CIN:U22193DL2024PLC428183

ANONDITA MEDICARE LIMITED

AN ISO 9001 : 2015 ISO 13485 : 2016 & CDSCO Certified Co.
Manufacturer of Condoms

To,
Binoy Yohannan
Vice President - Surveillance
National Stock Exchange of India Limited
Exchange Plaza, Bandra Kurla Complex,
Bandra (East), Mumbai-400051

Date: 08.10.2025

SYMBOL: **ANONDITA**
ISIN: **INE0VTV01012**

SUBJECT: Reply to query regarding "Movement in Price" from your good office dated 07th Oct, 2025.

Dear Sir,

This is with reference to your letter No. NSE/CM/Surveillance/15933 dated 07.10.2025, seeking information/announcement (including any impending announcements) from the Company with respect to the significant movement in the price of our Company's securities across the Stock Exchanges in the recent past.

In this regard, we wish to inform as under:

The Company has already submitted the latest information/announcement on **September 20, 2025**, vide **NEAPS Application No. 2025/Sep/197822/13568**, and subsequently again in XBRL format on **October 03, 2025**, vide **Application No. 2025/Oct/211068/1156**. Copies of the said announcements are enclosed herewith for your ready reference.

Sir, the Company confirms that it has disclosed all material information/event and there is no other information/event which is not there in public domain, that is required to be disclosed to the Stock Exchange pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 which in our opinion would have a bearing on the captioned volume / price behavior of the Scrip.

Therefore, the movement in the Company's share price appears to be purely **market-driven**, over which the Company has neither any control nor any specific knowledge of the reasons for such movement. Hence, as mentioned above, we are unable to offer any comments on the recent trading in price movement of the Company's securities across the Exchanges.

This is for your information and records.

Yours faithfully,
For Anondita Medicare Limited

Nutan Agrawal

Nutan Agrawal
Company Secretary & Compliance Officer
Membership No. 58113

Regd. off : Flat No. 704, Narmada Block N-6, Sec-D, Pocket-C, Vasant Kunj, New Delhi-110070
Corp Off. : D-001, Sector-80, Noida-201305, (U.P.) INDIA
Tel.: 0120-4520300/1/2/3 till 99 (100 Lines) Fax : 0120-4520314
E-mail : accounts@anonditahealthcare.com | info@anonditahealthcare.com
Website: www.anonditahealthcare.net

Dated: 20th September, 2025

To,
National Stock Exchange of India Ltd.
Exchange Plaza, Bandra Kurla Complex
Bandra (E), Mumbai – 400051

Subject: Disclosure regarding **under Part B of sub-regulation (4) of regulation (30)** of Securities and Exchange
Board Of India (Listing Obligations and Disclosure Requirements) Regulations, 2015

Dear Sir/Madam,

This is to inform you that Anondita Medicare Limited participated in the tender issued by Central Medical Services Society (CMSS) on GeM portal vide **Bid Number: GEM/2025/B/6416312, on 04th July 2025**, **Tender No. CMSS/PROC/2025-26/FP/017, dated 04th July 2025.**

The Company participated in the above **Bid Number: GEM/2025/B/6416312, on 04th July 2025**.

We hereby disclose that the Company has been awarded (L1, Lowest One) the tender, in compliance with Part B of sub-regulation (4) of regulation (30) of the Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015.

The relevant **bid document and screenshot evidencing** the award of the order are enclosed herewith for your reference.

This disclosure is made for your information and dissemination to the stakeholders.

Thanking you.

Yours sincerely,
For Anondita Medicare Limited

Anupam Ghosh

Digitally signed by Anupam Ghosh
DN: c=IN, o=Personal, postalCode=110070, l=South West Delhi, st=Delhi, street=Flat No.704 Vasant Kunj, Vasant Kunj, Vasant Vihar Delhi India 110070, title=2285, 2.5.4.20=5026e72627fdccaa6d3273cdc125e07662 20b798b9fedf3d261ceed184455725, serialNumber=5dd2613aab2c4f7ab356bddda643c561813ae9d8e9f99e403e60259646b99570, email=anonditahealthcarefinance@gmail.com, cn=Anupam Ghosh
Date: 2025.09.20 16:21:41 +05'30'

Anupam Ghosh
Managing Director

बिड संख्या/Bid Number: GEM/2025/B/6416312

दिनांक /Dated: 04-07-2025

बिड दस्तावेज़ / Bid Document

बिड विवरण/Bid Details	
बिड बंद होने की तारीख/समय /Bid End Date/Time	28-07-2025 17:00:00
बिड खुलने की तारीख/समय /Bid Opening Date/Time	28-07-2025 17:30:00
बिड पेशकश वैधता (बंद होने की तारीख से)/Bid Offer Validity (From End Date)	150 (Days)
मंत्रालय/राज्य का नाम/Ministry/State Name	Ministry Of Health And Family Welfare
विभाग का नाम/Department Name	Department Of Health And Family Welfare
संगठन का नाम/Organisation Name	Central Medical Services Society (cmss)
कार्यालय का नाम/Office Name	Ii Floor Viswayuvak Kendra Chanakyapuri
कुल मात्रा/Total Quantity	257491100
वस्तु श्रेणी /Item Category	Condoms (Free Supply) for Family Planning Programme (Q1) , OCP (Free Supply) for Family Planning Programme (Q1) , Emergency Contraceptives Pills (ECP) for Family Planning Programme (Q1) , Pregnancy Test Kit for Family Planning Programme (Q1) , Injectable Contraceptive (Antara) for Family Planning Programme (Q1) , IUCD 380A for Family Planning Programme (Q1) , IUCD 375 for Family Planning Programme (Q1) , Tubal Rings for Family Planning Programme (Q1)
बिडर का न्यूनतम औसत वार्षिक टर्नओवर (3 वर्षों का) /Minimum Average Annual Turnover of the bidder (For 3 Years)	41 Lakh (s)
मूल उपकरण निर्माता का औसत टर्नओवर (गत 3 वर्षों का)/OEM Average Turnover (Last 3 Years)	82 Lakh (s)
उन्हीं/समान सेवा के लिए अपेक्षित विगत अनुभव के वर्ष/Years of Past Experience Required for same/similar service	2 Year (s)
टर्नओवर के लिए एमएसई को छूट प्राप्त है / MSE Exemption for Turnover	Yes | Partial | Turn over value - 0 (in lakhs)
टर्नओवर के लिए स्टार्टअप को छूट प्राप्त है / Startup Exemption for Turnover	Yes | Partial | Turn over value - 0 (in lakhs)

बिड विवरण/Bid Details	
विक्रेता से मांगे गए दस्तावेज़/Document required from seller	Experience Criteria,Past Performance,Bidder Turnover,Certificate (Requested in ATC),OEM Authorization Certificate,OEM Annual Turnover,Additional Doc 1 (Requested in ATC),Additional Doc 2 (Requested in ATC),Additional Doc 3 (Requested in ATC),Additional Doc 4 (Requested in ATC),Compliance of BoQ specification and supporting document *In case any bidder is seeking exemption from Experience / Turnover Criteria, the supporting documents to prove his eligibility for exemption must be uploaded for evaluation by the buyer
क्या आप निविदाकारों द्वारा अपलोड किए गए दस्तावेज़ों को निविदा में भाग लेने वाले सभी निविदाकारों को दिखाना चाहते हैं? संदर्भ मेनू है/Do you want to show documents uploaded by bidders to all bidders participated in bid?	No
बिड लगाने की समय-सीमा बढ़ाने के लिए आवश्यक न्यूनतम सहभागी विक्रेताओं की संख्या। / Minimum number of bids required to disable automatic bid extension	1
दिनों की संख्या, जिनके लिए बिड लगाने की समय-सीमा बढ़ाई जाएगी। / Number of days for which Bid would be auto-extended	7
विगत प्रदर्शन /Past Performance	40 %
बिड से रिवर्स नीलामी सक्रिय किया/Bid to RA enabled	No
बिड का प्रकार/Type of Bid	Two Packet Bid
प्राथमिक उत्पाद श्रेणी/Primary product category	Condoms (Free Supply) for Family Planning Programme
तकनीकी मूल्यांकन के दौरान तकनीकी स्पष्टीकरण हेतु अनुमत समय /Time allowed for Technical Clarifications during technical evaluation	2 Days
निरीक्षण आवश्यक (सूचीबद्ध निरीक्षण प्राधिकरण /जेम के साथ पूर्व पंजीकृत एजेंसियों द्वारा)/Inspection Required (By Empanelled Inspection Authority / Agencies pre-registered with GeM)	No
क्या पार्ट क्वांटिटी बोली लगाने की अनुमति है? / Is Part Quantity Bidding Allowed?	Yes
मूल्यांकन पद्धति/Evaluation Method	Item wise evaluation/
मध्यस्थता खंड/Arbitration Clause	No
सुलह खंड/Mediation Clause	No

ईएमडी विवरण/EMD Detail

एडवाईजरी बैंक/Advisory Bank	State Bank of India

Schedule 1 ईएमडी राशि/EMD Amount (In INR)	3736506
Schedule 2 ईएमडी राशि/EMD Amount (In INR)	2436709
Schedule 3 ईएमडी राशि/EMD Amount (In INR)	123992
Schedule 4 ईएमडी राशि/EMD Amount (In INR)	516239
Schedule 5 ईएमडी राशि/EMD Amount (In INR)	1405646
Schedule 6 ईएमडी राशि/EMD Amount (In INR)	972498
Schedule 7 ईएमडी राशि/EMD Amount (In INR)	661339
Schedule 8 ईएमडी राशि/EMD Amount (In INR)	205390

ईपीबीजी विवरण /ePBG Detail

आवश्यकता/Required	No

(a). जेम की शर्तों के अनुसार ईएमडी छूट के इच्छुक बिडर को संबंधित केटेगरी के लिए बिड के साथ वैध समर्थित दस्तावेज़ प्रस्तुत करने है। एमएसई केटेगरी के अंतर्गत केवल वस्तुओं के लिए विनिर्माता तथा सेवाओं के लिए सेवा प्रदाता ईएमडी से छूट के पात्र हैं। व्यापारियों को इस नीति के दायरे से बाहर रखा गया है।/EMD EXEMPTION: The bidder seeking EMD exemption, must submit the valid supporting document for the relevant category as per GeM GTC with the bid. Under MSE category, only manufacturers for goods and Service Providers for Services are eligible for exemption from EMD. Traders are excluded from the purview of this Policy.

