Tender Ref. No.: PMBI/SURGICAL/RC-201/2022 **Dated: 07/07/2022**

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

Website: janaushadhi.gov.in

e- TENDER FOR SUPPLY OF SURGICAL/ CONSUMABLES AND MEDICAL DEVICES

TO

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

LAST DATE FOR ONLINE SUBMISSION OF TENDER: 28/07/2022

PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI)

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

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

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

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

Website: **www.janaushadhi.gov.in,**

e-TENDER FOR TWO YEARS RATE CONTRACT

FOR SUPPLY OF SURGICAL/ CONSUMABLES AND MEDICAL DEVICES TO PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI)

Tender Reference		**PMBI/SURGICAL/RC-201/2022 Dated 07/07/2022**
Tender Website		https://eprocure.gov.in
Date of availability of tender documents on website		**On 07/07/2022 (Thursday) at 17:30 Hours**
Doubts and queries regarding Tender document should be sent by e-mail to e-mail id "proc10@janaushadhi.gov.in, procure14@janausadhi.gov.in, proc6@janausadhi.gov.in, proc9@janausadhi.gov.in" by the likely bidders latest by		**Till 13/07/2022 up to 17:00 Hours**
Time and date and place pre-bid meeting		**On 14/07/2022 (Thursday) at 11:00 AM** Pharmaceuticals & Medical Devices Bureau of India (PMBI), 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 28/07/2022 up to 17:00 Hours**
Last Date and time for submission of EMD and Original Required Documents as per ANNEXURE I (Check List) in physical Form and samples in office of Pharmaceuticals & Medical Devices Bureau of India, 8th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055		**On 01/08/2022 by 17:00 Hours**
Time and date of opening of Technical Bid		**On 02/08/2022 at 15.00 Hours (Tuesday)**
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 Assistant Manager (Procurement) Phone: - 011-49431829 Email: - proc6@janaushadhi.gov.in
		4. Sh. Manik Bera, Deputy 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:* www.janaushadhi.gov.in

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

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PHARMACEUTICALS & MEDICAL DEVICES BUREAU OF INDIA (PMBI)

e-TENDER FOR RATE CONTRACT FOR THE SUPPLY OF SURGICAL/ CONSUMABLES AND MEDICAL DEVICES 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, surgical & consumables, and food products 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 8700 stores are functional. It is proposed to channelize efforts to popularize PMBJP and ensure availability of the complete basket of quality generic medicines, surgical & consumables and food products at affordable prices.

Tender Inviting Authority – CEO, 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 Surgical/ Consumables and Medical Devices 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 Earnest Money Deposit (EMD) shall be submitted before the specified schedule at the office of PMBI super scribed, **"Tender Documents & Earnest Money Deposit for Tender Reference No.-PMBI/SURGICAL/RC-201/2022 dated 07/07/2022 for the procurement of Surgical/ Consumables and Medical Devices for the year 2022-2024".** However complete hard copy of uploaded tender shall be provided by the bidding firm along-with the mandatory required documents as per clause 3 of Bid document and Earnest Money Deposit (EMD) 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 items and** 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**, 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 **Surgical/ Consumables and Medical Devices** etc., on door delivery basis according to the unit ordered. Tender for the supply of **Surgical/ Consumables and Medical Devices** 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 ceiling price as fixed by **NPPA (National Pharmaceutical Pricing Authority)** as per the provision of "**Drugs Price Control Order (DPCO") if any**.

In case any tenderer quotes higher than the ceiling 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 28/07/2022 (Thursday) 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 EMD shall be submitted on or before the specified schedule at the below mentioned address of PMBI with super scribed, **"Tender Document &** Earnest Money Deposit (EMD) **for Tender Reference No.- PMBI/SURGICAL/RC-201/2022 dated 07/07/2022 for the procurement of Surgical/ Consumables and Medical Devices for the year 2022-2024".**

"To,
The Chief Executive Officer (CEO),
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) Earnest Money Deposit (EMD): EMD of ***Rs.100000/- (Rupees One Lakh only)*** as specified in Clause 6 of the Tender document in the form of ***Bank Guarantee or National Electronic Fund Transfer (NEFT) or Bankers Cheque or Demand Draft from Nationalized/Scheduled Bank favoring "Pharmaceuticals & Medical Devices Bureau of India "payable at Delhi*** which is to be submitted in original to PMBI, New Delhi on or before the date and time stipulated in tender document. *Name & full address of the bidder may be written at the back of the Demand Draft/Pay Order. Signed and scanned soft copy of the EMD instrument must be uploaded (ANNEXURE III) to the e-Procurement portal.*
EMD in any other form like Cheque/cash/postal order etc. will not be accepted. The Bid (in case not exempted for EMD as mentioned in tender document) without EMD shall be summarily rejected.

Account Details for National Electronic Fund Transfer (NEFT):

Bank Name: Bank of Baroda, Account No. 05860200001696, IFSC Code: BARB0PARLIA

Note: (i) Tenderer may be exempted from the payment of EMD, if valid registration certificate from NSIC/MSME/ Udyam Registration Certificate is uploaded and submitted self-attested copy with Technical Bid for the product for which bidder has submitted quotation.
(ii) The prior turnover and prior experience for Start-ups (as defined by Department of Industrial Policy and Promotion) shall not be applicable subject to submission of certificate of recognition as start up by Department of Industrial Policy and Promotion for quoted item.

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 such as Name, Address, Telephone Number, Fax Number, e-mail address of the firm and of the Managing Director / Partners / Proprietor should be submitted to support the fact that the bidding firm is a manufacturer.

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) Tenderer shall be a manufacturer and shall have registered from Director of Industries/District Industries centres, Ministry of Commerce or NSIC for non-drug items. For items covered under BIS, tenderer should have BIS certificate. In case, the products are covered under Drugs and Cosmetics Act 1940 / Medical Device Act 2017, the tenderer shall valid manufacturing licence duly licensed by licensing authorities.

