Tender Ref. No.: PMBI/DRUG/RC-192/2022 **Dated: 15/03/2022**

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- 49431800/49431874/49431833/49431829/49431854**

Website: janaushadhi.gov.in

e- TENDER FOR SUPPLY OF DRUGS

TO

PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI) FOR TWO YEARS

RATE CONTRACT

LAST DATE FOR ONLINE SUBMISSION OF TENDER: 05/04/2022

PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI)

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

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

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

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

Website: janaushadhi.gov.in

e-TENDER FOR TWO YEARS RATE CONTRACT

FOR SUPPLY OF DRUGS TO PMBI

Critical Dates:

Tender Reference No.	**PMBI/DRUG/RC-192/2022**
Tender Website	https://eprocure.gov.in
Date of availability of tender documents on website	**15/03/2022 (Tuesday)**
Doubts and queries regarding Tender document should be sent by e-mail-to-e-mail ids., proc10@janausadhi.gov.in procure14@janaushadhi.gov.in proc6@janaushadhi.gov.in proc9@janausadhi.gov.in by the likely bidders latest by	**21/03/2022 (Monday) up to 17.00 Hours**
Time and date and place of pre-bid meeting	**On 22/03/2022 (Tuesday) at 11:00 AM** Pharmaceuticals & Medical Devices Bureau of India, 9th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055
Last date and time for submission of Online Bid i.e., Bid Submission End Date and time	**On 05/04/2022(Tuesday) up to 17.00 Hours**
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, 8th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055	**On 11/04/2022 (Monday) by 15.00 hours**
Time and date of opening of Technical Bid	**On 12/04/2022 (Tuesday) at 16.00 hours**
Place of opening of tender	**Pharmaceuticals & Medical Devices Bureau of India (PMBI),** 8th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055
Opening of Tender Online	On https://eprocure.gov.in

Address for Communication		**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.***

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PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI)

e-TENDER FOR RATE CONTRACT 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 BHARTRIYA JANAUSHADHI KENDRA (PMBJK). PMBI 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 – CEO, 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) for Two Years.**

PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI) was formerly known as BUREAU OF PHARMA PSUs OF INDIA (BPPI).

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/DRUG/RC-192/2022 dated 15/03/2022 for the procurement of Drugs for the year 2022-2024".** However complete hard copy of uploaded tender shall be provided by the bidder firm along-with the mandatory required documents as per clause 3 of Bid 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 150 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 Packing Type etc. of drugs should be as per **ANNEXURE XIII** (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. (a) Online Bids [in two separate Cover {Technical bid (Cover "A") and price bid (Cover "B")}] shall be submitted till 17.00 Hours Up to 05/04/2022 (Tuesday) on CPP portal i.e., https://eprocure.gov.in.

(b) Hard copy of complete required documents as Per Clause 3. Eligibility Criteria of Bid and Bid Security Declaration shall be submitted as before the specified schedule at the below mentioned address of PMBI with super scribed, **"Tender Document & Bid Security Declaration for Tender Reference No.-PMBI/DRUG/RC-192/2022 dated 15/03/2022 for the procurement of Drugs for the year 2022-2024"**

"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 must submit a BID SECURITY DECLARATION as per Annexure-III 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 three (3) years from the date of disqualification.

Note: The Micro and Small enterprises (MSEs) and the firms registered under Udyam Aadhar Registration etc. are exempted from submitting the Bid Security as per prevailing rules. However, they will have to submit the valid documentary evidence in support of MSEs/Udyam Aadhar Registration ***issued by Ministry of MSME dated 06.08.2020*** *in reference to* ***Gazette notification CG-DL-E-26062020-220190 dated 26.06.2020 and Office Memorandum no. 21(5)/2019-P&G/Policy (pv. IV)*** along 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: -

a) Minimum three years old valid Manufacturing License of the quoted product.
b) Approved product list issued along with **the latest license renewal certificate** for quoted drugs.
c) 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 & IP Addendum 2019 the 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 latest three (3) consecutive 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: *(i) If Manufacturing License for the quoted product is issued under "for export only" category will not be accepted.*

(ii) 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 ***latest three (3) consecutive years*** of quoted product issued by the concerned Licensing Authority from Drugs Control Department. Self-attested copies are to be submitted.

F) Non-Conviction Certificate (NCC) issued by the concerned Licensing 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' 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 in hard copy.

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).** In case of loan licensee average annual turnover of manufacturing unit/ Host Company 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 on **Non-Judicial Stamp Paper Dully Notarized** for eligibility in participating the tender for quoted drugs in prescribed format as per **Annexure-II**

K) Tenderers shall furnish Company's bank details as per **Annexure V** (Mandate Form) with cancelled cheque.

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 duly signed to supply the drugs as per the design in Enclosure 1 and Enclosure 2 in 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 as per 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 on non-judicial stamp paper dully notarized.**

The category of supplier against each quoted drug shall be mentioned in Annexure X in accordance with Order issued by Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals vide no. *order no. 31026/65/2020-MD dated 30.12.2020* and as per table mentioned under Clause 5.B.(d).

The declaration of local content shall be made in accordance with Order issued by Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals vide no. *order no. 31026/65/2020-MD dated 30.12.2020* in ANNEXURE-X as per table mentioned under Clause 5.B.(d).

T) If the procurement value is more than Rs. 10 crores, the Class-I Local Supplier / Class-II Local Supplier shall be required to provide a certificate from the statutory auditor or cost auditor of the company (in the case of companies) or from a practicing cost accountant or practicing chartered accountant (in respect of suppliers other than companies) giving the percentage of local content as per pt. no. 9.b of DPIIT order no. P-45021/2/2017-PP(BE-II) dated 16.09.2020 in Annexure X duly notarized on Non-judicial stamp paper at the time of award of contract.

Note: -

(i) The certificates/ reports / annexure submitted with the bid document should be self-attested by the authorized signatory of the firm with official seal.

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') are Mandatory Documents and shall be submitted online only at CPPP 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 and approval list highlighting the quoted drugs with PMBI drug code should be uploaded. In case scanned copy of license uploaded is not visible or tempered or quoted drugs are not highlighted, PMBI shall not considered the license for such drug.

vi) In case, if renewal application for Manufacturing License has been filed by the bidder or joint inspection has been carried out by the concerned Licensing Authority and for the renewal of WHO-GMP certification, Scanned copy of same duly receipted by drug authorities must be uploaded along with the validity certificate from State Licensing Authority (SLA). It shall be issued before the last date of submission of tender by the Licensing Authority.

3.1 ELIGIBILITY OF BIDDERS FROM SPECIFIED COUNTRIES:

Compliance under Rule 144 (xi) of the General Financial Rules (GFRs), 2017 and ORDER NO: F. No. 6/18/2019-PPD DATED 23/07/2020 & 24/07/2020 issued by Department of Expenditure (MoF) restricting procurement from bidders from certain countries that share a land border with India shall apply to this procurement.

I. GoI vide Order (Public Procurement No.1, 2 & 3) dated 23 Jul 2020 & 24 Jul 2020 has imposed Restrictions under Rule 144 (xi) of the General Financial Rules (GFRs), 2017 on bidders from a country which shares a land border with India.

II. "Bidder" for the purpose of this Order (Public Procurement No.1, 2 & 3) (including the term 'tenderer', 'consultant' 'vendor' or 'service provider' in certain contexts) means any person or firm or company, including any member of a consortium or joint venture (that is an association of several persons, or firms or companies), every artificial juridical person not falling in any of the descriptions of bidders stated hereinbefore, including any agency, branch or office controlled by such person, participating in a procurement process.

III. "Bidder from a country which shares a land border with India" for the purpose of this Order (Public Procurement No.1, 2 & 3) means.

a. An entity incorporated, established, or registered in such a country; or
b. A subsidiary of an entity incorporated, established, or registered in such a country; or
c. An entity substantially controlled through entities incorporated, established, or registered in such acountry; or
d. An entity whose beneficial owner is situated in such a country; or
e. An Indian (or other) agent of such an entity; or
f. A natural person who is a citizen of such a country; or
g. A consortium or joint venture where any member of the consortium or joint venture falls under any ofthe above

Note: "Beneficial owner" for the purpose of above paragraph (3) will be as under:

i. In case of a company or Limited Liability Partnership, the beneficial owner is the natural person(s), who, whether acting alone or together, or through one or more juridical person(s), has a controlling ownership interest or who exercises control through other means.

Explanation:

a) "Controlling ownership interest" means ownership of, or entitlement to, more than twenty-fiveper cent of shares or capital or profits of the company.

b) "Control" shall include the right to appoint most of the directors or to control the management or policy decisions, including by virtue of their shareholding or management rights or shareholder's agreements or voting agreements.

ii. In case of a partnership firm, the beneficial owner is the natural person(s) who, whether acting alone or together, or through one or more juridical person, has ownership of entitlement to more than fifteen percent of capital or profits of the partnership.

iii. In case of an unincorporated association or body of individuals, the beneficial owner is the natural person(s), who, whether acting alone or together, or through one or more juridical person, has ownership of or entitlement to more than fifteen percent of the property or capital or profits of such association or **body of individuals.**

iv. Where no natural person is identified under (i) or (ii) or (iii) above, the beneficial owner is the relevant natural person who holds the position of senior managing official.

v. In case of a trust, the identification of beneficial owner(s) shall include identification of the author of the trust, the trustee, the beneficiaries with fifteen percent or more interest in the trust and any other natural person exercising ultimate effective control over the trust through a chain of control or ownership.

vi. "Agent" for the purpose of this Order (Public Procurement No.1, 2 & 3) dated 23 Jul 2020 & 24 Jul 2020 isa person employed to do any act for another, or to represent another in dealings with third persons.

Rule: Following shall be complied by the Bidders of the said countries while submitting bids.

A. Any bidder from a country who shares a land border with India will be eligible to bid in this tender only if the bidder is registered with the Competent Authority. The Competent Authority for the purpose of registration under this Order shall be the Registration Committee constituted by the

Department for Promotion of Industry and Internal Trade (DPIIT). However, Order will not apply to bidders from those countries (even if sharing a land border with India) to which the Government of India has extended lines of credit or in which the Government of India is engaged in development projects. Lists of countries to which lines of credit have been extended or in which development projects are undertaken are given in the website of the Ministry of External Affairs.

B. The Bidder shall have to submit declaration / certificate as per the attached Format towards compliance of Public Order on Restrictions under Rule 144 (xi) of the General Financial Rules (GFRs), 2017. B). Further as per above the format of declaration is added as Annexure XV. It shall be furnished by the bidder(s) on duly notarized Non-Judicial Paper.