(b). The EMD Amount will be applicable for each schedule/group selected during Bid creation.

(c).ईएमडी और संपादन जमानत राशि, जहां यह लागू होती है, लाभार्थी के पक्ष में होनी चाहिए। / EMD & Performance securityshould be in favour of Beneficiary, wherever it is applicable.

लाभार्थी /Beneficiary :

DG&CEO
II Floor ViswaYuvak Kendra Chanakyapuri, Department of Health and Family Welfare, Central Medical Services Society (CMSS), Ministry of Health and Family Welfare
(Vijay Nehra)

विभाजन/Splitting

विभाजन/Splitting

विभाजन/Splitting Applied	Yes
बोलीदाताओं की अधिकतम संख्या, जिनके बीच ऑर्डर विभाजित किया जा सकता है। / Maximum No. Of Bidders Amongst Which Order May Be Split	2

विभाजन मानदंड इस बात पर आधारित है कि कौन सी क्वांटिटी को वितरित किया जाएगा / Split Criteria based on which quantity will be distributed	70:30

एमआईआई खरीद वरीयता/MII Purchase Preference

एमआईआई खरीद वरीयता/MII Purchase Preference	Yes

एमएसई खरीद वरीयता/MSE Purchase Preference

एमएसई खरीद वरीयता/MSE Purchase Preference	Yes

1. If the bidder is a Micro or Small Enterprise (MSE) as per latest orders issued by Ministry of MSME, the bidder shall be exempted from the eligibility criteria of "Bidder Turnover" as defined above subject to meeting of quality and technical specifications. If the bidder itself is MSE OEM of the offered products, it would be exempted from the "OEM Average Turnover" criteria also subject to meeting of quality and technical specifications. The bidder seeking exemption from Turnover, shall upload the supporting documents to prove his eligibility for exemption.
2. If the bidder is a DPIIT registered Startup, the bidder shall be exempted from the the eligibility criteria of "Bidder Turnover" as defined above subject to their meeting of quality and technical specifications. If the bidder is DPIIT Registered OEM of the offered products, it would be exempted from the "OEM Average Turnover" criteria also subject to meeting of quality and technical specifications. The bidder seeking exemption from Turnover shall upload the supporting documents to prove his eligibility for exemption.
3. The minimum average annual financial turnover of the bidder during the last three years, ending on 31st March of the previous financial year, should be as indicated above in the bid document. Documentary evidence in the form of certified Audited Balance Sheets of relevant periods or a certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period shall be uploaded with the bid. In case the date of constitution / incorporation of the bidder is less than 3-year-old, the average turnover in respect of the completed financial years after the date of constitution shall be taken into account for this criteria.
4. Experience Criteria: In respect of the filter applied for experience criteria, the Bidder or its OEM of the product offered in the bid {themselves or through reseller(s)} should have regularly, manufactured and supplied same or similar Category Products to any Central / State Govt Organization / PSU for number of Financial years as indicated above in the bid document before the bid opening date. Copies of relevant contracts and delivery acceptance certificates like CRAC to be submitted along with bid in support of having supplied some quantity during each of the Financial year. In case of bunch bids, the category of primary product having highest value should meet this criterion.
5. OEM Turn Over Criteria: The minimum average annual financial turnover of the OEM of the offered product during the last three years, ending on 31st March of the previous financial year, should be as indicated in the bid document. Documentary evidence in the form of certified Audited Balance Sheets of relevant periods or a certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period shall be uploaded with the bid. In case the date of constitution / incorporation of the OEM is less than 3 year old, the average turnover in respect of the completed financial years after the date of constitution shall be taken into account for this criteria.
6. Preference to Make In India products (For bids < 200 Crore):Preference shall be given to Class 1 local supplier as defined in public procurement (Preference to Make in India), Order 2017 as amended from time to time and its subsequent Orders/Notifications issued by concerned Nodal Ministry for specific Goods/Products. The minimum local content to qualify as a Class 1 local supplier is denoted in the bid document. If the bidder wants to avail the Purchase preference, the bidder must upload a certificate from the OEM regarding the percentage of the local content and the details of locations at which the local value addition is made along with their bid, failing which no purchase preference shall be granted. In case the bid value is more than Rs 10 Crore, the declaration relating to percentage of local content shall be certified by the statutory auditor or cost auditor, if the OEM is a company and by a practicing cost accountant or a chartered accountant for OEMs other than companies as per the Public Procurement (preference to Make-in -India) order 2017 dated 04.06.2020. Only Class-I and Class-II Local suppliers as per MII order dated 4.6.2020 will be eligible to bid. Non - Local suppliers as per MII order dated 04.06.2020 are not eligible to participate. However, eligible micro and small enterprises will be allowed to participate .The buyers are advised to refer the OM No.F.1/4/2021-PPD dated 18.05.2023.

OM_No.1_4_2021_PPD_dated_18.05.2023 for compliance of Concurrent application of Public Procurement Policy for Micro and Small Enterprises Order, 2012 and Public Procurement (Preference to Make in India) Order, 2017.

7. Purchase preference will be given to MSEs having valid Udyam Registration and whose credentials are validated online through Udyam Registration portal as defined in Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of Micro, Small and Medium Enterprises and its subsequent Orders/Notifications issued by concerned Ministry. If the bidder wants to avail themselves of the Purchase preference, the bidder must be the manufacturer / OEM of the offered product on GeM. Traders are excluded from the purview of Public Procurement Policy for Micro and Small Enterprises and hence resellers offering products manufactured by some other OEM are not eligible for any purchase preference. In respect of bid for Services, the bidder must be the Service provider of the offered Service. Relevant documentary evidence in this regard shall be uploaded along with the bid in respect of the offered product or service and Buyer will decide eligibility for purchase preference based on documentary evidence submitted, while evaluating the bid. If L-1 is not an MSE and MSE Seller (s) has / have quoted price within L-1+ 15% (Selected by Buyer) of margin of purchase preference /price band defined in relevant policy, such MSE Seller shall be given opportunity to match L-1 price and contract will be awarded for 25% (selected by Buyer) percentage of total quantity. The buyers are advised to refer the OM No. F.1/4/2021-PPD dated 18.05.2023 OM_No.1_4_2021_PPD_dated_18.05.2023 for compliance of Concurrent application of Public Procurement Policy for Micro and Small Enterprises Order, 2012 and Public Procurement (Preference to Make in India) Order, 2017. Benefits of MSE will be allowed only if seller is validated on-line in GeM profile as well as validated and approved by Buyer after evaluation of documents submitted.

पार्ट क्वांटिटी बोली लगाना / **Part Quantity Bidding**

Buyer has allowed part quantity bidding, bidders can offer maximum quantity that they can deliver keeping in mind their capacity and delivery period requirements. The offer quantity has to be more than minimum bid quantity as specified by the Buyer in the bid. Offers with quantity less than Minimum are liable to be rejected. It may however be noted that there is no guarantee that full offer quantity will be ordered by the buyer. Quantity to be ordered by the buyer will depend on various factors including the Ranking of the bidder, Offered quantity, Splitting criteria indicated by the buyer in the bid and the requirement of the buyer to have multiple sources of supply for ensuring supply chain etc. Sellers would be notified about likely order quantity or range of possible order quantity at the time of price match request made by the buyer. ward of contract will be subject to acceptance of price match request along with min / max offer quantity as decided by the Buyer.

8. Estimated Bid Value indicated above is being declared solely for the purpose of guidance on EMD amount and for determining the Eligibility Criteria related to Turn Over, Past Performance and Project / Past Experience etc. This has no relevance or bearing on the price to be quoted by the bidders and is also not going to have any impact on bid participation. Also this is not going to be used as a criteria in determining reasonableness of quoted prices which would be determined by the buyer based on its own assessment of reasonableness and based on competitive prices received in Bid / RA process.
9. Past Performance: The Bidder or its OEM {themselves or through re-seller(s)} should have supplied same or similar Category Products for 40% of bid quantity, in at least one of the last three Financial years before the bid opening date to any Central / State Govt Organization / PSU. Copies of relevant contracts (proving supply of cumulative order quantity in any one financial year) to be submitted along with bid in support of quantity supplied in the relevant Financial year. In case of bunch bids, the category related to primary product having highest bid value should meet this criterion.

