Bid Document/ बिड दस्तावेज़

Bid Details/बिड विवरण	
Bid End Date/Time/बिड बंद होने की तारीख/समय	30-05-2025 18:00:00
Bid Opening Date/Time/बिड खुलने की तारीख/समय	30-05-2025 18:30:00
Bid Offer Validity (From End Date)/बिड पेशकश वैधता (बंद होने की तारीख से)	90 (Days)
Ministry/State Name/मंत्रालय/राज्य का नाम	Ministry Of Home Affairs
Department Name/विभाग का नाम	Central Armed Police Forces
Organisation Name/संगठन का नाम	Indo Tibetan Border Police (itbp)
Office Name/कार्यालय का नाम	Composite Hospital Itbp Dehradun
क्रेता ईमेल/Buyer Email	i.111109029@itbp.gov.in
Total Quantity/कुल मात्रा	9350
Item Category/मद केटेगरी	Azithromycin Oral Liquid (Q2) , Pantopra Liquid (Q2) , Ondansetron Injection (Q2) Injection (V2) (Q2) , Amiodarone Injectio Methylprednisolone Injection (Q2) , Hyd (V2) (Q2) , Dexamethasone Injection (Q Respirator Solution for use in Nebulizer Injection (Q2)
Years of Past Experience Required for same/similar service/उन्हीं/समान सेवाओं के लिए अपेक्षित विगत अनुभव के वर्ष	1 Year (s)
MSE Exemption for Years Of Experience/अनुभव के वर्षों से एमएसई छूट/	Yes
Startup Exemption for Years Of Experience/अनुभव के वर्षों से स्टार्टअप छूट/	Yes
Document required from seller/विक्रेता से मांगे गए दस्तावेज़	Experience Criteria,Certificate (Request *In case any bidder is seeking exemptio supporting documents to prove his eligi evaluation by the buyer
Do you want to show documents uploaded by bidders to all bidders participated in bid?/	Yes
Bid to RA enabled/बिड से रिवर्स नीलामी सक्रिय किया	Yes
RA Qualification Rule	H1-Highest Priced Bid Elimination
Type of Bid/बिड का प्रकार	Two Packet Bid
Primary product category	Paracetamol Injection

Bid Details/बिड विवरण	
Time allowed for Technical Clarifications during technical evaluation/तकनीकी मूल्यांकन के दौरान तकनीकी स्पष्टीकरण हेतु अनुमत समय	2 Days
Inspection Required (By Empanelled Inspection Authority / Agencies pre-registered with GeM)	No
Evaluation Method/मूल्यांकन पद्धति	Total value wise evaluation
Arbitration Clause	No
Mediation Clause	No

EMD Detail/ईएमडी विवरण

Required/आवश्यकता	No

ePBG Detail/ईपीबीजी विवरण

Required/आवश्यकता	No

MII Purchase Preference/एमआईआई खरीद वरीयता

MII Purchase Preference/एमआईआई खरीद वरीयता	No

MSE Purchase Preference/एमएसई खरीद वरीयता

MSE Purchase Preference/एमएसई खरीद वरीयता	Yes

1. If the bidder is a Micro or Small Enterprise as per latest definitions under MSME rules, the bidder shall be exempte and "Experience Criteria" subject to meeting of quality and technical specifications. If the bidder is OEM of the offere Average Turnover" criteria also subject to meeting of quality and technical specifications. In case any bidder is seeki the supporting documents to prove his eligibility for exemption must be uploaded for evaluation by the buyer.
2. If the bidder is a Startup, the bidder shall be exempted from the requirement of "Bidder Turnover" criteria and "Ex and technical specifications. If the bidder is OEM of the offered products, it would be exempted from the "OEM Avera quality and technical specifications. In case any bidder is seeking exemption from Turnover / Experience Criteria, the exemption must be uploaded for evaluation by the buyer.
3. Experience Criteria: In respect of the filter applied for experience criteria, the Bidder or its OEM of the product offe should have regularly, manufactured and supplied same or similar Category Products to any Central / State Govt Org indicated above in the bid document before the bid opening date. Copies of relevant contracts and delivery acceptar with bid in support of having supplied some quantity during each of the Financial year. In case of bunch bids, the cat should meet this criterion.
4. Purchase preference will be given to MSEs having valid Udyam Registration and whose credentials are validated o in Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry subsequent Orders/Notifications issued by concerned Ministry. If the bidder wants to avail themselves of the Purchas / OEM of the offered product on GeM. Traders are excluded from the purview of Public Procurement Policy for Micro a products manufactured by some other OEM are not eligible for any purchase preference. In respect of bid for Service offered Service. Relevant documentary evidence in this regard shall be uploaded along with the bid in respect of the eligibility for purchase preference based on documentary evidence submitted, while evaluating the bid. If L-1 is not a within L-1+ 15% (Selected by Buyer) of margin of purchase preference /price band defined in relevant policy, such M price and contract will be awarded for 25% (selected by Buyer) percentage of total quantity. The buyers are advised

18.05.2023 OM_No.1_4_2021_PPD_dated_18.05.2023 for compliance of Concurrent application of Public Procuremen and Public Procurement (Preference to Make in India) Order, 2017. Benefits of MSE will be allowed only if seller is val and approved by Buyer after evaluation of documents submitted.

5. Reverse Auction would be conducted amongst all the technically qualified bidders except the Highest quoting bidd bidder will not be allowed to participate in RA. However, H-1 will also be allowed to participate in RA in following cas

i. If number of technically qualified bidders are only 2 or 3.
ii. If Buyer has chosen to split the bid amongst N sellers, and H1 bid is coming within N.
iii. In case Primary product of only one OEM is left in contention for participation in RA on elimination of H-1.
iv. If L-1 is non-MSE and H-1 is eligible MSE and H-1 price is coming within price band of 15% of Non-MSE L-1
v. If L-1 is non-MII and H-1 is eligible MII and H-1 price is coming within price band of 20% of Non-MII L-1

Azithromycin Oral Liquid (500 pieces)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Medicine Name	Azithromycin
	Dosage Form	Oral Liquid
	Strength	200 mg/5 mL
PACKAGING	Type of primary packing	Bottle
	Primary pack size	15 ml, 30 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttrakhand	500

Pantoprazole Injection (500 pieces)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttrakhand	500