4. GENERAL CONDITIONS:

A) Tender 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 shall comply with 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 with regard to 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 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.

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) **Validity of Rate Contract: -**The rate contract will be applicable for 2(two) year from the date of issuance of LOA. The validity of contract may be extended with mutual consent for some specified period to the maximum of 1(one) year by PMBI, if necessary.

N) **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.**

O) 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 paisa 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 bidder(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* Class-I Local Supplier/ Class-II Local Supplier *based on* **Percentage (%) of minimum local content declared.**

The assessment of Class-I Local Supplier, Class-II Local Supplier or Non-Local Supplier shall be done as per below mentioned 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%

(i)Purchase preference: *The 'margin of Purchase preference' means the maximum extent to which the price quoted by the "Class-I local supplier" above the L1 (landed cost).*

*(ii) "**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 and Small Enterprises (MSE) 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 MSE and such MSE 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 Percent) quantity, a sub-target of 4% earmarked for procurement from MSEs 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 MSE to participate in tender process or meet tender requirements and L1 price, 4% sub-target shall be met from other MSE. MSEs would be treated as owned by SC/ ST entrepreneurs: a) In case of proprietary MSE, proprietor(s) shall be SC /ST b) In case of partnership MSE, 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 MSEs.

6. EARNEST MONEY DEPOSIT/ BID SECURITY DECLARATION:

A) Bidder should submit a ***Bid Security Declaration*** as per Annexure-III accepting that if they withdraw or modify their bids during the period of validity, or if they are awarded the contract and they fail to obliged/adhere the tender condition/ provision made in the bid document, they will be suspended/disqualified for the period of three (3) years from the date of disqualification.

B) The Micro and Small enterprises (MSEs) and the firms registered /Udyam Aadhar Registration etc. are exempted from submitting the Bid Security as per prevailing rules. However, bidders will have to submit the valid documentary evidence in support of MSEs/ Udyam Aadhar Registration ***issued by Ministry of MSME dated 06.08.2020*** *in reference to* ***Gazette notification CG-DL-E-26062020-220190 dated 26.06.2020 and Office Memorandum no. 21(5)/2019-P&G/Policy (pv. IV)*** along 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 150 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 website 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 on 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.

Note: Any reason *(whatsoever it may be except the Force Majeure events / condition as defined in the tender document or by the Government)* for withdrawal of bid / modification in bid / any request pertaining to have quoted wrong rates for any unit size instead of the desired unit size in tender document / BOQ shall not be considered. Bidder who are making such withdrawal request shall be penalized for alternate purchase of such drugs by PMBI besides blacklisting for a duration of not less than three (3) years as per clause no. 27 of the tender document.

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) & Annexure I (Check List) which are present on 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 in ratio of: -

"Minimum 50% of the tender quantity may be awarded to the qualified bidder(s) falling under Class I local supplier category, if qualified for award of contract and/or subject to the matching of L1 price for quoted drugs at the discretion of PMBI. PMBI would follow the guidelines and respective clauses of DPIIT order no. P-45021/2/2017-PP(BE-II) dated 16.09.2020." For Category of Class-I Local supplier & Local content refer clause no. 5.B.d

The following possible cases may be considered for the award of contract.

Case-I: If L1 is Class I local supplier, minimum 50% quantity shall be given to L1 bidder, 25% shall be given to MSEs (if comes within the price band (of L1 + 15%) & qualify) and remaining 25% shall be given to other eligible bidders (if comes within the Margin of Price Preference & qualify).

Case-II: If L1 is Class-II local supplier, as per PPE-MSE order, initially 25% shall be reserved for MSEs (if comes within the price band (of L1 + 15%) & qualify). Thereafter, preference shall be given to Class-I local supplier to award 50% of tender quantity and at last, if quantity remains balance, 25% quantity shall be given to Class-II L1 bidder following the guidelines and respective clauses of DPIIT and MSME.

C) However, in case the price quoted by the lowest responsive tenderer (L1) is not reasonable and un-acceptable, 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. To meet the demand, PMBI shall

conclude parallel rate contract by counter offering the L1 rate to higher eligible bidders as per above provision.

D) Negotiation if required will be done strictly as per Central Vigilance Commission guidelines.

E) Letter of acceptance of tenders for Rate Contract will be communicated to the Tenderers in writing as per **ANNEXURE XI.**

F) Purchase preference: The margin of Purchase preference shall be 20%.

16. AWARD OF CONTRACT:

A) The contract will be awarded to the lowest evaluated responsive bidder qualifying to the final round after Technical 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.

"Minimum 50% of the tender quantity may be awarded to the qualified bidder(s) falling under Class I local supplier category, if qualified for award of contract and/or subject to the matching of L1 price for quoted drugs at the discretion of PMBI. PMBI would follow the guidelines and respective clauses of DPIIT order no. P-45021/2/2017-PP(BE-II) dated 16.09.2020" **as mentioned in clause 15 (B).**

B) **Letter of Acceptance:**

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.

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 for Rate Contract, 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.

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.

A) **PMBI reserves right to issue purchase order for any drug on any one rate contract holder or more than one rate contract holder for same drugs**.

B) If two or more than two Tenderer(s) are declared as lowest suppliers for the same item(s), such Tenderers are eligible for Rate Contract and 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) 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) A purchase order is placed on supplier for supply of definite quantity in terms of Rate Contract during validity period of Rate Contract that purchase order is valid and binding contract.

F) No Minimum drawl is in the Rate Contract. The actual quantity may vary from nil to maximum required quantity during validity of Rate Contract.

G) 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.

H) The purchaser reserves the right to conclude one or more than one rate contract for the same item.

I) The purchaser has the option to renegotiate the price with the rate contract holders. In case of emergency, the purchaser may purchase the same item through Ad hoc contract with a new supplier.

J) Purchase orders, incorporating definite quantity of drugs/products to be supplied along with all other required conditions following the rate contract terms, shall be issued for obtaining supplies through the rate contract.

K) The purchaser is entitled to place purchase orders up to the last day of the validity of the rate contract and, though supplies against such purchase orders will be affected beyond the validity period of the rate contract, all such supplies will be guided by the terms & conditions of the rate contract.

L) 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 it is actual need**. Though the tentative quantity is indicated in the Rate Contract, the PMBI, will confirm the actual requirement through purchase order/orders from time to time. The tenderers shall supply the drugs only on the basis of the purchase order issued time to time within validity of Rate contract period by the PMBI. 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.

M) 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 the acceptance of tender for Rate Contract.

N) The rates quoted shall not be varied with the Purchase order quantity during the full contract period.

O) The rates quoted and accepted will be binding on the Tenderer for the full contract period of two years and any increase in the price will not be entertained till the completion of this contract period. Accordingly, this clause will be applicable for all orders placed during the contract period. However, Rate Contract validity period may be extended for period up to further one year at same rate, terms & conditions with the consent of the supplier.

P) 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.

Q) Supplies should be made directly by the tenderer and not through any other Agency / Dealer / Distributors.

R) 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.

S) "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.

T) The Rate Contract (RC) awarded under the present tender enquiry will be in the nature of standing offer. Purchase Order (PO) may be placed from time to time against Rate Contract (RC).

U) **FALL CLAUSE:**

If at any time during the execution of the contract, the controlled price becomes lower or the supplier reduces the sale price or sells or offers to sell such stores, as are covered under the contract, to any person / organization including the purchaser or any department of Central government/state Govt. or its procurement agencies at a price lower than the price chargeable under the contract, he shall forthwith notify such reduction or sale or offer of sale to the purchaser and the price payable under the contract for the stores supplied after the date of coming into force of such reduction or sale or offer of sale shall stand correspondingly reduced

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/mail about the confirmation for the receipt of the purchase order or queries (if any).

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 and customercare1@janaushadhi.gov.in.The supplier must supply the ordered quantity by abiding to the following delivery schedule or as mentioned on purchase orders:

Sl. No.	Nature of Product	Delivery Schedule (Days)
1	Delivery Schedule against first P.O. for injectable/Infusion/Vials (Products required sterility testing)	60 days
2	Delivery Schedule against subsequent P.O. for Injectable/Infusion/Vials (Products required sterility testing)	45 days
3	Delivery Schedule against first P.O. for all drugs except Injectable/Infusion/Vials (Products do not required sterility testing)	45 days
4	Delivery Schedule against subsequent P.O. for all drugs except Injectable/Infusion/Vials (Products do not required sterility testing)	45 days
5	For biological products	60 days
6	Vaccines and Blood products	120 Days

D) 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.

E) 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.

F) 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/Bank Guarantee/Performance security deposit and their bad performance shall be kept in record of PMBI for future dealing as considered appropriate by PMBI.

G) 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.

H) 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.**

I) 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.

J) Bidder must comply to the shelf life of each quoted drugs in accordance with 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. Bidders must declare the required shelf-life detail in Para VI of Annexure II**.

K) 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 suppliers, 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.

L) 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 November 2021 must be supplied by 31st January 2022 in case shelf life up to 2 Years.

M) 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.

N) 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.

O) 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.

P) Leaked, soiled, broken containers with damaged labels shall not be accepted.

Q) 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.

R) 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 as per **Enclosure 1 to ANNEXURE –VII** and **Enclosure 2 to ANNEXURE –VII.**

B) All dosage form has to be supplied in packing as specified in product list (**ANNEXURE XIII**) 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 terms of Rate Contract / 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, ANNEXURE -XII and ANNEXURE-XIII** and the package shall carry the logograms of proportionate size specified in 1 to **ANNEXURE –VII & 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 shall be provided with PMBI logogram as per provided design under clause 3. (h) of Enclosure- 2 to Annexure– VII, Ref. Clause No. 3(M) & 20. The cap/packing of bottle /preparations should not carry the name/logo/other details of the supplier.

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 & 27 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 conform 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)** with cancelled cheque 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 of 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. LIQIDATED 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.19.F, 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 for shelf-life losses @ 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.E 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

a) 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.

b) 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 **3 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.

(iv) 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(D) besides forfeiture of Performance Security Deposit.

(v) 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.**

F) 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)

G) 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.

H) 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:

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.

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 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.