Pre Bid Detail(s)

मूल्य भिन्नता खंड दस्तावेज़/Pre-Bid Date and Time	प्री-बिड स्थान/Pre-Bid Venue
09-07-2025 11:00:00	CMSS New Delhi

मूल्यांकन विधि(मदवार मूल्यांकन विधि) / **Evaluation Method** (Item Wise Evaluation Method)

Contract will be awarded schedulewise and the determination of L1 will be done separately for each schedule. The details of item-consignee combination covered under each schedule are as under:

मूल्यांकन अनुसूचियां / **Evaluation Schedules**	वस्तु/श्रेणी / **Item/Category**	मात्रा / **Quantity**
Schedule 1	Condoms (free Supply) For Family Planning Programme	197698750
Schedule 2	Ocp (free Supply) For Family Planning Programme	30535200
Schedule 3	Emergency Contraceptives Pills (ecp) For Family Planning Programme	4609350
Schedule 4	Pregnancy Test Kit For Family Planning Programme	15050700
Schedule 5	Injectable Contraceptive (antara) For Family Planning Programme	3982000
Schedule 6	Iucd 380a For Family Planning Programme	2652750
Schedule 7	Iucd 375 For Family Planning Programme	2010150
Schedule 8	Tubal Rings For Family Planning Programme	952200

विक्रेता से आवश्यक मदवार न्यूनतम क्षमता / Itemwise Minimum Capacity Required From Seller

S.No.	Schedule Name	Item Category	Item Quantity	Minimum Capacity
1	Schedule 1	Condoms (Free Supply) for Family Planning Programme	197698750	98849375
2	Schedule 2	OCP (Free Supply) for Family Planning Programme	30535200	15267600
3	Schedule 3	Emergency Contraceptives Pills (ECP) for Family Planning Programme	4609350	2304675
4	Schedule 4	Pregnancy Test Kit for Family Planning Programme	15050700	7525350
5	Schedule 5	Injectable Contraceptive (Antara) for Family Planning Programme	3982000	1991000
6	Schedule 6	IUCD 380A for Family Planning Programme	2652750	1326375
7	Schedule 7	IUCD 375 for Family Planning Programme	2010150	1005075
8	Schedule 8	Tubal Rings for Family Planning Programme	952200	476100

Condoms (Free Supply) For Family Planning Programme (197698750 pieces)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

[* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification]

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
PRODUCT INFORMATION	**Product Description**	Condom (Free Supply)
	Conformity to technical specifications	As per detailed technical specification document attached/uploaded
	Attached/uploaded technical specification has been seen, read and understood	Yes

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
CERTIFICATIONS	Compliance to Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid medical device manufacturing license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Manufacturing Facility Certification	ISO:13485 (Latest)
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission and/or along with supplies as per buyer requirement	Yes

अतिरिक्त विशिष्टि दस्तावेज़ /Additional Specification Documents

Applicable Specification Document	View

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Anurodh Singh	110021,Second Floor , Viswa Yuvak Kendra , Chanakyapuri New Delhi -110021	197698750	270

OCP (Free Supply) For Family Planning Programme (30535200 packet)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
PRODUCT INFORMATION	**Product Description**	Oral Contraceptive Pill (Free Supply)
	Conformity to technical specifications	As per detailed technical specification document attached/uploaded
	Attached/uploaded technical specification has been seen, read and understood	Yes
CERTIFICATIONS	Availability of valid drug manufacturing license issued from the competent authority defined under Drugs and Cosmetic Act and Rules there under as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission and/or along with supplies as per buyer requirement	Yes

अतिरिक्त विशिष्टि दस्तावेज़ /Additional Specification Documents

Applicable Specification Document	View

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Anurodh Singh	110021,Second Floor , Viswa Yuvak Kendra , Chanakyapuri New Delhi -110021	30535200	270

Emergency Contraceptives Pills (ECP) For Family Planning Programme (4609350 packet)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
PRODUCT INFORMATION	**Product Description**	Emergency Contraceptive Pills (ECP)
	Conformity to technical specifications	As per detailed technical specification document attached/uploaded
	Attached/uploaded technical specification has been seen, read and understood	Yes
CERTIFICATIONS	Availability of valid drug manufacturing license issued from the competent authority defined under Drugs and Cosmetic Act and Rules there under as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission and/or along with supplies as per buyer requirement	Yes

अतिरिक्त विशिष्टि दस्तावेज़ /Additional Specification Documents

Applicable Specification Document	View

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Anurodh Singh	110021,Second Floor , Viswa Yuvak Kendra , Chanakyapuri New Delhi -110021	4609350	270

Pregnancy Test Kit For Family Planning Programme (15050700 packet)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
PRODUCT INFORMATION	**Product Description**	Pregnancy Test Kit
	Conformity to technical specifications	As per detailed technical specification document attached/uploaded
	Attached/uploaded technical specification has been seen, read and understood	Yes
CERTIFICATIONS	Compliance to Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid medical device manufacturing license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Manufacturing Facility Certification	ISO:13485 (Latest)
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission and/or along with supplies as per buyer requirement	Yes

अतिरिक्त विशिष्टि दस्तावेज़ /Additional Specification Documents

Applicable Specification Document	View

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Anurodh Singh	110021,Second Floor , Viswa Yuvak Kendra , Chanakyapuri New Delhi -110021	15050700	270

Injectable Contraceptive (Antara) For Family Planning Programme (3982000 dose(s))

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
PRODUCT INFORMATION	**Product Description**	Injectable Contraceptive (Medroxyprogesterone Acetate)
	Conformity to technical specifications	As per detailed technical specification document attached/uploaded
	Attached/uploaded technical specification has been seen, read and understood	Yes
CERTIFICATIONS	Availability of valid drug manufacturing license issued from the competent authority defined under Drugs and Cosmetic Act and Rules there under as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission and/or along with supplies as per buyer requirement	Yes

अतिरिक्त विशिष्टि दस्तावेज़ /Additional Specification Documents

Applicable Specification Document	View

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Anurodh Singh	110021,Second Floor , Viswa Yuvak Kendra , Chanakyapuri New Delhi -110021	3982000	270

IUCD 380A For Family Planning Programme (2652750 pieces)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local

Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

[* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification]

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
PRODUCT INFORMATION	**Product Description**	Copper-T 380A
	Conformity to technical specifications	As per detailed technical specification document attached/uploaded
	Attached/uploaded technical specification has been seen, read and understood	Yes
CERTIFICATIONS	Compliance to Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid medical device manufacturing license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Manufacturing Facility Certification	ISO:13485 (Latest)
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission and/or along with supplies as per buyer requirement	Yes

अतिरिक्त विशिष्टि दस्तावेज़ /Additional Specification Documents

Applicable Specification Document	View

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Anurodh Singh	110021,Second Floor , Viswa Yuvak Kendra , Chanakyapuri New Delhi -110021	2652750	270

IUCD 375 For Family Planning Programme (2010150 pieces)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
PRODUCT INFORMATION	**Product Description**	Copper Intra Uterine Contraceptive Device 375
	Conformity to technical specifications	As per detailed technical specification document attached/uploaded
	Attached/uploaded technical specification has been seen, read and understood	Yes
CERTIFICATIONS	Compliance to Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid medical device manufacturing license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Manufacturing Facility Certification	ISO:13485 (Latest)
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission and/or along with supplies as per buyer requirement	Yes

अतिरिक्त विशिष्टि दस्तावेज़ /Additional Specification Documents

Applicable Specification Document	View

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Anurodh Singh	110021,Second Floor , Viswa Yuvak Kendra , Chanakyapuri New Delhi -110021	2010150	270

Tubal Rings For Family Planning Programme (952200 pairs)

(क्रमशः श्रेणी 1 और श्रेणी 2 के स्थानीय आपूर्तिकर्ता के रूप में अर्हता प्राप्त करने के लिए आवश्यक/Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier respectively)

तकनीकी विशिष्टियाँ /Technical Specifications

* जेम केटेगरी विशिष्टि के अनुसार / As per GeM Category Specification

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
PRODUCT INFORMATION	**Product Description**	Tubal Rings
	Conformity to technical specifications	As per detailed technical specification document attached/uploaded
	Attached/uploaded technical specification has been seen, read and understood	Yes
CERTIFICATIONS	Compliance to Medical Device Rules (MDR) 2017 as amended till date	Yes
	Availability of valid medical device manufacturing license for the product issued from the competent authority defined under Drugs and Cosmetic Act 1940 and Rules made there under as amended till date	Yes
	Manufacturing Facility Certification	ISO:13485 (Latest)
	Availability of Test Report for each supplied batch/product as per Medical Device Rules (MDR) 2017 as amended till date	Yes

विवरण/Specification	विशिष्टि का नाम /Specification Name	बिड के लिए आवश्यक अनुमत मूल्य /Bid Requirement (Allowed Values)
	Submission of all necessary certifications, licenses and test reports to the buyer at the time of bid submission and/or along with supplies as per buyer requirement	Yes

अतिरिक्त विशिष्टि दस्तावेज़ /Additional Specification Documents

Applicable Specification Document	View

परेषिती/रिपोर्टिंग अधिकारी तथा मात्रा/Consignees/Reporting Officer and Quantity

क्र.सं./S.No.	परेषिती/रिपोर्टिंग अधिकारी /Consignee Reporting/Officer	पता/Address	मात्रा /Quantity	डिलीवरी के दिन/Delivery Days
1	Anurodh Singh	110021,Second Floor , Viswa Yuvak Kendra , Chanakyapuri New Delhi -110021	952200	270

Special terms and conditions-Version:1 effective from 29-07-2024 for category Condoms (Free Supply) for Family Planning Programme

1. 1. *A*ll Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
   2. The sellers are registered on GeM based on self-declaration of valid Medical Device License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of license, product certification, manufacturer certification/licenses, test reports etc.
   3. In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including verifying the validity and authenticity of Medical Device License license held by them.
   4. The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
   5. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC/GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure items are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 29-07-2024 for category OCP (Free Supply) for Family Planning Programme

1. 1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the undertaking & submitted copy of a valid Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitting the relevant valid drug license and other regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., validity, authenticity/genuineness, name of the drug/medicine under procurement, the license issuing authority etc. at their end.
   2. The Buyer shall ask the seller to submit the “Notarized Undertaking” in the mentioned below format (scanned copy and hard copy). Details of the same may be verified by the buyer at their end.

