



PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI)

(Set up under the Department of Pharmaceuticals, Govt. of India)

8th Floor, Videocon Tower, Block E1

Jhandewalan Extension, New Delhi-110055

Telephone: 011-49431800/49431811/49431829/49431854/49431833/49431874

Website: janaushadhi.gov.in

LIMITED e- TENDER No.: PMBI/LTD/DRUG-179/2021 FOR SUPPLY OF DRUGS

TO

PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI)

LAST DATE FOR ONLINE SUBMISSION OF TENDER: 03.01.2021



ATTENTION: PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI) WAS FORMERLY KNOWN AS BUREAU OF PHARMA PSUs OF INDIA (BPPI).

PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI)

(SET UP UNDER THE DEPARTMENT OF PHARMACEUTICALS, GOVERNMENT OF INDIA)

Regd. Office: Core No. 6, First Floor, SCOPE Complex, Lodi Road, New Delhi-110003

Working Office: 8th Floor, Videocon Tower, Block E1, Jhandewalan Extension, New Delhi-110055

Telephone: 011- 49431800/49431811/49431829/49431854/49431833/49431874

Website: janaushadhi.gov.in

LIMITED e- TENDER No.: PMBI/LTD/DRUG-179/2021

FOR SUPPLY OF DRUGS TO PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI)

NOTE: -THE UNSOLICITED BID SHALL NOT BE ACCEPTED.

Tender Reference	PMBI/LTD/DRUG-179/2021
Tender Website	Dated. 24.12.2021
Date of availability of tender documents on website	https://eprocure.gov.in
Last date and time for submission of Online Bid i.e., Bid Submission End Date and time	24.12.2021 (Friday)
Last Date and time for submission of Bid Security Declaration and Original Required Documents as per ANNEXURE I (Check List), in physical Form in office of PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI), 8th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055	On 03.01.2022 (Monday) up to 16:00 Hours.
Time and date of opening of Technical Bid (Cover - A)	On 04.01.2022 (Tuesday) by 15:00 Hours
Place of opening of tender	On 04.01.2022 (Tuesday) at 16:00 Hours
Opening of Tender	PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI), 8th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055
Address for Communication	Online on https://eprocure.gov.in
	PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI), 8th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055

Cost of the Tender Document		Free of cost
Contact Person for clarification if any,		1. Ms. Priyanka Thakur Executive (Procurement) Phone: - 011-49431874 Email: - proc10@janaushadhi.gov.in
		2. Ms. Vakta Parth Belani Executive (Procurement) Phone: - 011-49431833 Email: - procure14@janaushadhi.gov.in
		3. Sh. P. K. Thakur Sr. Executive (Procurement) Phone: - 011-49431829 Email: - proc6@janaushadhi.gov.in
		4. Sh. Manik Bera, Dy. Manager (Procurement) Phone: - 011-49431854 Email: - proc9@janaushadhi.gov.in

The tender document can be downloaded free of cost from the CPPP e-Procurement Portal <https://eprocure.gov.in> and from the website of PMBI: janaushadhi.gov.in.

Note: *The bidders shall be solely responsible for checking these websites at least 3 days prior to closing date of submission of tender for any addendum/amendment issued subsequently to the bid document and take into consideration the same while preparing and submitting the bids. Bids will be opened online.*

TABLE OF CONTENTS

Sl. No.	Description	Page No.
1.	Tendering System	7
2.	Last Date and time for submission of ONLINE Tender	8
3.	Eligibility Criteria (Technical Bid -Cover “A”)	8
4.	General Conditions	10
5.	Price Bid – Cover “B” (Financial Bid/BOQ)	12
6.	Earnest Money Deposit/Bid Security Declaration	13
7.	Guidelines for the Preparation of Tender	13
8.	Period of validity of tender	14
9.	Amendment of tender documents	14
10.	Method of submission of tender	14
11.	Modification and withdrawal of bids	15
12.	Opening of tender	15
13.	Evaluation of tender	15
14.	Inspection of manufacturing facilities	16
15.	Acceptance /rejection of bids	16
16.	Award of contract	16
17.	Performance security deposit	16
18.	Methodology for placing orders	17
19.	Supply Conditions	18
20.	Logograms	20
21.	Packing	21
22.	Quality testing & quality control	22
23.	Payment provision	23
24.	Handling & Testing Charges	24
25.	Liquidated Damages and other penalties	24
26.	Deduction and other penalties on account of Quality failure	25
27.	Blacklisting in the event of withdrawal from the tender, and Non-Adherence to the Quality Standards and supply schedule	26
28.	Saving Clause	27
29.	Resolution of Disputes	28
30.	Contacting the Purchaser by the Bidder	28
31.	Fraudulent and Corrupt Practices	28
32.	Jurisdiction	30

33.	ANNEXURE - I (Check List)	31
34.	ANNEXURE - II (Declaration for eligibility in participating the tender)	33
35.	ANNEXURE - III (Format for submission of Bid Security Declaration)	35
36.	ANNEXURE - IV – (A certificate from CA or Company Secretary).	36
37.	ANNEXURE - V (Mandate Form)	38
38.	ANNEXURE -VI (Details of Manufacturing License & Market Standing Certificate)	40
39.	ANNEXURE - VII (Declaration for Logogram)	41
40.	ANNEXURE - VIII (Packing Specifications)	45
41.	ANNEXURE - IX (BARCODE REQUIREMENTS)	47
42.	ANNEXURE - X (Format for submission of Local Content Declaration)	53
43.	ANNEXURE - XI (Letter of acceptance of Limited Tender)	54
44.	ANNEXURE - XII (Details of requirements for Drugs)	55
45.	ANNEXURE - XIII (Details for Shelf Life & Manufacturing Capacity)	56
46.	ANNEXURE - XIV (Shape, Colour, Packing Type etc. of drugs)	57

PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI)

LIMITED e- TENDER No.: PMBI/LTD/DRUG-179/2021 FOR THE SUPPLY OF DRUGS TO

PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI)

PRADHAN MANTRI BHARTIYA JANAUSHADHI PARIYOJANA (PMBJP) is the initiative of Department of Pharmaceuticals, Ministry of Chemical and Fertilizer, Government of India launching with the noble objective of making quality generic medicines available at affordable prices for all, particularly the poor and disadvantaged, through specialized outlets called PRADHAN MANTRI BHARTIYA JANAUSHADHI KENDRA (PMBJK). PMBI (*formerly known as BPPI*) was established in December 2008 under the Department of Pharmaceuticals, Government of India, with the support of all the CPSUs, and identified as the executing agency for PMBJP.

The Bureau has been registered as an independent society under the Societies Registration Act, 1860, in April 2010.

At present, more than **8600** stores are functional. It is proposed to channelize efforts to popularize PMBJP and ensure availability of the complete basket of medicines at affordable prices.

Tender Inviting Authority – C.E.O, Pharmaceuticals & Medical Devices Bureau of India, 8th Floor, Videocon Tower, Block E1, Jhandewalan Extension, New Delhi-110055 (hereinafter referred as **Tender Inviting Authority** unless the context otherwise requires).

Tender Accepting Authority –C.E.O, Pharmaceuticals & Medical Devices Bureau of India (hereinafter referred as PMBI unless the context otherwise requires).

Tender Inviting Authority invites **Tender for the supply of Drugs to Pharmaceuticals & Medical Devices Bureau of India (PMBI)**.

1.TENDERING SYSTEM:

The Bids are to be submitted in two Parts i.e.

- i. Technical Bid (**Cover “A”**)
- ii. Financial Bid / Price Bid (**Cover “B”**)

- i. The **TECHNICAL BID** shall contain the complete technical details of the firm and the documents to provide the eligibility and competency of the bidder and shall be submitted online only in the manner prescribed in Bid document.

The documents like Tender Document and Bid Security Declaration shall be submitted before the specified schedule at the office of PMBI super scribed, **“Tender Documents & Bid Security Declaration for Tender Reference No.-PMBI/LTD/DRUG-179/2021 dated 24.12.2021 for the procurement of Drugs for the year 2021”**. However complete hard copy of uploaded tender shall be provided by the bidding firm along-with the mandatory required documents as per clause 3 of Bid document and Bid Security Declaration for evaluation purpose only. This hard copy shall under no case substitute/modify the provisions of e-tender system.

- ii. The **Financial Bid/Price Bid** shall be valid for a period of 60 days from the date of opening of Technical Bid. Prior to the expiry of the bid validity, the Tender Inviting Authority may request the Tenderers to extend the bid validity for further period as deemed fit on their original quoted prices and all terms & conditions. However, PMBI reserves the right to place purchase orders at the quoted rate till such period.

- a) The Tenderer shall fill in the rate per unit size, % age rate of GST in respective column of BOQ for the items quoted.
- b) In determining the lowest evaluated price, the rate quoted per unit size exclusive of GST as indicated in column No. 7 of the BOQ shall be taken into consideration.
- c) Tender has been called for in the Generic name of drugs. The Tenderers should quote the rates for the generic products only. The composition, strength and packing of each product should be as per specifications given in **ANNEXURE-XII** and Shape, Colour, Packing Type etc. of drugs should be as per **ANNEXURE XIV** (attached). Any variation, if found, will result in rejection of the tender.
- d) Rates (inclusive of customs duty, packing & forwarding charges, transportation, insurance and any incidental charges, but exclusive **GST** should be quoted for each of the required drugs, medicines etc., on door delivery basis according to the unit ordered. Tender for the supply of drugs, medicines, etc. with cross conditions like **“AT CURRENT MARKET RATES”** shall not be accepted. Handling, clearing, transport charges etc., will not be paid separately. The delivery should be made as stipulated in the purchase order placed with Tenderers.
- e) The price quoted by the tenderers shall not, in any case exceed the DPCO controlled price, if any, fixed by the Central/State Government, the Maximum Retail Price (MRP) and the selling price of the tenderer.

In case any tenderer quotes higher than the DPCO controlled price, competent authority shall be informed for appropriate action.

2. LAST DATE AND TIME FOR SUBMISSION OF ONLINE TENDER:

- i. Online Bids [in two separate Cover [Technical bid (Cover “A”) and price bid (Cover “B”)] shall be submitted/uploaded till 16.00 Hours Up to 03.01.2022 (Monday) on CPP portal i.e.

<https://eprocure.gov.in>.

Hard copy of complete required documents as Per Clause 3. Eligibility Criteria of Bid and Bid Security Declaration shall be submitted before the specified schedule at the below mentioned address of PMBI with super scribed, **“Tender Document & Bid Security Declaration for Tender Reference No.-PMBI/LTD/DRUG-179/2021 dated 24.12.2021 for the procurement of Drugs”**.

“To,

The Chief Executive Officer

Pharmaceuticals & Medical Devices Bureau of India (PMBI)

8th Floor, Videocon Tower, Block-E1,

Jhandewalan Extension, New Delhi-110055”

- ii. **Late Tender:** -There is NO PROVISION of uploading late tender beyond stipulated date & time in the e-tendering system.

3. ELIGIBILITY CRITERIA (TECHNICAL BID -COVER “A”):

Minimum Eligibility criteria along with list of documents to be submitted in Cover ‘A’. Bidders should meet the following criteria to be eligible for bidding and relevant papers/documents must be submitted by them in their technical bid (Cover- ‘A’) in support of their eligibility for the tender.

- A) Bidder should sign a Bid Security Declaration accepting that if they withdraw or modify their bids during the period of validity, or if they are awarded the contract and if they fail to obliged/adhere the tender condition/ provision made in the bid document, they will be suspended for the period of two (2) years from the date of disqualification.

Note: *The Micro and Small enterprises (MSEs) are exempted from submitting the Bid Security as per prevailing rules. However, they have to submit the valid “Udyam Registration Certificate” in reference to Gazette notification CG-DL-E-26062020-220191 dated 26.06.2020 and Office Memorandum no. 21(5)/2019-P&G/Policy (pt. IV), issued by Ministry of MSME dated 06.08.2020 with the technical bid.*

- B) Documentary evidence of the constitution of the company/firm/Proprietorship such as Memorandum and Articles of Association, Partnership Deed etc. should be submitted with details of the Name, Address, Telephone Number, Fax Number, e-mail address of the firm and of the Managing Director / Partners / Proprietor should be submitted.
- C) Power of Attorney or Resolution of the Board by which the authorized signatory has been authorized by the bidding firm to sign the documents should be submitted.
- D) Bidders must have: -
- Minimum three years old valid Manufacturing License of the product quoted with latest license renewal certificate.
 - Approved product list as per the license issued for quoted drugs for minimum three years.
 - Manufacturing License along with approved product list must be valid till the last date of the submission of tender.

- d) In Case of those drugs which are notified first time in IP 2018 then Manufacturing and Marketing license should be in any official compendium (USP/BP/IP) along with current valid License in IP in continuation.
- e) Market Standing Certificate & Manufacturing Certificate issued by the Licensing Authority as a Manufacturer for each drug quoted for the last 3 years (Certificate should be enclosed with list of items) except for the drugs falling under the category of ‘**New Drug**’ as defined by CDSCO (Central Drugs Standard Control Organisation). If permission in Form 46 from DCGI has been obtained, then the 3 years Manufacturing & Market standing clause will be relaxed. The provisions of Rule 122 E of Drugs and Cosmetics Act rule 1945 shall be applicable.
- f) FFS (Flow Fill & Seal Process) Technology will be accepted wherever applicable.

Note: If Manufacturing License for the quoted product is issued under “for export only” category will not be accepted.

Bidders shall submit dully attested copies of required manufacturing license and approved product list in support of above-mentioned condition, and they are required to specify the quoted product in their approved product list by highlighting it.

