

**Bid Document/ बिड दस्तावेज़**

Bid Details/बिड विवरण	
Bid End Date/Time/बिड बंद होने की तारीख/समय	12-05-2025 11:00:00
Bid Opening Date/Time/बिड खुलने की तारीख/समय	12-05-2025 11:30:00
Bid Offer Validity (From End Date)/बिड पेशकश वैधता (बंद होने की तारीख से)	30 (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	6020
Item Category/मद केटेगरी	Cefuroxime Oral Liquid (Q2) , Pantopraz Liquid (Q2) , Ondansetron Injection (Q2) Injection (V2) (Q2) , Metoclopramide Inje Hydrocortisone Injection (Q2) , Adrenali Dexamethasone Injection (Q2) , Phenira Solution for use in Nebulizer (Q2) , Folic
Years of Past Experience Required for same/similar service/उन्हीं/समान सेवाओं के लिए अपेक्षित विगत अनुभव के वर्ष	1 Year (s)
MSE Exemption for Years Of Experience/अनुभव के वर्षों से एमएसई छूट/	Yes
Startup Exemption for Years Of Experience/अनुभव के वर्षों से स्टार्टअप छूट/	Yes
Participation restricted to CPSE/DPSU seller	Yes (This bid is reserved for participatio CPSE/DPSU sellers will be exempted from
Document required from seller/विक्रेता से मांगे गए दस्तावेज़	Experience Criteria,Certificate (Request *In case any bidder is seeking exemptio supporting documents to prove his eligi evaluation by the buyer
Do you want to show documents uploaded by bidders to all bidders participated in bid?/	Yes
Bid to RA enabled/बिड से रिवर्स नीलामी सक्रिय किया	Yes
RA Qualification Rule	H1-Highest Priced Bid Elimination
Type of Bid/बिड का प्रकार	Two Packet Bid

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

#### EMD Detail/ईएमडी विवरण

Required/आवश्यकता	No
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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 definitions under MSME rules, the bidder shall be exempted and "Experience Criteria" subject to meeting of quality and technical specifications. If the bidder is OEM of the offered products, the bidder shall be exempted from the requirement of "Bidder Turnover" criteria and "Experience Criteria" also subject to meeting of quality and technical specifications. In case any bidder is seeking exemption from Turnover / Experience Criteria, the exemption must be uploaded for evaluation by the buyer.
2. If the bidder is a Startup, the bidder shall be exempted from the requirement of "Bidder Turnover" criteria and "Experience Criteria" also subject to meeting of quality and technical specifications. If the bidder is OEM of the offered products, it would be exempted from the "OEM Average Turnover" criteria also subject to meeting of quality and technical specifications. In case any bidder is seeking exemption from Turnover / Experience Criteria, the exemption must be uploaded for evaluation by the buyer.
3. Experience Criteria: In respect of the filter applied for experience criteria, the Bidder or its OEM of the product offered should have regularly, manufactured and supplied same or similar Category Products to any Central / State Govt Org indicated above in the bid document before the bid opening date. Copies of relevant contracts and delivery acceptance with bid in support of having supplied some quantity during each of the Financial year. In case of bunch bids, the category should meet this criterion.
4. Purchase preference will be given to MSEs having valid Udyam Registration and whose credentials are validated as per Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of Industrial Policy and Promotion, Government of India and subsequent Orders/Notifications issued by concerned Ministry. If the bidder wants to avail themselves of the Purchase Preference, the bidder shall be required to upload the documents in support of the Purchase Preference / 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, the bidder shall be required to upload the documents in support of the Purchase Preference / OEM of the 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 applicable, the bidder shall be required to upload the documents in support of the Purchase Preference / OEM of the offered Service.

within L-1+ 15% (Selected by Buyer) of margin of purchase preference /price band defined in relevant policy, such N price and contract will be awarded for 25% (selected by Buyer) percentage of total quantity. The buyers are advised 18.05.2023 [OM No.1 4 2021 PPD dated 18.05.2023](#) for compliance of Concurrent application of Public Procurement and Public Procurement (Preference to Make in India) Order, 2017. Benefits of MSE will be allowed only if seller is val and approved by Buyer after evaluation of documents submitted.

