

Bid Document/ बिड दस्तावेज़

Bid Details/बिड विवरण

Bid End Date/Time/बिड बंद होने की तारीख/समय	07-06-2025 20:00:00
Bid Opening Date/Time/बिड खुलने की तारीख/समय	07-06-2025 20:30:00
Bid Offer Validity (From End Date)/बिड पेशकश वैधता (बंद होने की तारीख से)	180 (Days)
Ministry/State Name/मंत्रालय/राज्य का नाम	Ministry Of Defence
Department Name/विभाग का नाम	Department Of Military Affairs
Organisation Name/संगठन का नाम	Indian Army
Office Name/कार्यालय का नाम	*****
क्रेता ईमेल/Buyer Email	sunilkumar.817k@gov.in
Total Quantity/कुल मात्रा	39783
Item Category/मद केटेगरी	Acyclovir Tablets (V2) (Q2) , Bicalutamic Efavirenz Tablets (V2) (Q2) , Imatinib Ta Lamivudine + Nevirapine Tablets (V2) (Q (V2) (Q2) , Amiodarone Tablets (V2) (Q2 (V2) (Q2) , Budesonide + Formoterol Fu (V2) (Q2) , Itraconazole Capsule (Q2) , I (V2) (Q2) , Flunarizine Tablet (Q2)
Minimum Average Annual Turnover of the bidder (For 3 Years)/बिडर का न्यूनतम औसत वार्षिक टर्नओवर (3 वर्षों का)	3 Lakh (s)
OEM Average Turnover (Last 3 Years)/मूल उपकरण निर्माता का औसत टर्नओवर (गत 3 वर्षों का)	10 Lakh (s)
Years of Past Experience Required for same/similar service/उन्हीं/समान सेवाओं के लिए अपेक्षित विगत अनुभव के वर्ष	3 Year (s)
MSE Exemption for Years of Experience and Turnover/ अनुभव के वर्षों से एमएसई छूट	No
Startup Exemption for Years of Experience and Turnover/ अनुभव के वर्षों से स्टार्टअप छूट	No
Document required from seller/विक्रेता से मांगे गए दस्तावेज़	Experience Criteria,Past Performance,Bi Authorization Certificate,OEM Annual Tu ATC),Compliance of BoQ specification a *In case any bidder is seeking exemptio supporting documents to prove his eligi evaluation by the buyer

Bid Details/बिड विवरण

Do you want to show documents uploaded by bidders to all bidders participated in bid?/	No
Past Performance/विगत प्रदर्शन	80 %
Bid to RA enabled/बिड से रिवर्स नीलामी सक्रिय किया	Yes
RA Qualification Rule	50% Lowest Priced Technically Qualifiec
Type of Bid/बिड का प्रकार	Two Packet Bid
Primary product category	Acyclovir Tablets (V2)
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
Estimated Bid Value/अनुमानित बिड मूल्य	659346.15
Evaluation Method/मूल्यांकन पद्धति	Item wise evaluation/
Arbitration Clause	No
Mediation Clause	No

EMD Detail/ईएमडी विवरण

Required/आवश्यकता	No
-------------------	----

ePBG Detail/ईपीबीजी विवरण

Advisory Bank/एडवाइजरी बैंक	State Bank of India
ePBG Percentage(%) / ईपीबीजी प्रतिशत (%)	3.00
Duration of ePBG required (Months) / ईपीबीजी की अपेक्षित अवधि (महीने).	3

(a). EMD & Performance security should be in favour of Beneficiary, wherever it is applicable./ईएमडी और संपादन जमानत

Beneficiary/लाभार्थी :

COMMANDANT 166 MH
MILITARY HOSPITAL JAMMU ARMY MEDICAL CORPS, Department of Military Affairs, Indian Army, Ministry of Defence
(Commandant 166 Mh)

MII Purchase Preference/एमआईआई खरीद वरीयता

MII Purchase Preference/एमआईआई खरीद वरीयता	Yes
--	-----

MSE Purchase Preference/एमएसई खरीद वरीयता

MSE Purchase Preference/एमएसई खरीद वरीयता	Yes
---	-----

1. The minimum average annual financial turnover of the bidder during the last three years, ending on 31st March or above in the bid document. Documentary evidence in the form of certified Audited Balance Sheets of relevant period Cost Accountant indicating the turnover details for the relevant period shall be uploaded with the bid. In case the date is more than 3-year-old, the average turnover in respect of the completed financial years after the date of constitution shall be considered.
2. 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 acceptances 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.
3. OEM Turn Over Criteria: The minimum average annual financial turnover of the OEM of the offered product during previous financial year, should be as indicated in the bid document. Documentary evidence in the form of certified A certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant period since constitution / incorporation of the OEM is less than 3 year old, the average turnover in respect of the completed financial years shall be taken into account for this criteria.
4. Preference to Make In India products (For bids < 200 Crore):Preference shall be given to Class 1 local supplier as per MII Order in India), Order 2017 as amended from time to time and its subsequent Orders/Notifications issued by concerned Ministry. Minimum local content to qualify as a Class 1 local supplier is denoted in the bid document. If the bidder wants to avail, upload a certificate from the OEM regarding the percentage of the local content and the details of locations at which the product is manufactured, failing which no purchase preference shall be granted. In case the bid value is more than Rs 10 Crore, the declaration shall be certified by the statutory auditor or cost auditor, if the OEM is a company and by a practicing cost accountant or Chartered Accountant, if the OEM is a company as per the Public Procurement (preference to Make-in -India) order 2017 dated 04.06.2020. Only Class-I suppliers as per MII order dated 04.06.2020 will be eligible to bid. Non - Local suppliers as per MII order dated 04.06.2020 are not eligible to participate in the bid. The buyers are advised to refer the OM No.F.1/4/2021-PPD dated 18.05.2023. [OM No.1 4 2021 PPD dated 18.05.2023](#) for concurrent application of Public Procurement Policy for Micro and Small Enterprises Order, 2012 and Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012.
5. 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 Commerce and Industries. Subsequent Orders/Notifications issued by concerned Ministry. If the bidder wants to avail themselves of the Purchase preference, they should declare the percentage of local content and the details of locations at which the product is manufactured / 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 should declare the percentage of local content and the details of locations at which the service is provided. Relevant documentary evidence in this regard shall be uploaded along with the bid in respect of the bid. The eligibility for purchase preference based on documentary evidence submitted, while evaluating the bid. If L-1 is not available, the bid within L-1+ 15% (Selected by Buyer) of margin of purchase preference /price band defined in relevant policy, such bid will be awarded for 25% (selected by Buyer) percentage of total quantity. The buyers are advised to refer the OM No.F.1/4/2021-PPD dated 18.05.2023 [OM No.1 4 2021 PPD dated 18.05.2023](#) for compliance of Concurrent application of Public Procurement Policy for Micro and Small Enterprises Order, 2012 and Public Procurement (Preference to Make in India) Order, 2017. Benefits of MSE will be allowed only if seller is valid and approved by Buyer after evaluation of documents submitted.
6. Estimated Bid Value indicated above is being declared solely for the purpose of guidance on EMD amount and for selection of bidder. It has no relevance or bearing on the price to be quoted. It has no impact on bid participation. Also this is not going to be used as a criteria in determining reasonableness of quoted price. The bidder should be based on its own assessment of reasonableness and based on competitive prices received in Bid / RA process.
7. Past Performance: The Bidder or its OEM {themselves or through re-seller(s)} should have supplied same or similar products to any Central / State Govt Organization / PSU (cumulative order quantity in any one financial year) to be submitted along with bid in support of quantity supplied in the category related to primary product having highest bid value should meet this criterion.
8. Reverse Auction would be conducted amongst first 50% of the technically qualified bidders arranged in the order of bid value. Bidders eligible for participating in RA would be rounded off to next higher integer value if number of technically qualified bidders is less than 50%. If then RA will be conducted amongst L-1 to L-4). In case number of technically qualified bidders are 2 or 3, RA will be conducted amongst L-1 to L-4). In case number of technically qualified bidders are 2 or 3, RA will be conducted amongst L-1 to L-4). In case number of technically qualified bidders are 2 or 3, RA will be conducted amongst L-1 to L-4). In case number of technically qualified bidders are 2 or 3, RA will be chosen to split the bid amongst N sellers, then minimum N sellers would be taken to RA round. In case Primary product is not available for RA based on lowest 50% bidders qualifying for RA, the number of sellers qualifying for RA would be decided by the buyer (directly participated or through its reseller) if available. Further, if bid(s) of any seller(s) eligible for MSE preference is / are coming within price band of 20% of non MII L-1 or if bid of any seller(s) eligible for Make in India preference is / are coming within price band of 20% of non MII L-1, then such seller(s) will be allowed to participate in the RA process.