E) Bidders must have: -

a. The bidder must have a valid manufacturing license and duly acknowledged renewal application with old license issued by the state licensing authority/Central licensing approving authority under Medical Devices Rules 2017/Drugs & Cosmetic Act 1940 wherever applicable.
b. Manufacturing License / permission along with approved product list issued as per the license issued for quoted Drug item / Medical Devices / Consumable / Surgical as per Medical Devices Rules 2017 / Drugs & Cosmetic Act 1940 must be valid till the last date of the submission of tender.
c. Bidders must submit test certificates/reports for all contraceptive items in the tender in support of its Biocompatibility conforming ISO 10993 along with other standards/reports conforming ISO 12243, ISO 29941 etc. items wherever applicable. Packaging shall confirm ISO 25841:2017.
d. Colour and flavours of Male and Female condom shall be flexible as mentioned in the detailed specification under Annexure-XII and PMBI may place purchase order based on demand of various Colour and flavours. Bidders shall consider all Colour and flavours as mentioned in the detailed specification while bidding.
e. In case if intending bidders is bidding for electronic items, they must comply the item specification, quality parameters, Safety and Product Standards mentioned in the detailed specification under Annexure-XII. Bidder may also submit additional certification as per international standard.
f. Bidders shall submit three consecutive Bioburden test reports for condoms.
g. Bidder must have valid manufacturing permission for non-drug item(s) where neither the Drugs & Cosmetic Act 1940 and Rules there under 1945 nor the Medical Device Rule 2017 is applicable. Bidder must submit an undertaking/Self declaration as per **Annexure-VII** in their letterhead that the item(s) quoted by the bidder is/are non-drug item(s) i.e., neither covered under Drug & Cosmetic Act 1940 nor Under Medical Device Rule 2017.

F) Bidder must have Market Standing Certificate of minimum three years issued by the concerned Licensing Authority/Drugs Control Department/Concerned Government Department for the quoted product. In case quoted item is not covered under either Drug & Cosmetic Act 1940 or Medical Device Rule 2017, Market standing Certificate (MSC) must be declared by the C.A./C.S certifying at least three batch No. of the quoted items that the firm/company has manufactured and marketed the items for last three consecutive years. Self-attested copies are to be submitted.

G) Declaration on company's letter head duly signed by authorized person stating that the firm & its quoted product is not blacklisted currently (as on the date of submission of the tender) by Central Government/ Central Government agencies/any State Government or any of the State Government agencies/ or any Drug procurement agencies or by PMBI in prescribed format as per **Annexure-XV.**

H) Bidder must submit the Quality Management System (QMS) certificate issued on behalf of their manufacturing unit by the Licensing Authority/ Drugs Control Department, Bureau of Indian Standards (BIS)/ Indian Standards Institute (ISI) certificate issued from the concerned department (as applicable). The QMS certificate should remain valid till the last date of submission of tender. Self-attested copies are to be submitted.

Note: a) If Manufacturing License/registration/permission for the quoted product(s) is issued under "for export only" category will not be accepted. Distributors/Suppliers/Marketer/ Agents/Importer/Loan Licensee/Non-local suppliers are not eligible to participate in the Tenders.

J) Tenderer must declare their Maximum Production Capacity (item wise) for quoted item(s) highlighting it in Annexure XIV.

K) 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 **2 Crores (Two crore).** Details shall be provided as per **Annexure IV**. Self-attested copies are to be submitted.

L) Declaration **on Nonjudicial Stamp Paper duly notarized** for eligibility in participating the tender for quoted items in prescribed format as per **Annexure-II.**

M) Tenderer shall furnish Company's bank details as per **Annexure V (Mandate Form).**

N) Tenderers are required to submit **Annexure-VI** indicating details of manufacturing License/ permission and market standing certificate.

O) Tenderer are required to submit declaration duly signed to supply the items as per the design in enclosure in **Annexure VII** as well as other instructions given in this regard.

P) Duly attested Checklist as per (**ANNEXURE- I**) shall be submitted.

Q) Copy of PAN Card of the bidder company should be submitted (self-attested).

R) Copy of certificate of valid GST registration of the bidder company should be submitted (self-attested).

S) Copy of Income Tax Return for any three of last four Consecutive Assessment years should be submitted (self-attested).

T) Duly attested Copy of valid GS-1 registration certificate from GS1 India.

U) *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 per below table:*

S. No.	Type of Class	Percentage (%) of minimum local content
1	Class-I Local Supplier	Local content equal to more than 50%
2	Class-II Local Supplier	Local content more than 20% but less than 50%
3	Non-Local Supplier	Local content less than or equal to 20%

The category of supplier based on the % of local content used 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 above.**

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.*

a) (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 MSE.

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, wherever required.

ii) Technical evaluation of the Bid will be done on the basis of the above-mentioned criteria and documents mentioned in Clause no.3 (Technical Bid- Cover 'A') Mandatory Documents shall be submitted online only at CPP portal: https://eprocure.gov.in Failing which the bid will not be considered for technical evaluation.

iii) Hard copy of required documents uploaded shall be submitted along with Earnest Money Deposit (EMD) 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 manufacturing license highlighting the item code should be uploaded. In case scanned copy of license uploaded is not visible or tempered, PMBI shall not considered the license for such items.

V) If the procurement for a 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.

W) Special Terms & Conditions:

i. Bidder must quote the product as per specification provided in Annexure XII.
ii. Catalog must be attached with the bid for technical evaluation along with dimension of quoted items.
iii. The supplier may be asked to arranging demonstration of their equipment for which rates have been quoted, to the PMBI, if required. The expenditure incurred for demonstrating the items will be borne by the supplier.
iv. Bidder shall have dedicated Customer Care Support Team for providing technical assistant at consumer level.
v. Directive 2011/65/EU – Restriction of Hazardous Substances Directive (ROHS) to be complied.

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.

1. 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.

2. "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 orcompanies), 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.

3. "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 the majority 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) dtd 23 Jul 2020 & 24 Jul 2020 is a 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 XVII. It shall be furnished by the bidder(s) on duly notarized Non-Judicial Paper.

4. GENERAL CONDITIONS:

A) Tender bid is invited directly from Manufacturers in India.

Loan licensee / Distributors / Agents / Contract Manufacturers / Importers / Non-Local supplier are not eligible to participate in the tender.

B) Manufacturer has Production & financial capacity to manufacture and deliver the items quoted by the firm in the tender as per quantity mentioned in tender during contract period.

C) Bidders are advised to quote such items only for which they meet the item specification as mentioned in Annexure XII of the tender document. Do not quote if it differs about any parameter. Bidder(s) shall also submit declaration as per Annexure XIV.

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 the awarded items are required to be submitted within 15 days from the date of issue of Letter of Acceptance.

F) The manufacturer shall declare the material used in manufacturing against all quoted items and declare that it is internationally accepted when ask by PMBI.

G) 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 items have not been failed in inhouse 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.

H) During the validity of the tender if the firm / Company is blacklisted/debarred/de-registered/banned by any State Government/ Central Government/ PMBI/ Central or State Government's Drug procurement

agencies / convicted by any Court of law in India, it shall be intimated to PMBI along with relevant authentic document by the tenderer firm/ company within one month.

I) 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 items from other bidders at L1 rate or may go for fresh tender as per discretion of PMBI.