Amoxicillin + Clavulanic Oral Liquid (500 pieces)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	**Strength**	200 mg + 28.5 mg / 5 mL

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttrakhand	500

Ondansetron Injection (400 pieces)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	**Primary pack size**	2 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttrakhand	400

Cefuroxime Oral Liquid (500 pieces)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	**Primary pack size**	30 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttrakhand	500

Bupivacaine Injection (V2) (50 pieces)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	**Strength**	0.5%
PACKAGING	**Primary pack size**	20 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttrakhand	50

Amiodarone Injection (V2) (50 pieces)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Medicine Name	Amiodarone
	Dosage Form	Injection
	Strength	50 mg/mL
PACKAGING	Type of primary packing	Ampoule
	Primary pack size	3 ml
SHELF LIFE	Shelf life in months from the date of manufacture	24, 36 Or higher **(month)**

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttrakhand	50

Metoclopramide Injection (200 pieces)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	**Primary pack size**	2 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttrakhand	200

Methylprednisolone Injection (50 pieces)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	**Primary pack size**	2 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttrakhand	50

Hydrocortisone Injection (200 pieces)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	**Strength**	100 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttrakhand	200

Adrenaline Injection (V2) (50 pieces)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttrakhand	50

Dexamethasone Injection (200 pieces)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	**Primary pack size**	2 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttrakhand	200

Pheniramine Injection (500 pieces)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	**Primary pack size**	2 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttrakhand	500

Budesonide Respirator Solution For Use In Nebulizer (1000 pieces)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Medicine Name	Budesonide
	Dosage Form	Respirator Solution for use in N

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
	Strength	0.5 mg
PACKAGING	Primary pack size	2 ml
SHELF LIFE	Shelf life in months from the date of manufacture	24, 36 Or higher **(month)**

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttrakhand	1000

Folic Acid Tablet (4000 tablet(s))

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	**Strength**	5 mg

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttrakhand	4000

Paracetamol Injection (150 pieces)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	**Strength**	150 mg/mL
PACKAGING	**Primary pack size**	2 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttrakhand	150

Paracetamol Injection (500 pieces)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	**Strength**	10 mg/mL
PACKAGING	**Primary pack size**	100 mL

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर्टिंग अधिकारी	Address/पता	Quantity/
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttrakhand	500

Special terms and conditions-Version:4 effective from 29-10-2024 for category Pantoprazole Injection

1. 1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the ur Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitt regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., val 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 (sc may be verified by the buyer at their end.

UNDERTAKING

(to be on non-judicial stamp paper of Rs 10 and not

I, _____, s/o / d/o / w/o _____, aged about _____resident of _____ undertake that;

1. I am the partner / proprietor / director of _____*(name of entity)* and duly _____. *(Name of entity)*
2. We are the manufacturers of the drug/medicine _____("Product") and intend to offer
3. We state that the license for the Product has been granted/obtained by us as per the provisions there under as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the 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 und information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic 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 a notifications issued by *Central Drugs Standard Control Organization* (*CDSCO*), Ministry of Health & Fam 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 a 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 aut 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly m License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submis

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

   Manufacturer shall be responsible for verifying the validity and authenticity of drug license held by thei

   If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the cop must be submitted with a certificate that application for renewal was made within time frame as per Dr 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 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the co 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/ highlighted.

   This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from t 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, whicl be allowed to submit only one bid for all units but necessary document regarding separate manufacturi 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 Certific Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned d product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia 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 stabil packing for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete sta (If manufacturer has licensed a formula from another company and such licensed formula is used for th should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted produ / Central or State Government's Drug procurement agencies at the time of submission of bid. Further, c house testing or testing by any State Government / Central Government / its Drug procurement agenci been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Par participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti 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 Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou or pending in any court of India by any department of Govt. under prevention of Corruption Act or for cl 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 o

    They will comply with all the statues &legislation regarding manufacturing, import, sale, and supply of Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as ar (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 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" 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 seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisi India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Ph
22. **Fall Clause**: Provision of fall clause will not be applicable on the sale of drugs which have an expiry da 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 a

    In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed r 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 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 pharmaceu buyer, providing full details about the reason leading to the recall, and shall take steps to replace the p ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refun 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 Repor** 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 pharma 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 requir buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government 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 locat inventory.

c) Post Delivery Surveillance: The Drugs/Medicines/goods shall have the active ingredients an indicated in official compendiums or technical specifications throughout the shelf-life period of the drug may also be organized by the buyer post-delivery.

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
- **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

  At post-delivery surveillance - The samples will be collected from the warehouse of buyer/or designated Quality Control Labs in respect of supplied drugs/medicines/goods at any point during

  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
- The supplies will be deemed to be completed only upon receipt of the quality certificates from th

  "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be

- **At any of testing stage**, Samples which do not meet quality requirement shall render the relev declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/b drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier whe
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/co fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after

  Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suital concerned State will also be informed by the buyer for initiating necessary action on the supplier be forfeited without any intimation.

  The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied dru

- In case any drug/medicine is found substandard either any of testing stage or during the shelf lif approved laboratory shall be accepted by the supplier/seller. If the same is disputed by the supp sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final an submitted within three months, from the date of communication of the disputed test report to th approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per own cost.

  The de-registration / debarment action will be taken by the buyer against the manufacturing uni category-A and category-B defects as per guidelines issued by the Ministry of Health & Family W communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning t

buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the produ
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
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Dru confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also w
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amend 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 (AT

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

If any batch of any product(s) supplied by the supplier is declared “NOT OF STANDARD QUALITY”, by ar authority, the supplier shall inform the same immediately to the buyer so that the use of the available s 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 defau whole or in part If the supplier fails to promptly replace any drug/medicine/goods rejected submitted fo applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports o of the recall.

29. **Warranty**

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

  “The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under th workmanship and shall be strictly in accordance with the specifications and particulars mentione the stores would continue to conform to the description of and quality aforesaid for a period of u specified shelf life from the date of delivery of the said stores to the buyer, have overages withir and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality Notwithstanding the above, the fact that the said stores fail to conform to the description and qu decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the discovered not to conform to the said description and quality. Losses due to premature deteriora 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 relatin supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of c forty five days or such further period as may be extended from time to time by the buyer at his supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice 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 be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without preju 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 A amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buye

Conditions (ATC) shall be complied with.