5. Reverse Auction would be conducted amongst all the technically qualified bidders except the Highest quoting 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

## 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	Strength	125 mg/5 mL
PACKAGING	Primary pack size	30 ml, 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

## 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
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**Consignees/Reporting Officer/परिषी/रिपोर्टिंग अधिकारी and/ तथा Quantity/मात्रा**

S.No./क्र.सं.	Consignee Reporting/Officer/परिषी/रिपोर्टिंग 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	Strength	125 mg + 31.25 / 5 mL, 200 mg

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

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

**Ondansetron Injection ( 400 pieces )****Technical Specifications/तकनीकी विशिष्टियाँ**

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	2 mg/mL
PACKAGING	Primary pack size	2 ml, 4 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	400

**Bupivacaine Injection (V2) ( 20 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	<b>Strength</b>	0.25%, 0.5%, 0.5% with 7.5% g
PACKAGING	<b>Primary pack size</b>	20 ml, 4 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	20

**Amiodarone Injection (V2) ( 20 pieces )****Technical Specifications/तकनीकी विशिष्टियाँ**

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	<b>Primary pack size</b>	1 ml, 2 ml, 3 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परिषी/रिपोर्टिंग अधिकारी	Address/पता	Quantity,
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttarakhand	20

### Metoclopramide Injection ( 200 pieces )

**Technical Specifications/तकनीकी विशिष्टियाँ**

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PACKAGING	Primary pack size	2 ml, 10 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परिषी/रिपोर्टिंग 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
PACKAGING	Primary pack size	1 ml, 2 ml

**Consignees/Reporting Officer/परिषी/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 ( 100 pieces )

#### Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	100 mg, 200 mg

#### 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	100

### Adrenaline Injection (V2) ( 30 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
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#### 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	30

### Paracetamol Injection ( 300 pieces )

#### Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	10 mg/mL
PACKAGING	Primary pack size	0.5 ml, 1 ml, 2 ml, 3 ml, 4 ml, 5

#### 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	300

### Dexamethasone Injection ( 100 pieces )

#### Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	4 mg/mL
PACKAGING	Primary pack size	2 ml, 10 ml, 20 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	100

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

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	22.75 mg/mL
PACKAGING	Primary pack size	2 ml, 10 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

**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	Strength	0.5 mg, 1 mg
CERTIFICATIONS & REPORTS	Submission of all necessary certifications, licenses and test reports to the buyer as per buyer requirement at the time of bid submission and along with supplies	Yes

**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

**Folic Acid Tablet ( 2000 tablet(s) )****Technical Specifications/तकनीकी विशिष्टियाँ**

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

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

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर् टिंग अधिकारी	Address/पता	Quantity,
1	Charat Singh	248146,office of the DIG(Medical), Composite Hospital ,ITBP force,Seemadwar,Dehradun,Uttarakhand	2000

**Paracetamol Injection ( 100 pieces )****Technical Specifications/तकनीकी विशिष्टियाँ**

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	150 mg/mL, 10 mg/mL
PACKAGING	Primary pack size	0.5 ml, 1 ml, 2 ml, 3 ml, 4 ml, 5

**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	100

**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 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 (sc may be verified by the buyer at their end.

**UNDERTAKING**

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

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

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

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

3. All Provisions of Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date will a notifications issued by Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Fam Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be a Substances.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing 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 submission.

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 them.

*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 Drug License 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 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 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 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 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) that they will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs.

*They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs. Acts/Enactments 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" as per 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 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 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 pharmacist/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. 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 and 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/medicine. This 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 product 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 receipt at 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 designated laboratories.
- "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 rejected.
- 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.

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 stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after

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

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

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

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

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

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

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

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

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

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

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

#### **29. Warranty**

- Supplies must fully comply in all respect with the Technical specifications and conditions laid down 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 relatins supplier/Seller shall if so called upon to do so by the buyer in writing, replace the stores free of c forty five days or such further period as may be extended from time to time by the buyer at his c supplier/seller after the stores or such portion of the stores thereof as is rejected by the buyer ar period shall apply to the stores replaced from the date of the replacement thereof otherwise the

as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

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

Signature name & 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 / 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 (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 authentic quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede sp shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

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

1. 1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the ur Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitt regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., val drug/medicine under procurement, the license issuing authority etc. at their end.
2. The Buyer shall ask the seller to submit the "Notarized Undertaking" in the mentioned below format (sc may be verified by the buyer at their end.

