of the serious complication (described above) that may occur. In reaching a decision about termination of pregnancy, you should be aware the risk associated with abortion increases with the length of time you have been pregnant.

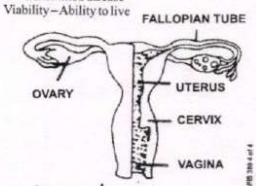
If you continue your pregnancy with the copper t in place, your clinician will have to follow your course more closely than usual throughout your pregnancy. Be sure to report immediately to the clinician if you have any of the following symptoms or signs.

- Bleeding from the vagina
- Pelvic or lower abdominal pain or cramping
- Flu-like symptoms such as chills or fever
- Unusual vaginal discharge
- Ruptured membranes (your water breaks)
- Any other signs/symptoms which gives you concern

Any of these symptoms could indicate that you are having a miscarriage or that you are beginning, or about to begin, premature labor. Premature labor may lead to delivery of a premature infant. Premature infants have a higher chance of dying, mental retardation, cerebral palsy, or other serious medical problems. Additionally, infection can cause infertility or death of the mother. Therefore, report any symptoms without delay to your clinician, so that you can obtain immediate treatment.

GLOSSARY

Cervix – Lower portion of the uterus visible in the vagina
Conception – same as pregnancy
Contraceptive – A means of preventing pregnancy
Ectopic Pregnancy – Pregnancy out side of the Uterus
Expel- To force out
Fallopian Tubes - Tubes which carry the egg from the ovary to the uterus
Fertilization – The process of the sperm Penetrating the egg of the female
Fetus-An unborn baby
Genital – Embedding of the fertilized egg into the wall of the uterus
Intrauterine – Within the uterus
Microscopic – Can be seen only by using a Microscope
Ovary – almond – shaped organ. One ovary is located on each side of the uterus. Produces and releases human eggs.
Ovulation – Release of an egg by the ovary
STD – Sexually transmitted disease
Spermatozoa-Male reproductive cells
Uterus (womb)- Pear – shaped organ, located deep in the pelvis, that contains and nourishes a fetus during pregnancy.
VD-Venereal disease- also called sexually transmitted disease
Viability – Ability to live



Manufactured by:
HLL Lifecare Limited
(A Government of India Enterprise)
Akkulam, Sreekariyam P.O.
Thiruvananthapuram-695 017, Kerala, India
Tel: 0471-2442641, Fax: 0471-2441383
Website: www.lifecarehll.com

Ref.No.CuT-PAT-380A
Rev.02 Dated 18.03.2019

PATIENT INFORMATION

Copper T Model TCu 380A brand of Intrauterine Copper Contraceptive

This product is intended to prevent pregnancy. It does not protect against HIV infection(AIDS) and other sexually transmitted diseases.

INTRODUCTION

The Copper T Model TCu 380A is a highly effective member of a family of copper-bearing IUDs which have been used extensively around the world. It is the first to contain copper on both the arms and the stem of the T. Tested in more than 4,900 women in the united States, and elsewhere, the Copper T Model TCu 380A is the product of over a decade of research involving an international group of scientists and family- planning specialists. However, as with all methods of contraception, its use is associated with some risk. The purpose of this brochure is to explain those risks to you.

This brochure provides information on the use of intrauterine contraceptive devices (IUDs) in general, and the Copper T Model TCu380A in particular. There are other birth control methods that may be suitable. Before deciding which type of birth control method to use, you should read this brochure and have the opportunity do discuss fully with your clinician any question you may have about the Copper T Model TCu380A, other IUDs, the Pill, and other methods of contraception.

A more technical leaflet is available which has been written for the medical profession. If you would like to read that leaflet, ask clinic personnel for a copy.

If you have difficulty understanding any of the technical terms in this brochure, check the glossary on page 4 and ask your clinician for clarification.

The Copper T is most appropriately used by women who have at least one child, who do not have multiple sexual partners or a partner who has multiple partners and so not have a history of pelvic infection. It is appropriate for those who require a revisable form of contraception, whether or not they believe they have completed their families. In general, an IUD is less desirable for women who want additional children.

DESCRIPTION

The Copper T Model TCu 380A (Intrauterine Copper Contraceptive) is a type of IUD that contains copper and is inserted into the uterus (womb) to prevent pregnancy. Like all other contraceptives it is not 100% effective. (See Effectiveness for pregnancy rates)

The Copper T is flexible and T-shaped with copper on both of the arms and stem of the T. The T itself is made of a flexible plastic material. The Copper T must be replaced every 10 years, to maintain its contraceptive effectiveness. Two white threads extend from the base of the T. They will extend into your vagina to indicate the presence of the Copper T, and aid in its removal.