- E) Bidder must have Market Standing Certificate (in India) of minimum two batches of quoted product in last three years issued by the concerned Licensing Authority from Drugs Control Department for the quoted product. Self-attested copies are to be submitted.
- F) Non-Conviction Certificate (NCC) issued by the concerned Licensing Authority of the state certifying that the firm/company has not been convicted in last three years should be submitted. It should be not more than 12 months old. Self-attested copies are to be submitted.
- G) **WHO-GMP** (WHO-Good Manufacturing Practice) as per revised Schedule- ‘M’/COPP Certificate of the manufacturing unit issued by the Licensing Authority/ Drugs Control Department. The WHO -GMP Certificate must be valid as on the last date of submission of tender. Self-attested copies are to be submitted.
Explanation- Generally the WHO-GMP Certificate issued for one-year validity. Hence the provision that it should not be older than one year from the last date of submission of tender implies mutatis mutandis that the GMP certificate should remain valid till the last date of submission of tender.
- H) Maximum Production Capacity Certificate (section wise) issued by concerned Licensing Authority from Drugs Control Department highlighting the quoted product section. Self-attested copies are to be submitted.
- I) Copies of the Audited Balance Sheet, Profit and Loss statement showing details of their annual average turnover for any three of the last four consecutive financial years not less than **25 Crores (Twenty-Five crore)**. Details shall be provided in Annexure IV. Self-attested copies are to be submitted.
- J) Declaration for eligibility in participating the tender for quoted drugs in prescribed format as per **Annexure-II**.
- K) Tenderer shall furnish Company’s bank details as per Annexure V (Mandate Form).
- L) Tenderers are required to submit **Annexure-VI** indicating details of manufacturing License and three years Market Standing Certificate (MSC) as mentioned therein.
- M) Tenderers are required to submit declaration as per **Annexure-VII** duly signed to supply the drugs as per the design shown in enclosure 1 and enclosure 2 of Annexure VII as well as other instructions given in this regard.
- N) Duly attested Checklist as per (**ANNEXURE- I**) shall be submitted.

- O) Copy of PAN Card of the bidder company should be submitted (self-attested).
- P) Copy of certificate of valid GST registration of the bidder company should be submitted (self-attested).
- Q) Copy of Income Tax Return for any three of last four Consecutive Assessment years should be submitted (self-attested).
- R) Duly attested Copy of valid GS-1 registration certificate from GS1 India.
- S) **Bidder shall declare the %age of local content used in the manufacturing of quoted item in accordance with the calculations for local content with point no. 6 of Order issued by Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals vide no. 31026/4/2018-Policy dated 01.01.2019 in ANNEXURE-X**

Note: -

- i) The certificates/ reports / annexures submitted with the bid document should be self-attested by the authorized signatory of the firm with official seal, wherever required.
- ii) Technical evaluation of the Bid will be done on the basis of the above-mentioned criteria and documents mentioned in Clause no. 3 (TECHNICAL BID- COVER 'A') Mandatory Documents shall be submitted online only at CPP portal: <https://eprocure.gov.in> failing which the bid will not be considered for technical evaluation.
- iii) Hard copy of required documents uploaded shall be submitted along with Bid Security Declaration and other required documents on or before the last day of submission of tender for purely evaluation purposes. However, the submission of hard copy of uploaded tender document submitted shall not substitute/modify the provisions of e-tendering system.
- iv) The technical evaluation shall be done only on the basis of documents/papers submitted by the bidder on <https://eprocure.gov.in>
- v) Clear copy of valid drug license highlighting the drug code should be uploaded. In case scanned copy of license uploaded is not visible or tempered, PMBI shall not considered the license for such drug.

4. GENERAL CONDITIONS:

- A) Tender bid is invited directly from Manufacturers in India falling only under category described as Class-I Local Supplier and Class-II Local Supplier in the tender. Non-local supplier whose local content is less than or equal to 50% shall not be eligible for participating in tender process. Loan licensee is also eligible. Distributors/agents/contract manufacturers/Importers are not eligible to participate in the tender
- B) Manufacturer has Production & financial capacity to manufacture and deliver the drugs quoted by the firm in the tender as per quantity mentioned in tender during contract period.
- C) Bidders are advised to quote only for such drugs which meets the drug specification as mentioned in Annexure XII. Do not quote if it differs in any parameter.
- D) The quantities specified in the tender is for the tender purpose only and it represents the basis of unit for ease of pricing. The actual quantity may vary from zero to the maximum required quantity during the contract. The quantity will be drawn from successful tenderers as and when required from time to time during the contract period.
- E) STP (Standard Testing Procedure) for Non- Pharmacopoeia awarded drugs are required to submit within 15 days from the date of Letter of Acceptance.
- F) **The bidder shall submit the complete stability data (long term stability studies and accelerated stability studies) for all awarded drugs whenever required by the PMBI. For New drugs,**

complete stability data of 6 months' period shall be acceptable. (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, then the stability data of the licensor should be submitted along with licensing agreement.)

- G) The manufacturer shall declare the active API polymorphic form used in formulation for all quoted drugs and declare that it is internationally accepted active polymorph when ask by PMBI.**
- H) The Tenderer should have not been blacklisted/debarred/de-registered/banned due to quality failure for the quoted product /firm by any State Government / Central Government/ PMBI/Central or State Government's Drug procurement agencies **at the time of submission of bid**. Further, quoted drugs have not been failed in house testing or testing by any State Government/Central Government / its Drug procurement agencies/ PMBI during last two years. If any tenderer has been blacklisted/debarred/de-registered/banned due to quality failure, such tenderer or their Partner/Director/Owner shall not be permitted to participate in the tender.**
- I) During the validity of the tender if the firm / company is blacklisted/debarred/de-registered/banned by any State Government/ Central Government/ PMBI / Central or State Government's Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to PMBI along with relevant authentic document by the tenderer firm/ company within one month.**
- (i) If the tenderer/bidder fails to inform about blacklisting/ debarring/ de-registration/ban or punitive actions taken by the state or central government or PMBI or any state/central drugs procurement agency against the bidder to PMBI within 30 days and the bidder continues the contract and the said action is brought/comes to the knowledge of PMBI, PMBI may ask an explanation from the tenderer which shall be clarified by the tenderer within 7 days of receiving the letter from PMBI. If the tenderer fails to reply within 7 days or reply is not to the satisfaction of PMBI, all the contracts awarded to the tenderer will be terminated, performance security deposits will be forfeited, and further tenderer will be backlisted up to 5 years from participating into any tender invited by PMBI.
- J) During tender or Rate Contract period, if L1 bidder is debarred/deregistered /blacklisted/ banned by any Central Government or State Government or its procurement agencies due to quality failure, PMBI may purchase the drugs from other bidders at L1 rate or may go for fresh tender as per discretion of PMBI.**
- K) The PMBI reserves the right to purchase any drugs from PSUs as per discretion of PMBI. In case of emergencies, PMBI may go to PSUs and price will be as per negotiation and at the discretion of PMBI.**
- L) The Tenderer should confirm that they have read tender document including Amendment(s) to Tender document (if any) along with terms and condition and these terms and condition of tender document including Amendment(s) to Tender document (if any) are acceptable unconditionally to them.**
- M) If a company/firm has two or more separate manufacturing units at different sites / States, which are not separate entities then the company will be allowed to submit only one tender for all units but necessary document regarding separate manufacturing units will uploaded as a separate set with the same tender. However, one bidder will be allowed to submit only one offer for one product.**
- N) Only authorized employee of the Company/Tenderer will be allowed to transact the business with the Tender Inviting Authority.**

5. PRICE BID – “COVER-B” (Financial Bid/BOQ)

A) Cover “B” (Financial Bid/BOQ) contains the Price Bid of the Tenderer. The Tenderer shall fill in the rate per unit size, % age rate of GST in respective column of BOQ for the items quoted.

B) Determination of L1 Bidder:

- a) In determining the lowest evaluated price, the rate quoted per unit size for the given specification, exclusive of GST as indicated in column No. 7 of the **BOQ** shall be taken into consideration. The rates quoted should be in rupees and paise up to 2 digits. The Tenderer is not permitted to change/alter specification or unit size given in the ANNEXURE-XII.
- b) GST (Goods and Services Tax)-The Tenderers must indicate the rate of GST applicable and payable by them. In case no information is given, it shall be presumed that rate is inclusive of GST and no GST shall be charged by them under any circumstances.
- c) The bidder is required to indicate rate of GST (%) as digit only in column 9 of BOQ without suffixing the % sign and not to indicate amount of GST in Rs. at particular cell of excel sheet of BOQ.
- d) *Purchase preference shall be given to Class-I local supplier(s) based on their declaration of the percentage (%) of minimum local content used in the manufacturing of quoted product as per **Public Procurement (Preference to make in India), Order 2017** notification issued by GoI, Ministry of Commerce and Industry, Department of Industrial Policy and Promotion (DIPP) vide **order no. P-45021/2/2017-PP (BE-II) dated 16.09.2020** and **order no. 31026/65/2020-MD dated 30.12.2020** issued by Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals and accordingly bidder(s) shall be categorized as per below table:*

S. No.	Type of Class	Percentage (%) of minimum local content
1	Class-I Local Supplier	Local content equal to more than 80%
2	Class-II Local Supplier	Local content more than 50% but less than 80%
3	Non-Local Supplier	Local content less than or equal to 50%

“Local Content” means the amount of value added in India which shall be the total value of the item procured (excluding net domestic indirect taxes) minus the value of imported content in the item (including all customs duties) as a proportion of the total value, in percent.

- e)
 - (i) If the participating Micro, Small & Medium Enterprises (MSEs) meets all the other eligibility criteria and their quoting price is within price band of L1+15 (fifteen) per cent shall also be allowed to supply a portion of requirement by bringing down their price to L1 price in a situation where L1 price is from someone other than a MSEs and such MSEs shall be allowed to supply up to 25 (twenty-five) per cent of total tendered value. The 25 (twenty-five) per cent quantity is to be distributed proportionately among these bidders, in case there are more than one MSEs within such price band.
 - (ii) Within this 25% (Twenty-five %) quantity, a purchase preference of four (4) per cent (that is, 20 (twenty) per cent out of 20 (twenty) per cent) will be reserved for MSMEs owned by Scheduled Caste (SC) / Scheduled Tribe (ST) entrepreneurs (if they participate in the tender process and match the L1 price). Provided that, in event of failure of such SC/ST MSME to participate in tender process or meet tender requirements and L1 price, four per cent sub-target shall be met from other MSEs. MSEs would be treated as owned by SC/ ST entrepreneurs: a) In

case of proprietary MSEs, proprietor(s) shall be SC /ST b) In case of partnership MSME, the SC/ST partners shall be holding at least 51% (fifty-one percent) shares in the unit c) In case of Private Limited Companies, at least 51% (fifty-one percent) share shall be held by SC/ST promoters.

(iii) Within this 25% (Twenty-five Percent) quantity, **a sub-target of 3% earmarked for procurement from MSEs owned by Women entrepreneurs** (if they participate in the tender process and match the L1 price). Provided that, in event of failure of such Women entrepreneurs MSE to participate in tender process or meet tender requirements and L1 price, 3% sub-target shall be met from other MSE.

6. EARNEST MONEY DEPOSIT/ BID SECURITY DECLARATION:

- A) Bidder should sign a BID SECURITY DECLARATION accepting that if they withdraw or modify their bids during the period of validity, or if they are awarded the contract and if they fail to obliged/adhere the tender condition/ provision made in the bid document, they will be suspended/disqualified for the period of two (2) years from the date of disqualification. In the absence of Bid Security Declaration in the prescribed proforma (Annexure- X), the tenders will be rejected.
- B) The Micro and Small enterprises (MSEs) are exempted from submitting the Bid Security as per prevailing rules. However, they have to submit the valid **“Udyam Registration Certificate”** in reference to Gazette notification CG-DL-E-26062020-220191 dated 26.06.2020 and Office Memorandum no. 21(5)/2019-P&G/Policy (pt. IV), issued by Ministry of MSME dated 06.08.2020 with the technical bid.
- C) PSUs are exempted from the submission of Bid Security Declaration.
- D) The tender submitted without Bid Security Declaration in the prescribed proforma (Annexure-III) will be summarily rejected.
- E) **The bid of the tender will be suspended/disqualified without further notice if:**
 - a) If the tenderer withdraws his bid any time after opening of price bid.
 - b) On refusal to supply medicine after the award of contract/Letter of Acceptance (LOA).
 - c) In case of the lowest bidder (L1 bidder), fails to execute the contract or fails to complete the first supply successfully within the stipulated time.
 - d) If the undertaking as Annexure II is not found correct at any stage during the contract period.

7. GUIDELINES FOR THE PREPARATION OF TENDER:

- A) The bidder shall bear all costs associated with the preparation and submission of its bid and Tender Inviting Authority will in no case be responsible or liable for these costs, regardless of the conduct or outcome of the bidding process.
- B) **Language of Bid:** - The Bid prepared by the bidder and all correspondence and documents relating to the bid exchanged by the bidder and the Tender Inviting Authority, shall be in English language, Supporting documents furnished by the bidder may be in other languages provided they are accompanied by an authenticated (by the authority concerned) accurate translation of the relevant passages in the English language in which case, for purposes of interpretation of the Bid, the English translation shall alone govern. Failure to submit authentic translation of documents would result in rejection of bids. No bid can be partly in one language and partly in another language.

- C) Power of Attorney or Resolution of the Board by which the authorized signatory has been authorized by the bidder firm should sign the documents in cases where person other than the Managing Director/Managing Partner or sole Proprietor signs the document.