Evaluation Method (Item Wise Evaluation Method)

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

Evaluation Schedules	Estimated Value	Item/Category
Schedule 1	8071.8	Acyclovir Tablets (v2)
Schedule 2	72450	Bicalutamide Tablets (v2)
Schedule 3	18831.3	Donepezil Tablet
Schedule 4	32724.45	Efavirenz Tablets (v2)
Schedule 5	6630	Imatinib Tablet
Schedule 6	3027	Lamivudine Tablet
Schedule 7	29160	Zidovudine + Lamivudine + Nevirapine Tablet
Schedule 8	35400	Metoprolol Tablet
Schedule 9	4260	Nevirapine Tablets (v2)
Schedule 10	66240	Amiodarone Tablets (v2)
Schedule 11	75000	Brimonidine Tartrate + Timolol Maleate Drops
Schedule 12	97440	Budesonide + Formoterol Fumarate Respules
Schedule 13	143100	Clobazam Tablets (v2)
Schedule 14	26019	Itraconazole Capsule
Schedule 15	12315.6	Ivermectin Tablet
Schedule 16	23322	Sodium Hyaluronate Drops (v2)
Schedule 17	5355	Flunarizine Tablet

Acyclovir Tablets (V2) (660 tablet(s))

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

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	400 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	*****	*****JAMMU	660

Bicalutamide Tablets (V2) (2100 tablet(s))

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

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	50 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	*****	*****JAMMU	2100

Donepezil Tablet (1230 tablet(s))

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

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

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	*****	*****JAMMU	1230

Efavirenz Tablets (V2) (495 tablet(s))

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

Technical Specifications/तकनीकी विशिष्टियाँ

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

Specification	Specification Name/विशिष्टि का नाम	Bid Requirement/बिड के
PRODUCT INFORMATION	Strength	200 mg, 400 mg, 600 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	*****	*****JAMMU	495

Imatinib Tablet (390 tablet(s))

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

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, 400 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	*****	*****JAMMU	390

Lamivudine Tablet (300 tablet(s))

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

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, 150 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	*****	*****JAMMU	300

Zidovudine + Lamivudine + Nevirapine Tablets (V2) (1620 tablet(s))

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

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	60 mg + 30 mg + 50 mg, 300 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	*****	*****JAMMU	1620

Metoprolol Tablet (6000 tablet(s))

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

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	25 mg, 100 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	*****	*****JAMMU	6000

Nevirapine Tablets (V2) (300 tablet(s))

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

Technical Specifications/तकनीकी विशिष्टियाँ

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

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

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	*****	*****JAMMU	300

Amiodarone Tablets (V2) (5760 tablet(s))

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

Technical Specifications/तकनीकी विशिष्टियाँ

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

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

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	*****	*****JAMMU	5760

Brimonidine Tartrate + Timolol Maleate Drops (V2) (150 pieces)

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

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	3 ml, 5 ml, 10 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर् टिंग अधिकारी	Address/पता	Quantity,
1	*****	*****JAMMU	150

Budesonide + Formoterol Fumarate Respules (V2) (1680 pieces)

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

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 + 20 mcg, 1 mg + 20 n

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	*****	*****JAMMU	1680

Clobazam Tablets (V2) (15900 tablet(s))

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

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	*****	*****JAMMU	15900

Itraconazole Capsule (1260 capsule(s))

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

Technical Specifications/तकनीकी विशिष्टियाँ

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

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

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	*****	*****JAMMU	1260

Ivermectin Tablet (330 tablet(s))

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

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	12 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	*****	*****JAMMU	330

Sodium Hyaluronate Drops (V2) (78 pieces)

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

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	0.1% w/v, 1% w/v
PACKAGING	Primary pack size	3 ml, 5 ml, 10 ml

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

S.No./क्र.सं.	Consignee Reporting/Officer/परेषिती/रिपोर् टिंग अधिकारी	Address/पता	Quantity,
1	*****	*****JAMMU	78

Flunarizine Tablet (1530 tablet(s))

(Minimum 50% and 20% Local Content required for qualifying as Class 1 and Class 2 Local Supplier resp
के रूप में अर्हता प्राप्त करने के लिए आवश्यक)

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, 10 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	*****	*****JAMMU	1530

Special terms and conditions-Version:1 effective from 06-07-2023 for category Acyclovir Tablets (V2)

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 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 auti 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 to the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of issue to the buyer at the time 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 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 (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 should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any Central / State Government's Drug procurement agencies at the time of submission of bid. Further, the bidder/seller should not have been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner should not participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any Central / State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to the buyer by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for criminal conspiracy 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 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.