31. **Bar Coding**

    All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (p and should encode the information within the barcodes as mentioned by the buyers in addition to othe requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions

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 inc found that temperature has not been maintained, supply against the said order is liable to be rej
    - The items requiring special cold storage conditions shall be supplied with cold chain transporting manufacturing unit to the warehouses/consignee location.

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any 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 ST Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authent quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede sp shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 26-10-2023 for category Amoxicillin + Clavulanic

1. 1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the ur Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitt regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., val 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 (sc may be verified by the buyer at their end.

UNDERTAKING

(to be on non-judicial stamp paper of Rs 10 and not

I, _____, s/o / d/o / w/o _____, aged about _____resident of _____ undertake that;

1. I am the partner / proprietor / director of _____ *(name of entity)* and duly _____. *(Name of entity)*
2. We are the manufacturers of the drug/medicine _____(“Product”) and intend to offer
3. We state that the license for the Product has been granted/obtained by us as per the provisions there under as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the 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 un information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic 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 a notifications issued by *Central Drugs Standard Control Organization* (*CDSCO*), Ministry of Health & Fam 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 a

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 aut 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly m License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submis

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

   Manufacturer shall be responsible for verifying the validity and authenticity of drug license held by thei

   If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the cop must be submitted with a certificate that application for renewal was made within time frame as per Dr 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 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the co 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/ highlighted.

   This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from t 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, whicl be allowed to submit only one bid for all units but necessary document regarding separate manufacturi 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 Certific Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned d product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia 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 stabil packing for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete sta (If manufacturer has licensed a formula from another company and such licensed formula is used for th should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted produ / Central or State Government's Drug procurement agencies at the time of submission of bid. Further, house testing or testing by any State Government / Central Government / its Drug procurement agenci been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Par 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's Drug procurement agencies / convicted by any Court of law in India, it shall be inti 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 Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou or pending in any court of India by any department of Govt. under prevention of Corruption Act or for c 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 o

    They will comply with all the statues &legislation regarding manufacturing, import, sale, and supply of Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as ar (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 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" 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 seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisi India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Ph

22. **Fall Clause**: Provision of fall clause will not be applicable on the sale of drugs which have an expiry da 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 a

    In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed r 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 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 pharmaceu buyer, providing full details about the reason leading to the recall, and shall take steps to replace the p ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refun 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 Repor** 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 pharma 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 requir buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government 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 locat inventory.

    c) Post Delivery Surveillance: The Drugs/Medicines/goods shall have the active ingredients an indicated in official compendiums or technical specifications throughout the shelf-life period of the drug may also be organized by the buyer post-delivery.

    - The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
    - **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

      At post-delivery surveillance - The samples will be collected from the warehouse of buyer/or designated Quality Control Labs in respect of supplied drugs/medicines/goods at any point durin

      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
    - The supplies will be deemed to be completed only upon receipt of the quality certificates from th

      "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be

    - **At any of testing stage**, Samples which do not meet quality requirement shall render the relev

declared to be “Not of Standard Quality” or spurious or adulterated or misbranded, such batch/b drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier whe

- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/co fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take stipulated time. The buyer will arrange to destroy the “NOT OF STANDARD QUALITY ITEMS” after

  Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suital concerned State will also be informed by the buyer for initiating necessary action on the supplie be forfeited without any intimation.

  The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied dru

- In case any drug/medicine is found substandard either any of testing stage or during the shelf lif approved laboratory shall be accepted by the supplier/seller. If the same is disputed by the supp sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final an submitted within three months, from the date of communication of the disputed test report to th approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per own cost.

  The de-registration / debarment action will be taken by the buyer against the manufacturing uni category-A and category-B defects as per guidelines issued by the Ministry of Health & Family W communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning t buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the produ 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
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Dru confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also wi
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amen 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 (AT

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

    If any batch of any product(s) supplied by the supplier is declared “NOT OF STANDARD QUALITY”, by ar authority, the supplier shall inform the same immediately to the buyer so that the use of the available s 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 defau whole or in part If the supplier fails to promptly replace any drug/medicine/goods rejected submitted fo applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports o of the recall.

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

      “The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under th workmanship and shall be strictly in accordance with the specifications and particulars mentione the stores would continue to conform to the description of and quality aforesaid for a period of u specified shelf life from the date of delivery of the said stores to the buyer, have overages withir and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality Notwithstanding the above, the fact that the said stores fail to conform to the description and qu decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the discovered not to conform to the said description and quality. Losses due to premature deteriora 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 relatin

supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of c forty five days or such further period as may be extended from time to time by the buyer at his supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

Sl. No. & Date	Nomenclature & Specification	Name & Address of Manufacturing Unit	Batch No.	DOM & DOE

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without preju 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 A amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buye Conditions (ATC) shall be complied with.

31. **Bar Coding**

    All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (p and should encode the information within the barcodes as mentioned by the buyers in addition to othe requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions

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 inc found that temperature has not been maintained, supply against the said order is liable to be rej
    - The items requiring special cold storage conditions shall be supplied with cold chain transporting manufacturing unit to the warehouses/consignee location.

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any 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 ST Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authent quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede sp shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 23-03-2024 for category Ondansetron Injection

1. 1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the ur Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitt regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., val 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 (s may be verified by the buyer at their end.

UNDERTAKING

(to be on non-judicial stamp paper of Rs 10 and not

I, _____, s/o / d/o / w/o _____, aged about _____resident of _____ undertake that;

1. I am the partner / proprietor / director of _____ *(name of entity)* and duly _____. *(Name of entity)*
2. We are the manufacturers of the drug/medicine _____("Product") and intend to offer
3. We state that the license for the Product has been granted/obtained by us as per the provisions there under as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the 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 und information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic 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 a notifications issued by *Central Drugs Standard Control Organization* (*CDSCO*), Ministry of Health & Fam 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 a 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 auth 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly m License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submis

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

   Manufacturer shall be responsible for verifying the validity and authenticity of drug license held by thei

   If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the cop must be submitted with a certificate that application for renewal was made within time frame as per Dr 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 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the d
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the co 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/ highlighted.