8. PERIOD OF VALIDITY OF TENDER:

- a) The tender must remain valid for minimum 60 days from the date of opening of Technical Bid. (As mentioned in Clause 1.II)
- b) Prior to the expiration of the bid validity the Tender Inviting Authority may extend the bid validity for further period with mutual consent of the bidder.
- c) The bidder who has extended the bid validity is not required or permitted to modify its bid.
- d) The bidder cannot withdraw the bid within validity of Tender.

9. AMENDMENT OF TENDER DOCUMENTS:

At any time prior to the last date of submission of online bid, Tender Inviting Authority may, for any reason, whether on own initiative or in response to a clarification requested by a prospective Tenderer, may modify the condition in Tender documents by uploading an amendment on PMBI website: www.janaushadhi.gov.in; and on CPP portal i.e., <https://eprocure.gov.in> will be binding on them. In order to provide reasonable time to take the amendment into account in preparing their bid, Tender Inviting Authority may at discretion, extend the date and time for submission of online bid.

- A) Bidders are advised to check the website of PMBI: www.janaushadhi.gov.in; and CPP Portal i.e., <https://eprocure.gov.in>; regularly at least 3 days prior to closing date of submission of tender for any corrigendum or amendment to the tender document.
- B) PMBI will not issue separate communication for any corrigendum or amendment.

10. METHOD OF SUBMISSION OF TENDER:

- A) The tender document shall be downloaded from the websites janaushadhi.gov.in; and CPP portal i.e., <https://eprocure.gov.in>. Tender Document is free of cost. No tender cost is to be deposited.
- B) Bids shall be submitted online only at CPP Portal i.e., <https://eprocure.gov.in>. Manual bids shall not be accepted except for the original documents/instruments as mentioned in Clause 3 of tender document.
- C) Bidders are advised to follow the 'Special Instructions to the Contractors/Bidders for the e-submission of the bids online' available through the link 'Help for Contractors' at the e-Procurement Portal <https://eprocure.gov.in>.
- D) If a particular document/Certificate to be uploaded as specified in bid, is not applicable for a bidder, the bidder shall attach a scanned copy of declaration in the letter head stating that the specific document is not applicable/exempted for the bidder in connection to this tender.
- E) Bidder shall not modify the downloaded tender form including downloaded price Bid template in any manner. In case any tender form/Price bid template is found to be tampered with/modified in any manner, such bid will be summarily rejected, Bid Security would be forfeited, and bidder is liable to be banned from doing business with PMBI.
- F) Interested eligible Tenderer may obtain further information in this regard from the office of the Tender Inviting Authority on all working days between 10:00 AM and 5:00 PM.
- G) Once the bid has been uploaded in the CPP Portal <https://eprocure.gov.in> the bidder has to make sure that he has uploaded the files in the correct format and the bidder has to download the uploaded files from their own end and has to check whether the files uploaded is in proper format or not, no corrupted files have to be uploaded.

11. MODIFICATION AND WITHDRAWAL OF BIDS:

- A) The bidder may modify or withdraw its bid after the bid submission before last time and date of submission of online Technical Bid.
- B) No bid will be allowed to be withdrawn after the last date & time of submission of online Technical Bids.

12. OPENING OF TENDER:

- A) The opening of the Technical Bid and the Price Bid will be done online as specified. The date of technical bid opening is published in advance. The date of opening of price bid will be announced only after the opening and evaluation of technical bid. The bidder who are found eligible and on satisfying the criteria for technical evaluation/based on undertakings & Declaration, will only be informed the time and date of opening of Price Bid - Cover "B" of the tender.
- B) Only authorized employee of tenderer is entitled to be present at the time of opening of Technical Bid - Cover "A" of the tender submitted by them.
- C) In case, the date for opening of technical bid is declared holiday, the technical bid shall be opened on next working day at 11.30 A.M.
- D) The original/attested hard copies (as mentioned in Clause no. 3, eligibility criteria) must reach the PMBI Head office on or before stipulated time, failing which the bid shall be summarily rejected.

13. EVALUATION OF TENDER:

- A) Technical evaluation of the Bid will be done on the basis of criteria and documents mentioned in S.N. 3 (TECHNICAL BID-COVER A) which are present in the CPP Portal i.e. <https://eprocure.gov.in>.
- B) Bids of firms who have furnished all the required documents for each of the product quoted will be considered.
- C) If at any stage, it is found that the contract has been successfully obtained by the bidder by submitting forged/fabricated certificates/documents/licenses and/or by concealing the fact about blacklisting/debarring/de-registration of the firm by Govt. of India/Suspension/Cancellation/non-renewal of the manufacturing license of the bidder firm, the tender bid/rate contract may be rejected/terminated and suitable punitive action may be taken against the firm.
- D) **In event of financial bid opening, due to provisions/compulsion of e-tendering system if complete quoted product list of financial bids of a bidder is opened then only those financial bids of quoted product shall be considered of whose technical bid has been found eligible by the Technical Evaluation Committee.**
- E) **After evaluation of technical bid of tenderer/bidder, PMBI may ask the objection/clarification from tenderer/ bidder.**

14. INSPECTION OF MANUFACTURING FACILITIES:

- A) PMBI or its authorized representative(s) has/have the right to inspect the manufacturing premises of Tenderers, before accepting the rate quoted by them or before releasing any purchase order(s) or at any point of time during the continuance of tender and also has the right to reject the tender or terminate/cancel the purchase orders issued and/or not to place further order, based on adverse reports brought out during such inspections. Copy of one full set of the documents submitted for the bid should be made available at the time of inspection.
- B) Originals of all the documents uploaded/submitted in the Technical Bids should be produced for verification during Site inspection and Physical Verification.

15. ACCEPTANCE /REJECTION OF BIDS:

- A) PMBI reserves the right to accept or reject the tender for the supply of all or any one or more items of the drugs tendered for in a tender without assigning any reason.
- B) Evaluation of the tender and determination of the L1 rate (Lowest rate) will be done based on rate per unit size exclusive of GST as mentioned in column 7 of **BOQ**. PMBI shall have the right to call other eligible bidders those are willing to match L1 rates. If such firms are found, then the order quantity may be dispersed.
- C) However, in case the price quoted by the lowest responsive tenderer (L1) is not reasonable and unacceptable, the price may be negotiated with L1 only as per CVC guidelines and, if it reduces the price to the desirable level, rate contract may be concluded with L1.
- D) Negotiation if required will be done strictly as per Central Vigilance Commission guidelines following the orders passed by Nodal Ministry any.

16. AWARD OF CONTRACT:

- A) The contract will be awarded to the lowest evaluated responsive bidder qualifying to the final round after technical bid and Price Bid evaluation as per the clause 5. (B) Determination of L1 bidder and clause 16. B. Acceptance /Rejection of bid, subject to the reservations and preferences to PMBI.

B) Letter of Acceptance (LoA):

The Tender Inviting Authority shall issue Letter of Acceptance (LOA) as per Annexure-XI to the lowest responsive bidder in respect of the drugs selected. Communication by e-mail / fax / letter will be deemed as valid communication.

Note: - LoA may be issued if required.

- C) The successful bidder, upon receipt of the Letter of Acceptance (LOA), shall communicate the acceptance of the same to the PMBI and shall furnish the documents, asked if any.
- D) The bidder shall not, at any time, assign, sub-let or make over the contract or the benefit thereof or any part thereof to any person or persons whatsoever. Such practices will be deemed as fraudulent practices and also as breach of terms of contract and shall invite punitive action.

17. PERFORMANCE SECURITY DEPOSIT:

- A) On being informed about the acceptance of the tender, the Performance Security Deposit @3% will be deducted from each running bills and accumulated security deposit will be refunded without any interest by PMBI to the tenderer within 60 days following the date of completion of tenderers performance obligations under the contract including the shelf-life obligation.

- B) The Security deposit of supplier will be returned by PMBI only after the supplier has given undertaking to replace such medicines and indemnify PMBI against any losses on account of quality parameters duly notarized.

18. METHODOLOGY FOR PLACING ORDERS:

For the above purpose, the following procedures will be adopted:

- A) After the conclusion of Price Bid opening (Cover B), the rates offered by tenderers for each product are evaluated and lowest acceptable rate (L1 Rate) arrived at is declared and that tenderer is informed.
- B) If two or more than two Tenderer's are declared as lowest suppliers for the same item(s), such Tenderers are eligible for the placement of Purchase Orders for such item(s) for which they are declared as lowest.
- C) The supplier shall start supply of the Drugs/Medicines to any or all the Warehouse (Address/Location) **as mentioned in clause 19. (A)** or any other place decided by PMBI, and supply shall confirm to the conditions mentioned in the provision of tender documents, viz, logo, nomenclature, specification etc. within the stipulated period.
- D) Once The supplier shall supply the Drugs/Medicines at any of the PMBI Warehouse **as mentioned in purchase order** (or any other place decided by PMBI) along with copy of Purchase order, copy of test reports and 3 original copies of Invoice. No payment will be processed without test reports.
- E) The Drugs/Medicines supplied in excess of the ordered quantity shall not be accepted and the supplier shall take back the excess at their cost. PMBI will not be responsible for the loss to the supplier and will not entertain any demand/claim.
- F) The details of the required drugs, medicines, etc. are shown in **ANNEXURE -XII. The tender quantity mentioned herein is not a fixed procurement quantity and it is only a tentative requirement and may be increased or decreased** by the PMBI, at its discretion, depending on its actual need. Any supply without a valid purchase order will not be acceptable by PMBI and the PMBI shall not be responsible for any loss on this account.
- G) However, once the purchase order/orders is/are issued by the PMBI, the tenderer shall not renege from the commitment of supplying the quantity mentioned in purchase order.
- H) The rates quoted shall not be varied with the Purchase order quantity.
- I) No Tenderer shall be allowed at any time and on any ground, whatsoever it may be, to claim revision or modification in the rates quoted by them. Representation to make correction in the tender documents on the ground of Clerical error, typographical error, etc., committed by the Tenderers in the Bids shall not be entertained after submission of the tenders. Cross Conditions such as "SUBJECT TO AVAILABILITY", "SUPPLIES WILL BE MADE AS AND WHEN SUPPLIES ARE RECEIVED" etc., will not be entertained under any circumstances and the tenders of those who have mentioned such conditions shall be treated as incomplete and accordingly the Tender will be summarily rejected.
- J) Supplies should be made directly by the tenderer and not through any other Agency / Dealer / Distributors.
- K) The supplier shall take utmost care in supplying the quality Drugs/Medicines and ensure that the batch number mentioned in the packages of the Drugs/Medicines tally with the batch number mentioned in the Invoice produced to PMBI for payment. Also, the supplier shall ensure the quantity

relevant to the Batch Number of the Drugs/Medicines is mentioned in the invoice. Drugs to be supplied of any batch shall not be accepted with different MRP.

- L) "MRP inclusive of all taxes" is to be printed on each unit/label. MRP will be intimated to successful bidders at the time of placing purchase orders.

NOTE: PMBI don't give any guarantee of minimum purchase under this Rate Contract.

19. SUPPLY CONDITIONS:

- A) Purchase orders will be issued to the Tenderer(s) at the discretion of the PMBI as per actual requirements. All the supplies shall be received at any or all of the following warehouse of PMBI or any other place decided by PMBI:

- i) **Central Warehouse Gurugram (Pharmaceuticals & Medical Devices Bureau of India (PMBI))**
Sugal Logistic Park, Warehouse No.1, Opp. GITM College, Bilaspur-Tauru Road
Village Bilaspur and Khasra No. 60//14/2, 17,24,6,15, 16, 25, 7/1, 14/1, 61//9, 10, 11,62//3/2, 4,10//17, 24, 19//3, 8/2, 9/1/1, 12/2/2/2 min 13/1/1 min.
Pin Code – 122413
Phone No. – 011-49431800
- ii) **Regional Warehouse Guwahati, Pharmaceuticals & Medical Devices Bureau of India (PMBI)**
DAG No. 884 of K P PATTA No. 04, Mughuapara, Pamohi Village, Dist. Kamrup(M) Guwahati, Assam India 781035.
Phone No. – 011-49431800
- iii) **Regional Warehouse Chennai, Pharmaceuticals & Medical Devices Bureau of India (PMBI)**
79, KIZHMUTHALAMPEDU, PANAPAKKAM,
City Tiruvallur, State Tamil Nadu
Pin Code – 601201
Phone No. – 011-49431800
- iv) **Regional Warehouse, Surat, Pharmaceuticals & Medical Devices Bureau of India (PMBI)**
Plot no. A-23/2 & A -24/1,
Ichhapore – Bhatpore GIDC,
Ichhapore Surat,
Gujarat - 394510

- B) Within 3 days from the receipt of purchase orders the Tenderer should inform PMBI through PMBI **vendor portal** the confirmation for the receipt of the purchase order.

- C) The Tenderer should also fill the details of supply/delivery schedule to PMBI through PMBI **vendor portal** within 7 days from the receipt of the purchase order with expected dispatch/supply date.

- i. The bidder shall have to fill Advance supply notice (ASN) on PMBI **vendor portal** with all other details i.e., invoice copy, Certificate of Analysis (COA), Batch no. Quantity, Date of Manufacturing (DOM) Date of Expiry (DOE), no. of shipper boxes etc.
- ii. Once the ASN is accepted by the PMBI, the bidder will be provided the date to execute the supplies at PMBI warehouse as mentioned in purchase order.