B) In case of a complaint received from any local supplier indicating a need for review / verification of Local content of successful vendor / awarded vendor, for accepting a complaint from such complainant (w.r.t the false declaration given by the successful vendor on the local content), a complaint fee of Rs.2 Lakhs or 1% of the locally manufactured items being procured (subject to a maximum Rs.5 Lakhs), whichever was higher, to be paid by demand draft by the complainant. In case, the complaint is found to be incorrect, the complaint fee shall be forfeited. In case, the complaint is upheld and found to be substantially correct, deposited fee of the complainant would be refunded without any interest.

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.

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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	MSE certificate/ Udyam Registration Certificate (If claimed to be under MSE category) 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 of quoted product for 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) certificate as per revised Schedule- 'M' 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 from Drug Control Department/FDA highlighting the quoted product section as per Clause no. 3.H			
12	ANNEXURE IV {certificate from the C.A. (Chartered Accountant) or Company Secretary. **Original Annexure IV delivered to PMBI as per clause 3. I.**			
13	Copy of Audited Annual Balance sheet and Profit and loss statement showing details of their annual turnover not less than 25 crores for any three of the last four consecutive financial years as per Clause 3. I.			
14	ANNEXURE-V **(Mandate form)** with cancelled cheque to furnish company bank details as per clause 3 (K) & 23(B)			
15	ANNEXURE-VI indicating manufacturing License, validity of license and market standing certificate details as per clause 3. L.			
16	ANNEXURE-VII (Declaration to supply the drugs as per the design in enclosure 1 and enclosure 2 in Annexure VII) as per clause 3(M), 20 & 21.			
17	Self-attested copy of PAN Card of the Bidder Company. As per Clause 3(O).			
18	Self-attested copy of Certificate of valid GST registration of the bidder company. As per Clause 3(P).			

19	Self-attested copy of Income Tax Return for any three of last four consecutive Assessment years. As per Clause 3(Q).			
20	Copy of valid GS-1 registration certificate for bar coding as per Clause 3. R.			
21	ANNEXURE-X (Declaration of Local Content as per clause no. 3(S) & 5(B)(d)			
22	Authorization letter nominating an employee of the tenderer to transact the business with the Tender Inviting Authority as per clause 4(O)			
23	Annexure XV (Clause No. 3.(1) Declaration towards Compliance of Order (Public Procurement No.1, 2 & 3) dated 23 Jul 2020& 24 Jul 2020 under Rule 144 (xi) of the General Financial Rules (GFRs), 2017 on Non-Judicial Paper duly notarized.			

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

Name of authorized signatory: ……..

Signature of authorized signatory with date: …….

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 at …….....and its factory premises at……..……..…… ……do hereby declare as under: -

(I) that I/we have carefully read all the terms and conditions of tender in ref. no**. PMBI/DRUG/RC-192/2022 dated 15/03/2022** 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) valid non conviction certificate not older than 12 months,(e) 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 (f) 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.

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.)

C. **that I/we shall supply the drugs as per the specification, composition, pack size given in ANNEXURE-XII, design, logo as given in ANNEXURE-VII & VIII and Color, Packing Type, etc. of drugs as given in ANNEXURE-XIII.**

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 Performance Security Deposit/Bank guarantee (if any) against tender no. **PMBI/DRUG/RC-192/2022 dated 15/03/2022** along with other action including 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 lied in schedule M of Drug & cosmetic act, 1940 the rules there under 1945.

C. I/We declare that the information of local content provided in Annexure X is correct.

I am / We are aware of the Tender inviting Authority's right to forfeit the Performance Security Deposit/impose penalty and suspending/disqualifying/blacklist me/us/our firm for a period of five (5) years

if, any information furnished by us proved to be false at the time 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/DRUG/RC-192/2022 dated 15/03/2022** for the following quoted products with mentioned shelf life as per clause 19.K: -

(1)	(2)	(3)	(4)	(5)
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.**

(VII) that I/we have quoted the rates in BOQ for above mentioned drug codes (table under para VI) in my/our full consciousness abiding by the terms and condition laid down in the tender document considering unit size, secondary pack, shelf life, packaging type etc. and declare it to be invariable.

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.: PMBI/DRUG/RC-192/2022

To:

The Chief Executive Officer (CEO)
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

I/We……., the undersigned on behalf of M/s……, 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 partnership firm, the **Bid Security Declaration** must be in the name of all partners of the firm that submits the bid.*
(ii) Only PSUs are exempted from the submission of Bid Security Declaration.
(iii) To be attested by Notary.

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 Limited/Limited/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/S ……is 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/DRUG/RC-192/2022** and eligible for exemption of submission of Bid Security Declaration.

(V) This MSEs is owned by Scheduled Caste (SC)/Scheduled Tribe (ST)/ Women entrepreneurs.

(VII)They are manufactured & marketed at least two (2) or more commercial batches of each quoted items in last three years.

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

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

ANNEXURE-V

Ref. clause 3 (K) & 23. (B)

MANDATE FORM

Sl. No.	Details Required	Information to be filled for correspondence
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.	Name and Designation of the company official Authorised for communication in respect of technical documents.	Name:
		Designation:
	Mobile No.	
	E-mail ID	
6	Name and Designation of the company official Authorised for communication in respect of status of Purchase Orders/artwork.	Name:
		Designation:
	Mobile No.	
	E-mail ID	
6.	**For Vendor Portal Registration**	
	Permanent E-mail ID	
	Permanent Mobile No.	
7.	**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: Signature :

Name :

Designation:

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

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

Signature of the authorized official of the bank

Bank Seal with address:

Annexure-VI

Ref. Clause No. 3 (L)

Date:

S. N.	Drug Code (Only Quoted Drugs as mentioned in Annexure II)	Drug Specification (As per Tender Specification)	Unit Size	Drug Manufacturing License *(Bidder must highlight the indicated drug codes with highlighter on reference page no.)*					Marketing standing Certificate (MSC) *(For latest three years)*		
				Drug Manufacturing License No.	License Issue date (first approval)	License Renewal Date (latest)	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 drug, the bid for such drug are liable to be rejected.

(ii) It is directed to not put page nos. in range and should indicate the page nos. one by one for all respective quoted drug codes.

Signed.....

Name: ……..

Designation…….…….

(Company Seal)

ANNEXURE -VII

Ref. Clause no. 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. 3(M) & 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 ARTWORK 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" 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. 3(M) & 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" should be running text only and should not be prominent.

Manufactured for:

प्रधानमंत्री भारतीय जन औषधि परियोजना

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

2. Ampoules or Vials less than 5 ml for primary packing

a. 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**.
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.
b) Title name of generic medicine should be minimum 12 font sizes and it may increase respectively according to size of label.
c) "Pharmaceuticals & Medical Devices Bureau of India" should be running text only and should not be prominent.

Manufactured for:

प्रधानमंत्री भारतीय जन औषधि परियोजना

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

3. LIQUID:

d) Liquid preparation should be supply with pilfer proof ROPP cap.
e) Bottle cap should not bear the manufacturer's logogram.
f) 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:
g) PMBI helpline number 1800 180 8080 should be printed.
h) "Pharmaceuticals & Medical Devices Bureau of India" should be running text only and should not be prominent.

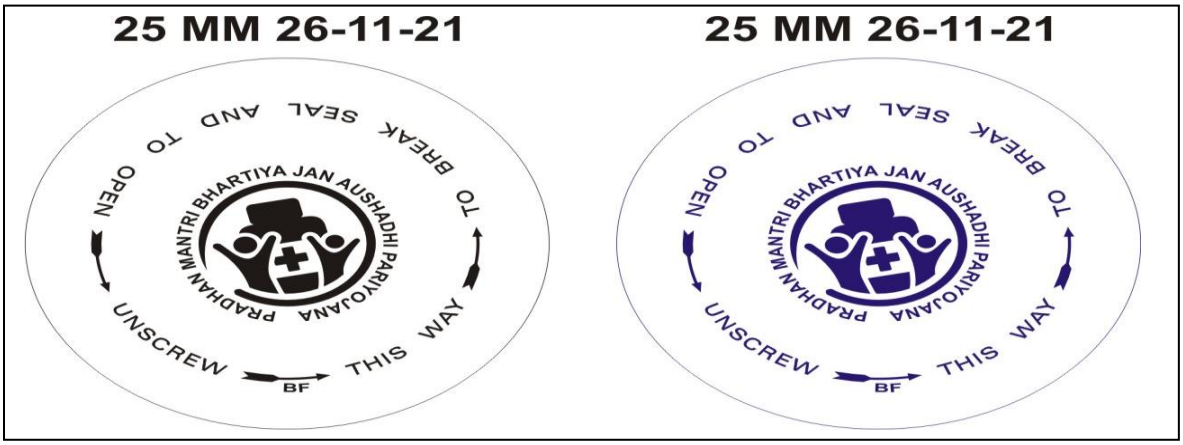
i) Font type should in CALIBIRI format for any type of title name of generic medicines
j) Title name of generic medicine should be minimum 12 font sizes and it may increase respectively according to size of label.

Manufactured for:

प्रधानमंत्री भारतीय जन औषधि परियोजना

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

k) Cap on bottle/jar type of packing shall contain printed logogram as per below design provided the direction to unscrew the seal.



4.. 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 ARTWORK approval before supply** as below:

Manufactured for:

प्रधानमंत्री भारतीय जन औषधि परियोजना

Pharmaceuticals & Medical Devices Bureau of India
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" 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

SCHEDULE FOR PACKAGING OF DRUGS

GENERAL SPECIFICATIONS

1. Strips of Aluminum foils should be 0.07 mm thickness and grammage of foil minimum 80 g/m^2, LDPE minimum 35 g/m^2 and total GSM not less than 110 g/m^2.
2. Aluminum foils back material for blisters should be minimum 0.025 mm thickness, grammage of foil minimum 75 g/m^2 and tensile strength minimum 400 Kg/cm^2.
3. The rigid PVC used in blister packing should be of not less than 250 microns (thickness) and grammage minimum 350 g/m^2.
4. ALU-ALU blisters, total grammage minimum 250 g/m^2, total minimum thickness 130 microns, and bursting strength minimum 15 Kg/cm^2.
5. Pin hole should be nil, and toxicity should be complied 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 colors 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 to14.0 Kg	7		
4	Ointment/gel/cream	Not more than 12.0 Kg	7		
5	Injection (vial, respules and ampules)	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 ampules 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.
e) Bidders shall strictly follow the Packaging guideline to ensure its easy handling and stability of packaging as per tender guideline and Schedule P of the Drugs & Cosmetics Act 1940 and Rules there under 1945.

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.