   This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from t 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, whicl be allowed to submit only one bid for all units but necessary document regarding separate manufacturi 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 Certific Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned d product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia 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 stabil packing for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete sta (If manufacturer has licensed a formula from another company and such licensed formula is used for th should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted produ

/ Central or State Government's Drug procurement agencies at the time of submission of bid. Further, c house testing or testing by any State Government / Central Government / its Drug procurement agenci been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Par participate in the bid.

16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti 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 Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou or pending in any court of India by any department of Govt. under prevention of Corruption Act or for c 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 o

    They will comply with all the statues &legislation regarding manufacturing, import, sale, and supply of d Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as ar (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 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" 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 seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisi India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Ph
22. **Fall Clause**: Provision of fall clause will not be applicable on the sale of drugs which have an expiry da 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 a

    In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed r 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 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 pharmaceu buyer, providing full details about the reason leading to the recall, and shall take steps to replace the p ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refun 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 Repor** 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 pharma 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 requir buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government 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 locat inventory.

c) Post Delivery Surveillance: The Drugs/Medicines/goods shall have the active ingredients an indicated in official compendiums or technical specifications throughout the shelf-life period of the drug may also be organized by the buyer post-delivery.

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
- **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

  At post-delivery surveillance - The samples will be collected from the warehouse of buyer/or designated Quality Control Labs in respect of supplied drugs/medicines/goods at any point durin

  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
- The supplies will be deemed to be completed only upon receipt of the quality certificates from th

  "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be

- **At any of testing stage**, Samples which do not meet quality requirement shall render the relev declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/b drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier whe
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/co fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after

  Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suital concerned State will also be informed by the buyer for initiating necessary action on the supplier be forfeited without any intimation.

  The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied dru

- In case any drug/medicine is found substandard either any of testing stage or during the shelf lif approved laboratory shall be accepted by the supplier/seller. If the same is disputed by the supp sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final an submitted within three months, from the date of communication of the disputed test report to th approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per own cost.

  The de-registration / debarment action will be taken by the buyer against the manufacturing uni category-A and category-B defects as per guidelines issued by the Ministry of Health & Family W communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning t buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the produ 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
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Dru confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also w
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amen 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 (AT

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

If any batch of any product(s) supplied by the supplier is declared "NOT OF STANDARD QUALITY", by ar

authority, the supplier shall inform the same immediately to the buyer so that the use of the available s
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 defau
whole or in part If the supplier fails to promptly replace any drug/medicine/goods rejected submitted fo
applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports o
of the recall.

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

      “The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under th
      workmanship and shall be strictly in accordance with the specifications and particulars mentione
      the stores would continue to conform to the description of and quality aforesaid for a period of u
      specified shelf life from the date of delivery of the said stores to the buyer, have overages withir
      and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality
      Notwithstanding the above, the fact that the said stores fail to conform to the description and qu
      decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the
      discovered not to conform to the said description and quality. Losses due to premature deteriora
      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 relatin
      supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of c
      forty five days or such further period as may be extended from time to time by the buyer at his c
      supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar
      period shall apply to the stores replaced from the date of the replacement thereof otherwise the
      as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice
      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 & designati

    - If the supplier, having been notified, fails to replace within the period specified above, the buyer
    may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without preju
    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 A
amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buye
Conditions (ATC) shall be complied with.

31. **Bar Coding**

All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (p
and should encode the information within the barcodes as mentioned by the buyers in addition to othe
requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions

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 inc
    found that temperature has not been maintained, supply against the said order is liable to be rej
    - The items requiring special cold storage conditions shall be supplied with cold chain transporting
    manufacturing unit to the warehouses/consignee location.

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any
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 ST
Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authent
quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede sp
shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 06-07-2023 for category Bupivacaine Injection (V

1. 1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the ur
Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitt
regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., val
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 (sc
may be verified by the buyer at their end.

UNDERTAKING

(to be on non-judicial stamp paper of Rs 10 and not

I, _____, s/o / d/o / w/o _____, aged about _____resident of _____
undertake that;

1. I am the partner / proprietor / director of _____ *(name of entity)* and duly
_____. *(Name of entity)*
2. We are the manufacturers of the drug/medicine _____(“Product”) and intend to offer
3. We state that the license for the Product has been granted/obtained by us as per the provisions
there under as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the
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 un
information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic
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 a
notifications issued by *Central Drugs Standard Control Organization* (*CDSCO*), Ministry of Health & Fam
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 a
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 aut
1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly m
License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submis

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

Manufacturer shall be responsible for verifying the validity and authenticity of drug license held by thei

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the cop
must be submitted with a certificate that application for renewal was made within time frame as per Dr
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 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the d
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the co 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/ highlighted.

   This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from t 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, whicl be allowed to submit only one bid for all units but necessary document regarding separate manufacturi 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 Certific Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned d product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia d 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 stabil packing for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete sta (If manufacturer has licensed a formula from another company and such licensed formula is used for th should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted produ / Central or State Government's Drug procurement agencies at the time of submission of bid. Further, d house testing or testing by any State Government / Central Government / its Drug procurement agenci been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Par participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti 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 Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou or pending in any court of India by any department of Govt. under prevention of Corruption Act or for cl 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 o

    They will comply with all the statues &legislation regarding manufacturing, import, sale, and supply of d Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as ar (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 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" 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 seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisi India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Ph
22. **Fall Clause**: Provision of fall clause will not be applicable on the sale of drugs which have an expiry da 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 a

    In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed r 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 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 pharmaceu buyer, providing full details about the reason leading to the recall, and shall take steps to replace the p ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refun

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 Repo** 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 pharma 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 requir buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government 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 locat inventory.

      c) Post Delivery Surveillance: The Drugs/Medicines/goods shall have the active ingredients an indicated in official compendiums or technical specifications throughout the shelf-life period of the drug may also be organized by the buyer post-delivery.

    - The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
    - **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

      At post-delivery surveillance - The samples will be collected from the warehouse of buyer/or designated Quality Control Labs in respect of supplied drugs/medicines/goods at any point durin

      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
    - The supplies will be deemed to be completed only upon receipt of the quality certificates from th

      "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be

    - **At any of testing stage**, Samples which do not meet quality requirement shall render the relev declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/b drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier whe
    - If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/co fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after

      Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suital concerned State will also be informed by the buyer for initiating necessary action on the supplier be forfeited without any intimation.