Note:

- In case, the supply shall not be made by the date as conveyed by the supplier, supply order shall be cancelled at their risk and cost. If no response is received through **PMBI vendor portal** within 7 days from the supplier / tenderer about supply of drugs as per purchase

order, it shall be presumed that the supplier/tenderer is not interested to supply the drugs ordered as per purchase order and PMBI shall purchase the drugs from alternative sources. In case of newly awarded bidder, bidder must share their permanent email ID and phone number for PMBI **vendor portal registration** to it1@janaushadhi.gov.in & customercare1@janaushadhi.gov.in

D) The supplier must supply the ordered quantity as follow delivery schedule:

Sl. No.	Nature of Product	Delivery Schedule (Days)
1	Delivery Schedule against first / subsequent purchase order(s)	45 days

- E) If the delivery date happened to be a holiday for PMBI, the supply should be completed by 5.00 PM on the next working day.
- F) In case of non-execution of the order, PMBI reserves the right to place purchase orders (partially/fully) on alternate source at the risk and cost of the default tenderer(s) without any notice/Information.
- G) If a supplier fails to execute supply as per Purchase Order, the 5% of value of unexecuted quantity of Purchase Order shall be recovered from pending bill or Bank Guarantee/Performance security deposit and their bad performance shall be kept in record of PMBI for future dealing as considered appropriate by PMBI.
- H) If the Tenderer fails to execute the supply within the stipulated time, the PMBI is at liberty to make alternative arrangement for purchase of the items for which the Purchase orders have been placed, from any other sources or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the defaulted supplier and in such cases the PMBI has every right to recover the cost and impose Liquidated Damages as mentioned in Clause 25.
- I) The liquidated damages as specified in clause 25. (B) of the tender conditions will be levied on the quantity supplied after the schedule as mentions in “Clause 19.(D) from the date of issue of purchase order. However, no supplies will be accepted after 30 days of the expiry of delivery date i.e., completion of specified liquidated damages period as per clause 25 (B), the purchase order shall be cancelled at the risk and cost of the supplier. **However, the supplier must take prior approval from PMBI for supply of drugs beyond stipulated delivery period in Purchase Order.**
- J) Supplier shall complete the earliest pending purchase order before commencing the supply of subsequent purchase orders. **Further, supplies against a purchase order are to be made in minimum numbers of batches as far as possible and same batch should not be supplied in repeated consignment.**
- K) **Bidder must comply to the shelf life of each quoted drugs as mentioned in the Annexure XIII of the tender document and they must fill the required shelf-life detail in Para VI of Annexure II.**
- L) The Tenderer must submit an Analysis report for every batch of drug along with invoice. In case of failure on part of the supplier to furnish such report, the batch of drugs will be returned to the supplier and he is bound to replenish the same with Govt. approved lab test report. The Drugs supplied by the successful Tenderer shall be of the best quality and shall comply with IP/BP/USP and the specifications, stipulations and conditions specified in the tender.
- M) Tenderer should supply the product as follow:**

- (i) Within 2 months excluding month of manufacture of products having shelf life up to 2 years,
- (ii) Within 3 months excluding month of manufacture of products having shelf life more than 2 years & up to 3 years and
- (iii) Within 4 months excluding month of manufacture of products having shelf life more than 3 years
- (iv) Within 3.5 months excluding month of manufacture of products for drug code 574 Human Rabies Vaccine Injection 2.5 IU.

Products supplied beyond the above-mentioned period from the date of manufacturing shall levied a LD as Per Clause 25. (E) of tender documents. For example, product having manufacturing of January 2021 must be supplied by 31st March 2021 in case shelf life up to 2 Years.

- N) If at any time the Tenderer has, in the opinion of the PMBI delayed the supply of drugs due to one or more reasons related to **Force Majeure events** such as riots, mutinies, wars, fire, storm, tempest or other exceptional events at the manufacturing premises, the time for supplying the drugs may be extended by the PMBI at discretion for such period as may be considered reasonable. However, such extension shall be considered only if a specific written request is made by the Tenderer within 10 days from the date of occurrence of such event with necessary documentary evidence. The supplier shall not be liable to pay LD and forfeiture of Security deposit for the delay in executing the contract on account of the extension of supply period on the ground of force majeure events.
- O) The exceptional events do not include the Scarcity of raw material, Increase in the cost of raw material, Electricity failure, Labour disputes/Strikes, Insolvency, and Closure of the Factory/Manufacturing unit on any grounds etc.
- P) Suppliers are required to supply the drugs within the delivery period mentioned in the purchase order. In this regard it is informed to the bidders that their performance shall be considered unsatisfactory in case of delayed supply (beyond delivery period) or non-supply of products. PMBI may reject their bid in future tenders considering their unsatisfactory performance of supplies.
- Q) Leaked, soiled, broken containers with damaged labels shall not be accepted.
- R) If PMBI observes some physical defects (like empty blisters, improper labelling) of the supplies during sampling, the batch shall be rejected. If supplier wants to take back the batch for rectification, they can take back at their cost, rectify and send back to PMBI within 15 days otherwise same batch shall not be accepted. Due to rectification, if its shelf life condition as per tender provision does not meet, it shall be discretion of PMBI depending upon requirement to accept the goods with penalty.
- S) Tenderers shall not supply the drugs declared banned by Government of India, even if Purchase Order is placed.

20. LOGOGRAM:

Logogram means, wherever the context occurs, the design as specified in **Enclosure 1 & 2 of ANNEXURE-VII. The name of the drug shall be mentioned in English and Hindi** as per pharmacopoeia and its strength.

- A)Tenders should supply for Drugs etc., as per the specifications such as name, strength, minimum size and packed with appropriate size of the strips/blisters/bottles/tubes etc. as per the design enclosed in **Enclosure 1 to ANNEXURE –VII** and **Enclosure 2 to ANNEXURE –VII.**
- B)All dosage form have to be supplied in packing as specified in product list (**ANNEXURE XII**) and shall also conform to Schedule P1 of the Drugs & Cosmetics Act & Rules 1945, wherever it

applies. Affixing of stickers and rubber stamps shall not be accepted and supplies will be returned at supplier's cost.

- C) Vials, Ampoules (more or equal than 5 ml) and Bottles containing the items tendered for should also carry the printed PMBJP logogram of proportionate size.
- D) Failure to supply Drugs etc., with the printed logogram of proportionate size will be treated as breach of the violation of tender conditions. The purchase order shall be cancelled at the risk and cost of the supplier. However, if such failure continuous despite notice, will be viewed as a serious lapse and initiate blacklisting of the supplier and levied a LD as per clause 25 (D) of tender documents.
- E) Drugs without GS-1 Standard Barcoding on Primary, Secondary and Tertiary Packaging will not be accepted.

21. PACKING:

- A) The drugs shall be supplied in the package specified in **ANNEXURE -VIII** and **ANNEXURE -XII** and the package shall carry the logograms of proportionate size specified in **Enclosure 1 to ANNEXURE –VII & Enclosure 2 to ANNEXURE –VII** and shall also conform to Schedule P1 of the Drug & Cosmetic Act & Rules 1945, whether it applicable.

Non-affixing of logograms will be treated as violation of tender conditions and fine will be deducted from the amount payable as per condition in Clause 25 (D) of tender documents.

- B) The drugs in any dosage form to be supplied by the supplier should not be embossed indicating any code no./logo or name of the company. Failure to comply with this shall lead to non-acceptance of the goods besides imposition of penalties as per clause 25. (D)
- C) The packing in each carton shall be strictly as per the specification mentioned in **Annexure-VIII**. The outer carton/secondary packaging should be of pearl white duplex board (**off white/grey is not acceptable**) with a minimum of 350 GSM with **Gloss laminated** packing for the strips, blisters, ointments, creams etc. and for ampoules and vials should be with pearl white board of 350 GSM (**off white/grey is not acceptable**). **The material to be used for carton should be from virgin chemical pulp**. Failure to comply with this shall lead to non-acceptance of the goods besides imposition of penalties as per clause 25 (D). Storage conditions must be indicated on outer label.
- D) **The** cap of bottle preparations should not carry the name/logo/other details of the supplier. However, cap may contain PMBI logogram.
- E) The labels in the case of Injectable preparations should clearly indicate whether the preparations are meant for Intravenous (IV), Intramuscular (IM), Intra Dermal (ID), Subcutaneous (SC) administration etc.
- F) It should be ensured that only virgin packaging material of uniform size, including bottle and vial, is used for packing.
- G) All primary packing containers should be strictly conforming to the specification included in the relevant pharmacopoeia.
- H) Packing should be able to prevent damage or deterioration during transit.
- I) The packings/labels of two different products of a same supplier should be clearly distinct from each other.
- J) In the event of items of drug supplied found to be **not as per specifications in respect of their packing and logogram**, the PMBI is at liberty to make alternative purchase of the items of drugs for which the Purchase orders have been placed from any other sources or in the open market or

from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier. In such cases the PMBI has every right to recover the cost and impose penalty as mentioned in Clause 25 & 26.

- K) Designs of packaging with the logograms shall be subject to approval by PMBI within 3 days of receipt of purchase order or within 30 days of release of letter of acceptance. Text matter of all type of label must be checked and responsibility shall be of manufacturer.

In case of failure of PMBI to do so, the supplier may go ahead with the design as per the specification in Enclosure-1 to ANNEXURE VII and Enclosure-2 to ANNEXURE VII.

STP (Standard Testing Procedure) for Non- Pharmacopoeia awarded drugs are required to submit within 15 days from the date of Letter of Acceptance.

- L) **The colour of the strength must be different from the colour of the generic name of the drug on primary and secondary packaging and the approval for the same should be taken from the quality/regulatory department while taking artwork approval. The printing ink used should be of good quality (clarity, brightness, contrast) which is easily readable.**
- M) **WHO-GMP certified, Therapeutic code & NABL lab tested shall be indicated on the primary and secondary packaging and shall be incorporated as per the approval from the quality/regulatory department while taking artwork approval.**
- N) **Barcodes as per GS-1 standards are required to be printed on products at various packaging levels (Primary, Secondary and Tertiary) as per Annexure-IX.**

22. QUALITY TESTING & QUALITY CONTROL:

- A. All the batches of the drugs supplied shall be supported by test/ analysis reports furnished by independent NABL Accredited Drugs Testing Laboratory/Central Drug Testing Laboratory/In House Quality Control Laboratory. The Tender Inviting Authority has the right to get the drugs tested at the laboratories of his choice for further verifications, from PMBI empanelled laboratories.
- B. Random samples of each supplied batch will be chosen at the point of supply or distribution/storage points for testing. The samples will be sent to different PMBI empanelled laboratories including Government Drugs Testing Laboratory/NIPER/PSU labs for testing. Handling and testing charges will be deducted by PMBI for the above purpose, as specified in Clause 24.
- C. **STP (Standard Testing Procedure) for Non- Pharmacopoeia awarded drugs are required to submit within 15 days from the date of Letter of Acceptance by mail to Quality and Regulatory officer of PMBI with artwork approval for design of packaging with the logogram as per Clause 21.K.**
- D. The Drugs shall have the active ingredients at the prescribed level as indicated in official compendiums throughout the shelf-life period of the drug. The samples will be drawn periodically throughout the shelf-life period and if found “Not of Standard Quality”, the cost of entire batch paid will be recovered whether consumed fully/partially. Also, action will be initiated for blacklisting as per clause 26 irrespective of the period of supply. The supplies will be deemed to be completed only upon receipt of the quality certificates from the laboratories. Samples which do not meet quality requirement shall render the relevant batches liable to be rejected. If the sample is declared to be “Not of Standard Quality” or spurious or adulterated or misbranded, such batch/batches will be deemed to be rejected goods.
- E. In the event of the samples of Drugs supplied fails in quality tests or found to be not as per specifications, the PMBI is at liberty to make alternative purchase of the items of drugs for which the Purchase orders have been placed from any other sources or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier and in

such cases the PMBI has every right to recover the cost and impose penalty as mentioned in Clause 26(I).

- F. If the product / sample fails in quality test, every failed batch shall be taken back by the supplier at their own cost and PMBI shall not be responsible for any damage during this period.
- G. The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the commercial final package on request by the PMBI. In case of any complaint in the field, the B.M.R/B.P.R for the particular batch of the product(s) supplied shall be produced when demanded. **For New drugs, complete stability data of 6 months' period shall be acceptable.**
- H. **The products should confirm to the standards of IP/BP/USP/EP/JP as the case may be. However, the drugs notified in the IP (amended up to date) shall be accepted only if supplied conforming to the standards outlined in the IP.** In case the product is not included in the any of the said compendiums, the supplier, upon award of the contract, must provide the reference standards and testing protocols for quality control testing.
- I. The case of admixture of drugs will be treated as a violation of tender conditions and fine will be levied as per clause 26. If such lapses happen more than twice in a tender period, such cases will be treated as "Misbranded Drugs".

23. PAYMENT PROVISION:

- A) No advance payments towards costs of drugs will be made to the supplier.
- B) Payments towards the supply of drugs will be made within 60 days from the date of receipt of goods, strictly as per the tender terms and condition. The payment will be made either by means of a/c payee Cheque or through RTGS (Real Time Gross Settlement System)/Core Banking/NEFT. The Tenderer shall furnish the relevant details in original (**ANNEXURE -V**) to make the payment through RTGS/Core Banking/NEFT.
- C) All bills/Invoices should be raised in triplicate and the bills should be drawn as per GST Rules in the name of Pharmaceuticals & Medical Devices Bureau of India (PMBI). 8th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055 or in the name of any other authority as may be designated.
- D) (i) Payments for supply will be considered only after supply of minimum 50% of Drugs ordered in the individual Purchase Order provided reports of Standard Quality on samples testing are received from Government Analyst or Approved Laboratories of PMBI.
(ii) However, in case of cancellation of a particular purchase order due to failure in delivery, payment for part supplies less than 50% of the purchase order quantity on the date of cancellation of the purchase order may be considered for release of payment subject to the following:
 - a) If the Tenderer have supplied at least 50% of the quantity ordered in the subsequent purchase order within delivery period stipulated in purchase order from the issue of such purchase order.
 - b) If further purchase order is not placed with the supplier due to any reason, not attributable to the supplier, the amount eligible will be paid within 60 days from the date of last supply.
 - c) The payment for part supply as mentioned above will subject to the deduction of liquidated damages, penalty towards unexecuted quantity, risk and cost etc., as per the tender conditions.