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 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) Act, 1950 (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 pharmaceutical product, the bidder/seller shall be responsible for the cost of recall.

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. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government approved laboratory or combination of or/ all following stages:

a) At Pre-Dispatch stage

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

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

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

At post-delivery surveillance - The samples will be collected from the warehouse of buyer or 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 buyer.
- 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 shall be recovered from the supplier.
- **At any of testing stage,** Samples which do not meet quality requirement shall render the relevant batch declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches 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/consignee location and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take back the rejected goods within stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after 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 requirement is not met. The supplier's license may 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 approved laboratory 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 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 in case of category-A and category-B defects as per guidelines issued by the Ministry of Health & Family Welfare as 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. 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 of the supply 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 Bill of Materials and Pharmacopoeia standards.
- Each supply should be accompanied with a "Warranty Certificate" duly signed by the Bidder as under.

"The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under the warranty shall be strictly in accordance with the specifications and particulars mentioned in the Bill of Materials. 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 the stores shall apply. The supplier/seller shall if so called upon to do so by the buyer in writing, replace the stores free of cost 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 shall not apply. The provisions of the contract shall not be prejudiced by the rejection of the stores 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
----------------	------------------------------	--------------------------------------	-----------	-----------

Signature name & designation

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

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

Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Rules, 1954 as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. Additional Terms and Conditions (ATC) shall be complied with.

31. **Bar Coding**

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

32. **Delivery Period**

- Minimum delivery period will be of 45 days from the date of issuing of the purchase order.
 - The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated). If found that temperature has not been maintained, supply against the said order is liable to be rejected.
 - The items requiring special cold storage conditions shall be supplied with cold chain transporting 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 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 Standard Terms and Conditions (STC) and Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authentic source shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:2 effective from 24-05-2024 for category Bicalutamide Tablets (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 (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 this undertaking. (Name of entity)
2. We are the manufacturers of the drug/medicine _____ ("Product") and intend to offer the same for sale.
3. We state that the license for the Product has been granted/obtained by us as per the provisions of the Drugs and Cosmetics Rules, 1954 as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the portal of the Drugs and Cosmetics Rules, 1954 as amended till date. Reference no. for SUGAM portal is _____.
5. We undertake that all the information provided above is true and complete in all respect. We understand that any false information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetics Rules, 1954 there under will be initiated.

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

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

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

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

If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the application must be submitted with a certificate that application for renewal was made within time frame as per Drugs and Cosmetics Act that has not been deleted by drug licensing authority.

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

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

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

19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only).
They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs and cosmetics viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Drugs (Price Control) Act, 1950, The Indian Statistical Institute Act, 1959, GST Act.

To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as notified by the Controller of India from time to time.

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Drugs and Cosmetics (India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmacy.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date beyond 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 bidder/seller, 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 consignee. 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 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 standards and the limits for the individual tests should be given
10. Conclusion
11. Qualified Person's signature

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet requirements. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government Laboratory or any combination of or/ all following stages:

a) At Pre-Dispatch stage

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

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratory for the purpose of inspection. The sampling quantities shall be borne by the supplier.
- The buyer's right to inspect, test and, where necessary reject the drugs/medicines/goods after their ultimate destination shall in no way be limited or waived by reason of the goods having previously been in the possession of the bidder/seller 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 laboratories).

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

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

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

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

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

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

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

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the products supplied 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 are up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Drug Control Authorities. The power of confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also vested with the DCGI (CDSCO)/ MoH& FW.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended, the buyer/ 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 adverse effects or of the recall.

29. **Warranty**

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

Pharmacopoeia standards.

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

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

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

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

Signature name & designati

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

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

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

31. **Bar Coding**

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

32. **Delivery Period**

- Minimum delivery period will be of 45 days from the date of issuing of the purchase
 - The supplier should maintain the recommended temperature of the drug/medicine (wherever inc found that temperature has not been maintained, supply against the said order is liable to be rej
 - The items requiring special cold storage conditions shall be supplied with cold chain transporting manufacturing unit to the warehouses/consignee location.
33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any Additional Terms and Conditions (ATC) in the bid will be applicable.
34. Any other Terms and Conditions which is not included or at variance with the conditions specified in ST Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authent quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede sp shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 06-07-2023 for category Efavirenz Tablets (V2)

1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the ur Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submitt

regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., val drug/medicine under procurement, the license issuing authority etc. at their end.

2. The Buyer shall ask the seller to submit the "Notarized Undertaking" in the mentioned below format (sc may be verified by the buyer at their end.

UNDERTAKING

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

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

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

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

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

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

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

If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the cop must be submitted with a certificate that application for renewal was made within time frame as per Dr that has not been deleted by drug licensing authority.

7. Bidder/Seller shall submit the valid GMP/WHO-GMP Certificate of the manufacturing site as per revised by the Concerned Drug Licensing Authority to the buyer at the time of bid submission.
8. Bidder/Seller shall submit a valid **non-Conviction** certificate for last two (2) consecutive years issued t buyer at the time of bid submission. The certificate must have been issued within 12 months from the c
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the co 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/ highlighted.

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

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which

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

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

They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs and cosmetics Acts/Enactments viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), 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 notified by the Controller of India from time to time.

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

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

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

24. **Recalls**

If products are recalled because of problems with product quality or adverse reaction to the pharmaceuticals, the manufacturer/buyer, providing full details about the reason leading to the recall, and shall take steps to replace the product at its ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund to the consumer. 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 manufacturer's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
 1. Generic name of the product
 2. Batch No.
 3. Pharmacopoeia Reference and/ or In-house method
 4. Batch quantity
 5. Date of manufacture
 6. Expiry date
 7. Date of test

8. Description (clarity, color etc)
9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharma results and the limits for the individual tests should be given
10. Conclusion
11. Qualified Person's signature

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet requirement. 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 inspection 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 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 buyer.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the laboratory. If the batch is 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 when the batch is rejected.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in inspection, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/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. The supplier's license shall 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, the batch 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 concerned Drug Control Authorities for getting the drugs/medicines tested, as per the guidelines. The cost of testing shall be borne by the supplier.

The de-registration / debarment action will be taken by the buyer against the manufacturing unit for category-A and category-B defects as per guidelines issued by the Ministry of Health & Family Welfare. The action shall 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
 - Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Drug Controller, sealing or prosecution with relation to drugs/medicines under the said Act is also with
 - In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended, the Drug Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

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

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

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

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

28. **Termination for Default**

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

29. **Warranty**

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

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

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

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

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.