UNDERTAKING

(to be on non-judicial stamp paper of Rs 10 and notarized)

I, _____, s/o / d/o / w/o _____, aged about _____resident of _____, do hereby declare and undertake that;

1. I am the partner / proprietor / director of _____ *(name of entity)* and duly authorized to sign this undertaking on behalf of _____. *(Name of entity)*
2. We are the manufacturers of the drug/medicine _____(“Product”) and intend to offer the same for sale through the GeM portal.
3. We state that the license for the Product has been granted/obtained by us as per the provisions of the Drug & Cosmetics Act, 1940 and rules framed there under as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the online ‘SUGAM’ portal of CDSCO as per rule 84AB of the Drugs and Cosmetics Rules, 1945 as amended till date. Reference no. for SUGAM portal is_____.
5. We undertake that all the information provided above is true and complete in all respect. We understand that in the event any false information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetics Act, 1940 as amended till date and rules made there under will be initiated.

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

3. All Provisions of Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date will always be applicable. This will include all notifications issued by *Central Drugs Standard Control Organization* (*CDSCO*), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be applicable in case of Narcotic Drugs & Psychotropic Substances.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing authority defined under the Drugs and Cosmetics Act 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly marked and highlighted in Drug Manufacturing License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submission/delivery as per buyer requirement.

   In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their authorized resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products.

   Manufacturer shall be responsible for verifying the validity and authenticity of drug license held by their authorized resellers/distributors.

   If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of application to State Drug / Licensing authority must be submitted with a certificate that

application for renewal was made within time frame as per Drug and Cosmetic Act as amended up to date and that has not been deleted by drug licensing authority.

7. Bidder/Seller shall submit the valid GMP/WHO-GMP Certificate of the manufacturing site as per revised Schedule-'M' for the quoted drugs/medicines issued by the Concerned Drug Licensing Authority to the buyer at the time of bid submission.
8. Bidder/Seller shall submit a valid **non-Conviction** certificate for last two (2) consecutive years issued by the Concerned Drug Licensing authority to the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of technical opening of the bid.
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the concerned drug licensing authority for at least latest 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine quoted should be clearly marked and highlighted.

   This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from the Drug Controller General (India) shall be required for all new drug formulations to this effect.

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which are not separate entities then the company will be allowed to submit only one bid for all units but necessary document regarding separate manufacturing units will be submitted to the buyer. However, one bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) as per Schedule "L1" of the Drugs & Cosmetics Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA for the quoted drugs/medicines (as applicable).
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug licensing authority highlighting the quoted product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia drugs/medicines are required to be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for all drugs/medicines in specified packing for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data of 6 months period shall be acceptable. (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, then the stability data of the licensor should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any State Government / Central Government / Central or State Government's Drug procurement agencies at the time of submission of bid. Further, quoted drugs / medicines have not been failed in house testing or testing by any State Government / Central Government / its Drug procurement agencies during last two years. If any bidder/seller has been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner / Director / Owner shall not be permitted to participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any State Government / Central Government/Central or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to the buyer along with relevant authentic document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government or State Government or its procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be convicted/ or a criminal case filed against or pending in any court of India by any department of Govt. under prevention of Corruption Act or for cheating/ defrauding Government/ embezzlement of Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only) duly attested by the Notary stating that:

    They will comply with all the statues &legislation regarding manufacturing, import, sale, and supply of drugs in India and in particular the following Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Legal Metrology Act, 2009, The Drugs (Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.

    To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act,

1940 (as amended). The bidder shall also undertake not to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as per the latest guidelines issued by the Drug Controller of India from time to time.

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or price fixed by the State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provision of Public Procurement (Preference to Make in India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceutical Formulations, will be applicable.
22. **Fall Clause**: Provision of fall clause will not be applicable on the sale of drugs which have an expiry date as per Ministry of Chemical and Fertilizer OM No 31026/1/2019-Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Rules, 1945 as amended up to date.

    In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed more than one sixth (1/6th) of the total shelf life of the drug/medicine at the time of delivery to the consignee.

    In case of pre-dispatch inspection, at the time when the stores are offered for inspection, the life of the drugs/medicines shall not have passed more than one sixth (1/6th) of the total shelf life of the drugs/medicines.

24. **Recalls**

    If products are recalled because of problems with product quality or adverse reaction to the pharmaceutical, the supplier will be obliged to notify the buyer, providing full details about the reason leading to the recall, and shall take steps to replace the product in question at suppliers own cost at the ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund of the unconsumed quantity if the product has been taken off the market due to safety problems.

25. **Inspection, Testing and Quality Control**
    - All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report/Certificate of Analysis** from the manufacturer's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:

    1. Generic name of the product
    2. Batch No.
    3. Pharmacopoeia Reference and/ or In-house method
    4. Batch quantity
    5. Date of manufacture
    6. Expiry date
    7. Date of test
    8. Description (clarity, color etc)
    9. 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
    10. Conclusion
    11. Qualified Person's signature

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

    - Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet required standards throughout specified shelf life. The buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government approved laboratories at any of, or any combination of or/ all following stages:

    a) At Pre-Dispatch stage

    b) At Delivery Stage: Inspection done once the drugs/medicines/goods reach at consignee location and before taking over supplied goods in inventory.

    c) Post Delivery Surveillance: The Drugs/Medicines/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/medicines/ goods. Quality Monitoring Activities may also be organized by the buyer post-delivery.

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratories for the purpose of Inspection & Quality Control. The sampling quantities shall be borne by the supplier.
- The buyer's right to inspect, test and, where necessary reject the drugs/medicines/goods after the drugs/medicines/goods arrival at the final destination shall in no way be limited or waived by reason of the goods having previously been inspected, tested and passed prior to the goods dispatch from the place of manufacture.
- **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each batch will be chosen for testing. The samples will be collected and sent to designated laboratories (NABL Accredited/Government approved laboratories) for testing as decided by the buyer.

  At post-delivery surveillance - The samples will be collected from the warehouse of buyer/or final consignee in States/UTs and sent to designated Quality Control Labs in respect of supplied drugs/medicines/goods at any point during specified shelf life as per decision of the buyer.

  Handling and testing charges will be borne by the buyer for the above purpose.

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

- **At any of testing stage**, Samples which do not meet quality requirement 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 drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier whether consumed fully/partially.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in quality tests, the buyer may reject them, and the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignee place at their own cost and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer to the supplier or as specified by the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take back the drugs/medicines/goods within the stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of 45 days.

  Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable period. The FDA/ Drugs Control Authority of concerned State will also be informed by the buyer for initiating necessary action on the supplier in their state. In addition, Security deposit will also be forfeited without any intimation.

  The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied drugs, medicines etc., shall be final and binding.

- In case any drug/medicine is found substandard either any of testing stage or during the shelf life of the item, the report of the NABL/Government approved laboratory shall be accepted by the supplier/seller. If the same is disputed by the supplier/seller giving the reasons, the sample will be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and conclusive report. However, the same should be submitted within three months, from the date of communication of the disputed test report to the supplier/seller. For this, supplier/seller should approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per procedure, from the Appellate Laboratory at their own cost.

  The de-registration / debarment action will be taken by the buyer against the manufacturing unit and contract holding firms (both) according to the category-A and category-B defects as per guidelines issued by the Ministry of Health & Family Welfare, Government of India and same will be communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the commercial final package on request by the buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the product(s) supplied shall be produced when demanded. For New drugs/medicines, complete stability data of 6 months period shall be acceptable.
- The case of admixture of drugs will be treated as a violation of terms and conditions and will not be accepted.
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines under the Drugs & Cosmetic Act, 1940 as amended up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Drug Testing Labs. Similarly, the authority for confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also with the DCGI/ State Drug Control Authorities.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended up to date, the DCGI/ CDSCO/ State Drug Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

26. **Deduction, Blacklisting, and other penalties on account of Quality failure**

    The suitable conditions may be added by the buyer in the bid through Additional Term & Conditions (ATC) as applicable.

27. **Quality Test by Statutory Authorities:**

    If any batch of any product(s) supplied by the supplier is declared “NOT OF STANDARD QUALITY”, by any government agencies or drug licensing authority, the supplier shall inform the same immediately to the buyer so that the use of the available stock of the particular item will be stopped. Further, the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

    The buyer may without prejudice to any other remedy for breach of contract, by written notice of default sent to the supplier, terminate the contract in whole or in part If the supplier fails to promptly replace any drug/medicine/goods rejected submitted for testing or subject to recall ordered by the applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports of adverse drugs reaction after giving prompt notice of the recall.

29. **Warranty**
    - Supplies must fully comply in all respect with the Technical specifications and conditions laid down in the contract and in accordance with the Pharmacopoeia standards.
    - Each supply should be accompanied with a "Warranty Certificate" duly signed by the Bidder as under:

      “The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under this contract shall be of the best quality and workmanship and shall be strictly in accordance with the specifications and particulars mentioned and the supplier/seller hereby guarantees that the stores would continue to conform to the description of and quality aforesaid for a period of useful life of minimum of five sixth (5/6th) of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the ranges set forth in the technical specification and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality or adverse Pharmaceuticals reaction. Notwithstanding the above, the fact that the said stores fail to conform to the description and quality aforesaid or have deteriorated and the decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the said stores, or such part thereof as may be discovered not to conform to the said description and quality. Losses due to premature deterioration due to biological and other activities during life potency will be made good and supplied by the firm at its own cost at consignee’s site.

      On such rejection, the stores will be at the seller's risk and all provisions herein contained relating to the rejection of stores shall apply. The supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of cost at the ultimate destination within a period of forty five days or such further period as may be extended from time to time by the buyer at his discretion, on application made there under by the supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer and in such an event the above mentioned warranty period shall apply to the stores replaced from the date of the replacement thereof otherwise the supplier/seller shall pay to the buyer such damage as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice any other rights of the buyer in that behalf under this contract or otherwise".