THE COPPER IN THE COPPER T

Available data indicate that the contractive effectiveness of the Copper T is enhanced by copper released continuously from the IUD into the uterine cavity. The Copper T model TCu 380A differs from earlier copper IUDs in that it contains copper on the stem and horizontal arms of the T. The placement of the copper on the arms of the Copper T increases effectiveness.

HOW THE COPPER T ACTS AS A CONTRACEPTIVE

How the Copper T prevents pregnancy is not completely understood at the present – time. Several theories have been suggested, including interference with sperm transport, ovum development, fertilization, and implantation. Clinical studies with copper-bearing IUDs suggest that the likelyhood of fertilization is greatly reduced due to the effects of copper on spermatozoa or ova. IUDs do not prevent ovulation (production and release of an egg by the ovary).

The Copper T does not always prevent ectopic pregnancy (pregnancy outside the uterus, sometimes called tubal pregnancy). Ectopic pregnancy can require surgery, and can make you unable to bear children, in some cases it can cause death. (See special Risk factors for Ectopic Pregnancy).

EFFECTIVENESS

In clinical trials the incidence of unplanned pregnancies in women who have used the Copper T Model TCu 380A continuously for one year was less than 1 per 100 woman-years. This means that if 100 women use the Copper T Model TCu 380A for a period of one year, one of these women would become pregnant. Data suggest that the pregnancy rate is higher in women under 20.

Table 1 – Lowest Expected and Typical Failure Rates During the First year of continuous use of a method, united States. Percentage Women Experiencing an Accidental pregnancy in the First Year of Continous use.

Method	Lowest Expected	Typical
(no contraception, planning Pregnancy	(85)	(85)
oralcontraceptives		3
combined	0.1	N/A
progestin only	0.5	N/A
IUD		3
Copper T 380A	<1	N/A
Condom without spermicidal	2	12
Diaphragm with spermicidal cream or jelly	6	18
Spermicides alone (foam, creams, jellies and vaginal suppositories)	3	21
Cap	6	18
Vaginal sponge		
nulliparous	6	18
parous	9	28
periodic abstinence (all methods)	1-9	20
Female sterilization	0.2	04
Male sterilization	0.1	0.15

Adapted from 3 Trussell et al. Table 1. Studies in Family Planning 21-51,1990 N/Anotavailable

In 10 years of continous use of the TCu 380A only 2.3per 100 women pregnant.

CONTINUATION RATES

The number of women in the clinical trials who used the Copper T model TCu 380A continuously for one year was 77 per 100 users. About 14% of the women who discontinued use during the first year did so for medical reasons, such as bleeding or pain, and about 6% discontinued because the IUD was expelled.

LACK OF CONTRACEPTIVE EFFECT AFTER COPPER T REMOVAL

After discontinuation of Copper T use, its contraceptive effect on the uterus is reversed. Usually but not always, a woman is able to become pregnant. In a study of 293 women, the lifetable pregnancy rate at one year was 78.4 percent.

COPPER T MODEL TCu 380 A

INTRAUTERINE COPPER CONTRACEPTIVE

कॉपर टी मॉडल टी सी यू 380 ए

इंट्रायूटेरिन कॉपर कॉन्ट्रासेप्टिव

STORE IN COOL DRY CONDITION AWAY FROM SUNLIGHT

धूप से बचाकर शीतल शुष्क अवस्था में रखना

Government of India FREE SUPPLY, Not for Sale.

भारत सरकार मुफ्त आपूर्ति, बिक्री के लिए नहीं।

Quantity / मात्रा : 01 Sterile units / 01 निरजंतु यूनिट

Mfg. Lic. No. / निर्माण लाइसेंस संख्या : 2728/93

Batch No. / बैच संख्या :

Month of Manufacture / निर्माण के महीने :

USE BEFORE 5 YEARS FROM THE MONTH OF MANUFACTURE.

