

## Bid Document/ बिड दस्तावेज़

Bid Details/बिड विवरण	
Bid End Date/Time/बिड बंद होने की तारीख/समय	07-06-2025 19:00:00
Bid Opening Date/Time/बिड खुलने की तारीख/समय	07-06-2025 19:30:00
Bid Offer Validity (From End Date)/बिड पेशकश वैधता (बंद होने की तारीख से)	120 (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	9450
Item Category/मद केटेगरी	Azithromycin Oral Liquid (Q2) , Pantoprazole Injection (Q2) , Ondansetron Injection (Q2) , Budesonide Inhaler (Q2) , Cefuroxime Oral Liquid (Q2) , Amoxicillin Injection (V2) (Q2) , Amiodarone Injection (Q2) , Methylprednisolone Injection (Q2) , Hydrocortisone Injection (V2) (Q2) , Dexamethasone 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/ and Turnover/टर्नओवर के लिए एमएसई को छूट प्राप्त है	Yes
Startup Exemption for Years Of Experience/अनुभव के वर्षों से स्टार्टअप छूट/ and Turnover/ टर्नओवर के लिए स्टार्टअप को छूट प्राप्त है	Yes
Document required from seller/विक्रेता से मांगे गए दस्तावेज़	Experience Criteria,Past Performance,Certificates *In case any bidder is seeking exemption supporting documents to prove his eligibility for evaluation by the buyer
Do you want to show documents uploaded by bidders to all bidders participated in bid?/	Yes
Past Performance/विगत प्रदर्शन	10 %
Bid to RA enabled/बिड से रिवर्स नीलामी सक्रिय किया	Yes
RA Qualification Rule	H1-Highest Priced Bid Elimination

Bid Details/बिड विवरण	
Type of Bid/बिड का प्रकार	Two Packet Bid
Primary product category	Paracetamol Injection
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	Item wise evaluation/
Arbitration Clause	No
Mediation Clause	No

#### EMD Detail/ईएमडी विवरण

Required/आवश्यकता	No
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#### ePBG Detail/ईपीबीजी विवरण

Required/आवश्यकता	No
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#### MII Purchase Preference/एमआईआई खरीद वरीयता

MII Purchase Preference/एमआईआई खरीद वरीयता	No
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#### MSE Purchase Preference/एमएसई खरीद वरीयता

MSE Purchase Preference/एमएसई खरीद वरीयता	Yes
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1. If the bidder is a Micro or Small Enterprise as per latest orders issued by Ministry of MSME, the bidder shall be exempted from the "Experience Criteria" as defined above subject to meeting of quality and technical specifications. The bidder seeking exemption from Experience Criteria shall upload supporting documents to prove his eligibility for exemption.
2. If the bidder is a Micro or Small Enterprise (MSE) as per latest orders issued by Ministry of MSME, the bidder shall be exempted from the "Turnover" as defined above subject to meeting of quality and technical specifications. If the bidder itself is MSE OEM the "OEM Average Turnover" criteria also subject to meeting of quality and technical specifications. The bidder seeking exemption from Turnover shall upload supporting documents to prove his eligibility for exemption.
3. If the bidder is a DPIIT registered Startup, the bidder shall be exempted from the the eligibility criteria of "Experience Criteria" as defined above subject to meeting of quality and technical specifications. The bidder seeking exemption from Experience Criteria, shall upload supporting documents for exemption.
4. If the bidder is a DPIIT registered Startup, the bidder shall be exempted from the the eligibility criteria of "Bidder Turnover" as defined above subject to meeting of quality and technical specifications. If the bidder is DPIIT Registered OEM of the offered products, it would be exempted from Turnover criteria also subject to meeting of quality and technical specifications. The bidder seeking exemption from Turnover shall upload supporting documents for exemption.
5. Experience Criteria: In respect of the filter applied for experience criteria, the Bidder or its OEM of the product offered should have regularly, manufactured and supplied same or similar Category Products to any Central / State Govt Org as indicated above in the bid document before the bid opening date. Copies of relevant contracts and delivery acceptance certificates with bid in support of having supplied some quantity during each of the Financial year. In case of bunch bids, the category wise quantity should be indicated.

should meet this criterion.

6. Purchase preference will be given to MSEs having valid Udyam Registration and whose credentials are validated in Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of Commerce and Industries. If the bidder wants to avail themselves of the Purchase Preference, they must be the OEM of the offered product on GeM. Traders are excluded from the purview of Public Procurement Policy for Micro and Small Enterprises. 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 within L-1+ 15% (Selected by Buyer) of margin of purchase preference /price band defined in relevant policy, such price and contract will be awarded for 25% (selected by Buyer) percentage of total quantity. The buyers are advised to refer OM No.1 4 2021 PPD dated 18.05.2023 for compliance of Concurrent application of Public Procurement Policy for Micro and Small Enterprises and Public Procurement (Preference to Make in India) Order, 2017. Benefits of MSE will be allowed only if seller is valid and approved by Buyer after evaluation of documents submitted.

7. Estimated Bid Value indicated above is being declared solely for the purpose of guidance on EMD amount and for Over, Past Performance and Project / Past Experience etc. This has no relevance or bearing on the price to be quoted or impact on bid participation. Also this is not going to be used as a criteria in determining reasonableness of quoted price based on its own assessment of reasonableness and based on competitive prices received in Bid / RA process.

8. Past Performance: The Bidder or its OEM {themselves or through re-seller(s)} should have supplied same or similar product (at least one of the last three Financial years before the bid opening date to any Central / State Govt Organization / PSU or cumulative order quantity in any one financial year) to be submitted along with bid in support of quantity supplied in the category related to primary product having highest bid value should meet this criterion.

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

- If number of technically qualified bidders are only 2 or 3.
- If Buyer has chosen to split the bid amongst N sellers, and H1 bid is coming within N.
- In case Primary product of only one OEM is left in contention for participation in RA on elimination of H-1.
- 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.
- 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.