J) The PMBI reserves the right to purchase any items 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.

K) 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.

L) Validity of Rate Contract: -The rate contract will be applicable for 2(two) year from the date of acceptance 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.

M) During the contract period at any stage, it is found that the tender 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/ legal action may be taken as per the tender terms and condition and in addition to penal action recovery shall be made (if any) against the firm.

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 should be declare in Annexure II and 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.

P) Samples:

i) Three (3) properly labeled samples shall be submitted against each quoted item as per the specification mentioned in Annexure XII of the tender document on or before stipulated date. Failure to do so, it shall entail your quotation being disqualified.

ii) Sealed sample boxes should contain samples the tenderer quoted for along with duly filled Annexure XVIII.

iii) Sample should be in the form of pack as specified in tender enquiry, otherwise the quotation against that particular item is liable to be rejected.

iv) Firm may take back their samples if unapproved within 10 days from the date of issue of the Rate contract, otherwise the same will be destroyed by PMBI.

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.

b) **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.**

c) Purchase preference shall be given over acceptable L1 bidder to bidder offering Products manufactured by using higher % age of Local Content computed on the basis of cost of domestic contents in order to promote "Make in India" subject to matching of acceptable L1 rate as per Public Procurement (Preference to make in India), order 2017**.**

d) (i) If the participating Micro and Small Enterprises (MSEs) meets all the other eligibility criteria and their quoted price is within price band of L1+15 (fifteen) per cent shall also be allowed to supply a portion of requirement by bringing down their price to L1 price in a situation where L1 price is from someone other than a MSEs and such MSEs shall be allowed to supply up to 25 (twenty-five) per cent of total tendered value. The 25 (twenty-five) per cent quantity is to be distributed proportionately among these bidders, in case there are more than one MSEs within such price band.

(iv) Within this 25% (Twenty-five Percent) quantity, a purchase preference of four per cent that is, 25 (twenty-five) per cent out of 25 (twenty-five) per cent will be reserved for 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 MSEs to participate in tender process or meet tender requirements and L1 price, four per cent sub-target shall be met from other MSEs. MSEs would be treated as owned by SC/ ST entrepreneurs: a) In case of proprietary MSEs, proprietor(s) shall be SC /ST b) In case of partnership MSEs, the SC/ST partners shall be holding at least 51% (fifty-one percent) shares in the unit c) In case of Private Limited Companies, at least 51% (fifty-one percent) share shall be held by SC/ST promoters.

(v) 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 (EMD)/Bid Security:

A) The Earnest Money Deposit referred to under Clause 3.A, shall be **Rs. 100000.00 (One lakhs). The Earnest Money Deposit shall be paid in the form of Bank Guarantee or National Electronic Fund Transfer (NEFT) or Bankers Cheque/ Demand Draft in favour of Pharmaceuticals & Medical Devices Bureau of India, payable at Delhi. EMD in form of Bank Guarantee, Irrevocable Bank Guarantee** in favour of Pharmaceuticals & Medical Devices Bureau of India, from any Nationalized/scheduled Bank should be valid for a period of 12 months **from the date of tender opening**. The format of Bank Guarantee is at **ANNEXURE-X.** PMBI will not pay interest on any deposit held in the form of **Bankers Cheque or Demand Draft or Electronic Fund Transfer.**

Account Details for National Electronic Fund Transfer (NEFT):

Bank Name: Bank of Baroda, Account No. 05860200001696, IFSC Code: BARB0PARLIA

B) Tenderer may be exempted from the payment of EMD, if valid **registration** certificate from NSIC/MSME is uploaded **for the product for which bidder has submitted quotation.**

C) PSUs are exempted from the payment of EMD.
D) The tender submitted without sufficient EMD will be summarily rejected.
E) Non-payment of EMD (except in cases where payment of EMD is specifically exempted) will result in rejection of the bid.
F) The Earnest Money Deposit will be refunded to the successful bidders after successful completion of first supply.
G) **The Earnest Money Deposit of the Tender will be forfeited without further notice if:**

a) If the tenderer withdraws his bid any time after opening of price bid.
b) On refusal to supply surgical & consumables 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 websites **www.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, if 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 have been uploaded in the CPP Portal https://eprocure.gov.in the bidder has to make sure that he has uploaded the files in the correct format and the bidder has to download the uploaded files from their own end and has to check whether the files uploaded is in proper format or not, no corrupted files have to be uploaded.

H) Bidder shall not wait till the last time for the submission of bid on CPP portal. In any case, if bidder fails to submit the bid online, PMBI will not be responsible.

Note: In any case if the prospective bidder fails to uploaded technical bid (Cover A)/ Price bid (Cover B) successfully on the CPP Portal online on or before the last date and time of submission of technical bids, the bid shall be summarily rejected without considering any facts.

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 defined in the tender document or by Government)* for withdrawal of bid or modification in bid or any request pertaining to have quoted wrong rates for any unit size instead of the unit size in tender document/BOQ shall not be considered. Bidder who are making such request shall be penalized as per tender clause no. 27 terms and conditions besides blacklisting for a duration of not less than three (3) years.

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 date and time, failing which the bid shall be summarily rejected without considering any fact.

13. EVALUATION OF TENDER:

E) Technical evaluation of the Bid will be done on the basis of criteria and documents mentioned in clause no. 3 (TECHNICAL BID-COVER A) & Annexure I (Check List) which are present in the CPP Portal i.e., **https://eprocure.gov.in.**

F) Bids of firms who have furnished all the required documents for each of the product quoted will be considered.

G) 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.

H) 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.

I) 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 items 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: -

a) "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 and remaining 50% of quantity may be awarded to the

eligible bidder following the guidelines and respective clauses of DPIIT order no. P-45021/2/2017-PP(BE-II) dated 16.09.2020."

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, Price Bid evaluation will be done as per the clause 5. B.

"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 items 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 against the total value in the purchase order 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 items and indemnify PMBI against any losses on account of quality parameters duly notarized on non-judicial paper.

18. METHODOLOGY FOR PLACING ORDERS:

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

A) After the conclusion of Price Bid opening (Cover B), the rates offered by tenderers for each product are evaluated and lowest acceptable rate (L1 Rate) arrived at is declared and that tenderer is informed**.**

B) PMBI reserves right to issue purchase order for any item on any one rate contract holder or more than one rate contract holder for same items.

C) 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. L1 quantity will be distributed equally among them as per clause no. 16.A.

D) The supplier shall supply the Items 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.

E) Once The supplier shall supply the Items 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.

F) 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.

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

H) The Items 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.

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

J) 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.