निर्माण के महीने से 5 वर्ष में प्रयोग करें

Manufactured by : HLL Lifecare Limited

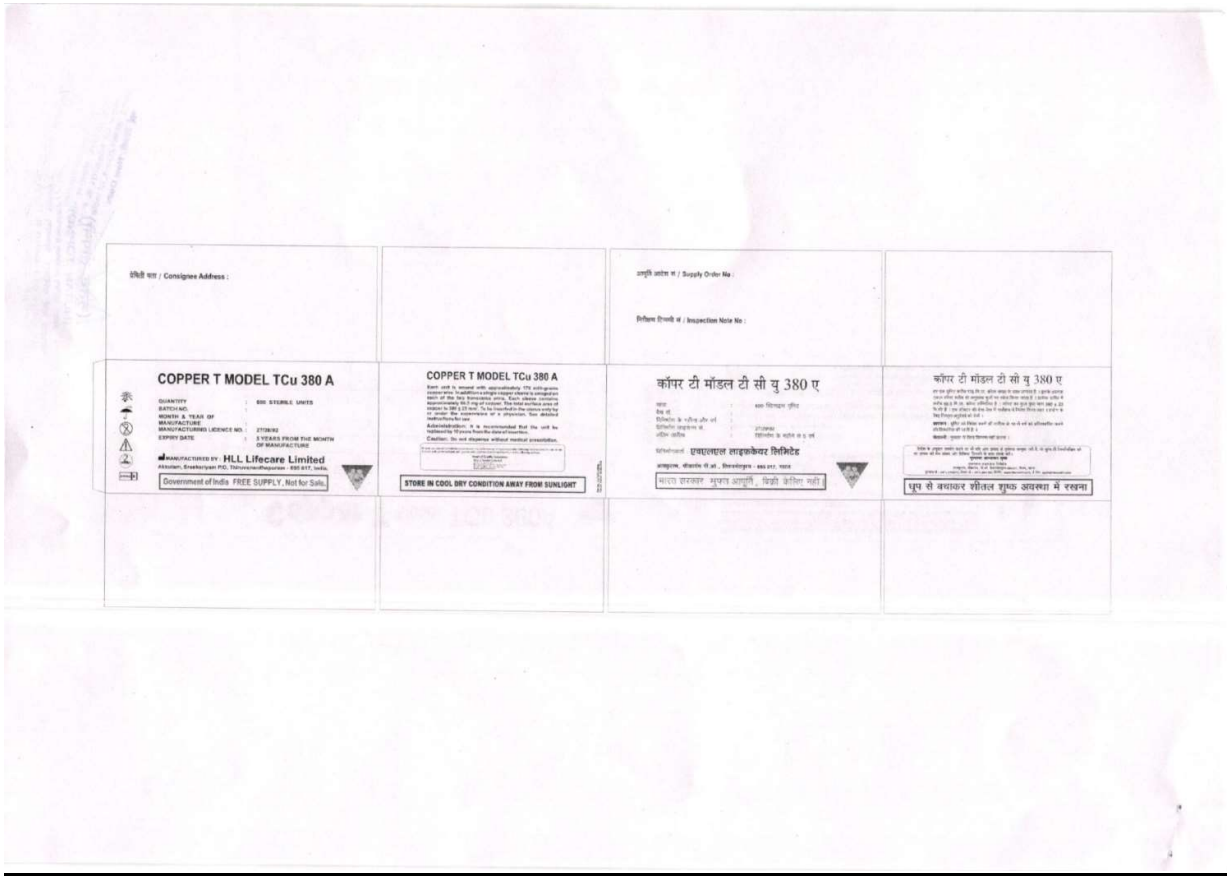
Akkulam,Sreekaryam,P.O,Thiruvananthapuram-695 017,India.

निर्माणकर्ता : एचएलएल लाइफकेयर लिमिटेड

अक्कुलम, श्रीकार्यम पी. ओ., तिरुवनंतपुरम - 695 017, भारत

(नूतन तोपनो)
(NUTAN TOPNO)
अवर सचिव/Under Secretary
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & F.W.
भारत सरकार/Govt. of India
नई दिल्ली/New Delhi

OPEN
STERILE R
Each unit is wound with approximately 176 mg of copper wire. In addition a single copper sleeve is placed on each of the two transverse arms. Each sleeve contains approximately 66.5 mg of copper. The total surface area of copper on the device is 380 + 23mm².
To be inserted in the uterus only by or under the supervision of physician. See detailed instructions for users.
Administration : It is recommended that the unit be replaced by 10 years from the date of insertion.
Storage : Store in cool, Dry condition away from Sunlight.
Mfg. Lic. Number 27728/92
Sterilization by Gamma Radiation
Do not insert after the expiry date
CAUTION : Do not dispense without medical prescription. Insertion Instrument should not be reused and should be destroyed after use.
Manufactured by HLL Lifecare Limited
(A Government of India Enterprise)
Akkulam, Sreekariyam P.O.,
Thiruvananthapuram - 695 017, India
Government of India FREE SUPPLY, Not for Sale.
Batch No. :
Mfg. Date :
Exp. Date :
Copper T Model TCu 380A
INTRAUTERINE COPPER CONTRACEPTIVE
SINGLE UNIT
CM
INCH
STERILE
Unless package is opened or damaged
see detailed instructions for
loading and use