**UNDERTAKING**

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

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

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

4. We further state that the details regarding the Product/licenses have been uploaded by us on the 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 no legal 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. 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 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 or reseller who are 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 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 court 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 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 licensed to manufacture the same product, 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.
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 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, 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 of the Drug procurement agencies, the bidder/seller shall be disqualified from participating in the bid.



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 Govt. agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be convicted 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) in the following format.

*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 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 seller/bidder shall 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. If the 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 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 required quality standards. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government approved 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 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.

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 period of validity of the contract.

*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 declared as such by the concerned State.
- **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 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/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 the same 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/claims concerned State will also be informed by the buyer for initiating necessary action on the supplier if the same 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 any of testing stage or during the shelf life, the batch shall be rejected by the approved laboratory 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 concerned State. The supplier shall approach the concerned Drug Control Authorities for getting the drugs/medicines tested, as per the guidelines issued by the concerned State on its own cost.

The de-registration / debarment action will be taken by the buyer against the manufacturing unit if found to be substandard 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 the said Act and will be dealt with accordingly, including 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 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 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 guarantee of 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, 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 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 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 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
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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 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 provisions of the contract (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 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 contract shall be void.

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 sp shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

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

1. 1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the ur Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitt regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., val drug/medicine under procurement, the license issuing authority etc. at their end.
2. 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 date of manufacture.
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 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 controller 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 (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, 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 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 involved 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.

*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 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 (Price Control) 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 31026/1/2019-Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics 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 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 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. 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 and 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 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 receipt at destination shall in no way be limited or waived by reason of the goods having previously been inspected or dispatched 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 laboratory).

**At post-delivery surveillance** - The samples will be collected from the warehouse of buyer or/ 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 where the batch is found defective.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any test, 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 corrective 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 reasons. The concerned State will also be informed by the buyer for initiating necessary action on the supplier if the batch is found defective.

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. The batch shall be accepted by the supplier/seller. If the same is disputed by the supplier, it 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.

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 product. 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 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 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, reject the 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 warranty 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 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 tender shall apply to the stores replaced from the date of the replacement thereof otherwise the provisions shall not apply. The provisions shall not prejudice the rights of the buyer 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. 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 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 Special Terms and Conditions (STC), 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 Uniform 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 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, 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 undertake that no legal action/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetics Rules, 1945 as amended till date 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 include 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 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 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 resellers 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 Drug 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 to the buyer.
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 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 Drug Licensing Authority under the 1940 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 along with the licensing agreement. (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, the stability data of 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 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 or testing by any State Government / Central Government / its Drug procurement agencies at the time of submission of bid, or has been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner shall not be allowed to 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 a 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 conspiracy 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 no paise) 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 (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 (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 not to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs"*

*Controller of India from time to time.*

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the 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 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 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 and 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 delivery to the destination shall in no way be limited or waived by reason of the goods having previously been inspected at 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
  - The supplies will be deemed to be completed only upon receipt of the quality certificates from the
- “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 declared to be “Not of Standard Quality” or spurious or adulterated or misbranded, such batch/b drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when
  - If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/col fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take stipulated time. The buyer will arrange to destroy the “NOT OF STANDARD QUALITY ITEMS” after

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

The decision of the buyer or any officer authorized by buyer, as to the quality of the supplied 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 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 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 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 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 (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 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 STC shall be given by the buyer through 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 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 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 (scanned copy) which may be verified by the buyer at their end.

**UNDERTAKING**

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 no 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 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 the Act and Rules.
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 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 court 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 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 manufacturing 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 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 and 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 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, 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 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 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 no paise).

*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 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 bidder/seller 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 bidder/seller 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 bidder'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 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 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 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 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 rejected.
- 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/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 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 batch 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 rejected. The batch shall be accepted by the supplier/seller. If the same is disputed by the supplier, it 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/her own cost.