#### Evaluation Method ( Item Wise Evaluation Method )

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

Evaluation Schedules	Item/Category
Schedule 1	Azithromycin Oral Liquid
Schedule 2	Pantoprazole Injection
Schedule 3	Paracetamol Injection
Schedule 4	Ondansetron Injection
Schedule 5	Budesonide Respirator Solution For Use In Nebulizer
Schedule 6	Cefuroxime Oral Liquid
Schedule 7	Amoxicillin + Clavulanic Oral Liquid
Schedule 8	Bupivacaine Injection (v2)
Schedule 9	Amiodarone Injection (v2)
Schedule 10	Metoclopramide Injection
Schedule 11	Methylprednisolone Injection
Schedule 12	Hydrocortisone Injection
Schedule 13	Adrenaline Injection (v2)
Schedule 14	Dexamethasone Injection

Schedule 15	Pheniramine Injection
Schedule 16	Folic Acid Tablet
Schedule 17	Paracetamol Injection

### 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,Uttarakhand	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
PRODUCT INFORMATION	Medicine Name	Pantoprazole
	Dosage Form	Injection
	Strength	40 mg
PACKAGING	Type of primary packing	Vial
	Primary pack size	Single Vial

**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,Uttarakhand	500

### 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	Medicine Name	Paracetamol
	Dosage Form	Injection
	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,Uttarakhand	500

### Ondansetron 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	Medicine Name	Ondansetron
	Dosage Form	Injection
	Strength	2 mg/mL
PACKAGING	Type of primary packing	Ampoule
	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,Uttarakhand	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
	Strength	0.5 mg
PACKAGING	Primary pack size	2 ml

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

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

### 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
PRODUCT INFORMATION	Medicine Name	Cefuroxime
	Dosage Form	Oral Liquid
	Strength	125 mg/5 mL
PACKAGING	Type of primary packing	Bottle
	Primary pack size	30 ml

#### Consignees/Reporting Officer/परेषिती/रिपोर् टिंग अधिकारी and/ तथा Quantity/मात्रा

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर् टिंग अधिकारी	Address/पता	Quantity,
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttarakhand	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	Medicine Name	Amoxicillin + Clavulanic Acid
	Dosage Form	Dry Syrup
	Strength	200 mg + 28.5 mg / 5 mL
PACKAGING	Type of primary packing	Bottle

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
	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,Uttarakhand	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	Medicine Name	Bupivacaine
	Dosage Form	Injection
	Strength	0.5%
PACKAGING	Type of primary packing	Vial
	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,Uttarakhand	50

### Amiodarone Injection (V2) ( 50 pieces )



**Technical Specifications/तकनीकी विशिष्टियाँ**

[\\* जेम कैटेगरी 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

**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,Uttarakhand	50

**Metoclopramide Injection ( 200 pieces )****Technical Specifications/तकनीकी विशिष्टियाँ**

[\\* जेम कैटेगरी विशिष्टि के अनुसार / As per GeM Category Specification](#)

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Medicine Name	Metoclopramide
	Dosage Form	Injection
	Strength	5 mg/mL
PACKAGING	Type of primary packing	Ampoule
	Primary pack size	2 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर् टिंग अधिकारी	Address/पता	Quantity,
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttarakhand	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
PRODUCT INFORMATION	Medicine Name	Methylprednisolone
	Dosage Form	Injection
	Strength	40 mg/mL
PACKAGING	Type of primary packing	Vial
	Primary pack size	2 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर् टिंग अधिकारी	Address/पता	Quantity,
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttarakhand	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	Medicine Name	Hydrocortisone
	Dosage Form	Powder for Injection
	Strength	100 mg
PACKAGING	Type of primary packing	Vial

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
	Primary pack size	Single Vial

**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,Uttarakhand	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
PRODUCT INFORMATION	Medicine Name	Adrenaline
	Dosage Form	Injection
	Strength	1 mg/mL
PACKAGING	Type of primary packing	Ampoule
	Primary pack size	1 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,Uttarakhand	50

### Dexamethasone Injection ( 200 pieces )

**Technical Specifications/तकनीकी विशिष्टियाँ**

[\\* जेम कैटेगरी विशिष्टि के अनुसार / As per GeM Category Specification](#)

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Medicine Name	Dexamethasone
	Dosage Form	Injection
	Strength	4 mg/mL
PACKAGING	Type of primary packing	Vial
	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,Uttarakhand	200

**Pheniramine Injection ( 500 pieces )****Technical Specifications/तकनीकी विशिष्टियाँ**

[\\* जेम कैटेगरी विशिष्टि के अनुसार / As per GeM Category Specification](#)

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Medicine Name	Pheniramine
	Dosage Form	Injection
	Strength	22.75 mg/mL
PACKAGING	Type of primary packing	Ampoule
	Primary pack size	2 ml

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

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

### 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	Medicine Name	Folic Acid
	Dosage Form	Tablet
	Strength	5 mg
PACKAGING	Type of primary packing	Strip
	Primary pack size (Number of tablets per strip/blister)	10

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर् टिंग अधिकारी	Address/पता	Quantity,
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttarakhand	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	Medicine Name	Paracetamol
	Dosage Form	Injection
	Strength	150 mg/mL

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,Uttarakhand	150

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

1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the un-issued Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submit 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 (scanned copy may be verified by the buyer at their end).

#### UNDERTAKING

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

I, \_\_\_\_\_, s/o / d/o / w/o \_\_\_\_\_, aged about \_\_\_\_\_resident of \_\_\_\_\_undertake that;

1. I am the partner / proprietor / director of \_\_\_\_\_ (name of entity) and duly registered. (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 of the Drugs and Cosmetics Rules, 1945 as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the portal 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 undertake that if any information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic Rules, 1945 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 & notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Family Welfare (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be applicable to these Substances.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing authority under the Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly marked with the License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submission.

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

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

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

*This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from the concerned authority for all new drug formulations to this effect.*

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which are not under the same management, only one bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) issued by the Central / State Drug Controller / FDA under the Drugs and Cosmetics 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 drug licensing authority for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia / Pharmacopoeia shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any Central or State Government's Drug procurement agencies at the time of submission of bid. Further, the bidder/seller should not have been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner shall not participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any Central or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to the buyer by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only) to the buyer.

*They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs and cosmetics Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended till date), The (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 and to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as per the order of 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 provision (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 date 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 &

In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed 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 pharmaceutical buyer, providing full details about the reason leading to the recall, and shall take steps to replace the product at its ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund if the product has been taken off the market due to safety problems.

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from 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 pharmaceutical standards 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 requirements. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government approved combination of or/ all following stages:

##### **a) At Pre-Dispatch stage**

**b) At Delivery Stage:** Inspection done once the drugs/medicines/goods reach at consignee location inventory.

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

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

**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 the shelf life.

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the supplier.



"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 relevant batch declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the batch is found to be "Not of Standard Quality".
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any other way, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/colleges and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take back the rejected goods within stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of the stipulated time.

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suits filed in the concerned State will also be informed by the buyer for initiating necessary action on the supplier if the supplier is found to be forfeited without any intimation.

The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied drugs/medicines/goods.