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

31. **Bar Coding**

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

32. **Delivery Period**

- Minimum delivery period will be of 45 days from the date of issuing of the purchase order.
 - The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated). If found that temperature has not been maintained, supply against the said order is liable to be rejected.
 - The items requiring special cold storage conditions shall be supplied with cold chain transporting from the manufacturing unit to the warehouses/consignee location.
33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other requirements shall be mentioned in Additional Terms and Conditions (ATC) in the bid will be applicable.
34. Any other Terms and Conditions which is not included or at variance with the conditions specified in ST-1 shall be void. Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authentic source and 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 Zidovudine + Lamivudine

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

UNDERTAKING

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

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

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

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

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

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

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

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

If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the license must be submitted with a certificate that application for renewal was made within time frame as per Drugs and Cosmetics Act that has not been deleted by drug licensing authority.

7. Bidder/Seller shall submit the valid GMP/WHO-GMP Certificate of the manufacturing site as per revised requirements issued by the Concerned Drug Licensing Authority to the buyer at the time of bid submission.
8. Bidder/Seller shall submit a valid **non-Conviction** certificate for last two (2) consecutive years issued by the competent authority to the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of submission.
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the competent authority for last 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine shall be highlighted.

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

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

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date.

- India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Ph
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date 31026/1/2019-Policy dated 12-9-2020.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs &

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

In case of pre-dispatch inspection, at the time when the stores are offered for inspection, the life of the one sixth (1/6th) of the total shelf life of the drugs/medicines.

24. **Recalls**

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

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
 1. Generic name of the product
 2. Batch No.
 3. Pharmacopoeia Reference and/ or In-house method
 4. Batch quantity
 5. Date of manufacture
 6. Expiry date
 7. Date of test
 8. Description (clarity, color etc)
 9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia. Results and the limits for the individual tests should be given
 10. Conclusion
 11. Qualified Person's signature

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet requirements. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government approved combination of or/ all following stages:

a) At Pre-Dispatch stage

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

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

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

At post-delivery surveillance - The samples will be collected from the warehouse of buyer/or 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 found "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 expiry of the stipulated time.

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

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

- In case any drug/medicine is found substandard either at any stage of testing or during the shelf life, the batch shall be rejected. If the same is disputed by the supplier, it shall be referred to the approved laboratory shall be accepted by the supplier/seller. If the same is disputed by the supplier, it shall be referred 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 found defective in category-A and category-B defects as per guidelines issued by the Ministry of Health & Family Welfare, Government of India.

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

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

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

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

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

28. **Termination for Default**

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

29. **Warranty**

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

"The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under the contract shall be strictly in accordance with the specifications and particulars mentioned in the tender. The stores would continue to conform to the description of and quality aforesaid for a period of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within the specified limits and are not subject to recall by the applicable Regulatory Authority due to unacceptable quality. Notwithstanding the above, the fact that the said stores fail to conform to the description and quality as specified in the tender, 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 rejection 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 date of rejection. Nothing herein contained shall 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
----------------	------------------------------	--------------------------------------	-----------	-----------

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.

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

Special terms and conditions-Version:1 effective from 23-03-2024 for category Metoprolol Tablet

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

UNDERTAKING

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

I, _____, s/o / d/o / w/o _____, aged about _____ resident of _____

undertake that;

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

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

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

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

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

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

should be submitted along with licensing agreement.)

15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product / Central or State Government's Drug procurement agencies at the time of submission of bid. Further, if the bidder/seller has been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner should not participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any Central or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated in writing by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government or State 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 proceedings or pending in any court of India by any department of Govt. under prevention of Corruption Act or for fraud involving Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred and only) to the buyer.

They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs and cosmetics viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Drugs 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 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 (India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmacy.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date more than 18 months from the date of manufacture.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

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

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

24. **Recalls**

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

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from the seller's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
 1. Generic name of the product
 2. Batch No.
 3. Pharmacopoeia Reference and/ or In-house method
 4. Batch quantity
 5. Date of manufacture
 6. Expiry date
 7. Date of test
 8. Description (clarity, color etc)
 9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia. Results and the limits for the individual tests should be given
 10. Conclusion
 11. Qualified Person's signature

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet requirements. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government Laboratory or combination of or/ all following stages:

a) At Pre-Dispatch stage

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

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

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

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

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

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

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

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

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

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

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

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

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

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

27. Quality Test by Statutory Authorities:

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

28. Termination for Default

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

29. Warranty

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

"The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under the best workmanship and shall be strictly in accordance with the specifications and particulars mentioned. The stores would continue to conform to the description of and quality aforesaid for a period of the specified shelf life from the date of delivery of the said stores to the buyer, have overages within 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 cost. The provisions of the contract shall apply to the stores replaced from the date of the replacement thereof otherwise the provisions as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice this contract or otherwise".

- Sl. No. & Date
- Nomenclature & Specification
- Name & Address of Manufacturing Unit
- Batch No.
- DOM & DOE
- 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, if necessary, deem 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.

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 facilities.

- 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 Nevirapine Tablets (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 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 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 the last 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/medicine shall be highlighted.

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

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which are 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 drug controller for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, it should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any Central 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 to the buyer by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be blacklisted or pending in any court of India by any department of Govt. under prevention of Corruption Act or for criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only) to the buyer.

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

To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 and to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as per the order of the Controller of India from time to time.

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Drugs (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.
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 not be less 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 inform the buyer, providing full details about the reason leading to the recall, and shall take steps to replace the products at the ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund to the buyer.

been taken off the market due to safety problems.

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
 1. Generic name of the product
 2. Batch No.
 3. Pharmacopoeia Reference and/ or In-house method
 4. Batch quantity
 5. Date of manufacture
 6. Expiry date
 7. Date of test
 8. Description (clarity, color etc)
 9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia. Results and the limits for the individual tests should be given
 10. Conclusion
 11. Qualified Person's signature

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet requirements. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government approved laboratory or combination of or/ all following stages:

a) At Pre-Dispatch stage

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

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

- The Buyer may engage the services of a Quality Control Agent & Quality Control Testing Laboratory for inspection and testing. The sampling quantities shall be borne by the supplier.
- The buyer's right to inspect, test and, where necessary reject the drugs/medicines/goods after their delivery to the destination shall in no way be limited or waived by reason of the goods having previously been in the possession of the supplier 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 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 substandard.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in any of the tests, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/consignees and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take the same within stipulated time. The buyer will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" after the expiry of the shelf life.