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-

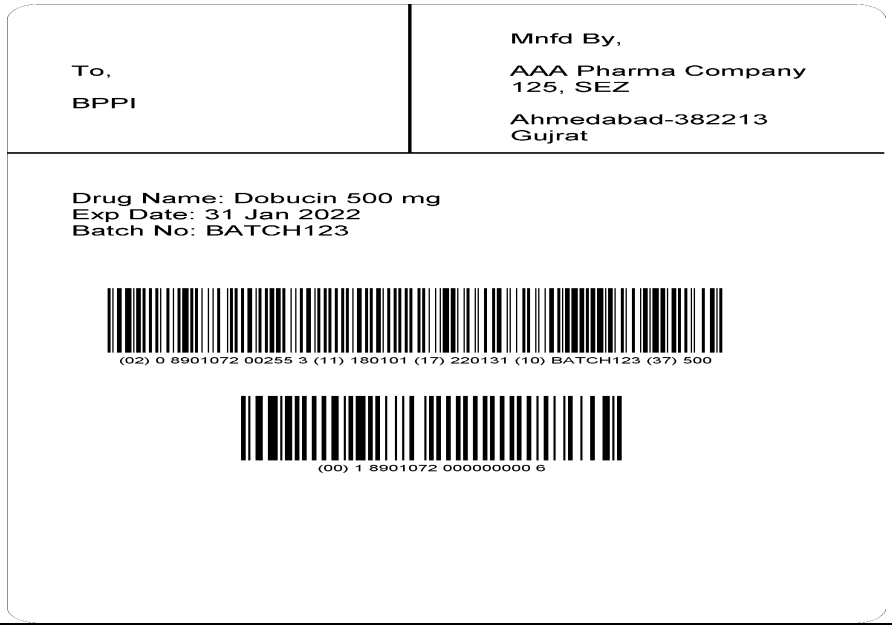
1) *While encoding Manufacturing and expiry date in the barcode, if a specific Manufacturing or expiry date is not printed on the finished pack/drug then Supplier should select first day of the month as the Manufacturing date and Last day of the month as expiry date.*

   Example- If Shelf life is 24 months, April 2019 manufacturing date should be encoded as 190401 and March 2022 expiry date as 210331.

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				

Secondary Level Pack:

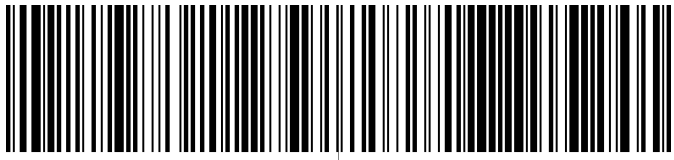
Is defined as a level of packaging that may contain one or more primary packages usually termed as Mono-carton/carton

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 Datamatrix,	(01) 0 8901072 00255 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 or Ms. Neha Sawakhande for the same at 011-42890846/42890818 or write email at ankit@gs1india.org or amrit@gs1india.org or implwest@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
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F +91-11-26168730
E ankit@gs1india.org
W http://www.gs1india.org

ANNEXURE-X

(On nonjudicial Stamp Paper)

(Refer 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. 31026/65/2020-MD policy dated 30.12.2020 and DPIIT order no. P-45021/2/2017-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 drugs/medicines are done in accordance with the guidelines laid down in Para 6 of Department of Pharmaceuticals order vide F. No. 31026/4/2018- policy dated 01.01.2019 and that I found our firm under Class …… local supplier for the quoted drugs/medicines.

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)

(To be furnished by person in capacity as per para 1)

Note: The category of supplier against each quoted drug shall be mentioned in accordance with Order issued by Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals vide no. *order no. 31026/65/2020-MD dated 30.12.2020* and as per table mentioned under Clause 5.B.(d).

ANNEXURE-XI

Ref. clause no. 15.E

Letter of acceptance (LoA) of tender for Rate Contract

Speed post/e-mail

Ref. No. PMBI/DRUG/RC-192/2022 **Date: …….**

To,

M/S_____

_____

Sub: Tender for the Supply of Drugs and Medicines to PMBI for two years: Acceptance tender for Rate Contract.

Ref: Your quotation against PMBI e-Tender No. PMBI/DRUG/RC-192/2022 dated: 15/03/2022 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

2. The contract will be with financial limit and PMBI can place the Purchase Order with unlimited variation in quantities indicated in the tender.
3. The estimated value of the contract awarded to you is Rs.....(in word).
4. 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.
5. 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, quality4@janaushadhi.gov.in & quality8@janaushadhi.gov.in)
6. 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, quality4@janaushadhi.gov.in & quality8@janaushadhi.gov.in) within 15 days from the date of Letter of Acceptance
7. As per clause 4.M of Tender document, the Rate Contract validity period may be extended for period up to further one year at same rate, terms & conditions with the consent of the supplier.
8. The terms and conditions of Rate Contract shall be applicable as mentioned in tender document. By issue of this acceptance letter, the Rate Contract is hereby concluded.

Please acknowledge receipt.

Authorized Signatory,
For and on behalf of PMBI

Annexure -XII
Clause 18 (M)

Pharmaceuticals & Medical Devices Bureau of India, New Delhi
Tender for supply of drugs (Tender No. PMBI/DRUG/RC-192/2022 dated-15/03/2022)

(1)	(2)	(3)	(4)	(5)	(6)	(7)
Sr. No.	**Item No.**	**Generic name of the Drug**	**Detailed specification**	**Unit Size**	**Pack size**	**Indicative Requirement in Unit Size**
1	1851	Thyroxine Sodium Tablets IP 25mcg	Each Uncoated tablet Contains: Thyroxine Sodium IP Equivalent to anhydrous Thyroxine Sodium 25 mcg	100's Bottle	1's Bottle X 10	3000000
2	1852	Thyroxine Sodium Tablets IP 75mcg	Each Uncoated tablet Contains: Thyroxine Sodium IP Equivalent to anhydrous Thyroxine Sodium 75 mcg	100's Bottle	1's Bottle X 10	3000000
3	1856	Disodium Hydrogen Citrate Syrup 1.53gm per 5ml	Each 5 ml contains: Disodium Hydrogen Citrate 1.53 gm	100ml Bottle	100 ml X 10	300000
4	1857	Citric Acid 334mg and Potassium Citrate 1100mg Syrup per 5ml	Each 5 ml contains: Citric Acid Monohydrate IP 334 mg Potassium Citrate IP 1100mg In flavoured palatable base qs.	200ml Bottle	200 ml X 10	300000
5	1858	Darifenacin Prolonged Release Tablets IP 7.5mg	Each Prolonged Release Tablets Contains: Darifenacin Hydrochloride IP equivalent to Darifenacin 7.5 mg	10's	10's X 10	1500000
6	1869	Solifenacin Succinate Tablets IP 5 mg	Each Film Coated Tablet Contains: Solifenacin Succinate IP 5 mg	10's	10's X 10	300000
7	1870	Solifenacin Succinate Tablets IP 10 mg	Each Film Coated Tablet Contains: Solifenacin Succinate IP 10 mg	10's	10's X 10	1500000
8	1877	Brinzolamide Ophthalmic Suspension IP 1% w/v	Each ml contains: Brinzolamide IP 1% w/v Benzalkonium Chloride Solution IP 0.02% w/v (As preservative)	5ml Drops	5ml Drops X 20	360000
9	1878	Bromfenac 0.09% w/v and Moxifloxacin 0.5% w/v Eye Drops	Compositions: Bromfenac Sodium equivalent to Bromfenac 0.09 % w/v Moxifloxacin Hydrochloride IP equivalent to Moxifloxacin 0.5 % w/v Benzalkonium Chloride Solution IP 0.02% w/v (As preservative)	5ml Drops	5ml Drops X 20	360000
10	1880	Epalrestat Tablets 50 mg	Each Film coated Tablet Contains: Epalrestat 50 mg	10's	10's X 10	2000000

11	1881	Gatifloxacin 0.3% w/v and Dexamethasone 0.1% w/v Eye Drops	Each ml contains: Gatifloxacin 0.3 % w/v Dexamethasone 0.1% w/v (As Dexamethasone Sodium Phosphate IP) Benzalkonium Chloride Solution IP 0.01% w/v (As preservative)	3ml Drops	3ml Drops X 20	360000
12	1882	Gatifloxacin 0.3 % w/v and Prednisolone 1% w/v Eye Drops	Each ml contains: Gatifloxacin 0.3 % w/v Prednisolone Acetate IP 1% w/v	10ml Drops	10ml Drops X 10	360000
13	1883	Gentamicin 0.3% w/v and Dexamethasone 0.1% w/v Eye Drops	Each ml contains: Gentamicin 0.3 % w/v (As Gentamicin Sulphate IP) Dexamethasone 0.1% w/v (As Dexamethasone Sodium Phosphate IP) Benzalkonium Chloride Solution IP 0.01% w/v (As preservative)	10ml Drops	10ml Drops X 10	360000
14	1885	Sodium Hyaluronate Eye Drops 0.1% w/v	Compositions: Sodium Hyaluronate 0.1 % w/v	5ml Drops	5ml Drops X 20	360000
15	1886	Levofloxacin Eye Drops 0.5 % w/v	Compositions: Levofloxacin Hemihydrate IP equivalent to Levofloxacin 0.5 % w/v Benzalkonium Chloride Solution IP 0.02% w/v (As preservative)	5ml Drops	5ml Drops X 20	360000
16	1891	Artesunate 100 mg and Mefloquine Hydrochloride 200 mg Tablets	Each Film coated tablet Contains: Artesunate IP 100 mg Mefloquine Hydrochloride IP 220 mg equivalent to Mefloquine 200 mg	6's	6's X 10	1000000
17	1893	Primaquine Phosphate Tablets IP 7.5 mg	Each Film coated tablet Contains: Primaquine Phosphate IP equivalent to Primaquine 7.5 mg	10's	10's X 10	500000
18	1894	Primaquine Phosphate Tablets IP 2.5 mg	Each Film coated tablet Contains: Primaquine Phosphate IP equivalent to Primaquine 2.5 mg	10's	10's X 10	500000
19	1895	Pyrimethamine 12.5mg and Sulphadoxine 250mg Suspension	Each ml contains: Pyrimethamine IP 12.5 mg Sulphadoxine IP 250 mg	10ml	10ml X 10	700000
20	1896	Pyrimethamine 25mg and Sulphadoxine 500mg Tablets IP	Each uncoated tablet contains: Pyrimethamine IP 25 mg Sulphadoxine IP 500 mg	2's	2's X 10	2000000
21	1897	Quinine Sulphate Tablets IP 600 mg	Each Film coated tablet Contains: Quinine Sulphate IP 600 mg	10's	10's X 10	200000