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

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

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the drugs/medicines to the buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the product shall be acceptable. For New drugs/medicines, complete stability data of 6 months period shall be acceptable.
- The case of admixture of drugs will be treated as a violation of terms and conditions and will not be acceptable.
- 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 Drug Control Authorities. Confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also within the purview of the said authorities.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended, the Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

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

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

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

If any batch of any product(s) supplied by the supplier is declared "NOT OF STANDARD QUALITY", by any authority, the supplier shall inform the same immediately to the buyer so that the use of the available stock of the product with all consignee/users will be retrieved.

## 28. **Termination for Default**

The buyer may without prejudice to any other remedy for breach of contract, by written notice of default, terminate the contract whole or in part if the supplier fails to promptly replace any drug/medicine/goods rejected submitted for testing or found defective by the applicable Regulatory Authority in the country of manufacture due to unacceptable quality or reports of recall.

## 29. **Warranty**

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

"The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under the contract are of good workmanship and shall be strictly in accordance with the specifications and particulars mentioned in the tender. The stores would continue to conform to the description of and quality aforesaid for a period of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the specified limits 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 quality as specified in the tender, or the decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the stores discovered not to conform to the said description and quality. Losses due to premature deterioration of the stores shall be the responsibility of the supplier/seller.

potency will be made good and supplied by the firm at its own cost at consignee's site.

On such rejection, the stores will be at the seller's risk and all provisions herein contained relating to the replacement of the stores by the supplier/seller shall if so called upon to do so by the buyer in writing, replace the stores free of cost within forty five days or such further period as may be extended from time to time by the buyer at his cost. The provisions of the contract shall apply to the stores replaced from the date of the replacement thereof otherwise the provisions of the contract as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice the 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 prejudice against the supplier under the contract.

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

Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Act, 1930 as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. The provisions of the Conditions (ATC) shall be complied with.

31. **Bar Coding**

All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (primary, secondary and tertiary) and should encode the information within the barcodes as mentioned by the buyers in addition to other 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 order.
  - The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated) and if found that temperature has not been maintained, supply against the said order is liable to be rejected.
  - The items requiring special cold storage conditions shall be supplied with cold chain transporting container from the manufacturing unit to the warehouses/consignee location.
33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other particulars shall be given by the buyer through Additional Terms and Conditions (ATC) in the bid will be applicable.
34. Any other Terms and Conditions which is not included or at variance with the conditions specified in the Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authentic source and quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede specific conditions and 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. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the valid Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitted regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., valid 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 (which may be verified by the buyer at their end).

**UNDERTAKING**

***(to be on non-judicial stamp paper of Rs 10 and not less than)***

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 undertake that if any information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic Act 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 also be in compliance with all notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Family Welfare, Government of India, 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 in compliance with all notifications issued by the Government of India in this regard.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing authority under the Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly mentioned in the license. The valid own manufacturing license shall be submitted to the buyer at the time of bid submission.

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

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

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the application for renewal must be submitted with a certificate that application for renewal was made within time frame as per Drugs and Cosmetics Act 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 to the bidder/seller by the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of bid submission.
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the concerned Drug Licensing Authority for last 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine shall be clearly mentioned and highlighted.

*This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from the Drug Licensing Authority for all new drug formulations to this effect.*

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which are all licensed by the concerned Drug Licensing Authority, only one bid will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) issued by the concerned Drug Licensing Authority under the Drugs and Cosmetics 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 Drug Licensing Authority for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted. (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, the bidder/seller shall submit complete stability data for the licensed formula).

should be submitted along with licensing agreement.)

15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product / Central or State Government's Drug procurement agencies at the time of submission of bid. Further, the bidder/seller should not have been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner should not participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any Central or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated in writing by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be under any legal proceedings or pending in any court of India by any department of Govt. under prevention of Corruption Act or for fraud involving 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 and only) to the buyer.

*They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs and cosmetics viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Drugs (Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.*

*To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" to the 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 ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Government of India order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceuticals.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date more than 18 months from the date of manufacture.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

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

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

#### 24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceuticals, the seller/bidder shall immediately inform the buyer, providing full details about the reason leading to the recall, and shall take steps to replace the product at its ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund to the buyer. The seller/bidder shall not be allowed to re-introduce the product into the market until it has been taken off the market due to safety problems.

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from the seller's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
  1. Generic name of the product
  2. Batch No.
  3. Pharmacopoeia Reference and/ or In-house method
  4. Batch quantity
  5. Date of manufacture
  6. Expiry date
  7. Date of test
  8. Description (clarity, color etc)
  9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia. 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 requirements. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government Laboratory or combination of or/ all following stages:

**a) At Pre-Dispatch stage**

**b) At Delivery Stage:** Inspection done once the drugs/medicines/goods reach at consignee location inventory.

**c) Post Delivery Surveillance:** The Drugs/Medicines/goods shall have the active ingredients and 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 Laboratory. 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 their destination shall in no way be limited or waived by reason of the goods having previously been in dispatch from the place of manufacture.
- **Inspection Methodology:** At pre-dispatch and/or delivery stage, samples of supplies in each batch collected and sent to designated laboratories (NABL Accredited/Government approved laboratories).

**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 the shelf life.

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the supplier.

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

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

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable concerned State will also be informed by the buyer for initiating necessary action on the supplier if the batch is found defective without any intimation.

The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied drugs/medicines/goods.

- In case any drug/medicine is found substandard either any of testing stage or during the shelf life, the batch shall be accepted by the supplier/seller. If the same is disputed by the supplier, the sample shall be 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 the buyer. The supplier shall approach the concerned Drug Control Authorities for getting the drugs/medicines tested, at their own cost.

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

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

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

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

**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 stock of the product with all consignee/users will be retrieved.

## 28. **Termination for Default**

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

## 29. **Warranty**

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

"The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under the best workmanship and shall be strictly in accordance with the specifications and particulars mentioned. The stores would continue to conform to the description of and quality aforesaid for a period of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the specified limits 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 quality as decided by the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the stores discovered not to conform to the said description and quality. Losses due to premature deterioration of potency will be made good and supplied by the firm at its own cost at consignee's site.

On such rejection, the stores will be at the seller's risk and all provisions herein contained relating to replacement. The supplier/seller shall if so called upon to do so by the buyer in writing, replace the stores free of cost within forty five days or such further period as may be extended from time to time by the buyer at his cost. The provisions of the contract shall apply to the stores replaced from the date of the replacement thereof otherwise the provisions 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
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Signature name & designation

- 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 prejudice against the supplier under the contract.

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

Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Act, 1930 as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. The provisions of the Conditions (ATC) shall be complied with.

## 31. **Bar Coding**

All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (primary, secondary and tertiary) and should encode the information within the barcodes as mentioned by the buyers in addition to other 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 order.
- The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated) during storage and transportation.