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 substandard. The supplier's license may 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 declared as "Not of Standard Quality" and the cost of the batch shall be recovered from the supplier.

approved laboratory 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 buyer shall approach the concerned Drug Control Authorities for getting the drugs/medicines tested, at the supplier's own cost.

The de-registration / debarment action will be taken by the buyer against the manufacturing unit 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. For New drugs/medicines, complete stability data of 6 months period shall be acceptable.
- The case of admixture of drugs will be treated as a violation of terms and conditions and will not be acceptable.
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Drug Control Authorities. Confiscation, sealing or prosecution with relation to drugs/medicines under the said Act is also within the purview of the said authorities.
- In accordance with the provisions of Sec 22 & 31 of the Drugs and Cosmetic Act, 1940, as amended, the Controller/ Drug Inspector may exercise their powers as an Inspecting Agency.

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

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

27. Quality Test by Statutory Authorities:

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

28. Termination for Default

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

29. Warranty

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

"The Supplier/Seller hereby declares that the stores as detailed below sold to the buyer under the guarantee of workmanship and shall be strictly in accordance with the specifications and particulars mentioned in the Bidding Document. 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 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 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 replacement shall be at the risk of the supplier. The replacement shall be made 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
-------------------	---------------------------------	---	-----------	-----------

Signature name & designation

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

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

Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Rules, 1945 as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. Additional Terms and Conditions (ATC) shall be complied with.

31. **Bar Coding**

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

32. **Delivery Period**

- Minimum delivery period will be of 45 days from the date of issuing of the purchase order.
 - The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated) and should ensure 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 Standard Terms and Conditions (STC) shall be subject to 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 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 Tablets (V2)

1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the valid Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for submit regulatory documents applicable with the bid. Buyers must also check and validate the details e.g., valid drug/medicine under procurement, the license issuing authority etc. at their end.
2. The Buyer shall ask the seller to submit the "Notarized Undertaking" in the mentioned below format (scanned copy) 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 the entity. (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 understand that if any false information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic Rules, 1945 there under will be initiated.

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

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

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

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

If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the application must be submitted with a certificate that application for renewal was made within time frame as per Drugs and Cosmetics Act that has not been deleted by drug licensing authority.

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

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

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

19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred and only) with the following terms and conditions:
- They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs and cosmetics viz., The Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), The Drugs (Price Control) Act, 1947, 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 notified by the Controller of India from time to time.

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs (Price Control) Order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmacy.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date less than 6 months from the date of sale.
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 provide full details about the reason leading to the recall, and shall take steps to replace the products at their ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund to the consignee. The products shall not be taken off the market due to safety problems.

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from the 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 standards and the limits for the individual tests should be given
 10. Conclusion
 11. Qualified Person's signature

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet required standards. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government Laboratory or any combination of or/ all following stages:

a) At Pre-Dispatch stage

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

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

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

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

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

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

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

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

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

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

The de-registration / debarment action will be taken by the buyer against the manufacturing unit found defective. The de-registration / debarment action shall be taken for 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. For New drugs/medicines, complete stability data of 6 months period shall be acceptable.
- The case of admixture of drugs will be treated as a violation of terms and conditions and will not be accepted.
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines are up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Drug Control Authorities. The supplier shall comply with the provisions of the said Act. 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 buyer/ 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 adverse effects or of the recall.

29. **Warranty**

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

Pharmacopoeia standards.

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

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

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

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

Signature name & designati

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

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

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

31. **Bar Coding**

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

32. **Delivery Period**

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

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any Additional Terms and Conditions (ATC) in the bid will be applicable.

34. Any other Terms and Conditions which is not included or at variance with the conditions specified in ST Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authent quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede sp shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 06-07-2023 for category Brimonidine Tartrate + 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 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 und information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic there under will be initiated.

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

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

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

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

If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the cop must be submitted with a certificate that application for renewal was made within time frame as per Dr that has not been deleted by drug licensing authority.

7. Bidder/Seller shall submit the valid GMP/WHO-GMP Certificate of the manufacturing site as per revised by the Concerned Drug Licensing Authority to the buyer at the time of bid submission.
8. Bidder/Seller shall submit a valid **non-Conviction** certificate for last two (2) consecutive years issued t buyer at the time of bid submission. The certificate must have been issued within 12 months from the c
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the co 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/ highlighted.

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

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which be allowed to submit only one bid for all units but necessary document regarding separate manufacturing one bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA.
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia (the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability testing for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data (If manufacturer has licensed a formula from another company and such licensed formula is used for the product should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product / 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 disclosure of Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only).

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

To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 and to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as notified by the Controller of India from time to time.

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the 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 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 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 pharma results and the limits for the individual tests should be given
10. Conclusion
11. Qualified Person's signature

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet requirement. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government combination of or/ all following stages:

a) At Pre-Dispatch stage

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

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

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

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

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the buyer.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the 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 substandard. The supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/colony 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 drugs/medicines/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 concerned State will also be informed by the buyer for initiating necessary action on the supplier if the batch is found substandard without any intimation.

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

- In case any drug/medicine is found substandard either at any of testing stage or during the shelf life, the batch shall be rejected and the cost of testing shall be borne by the supplier/seller. If the same is disputed by the supplier, it shall be referred 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 concerned Drug Control Authorities for getting the drugs/medicines tested, as per the guidelines issued by the Ministry of Health & Family Welfare.

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

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

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

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

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

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

If any batch of any product(s) supplied by the supplier is declared "NOT OF STANDARD QUALITY", by any statutory 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 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 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 discretion. The period shall apply to the stores replaced from the date of the replacement thereof otherwise the period shall be 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
-------------------	---------------------------------	---	-----------	-----------

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, 1940 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 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 the Additional Terms and Conditions (ATC) in the bid will be applicable.
34. Any other Terms and Conditions which is not included or at variance with the conditions specified in the 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 06-07-2023 for category Budesonide + Formoterol Inhaler

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 Cosmetic 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. For any 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 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 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 misappropriation of Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred only) that they will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines.

They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs/medicines 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 Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date.

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 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 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 expiry of the stipulated time.

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

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

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

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

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the product to the buyer. In case of any complaint in the field, the B.M.R/ B.P.R for the particular batch of the product shall be submitted. For New drugs/medicines, complete stability data of 6 months period shall be acceptable.
- The case of admixture of drugs will be treated as a violation of terms and conditions and will not be accepted.
- Statutory provisions on manufacture, distribution, storage and quality issues of drugs/medicines up to date is vested with the DCGI (CDSCO)/ MoH& FW, including its Central/ Zonal/ Regional Drug Control Authorities. Any violation of the provisions of the Act is also a violation of the provisions of the 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 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 rejection 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 date of rejection. Nothing herein contained shall 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
----------------	------------------------------	--------------------------------------	-----------	-----------

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.