- Sl. No. & Date
- Nomenclature & Specification
- Name & Address of Manufacturing Unit
- Batch No.
- DOM & DOE
- Qty. of each batch
- Remarks

Signature name & designation and date with rubber stamp

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may proceed to take such remedial action(s) as may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without prejudice to other rights which the buyer may have against the supplier under the contract.

30. **Packaging, Labelling and Marking Requirements**

    Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Act, 1940 and the Rules made there under as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer in the bid through Additional Terms and Conditions (ATC) shall be complied with.

31. **Bar Coding**

    All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (primary, secondary, and tertiary level packaging) and should encode the information within the barcodes as mentioned by the buyers in addition to other existing statutory labelling and marking requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions (ATC) in the bid.

32. **Delivery Period**

    - Minimum delivery period will be of 45 days from the date of issuing of the purchase
    - The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated) during transit, otherwise if on checking it is found that temperature has not been maintained, supply against the said order is liable to be rejected and cancelled.
    - The items requiring special cold storage conditions shall be supplied with cold chain transporting system under cold chain norms from the manufacturing unit to the warehouses/consignee location.

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other requirement mentioned by the buyer through Additional Terms and Conditions (ATC) in the bid will be applicable.
34. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC & GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede specific Special Terms and Condistions (STC) which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 29-07-2024 for category Emergency Contraceptives Pills (ECP) for Family Planning Programme

1. 1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the undertaking & submitted copy of a valid Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitting the relevant valid drug license and other regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., validity, authenticity/genuineness, name of the drug/medicine under procurement, the license issuing authority etc. at their end.
   2. The Buyer shall ask the seller to submit the “Notarized Undertaking” in the mentioned below format (scanned copy and hard copy). Details of the same may be verified by the buyer at their end.

UNDERTAKING

(to be on non-judicial stamp paper of Rs 10 and notarized)

I, _____, s/o / d/o / w/o _____, aged about _____resident of _____, do hereby declare and undertake that;

1. I am the partner / proprietor / director of _____ *(name of entity)* and duly authorized to sign this undertaking on behalf of _____. *(Name of entity)*
2. We are the manufacturers of the drug/medicine _____("Product") and intend to offer the same for sale through the GeM portal.
3. We state that the license for the Product has been granted/obtained by us as per the provisions of the Drug & Cosmetics Act, 1940 and rules framed there under as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the online 'SUGAM' portal of CDSCO as per rule 84AB of the Drugs and Cosmetics Rules, 1945 as amended till date. Reference no. for SUGAM portal is_____.
5. We undertake that all the information provided above is true and complete in all respect. We understand that in the event any false information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetics Act, 1940 as amended till date and rules made there under will be initiated.

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

3. All Provisions of Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date will always be applicable. This will include all notifications issued by *Central Drugs Standard Control Organization* (*CDSCO*), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be applicable in case of Narcotic Drugs & Psychotropic Substances.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing authority defined under the Drugs and Cosmetics Act 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly marked and highlighted in Drug Manufacturing License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submission/delivery as per buyer requirement.

   In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their authorized resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products.

   Manufacturer shall be responsible for verifying the validity and authenticity of drug license held by their authorized resellers/distributors.

   If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of application to State Drug / Licensing authority must be submitted with a certificate that application for renewal was made within time frame as per Drug and Cosmetic Act as amended up to date and that has not been deleted by drug licensing authority.

7. Bidder/Seller shall submit the valid GMP/WHO-GMP Certificate of the manufacturing site as per revised Schedule-'M' for the quoted drugs/medicines issued by the Concerned Drug Licensing Authority to the buyer at the time of bid submission.
8. Bidder/Seller shall submit a valid **non-Conviction** certificate for last two (2) consecutive years issued by the Concerned Drug Licensing authority to the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of technical opening of the bid.
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the concerned drug licensing authority for at least latest 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine quoted should be clearly marked and highlighted.

This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from the Drug Controller General (India) shall be required for all new drug formulations to this effect.

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which are not separate entities then the company will be allowed to submit only one bid for all units but necessary document regarding separate manufacturing units will be submitted to the buyer. However, one bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) as per Schedule “L1” of the Drugs & Cosmetics Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA for the quoted drugs/medicines (as applicable).
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug licensing authority highlighting the quoted product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia drugs/medicines are required to be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for all drugs/medicines in specified packing for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data of 6 months period shall be acceptable. (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, then the stability data of the licensor should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any State Government / Central Government / Central or State Government’s Drug procurement agencies at the time of submission of bid. Further, quoted drugs / medicines have not been failed in house testing or testing by any State Government / Central Government / its Drug procurement agencies during last two years. If any bidder/seller has been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner / Director / Owner shall not be permitted to participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any State Government / Central Government/Central or State Government’s Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to the buyer along with relevant authentic document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government or State Government or its procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be convicted/ or a criminal case filed against or pending in any court of India by any department of Govt. under prevention of Corruption Act or for cheating/ defrauding Government/ embezzlement of Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only) duly attested by the Notary stating that:

    They will comply with all the statues &legislation regarding manufacturing, import, sale, and supply of drugs in India and in particular the following Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Legal Metrology Act, 2009, The Drugs (Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.

    To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 (as amended). The bidder shall also undertake not to supply items/drugs “not of standard”, “Grossly sub-standard” and “Spurious and adulterated drugs” as per the latest guidelines issued by the Drug Controller of India from time to time.

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or price fixed by the State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provision of Public Procurement (Preference to Make in India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceutical Formulations, will be applicable.
22. **Fall Clause**: Provision of fall clause will not be applicable on the sale of drugs which have an expiry date as per Ministry of Chemical and Fertilizer OM No 31026/1/2019-Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of

Drugs and Cosmetics Rules, 1945 as amended up to date.

In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed more than one sixth (1/6th) of the total shelf life of the drug/medicine at the time of delivery to the consignee.

In case of pre-dispatch inspection, at the time when the stores are offered for inspection, the life of the drugs/medicines shall not have passed more than one sixth (1/6th) of the total shelf life of the drugs/medicines.

24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceutical, the supplier will be obliged to notify the buyer, providing full details about the reason leading to the recall, and shall take steps to replace the product in question at suppliers own cost at the ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund of the unconsumed quantity if the product has been taken off the market due to safety problems.

25. **Inspection, Testing and Quality Control**

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report/Certificate of Analysis** from the manufacturer's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:

1. Generic name of the product
2. Batch No.
3. Pharmacopoeia Reference and/ or In-house method
4. Batch quantity
5. Date of manufacture
6. Expiry date
7. Date of test
8. Description (clarity, color etc)
9. 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
10. Conclusion
11. Qualified Person's signature

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet required standards throughout specified shelf life. The buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government approved laboratories at any of, or any combination of or/ all following stages:

a) At Pre-Dispatch stage

b) At Delivery Stage: Inspection done once the drugs/medicines/goods reach at consignee location and before taking over supplied goods in inventory.

c) Post Delivery Surveillance: The Drugs/Medicines/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/medicines/ goods. Quality Monitoring Activities may also be organized by the buyer post-delivery.

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratories for the purpose of Inspection & Quality Control. The sampling quantities shall be borne by the supplier.
- The buyer's right to inspect, test and, where necessary reject the drugs/medicines/goods after the drugs/medicines/goods arrival at the final destination shall in no way be limited or waived by reason of the goods having previously been inspected, tested and passed prior to the goods dispatch from the place of manufacture.
- **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each batch will be chosen for testing. The samples will be collected and sent to designated laboratories (NABL Accredited/Government approved laboratories) for testing as decided by the buyer.

At post-delivery surveillance - The samples will be collected from the warehouse of buyer/or final consignee in States/UTs and sent to designated Quality Control Labs in respect of supplied drugs/medicines/goods at any point during specified shelf life as per decision of the buyer.

Handling and testing charges will be borne by the buyer for the above purpose.

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

- **At any of testing stage**, Samples which do not meet quality requirement 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 drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier whether consumed fully/partially.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in quality tests, the buyer may reject them, and the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignee place at their own cost and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer to the supplier or as specified by the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take back the drugs/medicines/goods within the stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of 45 days.

  Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable period. The FDA/ Drugs Control Authority of concerned State will also be informed by the buyer for initiating necessary action on the supplier in their state. In addition, Security deposit will also be forfeited without any intimation.

  The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied drugs, medicines etc., shall be final and binding.

- In case any drug/medicine is found substandard either any of testing stage or during the shelf life of the item, the report of the NABL/Government approved laboratory shall be accepted by the supplier/seller. If the same is disputed by the supplier/seller giving the reasons, the sample will be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and conclusive report. However, the same should be submitted within three months, from the date of communication of the disputed test report to the supplier/seller. For this, supplier/seller should approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per procedure, from the Appellate Laboratory at their own cost.

  The de-registration / debarment action will be taken by the buyer against the manufacturing unit and contract holding firms (both) according to the category-A and category-B defects as per guidelines issued by the Ministry of Health & Family Welfare, Government of India and same will be communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the commercial final package on request by the buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the product(s) supplied shall be produced when demanded. For New drugs/medicines, complete stability data of 6 months period shall be acceptable.
- The case of admixture of drugs will be treated as a violation of terms and conditions and will not be accepted.
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines under the Drugs & Cosmetic Act, 1940 as amended up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Drug Testing Labs. Similarly, the authority for confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also with the DCGI/ State Drug Control Authorities.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended up to date, the DCGI/ CDSCO/ State Drug Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

26. **Deduction, Blacklisting, and other penalties on account of Quality failure**

The suitable conditions may be added by the buyer in the bid through Additional Term & Conditions (ATC) as applicable.