- found that temperature has not been maintained, supply against the said order is liable to be rejected.
  - 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 other 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 authentic quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede special 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. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the valid Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submit regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., valid 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 (seller may be verified by the buyer at their end).

#### **UNDERTAKING**

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

I, \_\_\_\_\_, s/o / d/o / w/o \_\_\_\_\_, aged about \_\_\_\_\_ resident of \_\_\_\_\_ 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 of \_\_\_\_\_ 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 undertake that no information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic Act 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 be applicable and all notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Family Welfare, Government of India, Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be applicable to the Substances.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing authority under the Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly mentioned in the License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submission.

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

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

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the same shall be submitted to the buyer.*

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

*This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from the Drug Licensing Authority for all new drug formulations to this effect.*

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which shall be allowed to submit only one bid for all units but necessary document regarding separate manufacturing units. One bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP) Certificate issued by the Central / State Drug Controller / FDA.
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug licensing authority for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, the stability data should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any Central / State Government's Drug procurement agencies at the time of submission of bid. Further, the bidder/seller should not have been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner should not participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any Central / State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to the buyer by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for 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 and only) to the buyer.

*They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines as per the Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Drugs (Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.*

*To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 and to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as per the order of the 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 ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Drugs and Cosmetics Act, 1940 (India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceuticals.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date on or after 31/03/2020-Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

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

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

#### 24. **Recalls**



If products are recalled because of problems with product quality or adverse reaction to the pharmaceutical buyer, providing full details about the reason leading to the recall, and shall take steps to replace the product at its ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund if the product has been taken off the market due to safety problems.

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from the supplier's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
  1. Generic name of the product
  2. Batch No.
  3. Pharmacopoeia Reference and/ or In-house method
  4. Batch quantity
  5. Date of manufacture
  6. Expiry date
  7. Date of test
  8. Description (clarity, color etc)
  9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia. 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 requirements. The buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government approved laboratory or a combination of or/ all following stages:

**a) At Pre-Dispatch stage**

**b) At Delivery Stage:** Inspection done once the drugs/medicines/goods reach at consignee location inventory.

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratory for surveillance. 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 their delivery to the destination shall in no way be limited or waived by reason of the goods having previously been inspected or tested at the time of dispatch from the place of manufacture.
- **Inspection Methodology:** At pre-dispatch and/or delivery stage, samples of supplies in each batch shall be collected and sent to designated laboratories (NABL Accredited/Government approved laboratories).

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

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the supplier.
- If the batch is found to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be rejected and the cost of entire batch paid will be recovered from the supplier within 45 days from the date of intimation from the buyer.
- **At any of testing stage,** Samples which do not meet quality requirement shall render the relevant batch declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier within 45 days from the date of intimation from the buyer.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any of the tests, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignee location and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take back the rejected goods within stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after 45 days from the date of intimation from the buyer.

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable reasons. The concerned State will also be informed by the buyer for initiating necessary action on the supplier if the supplier is found to be forfeited without any intimation.

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

- In case any drug/medicine is found substandard either any of testing stage or during the shelf life approved laboratory shall be accepted by the supplier/seller. If the same is disputed by the supplier 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 the 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 Welfare communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the product. 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 Drug confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also with
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

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

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

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

If any batch of any product(s) supplied by the supplier is declared "NOT OF STANDARD QUALITY", by any authority, the supplier shall inform the same immediately to the buyer so that the use of the available stock of the product with all consignee/users will be retrieved.

**28. Termination for Default**

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

**29. Warranty**

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

"The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under the workmanship and shall be strictly in accordance with the specifications and particulars mentioned the stores would continue to conform to the description of and quality aforesaid for a period of the 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 quality 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 deterioration potency will be made good and supplied by the firm at its own cost at consignee's site.

On such rejection, the stores will be at the seller's risk and all provisions herein contained relating to supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of cost within forty five days or such further period as may be extended from time to time by the buyer at his cost. The supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer a 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

- 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 prejudice 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 Rules, 1945 as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. Additional Terms and Conditions (ATC) shall be complied with.

31. **Bar Coding**

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

32. **Delivery Period**

- Minimum delivery period will be of 45 days from the date of issuing of the purchase order.
  - The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated). If found that temperature has not been maintained, supply against the said order is liable to be rejected.
  - The items requiring special cold storage conditions shall be supplied with cold chain transporting from the manufacturing unit to the warehouses/consignee location.
33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other particulars shall be given by the buyer through Additional Terms and Conditions (ATC) in the bid will be applicable.
34. Any other Terms and Conditions which is not included or at variance with the conditions specified in Standard Terms and Conditions (STC) and Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authentic quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede STC and STC 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 50mcg/200mcg**

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

**UNDERTAKING**

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

I, \_\_\_\_\_, s/o / d/o / w/o \_\_\_\_\_, aged about \_\_\_\_\_ resident of \_\_\_\_\_ undertake that;

1. I am the partner / proprietor / director of \_\_\_\_\_ (name of entity) and duly authorized to sign on behalf of \_\_\_\_\_ (Name of entity)
2. We are the manufacturers of the drug/medicine \_\_\_\_\_ ("Product") and intend to offer for sale.
3. We state that the license for the Product has been granted/obtained by us as per the provisions of the Drugs and Cosmetics Rules, 1945 as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the website of the Drugs and Cosmetics Rules, 1945 as amended till date. Reference no. for SUGAM portal is \_\_\_\_\_.
5. We undertake that all the information provided above is true and complete in all respect. We understand that any false information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic Rules, 1945 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 also be applicable to all notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Family Welfare, Government of India, Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be applicable to all such Substances.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing authority under the Drugs Act, 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly marked with the License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submission.

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

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

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the application must be submitted with a certificate that application for renewal was made within time frame as per Drugs and Cosmetics Act 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 requirements issued by the Concerned Drug Licensing Authority to the buyer at the time of bid submission.
8. Bidder/Seller shall submit a valid **non-Conviction** certificate for last two (2) consecutive years issued by the competent authority to the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of submission.
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the concerned authority for last 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine shall be highlighted.

*This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from the concerned authority for all new drug formulations to this effect.*

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which are all licensed, it shall be allowed to submit only one bid for all units but necessary document regarding separate manufacturing units shall be submitted. One bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) issued by the concerned authority under the Drugs 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 drug licensing authority for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia products shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, it should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any Central / State Government's Drug procurement agencies at the time of submission of bid. Further, if the bidder/seller has been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner shall not participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any Central / State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to the buyer by document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for criminal offence or 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 and only) with the following undertakings:
- They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs and cosmetics viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Drugs (Price 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" to the 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 ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs (Price Control) Order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmacy.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date beyond 31/03/2026/1/2019-Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

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

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

24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceuticals, the seller/bidder shall provide full details about the reason leading to the recall, and shall take steps to replace the products at their ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund to the consignee. The products shall not be taken off the market due to safety problems.