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 source and quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede specific terms and conditions and 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 Clobazam Tablets (V2)

1. The sellers are registered on GeM and exempted from the Vendor Assessment process based on the valid Manufacturing Drug License certified by the issuing authority. Buyers must mandatorily ask for 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 _____ (Name of entity)
2. We are the manufacturers of the drug/medicine _____ ("Product") and intend to offer
3. We state that the license for the Product has been granted/obtained by us as per the provisions there under as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the _____ of the Drugs and Cosmetics Rules, 1945 as amended till date. Reference no. for SUGAM portal is _____.
5. We undertake that all the information provided above is true and complete in all respect. We undertake that if any information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic Act there under will be initiated.

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

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

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

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

If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the 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 to manufacture the same product, 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 authority under the Drugs and Cosmetics Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA.
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug licensing authority for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted. (If manufacturer has licensed a formula from another company and such licensed formula is used for the

should be submitted along with licensing agreement.)

15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product / Central or State Government's Drug procurement agencies at the time of submission of bid. Further, if the bidder/seller has been blacklisted / debarred / de-registered/banned due to quality failure, such bidder/seller or their Partner should not participate in the bid.
16. During the validity of the bid if the firm/Company is blacklisted/debarred/de-registered/banned by any Central or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated in writing by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories should not be under any criminal case or pending in any court of India by any department of Govt. under prevention of Corruption Act or for fraud involving Government fund or any criminal conspiracy in the said matter at the time of submission of bid.
19. Bidder/seller should submit a notarized undertaking on an affidavit of Rs. 100/- (Rupees One Hundred and only) to the buyer.

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

To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" to the Controller of India from time to time.

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Drugs and Cosmetics (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 less than 6 months from the date of sale.
23. **Shelf Life:** Shelf life of each quoted drugs/medicines shall be in accordance with Schedule P of Drugs and Cosmetics Act, 1940.

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

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

24. **Recalls**

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

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from the seller's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
 1. Generic name of the product
 2. Batch No.
 3. Pharmacopoeia Reference and/ or In-house method
 4. Batch quantity
 5. Date of manufacture
 6. Expiry date
 7. Date of test
 8. Description (clarity, color etc)
 9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia. Results and the limits for the individual tests should be given
 10. Conclusion
 11. Qualified Person's signature

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet requirements. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government Laboratory 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 as indicated in official compendiums or technical specifications throughout the shelf-life period of the drug may also be organized by the buyer post-delivery.

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

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

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

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

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

- **At any of testing stage,** Samples which do not meet quality requirement shall render the relevant batch declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches of drugs/medicines/goods and the cost of entire batch paid will be recovered from the supplier when the batch is found defective.
- If any inspected or tested drugs/medicines/goods fails to conform to the specifications or fails in inspection, the supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/colony and replace with fresh stock duly inspected and tested within 45 days from the date of intimation from the buyer. The buyer has the right to destroy such rejected drugs/medicines/goods if the supplier does not take action within 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 period. The concerned State will also be informed by the buyer for initiating necessary action on the supplier if the supplier is found to be forfeited without any intimation.

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

- In case any drug/medicine is found substandard either any of testing stage or during the shelf life, the batch shall be accepted by the supplier/seller. If the same is disputed by the supplier, the sample shall be sent to Central Drug Laboratory, Kolkata, and the report of CDL will only be accepted as final and 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 will be communicated to GeM.

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

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

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

27. Quality Test by Statutory Authorities:

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

28. **Termination for Default**

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

29. **Warranty**

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

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

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

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

Signature name & designation

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

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

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

31. **Bar Coding**

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

32. **Delivery Period**

- Minimum delivery period will be of 45 days from the date of issuing of the purchase order.
- The supplier should maintain the recommended temperature of the drug/medicine (wherever indicated) during storage and transportation.

- found that temperature has not been maintained, supply against the said order is liable to be rejected.
 - The items requiring special cold storage conditions shall be supplied with cold chain transporting manufacturing unit to the warehouses/consignee location.
33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any other Additional Terms and Conditions (ATC) in the bid will be applicable.
 34. Any other Terms and Conditions which is not included or at variance with the conditions specified in ST Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authentic quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede special shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 24-05-2024 for category Itraconazole Capsule

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

UNDERTAKING

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

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

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

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

3. All Provisions of Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date will be applicable and all notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Family Welfare, Government of India, Ministry of 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 the Substances.
5. The purchase shall be made through Bidding/RA only irrespective of the value.
6. Manufacturer shall have a valid own manufacturing license issued by the competent drug licensing authority under the Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date. The Drug/medicine quoted should be clearly mentioned in the License. The valid own manufacturing license shall be submitted to the buyer at the time of bid submission.

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

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

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

must be submitted with a certificate that application for renewal was made within time frame as per Dr that has not been deleted by drug licensing authority.

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

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

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

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

To supply drugs of standard quality as prescribed under the provisions of Drug and Cosmetic Act, 1940 and to supply items/drugs "not of standard", "Grossly sub-standard" and "Spurious and adulterated drugs" as per the order of the Controller of India from time to time.

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

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

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

24. **Recalls**

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

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from the supplier's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
 1. Generic name of the product
 2. Batch No.
 3. Pharmacopoeia Reference and/ or In-house method
 4. Batch quantity
 5. Date of manufacture
 6. Expiry date
 7. Date of test
 8. Description (clarity, color etc)
 9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia and the limits for the individual tests should be given
 10. Conclusion
 11. Qualified Person's signature

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet requirements. The buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government approved laboratory or a combination of or/ all following stages:

a) At Pre-Dispatch stage

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

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

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

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

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

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

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

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

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

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

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

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

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

27. Quality Test by Statutory Authorities:

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

28. Termination for Default

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

29. Warranty

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

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

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

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

- Qty. of each batch
- Remarks

Signature name & designation

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

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

Packaging, Labelling and Marking shall be as per the provisions contained in the Drugs and Cosmetics Rules, 1945 as amended up-to-date, other particulars of packaging, labelling & marking, if any, prescribed by the buyer. Additional Terms and Conditions (ATC) shall be complied with.