K) Purchase orders, incorporating definite quantity of items/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.

L) 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.

M) The details of the required items, medical devices, etc. are shown in **ANNEXURE -XII**. ***The tender quantity mentioned herein is not a fixed procurement quantity and it is only a tentative requirement and may be increased or decreased*** by the PMBI at its discretion depending on its actual need. 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 items 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 to PMBI and the PMBI shall not be responsible for any loss on this account.

N) 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.

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

P) 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.

Q) 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.

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

S) The supplier shall take utmost care in supplying the quality Items and ensure that the batch number mentioned in the packages of the Items 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 Items is mentioned in the invoice. Items to be supplied of any batch shall not be accepted with different MRP.

T) "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.

U) 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).

V) **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 do not 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:

ii) **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

iii) **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

iv) **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

v) **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 **mail** about the confirmation for the receipt of the purchase order.

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

i. The bidder shall have to fill Advance supply notice (ASN) on **PMBI vendor portal** with all other details i.e., invoice copy, Certificate of Analysis (COA), Batch no. Quantity, Date of Manufacturing (DOM) Date of Expiry (DOE), no. of shipper boxes etc.

ii. Once the ASN is accepted by the PMBI, the bidder will be provided the date to execute the supplies at PMBI warehouse as mentioned in purchase order.

Note:

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

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

Sl. No.	Nature of Product	Delivery Schedule (Days)
1	Delivery Schedule against first and subsequent P.O. for all tendered items i.e., **Surgical/ Consumables and Medical Devices etc**.	45 days

E) If the delivery date happened to be a holiday for PMBI, the supply should be completed by 5.00 PM on the next working day.

F) In case of non-execution of the order, PMBI reserves the right to place purchase orders (partially/fully) on alternate source at the risk and cost of the default tenderer(s) without any notice/Information.

G) If a supplier fails to execute supply as per Purchase Order, the 5% of value of unexecuted quantity of Purchase Order shall be recovered from pending bill or Bank Guarantee/Performance security deposit and their bad performance shall be kept in record of PMBI for future dealing as considered appropriate by PMBI.

H) If the Tenderer fails to execute the supply within the stipulated time, the PMBI is at liberty to make alternative arrangement for purchase of the items for which the Purchase orders have been placed, from any other sources or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the defaulted supplier and in such cases the PMBI has every right to recover the cost and impose Liquidated Damages as mentioned in Clause 25.

I) The liquidated damages as specified in clause 25(B) of the tender conditions will be levied on the quantity supplied after the schedule as mentions in Clause 19.(D) from the date of issue of purchase order. However, no supplies will be accepted after 30 days of the expiry of delivery date i.e., completion of specified liquidated damages period as per clause 25(B), the purchase order

shall be cancelled at the risk and cost of the supplier. **However, the supplier must take prior approval from PMBI for supply of items beyond stipulated delivery period in Purchase order.**

J) Supplier shall complete the earliest pending purchase order before commencing the supply of subsequent purchase orders. **Further, supplies against a purchase order are to be made in minimum numbers of batches as far as possible and same batch should not be supplied in repeated consignment.**

K) Bidder must supply the items with minimum 36 months shelf life. Bidders must declare the required shelf-life detail in **Annexure XIII.**

L) The Tenderer must submit an Analysis report for every batch of supplied product along with invoice. In case of failure on part of the supplier to furnish such report, the batch of items will be returned to the suppliers, and he is bound to replenish the same with Govt. approved lab test report.

M) Tenderer should supply the product as follow:

(i) Within 2 months excluding month of manufacture of products having shelf life up to 2 years,

(ii) Within 3 months excluding month of manufacture of products having shelf life more than 2 years & up to 3 years and

(iii) Within 4 months excluding month of manufacture of products having shelf life more than 3 years

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 2022 must be supplied by 31st January 2023 in case shelf life up to 2 Years.

N) If at any time the Tenderer has, in the opinion of the PMBI delayed the supply of items 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 items may be extended by the PMBI at discretion for such period as may be considered reasonable. However, such extension shall be considered only if a specific written request is made by the Tenderer within 10 days from the date of occurrence of such event with necessary documentary evidence. The supplier shall not be liable to pay LD and forfeiture of Security deposit for the delay in executing the contract on account of the extension of supply period on the ground of force majeure events.

O) The exceptional events do not include the Scarcity of raw material, Increase in the cost of raw material, Electricity failure, Labour disputes/Strikes, Insolvency, and Closure of the Factory/Manufacturing unit on any grounds etc.

P) Suppliers are required to supply the items within the delivery period mentioned in the purchase order. In this regard it is informed to the bidders that their performance shall be considered unsatisfactory in case of delayed supply (beyond delivery period) or non-supply of products. PMBI may reject their bid in future tenders considering their unsatisfactory performance of supplies.

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

R) If PMBI observes some physical defects (like empty blisters, improper labelling) of the supplies during sampling, the batch shall be rejected. If supplier wants to take back the batch for rectification, they can take back at their cost, rectify and send back to PMBI within 15 days otherwise same batch shall not be accepted. Due to rectification, if its shelf-life condition as per tender provision does not meet, it shall be discretion of PMBI depending upon requirement to accept the goods with penalty.

S) Tenderers shall not supply the items declared banned by Government of India, even if Purchase Order is placed.

T) If the supplier, or any of its approved items gets debarred/banned/blacklisted by any State Government / Central Government / Central or State Government's Drug procurement agencies after entering into agreement with PMBI, it shall be the responsibility of the supplier to inform PMBI without any delay about the same.

20. LOGOGRAM:

Logogram means, wherever the context occurs, the design as specified in **Enclosure of ANNEXURE-VII. The name of the product shall be mentioned in English and Hindi** as per **Pharmacopoeia/any official Compendium/Medical Device Act 2017** and its strength.

A) Tenders should supply for Items etc., as per the specifications such as name, strength, minimum size and packed with appropriate size of the item etc. as per the design enclosed as per **Enclosure to ANNEXURE –VII.**

B) All form of the supplied product has to be supplied in packing as specified in product list (**ANNEXURE XII**). Affixing of stickers and rubber stamps shall not be accepted and supplies will be returned back at supplier's cost.

C) All supplies/packs containing the items tendered for should also carry the printed PMBJP logogram of proportionate size.

D) Failure to supply Items 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 debarring/blacklisting of the supplier and levied a LD as per clause 25 (D) of tender documents.

E) Items without GS-1 Standard Barcoding on Primary, Secondary and Tertiary Packaging will not be accepted.