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from the seller's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
  1. Generic name of the product
  2. Batch No.
  3. Pharmacopoeia Reference and/ or In-house method
  4. Batch quantity
  5. Date of manufacture
  6. Expiry date
  7. Date of test
  8. Description (clarity, color etc)
  9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia. 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 requirements. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government Laboratory or any combination of or/ all following stages:

**a) At Pre-Dispatch stage**

**b) At Delivery Stage:** Inspection done once the drugs/medicines/goods reach at consignee local inventory.

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratory for the purpose of inspection. 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 their ultimate destination shall in no way be limited or waived by reason of the goods having previously been in dispatch from the place of manufacture.

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

**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 the contract period.

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the designated laboratories.
- **At any of testing stage**, Samples which do not meet quality requirement shall render the relevant batch declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the batch is found substandard.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any other way, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/colleges/hospitals and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take back the rejected goods within stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the necessary intimation.

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable reasons. The concerned State will also be informed by the buyer for initiating necessary action on the supplier if the supplier is found to be forfeited without any intimation.

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

- In case any drug/medicine is found substandard either at any stage of testing stage or during the shelf life, the batch shall be rejected. The batch shall be accepted by the supplier/seller. If the same is disputed by the supplier, the batch shall be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and the supplier shall submit the batch within three months, from the date of communication of the disputed test report to the buyer. The supplier shall approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per the guidelines issued by the Government of India at its own cost.

The de-registration / debarment action will be taken by the buyer against the manufacturing unit if the supplier is found to be defective in category-A and category-B defects as per guidelines issued by the Ministry of Health & Family Welfare, Government of India communicated to GeM.

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

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

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

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

If any batch of any product(s) supplied by the supplier is declared "NOT OF STANDARD QUALITY", by any authority, the supplier shall inform the same immediately to the buyer so that the use of the available stock of the product with all consignee/users will be retrieved.

## 28. **Termination for Default**

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

## 29. **Warranty**

- Supplies must fully comply in all respect with the Technical specifications and conditions laid down in the Bidding Document.

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 a 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 / 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 other 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. 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 autl 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 t buyer at the time of bid submission. The certificate must have been issued within 12 months from the c
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, which



be allowed to submit only one bid for all units but necessary document regarding separate manufacturing one bidder will be allowed to submit only one offer for one product.

11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) 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 department.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia (USP) the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data (If manufacturer has licensed a formula from another company and such licensed formula is used for the product should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by Central or State Government's Drug procurement agencies at the time of submission of bid. Further, if the bidder/seller has been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner should not participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any Central or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated in writing document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for misappropriation of Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only) that they will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines.

*They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines. Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Drugs (Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.*

*To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 and to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as notified by the 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 ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Government of India order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceuticals.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date on or after 31/03/2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

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

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

#### 24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceuticals, the manufacturer/buyer, providing full details about the reason leading to the recall, and shall take steps to replace the products at their ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund to the consumer. If products have been taken off the market due to safety problems.

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from the manufacturer's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
  1. Generic name of the product
  2. Batch No.
  3. Pharmacopoeia Reference and/ or In-house method
  4. Batch quantity
  5. Date of manufacture
  6. Expiry date
  7. Date of test

8. Description (clarity, color etc)
9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified 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 requirements. 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 local inventory.

**c) Post Delivery Surveillance:** The Drugs/Medicines/goods shall have the active ingredients as 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 Laboratory. 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 their destination shall in no way be limited or waived by reason of the goods having previously been in dispatch from the place of manufacture.
- **Inspection Methodology:** At pre-dispatch and/or delivery stage, samples of supplies in each batch shall be collected and sent to designated laboratories (NABL Accredited/Government approved laboratories).

**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 the shelf life.

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the buyer.
  - The supplies will be deemed to be completed only upon receipt of the quality certificates from the buyer.
- "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be rejected.

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

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for similar defects. The concerned State will also be informed by the buyer for initiating necessary action on the supplier if the batch is found substandard without any intimation.

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

- In case any drug/medicine is found substandard either at any of testing stage or during the shelf life, the batch shall be rejected and the cost of the batch shall be recovered from the supplier. If the same is disputed by the supplier, the batch shall be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and the batch shall be destroyed within three months, from the date of communication of the disputed test report to the buyer. The supplier shall approach the concerned Drug Control Authorities for getting the drugs/medicines tested, at his own cost.

The de-registration / debarment action will be taken by the buyer against the manufacturing unit if the batch is found substandard due to category-A and category-B defects as per guidelines issued by the Ministry of Health & Family Welfare, Government of West Bengal communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the drugs/medicines/goods. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the product shall be provided.

- 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 Drug Controller, sealing or prosecution with relation to drugs/medicines under the said Act is also with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Drug Controller.
  - In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended, the Drug Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

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

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

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

If any batch of any product(s) supplied by the supplier is declared "NOT OF STANDARD QUALITY", by any authority, the supplier shall inform the same immediately to the buyer so that the use of the available stock of the product with all consignee/users will be retrieved.

28. **Termination for Default**

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

29. **Warranty**

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

"The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under the contract are of good workmanship and shall be strictly in accordance with the specifications and particulars mentioned in the contract. The stores would continue to conform to the description of and quality aforesaid for a period of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the specified limits 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 quality as per the decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the stores discovered not to conform to the said description and quality. Losses due to premature deterioration of potency will be made good and supplied by the firm at its own cost at consignee's site.

On such rejection, the stores will be at the seller's risk and all provisions herein contained relating to replacement. The supplier/seller shall if so called upon to do so by the buyer in writing, replace the stores free of cost within forty five days or such further period as may be extended from time to time by the buyer at his discretion. The provisions of the contract shall apply to the stores replaced from the date of the replacement thereof otherwise the provisions of the contract shall apply to the stores 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
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Signature name & designation

- 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 prejudice against the supplier under the contract.

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

Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Act, 1940.

amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. Conditions (ATC) shall be complied with.

31. **Bar Coding**

All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (primary, secondary, tertiary) and should encode the information within the barcodes as mentioned by the buyers in addition to other 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 order.
  - The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated). If found that temperature has not been maintained, supply against the said order is liable to be rejected.
  - The items requiring special cold storage conditions shall be supplied with cold chain transporting from the manufacturing unit to the warehouses/consignee location.
33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other requirements shall be mentioned in 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-1 shall be void. Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authentic source and of good quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede specific terms and conditions, which 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. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the valid Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submission of regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., valid 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 (which may be verified by the buyer at their end).