31. **Bar Coding**

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

32. **Delivery Period**

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

Special terms and conditions-Version:1 effective from 15-05-2025 for category Ivermectin 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 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 for sale.
3. We state that the license for the Product has been granted/obtained by us as per the provisions of the Drugs and Cosmetics Rules, 1945 as amended till date.
4. We further state that the details regarding the Product/licenses have been uploaded by us on the website of the Drugs and Cosmetics Rules, 1945 as amended till date. Reference no. for SUGAM portal is _____.
5. We undertake that all the information provided above is true and complete in all respect. We understand that any false information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetics Rules, 1945 there under will be initiated.

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

3. All Provisions of Drugs and Cosmetics Act, 1940 and Rules made there under as amended till date will also be applicable to all notifications issued by *Central Drugs Standard Control Organization (CDSCO)*, Ministry of Health & Family Welfare (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 all 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 their authorized resellers/distributors.

If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the copy of the application must be submitted with a certificate that application for renewal was made within time frame as per Drugs and Cosmetics Act that has not been deleted by drug licensing authority.

7. Bidder/Seller shall submit the valid GMP/WHO-GMP Certificate of the manufacturing site as per revised requirements issued by the Concerned Drug Licensing Authority to the buyer at the time of bid submission.
8. Bidder/Seller shall submit a valid **non-Conviction** certificate for last two (2) consecutive years issued by the competent authority to the buyer at the time of bid submission. The certificate must have been issued within 12 months from the date of submission.
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the 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 all licensed, it shall be allowed to submit only one bid for all units but necessary document regarding separate manufacturing units shall be submitted. One bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) issued by the Central / State Drug Controller / FDA under the Drugs Act and Rules made thereunder as amended up to date.
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug licensing authority for the product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia shall be submitted by the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability studies) for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data shall be submitted (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, it should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product by any Central / 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 / Central or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to the buyer by document by the bidder/seller firm/ company within one month.
17. During Contract period, if the supplier is debarred/deregistered /blacklisted/ banned by any Central Government's Drug procurement agencies due to quality failure, buyer may cancel the contract and go for fresh bid as per discretion of the buyer.
18. The firm/company/ corporation and any of its director/proprietors/ partners/ Authorized signatories shall 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 and only) in the following terms:-
They will comply with all the statutes & legislation regarding manufacturing, import, sale, and supply of drugs and cosmetics as per the provisions of the Drugs and Cosmetics Act, 1940, The Drugs and Cosmetics Rules, 1945 (as amended), 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 notified by the Controller of India from time to time.

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 (as amended) in India) order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmacy.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date beyond 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 bidder/seller shall provide full details about the reason leading to the recall, and shall take steps to replace the products at their ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund to the consignee. The products shall not be taken off the market due to safety problems.

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

- All the batches of the drugs/medicines supplied shall be accompanied with in-house **Test Report** from the 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 standards and the limits for the individual tests should be given
 10. Conclusion
 11. Qualified Person's signature

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet requirements. The buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government Laboratory or any combination of or/ all following stages:

a) At Pre-Dispatch stage

b) At Delivery Stage: Inspection done once the drugs/medicines/goods reach at consignee location and before releasing to 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 the purpose of 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 release at the destination shall in no way be limited or waived by reason of the goods having previously been released 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 contract period.

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

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

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

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

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

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

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

29. **Warranty**

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

Pharmacopoeia standards.

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

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

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

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

Signature name & designati

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

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

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

31. **Bar Coding**

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

32. **Delivery Period**

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

33. Any specific requirements for the packaging, labelling, logograms, printing, artwork, bar coding or any Additional Terms and Conditions (ATC) in the bid will be applicable.

34. Any other Terms and Conditions which is not included or at variance with the conditions specified in ST Additional Terms and Conditions (ATC) in the bid to ensure drugs/medicines are procured from authent quality. The above terms and conditions are in reverse order of precedence i.e., ATC shall supersede sp shall supersede General Terms and Conditions (GTC), whenever there are any conflicting provisions.

Special terms and conditions-Version:1 effective from 06-07-2023 for category Sodium Hyaluronate Dro

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 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 und information/declaration is provided by us, suitable legal action/action as per Drugs and Cosmetic there under will be initiated.

Place:

Date:

.....

Signature, Name, Designation & Seal

on behalf of the Manufacturer

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

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

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

If revalidation of drug license has been applied for, the buyer shall be informed accordingly and the cop must be submitted with a certificate that application for renewal was made within time frame as per Dr that has not been deleted by drug licensing authority.

7. Bidder/Seller shall submit the valid GMP/WHO-GMP Certificate of the manufacturing site as per revised by the Concerned Drug Licensing Authority to the buyer at the time of bid submission.
8. Bidder/Seller shall submit a valid **non-Conviction** certificate for last two (2) consecutive years issued t buyer at the time of bid submission. The certificate must have been issued within 12 months from the c
9. Bidder/Seller shall submit **Manufacturing & Market Standing certificate** (in India) issued by the co 2 consecutive years for the drug/medicine quoted to the buyer at the time of bid submission. The drug/ highlighted.

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

10. If a company/firm has two or more separate manufacturing units at different sites / States/region, which be allowed to submit only one bid for all units but necessary document regarding separate manufacturing one bidder will be allowed to submit only one offer for one product.
11. The manufacturer shall have in house testing facilities and valid Good Laboratory Practice (GLP Certificate) Act and Rules made thereunder as amended up to date issued by Central / State Drug Controller / FDA.
12. Bidder/Seller shall have Maximum Production Capacity Certificate (section wise) issued by concerned drug product.
13. STP (Standard Testing Procedure) along with the required reference standards for non-Pharmacopoeia (the bidder/seller at the time of submission of the bid.
14. The bidder/seller shall submit complete stability data (long term stability studies and accelerated stability testing for at least 3 batches whenever required by the buyer. For New drugs/medicines, complete stability data (If manufacturer has licensed a formula from another company and such licensed formula is used for the product should be submitted along with licensing agreement.)
15. The bidder/seller should have not been blacklisted/debarred/de-registered/banned for the quoted product / 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 disclosure 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 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 notified by the Controller of India from time to time.