      The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied dru

    - In case any drug/medicine is found substandard either any of testing stage or during the shelf lif

approved laboratory shall be accepted by the supplier/seller. If the same is disputed by the supp sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final anc submitted within three months, from the date of communication of the disputed test report to th approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per own cost.

The de-registration / debarment action will be taken by the buyer against the manufacturing unit category-A and category-B defects as per guidelines issued by the Ministry of Health & Family W communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning t buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the produ 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
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Dru confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also wi
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amenc 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 (AT

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

If any batch of any product(s) supplied by the supplier is declared “NOT OF STANDARD QUALITY”, by ar authority, the supplier shall inform the same immediately to the buyer so that the use of the available s 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 defau whole or in part If the supplier fails to promptly replace any drug/medicine/goods rejected submitted fo applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports o of the recall.

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

    “The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under th workmanship and shall be strictly in accordance with the specifications and particulars mentione the stores would continue to conform to the description of and quality aforesaid for a period of u specified shelf life from the date of delivery of the said stores to the buyer, have overages withir and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality Notwithstanding the above, the fact that the said stores fail to conform to the description and qu decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the discovered not to conform to the said description and quality. Losses due to premature deteriora 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 relatin supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of c forty five days or such further period as may be extended from time to time by the buyer at his c supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

Sl. No. & Date	Nomenclature & Specification	Name & Address of Manufacturing Unit	Batch No.	DOM & DOE

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without preju 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 A amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buye Conditions (ATC) shall be complied with.

31. **Bar Coding**

    All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (p and should encode the information within the barcodes as mentioned by the buyers in addition to othe requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions

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 inc found that temperature has not been maintained, supply against the said order is liable to be rej
    - The items requiring special cold storage conditions shall be supplied with cold chain transporting manufacturing unit to the warehouses/consignee location.

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any 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 ST Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authent quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede sp shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 06-07-2023 for category Amiodarone Injection (V

1. 1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the ur Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitt regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., val 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 (sc may be verified by the buyer at their end.

UNDERTAKING

(to be on non-judicial stamp paper of Rs 10 and not

I, _____, s/o / d/o / w/o _____, aged about _____resident of _____ undertake that;

1. I am the partner / proprietor / director of _____*(name of entity)* and duly _____. *(Name of entity)*
2. We are the manufacturers of the drug/medicine _____(“Product”) and intend to offer
3. We state that the license for the Product has been granted/obtained by us as per the provisions there under as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the 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 un information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic 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 a notifications issued by *Central Drugs Standard Control Organization* (*CDSCO*), Ministry of Health & Fam 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 a 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 aut 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly m License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submis

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

   Manufacturer shall be responsible for verifying the validity and authenticity of drug license held by thei

   If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the cop must be submitted with a certificate that application for renewal was made within time frame as per Dr 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 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the d
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the co 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/ highlighted.

   This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from t 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, whicl be allowed to submit only one bid for all units but necessary document regarding separate manufacturi 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 Certific Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned d product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia d 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 stabil packing for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete sta (If manufacturer has licensed a formula from another company and such licensed formula is used for th should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted produ / Central or State Government's Drug procurement agencies at the time of submission of bid. Further, d house testing or testing by any State Government / Central Government / its Drug procurement agenci been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Par participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti 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 Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou or pending in any court of India by any department of Govt. under prevention of Corruption Act or for cl 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 o

    They will comply with all the statues &legislation regarding manufacturing, import, sale, and supply of d Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as ar (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 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" 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 seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisi India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Ph
22. **Fall Clause**: Provision of fall clause will not be applicable on the sale of drugs which have an expiry da 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 a

    In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed r 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 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 pharmaceu buyer, providing full details about the reason leading to the recall, and shall take steps to replace the p ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refun 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 Repor** 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 pharma 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 requir buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government 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 locat inventory.

    c) Post Delivery Surveillance: The Drugs/Medicines/goods shall have the active ingredients an indicated in official compendiums or technical specifications throughout the shelf-life period of the drug may also be organized by the buyer post-delivery.

    - The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.

- **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

  At post-delivery surveillance - The samples will be collected from the warehouse of buyer/or designated Quality Control Labs in respect of supplied drugs/medicines/goods at any point durin

  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
- The supplies will be deemed to be completed only upon receipt of the quality certificates from th

  "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be

- **At any of testing stage**, Samples which do not meet quality requirement shall render the relev declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/b drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier whe
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/co fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after

  Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suital concerned State will also be informed by the buyer for initiating necessary action on the supplier be forfeited without any intimation.

  The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied dru

- In case any drug/medicine is found substandard either any of testing stage or during the shelf lif approved laboratory shall be accepted by the supplier/seller. If the same is disputed by the supp sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and submitted within three months, from the date of communication of the disputed test report to th approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per own cost.

  The de-registration / debarment action will be taken by the buyer against the manufacturing unit category-A and category-B defects as per guidelines issued by the Ministry of Health & Family W communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning t buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the produ 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
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Dru confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also wi
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amend 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 (AT

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

    If any batch of any product(s) supplied by the supplier is declared "NOT OF STANDARD QUALITY", by an authority, the supplier shall inform the same immediately to the buyer so that the use of the available s 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 defau whole or in part If the supplier fails to promptly replace any drug/medicine/goods rejected submitted fo applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports o of the recall.

29. **Warranty**
    - Supplies must fully comply in all respect with the Technical specifications and conditions laid dow

Pharmacopoeia standards.

- Each supply should be accompanied with a "Warranty Certificate" duly signed by the Bidder as u

  “The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under th workmanship and shall be strictly in accordance with the specifications and particulars mentione the stores would continue to conform to the description of and quality aforesaid for a period of u specified shelf life from the date of delivery of the said stores to the buyer, have overages withir and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality Notwithstanding the above, the fact that the said stores fail to conform to the description and qu decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the discovered not to conform to the said description and quality. Losses due to premature deteriora 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 relatin supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of c forty five days or such further period as may be extended from time to time by the buyer at his c supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

Sl. No. & Date	Nomenclature & Specification	Name & Address of Manufacturing Unit	Batch No.	DOM & DOE

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without preju 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 A amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buye Conditions (ATC) shall be complied with.