**UNDERTAKING**

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

I, \_\_\_\_\_, s/o / d/o / w/o \_\_\_\_\_, aged about \_\_\_\_\_ resident of \_\_\_\_\_  
undertake that;

1. I am the partner / proprietor / director of \_\_\_\_\_ (name of entity) and duly registered. (Name of entity)
2. We are the manufacturers of the drug/medicine \_\_\_\_\_ ("Product") and intend to offer for sale.
3. We state that the license for the Product has been granted/obtained by us as per the provisions of the Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the website of the Drugs and Cosmetics Rules, 1945 as amended till date. Reference no. for SUGAM portal is \_\_\_\_\_.
5. We undertake that all the information provided above is true and complete in all respect. We understand that if any information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetics Act, 1940 and Rules made there under will be initiated.

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

3. All Provisions of Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date will be applicable. Notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare, Government of India, Ministry of Chemicals & Fertilizers time to time in this regard.

4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be applicable to these Substances.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing authority under the Drugs Act, 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly marked with the License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submission.

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

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

*If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the license must be submitted with a certificate that application for renewal was made within time frame as per Drugs and Cosmetics Act 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 requirements issued by the Concerned Drug Licensing Authority to the buyer at the time of bid submission.
8. Bidder/Seller shall submit a valid **non-Conviction** certificate for last two (2) consecutive years issued by the competent authority to the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of submission.
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the competent authority for last 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine shall be highlighted.

*This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from the competent authority for all new drug formulations to this effect.*

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which are licensed by the concerned Drug Licensing Authority, only one bid will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) issued by the Central / State Drug Controller / FDA.
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug licensing authority for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia (USP, BP, IP) shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any Central or State Government's Drug procurement agencies at the time of submission of bid. Further, if the bidder/seller has been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner shall not participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any Central or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to the buyer by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for criminal offence or Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only) that they will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines under the Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended till date), The Drugs (Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.

*They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines under the Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended till date), The Drugs (Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.*

*To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as per the order of the 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 ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date.

- 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 date 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 &

In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed 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 pharmaceutical buyer, providing full details about the reason leading to the recall, and shall take steps to replace the product at its ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund if the product has been taken off the market due to safety problems.

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
  1. Generic name of the product
  2. Batch No.
  3. Pharmacopoeia Reference and/ or In-house method
  4. Batch quantity
  5. Date of manufacture
  6. Expiry date
  7. Date of test
  8. Description (clarity, color etc)
  9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia. 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 requirements. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government approved laboratory at any combination of or/ all following stages:

**a) At Pre-Dispatch stage**

**b) At Delivery Stage:** Inspection done once the drugs/medicines/goods reach at consignee location inventory.

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

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

**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 the shelf life.

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the supplier. If the supplies are found to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be rejected.

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

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable reasons. The concerned State will also be informed by the buyer for initiating necessary action on the supplier if the supplier is found to be forfeited without any intimation.

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

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

The de-registration / debarment action will be taken by the buyer against the manufacturing unit if found defective category-A and category-B defects as per guidelines issued by the Ministry of Health & Family Welfare, Government of India.

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

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

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

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

If any batch of any product(s) supplied by the supplier is declared "NOT OF STANDARD QUALITY", by any authority, the supplier shall inform the same immediately to the buyer so that the use of the available stock of the product with all consignee/users will be retrieved.

#### 28. **Termination for Default**

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

#### 29. **Warranty**

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

"The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under the contract shall be strictly in accordance with the specifications and particulars mentioned in the contract. The stores would continue to conform to the description of and quality aforesaid for a period of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the specified limits 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 quality as specified in the contract, the decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the stores discovered not to conform to the said description and quality. Losses due to premature deterioration of the stores will be made good and supplied by the firm at its own cost at consignee's site.

On such rejection, the stores will be at the seller's risk and all provisions herein contained relating to the stores 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
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Signature name & designation

- 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 prejudice against the supplier under the contract.

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

Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Act, 1930 and amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. Conditions (ATC) shall be complied with.

31. **Bar Coding**

All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (primary, secondary and tertiary) and should encode the information within the barcodes as mentioned by the buyers in addition to other 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 order.
  - The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated). If found that temperature has not been maintained, supply against the said order is liable to be rejected.
  - The items requiring special cold storage conditions shall be supplied with cold chain transporting facility from manufacturing unit to the warehouses/consignee location.
33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other particulars shall be given by the buyer through Additional Terms and Conditions (ATC) in the bid will be applicable.
34. Any other Terms and Conditions which is not included or at variance with the conditions specified in the Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authentic quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede specific terms and conditions, which 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. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the valid Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitting regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., valid 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 (which may be verified by the buyer at their end).

**UNDERTAKING**

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

I, \_\_\_\_\_, s/o / d/o / w/o \_\_\_\_\_, aged about \_\_\_\_\_ resident of \_\_\_\_\_



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 undertake that if any information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic Act 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 also be in compliance with all notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Family Welfare, Government of India, 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 in compliance with all notifications issued by the Government of India in this regard.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing authority under the Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly mentioned in the License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submission.

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

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

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

*This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from the Drug Licensing Authority for all new drug formulations to this effect.*

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which are licensed to manufacture the same drug/medicine, only one bid will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP) Certificate issued by the concerned Drug Licensing Authority under the Drugs and Cosmetics 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 Drug Licensing Authority for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted. (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, the bidder/seller shall submit complete stability data for the licensed formula.)

should be submitted along with licensing agreement.)

15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product / Central or State Government's Drug procurement agencies at the time of submission of bid. Further, if the bidder/seller has been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner should not participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any Central or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated in writing by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be under any legal proceedings or pending in any court of India by any department of Govt. under prevention of Corruption Act or for fraud involving 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 and only) to the buyer.

*They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs and cosmetics viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Drugs (Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.*

*To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 and to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as notified by the 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 ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Drugs and Cosmetics (India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmacy.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date less than 18 months from the date of manufacture.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

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

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

#### 24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceuticals, the seller/bidder shall immediately inform the buyer, providing full details about the reason leading to the recall, and shall take steps to replace the products at their ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund to the buyer. The products shall not be taken off the market due to safety problems.