- E) If at any time during the period of contract, the price of tendered items is reduced or brought down by any law or Act of the Central or State Government or by the Tenderer himself, the Tenderer shall be bound to inform the PMBI immediately about such reduction in the contracted prices. Tender Inviting Authority is empowered to unilaterally effect such reduction as is necessary in rates in case the Tenderer fails to notify or fails to agree for such reduction of rates.
- F) In case of any increase or decrease in the Taxes/GST after the date of submission of tenders and during the tender period, such variation in the taxes/GST will be to the account of the PMBI. For claiming the additional cost on account of the increase in taxes/GST, the Tenderer should produce the proof of having paid additional amount on this account on the goods supplied to PMBI from the concerned authorities and also must claim the same in the invoice separately. However, the basic price structure and the price of the Drugs approved under the tender shall not be altered. Similarly, if there is any reduction in the taxes/GST and statutory levies as notified by the Govt., after the date of submission of tender, the Tenderer will be paid based on the unit rate worked out on the basis of the reduced taxes/GST/statutory levies without any change in the basic price or the price structure of the drugs approved under the tender. Any increase or decrease in taxes/GST and statutory levies will be considered based on the notification issued by the Government.
- G) However, if the firm supplies after originally stipulated Delivery period, increase in taxes/GST due to statutory variation in taxes/GST shall be borne by the supplier. In case of decrease in taxes/GST due to statutory variation in taxes/GST, the same shall be passed on by the supplier to the PMBI.

24. HANDLING & TESTING CHARGES:

In all supplies, 1.5% of the supply value shall be deducted towards handling & testing charges.

25. LIQUIDATED DAMAGES & OTHER PENALTIES:

- A) All supply should be made within the stipulated time as per the clause 19.D of the Delivery Schedule and quantity as mentioned in the Purchase Order.
- B) If the supply reaches the Drug Warehouses beyond the stipulated time as mentioned in PO/Bid document, liquidated damages will be levied at the rates 2% per week or part thereof, subject to maximum of 10% irrespective of the fact that whether the PMBI has suffered any damage/loss or not, on account of delay in effecting supply.
- C) If the supply is received in damaged condition, it shall not be accepted. The supplier shall have to replace the goods with damage and the penalty equal to the penalty for unexecuted supplies will be levied for the damaged goods and payments will be withheld till proper replacement.
- D) All the Tenderers are required to supply the product(s) with printed MRP as per purchase order and logogram of appropriate size on the strips, blisters, vials, ampoules & bottles and with prescribed packing specification. If there are any deviation in these Tender conditions, action will be taken to blacklist the product, and/or a separate damage will be levied @ 5% of value of the defaulted quantity irrespective of the Tender Inviting Authority having actually suffered any damage/loss or not, without prejudice the rights of alternative purchase specified in Clause No.19F, 19 H and 21.J.
- E) If supplier supplied the drug time beyond the manufacturing date as mentioned in clause 19. (M) of supply conditions, a liquidation damage will be levied @ 5% per month subject to maximum 30% (Up to 6 months).
- F) In all the above conditions, the decision of the Tender Inviting Authority shall be final and binding.

26. DEDUCTION & OTHER PENALTIES ON ACCOUNT OF QUALITY FAILURE:

- A) If the samples do not conform to statutory standards, the Tenderer will be liable for relevant action under the existing laws and the entire stock in such batch has to be taken back by the Tenderer within a period of 30 days of the issue of the letter from the PMBI. Such stock shall be taken back at the expense of the Tenderer. Further, actual handling and testing charges shall be paid to PMBI by the supplier otherwise these charges shall be recovered from their pending bill/Performance Security Deposit.
- B) The PMBI has the right to destroy such “NOT OF STANDARD QUALITY DRUGS” if the Tenderer does not take back the goods within the stipulated time. The PMBI will arrange to destroy the “NOT OF STANDARD QUALITY DRUGS” after the expiry of 30 days mentioned above without further notice and shall also collect handling charges (in case the product is sent back to supplier on freight to pay basis)/ demurrage charges calculated at the rate of 2% per week on the value of the drugs rejected till such time stipulated. Further, the cost of disposal shall be recovered from the supplier.
- C) If any items of Drugs/Medicines supplied by the Tenderer have been partially or wholly used or consumed after supply and are subsequently found to be in bad odour, unsound, inferior in quality or description(Adulterated/Spurious/Misbranded) or otherwise faulty or unfit for consumption, then the contract price or prices of total such batches supplied will be recovered from the Tenderer, if payment had already been made to him. In other words, the Tenderer will not be entitled to any payment whatsoever for Items of drugs found to be of “NOT OF STANDARD QUALITY” whether consumed or not consumed and the Tender Inviting Authority is entitled to deduct the cost of such batch of drugs from any amount payable to the Tenderer. On the basis of the nature of failure, action will be initiated to blacklist the product/supplier.
- D) For the supply of Adulterated/Spurious/Misbranded, as defined in the Drugs and Cosmetics Act, 1940, to PMBI. PMBI reserves the right to blacklist the supplier. No further supplies shall be accepted from the firm/company.
If the tenderer is blacklisted, the tenderer shall also not be eligible to participate in tenders of Tender Inviting Authority of PMBI for supply of Drugs for a period of 5 years from the date of blacklisting.
In case of supply of NOT OF STANDARD QUALITY drug(s) to PMBI, the product shall be blacklisted by PMBI, and no further supplies shall be accepted for the particular drug(s). The Tenderer shall also not be eligible to participate in tenders of PMBI for supply of such Drugs for a period of 2 years from the date of blacklisting.
In addition, the Director of Drugs Control of concerned State will be informed for initiating necessary action on the Tenderer in their state. Performance Security Deposit will also be forfeited without any intimation.
- E) The Tenderer shall furnish the source of procurement of raw material utilized in the formulations, if required by the PMBI. The PMBI reserves the right to cancel the purchase orders, if the source of supply is not furnished.
- F) The decision of the PMBI or any officer authorized by him, as to the quality of the supplied drugs, medicines etc., shall be final and binding. In such cases, the PMBI will be at liberty to terminate, the contract either wholly or in part on 30 days’ notice. The Tenderer will not be entitled for any compensation whatsoever in respect of such termination besides forfeiture of Performance Security Deposit.

- G) For contravention of the stipulations of the contract or for other justifiable reasons, the contract may be terminated by the PMBI, and the Tenderer shall be liable to pay for all losses sustained by the PMBI in consequence of the termination which may be recovered from the Tenderer, as per rules besides forfeiture of Performance Security Deposit.
- H) Non-performance of any of the contract conditions and provisions will disqualify a firm from participating in the tender for the next 2 years/ Blacklisting the tenderer.
- I) In the event of making Alternative Purchase, as specified in Clause 19.H, Clause 21.J and in Clause 22.F penalty will be imposed on the supplier. The excess expenditure over and above contracted prices incurred by the PMBI in making such purchases from any other sources or in the open market or from any other Tenderer who has quoted higher rates and other losses sustained in the process, shall be recovered from the Performance Security Deposit or from any other money due and become due to the supplier and in the event of such amount being insufficient, the balance will be recovered personally from the supplier as per rules.
- J) In all the above conditions, the decision of the PMBI shall be final and binding.

27. BLACKLISTING IN THE EVENT OF WITHDRAWAL FROM THE TENDER, AND NON-ADHERENCE TO THE QUALITY STANDARDS AND SUPPLY SCHEDULE:

A) BLACKLISTING OF PRODUCT/TENDERER ON WITHDRAWAL OF TENDER

If the Tenderer fails to perform the obligations under the tender conditions / commits default in the performance of the contract/LOA, such Tenderers will be blacklisted for a period of **2 years** by PMBI from the date of intimation besides forfeiture of Performance security deposit.

The Tenderers who have withdrawn after participating in the tender after the last date and time of submission of online bid, either fully or partially, **the entire firm/company** will be blacklisted for a period of **2 years** from the date of intimation by PMBI apart from forfeiture of the Security Deposit.

B) BLACKLISTING FOR QUALITY FAILURE/QUALITY TEST BY THE EMPANELLED LABORATORIES OF PMBI.

a) Each and every batch of drugs/medicines supplied by the supplier shall be subjected to quality test by the Empaneled laboratories as per the procedure adopted by PMBI.

PMBI shall also draw the samples of products supplied in the marketplace and get the same tested, to make sure the products are conforming to quality requirements till Self life.

b) If the sample of any batch fails in quality test and report is received stating “Not of standard quality “in any test the report along with the chromatograms etc. such batch of drugs shall be rejected & no further procurement of that drug from the supplier will be taken for two years from the date of sample being declared not of standard quality.

- (i) If the supplier challenges and request for retesting, the sample shall be tested at government testing laboratory or reputed govt. institute like NIPER. The test report of govt. lab or NIPER will be final and will be binding to the supplier.
- (ii) The cost of such Re-testing shall be recovered from the supplier.

- (iii) If 2 batches of item/drug supplied by the same supplier is reported to NOT OF STANDARD QUALITY in specification, then the firm shall be blacklisted for 2 years after observing procedure laid down in Para 27.B.(d) besides forfeiture of Performance Security Deposit.
- (iv) If a single batch of any product(s) supplied by the company/firm declared as Adulterated/spurious/ Misbranded by the Government Authorities during the shelf life of the product supplied irrespective of tender period, the company/firm shall be blacklisted for a period of **2 years from the date of intimation & forfeiture of security deposit.**

C) Quality Test by Statutory Authorities:

- (i) If any drug is declared “NOT OF STANDARD QUALITY”, by any government agencies or drug licensing authority, the issue of available stock of the particular item will be stopped. Further, the available stock of the product in hospitals/JAS will be retrieved.
- (ii) If any batch of any product(s) supplied by the company/firm declared, NOT OF STANDARD QUALITY in specification as defined in the Drugs and Cosmetics Act, 1940, by the Government Authorities during the relevant tender period or during quality check within shelf-life period, the company/firm shall be blacklisted for a period of **2 years from the date of blacklisting** after observing procedure laid down in Para 27.B(d)

D) Procedure for Blacklisting:

- (i) On receipt of complaint from Distributer/retailers/customers or report from Govt. Analyst/Drug Testing Laboratory indicating that a particular Item/Drug is “**NOT OF STANDARD QUALITY/ ADULTERATED/ SPURIOUS/MISBRANDED**” (As the case may be), a show cause notice shall be issued to the supplier calling for explanation within 7 days from the date of notice. On receipt of explanation from the supplier, the CEO, PMBI may take appropriate action on merits of the case and impose penalty including the blacklisting of the item of the product/company or firm as deemed fit besides forfeiture of Performance Security Deposit.
- (ii) If a particular item of the drug has been blacklisted according to the procedure stated above, the supplier is not eligible to participate in any of the tenders for such item floated by the PMBI until the period of blacklisting is over.
- (iii) If a supplier company/firm is blacklisted according to the procedure stated above, such supplier is not eligible to participate in any of the tenders floated by the PMBI until the period of blacklisting is over.

E) BLACKLISTING FOR NON-SUPPLY:

Due to non-supply of item against any purchase order, 5 % value of purchase order shall be recovered from the supplier in addition of other penal like risk purchase.

In case of repeated circumstances of non-supply of items i.e. 2 times, the supplier may be blacklisted for 2 years in addition of forfeiture of Performance Security Deposit and other penal action.

28. SAVING CLAUSE:

- A. No suit, prosecution or any legal proceedings shall lie against the Tender Inviting Authority or any person for anything that is done in good faith or intended to be done in pursuance of the tender.
- B. The tender is being invited following all the orders/rules issued on time to time regarding the supply of Drugs. However, during the course of the dealing, any directions/orders/rules brought

before the PMBI or any provision appears contrary to the orders/ rules passed regarding supply of Drugs, the PMBI may amend the tender policy as required at any point of time. The said amendment shall be final and binding upon all the parties.

29. RESOLUTION OF DISPUTES

The PMBI and the supplier shall make every effort to resolve, amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the contract.

A) ARBITRATION AND JURISDICTION.

Normally, there should not be any scope of dispute between the PMBI and the supplier after entering into a mutually agreed valid contract/ Rate Contract.

However, due to various unforeseen reasons, problems may arise during the progress of the contract/ Rate Contract leading to disagreement PMBI and the supplier shall first try to resolve the same amicably by mutual Consultation. If the parties fail to resolve the dispute by such mutual consultation within twenty-one days, then, depending on the position of the case, either the PMBI or the supplier shall give notice to other party of its intension to commence Arbitration procedure as per Indian Arbitration and Conciliation Act, 1996. Such disputes/differences shall be referred to Sole Arbitrator to be appointed by the CEO of PMBI. The venue of Arbitration Shall be at New Delhi. The award published by the Arbitrator shall be final and binding on the parties.