The de-registration / debarment action will be taken by the buyer against the manufacturing unit if found to be defective. Category-A and category-B defects as per guidelines issued by the Ministry of Health & Family Welfare will be 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 be acceptable.
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines/goods 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 Act.
- 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 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 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 guarantee of 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 decided by 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 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
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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/deemed fit by the buyer, at the suppliers' risk and expense and without prejudice to the contract, reject the stores 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 in the Additional 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 information.



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 authentic quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede sp shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

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

1. 1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the ur Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitt regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., val drug/medicine under procurement, the license issuing authority etc. at their end.
2. The Buyer shall ask the seller to submit the "Notarized Undertaking" in the mentioned below format (sc may be verified by the buyer at their end.

#### UNDERTAKING

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

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

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

Place:

Date:

.....

*Signature, Name, Designation & Seal*

*on behalf of the Manufacturer*

3. All Provisions of Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date will a notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Fam Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.
4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be a Substances.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing 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 the

*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 Drug License 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 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 authority for last two 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 shall be allowed to submit only one bid for all units but necessary document regarding separate manufacturing units for each unit 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 each 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 license 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 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 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 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as per order of the Drug Controller of India from time to time.*

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or 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 Drug Price Control 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 31026/1/2019-Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

In case pre-dispatch inspection is not applicable, the life of the drugs/medicines shall not have passed the shelf life of the drug/medicine at the time of delivery to the consignee.

In case of pre-dispatch inspection, at the time when the stores are offered for inspection, the life of the 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 pharmacist/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 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 strength as 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 receipt at the destination shall in no way be limited or waived by reason of the goods having previously been in receipt at the destination 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 laboratory).

**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 a batch is declared "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/ batches will be rejected and the cost of the 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/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 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 suital concerned State will also be informed by the buyer for initiating necessary action on the supplier be forfeited without any intimation.

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

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

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

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

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

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

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

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

28. **Termination for Default**

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

29. **Warranty**

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

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

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

Sl. No. & Date	Nomenclature & Specification	Name & Address of Manufacturing Unit	Batch No.	DOM & DOE
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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, 1955 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 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 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 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 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, 1955 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, 1955 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 & 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 Manufacturer.
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 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 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 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 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 (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. (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, the stability data of 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 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, it shall be intimated to the buyer by the bidder/seller firm/ company within one month.

- 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 civil or 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 the Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), 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 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 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/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 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 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 terms and conditions and will not be accepted. 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 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, 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 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 for loss 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 to accept the stores at the suppliers' risk and expense and without prejudice to the claim 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. 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 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 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 sources and of good 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.

## Special terms and conditions-Version:1 effective from 23-03-2024 for category Budesonide Respirator 5

1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the 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 (sc may be verified by the buyer at their end.

### UNDERTAKING

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

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 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 also be in compliance with all 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 in compliance with the Act and Rules.
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 who 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 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 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 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 bidder/seller 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 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, 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 for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia (USP, BP, IP) 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 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 / State Government's Drug procurement agencies at the time of submission of bid. Further, the bidder/seller should not have been blacklisted or testing by any State Government / Central Government / its Drug procurement agencies at the time of submission of bid. 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 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 under any criminal case or pending in any court of India by any department of Govt. under prevention of Corruption Act or for cheating or 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 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 (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 and to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as per the order of the Drug Controller of India from time to time.*

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or 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 (Price Control) 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. PPO 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 the shelf life of the drug/medicine at the time of delivery to the consignee.

In case of pre-dispatch inspection, at the time when the stores are offered for inspection, the life of the drugs/medicines shall be 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 bidder/seller shall 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 bidder'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 pharmaceutical 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 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 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.
- **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 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 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 supplied drugs/medicines/goods 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 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 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 batch shall be 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, 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 the batch is found defective 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 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, 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 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 warranty 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, and 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 warranty period shall apply to the stores replaced from the date of the replacement thereof otherwise the warranty period as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice the rights of the buyer under this contract or otherwise".

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

Signature name & designation

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may deem it 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 as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyers in Additional Terms and Conditions (ATC) shall be complied with.