31. **Bar Coding**

    All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (p and should encode the information within the barcodes as mentioned by the buyers in addition to othe requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions

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 inc found that temperature has not been maintained, supply against the said order is liable to be rej
    - The items requiring special cold storage conditions shall be supplied with cold chain transporting manufacturing unit to the warehouses/consignee location.

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any 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 ST Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authent quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede sp shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 06-07-2023 for category Adrenaline Injection (V2

1. 1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the ur

Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitt
regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., val
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 (sc
may be verified by the buyer at their end.

UNDERTAKING

(to be on non-judicial stamp paper of Rs 10 and not

I, _____, s/o / d/o / w/o _____, aged about _____resident of _____
undertake that;

1. I am the partner / proprietor / director of _____ *(name of entity)* and duly
_____. *(Name of entity)*
2. We are the manufacturers of the drug/medicine _____(“Product”) and intend to offer
3. We state that the license for the Product has been granted/obtained by us as per the provisions
there under as amended till date.
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24. **Recalls**

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25. **Inspection, Testing and Quality Control**
    - All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Repor** 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 pharma 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 requir buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government combination of or/ all following stages:

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  Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suital concerned State will also be informed by the buyer for initiating necessary action on the supplier be forfeited without any intimation.

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29. **Warranty**

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

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Sl. No. & Date	Nomenclature & Specification	Name & Address of Manufacturing Unit	Batch No.	DOM & DOE

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without preju against the supplier under the contract.

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Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics A amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buye Conditions (ATC) shall be complied with.

31. **Bar Coding**

    All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (p and should encode the information within the barcodes as mentioned by the buyers in addition to othe requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions

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    - Minimum delivery period will be of 45 days from the date of issuing of the purchase
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    - The items requiring special cold storage conditions shall be supplied with cold chain transporting manufacturing unit to the warehouses/consignee location.

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any 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 ST Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authent quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede sp shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 23-03-2024 for category Budesonide Respirator S

1. 1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the ur Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitt regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., val 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 (s may be verified by the buyer at their end.

UNDERTAKING

(to be on non-judicial stamp paper of Rs 10 and not

I, _____, s/o / d/o / w/o _____, aged about _____resident of _____ undertake that;

1. I am the partner / proprietor / director of _____*(name of entity)* and duly _____. *(Name of entity)*
2. We are the manufacturers of the drug/medicine _____(“Product”) and intend to offer
3. We state that the license for the Product has been granted/obtained by us as per the provisions there under as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the 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 un information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic 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 a notifications issued by *Central Drugs Standard Control Organization* (*CDSCO*), Ministry of Health & Fam

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 a 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 aut 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly m License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submis

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

   Manufacturer shall be responsible for verifying the validity and authenticity of drug license held by thei

   If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the cop must be submitted with a certificate that application for renewal was made within time frame as per Dr 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 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the d
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the co 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/ highlighted.

   This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from t 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, whicl be allowed to submit only one bid for all units but necessary document regarding separate manufacturi 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 Certific Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned d product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia d 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 stabil packing for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete sta (If manufacturer has licensed a formula from another company and such licensed formula is used for th should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted produ / Central or State Government's Drug procurement agencies at the time of submission of bid. Further, d house testing or testing by any State Government / Central Government / its Drug procurement agenci been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Par participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti 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 Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou or pending in any court of India by any department of Govt. under prevention of Corruption Act or for cl 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 o

    They will comply with all the statues &legislation regarding manufacturing, import, sale, and supply of d Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as ar (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 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" 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 seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State

21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisi India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Ph
22. **Fall Clause**: Provision of fall clause will not be applicable on the sale of drugs which have an expiry da 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 a

    In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed r 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 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 pharmaceu buyer, providing full details about the reason leading to the recall, and shall take steps to replace the p ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refun 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 Repor** 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 pharma 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 requir buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government 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 locat inventory.

    c) Post Delivery Surveillance: The Drugs/Medicines/goods shall have the active ingredients an indicated in official compendiums or technical specifications throughout the shelf-life period of the drug may also be organized by the buyer post-delivery.

    - The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
    - **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

      At post-delivery surveillance - The samples will be collected from the warehouse of buyer/or designated Quality Control Labs in respect of supplied drugs/medicines/goods at any point durin

      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
    - The supplies will be deemed to be completed only upon receipt of the quality certificates from th

      "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be

- **At any of testing stage**, Samples which do not meet quality requirement shall render the relev declared to be “Not of Standard Quality” or spurious or adulterated or misbranded, such batch/b drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier whe
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/cor fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take stipulated time. The buyer will arrange to destroy the “NOT OF STANDARD QUALITY ITEMS” after

  Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suital concerned State will also be informed by the buyer for initiating necessary action on the supplier be forfeited without any intimation.

  The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied dru

- In case any drug/medicine is found substandard either any of testing stage or during the shelf lif approved laboratory shall be accepted by the supplier/seller. If the same is disputed by the supp sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and submitted within three months, from the date of communication of the disputed test report to th approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per own cost.

  The de-registration / debarment action will be taken by the buyer against the manufacturing unit category-A and category-B defects as per guidelines issued by the Ministry of Health & Family W communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning t buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the produ 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
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Dru confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also wi
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amend 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 (AT

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

    If any batch of any product(s) supplied by the supplier is declared “NOT OF STANDARD QUALITY”, by an authority, the supplier shall inform the same immediately to the buyer so that the use of the available s 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 defau whole or in part If the supplier fails to promptly replace any drug/medicine/goods rejected submitted fo applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports of of the recall.

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

      “The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under th workmanship and shall be strictly in accordance with the specifications and particulars mentione the stores would continue to conform to the description of and quality aforesaid for a period of u specified shelf life from the date of delivery of the said stores to the buyer, have overages within and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality Notwithstanding the above, the fact that the said stores fail to conform to the description and qu decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the discovered not to conform to the said description and quality. Losses due to premature deteriora 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 relatin supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of c forty five days or such further period as may be extended from time to time by the buyer at his supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice 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 & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without preju 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 A amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buye Conditions (ATC) shall be complied with.