22	1901	Alprazolam 0.5mg and Sertraline Hydrochloride 25mg Tablets	Each uncoated tablet contains: Alprazolam IP 0.5 mg Sertraline Hydrochloride IP equivalent to Sertraline 25 mg	10's	10's X 10	1000000
23	1902	Alprazolam 0.5mg and Sertraline Hydrochloride 50mg Tablets	Each uncoated tablet contains: Alprazolam IP 0.5 mg Sertraline Hydrochloride IP equivalent to Sertraline 50 mg	10's	10's X 10	1000000
24	1907	Amitriptyline Hydrochloride Tablets IP 5 mg	Each Film Coated Tablet Contains: Amitriptyline Hydrochloride IP 5 mg	10's	10's X 10	1000000
25	1909	Amoxapine Tablets IP 50mg	Each uncoated tablet contains: Amoxapine IP 50 mg	10's	10's X 10	1000000
26	1900	Amoxapine Tablets IP 100mg	Each uncoated tablet contains: Amoxapine IP 50 mg	10's	10's X 10	500000
27	1901	Aripiprazole Tablets IP 2.5 mg	Each uncoated tablet contains: Aripiprazole IP 2.5 mg	10's	10's X 10	500000
28	1905	Aripiprazole Tablets IP 7.5 mg	Each uncoated tablet contains: Aripiprazole IP 7.5 mg	10's	10's X 10	500000
29	1906	Aripiprazole Tablets IP 30 mg	Each uncoated tablet contains: Aripiprazole IP 30 mg	10's	10's X 10	500000
30	1907	Asenapine Sublingual Tablets 5mg	Each Sublingual tablet Contains: Asenapine Maleate IP equivalent to Asenapine 5 mg	10's	10's X 10	500000
31	1908	Asenapine Sublingual Tablets 10mg	Each Sublingual tablet Contains: Asenapine Maleate IP equivalent to Asenapine 10 mg	10's	10's X 10	500000
32	1924	Chlorpromazine Tablets IP 25 mg	Each Film Coated Tablet Contains: Chlorpromazine Hydrochloride IP 25 mg	10's	10's X 10	500000
33	1925	Chlorpromazine 50mg and Trihexyphenidyl 2mg Tablets	Each Film Coated Tablet Contains: Chlorpromazine Hydrochloride IP 50 mg Trihexyphenidyl Hydrochloride IP 2 mg	10's	10's X 10	500000
34	1926	Chlorpromazine 50mg, Trihexyphenidyl 2mg and Trifluoperazine 5mg Tablets	Each Film Coated Tablet Contains: Chlorpromazine Hydrochloride IP 50 mg Trihexyphenidyl Hydrochloride IP 2 mg Trifluoperazine Hydrochloride IP equivalent to Trifluoperazine 5 mg	10's	10's X 10	500000

35	1928	Citalopram Tablets IP 20mg	Each Film Coated Tablet Contains: Citalopram Hydrochloride IP equivalent to Citalopram 20 mg	10's	10's X 10	500000
36	1929	Citalopram Tablets IP 40mg	Each Film Coated Tablet Contains: Citalopram Hydrochloride IP equivalent to Citalopram 40 mg	10's	10's X 10	500000
37	1932	Clomipramine Hydrochloride Tablets 10mg	Each Film Coated Tablet Contains: Clomipramine Hydrochloride IP 10 mg	10's	10's X 10	500000
38	1933	Clomipramine Hydrochloride Tablets 25mg	Each Film Coated Tablet Contains: Clomipramine Hydrochloride IP 25 mg	10's	10's X 10	500000
39	1934	Clomipramine Hydrochloride Tablets 50mg	Each Film Coated Tablet Contains: Clomipramine Hydrochloride IP 50 mg	10's	10's X 10	500000
40	1936	Clozapine Tablets IP 50 mg	Each uncoated tablet Contains: Clozapine IP 50 mg	10's	10's X 10	500000
41	1937	Clozapine Tablets IP 100 mg	Each uncoated tablet Contains: Clozapine IP 100 mg	10's	10's X 10	500000
42	1939	Diazepam Tablets IP 10 mg	Each uncoated tablet Contains: Diazepam IP 10 mg	10's	10's X 10	700000
43	1941	Doxepin Capsules IP 25mg	Each Hard Gelatin Capsule Contains: Doxepine Hydrochloride IP equivalent to Doxepine 25 mg	10's	10's X 10	300000
44	1942	Doxepin Capsules IP 75mg	Each Hard Gelatin Capsule Contains: Doxepine Hydrochloride IP equivalent to Doxepine 75 mg	10's	10's X 10	300000
45	1944	Escitalopram Tablets IP 5 mg	Each Film Coated Tablet Contains: Escitalopram Oxalate IP equivalent to Escitalopram 5 mg	10's	10's X 10	700000
46	1946	Lamotrigine Dispersible Tablets IP 25mg	Each Dispersible uncoated tablet Contains: Lamotrigine IP 25 mg	10's	10's X 10	700000
47	1947	Lamotrigine Dispersible Tablets IP 50mg	Each Dispersible uncoated tablet Contains: Lamotrigine IP 50 mg	10's	10's X 10	700000
48	1955	Paroxetine Extended Release 12.5mg and Clonazepam 0.25mg Capsules	Each hard gelatin capsule contains: Paroxetine Hydrochloride 12.5 mg (Extended Release) Clonazepam 0.25 mg	10's	10's X 10	500000
49	1956	Risperidone Orally Disintegrating Tablet 0.5mg	Each uncoated tablet Contains: Risperidone USP 0.5 mg	10's	10's X 10	1500000

50	1960	Aloe Vera 10% W/W and Vitamin E 1% W/W Moisturizing Cream	Composition: Aloe Vera 10% W/W Vitamin E 1% W/W	60gm Tube	60gm Tube X 10	1000000
51	1964	Biphasic Insulin Lispro Injection IP 100IU per ml (25:75)	Each ml contains: Biphasic Insulin Lispro 100 IU Insulin Lispro IP (25%) Insulin Lispro Protamine (75%)	3ml Pre-Filled Cartridge	3ml Pre-filled Cartridge e X 5	1000000
52	1965	Insulin Aspart Injection IP 100IU per ml	Each ml solution contains: Insulin Aspart (rDNA) 100IU (Eqv. to 3.5mg)	10ml Vial	1's X 10	1000000
53	1969	Repaglinide 1mg and Metformin Hydrochloride (Sustained release) 500mg Tablets IP	Each uncoated tablets contains: Repaglinide 1mg Metformin hydrochloride IP (as sustained release form) 500mg	10's	10's X 10	2000000
54	1970	Repaglinide 2mg and Metformin Hydrochloride (Sustained release) 500mg Tablets IP	Each uncoated tablets contains: Repaglinide 2mg Metformin hydrochloride IP (as sustained release form) 500mg	10's	10's X 10	2000000
55	1973	Amoxycillin 200Mg , Clavulanic Acid 28.5Mg And Lactic Acid Bacillus 30 Million Spore Dry syrup	Each 5ml re-constituted Suspension Contains: Amoxycillin Trihydrate IP equivalent to Anhydrous Amoxycillin 200mg Potassium Clavulanate equivalent to Clavulanic Acid 28.5mg Lactic Acid Bacillus 30 Million Spore	30ml	30 ml X 10	500000
56	1974	Amoxycillin 250mg, Cloxacillin 250mg And Lactic Acid Bacillus 100 Million Spore Tablets	Each film coated tablet Contains: Amoxycillin Trihydrate IP equivalent to Anhydrous Amoxycillin 250mg Cloxacillin Sodium IP equivalent to Cloxacillin 250mg Lactic Acid Bacillus 100 million Spore	6's	6's X 10	2000000
57	1975	Amoxycillin 125Mg, Cloxacillin 125Mg And Lactic Acid Bacillus 60 Million Spore Tablets	Each film coated tablet Contains: Amoxycillin Trihydrate IP equivalent to Anhydrous Amoxycillin 250mg Cloxacillin Sodium IP equivalent to Cloxacillin 250mg Lactic Acid Bacillus 100 Million Spore	10's	10's X 10	2000000
58	1979	Cefdinir Oral Suspension IP 125mg per 5ml	Each 5ml Re-constituted Suspension Contains: Cefdinir IP 125mg	30ml with Water for Reconstitution	30ml with Water for Reconstitute X 10	300000
59	1992	Bacitracin 400 IU, Neomycin 3400 IU and Polymyxin B 5000 IU Ophthalmic Ointment	Each gram contains: Bacitracin Zinc IP equivalent to Bacitracin 400IU Neomycin Sulphate equivalent to Neomycin 3400 IU Polymyxin B Sulphate equivalent to Polymyxin B 5000IU	10gm Tube	10 gm Tube X 10	700000

60	1993	Glycolic Acid 1% w/w and Aloe Vera 5% w/w Face Wash	Composition: Glycolic Acid 1% W/W Aloe Vera 5% W/W	100gm Tube	100gm Tube X 10	1000000
61	1994	Glycolic Acid 1% w/w, Aloe Vera 5% w/w and Salicylic Acid 2% w/w Facewash	Composition: Glycolic Acid 1% W/W, Aloe Vera 5% W/W Salicylic Acid 2% W/W	60ml Flip top Lemitube	60ml tube X 20	1000000
62	1995	Selenium Sulphide Shampoo 1% w/w	Composition: Selenium Sulphide 1% W/W	60ml Flip top Jar	60ml Flip top Lemitube X 20	1500000
63	1999	Carboprost Injection 125mcg	Each 0.5ml Contains: Carboprost 125 mcg (as Carboprost Tromethamine IP)	0.5ml Ampoule	0.5ml Ampoule X 10	500000
64	2001	Ethinyl Estradiol 15Mcg And Gestodene 60 mcg Tablet	Each cycle pack consists of: 24 Pink active tablets of: Each Uncoated Tablet contains: Ethinyl Estradiol 15mcg Gestodene 60 mcg 4 white inactive Tablets: Each uncoated tablet contains: Lactose IP 45 mg	28's Monopack	28's Monopack X 10	1000000
65	2011	Racecadotril Sachet IP 15mg	Each Sachet contains: Racecadotril IP 15mg	1gm Sachet	1gm Sachet X 10	500000
66	2013	Rabeprazole 10mg, Chlordiazepoxide 5mg, Dicyclomine 10mg and Clidinium 2.5 mg Capsule	Each Hard Gelatin Capsule contains: Rabeprazole Sodium IP 10mg (As enteric Coated) As Film Coated Chlordiazepoxide 5mg Clidinium 2.5 mg As powder form Dicyclomine Hydrochloride 10mg	10's	10's X 10	700000
67	2014	Daclatasvir Tablets 60 mg	Each Film coated Tablet contains: Daclatasvir Dihydrochloride equivalent to Daclatasvir 60 Mg	28's Bottle	1's Bottle X 10	200000
68	2016	Minoxidil Tablets IP 10mg	Each Uncoated Tablet contains: Minoxidil IP 10mg	10's	10's X 10	300000
69	2017	Ulipristal Acetate Tablets 5mg	Each Film coated Tablet Contains: Ulipristal Acetate 5mg	10's	10's X 10	300000
70	2018	Mesalazine Prolonged release Tablets IP 500mg	Each uncoated prolonged-release tablet contains: Mesalazine IP 500mg	10's	10's X 10	700000
71	2019	Metformin Hydrochloride 1000mg (Prolonged release) and Glimepiride 3mg Tablets IP	Each Film coated bilayered Tablet contains: Glimepiride 3 mg Metformin Hydrochloride 1000 mg (As Prolonged-release form)	10's	10's X 10	1000000
72	2020	Desmopressin Tablets 0.1 mg	Each Tablet contains: Desmopressin Acetate 0.1 mg	15's in bottle	1's Bottle X 10	500000