31. **Bar Coding**

All drugs/medicines supplied should incorporate GS1 barcodes standards at various packaging levels (primary, secondary and tertiary) 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 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 applicable. 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 Special Terms and Conditions (STC), which 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 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 shall 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 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 false information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetics Act, 1940 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.

Pharmaceuticals (DOP), Ministry of Chemicals & Fertilizers time to time in this regard.

4. All provisions of Narcotic Drugs & Psychotropic Substances Act, 1985 as amended till date will also be applicable 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 resellers 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 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 concerned Drug Licensing Authority to the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of 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 name 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 by the concerned Drug Licensing Authority, 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.
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.

*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 and Cosmetics (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 provisions 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 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 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 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 surveillance 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 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 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 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/colleges 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 any action within the stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after 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.

- 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, it 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 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. The buyer will communicate 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 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 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 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 discretion. The period shall apply to the stores replaced from the date of the replacement thereof otherwise the period shall apply to the stores rejected by the buyer at the time 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. 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). 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 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 STIPULATED TERMS AND CONDITIONS (STC) 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. **Generic**

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

### 2. **Buyer Added Bid Specific ATC**

**PRODUCT SPECIFICATION AND ATC**

SL NO	NAME OF MEDICINES	A/U
	DRY SYP CUFUROXIME 125MG/5ML, 30ML	BOTT
	INJ. PANTOPRAZOLE 40MG	VIAL
	DRY SYP AMOXICILIN+CLAVULANIC ACID 30ML, 200MG+28.5MG/5ML	BOTT
	INJ ONDANETRON 4MG/2ML	AMP
	INJ BUPIVACAINE 20ML 0.5%	VIAL
	INJ AMIODARONE 3ML, 50MG/ML	AMP
	INJ METOCLOPRAMIDE 5MG/ML, 2ML	AMP
	INJ METHYLPREDNISILOLONE ACETATE, 40MG/ML, 2ML	VIAL
	INJ HYDROCORTISONE SODIUM 100MG	VIAL
	INJ ADRENALINE 1MG/ML, 1ML	AMP
	INJ PARACETAMOL 100ML IV , 10MG/ML	NOS
	INJ DEXAMETHASONE MG/ML, 2ML	AMP
	INJ. PHENIRAMINE MALEATE 22.75MG/ML, 2ML	AMP
	BUDESONIDE REPIRATOR SOLUTION, 0.5MG, 2ML	NOS
15.	TAB. FOLIC ACID 5MG	NOS
16.	INJ PARACETAMOL 150MG/ML, 2ML	AMP

NOTE-1. SHORT EXPIRY MEDICINES WILL NOT BE ACCEPTED

2. MEDICINES IF NOT FOUND AS PER SPECIFICATION WILL BE REJECTED AND COLLECTION OF SAME WILL DONE BY SUPPLIER AT CONSIGNEE LOCATION.

**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 consequence arising in the bidding process due to these ATCs and due to modification of technical specifications and / or terms at

are incorporated by the Buyer regarding following, the bid and resultant contracts shall be treated as null and void at 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 extant 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](#) procurement policy of the buyer nodal Ministries)
9. Mandating foreign / international certifications even in case of existence of Indian Standards without specifying.
10. Seeking experience from specific organization / department / institute only or from foreign / export experience.
11. Creating bid for items from irrelevant categories.
12. Incorporating any clause against the MSME policy and Preference to Make in India Policy.
13. Reference of conditions published on any external site or reference to external documents/clauses.
14. Asking for any Tender fee / Bid Participation fee / Auction fee in case of Bids / Forward Auction, as the case may be.

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

**All GeM Sellers / Service Providers are mandated to ensure compliance with all the applicable laws / 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 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 land border with India 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. **जिसे भारत के साथ भूमि सीमा साझा करने वाले देश के बिडर से खरीद वाले देश का कोई भी बिडर इस निविदा में बिड देने के लिए तभी पात्र होगा जब वह बिड देने वाला सक्षम प्राधिकारी के पास पंजीकृत हो। बिड कोई भी गलत घोषणा किए जाने व इसका अनुपालन न करने पर अनुबंध को तत्काल समाप्त करने और कानून के अनुसार आगे की कानूनी कार्यवाही के लिए जिम्मेदार होगा।**

**---Thank You/धन्यवाद---**