30. CONTACTING THE PMBI BY THE BIDDER:

- A) No bidder shall contact the PMBI on any matter relating to its bid, from the time of bid opening to the time the contract is awarded.*
- B) Any effort by a bidder to influence the PMBI in the Purchaser's bid evaluation, bid comparison or contract award decisions may result in rejection of the bidder's bid.*
- C) The bidder shall not make any attempt to establish unsolicited and unauthorized contact with the Tender Accepting Authority, Tender Inviting Authority or Tender Scrutiny Committee after opening of the bids and prior to the notification of award and any attempt by any bidder to bring to bear extraneous pressures on the Tender Accepting Authority, Inviting Authority or Tender Scrutiny Committee, shall be sufficient reason to disqualify the bidder.*
- D) Notwithstanding anything contained in clause (C) above the Tender Inviting Authority or the Tender Accepting Authority, may seek bonafide clarifications from bidders relating to the bids submitted by them during the evaluation of bids.*

31. FRAUDULENT AND CORRUPT PRACTICES:

A)For Bidders:

It is purchaser's policy to ensure that suppliers and their authorized representatives/agents observe the highest standard of ethics during the procurement and execution of such contracts. (In this context, any action taken by a bidder, supplier, contractor, or by their authorized representatives/agent, to influence the procurement process or contract execution for undue advantage is improper) In pursuance of this policy, the purchaser.

a) Defines, for the purposes of this provision, the terms set forth below as follows:

- (i) "corrupt practice" is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party ("another party" refers to a public official acting in relation to the procurement process or contract execution]. In*

this context, “public official” includes staff and employees of other organizations taking or reviewing procurement decisions.

- (ii) “fraudulent practice” is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation (a “party” refers to a public official; the terms “benefit” and “obligation” relate to the procurement process or contract execution; and the “act or omission” is intended to influence the procurement process or contract execution).*
- (iii) “collusive practice” is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party [“parties” refers to participants in the procurement process (including public officials) attempting to establish bid prices at artificial, non-competitive level].*
- (iv) “coercive practice” is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party (a “party” refers to a participant in the procurement process or contract execution).*
- (v) “obstructive practice” is (a) deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or acts intended to materially impede the exercise of the purchaser’s inspection and audit rights provided for under sub-clause (e) below.*
- b) Will reject a proposal for award if it determines that the bidder considered for award has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive, or obstructive practices in competing for the contract in question.*
- c) will cancel the contract if the purchaser determines at any time that the bidder, supplier and contractors and their sub-contractors engaged in corrupt, fraudulent, collusive, or coercive practices*
- d) will sanction a firm or individual, including declaring in eligible, either indefinitely or for a stated period of time, to be awarded a contract if it at any time determines that the firm has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for, or in executing, a contract; and*
- e) will have the right to inspect the accounts and records of the bidders, supplier, and contractors and their subcontractors/authorized representatives and to have them audited by auditors appointed by the purchaser.*

B) For Suppliers:

If the PMBI determines that a Supplier has engaged in corrupt, fraudulent, collusive, coercive or obstructive practices, in competing for or in executing the Contract, then the PMBI may, after giving 7 days’ notice to the Supplier, terminate the Supplier's engagement under the Contract and cancel the contract, and the procurement will be made at the risk and cost of the supplier besides blacklisting the bidder for 5 years with forfeiture of Performance Security Deposit apart from other penal actions.

a) For the purposes of this Sub-Clause:

- (i) “Corrupt practice” is the offering, giving, receiving, or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party.*

- (ii) “Fraudulent practice” is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation.
- (iii) “Collusive practice” is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party.
- (iv) “Coercive practice” is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party.
- (v) “obstructive practice” is (aa) deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a purchaser investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or (bb) acts intended to materially impede the exercise of the purchaser’s inspection and audit rights provided for.

32. JURISDICTION:

In the event of any dispute arising out of the tender such dispute would subject to the jurisdiction of the Civil Court within the city of Delhi only.

.....

ANNEXURE – I

Ref. Clause 3 (N)

CHECK-LIST (Whether uploaded the documents)

COVER – A

S. N.	Check List	YES/ No	Page No.	Remarks
1	Check list – ANNEXURE – I as per clause 3. N.			
2	ANNEXURE –II (Declaration on non-judicial Stamp Paper for eligibility in participating the tender) original Annexure II delivered to PMBI as per clause 3. J.			
3	Bid Security declaration on non-judicial stamp paper as per ANNEXURE-III (Clause 3. A & 6. A).			
4	Udyam Registration Certificate (If claimed for EMD exemption) as per Clause No. 3.A Note.			
5	Copies of documentary evidence for the constitutions of the company / Firm/ Proprietorship such as Memorandum and Article of Association, Partnership deed with complete address as per Clause 3. B.			
6	Power of attorney or Resolution of board by which the authorized signatory has been authorized by the Tenderer to sign the tender documents as per clause 3. C.			
7	Copy of Minimum three years old valid Manufacturing License of the product quoted with latest license renewal certificate as per Clause 3. D.			
8	Copy of Market Standing Certificate issued by the Licensing Authority from Drug Controller Administration of the State for minimum 2 batches in last 3 Years as per Clause no. 3. E.			
9	Copy of Non-Conviction Certificate issued by the concerned Licensing Authority from Drug Controller Administration of the State, not older than 12 months as per Clause no. 3.F.			
10	Copies of WHO-GMP (WHO-Good Manufacturing Practice) as per revised Schedule- 'M'/COPP Certificate of the manufacturing unit issued by the Licensing Authority/ Drugs Control Department/FDA. The WHO - GMP Certificate must be valid as on the last date of submission of tender as per clause 3. G.			
11	Copy of Maximum Production Capacity Certificate (section wise) issued by concerned Licensing Authority Form Drugs Control Department/FDA highlighting the quoted product section as per Clause no. 3. H.			
12	ANNEXURE—V (Mandate form) to furnish company bank details as per clause 3 (K) & 23(B)			
13	ANNEXURE-VI indicating manufacturing License, validity of license and market standing certificate details as per clause 3. L.			
14	Self-attested copy of ANNEXURE VII (Declaration to supply the drug as per the design in Enclosure 1 to Annexure VII & Enclosure 2 to Annexure VII) as per clause 3(M), 20 & 21.			
15	Annexure – X Declaration of Local Content on non-judicial stamp paper as per clause 3(S) & 5(B)(d)			
16	Copy of valid GS-1 registration certificate for bar coding as per Clause 3. R.			
17	Copy of Audited Annual Balance sheet and Profit and loss			

	statement showing details of their annual average turn over not less than 25 crores for any three of the last four consecutive financial years as per Clause 3. I.			
18	ANNEXURE IV {certificate from the C.A. (Chartered Accountant) or Company Secretary. Original Annexure IV delivered to PMBI as per clause 3. I..			
19	Self-attested copy of PAN Card of the Bidder Company. As per Clause 3(O).			
20	Self-attested copy of Certificate of valid GST registration of the bidder company. As per Clause 3(P).			
21	Self-attested copy of Income Tax Return for any three of last four consecutive Assessment years. As per Clause 3(Q).			
22	Authorization letter nominating an employee of the tenderer to transact the business with the Tender Inviting Authority as per clause 4. N.			

NOTE: - Bid Security Declaration (ANNEXURE III), ANNEXURE II, ANNEXURE IV, ANNEXURE V, ANNEXURE VI and Annexure X (Declaration of Local Content) are to be delivered in original to PMBI, rest of the document duly authorized should be submitted on or before stipulate date as mentioned in the tender document “technical cover A”.

Name of authorized signatory:

Signature of authorized signatory:

Company seal:

ANNEXURE –II
(On nonjudicial Stamp Paper)
Ref. Clause No. 3. (J)
DECLARATION

I/We M/s. represented by its Proprietor/Managing Partner /Managing Director having its registered office atand its factory premises atdo hereby declare as under: -

(I) that I/we have carefully read all the terms and conditions of tender in ref. no. **PMBI/LTD/DRUG-179/2021 dated 24.12.2021** including Amendment(s) to Tender document (if any) issued by Pharmaceuticals & Medical Devices Bureau of India (PMBI), New Delhi, 110055 and accept unconditionally all terms and condition of tender document including Amendment(s) to Tender document (if any).

(II) **A.** that I/We are holding and have uploaded (a) valid drug license for quoted drugs, (b) valid WHO-GMP certificate, (c) 3 years market standing certificate for quoted products issued by licensing authority, (d) a certificate manufactured & marketed two batches within 3 years issued by C.A. for quoted drugs, (e) valid non conviction certificate not older than 12 months, (f) declaration of the active API polymorphic form used in formulation for quoted drugs and declare that it is internationally accepted active polymorph (**if any**) and (h) the copies of the specifications for all quoted drugs and STP (standard testing procedure) for Non-Pharmacopoeia quoted drugs and also enclosed all undertaking/declaration as per Annexure mentioned in the tender document.

(II) B. that I/We shall submit the complete stability data (long term stability studies and accelerated stability studies) for all awarded drugs within 15 days from the date of issue Letter of Acceptance. (If manufacturer has licensed a formula from another company and such licensed formula is used for the product, then the stability data of the licensor shall be submitted along with licensing agreement.)

(II) C. that I/we shall supply the drugs as per specification, composition, strength, design, logo and packing given in ANNEXURE-XIII and Shape, Colour, Packing Type, etc. of drugs shall be as given in ANNEXURE-XIV

On the basis of above undertaking/declaration, the price bid shall be opened subsequently after opening of technical bid. However, any document uploaded with technical bid is not complying as per undertaking, the contract/ Rate Contract shall be cancelled with forfeiture of Performance Security Deposit/Bank guarantee against tender no. PMBI/LTD/DRUG-179/2021 dated **24.12.2021** along with other action suspension/disqualification of contract.

(III) a.) I/We declare that we possess the valid drug manufacturing license for PMBI's tendered items as per details below:

Sr. No.	Drug Code	Description of Drug as per PMBI Tender	Unit Size	Drug Lic. No.	Date of Issue	Validity of Drug Lic.	Address of Manufacturing Unit

b.) I/We declare that we possess the valid WHO-GMP (World Health Organization-Good Manufacturing Practices) Certificate issued by competent authority and complies and continue to comply with the condition laid in schedule M of Drug & cosmetic act, 1940 the rules made there under.

I am / We are aware of the Tender Inviting Authority's right to forfeit the Performance Security Deposit and suspending/disqualifying/blacklist me/us for a period of 5 years if, any information furnished by

us proved to be false at time the of inspection and not complying the condition as per schedule M of the said Act for a period of five years.

(IV) I do hereby declare that I have uploaded valid GS1 registration certificate for bar coding and will supply the drug with bar code as per ANNEXURE IX and as per the design as per enclosures to ANNEXURE XII enclosed with tender document as well as other instruction given in this regard.

(V) that in pursuant to the conditions in Clause No. 6. (A) of the tender, the bids can be suspended/disqualified by the Tender Inviting Authority in case of violation of any of the conditions and non-performance of the obligation under tender document.

(VI) that our company/applied items have not been blacklisted/debarred/de-registered/banned **due to quality failure for the quoted product /firm by any State Government / Central Government/ PMBI / Central or State Government's Drug procurement agencies** for the following products quoted in the tender at the time of submission of bid. Further, quoted drugs have not been failed in house testing or testing by any State Government/Central Government / its Drug procurement agencies/ PMBI during last two years. We are eligible to participate in the tender ref. No. **PMBI/LTD/DRUG-179/2021 dated 24.12.2021** for the following quoted products with mentioned shelf life in Annexure XIII: -

S. No.	Drug Code	Description of Drug as per PMBI Tender	Unit Size	Shelf life complying the Schedule-P" of the Drugs and Cosmetics Rule, 1945.

Signed.....

Name:

Designation.....

(Company Seal)

Witness: -

(1) Signed:

Name:

Designation:

(2) Signed:

Name:

Designation:

To be attested by the Notary

ANNEXURE-III

BID SECURITY DECLARATION

(On nonjudicial Stamp Paper)

Ref. Clause No. 3. (A) & 6.(A)

Date : [DD/MM/YYYY]

Tender No.:

To:

[Purchaser]

I/We....., the undersigned, declare that: I/We understand that, according to **Pharmaceuticals & Medical Devices Bureau of India (PMBI)** tender conditions, bids must be supported by a Bid-Security Declaration.

I/We accept that I/we may be disqualified/ suspended from bidding for any contract with the **Pharmaceuticals & Medical Devices Bureau of India (PMBI)** for the period of two (2) years, if I am/we are in a breach of any obligation under the bid conditions, because I/we:

- (a) have withdrawn or modified my/our Bid during the period of bid validity specified in the Form of Bid; or
- (b) having been notified of the acceptance of our Bid by the **PMBI** during the period of bid validity, (i) fail or refuse to execute the Contract, if required, or (ii) fail or refuse to furnish the Performance Security, in accordance with the Instruction to Bidders.

I/We understand this BID SECURITY DECLARATION shall cease to be valid if I am/we are not the successful Bidder, upon the earlier of (i) the receipt of your notification of the name of the successful Bidder; or (ii) thirty days after the expiration of the validity of my/our Bid.

Signed: [signature of person whose name and capacity are shown] In the capacity of [insert legal capacity of person signing the BID SECURITY DECLARATION]

Name: insert complete name of person signing the BID SECURITY DECLARATION

Duly authorized to sign the bid for and on behalf of: [insert complete name of Bidder]

Dated on _____ day of _____, _____.

Corporate/Company Seal:

Note: (i) In case of a Joint Venture, the BID SECURITY DECLARATION must be in the name of all partners to the Joint Venture that submits the bid.

(ii) The Micro and Small enterprises (MSEs) & PSU's are exempted from the submission of Bid Security Declaration.