73	2021	Teriparatide Injection 750 mcg per 3 ml	Each ml (r-Human Parathyroid hormone Injection) contains: Recombinant Human Parathyroid hormone 250mg.	3ml Cartridge	3ml Cartridge X 5	500000
74	2024	Ropinirole Tablets IP 4 mg	Each Film coated tablet Contains: Ropinirole Hydrochloride equivalent to Ropinirole 4 mg	10's	10's X 10	700000
75	2027	Mesalazine Delayed release Tablets 800 mg	Each Uncoated delayed release tablet contains: Mesalazine 800mg	10's	10's X 10	500000
76	2031	Sofosbuvir 400mg and Velpatasvir 100mg Tablets	Each Film coated Tablet Contains: Sofosbuvir 400mg Velpatasvir 100mg	28's Bottle	1's Bottle X 10	1000000
77	2032	Atazanavir 300mg and Ritonavir 100mg Tablets	Each Film coated Tablet Contains: Atazanavir Sulphate IP equivalent to Atazanavir 300mg Ritonavir 100mg	30's Bottle	1's Bottle X 10	500000
78	2039	Papain 60mg , Fungal Diastase 20mg (Alpha Amylase 1:2000) and Simethicone 25mg Effervescent Tablet	Each Effervescent Tablet Contains: Papain IP 60mg Alpha Amylase IP (1:2000) 20mg (Fungal Diastase) Simethicon IP 25mg	4's	4's X 10	700000
79	2041	Tadalafil 10Mg And Dapoxetine 30 Mg Tablets	Each Film coted tablet contains: Tadalafil 10mg Dapoxetine Hydrochloride equivalent to Dapoxetine 30 mg	4's	4's X 10	700000
80	2043	Domperidone 10mg and Paracetamol 325mg Tablets	Each Film coted tablet contains: Domperidone Maleate IP equivalent to Domperidone 10mg Paracetamol 325mg	10's	10's X 10	1200000
81	2046	Riboflavin 10Mg,Folic Acid 1.5Mg, Niacinamide 100Mg & Lactic Acid Bacillus 60 Million Spores Tablets	Each Uncoated tablet Contains: Riboflavin IP 10mg Folic Acid IP 1.5mg Niacinamide IP 100mg Lactic Acid Bacillus 60 Million Spores	10's	10's X 10	700000
82	2049	Divalproex Prolonged release Tablets IP 500mg	Each film coated prolonged release tablet contains: Divalproex Sodium IP eq. to Valproic Acid 500mg	10's	10's X 10	700000
83	2053	Telmisartan 40mg and Atorvastatin 10mg Tablet	Each film coated tablet contains: Telmisartan IP 40mg Atorvastatin Calcium IP eq. to Atorvastatin 10mg	10's	10's X 10	2000000

84	2054	Mecobalamin 1500 mcg, Alpha Lipoic Acid 100mg, Inositol 100mg, Folic Acid 1.5mg, Chromium Picolinate 200mcg, Selenium Dioxide 55mcg and Benfotiamine 15mg Tablets	Each film coated tablets contains: Mecobalamine IP 1500mcg Alfa Lipoic Acid 100mg Inositol 100mg Folic Acid IP 1.5mg Chromium Picolinate 200mcg Selenium Dioxide 55mcg Benfotiamine 150mg	10's	10's X 10	1200000
85	2055	Halobetasol Propionate Ointment 0.05% w/w	Each gram contains: Halobetasol Propionate 0.05% w/w	15gm Lemi Tube	15gm Lemi Tube X 10	1000000
86	2056	Metronidazole Gel IP 2% w/w	Each gram contains: Metronidazole IP 2% w/w	30gm LemiTube	30gm LemiTube X 10	1000000
87	2057	Beclomethasone Dipropionate 0.025% w/v, Neomycin Sulphate 0.5% w/v, Clotrimazole 1% w/v and Anhydrous Lignocaine Hydrochloride 2% w/v Ear Drops	Composition: Beclomethasone Dipropionate IP 0.025% W/V, Neomycin Sulphate IP 0.5% W/V, Clotrimazole IP 1% W/V Lignocaine Hydrochloride eq. to Anhydrous Lignocain Hydrochloride 2% W/V	5ml Drops	5ml Drops X 10	360000
88	2218	Sacubitril and Valsartan Tablets 200mg	Each film coated tablet contains: Sacubitril 97mg Valsartan (as Sodium salt complex) 103mg	7’s	7's x 10	600000
89	2219	Sacubitril and Valsartan Tablets 100mg	Each film coated tablet contains: Sacubitril mg 49 Valsartan (as Sodium salt complex) 51mg	14's	14's x 10	600000
90	2220	Sacubitril and Valsartan Tablets 50mg	Each film coated tablet contains: Sacubitril 24mg Valsartan (as Sodium salt complex) 26mg	14's	14's x 10	600000

Annexure-XIII

Ref. Clause No. 1(ii)(c), 20(B) & 21(A)

(1)	(2)	(3)	(4)	(5)	(6)	(7)
Sr. No.	**Item No.**	**Generic name of the Drug**	**Detailed specification**	**Unit Size**	**Packing type**	**PVC/PVDC colour /Bottle**
1	1851	Thyroxine Sodium Tablets IP 25mcg	Each Uncoated tablet Contains: Thyroxine Sodium IP Equivalent to anhydrous Thyroxine Sodium 25 mcg	100's Bottle	Market Standard	Amber coloured bottle
2	1852	Thyroxine Sodium Tablets IP 75mcg	Each Uncoated tablet Contains: Thyroxine Sodium IP Equivalent to anhydrous Thyroxine Sodium 75 mcg	100's Bottle	Market Standard	Amber coloured bottle
3	1856	Disodium Hydrogen Citrate Syrup 1.53gm per 5ml	Each 5 ml contains: Disodium Hydrogen Citrate 1.53 gm	100ml Bottle	Market Standard	Amber coloured bottle
4	1857	Citric Acid 334mg and Potassium Citrate 1100mg Syrup per 5ml	Each 5 ml contains: Citric Acid Monohydrate IP 334 mg Potassium Citrate IP 1100mg In flavoured palatable base qs.	200ml Bottle	Market Standard	Amber coloured bottle
5	1858	Darifenacin Prolonged Release Tablets IP 7.5mg	Each Prolonged Release Tablets Contains : Darifenacin Hydrochloride IP equivalent to Darifenacin 7.5 mg	10's	Blister	Transparent
6	1869	Solifenacin Succinate Tablets IP 5 mg	Each Film Coated tablet Contains: Solifenacin Succinate IP 5 mg	10's	Blister	Transparent
7	1870	Solifenacin Succinate Tablets IP 10 mg	Each Film Coated tablet Contains: Solifenacin Succinate IP 10 mg	10's	Blister	Transparent
8	1877	Brinzolamide Ophthalmic Suspension IP 1% w/v	Each ml contains: Brinzolamide IP 1% w/v Benzalkonium Chloride Solution IP 0.02% w/v (As preservative)	5ml Drops	Market Standard	Market Standard
9	1878	Bromfenac 0.09% w/v and Moxifloxacin 0.5% w/v Eye Drops	Compositions: Bromfenac Sodium equivalent to Bromfenac 0.09 % w/v Moxifloxacin Hydrochloride IP equivalent to Moxifloxacin 0.5 % w/v Benzalkonium Chloride Solution IP 0.02% w/v (As preservative)	5ml Drops	Market Standard	Market Standard
10	1880	Epalrestat Sustained Release Tablets 50 mg	Each Film coated Tablet Contains: Epalrestat 50 mg	10's	Blister	Transparent
11	1881	Gatifloxacin 0.3% w/v and Dexamethasone 0.1% w/v Eye Drops	Each ml contains: Gatifloxacin 0.3 % w/v Dexamethasone 0.1% w/v (As Dexamethasone Sodium Phosphate IP)	3ml Drops	Market Standard	Market Standard