27. **Quality Test by Statutory Authorities:**

If any batch of any product(s) supplied by the supplier is declared “NOT OF STANDARD QUALITY”, by any government agencies or drug licensing authority, the supplier shall inform the same immediately to the buyer so that the use of the available stock of the particular item will be stopped. Further, the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

The buyer may without prejudice to any other remedy for breach of contract, by written notice of default sent to the supplier, terminate the contract in whole or in part If the supplier fails to promptly replace any drug/medicine/goods rejected submitted for testing or subject to recall ordered by the applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports of adverse drugs reaction after giving prompt notice of the recall.

29. **Warranty**

- Supplies must fully comply in all respect with the Technical specifications and conditions laid down in the contract and in accordance with the Pharmacopoeia standards.
- Each supply should be accompanied with a "Warranty Certificate" duly signed by the Bidder as under:

  “The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under this contract shall be of the best quality and workmanship and shall be strictly in accordance with the specifications and particulars mentioned and the supplier/seller hereby guarantees that the stores would continue to conform to the description of and quality aforesaid for a period of useful life of minimum of five sixth (5/6th) of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the ranges set forth in the technical specification and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality or adverse Pharmaceuticals reaction. Notwithstanding the above, the fact that the said stores fail to conform to the description and quality aforesaid or have deteriorated and the decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the said stores, or such part thereof as may be discovered not to conform to the said description and quality. Losses due to premature deterioration due to biological and other activities during life potency will be made good and supplied by the firm at its own cost at consignee’s site.

  On such rejection, the stores will be at the seller's risk and all provisions herein contained relating to the rejection of stores shall apply. The supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of cost at the ultimate destination within a period of forty five days or such further period as may be extended from time to time by the buyer at his discretion, on application made there under by the supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer and in such an event the above mentioned warranty period shall apply to the stores replaced from the date of the replacement thereof otherwise the supplier/seller shall pay to the buyer such damage as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice any other rights of the buyer in that behalf under this contract or otherwise".

- Sl. No. & Date
- Nomenclature & Specification
- Name & Address of Manufacturing Unit
- Batch No.
- DOM & DOE
- Qty. of each batch
- Remarks

Signature name & designation and date with rubber stamp

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may proceed to take such remedial action(s) as may be necessary/deemed fit by the

buyer, at the suppliers' risk and expense and without prejudice to other rights which the buyer may have against the supplier under the contract.

30. **Packaging, Labelling and Marking Requirements**

    Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Act, 1940 and the Rules made there under as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer in the bid through Additional Terms and Conditions (ATC) shall be complied with.

31. **Bar Coding**

    All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (primary, secondary, and tertiary level packaging) and should encode the information within the barcodes as mentioned by the buyers in addition to other existing statutory labelling and marking requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions (ATC) in the bid.

32. **Delivery Period**

    - Minimum delivery period will be of 45 days from the date of issuing of the purchase
    - The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated) during transit, otherwise if on checking it is found that temperature has not been maintained, supply against the said order is liable to be rejected and cancelled.
    - The items requiring special cold storage conditions shall be supplied with cold chain transporting system under cold chain norms from the manufacturing unit to the warehouses/consignee location.

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other requirement mentioned by the buyer through Additional Terms and Conditions (ATC) in the bid will be applicable.
34. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC & GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede specific Special Terms and Condistions (STC) which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 29-07-2024 for category Pregnancy Test Kit for Family Planning Programme

1. 1. *A*ll Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
   2. The sellers are registered on GeM based on the self declaration of valid Medical Device License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of license, product certification, manufacturer certification/licenses, test reports etc.
   3. In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including verifying the validity and authenticity of license held by them.
   4. The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
   5. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC/GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure items are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 29-07-2024 for category Injectable Contraceptive (Antara) for Family Planning Programme

1. 1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the undertaking & submitted copy of a valid Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitting the relevant valid drug license and other regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., validity, authenticity/genuineness, name of the drug/medicine under procurement, the license issuing authority etc. at their end.
   2. The Buyer shall ask the seller to submit the “Notarized Undertaking” in the mentioned below format (scanned copy and hard copy). Details of the same may be verified by the buyer at their end.

UNDERTAKING

(to be on non-judicial stamp paper of Rs 10 and notarized)

I, _____, s/o / d/o / w/o _____, aged about _____resident of _____, do hereby declare and undertake that;

1. I am the partner / proprietor / director of _____ *(name of entity)* and duly authorized to sign this undertaking on behalf of _____. *(Name of entity)*
2. We are the manufacturers of the drug/medicine _____(“Product”) and intend to offer the same for sale through the GeM portal.
3. We state that the license for the Product has been granted/obtained by us as per the provisions of the Drug & Cosmetics Act, 1940 and rules framed there under as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the online ‘SUGAM’ portal of CDSCO as per rule 84AB of the Drugs and Cosmetics Rules, 1945 as amended till date. Reference no. for SUGAM portal is_____.
5. We undertake that all the information provided above is true and complete in all respect. We understand that in the event any false information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetics Act, 1940 as amended till date and rules made there under will be initiated.

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

3. All Provisions of Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date will always be applicable. This will include all notifications issued by *Central Drugs Standard Control Organization* (*CDSCO*), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be applicable in case of Narcotic Drugs & Psychotropic Substances.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing authority defined under the Drugs and Cosmetics Act 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly marked and highlighted in Drug Manufacturing License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submission/delivery as per buyer requirement.

   In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their authorized resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products.

   Manufacturer shall be responsible for verifying the validity and authenticity of drug license held by their authorized resellers/distributors.

   If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of application to State Drug / Licensing authority must be submitted with a certificate that

application for renewal was made within time frame as per Drug and Cosmetic Act as amended up to date and that has not been deleted by drug licensing authority.

7. Bidder/Seller shall submit the valid GMP/WHO-GMP Certificate of the manufacturing site as per revised Schedule-'M' for the quoted drugs/medicines issued by the Concerned Drug Licensing Authority to the buyer at the time of bid submission.
8. Bidder/Seller shall submit a valid **non-Conviction** certificate for last two (2) consecutive years issued by the Concerned Drug Licensing authority to the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of technical opening of the bid.
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the concerned drug licensing authority for at least latest 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine quoted should be clearly marked and highlighted.

   This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from the Drug Controller General (India) shall be required for all new drug formulations to this effect.

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which are not separate entities then the company will be allowed to submit only one bid for all units but necessary document regarding separate manufacturing units will be submitted to the buyer. However, one bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) as per Schedule "L1" of the Drugs & Cosmetics Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA for the quoted drugs/medicines (as applicable).
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug licensing authority highlighting the quoted product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia drugs/medicines are required to be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for all drugs/medicines in specified packing for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data of 6 months period shall be acceptable. (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, then the stability data of the licensor should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any State Government / Central Government / Central or State Government's Drug procurement agencies at the time of submission of bid. Further, quoted drugs / medicines have not been failed in house testing or testing by any State Government / Central Government / its Drug procurement agencies during last two years. If any bidder/seller has been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner / Director / Owner shall not be permitted to participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any State Government / Central Government/Central or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to the buyer along with relevant authentic document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government or State Government or its procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be convicted/ or a criminal case filed against or pending in any court of India by any department of Govt. under prevention of Corruption Act or for cheating/ defrauding Government/ embezzlement of Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only) duly attested by the Notary stating that:

    They will comply with all the statues &legislation regarding manufacturing, import, sale, and supply of drugs in India and in particular the following Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Legal Metrology Act, 2009, The Drugs (Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.

    To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act,

1940 (as amended). The bidder shall also undertake not to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as per the latest guidelines issued by the Drug Controller of India from time to time.

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or price fixed by the State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provision of Public Procurement (Preference to Make in India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceutical Formulations, will be applicable.
22. **Fall Clause**: Provision of fall clause will not be applicable on the sale of drugs which have an expiry date as per Ministry of Chemical and Fertilizer OM No 31026/1/2019-Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Rules, 1945 as amended up to date.

    In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed more than one sixth (1/6th) of the total shelf life of the drug/medicine at the time of delivery to the consignee.

    In case of pre-dispatch inspection, at the time when the stores are offered for inspection, the life of the drugs/medicines shall not have passed more than one sixth (1/6th) of the total shelf life of the drugs/medicines.

24. **Recalls**

    If products are recalled because of problems with product quality or adverse reaction to the pharmaceutical, the supplier will be obliged to notify the buyer, providing full details about the reason leading to the recall, and shall take steps to replace the product in question at suppliers own cost at the ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund of the unconsumed quantity if the product has been taken off the market due to safety problems.

25. **Inspection, Testing and Quality Control**
    - All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report/Certificate of Analysis** from the manufacturer's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:

    1. Generic name of the product
    2. Batch No.
    3. Pharmacopoeia Reference and/ or In-house method
    4. Batch quantity
    5. Date of manufacture
    6. Expiry date
    7. Date of test
    8. Description (clarity, color etc)
    9. 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
    10. Conclusion
    11. Qualified Person's signature

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

    - Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet required standards throughout specified shelf life. The buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government approved laboratories at any of, or any combination of or/ all following stages:

    a) At Pre-Dispatch stage

    b) At Delivery Stage: Inspection done once the drugs/medicines/goods reach at consignee location and before taking over supplied goods in inventory.

    c) Post Delivery Surveillance: The Drugs/Medicines/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/medicines/ goods. Quality Monitoring Activities may also be organized by the buyer post-delivery.

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratories for the purpose of Inspection & Quality Control. The sampling quantities shall be borne by the supplier.
- The buyer's right to inspect, test and, where necessary reject the drugs/medicines/goods after the drugs/medicines/goods arrival at the final destination shall in no way be limited or waived by reason of the goods having previously been inspected, tested and passed prior to the goods dispatch from the place of manufacture.
- **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each batch will be chosen for testing. The samples will be collected and sent to designated laboratories (NABL Accredited/Government approved laboratories) for testing as decided by the buyer.