प्रेषिती पता / Consignee Address :
आपूर्ति आदेश सं / Supply Order No :
निरीक्षण टिप्पणी सं / Inspection Note No :
COPPER T MODEL TCu 380 A
QUANTITY : 500 STERILE UNITS
BATCH NO.
MONTH & YEAR OF MANUFACTURE
MANUFACTURING LICENCE NO. : 2728/82
EXPIRY DATE : 5 YEARS FROM THE MONTH OF MANUFACTURE
MANUFACTURED BY : HLL Lifecare Limited
Government of India FREE SUPPLY, Not for Sale.
COPPER T MODEL TCu 380 A
STORE IN COOL DRY CONDITION AWAY FROM SUNLIGHT
कॉपर टी मॉडल टी सी यू 380 ए
एचएलएल लाइफकेयर लिमिटेड
भारत सरकार मुफ्त आपूर्ति, बिक्री करना नहीं
कॉपर टी मॉडल टी सी यू 380 ए
धूप से बचाकर शीतल शुष्क अवस्था में रखना

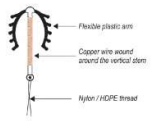
Schedule III

Cu 375

Cu 375 with a pearl index of <1 is one of the most effective intra uterine reversible contraceptive device which is more convenient to insert than other IUCDs.

Structure:

Cu 375 made of polyethylene impregnated with barium sulphate for visibility on X-ray consists of a 3.5 cm. long vertical rod wound with copper wire having surface area of 375 sq mm. and holding a pair of flexible side arms covering a width of 1.8 cm. This structure and shape offers more convenience during insertion and helps to keep the device adjacent to the fundus without stretching the uterine cavity. A thin monofilament nylon/HDPE thread is attached to the bottom end of the vertical rod.



Contraceptive action:

Cu 375 induces a spermicidal inflammatory response on the endometrium resulting in release of leucocytes and prostaglandins making it hostile to the sperm and largely prevents fertilisation as also implantation if at all the former occurs. Contraception is immediate if inserted early in the cycle.

Contra-indications:

Absolute, permanent:

- Very distorted uterine cavity, or cavity depth less than 5.5 cm
- Uterine or cervical cancer
- Allergy to known constituent
- Wilson's disease or disorders of copper metabolism
- Previous history of bacterial endocarditis

Absolute, temporary:

Suspected pregnancy

Undiagnosed, irregular vaginal bleeding

Significant pelvic infection

Significant immuno suppression

Relative - usable with caution:

- Nulliparous, young age
- Definite history of pelvic infection
- Known HIV infection or high risk of STD
- Structural heart disease, with risk of endocarditis
- History of ectopic pregnancy or tubal disease, endo-metritis or pelvic peritonitis.
- Thrombo-cytopenia or treatment with anti-coagulants
- Benign trophoblastic disease
- Severe cervical stenosis
- Fibroids or congenital abnormality of uterus, but no marked distortion of the cavity
- Polygamy

For detailed information on Medical Eligibility Criteria for IUD, refer www.who.int/reproductive-health/publication/mec/mec.pdf

Ideal time for insertion:

During menstrual period, the cervix is more open and there is little chance of a current pregnancy which is the most ideal. There is, however, a greater chance of expulsion if Cu 375 is introduced early in the cycle. It would seem that the best time for insertion is just after the period. Cu 375 can also be inserted during termination of pregnancy or carefully just after normal delivery. After caesarean section, insertion may be done after 3 months.

Cu 375 can be employed for emergency contraception if inserted within 120 hours of the coitus.

Directions for insertion:

Cu 375 has been carefully sterilised. Do not use if the pack is not intact. Cu 375 should be inserted by a registered medical practitioner or by a trained person under medical supervision. Cu 375 with flexible side arms for easy insertion is pre-loaded in a tube. Cu 375 should be placed correctly while minimising the woman's discomfort and the risk of complications. Women in whom Cu 375 is contra-indicated should be excluded.

Successful Cu 375 insertion requires:

- explaining the procedure to the woman and responding to her questions and concerns. This helps her relax, making insertion easier and less painful.
- infection-prevention procedures include use of sterile environment, disinfected instruments and cleaning of the cervix and vaginal walls with antiseptic and wiping off secretions if any. No-touch technique has to be followed to ensure sterility.
- speculum examination and bimanual pelvic examination. The speculum exam should come first, to check for signs of genital tract infection. The bimanual exam determines the size, position, consistency, and mobility of the uterus and identifies any tenderness, which might indicate infection. A retroverted uterus requires special care during insertion.
- sounding of the uterus slowly and gently determining its depth and direction and reducing the risk of perforating the uterus.
- careful and slow technique during all phases of sounding and insertion will be apt. This reduces discomfort and minimises the chances of uterine perforation, cervical laceration, and other complications. Parenteral local anaesthetic or para cervical block may be employed as per requirement.