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from the seller's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
  1. Generic name of the product
  2. Batch No.
  3. Pharmacopoeia Reference and/ or In-house method
  4. Batch quantity
  5. Date of manufacture
  6. Expiry date
  7. Date of test
  8. Description (clarity, color etc)
  9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia. 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 requirements. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government Laboratory. The combination of or/ all following stages:

**a) At Pre-Dispatch stage**

**b) At Delivery Stage:** Inspection done once the drugs/medicines/goods reach at consignee location inventory.

**c) Post Delivery Surveillance:** The Drugs/Medicines/goods shall have the active ingredients and 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 Laboratory. 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 their destination shall in no way be limited or waived by reason of the goods having previously been in dispatch from the place of manufacture.
- **Inspection Methodology:** At pre-dispatch and/or delivery stage, samples of supplies in each batch collected and sent to designated laboratories (NABL Accredited/Government approved laboratories).

**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 the shelf life.

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the supplier.

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

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

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable concerned State will also be informed by the buyer for initiating necessary action on the supplier if the batch is found defective without any intimation.

The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied drugs/medicines/goods.

- In case any drug/medicine is found substandard either any of testing stage or during the shelf life, the batch shall be accepted by the supplier/seller. If the same is disputed by the supplier, the sample shall be 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 the buyer. The supplier shall approach the concerned Drug Control Authorities for getting the drugs/medicines tested, at their own cost.

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

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

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

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

**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 stock of the product with all consignee/users will be retrieved.

## 28. **Termination for Default**

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

## 29. **Warranty**

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

"The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under the workmanship and shall be strictly in accordance with the specifications and particulars mentioned the stores would continue to conform to the description of and quality aforesaid for a period of the 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 quality 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 deterioration potency will be made good and supplied by the firm at its own cost at consignee's site.

On such rejection, the stores will be at the seller's risk and all provisions herein contained relating to the supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of cost within forty five days or such further period as may be extended from time to time by the buyer at his cost. The supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer at the period shall apply to the stores replaced from the date of the replacement thereof otherwise the liability 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
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Signature name & designation

- 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 prejudice against the supplier under the contract.

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

Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Act, 1930 as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. The Conditions (ATC) shall be complied with.

## 31. **Bar Coding**

All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (primary, secondary and tertiary) and should encode the information within the barcodes as mentioned by the buyers in addition to other 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 order.
- The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated).

- found that temperature has not been maintained, supply against the said order is liable to be rejected.
  - 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 other 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 authentic quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede special 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. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the valid Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submit regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., valid 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 (seller may be verified by the buyer at their end).

**UNDERTAKING**

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

I, \_\_\_\_\_, s/o / d/o / w/o \_\_\_\_\_, aged about \_\_\_\_\_ resident of \_\_\_\_\_ 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 of \_\_\_\_\_ 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 undertake that no legal 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 be applicable and all notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare, Government of India, Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be applicable to the Substances.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing authority under the Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly mentioned in the License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submission.

In case of authorized resellers/distributors, it will be the legal & regulatory liability of the manufacturer and its authorized resellers/distributors 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 their

If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the same shall be submitted to the buyer.

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

*This would not apply to drugs, which were introduced in India less than 2 years ago. A certificate from the Drug Licensing Authority for all new drug formulations to this effect.*

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which shall be allowed to submit only one bid for all units but necessary document regarding separate manufacturing units. One bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP) Certificate issued by the Central / State Drug Controller / FDA.
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug licensing authority for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, the stability data should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any Central / State Government's Drug procurement agencies at the time of submission of bid. Further, the bidder/seller should not have been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner should not participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any Central / State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to the buyer by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for criminal offence involving 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 and only) to the buyer.

*They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines as per the Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Drugs (Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.*

*To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 and to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as per the order of the 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 ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Drugs and Cosmetics Act, 1940 (India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceuticals.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date on or after 31/03/2026/1/2019-Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

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

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

#### 24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceutical buyer, providing full details about the reason leading to the recall, and shall take steps to replace the product at its ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund if the product has been taken off the market due to safety problems.

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from the supplier's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
  1. Generic name of the product
  2. Batch No.
  3. Pharmacopoeia Reference and/ or In-house method
  4. Batch quantity
  5. Date of manufacture
  6. Expiry date
  7. Date of test
  8. Description (clarity, color etc)
  9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia and 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 requirements. The buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government approved laboratory or combination of or/ all following stages:

**a) At Pre-Dispatch stage**

**b) At Delivery Stage:** Inspection done once the drugs/medicines/goods reach at consignee location inventory.

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratory for inspection and testing. 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 their delivery to the destination shall in no way be limited or waived by reason of the goods having previously been inspected and tested at the time of dispatch from the place of manufacture.
- **Inspection Methodology:** At pre-dispatch and/or delivery stage, samples of supplies in each batch shall be collected and sent to designated laboratories (NABL Accredited/Government approved laboratories).

**At post-delivery surveillance** - The samples will be collected from the warehouse of buyer or from the supplier's designated Quality Control Labs in respect of supplied drugs/medicines/goods at any point during the shelf-life period.

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the supplier.
- If the quality of the supplies is found to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be rejected and the cost of the entire batch shall be recovered from the supplier.
- **At any of testing stage,** Samples which do not meet quality requirement shall render the relevant batch declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches shall be rejected and the cost of entire batch paid will be recovered from the supplier when the batch is found to be "Not of Standard Quality".
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any of the tests, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignees and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take back the rejected goods within the stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of the stipulated time.

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable reasons. The concerned State will also be informed by the buyer for initiating necessary action on the supplier if the quality of the supplies is found to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be rejected and the cost of the entire batch shall be recovered from the supplier.

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

- In case any drug/medicine is found substandard either any of testing stage or during the shelf life approved laboratory shall be accepted by the supplier/seller. If the same is disputed by the supplier 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 the 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 Welfare communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the product. 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 Drug confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also with
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

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

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

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

If any batch of any product(s) supplied by the supplier is declared "NOT OF STANDARD QUALITY", by any authority, the supplier shall inform the same immediately to the buyer so that the use of the available stock of the product with all consignee/users will be retrieved.

**28. Termination for Default**

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

**29. Warranty**

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

"The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under the workmanship and shall be strictly in accordance with the specifications and particulars mentioned the stores would continue to conform to the description of and quality aforesaid for a period of the 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 quality 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 deterioration potency will be made good and supplied by the firm at its own cost at consignee's site.

On such rejection, the stores will be at the seller's risk and all provisions herein contained relating to supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of cost within forty five days or such further period as may be extended from time to time by the buyer at his cost. The supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer at the period shall apply to the stores replaced from the date of the replacement thereof otherwise the losses 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
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Signature name & designation

- 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 prejudice 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 Rules, 1954 as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. The Additional Terms and Conditions (ATC) shall be complied with.