  At post-delivery surveillance - The samples will be collected from the warehouse of buyer/or final consignee in States/UTs and sent to designated Quality Control Labs in respect of supplied drugs/medicines/goods at any point during specified shelf life as per decision of the buyer.

  Handling and testing charges will be borne by the buyer for the above purpose.

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

- **At any of testing stage**, Samples which do not meet quality requirement 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 drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier whether consumed fully/partially.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in quality tests, the buyer may reject them, and the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignee place at their own cost and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer to the supplier or as specified by the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take back the drugs/medicines/goods within the stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of 45 days.

  Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable period. The FDA/ Drugs Control Authority of concerned State will also be informed by the buyer for initiating necessary action on the supplier in their state. In addition, Security deposit will also be forfeited without any intimation.

  The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied drugs, medicines etc., shall be final and binding.

- In case any drug/medicine is found substandard either any of testing stage or during the shelf life of the item, the report of the NABL/Government approved laboratory shall be accepted by the supplier/seller. If the same is disputed by the supplier/seller giving the reasons, the sample will be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and conclusive report. However, the same should be submitted within three months, from the date of communication of the disputed test report to the supplier/seller. For this, supplier/seller should approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per procedure, from the Appellate Laboratory at their own cost.

  The de-registration / debarment action will be taken by the buyer against the manufacturing unit and contract holding firms (both) according to the category-A and category-B defects as per guidelines issued by the Ministry of Health & Family Welfare, Government of India and same will be communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the commercial final package on request by the buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the product(s) supplied shall be produced when demanded. For New drugs/medicines, complete stability data of 6 months period shall be acceptable.
- The case of admixture of drugs will be treated as a violation of terms and conditions and will not be accepted.
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines under the Drugs & Cosmetic Act, 1940 as amended up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Drug Testing Labs. Similarly, the authority for confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also with the DCGI/ State Drug Control Authorities.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended up to date, the DCGI/ CDSCO/ State Drug Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

26. **Deduction, Blacklisting, and other penalties on account of Quality failure**

    The suitable conditions may be added by the buyer in the bid through Additional Term & Conditions (ATC) as applicable.

27. **Quality Test by Statutory Authorities:**

    If any batch of any product(s) supplied by the supplier is declared “NOT OF STANDARD QUALITY”, by any government agencies or drug licensing authority, the supplier shall inform the same immediately to the buyer so that the use of the available stock of the particular item will be stopped. Further, the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

    The buyer may without prejudice to any other remedy for breach of contract, by written notice of default sent to the supplier, terminate the contract in whole or in part If the supplier fails to promptly replace any drug/medicine/goods rejected submitted for testing or subject to recall ordered by the applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports of adverse drugs reaction after giving prompt notice of the recall.

29. **Warranty**
    - Supplies must fully comply in all respect with the Technical specifications and conditions laid down in the contract and in accordance with the Pharmacopoeia standards.
    - Each supply should be accompanied with a "Warranty Certificate" duly signed by the Bidder as under:

      “The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under this contract shall be of the best quality and workmanship and shall be strictly in accordance with the specifications and particulars mentioned and the supplier/seller hereby guarantees that the stores would continue to conform to the description of and quality aforesaid for a period of useful life of minimum of five sixth (5/6th) of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the ranges set forth in the technical specification and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality or adverse Pharmaceuticals reaction. Notwithstanding the above, the fact that the said stores fail to conform to the description and quality aforesaid or have deteriorated and the decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the said stores, or such part thereof as may be discovered not to conform to the said description and quality. Losses due to premature deterioration due to biological and other activities during life potency will be made good and supplied by the firm at its own cost at consignee’s site.

      On such rejection, the stores will be at the seller's risk and all provisions herein contained relating to the rejection of stores shall apply. The supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of cost at the ultimate destination within a period of forty five days or such further period as may be extended from time to time by the buyer at his discretion, on application made there under by the supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer and in such an event the above mentioned warranty period shall apply to the stores replaced from the date of the replacement thereof otherwise the supplier/seller shall pay to the buyer such damage as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice any other rights of the buyer in that behalf under this contract or otherwise".

- Sl. No. & Date
- Nomenclature & Specification
- Name & Address of Manufacturing Unit
- Batch No.
- DOM & DOE
- Qty. of each batch
- Remarks

Signature name & designation and date with rubber stamp

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may proceed to take such remedial action(s) as may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without prejudice to other rights which the buyer may have against the supplier under the contract.

30. **Packaging, Labelling and Marking Requirements**

    Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Act, 1940 and the Rules made there under as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer in the bid through Additional Terms and Conditions (ATC) shall be complied with.

31. **Bar Coding**

    All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (primary, secondary, and tertiary level packaging) and should encode the information within the barcodes as mentioned by the buyers in addition to other existing statutory labelling and marking requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions (ATC) in the bid.

32. **Delivery Period**

    - Minimum delivery period will be of 45 days from the date of issuing of the purchase
    - The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated) during transit, otherwise if on checking it is found that temperature has not been maintained, supply against the said order is liable to be rejected and cancelled.
    - The items requiring special cold storage conditions shall be supplied with cold chain transporting system under cold chain norms from the manufacturing unit to the warehouses/consignee location.

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other requirement mentioned by the buyer through Additional Terms and Conditions (ATC) in the bid will be applicable.
34. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC & GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede specific Special Terms and Condistions (STC) which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 29-07-2024 for category IUCD 380A for Family Planning Programme

1. 1. *A*ll Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
   2. The sellers are registered on GeM based on self-declaration of valid Medical Device License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of license, product certification, manufacturer certification/licenses, test reports etc.
   3. In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including

verifying the validity and authenticity of Medical Device License license held by them.
4. The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
5. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC/GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure items are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 29-07-2024 for category IUCD 375 for Family Planning Programme

1. 1. *A*ll Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
   2. The sellers are registered on GeM based on self-declaration of valid Medical Device License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of license, product certification, manufacturer certification/licenses, test reports etc.
   3. In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including verifying the validity and authenticity of Medical Device License license held by them.
   4. The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
   5. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC/GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure items are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 29-07-2024 for category Tubal Rings for Family Planning Programme

1. 1. *A*ll Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
   2. The sellers are registered on GeM based on self-declaration of valid Medical Device License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of license, product certification, manufacturer certification/licenses, test reports etc.
   3. In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including verifying the validity and authenticity of Medical Device License license held by them.
   4. The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any.
   5. Any other Terms and Conditions which is not included or at variance with the conditions specified in STC/GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure items are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

क्रेता द्वारा जोड़ी गई बिड की विशेष शर्तें/Buyer Added Bid Specific Terms and Conditions

1. **Buyer Added Bid Specific ATC**

   Buyer uploaded ATC document Click here to view the file.

अस्वीकरण/Disclaimer

The additional terms and conditions have been incorporated by the Buyer after approval of the Competent Authority in Buyer Organization, whereby Buyer organization is solely responsible for the impact of these clauses on the bidding process, its outcome, and consequences thereof including any eccentricity / restriction arising in the bidding process due to these ATCs and due to modification of technical specifications and / or terms and conditions governing the bid. If any clause(s) is / are incorporated by the Buyer regarding following, the bid and resultant contracts shall be treated as null and void and such bids may be cancelled by GeM at any stage of bidding process without any notice:-

1. Definition of Class I and Class II suppliers in the bid not in line with the extant Order / Office Memorandum issued by DPIIT in this regard.
2. Seeking EMD submission from bidder(s), including via Additional Terms & Conditions, in contravention to exemption provided to such sellers under GeM GTC.
3. Publishing Custom / BOQ bids for items for which regular GeM categories are available without any Category item bunched with it.
4. Creating BoQ bid for single item.
5. Mentioning specific Brand or Make or Model or Manufacturer or Dealer name.
6. Mandating submission of documents in physical form as a pre-requisite to qualify bidders.
7. Floating / creation of work contracts as Custom Bids in Services.
8. Seeking sample with bid or approval of samples during bid evaluation process. (However, in bids for attached categories, trials are allowed as per approved procurement policy of the buyer nodal Ministries)
9. Mandating foreign / international certifications even in case of existence of Indian Standards without specifying equivalent Indian Certification / standards.
10. Seeking experience from specific organization / department / institute only or from foreign / export experience.
11. Creating bid for items from irrelevant categories.
12. Incorporating any clause against the MSME policy and Preference to Make in India Policy.
13. Reference of conditions published on any external site or reference to external documents/clauses.
14. Asking for any Tender fee / Bid Participation fee / Auction fee in case of Bids / Forward Auction, as the case may be.
15. Buyer added ATC Clauses which are in contravention of clauses defined by buyer in system generated bid template as indicated above in the Bid Details section, EMD Detail, ePBG Detail and MII and MSE Purchase Preference sections of the bid, unless otherwise allowed by GeM GTC.
16. In a category based bid, adding additional items, through buyer added additional scope of work/ additional terms and conditions/or any other document. If buyer needs more items along with the main item, the same must be added through bunching category based items or by bunching custom catalogs or bunching a BoQ with the main category based item, the same must not be done through ATC or Scope of Work.

Further, if any seller has any objection/grievance against these additional clauses or otherwise on any aspect of this bid, they can raise their representation against the same by using the Representation window provided in the bid details field in Seller dashboard after logging in as a seller within 4 days of bid publication on GeM. Buyer is duty bound to reply to all such representations and would not be allowed to open bids if he fails to reply to such representations.