A. The flexibility of Cu375 allows it to go through the cervix easily.

B. This picture shows Cu375 when completely inserted into the womb.

- Cu 375 placement high in the uterus at the fundus minimises expulsion, accidental pregnancy, and possible bleeding.
- holding the distal end of the insertion tube, carefully insert Cu 375 into the uterus until it touches the fundus and the cervical stop rests on the external os while maintaining steady downward traction with the tenaculum to straighten the uterine axis without forcing. When Cu375 touches the fundus it is inserted into the uterine cavity by simply withdrawing the insertion tube ensuring that the device is entirely within the uterine cavity. Trim the thread to 2 to 3 cm. outside so that they reach the vagina enabling the user to check with fingers.

C. After the removal of the insertion tube Cu375 is left high in the womb.

Side effects:

Some women may experience side effects; but most cases will normalise over 3 cycles. Increased menstrual flow, dysmenorrhoea and or low back pain will respond to appropriate NSAIDs. Spotting has also been reported.

Possible complications:

Serious problems with Cu 375 are rare. It is critical to observe any symptoms to avoid further complications.

Perforation: The devise, very rarely, may be pushed through the uterine wall during insertion. Generally, this can be discovered and corrected right away. If not, it can move into other parts of the pelvic area and may damage internal organs. Surgery may then be needed to remove the device.

Infection: Although there is some risk of pelvic inflammatory disease associated with Cu 375 use, the risk is small after the first 20 days following insertion. Generally, PID after first 3 weeks of insertion is sexually transmitted. The risk of infection is higher with multiple partners.

Expulsion: Cu 375 can partially or completely slip out of the uterus with the risk of pregnancy. This is more likely to happen in younger women, women who have never had a baby, and during the first few months of use. Cu 375 must be removed if it becomes partially expelled. User must be vigilant about this and should monitor the threads periodically especially during menstrual period.

Tear on

User guide

Copper IUCD 375

Name:

Age:

Address:

No. of children:

Date of insertion:

HLL Lifecare Limited
(A Government of India Enterprise)

For the user

Batch No. :
Doctor's name :
Address :
Contact No. :

Dear customer,

Your doctor has inserted Cu 375 for you. Now you can stay away safely from pregnancy for at least 5 years. Your doctor would have briefed you on all aspects. You have to be aware and vigilant about the following:

1) Some women may have increased menstrual flow and abdominal pain after insertion. However they will return to normalcy in most cases within 3 menstrual cycles. Still, if symptoms are severe, please consult your doctor. In some, periods may appear early in the first 2 cycles after insertion, or experience slight bleeding in between 2 cycles. They will also be normal in 2 or 3 cycles. Other rare symptoms are pain on the back or legs or pain during intercourse or mild itching of the skin. These may be reported to the doctor if severe; else ignored.

2) Pregnancy after inserting Cu 375 : Though chances are extremely rare, you may become pregnant even after inserting Cu 375. You should be very vigilant about this. Pregnancy can develop either

i) inside the uterus if Cu 375 is either expelled or displaced. Expulsion can happen usually within the first 3 cycles. Threads are attached to the tip of Cu 375 which can be felt by you outside the cervix through the vaginal with your fingers. Check for threads after each period. Before attempting, you should ensure that the fingers are clean. This also will help you to ascertain whether inserted Cu 375 has not passed the uterine wall. Contact your doctor if you cannot feel the threads.

If your periods are delayed by 2 weeks or more, you should report to your doctor for necessary action.

ii) Pregnancy outside the uterus (ectopic) is very dangerous. Following are the symptoms:

a) Delay in periods for 2 weeks or more.
b) Severe pain on one side of the abdomen.
c) Vaginal bleeding
d) Pain on the shoulder tip.
e) Feeling of unsteadiness or fainting.

Contact your doctor at the earliest if you will experience any of the above symptoms.

3) Infections of the genitor-urinary tract after insertion of Cu 375 :

If you experience any of the following symptoms, please consult your doctor:

i) High fever.
ii) Persistent lower abdominal pain
iii) Heavy vaginal bleeding or foul smelling discharge
iv) Pain or burning sensation while passing urine.

If you have to undergo physiotherapy for any ailment on the lower abdomen or back, please inform the physiotherapist that Cu 375 has been inserted.

Periodical check ups are suggested. The schedule is given below by your doctor.

Activity	Date	Month	Year
Cu 375 insertion			
1st follow up visit			
2nd follow up visit			
3rd follow up visit			
4th follow up visit			
5th follow up visit			

You can conceive if desired once Cu 375 is removed without any waiting if there is no other problem.

Wishing you a spontaneity, harmony and enjoyable days ahead,

HLL Lifecare Limited,

Pioneers and leaders in contraceptive products and services and committed to women's health.

Effectiveness:

Cu 375 is one of the most effective reversible method of birth control available with 99.2 to 99.4 % effectiveness.

Of special caution: Pregnancies with Cu 375 happen when the device slides out without the women realising it. Immediate removal is mandatory.

Safety during lactation:

Cu 375 is safe for use in lactating mothers.