21. PACKING:

A) The items shall be supplied in the package specified in **ANNEXURE -VIII** and **ANNEXURE - XII** and the package shall carry the logograms of proportionate size specified in **Enclosures to ANNEXURE –VII** along with other guideline in this regard (if any) whether it is applicable.

a. Male and Female condom must be packed conforming ISO 25841:2017.
b. Menstrual Cup shall be packed in recyclable/ biodegradable materials packaging.
c. Medical devices shall be packed in high quality recyclable/ biodegradable material conforming the Standards and Safety parameters if any.

Note: Final product must be supplied with PMBJP logogram on primary, secondary, and tertiary packing as per Enclose to ANNEXURE –VII. PMBI may ask the awardee/supplier to develop customize artwork if the product is decided for launching.

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 items 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**. 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) It should be ensured that only virgin packaging material of uniform size is used for packing.

E) All primary packing containers should be strictly conforming to the specification included in the relevant pharmacopoeia/official Compendium.

F) **Packing** should be able to prevent damage or deterioration during transit.

G) The packings/labels of two different products of a same supplier should be clearly distinct from each other

H) In the event of items / product 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 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 supplier. In such cases the PMBI has every right to recover the cost and impose penalty as mentioned in Clause 25 & 26.

I) 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 to ANNEXURE VII.
STP (Standard Testing Procedure) for the awarded items are required to submit within 15 days from the date of Letter of Acceptance.

Note: The bidder shall be solely responsible for the labeling on the packing /product, complying with the official compendium/notification/guideline.

J) The colour of the strength must be different from the colour of the generic name of the product on primary and secondary packaging and the approval for the same should be taken from the procurement/ quality/regulatory department while taking artwork approval. The printing ink used should be of good quality (clarity, brightness, contrast) which is easily readable.

K) Therapeutic code, NABL lab tested and other standard confirming the quality of the product 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.

L) 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 items supplied shall be supported by test/ analysis reports furnished by independent NABL Accredited Items Testing Laboratory/Central Drug Testing Laboratory/In House Quality Control Laboratory. The Tender Inviting Authority has the right to get the items 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 Items 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 awarded items are required to be submitted 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 Items shall have the ingredients at the prescribed level as indicated in official compendiums throughout the shelf-life period of the supplied item. The samples will be drawn periodically throughout the shelf-life period and if found "Not of Standard Quality", the cost of entire batch paid will be recovered whether consumed fully/partially. Also, action will be initiated for blacklisting as per clause 26 irrespective of the period of supply. The supplies will be deemed to be completed only upon receipt of the quality certificates from the laboratories. Samples which do not meet quality requirement shall render the relevant batches liable to be rejected. If the sample is declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches will be deemed to be rejected goods.

E. In the event of the samples of Items 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 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 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 items, complete stability data of 6 months' period shall be acceptable.**

H. The products should conform to the standards of **ISO/CE/ISI/any equivalent guideline as the case may be.** In case the product is not included in the any of the said standard/compendium/guideline, the supplier upon award of the contract must provide the reference and standard testing protocols for product testing.

I. The case of admixture of items 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 Items".

23. PAYMENT PROVISION:

A) No advance payments towards costs of items will be made to the supplier.

B) Payments towards the supply of items 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 Mandate form **(ANNEXURE -V)** to make the payment through RTGS/Core Banking/NEFT.

C) All bills/Invoices should be raised in triplicate and the bills should be drawn as per GST Rules in the name of Pharmaceuticals & Medical Devices Bureau of India. 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 Items ordered in the individual Purchase Order provided reports of Standard Quality on samples testing are received from Government Analyst or Approved Laboratories of PMBI.

(ii) However, in case of cancellation of a particular purchase order due to failure in delivery, payment for part supplies less than 50% of the purchase order quantity on the date of cancellation of the purchase order may be considered for release of payment subject to the following:

a) If the Tenderer have supplied at least 50% of the quantity ordered in the subsequent purchase order within delivery period stipulated in purchase order from the issue of such purchase order.
b) If further purchase order is not placed with the supplier due to any reason, not attributable to the supplier, the amount eligible will be paid within 60 days from the date of last supply.
c) The payment for part supply as mentioned above will subject to the deduction of liquidated damages, penalty towards unexecuted quantity, risk and cost etc., as per the tender conditions.

E) If at any time during the period of contract, the price of tendered items is reduced or brought down by any law or Act of the Central or State Government or by the Tenderer himself, the Tenderer shall be bound to inform the PMBI immediately about such reduction in the contracted prices. Tender Inviting Authority is empowered to unilaterally effect such reduction as is necessary in rates in case the Tenderer fails to notify or fails to agree for such reduction of rates.

F) In case of any increase or decrease in the Taxes/GST after the date of submission of tenders and during the tender period, such variation in the taxes/GST will be to the account of the PMBI. For claiming the additional cost on account of the increase in taxes/GST, the Tenderer should produce the proof of having paid additional amount on this account on the goods supplied to PMBI from the concerned authorities and also must claim the same in the invoice separately. However, the basic price structure and the price of the Items 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 items 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 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 pack 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 suffered any damage/loss or not, without prejudice the rights of alternative purchase specified in Clause No.19F,19 H and 21.

E) If the supplier supplies the product beyond the manufacturing date as mentioned in clause 19. (M) of supply conditions, a liquidation damage will be levied @ 5% per month subject to maximum 30% (Up to 6 months).

F) In all the above conditions, the decision of the Tender Inviting Authority shall be final and binding.

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

A) If the samples do not conform to statutory standards, the Tenderer will be liable for relevant action under the existing laws and the entire stock in such batch has to be taken back by the Tenderer within a period of 30 days of the issue of the letter from the PMBI. Such stock shall be taken back at the expense of the Tenderer. Further, actual handling and testing charges shall be paid to PMBI by the supplier otherwise these charges shall be recovered from their pending bill/Performance Security Deposit.

B) The PMBI has the right to destroy such "NOT OF STANDARD QUALITY ITEMS" if the Tenderer does not take back the goods within the stipulated time. The PMBI will arrange to destroy the "NOT OF STANDARD QUALITY ITEMS" 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 items rejected till such time stipulated. Further, the cost of disposal shall be recovered from the supplier.

C) If any item or Items 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 Item or items 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 items 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/ Medical Device Rule 2017 other official compendium 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 not be eligible to participate in tenders of PMBI for supply of Items for a period of 5 years from the date of blacklisting.

In case of supply of "NOT OF STANDARD QUALITY" items to PMBI, the product shall be debarred/blacklisted by PMBI, and no further supplies shall be accepted for the particular product. The Tenderer shall also not be eligible to participate in tenders of PMBI for supply of such Items for a period of 2 years from the date of blacklisting.