All GeM Sellers / Service Providers are mandated to ensure compliance with all the applicable laws / acts / rules including but not limited to all Labour Laws such as The Minimum Wages Act, 1948, The Payment of Wages Act, 1936, The Payment of Bonus Act, 1965, The Equal Remuneration Act, 1976, The Payment of Gratuity Act, 1972 etc. Any non-compliance will be treated as breach of contract

and Buyer may take suitable actions as per GeM Contract.

यह बिड सामान्य शर्तों के अंतर्गत भी शासित है /This Bid is also governed by the General Terms and Conditions

जेम की सामान्य शर्तों के खंड 26 के संदर्भ में भारत के साथ भूमि सीमा साझा करने वाले देश के बिडर से खरीद पर प्रतिबंध के संबंध में भारत के साथ भूमि सीमा साझा करने वाले देश का कोई भी बिडर इस निविदा में बिड देने के लिए तभी पात्र होगा जब वह बिड देने वाला सक्षम प्राधिकारी के पास पंजीकृत हो।बिड में भाग लेते समय बिडर को इसका अनुपालन करना होगा और कोई भी गलत घोषणा किए जाने व इसका अनुपालन न करने पर अनुबंध को तत्काल समाप्त करने और कानून के अनुसार आगे की कानूनी कार्रवाई का आधार होगा।/In terms of GeM GTC clause 26 regarding Restrictions on procurement from a bidder of a country which shares a land border with India, any bidder from a country which shares a land border with India will be eligible to bid in this tender only if the bidder is registered with the Competent Authority. While participating in bid, Bidder has to undertake compliance of this and any false declaration and non-compliance of this would be a ground for immediate termination of the contract and further legal action in accordance with the laws.

---धन्यवाद/Thank You---

1. BID DETAILS - GEM/2025/B/6416312

2. TECHNICAL EVALUATION

3. FINANCIAL EVALUATION

Disclaimer : These are offered prices in bid and not approved / accepted prices. These may change if Buyer resorts to negotiation or price match as per Bid Conditions.

List Of Schedules

S.No.	Schedule Title	L1 Seller Name	Total L1 Price	Schedule Details
1	Schedule 1	ANONDITA MEDICARE LIMITED	363765700	View (/bidding/bid/getBidResultViewScheduleSellers/ZxpzwiEv2Lm7njTmSb9tAaj4I

S.No.	Schedule Title	L1 Seller Name	Total L1 Price	Schedule Details
2	Schedule 2	ESKAG PHARMA PVT LTD	247335120	View (/bidding/bid/getBidResultViewScheduleSellers/ZxpzwiEv2Lm7njTmSb9tAaj4I
3	Schedule 3	AKUMS DRUGS AND PHARMACEUTICALS LIMITED	13781956.5	View (/bidding/bid/getBidResultViewScheduleSellers/ZxpzwiEv2Lm7njTmSb9tAaj4I
4	Schedule 4	SUNWEST BIO MEDICAL PRIVATE LIMITED	47259198	View (/bidding/bid/getBidResultViewScheduleSellers/ZxpzwiEv2Lm7njTmSb9tAaj4I
5	Schedule 5	LENUS LIFE CARE PRIVATE LIMITED	146935800	View (/bidding/bid/getBidResultViewScheduleSellers/ZxpzwiEv2Lm7njTmSb9tAaj4I
6	Schedule 6	PREGNA INTERNATIONAL LIMITED	106773187.5	View (/bidding/bid/getBidResultViewScheduleSellers/ZxpzwiEv2Lm7njTmSb9tAaj4I
7	Schedule 7	CORPORATE CHANNELS (INDIA) PVT. LTD	77370673.5	View (/bidding/bid/getBidResultViewScheduleSellers/ZxpzwiEv2Lm7njTmSb9tAaj4I
8	Schedule 8	CORPORATE CHANNELS (INDIA) PVT. LTD	24004962	View (/bidding/bid/getBidResultViewScheduleSellers/ZxpzwiEv2Lm7njTmSb9tAaj4I

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Miscellaneous (https://gem.gov.in/support/miscellaneous)

MoUs (https://gem.gov.in/mou)

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(https://www.slideshare.net/GeMProcurementReimag)

1. BID DETAILS - GEM/2025/B/6416312

2. TECHNICAL EVALUATION

3. FINANCIAL EVALUATION

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S.No.	Schedule Title	L1 Seller Name	Total L1 Price	Schedule Details
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2	Schedule 2	ESKAG PHARMA PVT LTD	247335120	View
3	Schedule 3	AKUMS DRUGS AND PHARMACEUTICALS LIMITED	13781956.5	View
4	Schedule 4	SUNWEST BIO MEDICAL PRIVATE LIMITED	47259198	View
5	Schedule 5	LENUS LIFE CARE PRIVATE LIMITED	146935800	View
6	Schedule 6	PREGNA INTERNATIONAL LIMITED	106773187.5	View
7	Schedule 7	**********	-	View
8	Schedule 8	**********	-	View

CIN:U22193DL2024PLC428183

ANONDITA MEDICARE LIMITED

AN ISO 9001 : 2015 ISO 13485 : 2016 & CDSCO Certified Co.
Manufacturer of Condoms

Date: 3rd October, 2025

To,
The Manager,
Listing Compliance Department
National Stock Exchange of India Limited
Exchange Plaza, Bandra Kurla Complex,
Bandra (East), Mumbai-400051

Sub: **Discloser under SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 read with SEBI Circular No. SEBI/HO/CFD/PoD2/CIR/P/0155 dated November 11, 2024.P**

SYMBOL: ANONDITA
ISIN: INE0VTV01012

Dear Sir/Madam,

Pursuant to the provisions of Securities and Exchange Board of (Listing Obligations and Disclosure Requirements) Regulations, 2015 read with Para B Part A to schedule III and SEBI Circular No. SEBI/HO/CFD/PoD2/CIR/P/0155 dated November 11, 2024, also enclosed herewith as Annexure-A.

You are requested to take the above intimation on your records.

Thanking you,

Yours faithfully,

For and on behalf of
Anondita Medicare Limited

ANONDITA MEDICARE LTD.

Nutan Agrawal

Nutan Agrawal
Company Secretary and Compliance Officer
Membership No. 58113

Regd. off : Flat No. 704, Narmada Block N-6, Sec-D, Pocket-C, Vasant Kunj, New Delhi-110070
Corp Off. : D-001, Sector-80, Noida-201305, (U.P.) INDIA
Tel.: 0120-4520300/1/2/3 till 99 (100 Lines) Fax : 0120-4520314
E-mail : accounts@anonditahealthcare.com | info@anonditahealthcare.com
Website: www.anonditahealthcare.net

CIN:U22193DL2024PLC428183

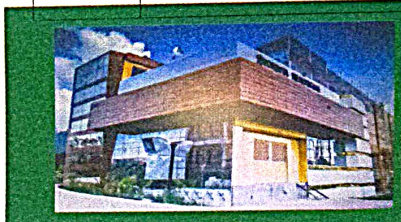
ANONDITA MEDICARE LIMITED

AN ISO 9001 : 2015 ISO 13485 : 2016 & CDSCO Certified Co.
Manufacturer of Condoms

Annexure A

Details as required under SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 read with SEBI Circular No. SEBI/HO/CFD/PoD2/CIR/P/0155 dated November 11, 2024

1.	Name of the entity to which order(s)/contract(s) is awarded;	Central Medical Services Society (CMSS)
2.	Whether order(s) / contract(s) is awarded to domestic/ / international entity	Domestic
3.	Significant terms and conditions of order(s)/contract(s) awarded, in brief;	All Provisions of Drugs and Cosmetics Act, 1940 and Rules (including Medical Device Rule 2017) made there under as amended till date will always be applicable. This will include all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare (MoHFW) and Department of Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard. 2. The sellers are registered on GeM based on self-declaration of valid Medical Device License, product certification, test reports etc. However, buyers must check and validate the details at their end for all applicable licenses and certifications e.g., validity and authenticity/genuineness of license, product certification, manufacturer certification/licenses, test reports etc. 3. In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer to ensure that their resellers/distributors are operating in compliance with all relevant laws and regulations and are properly licensed to sell the manufacturer's products, including verifying the validity and authenticity of Medical Device License license held by them. 4. The price offered by the seller/bidder shall not, in any case exceed the DPCO/NPPA controlled price or price fixed by State Government, if any. The seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government, if any. 5. Any other Terms and Conditions which is not included or at variance with the conditions specified in


UNIT


OFFICE


DIPPING AREA


TESTING AREA

Regd. off : Flat No. 704, Narmada Block N-6, Sec-D, Pocket-C, Vasant Kunj, New Delhi-110070
Corp Off. : D-001, Sector-80, Noida-201305, (U.P.) INDIA
Tel.: 0120-4520300/1/2/3 till 99 (100 Lines) Fax : 0120-4520314
E-mail : accounts@anonditahealthcare.com | info@anonditahealthcare.com
Website: www.anonditahealthcare.net

		STC/GTC, may be added by the buyer through Additional Terms and Conditions (ATC) in the bid to ensure items are procured from authentic/validated source with appropriate and applicable quality. The above terms and conditions are in reverse order of precedence i.e. ATC shall supersede specific STC which shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.
4.	Time period, if any, associated with the order(s)/contract(s);	NA
5.	Broad commercial consideration or size of the order(s)/contract(s);	363765700
6.	Whether the promoter/ promoter group/group companies have any interest in that entity to whom the order(s)/contract(s) is awarded? If Yes, nature of interest and details thereof;	No
7.	Whether the same would fall within related party transactions? If yes, whether the same is done at"arm's length"	NO

For and on behalf of
Anondita Medicare Limited

Nutan Agrawal

ANONDITA MEDICARE LTD.

Nutan Agrawal
Company Secretary and Compliance Officer
Membership No. 58113