ANNEXURE- IV

Ref. Clause No. 3. (I)

{Format for a certificate from the C.A. (Chartered Accountant) or Company Secretary}

I. It is certified that M/s..... is a Private Ltd./Ltd. /Proprietorship/Partnership company/firm and they have PAN no.....and GST registration no.....They have filed Income tax returned and GST returned up to date. The authorized signatory of the company/firm is Shri.....and whose signature is attested as under:.....

II. The annual Turnover of M/s. for any three of the last four consecutive financial years for manufacturing of drugs are given below and certified that the statement is true and correct.

Sl. No.	Financial Year	Turnover in Rupees (₹) in Crore (Rs.)	Turnover in Rupees in Crore (in words)
1.	2017-18	₹	
2.	2018-19	₹	
3.	2019-20	₹	
4.	2020-21	₹	
Total Turnover		Rs (₹)..... Crore	Rs (in words).....
Average Turnover per annual		Rs (₹)..... Crore	Rs (in words).....

It is certified that M/S(Name of company and address)having factory at..... (address of factory) have required plant/plants, machinery/machineries, building/buildings & other infrastructure to manufacture the tendered drugs. It is also certified that the statement is true and correct.

III. It is certified that M/s _____ has Production & financial capacity to manufacture and deliver the drugs quoted by them in the tender as per quantity & delivery schedule mentioned in tender. This certificate is based on their Manufacturing capacity, inventory of raw Material and financial statement.

IV. Further, It is certified that M/Sis Micro and Small Enterprises (MSE) and registered with Director of Industries of concerned State/UT or appropriate authorities for quoted drugs against PMBI tender No. **PMBI/LTD./DRUG-179/2021** and eligible for exemption of submission of Bid Security Declaration. This MSEs is owned by Scheduled Caste (SC)/Scheduled Tribe (ST) entrepreneurs.

V. They have manufactured & marketed 2 or more commercial batches of each quoted drugs in last three years.

Note: Turnover certificate (Annexure-IV) shall be submitted in original on CA/CS letter head.

Date:

Name:

Signature:

Stamp:

Registration No.:.....

NOTE

- (i) Strike which is not applicable in above certificate.
- (ii) MSEs would be treated as owned by SC/ ST entrepreneurs: a) In case of proprietary MSEs, proprietor(s) shall be SC /ST b) In case of partnership MSEs, the SC/ST partners shall be holding at least 51% (fifty-one percent) shares in the unit c) In case of Private Limited Companies, at least 51% (fifty-one percent) share shall be held by SC/ST promoters.

ANNEXURE V
Ref. clause 3 (K) & 23.(B)
MANDATE FORM

Sl. No.	Details Required	
1.	Company Name	
2.	Postal Address of the Company	
	GST No.	
	Telephone No.	
	Fax No.	
	E-mail ID	
3.	Name of the Managing Director / Director / Manager	
	Mobile No. / Phone No	
	E-mail ID	
4.	Name and Designation of the authorized company official	Name:
		Designation:
	Mobile No.	
	E-mail ID	
5.	For Vendor Portal Registration	
	Permanent E-mail ID	
	Permanent Mobile No.	
6.	Bank Details	
	a) Name of the Bank	
	b) Branch Name & address	
	c) Branch Code No.	
	d) Branch Manager Mobile No.	
	e) Branch Telephone no	
	f) Branch E-mail ID	
	g) 9-digit MICR code number of the bank and branch appearing on the MICR cheque issued by the bank	
	h) IFSC Code of the Branch	
	i) Type of Account (Current / Savings)	
	j) Account Number (as appear in cheque book)	

(In lieu of the bank certificate to be obtained, please **attach the original cancelled cheque** issued by your bank for verification of the above particulars).

I / We hereby declare that the particulars given above are correct and complete. If the transaction is delayed or not effected at all the reasons of incomplete or incorrect information, I would not hold Pharmaceuticals & Medical Devices Bureau of India (PMBI) responsible. I have

read the conditions of the tender / Rate contract entered and agree to discharge the responsibility expected of me / from the company as a tenderer / successful tenderer.

Date:	Company Seal	Signature
Place:		(Name of the person signing & designation)

CERTIFIED THAT THE PARTICULARS FURNISHED ABOVE BY THE COMPANY ARE CORRECT AS PER OUR RECORDS.

Bank Seal with address:	Signature of the authorized official of the bank

Annexure VI
Additional Document
Tender No. PMBI/DRUG/RC-159/2021
Ref Clause No. 3 (L)

Date:

REF: GRADE NO. 3 (E)											
S. N.	Drug Code (Only Quoted Drugs as mentioned in Annexure II)	Drug Specification (As per Tender Specification)	Unit Size	Drug Manufacturing License					Marketing standing Certificate (MSC)		
				Drug Manufacturing License No.	License Issue date	License Renewal Date	License Validity Date	Page no. of Document in uploaded Scan Copy (Do not put page nos. in range)	Market Standing Certificate Issue Date	Period of Marketing as per Marketing standing Certificate (MSC)	Page no. of Document in uploaded Scan Copy (Do not put page nos. in range)

Note:

- (i) In case any details as desired above is missing/not submitted against quoted drugs, the bid for such drugs is liable to be rejected.
- (ii) It is strictly do not put page nos. in range, indicate the page nos. one by one for all respective quoted drugs codes.

Signature:

Name:

Authorized Signatory:

Seal of the Company:

ANNEXURE -VII

Ref. Clause no 3.(L), 20 & 21

DECLARATION

I/We do hereby declare that I/we will supply the drug as per the design in Enclosure 1 to Annexure VII & Enclosure 2 to Annexure VII as well as other instruction given in this regard.

Signature of the Tenderer

Name

Designation

(Company Seal)

Enclosure-1 to ANNEXURE - VII

Ref. Clause No. 20

DESIGN FOR: Foil / blister of tablet and capsule

1. **Text Matter Printing on Foil /Blister** should be in minimum two colour i.e. Black & red.
However, colour and design of PMBJP (Pradhan Mantri Bhartiya Janaushadhi Pariyojana) logogram in standard colour format & PMBI Drug code-XXXX as given in PO as per approval at the time of ART WORK approval before supply should be as given below.
2. PMBJP Logogram should be placed along with the address as given below.
3. PMBI helpline number 1800 180 8080 should be printed.
4. Font type should in CALIBIRI format for any type of title name of generic medicines.
5. Title name of generic medicine should be **bold** in minimum 12 font size & the strength corresponding to it must be **bold** in minimum 14 font sizes and it may increase respectively according to size of label & the rest text matter should be in minimum 8 font size.
6. The stereo printing of batch no./manufacturing /expiry date & other details shouldn't overlap the text matter.
7. "Pharmaceuticals & Medical Devices Bureau of India (PMBI)" should be running text only and should not be prominent.



1. Pradhan Mantri Bharitya Janaushadhi Priyojana should be printed in Hindi at side of strips.

Enclosure – 2 to ANNEXURE – VII
Ref. Clause No. 20

1. Design for injection for primary packing

- a) Vial (5ml or more) should be supplied with the following PMBJP logogram & PMBI Drug code-XXXX as given in PO as per approval at the time of ARTWORK approval before supply as under:
- b) PMBI helpline number 1800 180 8080 should be printed.
- c) Font type should in CALIBIRI format for any type of title name of generic medicines
- d) Title name of generic medicine should be minimum 12 font sizes and it may increase respectively according to size of label.
- e) “Pharmaceuticals & Medical Devices Bureau of India (PMBI)” should be running text only and should not be prominent.

Manufactured for:



Pharmaceuticals & Medical Devices Bureau of India (PMBI)
8th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055
PMBI helpline number 1800 180 8080 PMBI DRUG CODE—XXXX

b) Ampoules or Vials less than 5 ml for primary packing

- (i) Injection in ampoule or vial (less than 5 ml) should be supplied with PMBJP logogram & PMBI Drug code-XXXX as given in PO as per approval at the time of ARTWORK approval before supply.
- (ii) PMBI helpline number 1800 180 8080 should be printed.
- (i) Font type should in CALIBIRI format for any type of title name of generic medicines.
- (ii) Title name of generic medicine should be minimum 12 font sizes and it may increase respectively according to size of label.
- (iii) “Pharmaceuticals & Medical Devices Bureau of India (PMBI)” should be running text only and should not be prominent.

Manufactured for :



Pharmaceuticals & Medical Devices Bureau of India (PMBI)
8th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055
PMBI helpline number 1800 180 8080 PMBI DRUG CODE—XXXX

(ii) LIQUID:

- a) Liquid preparation should be supply with pilfer proof ROPP cap.
- b) Bottle cap should not bear the manufacturer's logogram
- c) Bottle label should bear PMBJP logogram & PMBI Drug code-XXXX as given in PO as per approval at the time of ARTWORK approval before supply as below:
- d) PMBI helpline number 1800 180 8080 should be printed
- e) "Pharmaceuticals & Medical Devices Bureau of India (PMBI)" should be running text only and should not be prominent
- f) Font type should in CALIBIRI format for any type of title name of generic medicines
- g) Title name of generic medicine should be minimum 12 font sizes and it may increase respectively according to size of label.

Manufactured for :



Bureau of Pharma PSUs of India

8th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055

PMBI helpline number 1800 180 8080

PMBI DRUG CODE—XXXX

OINTMENTS / CREAMS

- a) Ointment / Cream /Gel /Glass Jar should bear PMBJP logogram & PMBI Drug code-XXXX as given in PO as per approval at the time of ART WORK approval before supply as below:

Manufactured for :



Pharmaceuticals & Medical Devices Bureau of India (PMBI)

8th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055

PMBI helpline number 1800 180 8080

PMBI DRUG CODE—XXXX

- b) PMBI helpline number 1800 180 8080 should be printed
- c) Ointment / cream tube should be packed in mono carton (secondary packing) with PMBJP logogram & PMBI Drug code-XXXX as given in PO as per approval at the time of ARTWORK approval before supply as given below.
- d) "Pharmaceuticals & Medical Devices Bureau of India (PMBI)" should be running text only and should not be prominent
- e) Font type should in CALIBIRI format for any type of title name of generic medicines
- f) Title name of generic medicine should be minimum 12 font sizes and it may increase respectively according to size of label.

ANNEXURE-VIII

Ref. Clause No. 21(C)

SCHEDULE FOR PACKAGING OF DRUGS

GENERAL SPECIFICATIONS

1. Strips of Aluminium foils should be 0.07 mm thickness and grammage of foil minimum 80 g/m², LDPE minimum 35 g/m² and total GSM not less than 110 g/m².
2. Aluminium foils back material for blisters should be minimum 0.025 mm thickness, grammage of foil minimum 75 g/m² and tensile strength minimum 400 Kg/cm².
3. The rigid PVC used in blister packing should be of not less than 250 microns (thickness) and grammage minimum 350 g/m².
4. ALU-ALU blisters, total grammage minimum 250 g/m², total minimum thickness 130 microns, and bursting strength minimum 15 Kg/cm².
5. Pin hole should be nil and toxicity should be comply as per USP in all foil and PVC.
6. All glass bottles should be new neutral glass, Type-1, free from visual defects.
7. Pet bottles used for syrups/solution should be clean, standard for market and so accepted as per drug laws stipulation.
8. Ointments should be packed in lacquer zed Aluminium Tubes or Lami tubes and properly sealed.
9. Small Tablets packed in blisters should be packed to facilitate easy removal of the tablet without breaking / crushing.
10. Specification of outer cartons should be as per given in their Schedule.
11. In case of any conflict between Carton specifications and packets per carton specification the specification of the packets / carton shall prevail.
12. All plastic containers should be made of virgin grade plastics
13. Injection in vials should have a flip-off seals.
14. Container used for infusions should be as per market standard and must not leak during use.
15. The strips shall be aluminium strip / blisters with aluminium foil back.
16. The outer carton/secondary packaging should be of pearl white duplex board (**off white/grey is not acceptable**) with a minimum of 350 GSM with **Gloss laminated** packing for the strips, blisters, ointments, creams etc. and for ampoules and vials should be with

pearl white board of 350 GSM (off white/grey is not acceptable). The material to be used for carton should be from virgin chemical pulp.

17. All liquid oral preparations to be provided with a measuring plastic cup, fitted over the cap of the bottle in a mono carton. In case of Pediatric Preparation, all liquid oral has to be provided with a measuring plastic cup, dropper fitted over the cap of the bottle in a mono carton.
18. All primary/secondary/tertiary packaging should have PMBJP logo and drug code mentioned as per purchase order.
19. Two Horizontal/vertical/standing lines in two different colour will be there on Primary and secondary packaging, to differentiate therapy groups. The colours of lines will be intimated during Artwork approval.

Shipper size or corrugated box specification with weights

S. N	Particulars	Weight	Ply	Grammage	Bursting strength
1	Tablets	Not more than 12.0 Kg	7	Outer box should be 150 GSM and inside partition/lining should be 120 GSM.	Not less than 10 Kg/cm ² .
2	Capsules (Hard gel and soft gel)	Not more than 12.0 Kg	7		
3	Syrups	Not more than 12 to 14.0 Kg	7		
4	Ointment/gel/cream	Not more than 12.0 Kg	7		
5	Injection (vial, respules and ampoules)	Not more than 8-12.0 Kg	7		
6	IV fluids	Not more than 12.0 Kg	7		
7	Bottles/Jars	Not more than 12.0 Kg	7		

Note:

- a) In the case of 10 ml Ampoules, 20 or 25 ampoules may be packed in a mono carton. Multiples of mono carton boxes should be packed in CB.
- b) If the vial is packed in individual carton, there is no necessity for grey board box packing. The individual carton may be packed as such in the CB with center pad.
- c) In case of ampoules less than 10 ml, every 10 or 5 ampoules should be inside the tray with printed white board box.
- d) Vials of eye, ear drops, and nasal drops should be packed in an individual mono carton with a dispensing device. If the vial is of FFS/BFS technology, they should be packed as per approved artwork and market standard.