Monitoring:

After insertion monitoring is very important. A part of this information insert is addressed to the beneficiary who should be properly explained about follow up at her end for trouble-free contraceptive benefit.

Failure:

Pregnancy after inserting Cu 375 has following risks:

- Ectopic pregnancy. Early diagnosis is vital.
- Pelvic infection
- Miscarriage
- Early labour and delivery

Life of Cu 375:

Optimum contraceptive efficacy is for 5 years, after which it may be replaced.

Removal:

Cu 375 may have to be removed due to:

- desire for another pregnancy. Normally fertility returns immediately to and within a few months after removal unless there is some other cause.
- Heavy bleeding or pain
- PID
- Accidental pregnancy-normal or possibly ectopic
- Spontaneous expulsion
- Perforation of uterus or missing threads which will have to be evaluated and investigated with the help of X-rays, ultrasound or hysteroscopy.

Procedure:

Clean the whole area using antiseptic, grasp both threads of Cu 375 with a forceps near to the external os and withdraw the device from the uterus gently without using excessive force and straightening out the uterine axis using a speculum thereby minimising the possibility of side arms breakage.

Return to fertility:

Immediately on removal and within a few cycles, if there is no other underlying aetiology.

Pack:

One device individually packed in a pouch with shelf life upto 5 years from the date of manufacturing.

Storage condition:

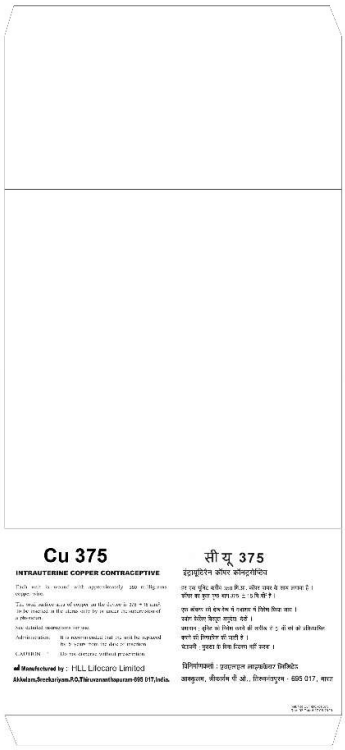
Keep in cool & dry place away from sunlight

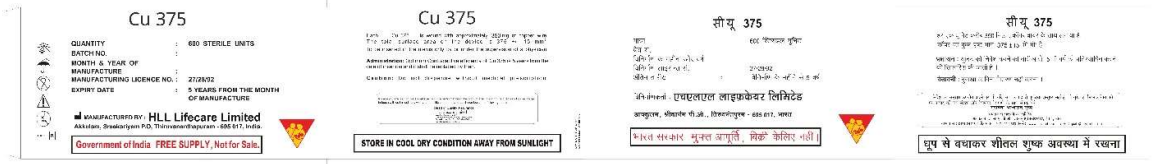
HLL Lifecare Limited
(A Government of India Enterprise)
AKKULAM FACTORY
Sreekariyam P.O,
Thiruvananthapuram- 695 017,
kerala, India
Tel: + 91-471-2442641/42/92
Fax: + 91-471-2441383
email:qaafl@lifecarehll.com
www.lifecarehll.com

Copper IUCD 375

Customer Care Address

Head of Quality Assurance
HLL Lifecare Limited
Akkulam, Sreekariyam P.O.
Thiruvananthapuram 695 017, Kerala, India
Tel: 0471-2442641, Fax: 0471-2441383
Email id: qaafl@lifecarehll.com