31. **Bar Coding**

    All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (p and should encode the information within the barcodes as mentioned by the buyers in addition to othe requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions

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 inc found that temperature has not been maintained, supply against the said order is liable to be rej
    - The items requiring special cold storage conditions shall be supplied with cold chain transporting manufacturing unit to the warehouses/consignee location.

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any 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 ST Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authent quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede sp shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 26-10-2023 for category Folic Acid Tablet

1. 1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the ur Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitt regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., val 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 (s may be verified by the buyer at their end.

UNDERTAKING

(to be on non-judicial stamp paper of Rs 10 and not

I, _____, s/o / d/o / w/o _____, aged about _____resident of _____ undertake that;

1. I am the partner / proprietor / director of _____ *(name of entity)* and duly _____. *(Name of entity)*
2. We are the manufacturers of the drug/medicine _____("Product") and intend to offer
3. We state that the license for the Product has been granted/obtained by us as per the provisions there under as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the 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 und information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic 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 a notifications issued by *Central Drugs Standard Control Organization* (*CDSCO*), Ministry of Health & Fam 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 a 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 auth 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly m License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submis

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

   Manufacturer shall be responsible for verifying the validity and authenticity of drug license held by thei

   If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the cop must be submitted with a certificate that application for renewal was made within time frame as per Dr 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 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the d
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the co 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/ highlighted.

   This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from t 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, whicl be allowed to submit only one bid for all units but necessary document regarding separate manufacturi 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 Certific Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned d product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia 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 stabil packing for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete sta (If manufacturer has licensed a formula from another company and such licensed formula is used for th should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted produ

/ Central or State Government's Drug procurement agencies at the time of submission of bid. Further, c house testing or testing by any State Government / Central Government / its Drug procurement agenci been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Par participate in the bid.

16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti 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 Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou or pending in any court of India by any department of Govt. under prevention of Corruption Act or for c 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 o

    They will comply with all the statues &legislation regarding manufacturing, import, sale, and supply of Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as ar (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 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" 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 seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisi India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Ph
22. **Fall Clause**: Provision of fall clause will not be applicable on the sale of drugs which have an expiry da 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 a

    In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed r 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 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 pharmaceu buyer, providing full details about the reason leading to the recall, and shall take steps to replace the p ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refun 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 Repor** 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 pharma 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 requir buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government 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 locat inventory.

c) Post Delivery Surveillance: The Drugs/Medicines/goods shall have the active ingredients an indicated in official compendiums or technical specifications throughout the shelf-life period of the drug may also be organized by the buyer post-delivery.

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
- **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

  At post-delivery surveillance - The samples will be collected from the warehouse of buyer/or designated Quality Control Labs in respect of supplied drugs/medicines/goods at any point durin

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- In case of failure of batches during or at any stage (indicated above), the testing charges would
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  "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be

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- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/co fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after

  Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suital concerned State will also be informed by the buyer for initiating necessary action on the supplier be forfeited without any intimation.

  The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied dru

- In case any drug/medicine is found substandard either any of testing stage or during the shelf lif approved laboratory shall be accepted by the supplier/seller. If the same is disputed by the supp sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final an submitted within three months, from the date of communication of the disputed test report to th approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per own cost.

  The de-registration / debarment action will be taken by the buyer against the manufacturing uni category-A and category-B defects as per guidelines issued by the Ministry of Health & Family W communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning t buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the produ 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
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Dru confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also w
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amen 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 (AT

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

If any batch of any product(s) supplied by the supplier is declared "NOT OF STANDARD QUALITY", by ar

authority, the supplier shall inform the same immediately to the buyer so that the use of the available s 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 defau whole or in part If the supplier fails to promptly replace any drug/medicine/goods rejected submitted fo applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports o of the recall.

29. **Warranty**

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

  “The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under th workmanship and shall be strictly in accordance with the specifications and particulars mentione the stores would continue to conform to the description of and quality aforesaid for a period of u specified shelf life from the date of delivery of the said stores to the buyer, have overages withir and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality Notwithstanding the above, the fact that the said stores fail to conform to the description and qu decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the discovered not to conform to the said description and quality. Losses due to premature deteriora 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 relatin supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of c forty five days or such further period as may be extended from time to time by the buyer at his supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

Sl. No. & Date	Nomenclature & Specification	Name & Address of Manufacturing Unit	Batch No.	DOM & DOE

Signature name & designati

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may be necessary/deemed fit by the buyer, at the suppliers' risk and expense and without preju 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 A amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buye Conditions (ATC) shall be complied with.

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All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (p and should encode the information within the barcodes as mentioned by the buyers in addition to othe requirements. Details of bar-coding will be given by the buyer through Additional Terms and Conditions

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- Minimum delivery period will be of 45 days from the date of issuing of the purchase
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- The items requiring special cold storage conditions shall be supplied with cold chain transporting manufacturing unit to the warehouses/consignee location.

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any 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 ST Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authent quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede sp shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 25-09-2024 for category Paracetamol Injection

1. 1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the ur Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitt regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., val 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 (sc may be verified by the buyer at their end.

UNDERTAKING

(to be on non-judicial stamp paper of Rs 10 and not

I, _____, s/o / d/o / w/o _____, aged about _____resident of _____ undertake that;

1. I am the partner / proprietor / director of _____ *(name of entity)* and duly _____. *(Name of entity)*
2. We are the manufacturers of the drug/medicine _____(“Product”) and intend to offer
3. We state that the license for the Product has been granted/obtained by us as per the provisions there under as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the 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 un information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic 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 a notifications issued by *Central Drugs Standard Control Organization* (*CDSCO*), Ministry of Health & Fam 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 a 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 aut 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly m License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submis

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

   Manufacturer shall be responsible for verifying the validity and authenticity of drug license held by thei

   If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the cop must be submitted with a certificate that application for renewal was made within time frame as per Dr

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 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 b buyer at the time of bid submission. The certificate must have been issued within 12 months from the d
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the co 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/ highlighted.