ANNEXURE IX
(BARCODE REQUIREMENTS}
Reference clause 3(R)

**GS1 barcode requirements on Drugs procured by Pharmaceuticals & Medical
Devices Bureau of India (PMBI)**

These requirements cover medicines/drugs procured by Pharmaceuticals & Medical Devices Bureau of India (PMBI), New Delhi meant for supply and distribution through PMBI regulated distribution channel.

Barcode based on GS1 identification standards are provided below at various levels of product packaging which includes primary, secondary and shipper/carton levels and need to be complied with while supplying medicines/drugs to PMBI.

GS1 India is unique identification & barcoding standards body setup by Ministry of Commerce & Industry, Govt. of India along with APEDA, BIS, Spices board, IIP and apex industry chambers like CII, FICCI, ASSOCHAM to assist India industry and govt. bodies on adoption of global standards.

Suppliers are also required to provide GS1 subscription validity certificate at the time of supply of medicines/drugs issued by GS1 India. For validity certificate suppliers can contact GS1 India at 011-42890-846.

Barcodes based on GS1 global standards are required to be printed on product packaging at primary, secondary and tertiary packaging levels **in addition** to other, existing statutory labelling & marking requirements.

Technical Specification for GS1 Standards

Tertiary Level Pack:

Is defined as a level of packaging that shall contain one or more secondary/primary levels of packaging and is also considered as the final logistics unit like shippers/pallets.

The Tertiary label will carry two barcodes in GS1-128 format.

First Barcode

- a) Unique product identification code (GTIN - Global Trade Identification Number)
- b) Manufacturing Date
- c) Expiry date
- d) Batch no.
- e) Quantity

Second Barcode

- f) Serial Shipping Container Code (SSCC) –

Note-

- 1) While encoding Manufacturing and expiry date in the barcode, if a specific Manufacturing or expiry date is not printed on the finished pack/drug then Supplier should select first day of the month as the Manufacturing date and Last day of the month as expiry date.

Example- If Shelf life is 24 months, April 2021 manufacturing date should be encoded as 210401 and March 2023 expiry date as 230331.

- 2) SSCC number of the Tertiary pack should never be reused on another Tertiary pack irrespective the Item, Batch or expiry is different.
- 3) For converting, GTIN-13 into GTIN-14, kindly use “0” as a prefix for all levels of packaging.

Attribute	Description	Length	Nature	Data Type
(02)	Application Identifier to indicate GTIN-14 Brackets not encoded in the barcode	2	Fixed	Numeric
0 8901072 00253 3	Unique Product Number-GTIN-14	14	Fixed	Numeric
(11)	Application Identifier to indicate Manufacturing date Brackets not encoded in the barcode	2	Fixed	Numeric
180101	Expiry Date in YYMMDD format	6	Fixed	Date
(17)	Application Identifier to indicate Expiry date Brackets not encoded in the barcode	2	Fixed	Numeric
220131	Expiry Date in YYMMDD format	6	Fixed	Date

(10)	Application identifier to indicate Lot/batch number Brackets not encoded in the barcode	2	Fixed	Numeric
BATCH123	Batch No / Lot No	20	Variable	Alphanumeric
(37)	Application identifier to indicate Quantity in Outer Carton	2	Fixed	Numeric
500	No of Primary packs like number of strips/Bottles in the tertiary.	Upto 8	Variable	Numeric
(00)	Application identifier to indicate the SSCC Brackets not encoded in the barcode	2	Fixed	Numeric
1 8901072 000000000 6	Unique number of the tertiary pack. It should never be reused.	18	Fixed	Numeric

Recommended Barcode – GS-128

To, BPPI	Mnfd By, AAA Pharma Company 125, SEZ Ahmedabad-382213 Gujrat
-------------	--

Drug Name: Dobucin 500 mg
Exp Date: 31 Jan 2022
Batch No: BATCH123



(02) 0 8901072 00255 3 (11) 180101 (17) 220131 (10) BATCH123 (37) 500



(00) 1 8901072 000000000 6

Secondary Level Pack:

Is defined as a level of packaging that may contain one or more primary packages usually termed as Mono-carton/carton

Secondary level barcode can be generated using 2D- GS1 Datamatrix or 1D- GS1-128 format.

Note-

- 1) Shrink wrap packaging will not be considered as Secondary level packaging.
- 2) For converting, GTIN-13 into GTIN-14, kindly use "0" as a prefix for all levels of packaging.

Data Attributes Captured in GS1 Datamatrix format

- 1) Unique product identification code (GTIN)

- 2) Batch No.
3) Qty- No of strips/bottle

Attribute	Description	Length	Nature	Data Type
(02)	Application Identifier to indicate GTIN-14. Brackets not encoded in the barcode	2	Fixed	Numeric
0 8901072 00253 3	GTIN-14- Unique product code with first digit being the packaging indicator	14	Fixed	Numeric
(10)	Application identifier to indicate Lot/batch Brackets not encoded in the barcode	2	Fixed	Numeric
BATCH123	Batch No / Lot No	Upto 20	Variable	Alphanumeric
(37)	Application Identifier to indicate serial number Brackets not encoded in the barcode	2	Fixed	Numeric
5	Quantity/Units in Secondary pack	Upto 8	Variable	Alphanumeric
Recommended Barcode depending upon the space available – GS1 Data matrix Or GS1-128	 (02) 0 8901072 00255 3 (10) BATCH123 (37) 5 or  (02) 0 8901072 00255 3 (10) BATCH123 (37) 5			

Primary Level Pack:

Is defined as the first level of packaging in direct contact with the product like Strip, Vial, Bottle etc

Scenario-I Primary pack with a Mono-carton/Carton/Secondary level pack

For primary packaging packed in a Mono-carton/Secondary pack carton

Unique product identification code (GTIN)

Note-

For converting, GTIN-13 into GTIN-14, kindly use “0” as a prefix for all levels of packaging.

Attribute	Description	Length	Nature	Data Type
(01)	Application Identifier to indicate GTIN-14 Brackets not encoded in the barcode	2	Fixed	Numeric
0 8901072 00253 3	GTIN-14 with first digit being the packaging indicator	14	Fixed	Numeric
Recommended Barcode – GS1 Data matrix,	 (01) 0 8901072 00253 3			

Scenario-II Primary pack without Mono-carton/Secondary level pack

For Primary packaging going directly into Tertiary pack without a Carton/Mono-carton/Secondary pack

Unique product identification code (GTIN)

Batch No.

Note-

For converting, GTIN-13 into GTIN-14, kindly use “0” as a prefix for all levels of packaging.



(01)08901072002533

(10)BATCH123

Attribute	Description	Length	Nature	Data Type
(01)	Application Identifier to indicate GTIN-14. Brackets not encoded in the barcode	2	Fixed	Numeric
0 8901072 00253 3	GTIN-14- Unique product code with first digit being the packaging indicator	14	Fixed	Numeric
(10)	Application identifier to indicate Lot/batch Brackets not encoded in the barcode	2	Fixed	Numeric
BATCH123	Batch No / Lot No	Upto 20	Variable	Alphanumeric

Mapping of Manufacturer GTIN with PMBI Drug code-

- GS1 has facilitated an online application to link Manufacturer GTIN code with PMBI Drug code. The manufacturer must update the same before sending the physical consignment to PMBI.
- Kindly contact Mr. Ankit Arora or Mr. Amrit Garg for the same at 011-42890846/42890818 or write email at ankit@gs1india.org or amrit@gs1india.org

Barcode Design and Printing-

- For PMBI suppliers, GS1 India has facilitated an online application to generate the barcode designs for each level of packaging.
- Using the same, the supplier will be able to generate Primary, secondary and Tertiary barcodes as per PMBI format.
- Kindly contact Mr. Ankit Arora or Mr. Amrit Garg for the same at 011-42890846/42890818 or write email at ankit@gs1india.org or amrit@gs1india.org.

Please contact GS1 India office for any further assistance –

GS1 India

(Under Min. of Commerce, Govt. of India)
 330, 2nd Floor, 'C' Wing, August Kranti Bhawan,
 Bhikaji Cama Place, New Delhi - 110066
T +91-11-42890890, (D) +91-11-42890846
F +91-11-26179730
E ankit@gs1india.org
W <http://www.gs1india.org>

ANNEXURE X
(Ref. Clause No. - 3.S)
(To be submitted on Non-judicial Stam paper duly notarized)

DECLARATION OF LOCAL CONTENT

I.....S/o, D/o, W/o.....Resident at
..... in the capacity of Proprietor/Managing
Partner/Managing Director in M/s.....having its
registered office at.....and
factory premises at.....do
hereby solemnly affirms and declare the local content for the quoted item(s) as under:

S. No.	Item code	Item Name	Details of Location(s) at which value addition is made	Percentage (%) of Local content	Category
1					
2					
3					

That I.....abide by the terms and conditions laid down in guidelines issued by Department of Pharmaceuticals, Ministry of Chemicals & fertilizers, Government of India vide F. No. 31026/36/2016-MD dated 09.11.2020 and DPIIT order no. P45021/2/2017-PP(BE-II) dated 16.09.2020 for the implementation of provisions of Public Procurement (Preference to Make in India) Order (PPO) 2017 related to procurement of Goods and Services on behalf of M/s..... Further, the calculations of local content used in manufacturing of quoted items are done in accordance with the guidelines laid down in Para 1/2/3/4 of Department of Pharmaceuticals order vide F. No. 31026/36/2016-MD dated 09.11.2020 and I found that items quoted by our firm comes under Class local content.

That the information furnished hereinafter is correct to the best of my knowledge and belief and on behalf of M/s..... I hereby undertake to produce relevant records before the procuring entity, or any authority so nominated by the Tender inviting Authority/ Department/ Any assigned by the Tender inviting Authority for the purpose of assessing the local content and verification.

Signature.....

Name:

Designation.....

(Company Seal/Stamp)

(Above shall be furnished by Authorized Signatory)

ANNEXURE-XI

Ref: Clause No. 16(B)

Letter of acceptance of tender for Limited Tender

Speed post/e-mail

Ref. No. PMBI/LTD/DRUG-179/2021

Date:

To,
M/S -----

Sub: Tender for the Supply of Drugs and Medicines to PMBI: Acceptance tender for Limited Tender.

Ref: Your quotation against PMBI limited e-Tender No. PMBI/LTD/DRUG-179/2021 dated: 24.12.2021 opened on (Technical Bid) & on (Price bid).

Please refer to your quotation i.e., technical and price bid (BOQ) along with enclosures/Annexure against subject tender read with your subsequent clarification/confirmation for the supply of Drugs to PMBI, the rate offered/accepted by your firm has been approved for Rate Contract for two years from the date of issue of this letter.

S. N.	Drug Code	Drug Name	Unit Size	Rates in Rs. Per unit exclusive of GST	Rate of GST (%)	Rates in Rs. Per unit inclusive of GST

- The contract will be with financial limit and PMBI can place the Purchase Order with unlimited variation in quantities indicated in the tender.
- The estimated value of the contract awarded to you is Rs.....(in word).
- Performance Security Deposit @3% will be deducted from each bill and accumulated security deposit will be refunded by PMBI to the tenderer within 60 days following the date of completion of tenderers performance obligations under the contract including the shelf-life obligation.
- Approval for Artwork should be obtained from our Quality Control department by you within 30 days of release of this letter. (e-mail id: procure13@janaushadhi.gov.in; procure12@janaushadhi.gov.in; Procure11@janaushadhi.gov.in; quality4@janaushadhi.gov.in & quality8@janaushadhi.gov.in)
- STP (Standard Testing Procedure) for Non- Pharmacopoeia awarded drugs are required to submit to Quality Control department (e-mail id: procure13@janaushadhi.gov.in; procure12@janaushadhi.gov.in; Procure11@janaushadhi.gov.in; quality4@janaushadhi.gov.in & quality8@janaushadhi.gov.in) within 15 days from the date of Letter of Acceptance

Please acknowledge receipt.

**Authorized Signatory,
For and on behalf of PMBI**

Annexure -XII
Clause 18 (F)

Pharmaceuticals & Medical Devices Bureau of India (PMBI), New Delhi
Tender for supply of drugs (Tender No. PMBI/LTD/DRUG-179/2021 dated 24.12.2021)

(1)	(2)	(3)	(4)	(5)	(6)	(7)
S.N.	Drug Code	Generic Name of Drug	Composition / Strength	Unit Size	Pack Size	Indicative Requirement in Unit Size
1	180	Bisacodyl Tablets IP 5mg	Each enteric coated tablet contains: Bisacodyl IP 5mg	10's	10's X 10	500000

Annexure – XIII

{Ref: - clause 19(K)}

For All the tendered drugs, bidder must comply the shelf life of each quoted drugs in accordance with the “Schedule - P” of Drugs and Cosmetics Rules, 1945. In case drug/medicine not covered in Schedule P of Drugs and Cosmetics Rules, 1945, the bidder must supply the drug/medicine with minimum 24 months shelf life.

Note: Bidders have to declare the required shelf-life detail in Para VI of Annexure II.

ANNEXURE- XIV
Ref. Clause No. 1(ii) C
(Shape, Colour, Packing Type etc. of drugs)

Sl. No.	Drug Code	Generic Name of Drug	Unit Size	Packing type
1	180	Bisacodyl Tablets IP 5mg	10's	Blister (Amber PVC)

Yours faithfully,

Sd/-

DGM (Procurement & Quality)
For & on behalf of PMBI
Ph: 011-49431800(811)