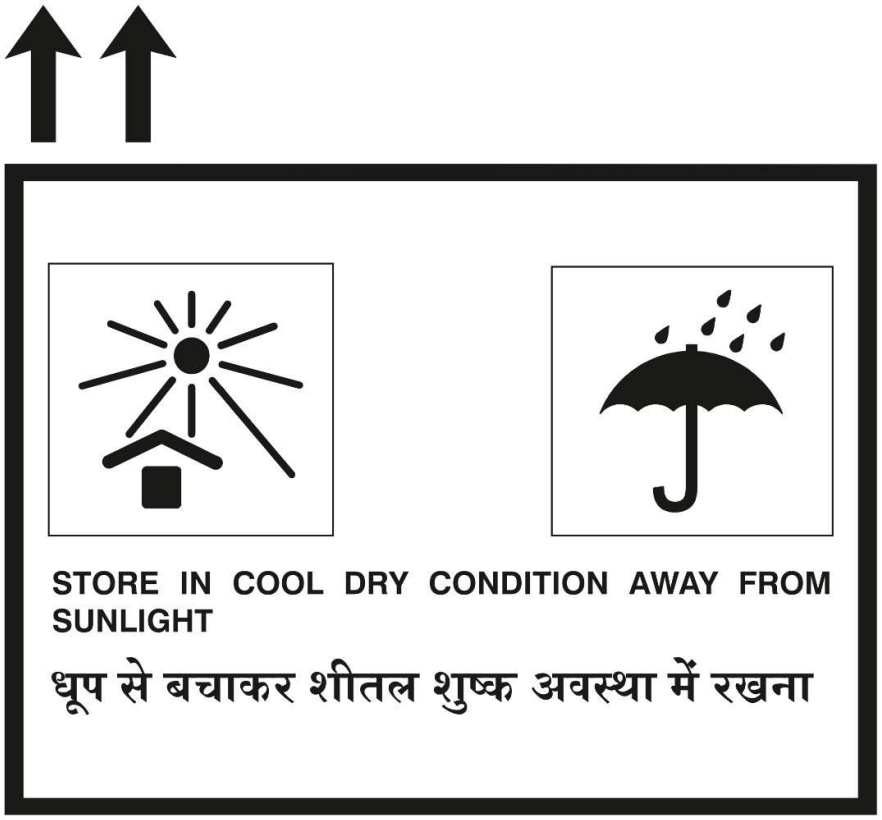



Cu 375
QUANTITY : 600 STERILE UNITS
BATCH NO. :
MONTH & YEAR OF MANUFACTURE :
MANUFACTURING LICENCE NO. : 27/28/92
EXPIRY DATE : 5 YEARS FROM THE MONTH OF MANUFACTURE
MANUFACTURED BY : HLL Lifecare Limited
Akkulam, Sreekaryam P.O, Thiruvananthapuram - 695 017, India
Government of India FREE SUPPLY, Not for Sale.
Cu 375
STORE IN COOL DRY CONDITION AWAY FROM SUNLIGHT
सी यू 375
एचएलएल लाइफकेयर लिमिटेड
भारत सरकार मुफ्त आपूर्ति, बेचने केलिए नहीं।
सी यू 375
धूप से बचाकर शीतल शुष्क अवस्था में रखना

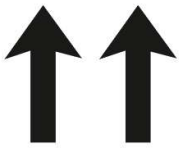

STERILE
Unless package is opened or damaged
see detailed instructions for use
Cu 375
Batch No. :
Mfg. Date :
Exp. Date :
INTRAUTERINE COPPER CONTRACEPTIVE
HLL Lifecare Limited
(A Government of India Enterprise)
CM
INCH
Government of India FREE SUPPLY. Not for Sale.
भारत सरकार मुफ्त आपूर्ति, बिक्री के लिए नहीं।
Cu375 is wound with approximately 350 mg of copper wire. The total surface area of copper on the device is 375 ± 15 mm².
To be inserted in the uterus only by or under the supervision of qualified registered medical practitioner trained in its insertion.
Administration: Optimum contraceptive efficacy of Cu375 is 5 years from the date of insertion and it shall be replaced by then.
Storage: Store in Cool, Dry condition & Away from Sunlight.
Mfg. Lic. Number 27/28/92
Do not insert after the expiry date
CAUTION : Do not dispense without medical prescription.
Insertion device to be destroyed after use and not to be reused.
Manufactured by HLL Lifecare Limited
(A Government of India Enterprise)
Akkulam, Sreekaryam P.O.
Thiruvananthapuram - 695 017, India
STERILE R
OPEN
ID Cu375-02
27.08.2020

Schedule IV

Tubal Ring Outer carton without CE mark for MOH INDIA, Left Side | SPE/QA/7031/D | Date - 26/12/2016 | Size - 350 x 325 mm.



Tubal Ring Outer carton without CE mark for MOH INDIA, Right Side | SPE/QA/7031/D | Date - 26/12/2016 | Size - 350 x 325 mm.



	QTY.	5000 UNITS
	MFG. LIC. NO.	DD/296
	STERILIZATION DATE	
LOT	BATCH NO.	
	MFG. DATE	
	USE BEFORE	

Tubal Ring Outer carton without CE mark for MOH INDIA, Front Side | SPE/QA/7031/D | Date -18/09/2017 | Size - 470 x 325 mm.

TUBAL RING
(A DEVICE FOR FEMALE STERILIZATION)

Manufactured by :

PREGNA
INTERNATIONAL LTD.

WORKS : Plot No.: 219, Survey No.: 168
Dabhel Industrial Co-Operative Society Ltd.,
Dabhel, Daman (U.T) - 396 210 - India
OFFICE : 13 SURYODAY ESTATE,
136 TARDEO ROAD,
MUMBAI - 400 034, INDIA
Email : sales@pregna.com
Website : www.pregna.com

Government of India FREE SUPPLY.
Not for Sale

Tubal Ring Inner carton without CE mark for MOH INDIA, Top side | SPE/QA/7030/D | Date - 26/12/2016 | Size - 165 x 85 mm.