			Benzalkonium Chloride Solution IP 0.01% w/v (As preservative)			
12	1882	Gatifloxacin 0.3 % w/v and Prednisolone 1% w/v Eye Drops	Each ml contains: Gatifloxacin 0.3 % w/v Prednisolone Acetate IP 1% w/v	10ml Drops	Market Standard	Market Standard
13	1883	Gentamicin 0.3% w/v and Dexamethasone 0.1% w/v Eye Drops	Each ml contains: Gentamicin 0.3 % w/v (As Gentamicin Sulphate IP) Dexamethasone 0.1% w/v (As Dexamethasone Sodium Phosphate IP) Benzalkonium Chloride Solution IP 0.01% w/v (As preservative)	10ml Drops	Market Standard	Market Standard
14	1885	Sodium Hyaluronate Eye Drops 0.1% w/v	Compositions: Sodium Hyaluronate 0.1 % w/v	5ml Drops	Market Standard	Market Standard
15	1886	Levofloxacin Eye Drops 0.5 % w/v	Compositions: Levofloxacin Hemihydrate IP equivalent to Levofloxacin 0.5 % w/v Benzalkonium Chloride Solution IP 0.02% w/v (As preservative)	5ml Drops	Market Standard	Market Standard
16	1891	Artesunate 100 mg and Mefloquine Hydrochloride 200 mg Tablets	Each Film coated tablet Contains: Artesunate IP 100 mg Mefloquine Hydrochloride IP 220 mg equivalent to Mefloquine 200 mg	6's	Strip	Aluminium
17	1893	Primaquine Phosphate Tablets IP 7.5 mg	Each Film coated tablet Contains: Primaquine Phosphate IP equivalent to Primaquine 7.5 mg	10's	Alu-Alu	Market Standard
18	1894	Primaquine Phosphate Tablets IP 2.5 mg	Each Film coated tablet Contains: Primaquine Phosphate IP equivalent to Primaquine 2.5 mg	10's	Alu-Alu	Market Standard
19	1895	Pyrimethamine 12.5mg and Sulphadoxine 250mg Suspension	Each ml contains: Pyrimethamine IP 12.5 mg Sulphadoxine IP 250 mg	10ml	Market Standard	Amber colour bottle
20	1896	Pyrimethamine 25mg and Sulphadoxine 500mg Tablets IP	Each uncoated tablet contains: Pyrimethamine IP 25 mg Sulphadoxine IP 500 mg	2's	Blister	Transparent
21	1897	Quinine Sulphate Tablets IP 600 mg	Each Film coated tablet Contains: Quinine Sulphate IP 600 mg	10's	Blister	Transparent
22	1901	Alprazolam 0.5mg and Sertraline Hydrochloride 25mg Tablets	Each uncoated tablet contains: Alprazolam IP 0.5 mg Sertraline Hydrochloride IP equivalent to Sertraline 25 mg	10's	Alu-Alu	Market Standard
23	1902	Alprazolam 0.5mg	Each uncoated tablet contains:	10's	Alu-Alu	Market

		and Sertraline Hydrochloride 50mg Tablets	Alprazolam IP 0.5 mg Sertraline Hydrochloride IP equivalent to Sertraline 50 mg			Standard
24	1907	Amitriptyline Hydrochloride Tablets IP 5 mg	Each Film Coated tablet Contains: Amitriptyline Hydrochloride IP 5 mg	10's	Blister	Transparent
25	1909	Amoxapine Tablets IP 50mg	Each uncoated tablet contains: Amoxapine IP 50 mg	10's	Blister	Transparent
26	1910	Amoxapine Tablets IP 100mg	Each uncoated tablet contains: Amoxapine IP 50 mg	10's	Blister	Transparent
27	1911	Aripiprazole Tablets IP 2.5 mg	Each uncoated tablet contains: Aripiprazole IP 2.5 mg	10's	Blister	Transparent
28	1915	Aripiprazole Tablets IP 7.5 mg	Each uncoated tablet contains: Aripiprazole IP 7.5 mg	10's	Blister	Transparent
29	1916	Aripiprazole Tablets IP 30 mg	Each uncoated tablet contains: Aripiprazole IP 30 mg	10's	Blister	Transparent
30	1917	Asenapine Sublingual Tablets 5mg	Each Sublingual tablet Contains: Asenapine Maleate IP equivalent to Asenapine 5 mg	10's	Strip	Aluminium
31	1918	Asenapine Sublingual Tablets 10mg	Each Sublingual tablet Contains: Asenapine Maleate IP equivalent to Asenapine 10 mg	10's	Strip	Aluminium
32	1924	Chlorpromazine Tablets IP 25 mg	Each Film Coated tablet Contains: Chlorpromazine Hydrochloride IP 25 mg	10's	Blister	Transparent
33	1925	Chlorpromazine 50mg and Trihexyphenidyl 2mg Tablets	Each Film Coated tablet Contains: Chlorpromazine Hydrochloride IP 50 mg Trihexyphenidyl Hydrochloride IP 2 mg	10's	Blister	Transparent
34	1926	Chlorpromazine 50mg, Trihexyphenidyl 2mg and Trifluoperazine 5mg Tablets	Each Film Coated tablet Contains: Chlorpromazine Hydrochloride IP 50 mg Trihexyphenidyl Hydrochloride IP 2 mg Trifluoperazine Hydrochloride IP equivalent to Trifluoperazine 5 mg	10's	Blister	Transparent
35	1928	Citalopram Tablets IP 20mg	Each Film Coated tablet Contains: Citalopram Hydrochloride IP equivalent to Citalopram 20 mg	10's	Blister	Transparent
36	1929	Citalopram Tablets IP 40mg	Each Film Coated tablet Contains: Citalopram Hydrochloride IP equivalent to Citalopram	10's	Blister	Transparent

			40 mg			
37	1932	Clomipramine Hydrochloride Tablets 10mg	Each Film Coated tablet Contains: Clomipramine Hydrochloride IP 10 mg	10's	Blister	Transparent
38	1933	Clomipramine Hydrochloride Tablets 25mg	Each Film Coated tablet Contains: Clomipramine Hydrochloride IP 25 mg	10's	Blister	Transparent
39	1934	Clomipramine Hydrochloride Tablets 50mg	Each Film Coated tablet Contains: Clomipramine Hydrochloride IP 50 mg	10's	Blister	Transparent
40	1936	Clozapine Tablets IP 50 mg	Each uncoated tablet Contains: Clozapine IP 50 mg	10's	Alu-Alu	Market Standard
41	1937	Clozapine Tablets IP 100 mg	Each uncoated tablet Contains: Clozapine IP 100 mg	10's	Alu-Alu	Market Standard
42	1939	Diazepam Tablets IP 10 mg	Each uncoated tablet Contains: Diazepam IP 10 mg	10's	Blister	Transparent
43	1941	Doxepin Capsules IP 25mg	Each Hard Gelatin Capsule Contains : Doxepine Hydrochloride IP equivalent to Doxepine 25 mg	10's	Blister	Transparent
44	1942	Doxepin Capsules IP 75mg	Each Hard Gelatin Capsule Contains : Doxepine Hydrochloride IP equivalent to Doxepine 75 mg	10's	Blister	Transparent
45	1944	Escitalopram Tablets IP 5 mg	Each Film Coated tablet Contains: Escitalopram Oxalate IP equivalent to Escitalopram 5 mg	10's	Blister	Transparent
46	1946	Lamotrigine Dispersible Tablets IP 25mg	Each Dispersible uncoated tablet Contains: Lamotrigine IP 25 mg	10's	Blister	Transparent
47	1947	Lamotrigine Dispersible Tablets IP 50mg	Each Dispersible uncoated tablet Contains: Lamotrigine IP 50 mg	10's	Blister	Transparent
48	1955	Paroxetine Extended Release 12.5mg and Clonazepam 0.25mg Capsules	Each hard gelatin capsule contains: Paroxetine Hydrochloride 12.5 mg (Extended Release) Clonazepam 0.25 mg	10's	Strip	Aluminium
49	1956	Risperidone Orally Disintegrating Tablet 0.5mg	Each uncoated tablet Contains: Risperidone USP 0.5 mg	10's	Blister	Transparent
50	1960	Aloe Vera 10% W/W and Vitamin E 1% W/W Moisturising Cream	Composition: Aloe Vera 10% W/W Vitamin E 1% W/W	60gm Tube	Market Standard	Market Standard
51	1964	Biphasic Insulin Lispro Injection IP 100IU per ml (25:75)	Each ml contains: Biphasic Insulin Lispro 100 IU Insulin Lispro IP (25%)	3ml Pre-Filled Cartridge	Market Standard	Market Standard

			Insulin Lispro Protamine (75%)			
52	1965	Insulin Aspart Injection IP 100IU per ml	Each ml solution contains: Insulin Aspart (rDNA) 100IU (Eqv. to 3.5mg)	10ml Vial	Market Standard	Market Standard
53	1969	Repaglinide 1mg and Metformin Hydrochloride (Sustained-release) 500mg Tablets IP	Each uncoated tablets contains: Repaglinide 1mg Metformin hydrochloride IP (as sustained release form) 500mg	10's	Blister	Transparent
54	1970	Repaglinide 2mg and Metformin Hydrochloride (Sustained-release) 500mg Tablets IP	Each uncoated tablets contains: Repaglinide 2mg Metformin hydrochloride IP (as sustained release form) 500mg	10's	Blister	Transparent
55	1973	Amoxycillin 200Mg , Clavulanic Acid 28.5Mg And Lactic Acid Bacillus 30 Million Spore Dry syrup	Each 5ml Unconstituted Suspension Contains: Amoxycillin Trihydrate IP equivalent to Anhydrous Amoxycillin 200mg Potassium Clavulanate equivalent to Clavulanic Acid 28.5mg Lactic Acid Bacillus 30 Million Spore	30ml	Market Standard	Amber colour bottle
56	1974	Amoxycillin 250mg, Cloxacillin 250mg And Lactic Acid Bacillus 100 Million Spore Tablets	Each film coated tablet Contains: Amoxycillin Trihydrate IP equivalent to Anhydrous Amoxycillin 250mg Cloxacillin Sodium IP equivalent to Cloxacillin 250mg Lactic Acid Bacillus 100 Million Spore	6's	Blister	Transparent
57	1975	Amoxycillin 125Mg , Cloxacillin 125Mg And Lactic Acid Bacillus 60 Million Spore Tablets	Each film coated tablet Contains: Amoxycillin Trihydrate IP equivalent to Anhydrous Amoxycillin 250mg Cloxacillin Sodium IP equivalent to Cloxacillin 250mg Lactic Acid Bacillus 100 Million Spore	10's	Blister	Transparent
58	1979	Cefdinir Oral Suspension IP 125mg per 5ml	Each 5ml Re-constituted Suspension Contains: Cefdinir IP 125mg	30ml with Water for Reconstitution	Market Standard	Amber colour bottle
59	1992	Bacitracin 400 IU, Neomycin 3400 IU and Polymyxin B 5000 IU Ophthalmic	Each gram contains: Bacitracin Zinc IP equivalent to Bacitracin 400IU Neomycin Sulphate equivalent to Neomycin 3400 IU	10gm Tube	Lami Tube	Market Standard