In addition, the Director of Drug 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 PMBI, as to the quality of the supplied items 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, penalty will be imposed on the supplier. The excess expenditure over and above contracted prices incurred by the PMBI in making such purchases from any other sources or in the open market or from any other Tenderer who has quoted higher rates and other losses sustained in the process, shall be recovered from the Performance Security Deposit or from any other money due and become due to the supplier and in the event of such amount being insufficient, the balance will be recovered personally from the supplier as per rules.

J) In all the above conditions, the decision of the PMBI shall be final and binding.

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

A) BLACKLISTING OF PRODUCT/TENDERER ON WITHDRAWAL OF TENDER

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

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

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

a) Each and every batch of items 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 items shall be rejected.

(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.

(vi) If **2** batches of item supplied by the same supplier is reported to NOT OF STANDARD QUALITY in specification, then the firm shall be debarred/blacklisted for 2 years after observing procedure laid down in Para 27.B.(d) besides forfeiture of Performance Security Deposit.

(vii) 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 debarred/blacklisted for a period of **2 years from the date of intimation & forfeiture of security deposit.**

c) **Quality Test by Statutory Authorities:**

(i) If any item is declared "NOT OF STANDARD QUALITY", by any government agencies or 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 as per the standard mentioned in ISO/CE/ISI/any equivalent guideline by the Government Authorities during the relevant tender period or during quality check within shelf-life period, the company/firm shall be debarred/blacklisted for a period of 2 **years from the date of blacklisting** after observing procedure laid down in Para 27.B (d).

d) Procedure for Blacklisting:

(i) On receipt of complaint from Distributer/retailers/customers or report from Govt. Analyst/ Drug Testing Laboratory indicating that a particular Item 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 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.

G) BLACKLISTING FOR NON-SUPPLY/PART SUPPLY:

i. 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 at the discretion of PMBI.

ii. If the supplier fails to execute at least 50% of the quantity mentioned in a purchase order and such part supply is come into existence in three Purchase orders during the currency of contract period, then supplier shall be liable for debarment for the particular product for two years. Two years period will be reckoned from the date of issuance of such debarment order.

iii. If a supplier does not supply any quantity against two successive purchase orders, then supplier shall be liable for debarment for the particular product for two years. Two-year period will be reckoned from the date of issuance of such debarment order at the discretion of PMBI.

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.

…….

ANNEXURE – I

Ref. Clause 3 (P)

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. P.			
2	Bid Security declaration on non-judicial stamp paper as per **ANNEXURE-III (Clause 3. A & 6. A)**.			
3	NSIC or MSME or SSI certificate (If EMD is exempted) as per Clause No. 3.A.			
4	Scanned copy of **certificate of recognition as start up** by Department of Industrial Policy and Promotion for quoted item for relaxation of prior turnover and prior experience for Start-ups (as defined by Department of Industrial Policy and Promotion) as per clause no. 3.A.(ii)			
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 valid Manufacturing License/permission of the product quoted as per Clause 3. E.			
8	Copy of valid Quality Management System (QMS) certificate issued on behalf of manufacturing unit by the Licensing Authority/ Drugs Control Department, Bureau of Indian Standards (BIS)/ Indian Standards Institute (ISI) certificate issued from the concerned department (as applicable). The certificate should remain valid till the last date of submission of tender as per Clause 3. (H).			
9	Valid Market standing Certificate (MSC) issued by the C.A. certifying batch No. that the firm/company has manufactured quoted items for last three years.			
10	Self- declaration is to be submitted on company's letter head duly signed by authorized signatory certifying that the firm/company has not been convicted in last three years.			
11	Tenderer must declare their maximum Production Capacity (item wise) issued by concerned Licensing Authority / self-declaration highlighting the quoted product as per Clause no. 3. J.			
12	ANNEXURE –II (Declaration On non-judicial Stamp Paper for eligibility in participating the tender) original Annexure II delivered to PMBI as per clause 3. L.			
13	ANNEXURE IV (Certificate from the C.A. (Chartered Accountant) or Company Secretary. Original Annexure IV delivered to PMBI as per clause 3. K.			
14	ANNEXURE-V (Mandate form) to furnish company bank details as per clause 3 (M) & 23(B)			
15	ANNEXURE-VI indicating manufacturing **License/Permission/ Registration**, validity of license and market standing certificate details as per clause 3. N.			
16	ANNEXURE-VII (Declaration to supply the items as per the design in enclosure in Annexure VII) as per clause 3(O), 20 & 21			
17	ANNEXURE-XV (Declaration on Non-judicial Stamp Paper duly			

	notarized stating that the firm & its quoted product is not blacklisted currently (as on the date of submission of the tender) by Central Government/ Central Government agencies/any State Government or any of the State Government agencies/ or any Drug procurement agencies or by PMBI as per clause 3. D(f).			
19	ANNEXURE – XVI (Declaration % of Local content used in the manufacturing of quoted product) as per clause 3.U.			
20	Copy of valid GS-1 registration certificate for bar coding as per Clause 3. T.			
21	Copy of Audited Annual Balance sheet and Profit and loss statement showing details of their annual average turn over not less than 2 crores for any three of the last four consecutive financial years as per Clause 3. K.			
22	Self-attested copy of PAN Card of the Bidder Company. As per Clause 3. Q.			
23	Self-attested copy of Certificate of valid GST registration of the bidder company. As per Clause 3. R.			
24	Self-attested copy of Income Tax Return for any three of last four consecutive Assessment years. As per Clause 3. S.			
25	Authorization letter nominating an employee of the tenderer to transact the business with the Tender Inviting Authority as per clause 4.0.			
26	Annexure XVII (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.			
27	Self-attested copies of Test Reports as per ISO 10993/ISO12243/ISO 29941.			
28	Self-attested copies of Catalogues along with dimension and design of quoted items as per clause no. 3.W.			

NOTE: - ANNEXURE II, ANNEXURE III (EMD), ANNEXURE IV, ANNEXURE V, ANNEXURE VI, ANNEXURE XV, ANNEXURE XVI, ANNEXURE XVII in original and rest of the document as per checklist duly authorized along with samples should be submitted on or before stipulate date as mentioned in the tender document "technical cover A".

Name of authorized signatory: …….

Signature of authorized signatory: …….