TUBAL RING
(A Device for Female Sterilization)

STERILE | R

- **Wet the dilator cone with sterile water before placing the ring into the cone.**
- **Ring should preferably be kept on the Laparoscope in stretched state for less than 5 minutes and in no case longer than 15 minutes.**

Tubal Ring Outer carton without CE mark for MOH INDIA, Back Side | SPE/QA/7031/D | Date - 18/09/2017 | Size - 470 x 325 mm.

TUBAL RING

(A DEVICE FOR FEMALE STERILIZATION)

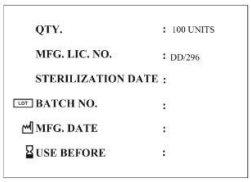
STERILE	R

Manufactured by :

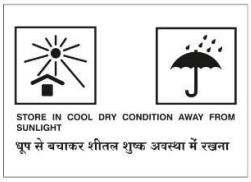
Government of India
FREE SUPPLY. Not for Sale.

Tubal Ring Inner carton without CE mark for MOH INDIA, Front side | SPE/QA/7030/D | Date - 26/12/2016 | Size - 165 x 60 mm.

Tubal Ring Inner carton without CE mark for MOH INDIA, Right Side | SPE/QA/7030/D | Date - 26/12/2016 | Size - 85 x 60 mm.

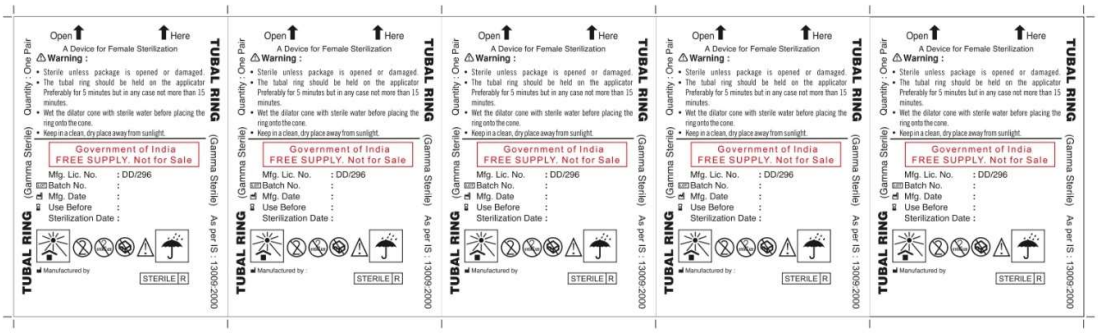


Tubal Ring Inner carton without CE mark for MOH INDIA, Left side | SPE/QA/7030/D | Date - 26/12/2016 | Size - 85 x 60 mm.



Annexure-12 a

Tubal Ring Artwork for DAMAN: Pouch Size: 250 X 70 mm



Schedule V


RSG 29.11.12
SIZE:115x65x70mm
Nishchay
निश्चय
Rapid One Step hCG-Urine Pregnancy Test Card
(Anti hCG Anti Sera on membrane)
Government of India Free Supply. Not for sale
(नूतन तोपनो)
(NUTAN TOPNO)
अवर सचिव/Under Secretary
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & F.W.
भारत सरकार/Govt. of India
नई दिल्ली/New Delhi


RSG 14.03.2018
Size: 110 x 60 x 60 mm
Nishchay
निश्चय
Nishchay
Rapid One Step hCG-Urine Pregnancy Test Card
(Anti hCG Anti Sera on membrane)
स्वस्थ मातृत्व, अब आपके हाथ
Healthy Motherhood, Now in your control
Nishchay
Rapid One Step hCG-Urine Pregnancy Test Card
(Anti hCG Anti Sera on membrane)
Government of India Free Supply, Not for sale.
निश्चय
Nishchay
Rapid One Step hCG-Urine Pregnancy Test Card
(Anti hCG Anti Sera on membrane)
स्वस्थ मातृत्व, अब आपके हाथ
Healthy Motherhood, Now in your control
Contents:
1. Laminated pouches : 10 Nos
Each pouch contains
one test card + one dropper + one silica gel
2. Product Insert : 1 Nos
Manufactured by:
HLL Lifecare Limited
(A Government of India Enterprise)
Plot No.71, Sector-7, IMT,
Manesar, Distt. Gurgaon(Haryana)-122051, INDIA
Email: qamfg@lifecarehll.com
www.lifecarehll.com
Store at room temperature. For in vitro use only.

Size 110 x 65 mm

CMYK Blue

(नूतन तोपनो)
(NUTAN TOPNO)
अवर सचिव/Under Secretary
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & F.W.
भारत सरकार/Govt. of India
नई दिल्ली/New Delhi