		Ointment	Polymyxin B Sulphate equivalent to Polymyxin B 5000IU			
60	1993	Glycolic Acid 1% w/w and Aloe Vera 5% w/w Face Wash	Composition: Glycolic Acid 1% W/W Aloe Vera 5% W/W	100gm Tube	Market Standard	Market Standard
61	1994	Glycolic Acid 1% w/w, Aloe Vera 5% w/w and Salicylic Acid 2% w/w Facewash	Composition: Glycolic Acid 1% W/W, Aloe Vera 5% W/W Salicylic Acid 2% W/W	60ml Fliptop Lemitube	Market Standard	Market Standard
62	1995	Selenium Sulphide Shampoo 1% w/w	Composition: Selenium Sulphide 1% W/W	60ml Fliptop Jar	Market Standard	Market Standard
63	1999	Carboprost Injection 125mcg	Each 0.5ml Contains: Carboprost 125 mcg (as Carboprost Tromethamine IP)	0.5ml Ampoule	Market Standard	Market Standard
64	2001	Ethinyl Estradiol 15Mcg And Gestodene 60 Mcg Tablet	Each cycle pack consists of: 24 Pink active tablets of: Each Uncoated Tablet contains: Ethinyl Estradiol 15mcg Gestodene 60 mcg 4 white inactive Tablets: Each uncoated tablet contains: Lactose IP 45 mg	28's Monopack	Blister	Transparent
65	2011	Racecadotril Sachet IP 15mg	Each Sachet contains: Racecadotril IP 15mg	1gm Sachet	Market Standard	Market Standard
66	2013	Rabeprazole 10mg, Chlordiazepoxide 5mg, Dicyclomine 10mg and Clidinium 2.5 mg Capsule	Each Hard Gelatin Capsule contains: Rabeprazole Sodium IP 10mg (As enteric Coated) As Film Coated Chlordiazepoxide 5mg Clidinium 2.5 mg As powder form Dicyclomine Hydrochloride 10mg	10's	Strip	Aluminium
67	2014	Daclatasvir Tablets 60 mg	Each Film coated Tablet contains: Daclatasvir Dihydrochloride equivalent to Daclatasvir 60 Mg	28's Bottle	Market Standard	Market Standard
68	2016	Minoxidil Tablets IP 10mg	Each Uncoated Tablet contains: Minoxidil IP 10mg	10's	Alu-Alu	Market Standard
69	2017	Ulipristal Acetate Tablets 5mg	Each Film coated Tablet Contains: Ulipristal Acetate 5mg	10's	Alu-Alu	Market Standard
70	2018	Mesalazine Prolonged release Tablets IP 500mg	Each uncoated prolonged-release tablet contains: Mesalazine IP 500mg	10's	Alu-Alu	Market Standard
71	2019	Metformin Hydrochloride 1000mg (Prolonged release) and Glimepiride 3mg	Each Film coated bilayered Tablet contains: Glimepiride 3 mg Metformin Hydrochloride 1000 mg (As Prolonged-release form)	10's	Blister	Transparent

		Tablets IP				
72	2020	Desmopressin Tablets 0.1 mg	Each Tablet contains: Desmopressin Acetate 0.1 mg	15's in bottle	Market Standard	Market Standard
73	2021	Teriparatide Injection 750 mcg per 3 ml	Each ml (r-Human Parathyroid hormone Injection) contains: Recombinant Human Parathyroid hormone 250mg.	3ml Cartridge	Market Standard	Market Standard
74	2024	Ropinirole Tablets IP 4 mg	Each Film coated tablet Contains: Ropinirole Hydrochloride equivalent to Ropinirole 4 mg	10's	Strip	Aluminium
75	2027	Mesalazine Delayed release Tablets 800 mg	Each Uncoated delayed release tablet contains: Mesalazine 800mg	10's	Alu-Alu	Market Standard
76	2031	Sofosbuvir 400mg and Velpatasvir 100mg Tablets	Each Film coated Tablet Contains: Sofosbuvir 400mg Velpatasvir 100mg	28's Bottle	Market Standard	Market Standard
77	2032	Atazanavir 300mg and Ritonavir 100mg Tablets	Each Film coated Tablet Contains: Atazanavir Sulphate IP equivalent to Atazanavir 300mg Ritonavir 100mg	30's Bottle	Market Standard	Market Standard
78	2039	Papain 60mg , Fungal Diastase 20mg (Alpha Amylase 1:2000) and Simethicone 25mg Effervescent Tablet	Each Effervescent Tablet Contains: Papain IP 60mg Alpha Amylase IP (1:2000) 20mg (Fungal Diastase) Simethicon IP 25mg	4's	Market Standard	Market Standard
79	2041	Tadalafil 10Mg And Dapoxetine 30 Mg Tablets	Each Film coted tablet contains: Tadalafil 10mg Dapoxetine Hydrochloride equivalent to Dapoxetine 30 mg	4's	Alu-Alu	Market Standard
80	2043	Domperidone 10mg and Paracetamol 325mg Tablets	Each Film coted tablet contains: Domperidone Maleate IP equivalent to Domperidone 10mg Paracetamol 325mg	10's	Blister	Transparent
81	2046	Riboflavin 10Mg,Folic Acid 1.5Mg, Niacinamide 100Mg & Lactic Acid Bacillus 60 Million Spores Tablets	Each Uncoated tablet Contains: Riboflavin IP 10mg Folic Acid IP 1.5mg Niacinamide IP 100mg Lactic Acid Bacillus 60 Million Spores	10's	Blister	Amber coloured PVC
82	2049	Divalproex Prolonged release Tablets IP 500mg	Each film coated prolonged release tablet contains: Divalproex Sodium IP eq. to Valproic Acid 500mg	10's	Alu-Alu	Market Standard
83	2053	Telmisartan 40mg and Atorvastatin 10mg Tablet	Each film coated tablet contains: Telmisartan IP 40mg Atorvastatin Calcium IP eq. to Atorvastatin 10mg	10's	Alu-Alu	Market Standard
84	2054	Mecobalamin 1500	Each film coated tablets	10's	Alu-Alu	Market

		mcg, Alpha Lipoic Acid 100mg, Inositol 100mg, Folic Acid 1.5mg, Chromium Picolinate 200mcg, Selenium Dioxide 55mcg and Benfotiamine 15mg Tablets	contains: Mecobalamine IP 1500mcg Alfa Lipoic Acid 100mg Inositol 100mg Folic Acid IP 1.5mg Chromium Picolinate 200mcg Selenium Dioxide 55mcg Benfotiamine 150mg			Standard
85	2055	Halobetasol Propionate Ointment 0.05% w/w	Each gram contains: Halobetasol Propionate 0.05% w/w	15gm Lemi Tube	Lami Tube	Market Standard
86	2056	Metronidazole Gel IP 2% w/w	Each gram contains: Metronidazole IP 2% w/w	30gm LemiTube	Lami Tube	Market Standard
87	2057	Beclomethasone Dipropionate 0.025% w/v, Neomycin Sulphate 0.5% w/v, Clotrimazole 1% w/v and Anhydrous Lignocaine Hydrochloride 2% w/v Ear Drops	Composition: Beclomethasone Dipropionate IP 0.025% W/V, Neomycin Sulphate IP 0.5% W/V, Clotrimazole IP 1% W/V Lignocaine Hydrochloride eq. to Anhydrous Lignocain Hydrochloride 2% W/V	5ml Drops	Market Standard	Market Standard
88	2218	Sacubitril and Valsartan Tablets 200mg	Each film coated tablet contains: Sacubitril 97mg Valsartan (as Sodium salt complex) 103mg	7's	Alu-Alu	Market Standard
89	2219	Sacubitril and Valsartan Tablets 100mg	Each film coated tablet contains: Sacubitril mg 49 Valsartan (as Sodium salt complex) 51mg	14's	Alu-Alu	Market Standard
90	2220	Sacubitril and Valsartan Tablets 50mg	Each film coated tablet contains: Sacubitril 24mg Valsartan (as Sodium salt complex) 26mg	14's	Alu-Alu	Market Standard

Note:

- ***Light sensitive drugs shall be provided in an "Amber color PVC" in case of Blister packing.***
- ***Vials of eye drops, ear drops, and nasal drops should be packed in an individual mono carton with a dispensing device.***
- ***PMBI may ask the awarded bidder for necessary modification on design/artwork in case if product is decided to be launched at wider platform.***
- ***Cap on bottle/jar type of packing shall contain printed design as per specimen design provided under clause 3. (h) of Enclosure - 2 to Annexure – VII, Ref. Clause No. 3(M) & 20***

Annexure – XIV

{Ref: - clause 19(J), Para VI of Annexure II}

(For declaration of shelf-life under Annexure-II)

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:

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

II. In case bidder(s) has not complied to either "Schedule P of Drugs and Cosmetics Rules, 1945" or as per market standard (not less than 24 months for drugs not covered under Schedule P of Drugs and Cosmetics Rules, 1945) while declaring the shelf life on Annexure II.

III. Bids shall be rejected if bidder(s) fails to declare shelf life.

IV. Bidder(s) must have supporting stability data (long term stability studies and accelerated stability studies) for all quoted/awarded drugs for producing to PMBI on requirement. For New drugs, complete stability data of 6 months' period shall be acceptable as mentioned in clause 4. F.

…….

ANNEXURE- XV

(Ref. Clause no.3.1)

DECLARATION BY AUTHORISED SIGNATORY OF THE FIRM

(On Non-Judicial Paper duly notarized)

(Declaration towards Compliance of Order (Public Procurement No.1, 2 & 3) dated 23 Jul 2020 & 24 Jul 2020 on Restrictions under Rule 144 (xi) of the General Financial Rules (GFRs), 2017.)

I, the undersigned,…… (full names), do hereby declare, in my capacity as……..……..……of M/s ……., that:

1) The facts contained herein are within my own personal knowledge.

2) I have read the Order (Public Procurement No.1, 2 & 3) dated 23 Jul 2020 & 24 Jul 2020 on the subject of Restrictions under Rule 144 (xi) of the General Financial Rules (GFRs), 2017 regarding restrictions on procurement from a bidder of a country which shares a land border with India and comply to all the provisions of the Order.

3) I certify that M/s .....(name of bidder/entity) is not from such a country or, is from such a country **(strike out whichever is not applicable)**, has been registered with the Competent Authority. I hereby certify that this SUPPLIER fulfils all requirements in this regard and is eligible to be considered. [Where applicable, evidence of valid registration by the Competent Authority is attached].

4) I understand that the submission of incorrect data and / or if certificate / declaration given by M/s.....(name of bidder entity) is found to be false, this would be a ground for immediate termination and further legal action in accordance with law as per Clause 12 of the Public Order on Restrictions under Rule 144 (xi) of the General Financial Rules (GFRs), 2017.

Authorized Signature:

Signature with date…….

Name: …….

Designation/ capacity ……..…

(Seal / Stamp of Bidder)

Yours faithfully,

Sd/-

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