Company seal: ……

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

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/SURGICAL/RC-201/2022 dated 07/07/2022** including Amendment(s) to Tender document (if any) issued by Pharmaceuticals & Medical Devices Bureau of India, 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 Quality Management System (QMS) of the manufacturing unit issued by the Licensing Authority/ Drugs Control Department/ISO/CE/ISI certificate issued from the concerned department (b) valid manufacturing permission/license/registration for quoted drug/non-drug item/medical devices along with all relevant certificate conforming QMS/ISO/CE/ISI and mentioned requirements in the specification (c) valid self-declaration of non-conviction certificate on company's letter head as per Annexure XV (d) valid Market Standing Certificate issued by C.A/C.S confirming that we have manufactured & marketed two batches in last 3 years, (e) declaration of the internationally accepted material **(if any)** and (f) the copies of the specifications for all quoted items and STP (standard testing procedure) quoted items and also enclosed all undertaking/declaration as per Annexure mentioned in the tender document.

(II) B. that I/we shall supply the items as per specification, design, logo and packing given in ANNEXURE-XII, ANNEXURE-VII, ANNEXURE-VIII. That we agree to develop artwork if required by PMBI.

On the basis of above undertaking/declaration, the price bid shall be opened subsequently after opening of technical bid. However, any document uploaded with technical bid is not complying as per undertaking, the contract/ Rate Contract shall be cancelled with forfeiture of Performance Security Deposit/Bank guarantee against tender no. PMBI/SURGICAL/RC-201/2022 dated **07/07/2022** along with other penal action**.**

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

Sr. No.	Item Code	Description of Item as per PMBI Tender	Unit Size	Manufacturing Lic. / Permission / Registration. No.	Date of Issue	Address of Manufacturing Unit

b.) I/We declare that we possess the valid Manufacturing license/Permission/Registration Certificate issued by competent authority and complies and continue to comply with the condition lied there under to manufacture the items.

I am / We are aware of the Tender inviting Authority's right to forfeit the Earnest Money Deposit and /or Performance Security Deposit and blacklist me/us for a period of 5 years if, any

information furnished by us proved to be false at time the of inspection and not complying the condition 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 item with bar code as per ANNEXURE IX and as per the design as per enclosures to ANNEXURE VII 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 Earnest Money Deposit can be forfeited 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 items 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/SURGICAL/RC-201/2022 dated 07/07/2022** for the following quoted products with mentioned shelf life in Annexure XIII: -

S. No.	Item Code	Description of Item as per PMBI Tender	Unit Size	Shelf life as per Annexure XIII

(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 too be invariable.

Signed……
Name: ……
Designation…….……

(Company Seal)

Witness: -

(1) Signed: …….
Name: ……...
Designation: …….

(2) Signed: ……
Name: ……...
Designation: …….

To be attested by the Notary

ANNEXURE-III

(Ref: -Clause **3(A),** 6.A)

DETAILS OF EMD SUBMITTED

(UPLOAD THE SCANNED COPY OF DRAFT/ PAY ORDER/BANK GURANTEE/NEFT RECEIPT)

In case bidder willing to submit Bank Guarantee (BG)

MODEL BANK GUARANTEE (BG) FORMAT FOR FURNISHING EMD (if bidder intends to submit BG)

Whereas……(hereinafter called the "tenderer") has submitted their offer dated…….…… for the supply of Items (hereinafter called the "tender") against the purchaser's tender enquiry No. PMBI/SURGICAL/RC-201/2022 know all men by these presents that we……. of…….……..……having our registered office at...…… …… are bound unto Pharmaceuticals and Medical Devices Bureau of India (PMBI) of India New Delhi(hereinafter called the "Purchaser) in the sum of Rs. 100000.00 (One lakh) only for which payment will and truly to be made to the said Purchaser, the Bank binds itself, its successors and assigns by these presents. Sealed with the Common Seal of the said Bank this…… day of …….202..

The conditions of this obligation are:

(1) If the tenderer withdraws or amends, impairs or derogates from the tender in any respect within the period of validity of this tender.

(2) If the tenderer having been notified of the acceptance of his tender by the Purchaser during the period of its validity: -

(a) Fails or refuses to accept/execute the contract.

We undertake to pay the Purchaser up to the above amount upon receipt of its first written demand, without the Purchaser having to substantiate its demand, provided that in its demand the Purchaser will note that the amount claimed by it is due to it owing to the occurrence of one or both the two conditions, specifying the occurred condition or conditions.

This guarantee will remain in force up to 12 months from the due date of tender i.e., ...and any demand in respect thereof should reach the Bank not later than the above date.

(Signature of the authorized officer of the Bank) …….

Name of the officer……

Designation of the officer……..

Seal, name & address of the Bank and address of the Branch……...

ANNEXURE- IV

Ref. Clause No. 3. (K)

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

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

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

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

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 items. 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 items 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 & Small Enterprises (MSE) and registered with Director of Industries of concerned State/UT or appropriate authorities for quoted items against PMBI tender No. **PMBI/SURGICAL/RC-201/2022** and eligible for exemption of paying EMD. This MSEs is owned by Scheduled Caste (SC)/Scheduled Tribe (ST) entrepreneurs.

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

Date:

Name: ……

Signature: ……..

Stamp: ……

Registration No.:…….

NOTE

(i) Strike which is not applicable in above certificate.

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

ANNEXURE V

Ref. clause 3 (M) & 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 / artwork (technical person).***	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 / Logistic support. /Artwork***	Name:
		Designation:
	Mobile No.	
	E-mail ID	
7.	**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 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:

Note: Above format without the Signature of the authorized official of the bank and seal/stamp shall not be accepted.

Annexure VI

Ref Clause No. 3 (N)

S.N.	Item Code (Only Quoted items as mentioned in Annexure II)	Unit Size	Item Manufacturing License / Permission					Marketing standing Certificate (MSC)		
			Manufacturing License / Permission/ Registration No.	Manufacturing License / Permission/ Registration Issue date	Manufacturing License / permission/ Registration Renewal Date	License Validity Date	Page no. of Document in uploaded Scan Copy (Do not put page nos. in range)	Market Standing Certificate Issue Date	Period of Marketing as per Marketing standing Certificate (MSC)	Page no. of Document in uploaded Scan Copy (Do not put page nos. in range)

Note:

(i) In case any details as desired above is missing/not submitted against quoted items, the bid for such items is liable to be rejected.

(ii) It is strictly, do not put page nos. in range, indicate the page nos. one by one for all respective quoted items codes.

Signature:

Name:

Authorized Signatory:

Seal of the Company:

ANNEXURE -VII

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

DECLARATION

I/We do hereby declare that I/we will supply the item as per the design in Enclosure to Annexure VII as well as other instruction given in this regard. I/We do hereby also declare that I/we will supply the final product with "PMBJP" logogram on it.

Signature of the Tenderer

Name: ……

Designation: …….