20. The price offered by the seller/bidder shall not, in any case, exceed the DPCO/NPPA controlled price or ceiling price. If the seller must reduce the prices if there is any reduction in DPCO/NPPA ceiling price or price fixed by State Government.
21. Guidelines of Department of Pharmaceuticals applicable as nodal ministry for implementing the provisions of the Government of India order (PPO) 2017-revision as amended to date, related to procurement of Goods & Services in Pharmaceuticals.
22. **Fall Clause:** Provision of fall clause will not be applicable on the sale of drugs which have an expiry date on or after 31/03/2020-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 manufacturer/buyer, providing full details about the reason leading to the recall, and shall take steps to replace the products at their ultimate destination with a fresh batch of acceptable pharmaceuticals or withdraw and give a full refund to the consumer. 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 manufacturer's own Quality Control Lab. The Test Report/Certificate of Analysis shall include:
 1. Generic name of the product
 2. Batch No.
 3. Pharmacopoeia Reference and/ or In-house method
 4. Batch quantity
 5. Date of manufacture
 6. Expiry date

7. Date of test
8. Description (clarity, color etc)
9. All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharma results and the limits for the individual tests should be given
10. Conclusion
11. Qualified Person's signature

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

- Buyer will embark on stringent quality checks to ensure that drugs/medicines/goods meet requirement. Buyer reserves the right to carry necessary inspections/tests from NABL Accredited/Government combination of or/ all following stages:

a) At Pre-Dispatch stage

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

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

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

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

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

- In case of failure of batches during or at any stage (indicated above), the testing charges would be borne by the buyer.
- The supplies will be deemed to be completed only upon receipt of the quality certificates from the 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 substandard. The supplier will be responsible to take back the rejected drugs/medicines/goods from the depots/colony 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 drugs/medicines/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 concerned State will also be informed by the buyer for initiating necessary action on the supplier if the batch is found substandard without any intimation.

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

- In case any drug/medicine is found substandard either at any of testing stage or during the shelf life, the batch shall be rejected and the batch shall not be accepted by the supplier/seller. If the same is disputed by the supplier, it shall be referred 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 concerned Drug Control Authorities for getting the drugs/medicines tested, as per the guidelines issued by the Ministry of Health & Family Welfare.

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

- The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the drugs/medicines/goods.

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

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

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

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

If any batch of any product(s) supplied by the supplier is declared "NOT OF STANDARD QUALITY", by any statutory 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 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 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 discretion. The provisions of the contract shall apply to the stores replaced from the date of the replacement thereof otherwise the provisions of the contract shall apply to the stores as may arise by reason of the breach of the conditions. Nothing herein contained shall prejudice the contract or otherwise".

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

Signature name & designation

- If the supplier, having been notified, fails to replace within the period specified above, the buyer may deem 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 / 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.

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

1. **Scope of Supply**

Scope of supply (Bid price to include all cost components) : Only supply of Goods

2. **Turnover**

Bidder Turn Over Criteria: The minimum average annual financial turnover of the bidder during the last three financial year, should be as indicated in the bid document. Documentary evidence in the form of certified Aud certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for the relevant pe date of constitution / incorporation of the bidder is less than 3 year old, the average turnover in respect of the constitution shall be taken into account for this criteria.

3. **Turnover**

OEM Turn Over Criteria: The minimum average annual financial turnover of the OEM of the offered product du the previous financial year, should be as indicated in the bid document. Documentary evidence in the form of periods or a certificate from the Chartered Accountant / Cost Accountant indicating the turnover details for th case the date of constitution / incorporation of the OEM is less than 3 year old, the average turnover in respect constitution shall be taken into account for this criteria. In case of bunch bids, the OEM of CATEGORY RELATEI should meet this criterion.

4. **Forms of EMD and PBG**

Bidders can also submit the EMD with Account Payee Demand Draft in favour of

COMMANDANT 166 MH
payable at
COMMANDANT 166 MH

Bidder has to upload scanned copy / proof of the DD along with bid and has to ensure delivery of hardcopy to Opening date.

5. **Buyer Added Bid Specific ATC**

Buyer Added text based ATC clauses

a). Marketing Trade Label should be marked with the following(i) Nomenclature (ii) Batch No (

ained there in.

b). Particulars of Government supplies IP/BP/USP/Claim & Drugs & Cosmetics Act 1940 as amended will be furnished.

c). LD Charges at the rate of 0.5% of the price of any store which the contractor has failed to complete or part thereof. The total liquidated damages shall not exceed value of 10% of undelivered quantity requested for by the vendor within due DP. Maximum DP-Twice the original DP with LD Charges.

d). Indigenous drugs will have 5/6 of shelf life and foreign products with 2/3 of shelf life remain.

e). Supplier will undertake to replace unconsumed stock before three months of the expiry date.

f). Dealer will replace any stock found defective during shelf life g. No substitute of manufacturer's order will be accepted.

g). if you have any doubt regarding Nomenclature while quoting the product please conform with the ATC document)

h) Please upload brochure of delivering product with specification on additional document with product specifically.

Disclaimer/अस्वीकरण

The additional terms and conditions have been incorporated by the Buyer after approval of the Competent Authority. The organization is solely responsible for the impact of these clauses on the bidding process, its outcome, and consequences arising in the bidding process due to these ATCs and due to modification of technical specifications and / or terms and conditions are incorporated by the Buyer regarding following, the bid and resultant contracts shall be treated as null and void at any stage of bidding process without any notice:-

1. Definition of Class I and Class II suppliers in the bid not in line with the extant Order / Office Memorandum issued.
2. Seeking EMD submission from bidder(s), including via Additional Terms & Conditions, in contravention to existing policy.
3. Publishing Custom / BOQ bids for items for which regular GeM categories are available without any Category restriction.
4. Creating BoQ bid for single item.
5. Mentioning specific Brand or Make or Model or Manufacturer or Dealer name.
6. Mandating submission of documents in physical form as a pre-requisite to qualify bidders.
7. Floating / creation of work contracts as Custom Bids in Services.
8. Seeking sample with bid or approval of samples during bid evaluation process. (However, in bids for [attached](#) 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.
15. Buyer added ATC Clauses which are in contravention of clauses defined by buyer in system generated bid terms and conditions, EMD Detail, ePBG Detail and MII and MSE Purchase Preference sections of the bid, unless otherwise allowed by the system.
16. In a category based bid, adding additional items, through buyer added additional scope of work/ additional terms and conditions, needs more items along with the main item, the same must be added through bunching category based item BoQ with the main category based item, the same must not be done through ATC or Scope of Work.

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

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 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 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 will be taken as action in accordance with the laws./जेम की सामान्य शर्तों के खंड 26 के संदर्भ में भारत के साथ भूमि सीमा साझा करने वाले देश के बिडर से खरीद वाले देश का कोई भी बिडर इस निविदा में बिड देने के लिए तभी पात्र होगा जब वह बिड देने वाला सक्षम प्राधिकारी के पास पंजीकृत हो। बिड कोई भी गलत घोषणा किए जाने व इसका अनुपालन न करने पर अनुबंध को तत्काल समाप्त करने और कानून के अनुसार आगे की कानूनी कार्य

---Thank You/धन्यवाद---