31. **Bar Coding**

All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (primary, secondary, tertiary) and should encode the information within the barcodes as mentioned by the buyers in addition to other 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 order.
  - The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated). If found that temperature has not been maintained, supply against the said order is liable to be rejected.
  - The items requiring special cold storage conditions shall be supplied with cold chain transporting facility from the manufacturing unit to the warehouses/consignee location.
33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other particulars shall be given by the buyer through Additional Terms and Conditions (ATC) in the bid will be applicable.
34. Any other Terms and Conditions which is not included or at variance with the conditions specified in the Standard Terms and Conditions (STC) and Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authentic source and of good quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede STC and STC 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. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the valid Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submission of regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., valid 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 (which may be verified by the buyer at their end).

**UNDERTAKING**

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

I, \_\_\_\_\_, s/o / d/o / w/o \_\_\_\_\_, aged about \_\_\_\_\_ resident of \_\_\_\_\_ undertake that;

1. I am the partner / proprietor / director of \_\_\_\_\_ (name of entity) and duly authorized to sign on behalf of \_\_\_\_\_ (Name of entity)
2. We are the manufacturers of the drug/medicine \_\_\_\_\_ ("Product") and intend to offer the same for sale.
3. We state that the license for the Product has been granted/obtained by us as per the provisions of the Drugs and Cosmetics Rules, 1954 as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the website of the Drugs and Cosmetics Rules, 1954 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 undertake to provide the same to the buyer.

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 autl 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 copy 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 to buyer at the time of bid submission. The certificate must have been issued within 12 months from the c
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, which 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 i 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 State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intil 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 should not be involved in any court of India by any department of Govt. under prevention of Corruption Act or for cheating 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 and only)

*They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines as per Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Narcotic Control (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 and to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as per the order of 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 ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Government of India order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceuticals.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date on or after 31/03/2020-Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

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

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

#### 24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceuticals, the buyer, providing full details about the reason leading to the recall, and shall take steps to replace the products with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund to the consignee. The products shall not be taken off the market due to safety problems.

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

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

1. Generic name of the product
2. Batch No.
3. Pharmacopoeia Reference and/ or In-house method
4. Batch quantity
5. Date of manufacture
6. Expiry date
7. Date of test
8. Description (clarity, color etc)
9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia. The 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 requirements. The buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government Laboratory or any combination of or/ all following stages:

##### **a) At Pre-Dispatch stage**

**b) At Delivery Stage:** Inspection done once the drugs/medicines/goods reach at consignee location and inventory.

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratory for the purpose of inspection and testing.

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 their destination shall in no way be limited or waived by reason of the goods having previously been in dispatch from the place of manufacture.
- **Inspection Methodology:** At pre-dispatch and/or delivery stage, samples of supplies in each batch shall be collected and sent to designated laboratories (NABL Accredited/Government approved laboratories).

**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 the contract period.

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the supplier.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the concerned State.

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

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

Action may also be initiated by the buyer for debarring/blacklisting against the supplier for suitable reasons. The concerned State will also be informed by the buyer for initiating necessary action on the supplier if the supplier is found to be forfeited without any intimation.

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

- In case any drug/medicine is found substandard either at any of testing stage or during the shelf life, the batch shall be accepted by the supplier/seller. If the same is disputed by the supplier, the batch shall be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and the supplier shall submit the same within three months, from the date of communication of the disputed test report to the buyer. The supplier shall approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per the guidelines issued by the Ministry of Health & Family Welfare, Government of India, at their own cost.

The de-registration / debarment action will be taken by the buyer against the manufacturing unit if found to be defective in category-A and category-B defects as per guidelines issued by the Ministry of Health & Family Welfare, Government of India, communicated to GeM.

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the product to the buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the product shall be submitted to the buyer. For New drugs/medicines, complete stability data of 6 months period shall be acceptable.
- The case of admixture of drugs will be treated as a violation of terms and conditions and will not be acceptable.
- 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 Drug Control Authorities. Any violation of the said provisions shall be treated as a violation of terms and conditions and will not be acceptable. Confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also within the powers of the said authorities.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended, the Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

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

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

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

If any batch of any product(s) supplied by the supplier is declared "NOT OF STANDARD QUALITY", by any authority, the supplier shall inform the same immediately to the buyer so that the use of the available stock of the product with all consignee/users will be retrieved.

## 28. **Termination for Default**

The buyer may without prejudice to any other remedy for breach of contract, by written notice of default terminate the contract in whole or in part if the supplier fails to promptly replace any drug/medicine/goods rejected submitted for testing to the 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 down in the Pharmacopoeia standards.
- Each supply should be accompanied with a "Warranty Certificate" duly signed by the Bidder as under.

"The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under the guarantee of workmanship and shall be strictly in accordance with the specifications and particulars mentioned. The stores would continue to conform to the description of and quality aforesaid for a period of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the tolerance 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 quality, the decision of the buyer in that behalf is final and conclusive, the buyer will be entitled to reject the stores discovered not to conform to the said description and quality. Losses due to premature deterioration of potency will be made good and supplied by the firm at its own cost at consignee's site.

On such rejection, the stores will be at the seller's risk and all provisions herein contained relating to replacement. The supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of cost within forty five days or such further period as may be extended from time to time by the buyer at his option. The supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer at the end of the period shall apply to the stores replaced from the date of the replacement thereof otherwise the liability shall as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice the operation of this contract or otherwise".

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

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

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

Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Act, 1930 as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. The Conditions (ATC) shall be complied with.

31. **Bar Coding**

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

32. **Delivery Period**

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

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

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

### 1. Buyer Added Bid Specific ATC

Buyer Added text based ATC clauses

Bidder should have valid Drugs 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 consequences arising in the bidding process due to these ATCs and due to modification of technical specifications and / or terms are incorporated by the Buyer regarding following, the bid and resultant contracts shall be treated as null and void at any stage of bidding process without any notice:-

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

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

**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 of Bonus Act, 1965, The Payment of Gratuity Act, 1972 etc. Any non-compliance will be treated as breach of contract and will be dealt with as per GeM Contract.**

[This Bid is also governed by the General Terms and Conditions/ यह बिड सामान्य शर्तों के अधीन है](#)

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 a land border with India and is registered with the Competent Authority. While participating in bid, Bidder has to undertake compliance of this and any false declaration and non-compliance of this would be treated as breach of contract and will be dealt with as per GeM Contract. **जम की सामान्य शर्तों के खंड 26 के संदर्भ में भारत के साथ भूमि सीमा साझा करने वाले देश के बिडर से खरीद के लिए तैयार होने 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 कार्य

**---Thank You/धन्यवाद---**

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