   This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from t 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, whicl be allowed to submit only one bid for all units but necessary document regarding separate manufacturi 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 Certific Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned d product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia d 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 stabil packing for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete sta (If manufacturer has licensed a formula from another company and such licensed formula is used for th should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted produ / Central or State Government's Drug procurement agencies at the time of submission of bid. Further, d house testing or testing by any State Government / Central Government / its Drug procurement agenci been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Par participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any S State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be inti 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 Gov agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of t
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shou or pending in any court of India by any department of Govt. under prevention of Corruption Act or for cl 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 o

    They will comply with all the statues &legislation regarding manufacturing, import, sale, and supply of d Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as ar (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 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" 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 seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisi India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Ph
22. **Fall Clause**: Provision of fall clause will not be applicable on the sale of drugs which have an expiry da 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 a

    In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed r 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 one sixth (1/6th) of the total shelf life of the drugs/medicines.

24. **<u>Recalls</u>**

    If products are recalled because of problems with product quality or adverse reaction to the pharmaceu

buyer, providing full details about the reason leading to the recall, and shall take steps to replace the p ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refun 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 Repo** 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 pharma 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 requir buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government 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 locat inventory.

    c) Post Delivery Surveillance: The Drugs/Medicines/goods shall have the active ingredients an indicated in official compendiums or technical specifications throughout the shelf-life period of the drug may also be organized by the buyer post-delivery.

    - The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laborat 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 th destination shall in no way be limited or waived by reason of the goods having previously been i dispatch from the place of manufacture.
    - **Inspection Methodology**: At pre-dispatch and/or delivery stage, samples of supplies in each ba collected and sent to designated laboratories (NABL Accredited/Government approved laboratori

      At post-delivery surveillance - The samples will be collected from the warehouse of buyer/or designated Quality Control Labs in respect of supplied drugs/medicines/goods at any point durin

      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
    - The supplies will be deemed to be completed only upon receipt of the quality certificates from th

      "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be

    - **At any of testing stage**, Samples which do not meet quality requirement shall render the relev declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/b drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier whe
    - If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/co fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after

      Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suital concerned State will also be informed by the buyer for initiating necessary action on the supplier be forfeited without any intimation.

      The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied dru

- In case any drug/medicine is found substandard either any of testing stage or during the shelf lif approved laboratory shall be accepted by the supplier/seller. If the same is disputed by the supp sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final anc submitted within three months, from the date of communication of the disputed test report to th approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per own cost.

  The de-registration / debarment action will be taken by the buyer against the manufacturing unit category-A and category-B defects as per guidelines issued by the Ministry of Health & Family W communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning t buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the produ 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
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Dru confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also wi
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amenc 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 (AT

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

If any batch of any product(s) supplied by the supplier is declared “NOT OF STANDARD QUALITY”, by ar authority, the supplier shall inform the same immediately to the buyer so that the use of the available s 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 defau whole or in part If the supplier fails to promptly replace any drug/medicine/goods rejected submitted fo applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports o of the recall.

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

      “The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under th workmanship and shall be strictly in accordance with the specifications and particulars mentione the stores would continue to conform to the description of and quality aforesaid for a period of u specified shelf life from the date of delivery of the said stores to the buyer, have overages within and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality Notwithstanding the above, the fact that the said stores fail to conform to the description and qu decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the discovered not to conform to the said description and quality. Losses due to premature deteriora 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 relatin supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of c forty five days or such further period as may be extended from time to time by the buyer at his supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

Sl. No. & Date	Nomenclature & Specification	Name & Address of Manufacturing Unit	Batch No.	DOM & DOE

Signature name & designati

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

1. **Generic**

   OPTION CLAUSE: The Purchaser reserves the right to increase or decrease the quantity to be ordered up to 25 of contract. The purchaser also reserves the right to increase the ordered quantity up to 25% of the contracte the contracted rates. The delivery period of quantity shall commence from the last date of original delivery or during the extended delivery period the additional time shall commence from the last date of extended delive (Increased quantity ÷ Original quantity) × Original delivery period (in days), subject to minimum of 30 days. I the additional time equals the original delivery period. The Purchaser may extend this calculated delivery dur exercising the option clause. Bidders must comply with these terms.

2. **Buyer Added Bid Specific ATC**

   Buyer Added text based ATC clauses

   Bidder should have valid drug licence.

   .

Disclaimer/अस्वीकरण

The additional terms and conditions have been incorporated by the Buyer after approval of the Competent Authority organization is solely responsible for the impact of these clauses on the bidding process, its outcome, and conseque arising in the bidding process due to these ATCs and due to modification of technical specifications and / or terms ar

are incorporated by the Buyer regarding following, the bid and resultant contracts shall be treated as null and void a 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 issu
2. Seeking EMD submission from bidder(s), including via Additional Terms & Conditions, in contravention to exer
3. Publishing Custom / BOQ bids for items for which regular GeM categories are available without any Category i
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 procurement policy of the buyer nodal Ministries)
9. Mandating foreign / international certifications even in case of existence of Indian Standards without specifyir
10. Seeking experience from specific organization / department / institute only or from foreign / export experienc
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 m
15. Buyer added ATC Clauses which are in contravention of clauses defined by buyer in system generated bid ter EMD Detail, ePBG Detail and MII and MSE Purchase Preference sections of the bid, unless otherwise allowed b
16. In a category based bid, adding additional items, through buyer added additional scope of work/ additional te needs more items along with the main item, the same must be added through bunching category based item 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 same by using the Representation window provided in the bid details field in Seller dashboard after logging in as a s is duty bound to reply to all such representations and would not be allowed to open bids if he fails to reply to such re

All GeM Sellers / Service Providers are mandated to ensure compliance with all the applicable laws / Labour Laws such as The Minimum Wages Act, 1948, The Payment of Wages Act, 1936, The Payment Act, 1976, The Payment of Gratuity Act, 1972 etc. Any non-compliance will be treated as breach of con per GeM Contract.

This Bid is also governed by the General Terms and Conditions/ यह बिड सामान्य शर्तों दे

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 share 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 wo action in accordance with the laws./जेम की सामान्य शर्तों के खंड 26 के संदर्भ में भारत के साथ भूमि सीमा साझा करने वाले देश के बिडर से खरीद 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 कोई भी गलत घोषणा किए जाने व इसका अनुपालन न करने पर अनुबंध को तत्काल समाप्त करने और कानून के अनुसार आगे की कानूनी कार्र

---Thank You/धन्यवाद---