(Company Seal)

Enclosure to ANNEXURE - VII

Ref. Clause No. 20

DESIGN FOR: Mono pack

1. **Text Matter Printing on** mono pack 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 Item 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 the product.
5. Title name of generic item should be **bold** in minimum 12 font size & the strength corresponding to it must be **bold** in minimum 14 font sizes and it may increase respectively according to size of label & the rest text matter should be in minimum 8 font size.
6. The stereo printing of batch no./manufacturing /expiry date & other details shouldn't overlap the text matter.
7. "Pharmaceuticals & Medical Devices Bureau of India(PMBI)" should be running text only and should not be prominent.

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

SPECIMEN LABEL FOR MONO CARTON (Secondary Packing)

Generic Name of Product: **XXXXXXX**

प्रधानमंत्री
भारतीय
जन औषधि
परियोजना

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

Note: An additional to any statuary requirement.

ANNEXURE-VIII

Ref. Clause No. 21.(A), 21 (A) .(c)

SCHEDULE FOR PACKAGING OF ITEMS

GENERAL SPECIFICATIONS

A.

(i) **Primary Package:**

Each Primary Package shall contain ordered product in standard packing material with a minimum micron thickness that ensures that the pack does not tear in routine handling (subject to approval of sample by concerned Officer/Committee) which will confirm to size of the product and sealed properly.

(ii) **Secondary Package:**

a. 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 product, it shall be with minimum bursting strength of 9-10 Kg/cm2.

b. **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.

c. One Box shall contain primary packages of supplied products as described in Column 5 of Annexure XII.

ANNEXURE IX
(BARCODE REQUIREMENTS}
Reference clause 21(L)

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

These requirements cover items 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 items 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 items 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-

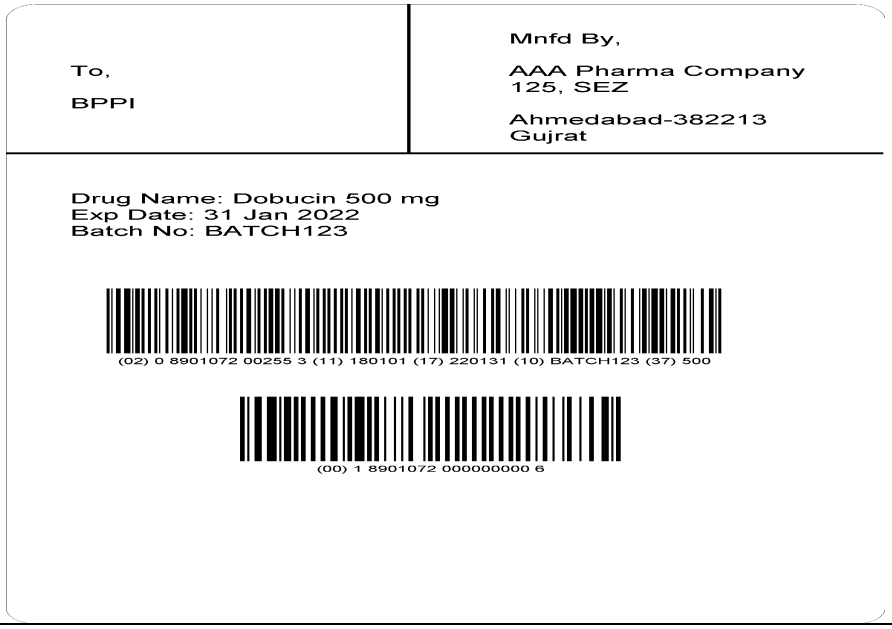
1) *While encoding Manufacturing and expiry date in the barcode, if a specific Manufacturing or expiry date is not printed on the finished pack/ then Supplier should select first day of the month as the Manufacturing date and Last day of the month as expiry date.*

   Example- If Shelf life is 24 months, April 2022 manufacturing date should be encoded as 220401 and March 2024 expiry date as 240331.

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 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.

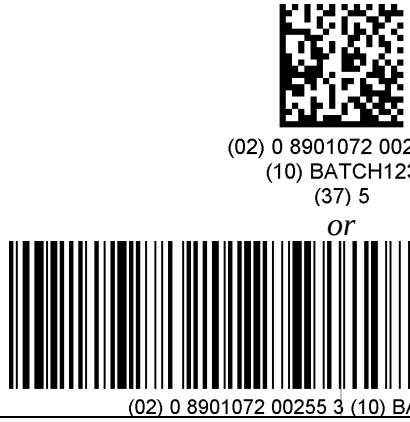
Note-

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 packs*

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*				

Primary Level Pack:

Is defined as the first level of packaging in direct contact with the product.

<u>Scenario-I</u> 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*	*2*	*Fixed*	*Numeric*

	indicate GTIN-14 Brackets not encoded in the barcode			
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 Item code-

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

Barcode Design and Printing-

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

Please contact GS1 India office for any further assistance –

GS1 India
(Under Min. of Commerce, Govt. of India)
330, 2nd Floor, 'C' Wing, August Kranti Bhawan,
Bhikaji Cama Place, New Delhi - 110066
T +91-11-42890890, (D) +91-11-42890846
F +91-11-26168730
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 claimed
1					
2					
3					

That I……..abide by the terms and conditions laid down in guidelines issued by Department of Pharmaceuticals, Ministry of Chemicals & fertilizers, Government of India vide F. No. 31026/36/2016-MD policy dated 09.11.2020 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*. P-45021/2/2017-PP(BE-II) dated 16.09.2020 and as per table mentioned under Clause 3.U.

ANNEXURE-XI

Ref: Clause No. 15.E

Letter of acceptance of tender for Rate Contract

Speed post/e-mail

Ref. No. PMBI/SURGICAL/RC-201/2022 **Date: …….**

To,
M/S_____
_____

Sub: Tender for the Supply of Surgical/ Consumables and Medical Devices to PMBI for two years: Acceptance tender for Rate Contract.
Ref: Your quotation against PMBI e-Tender No. PMBI/SURGICAL/RC-201/2022 dated: 07/07/2022 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 Items 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.	Item Code	Item 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: procure11@janaushadhi.gov.in; procure13@janaushadhi.gov.in; procure12@janaushadhi.gov.in & quality8@janaushadhi.gov.in)
6. STP (Standard Testing Procedure) for Non- Pharmacopoeia awarded items are required to submit to Quality Control department (e-mail id: procure11@janaushadhi.gov.in; procure13@janaushadhi.gov.in; procure12@janaushadhi.gov.in & quality8@janaushadhi.gov.in) within 15 days from the date of Letter of Acceptance.
7. As per clause 4. L 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 (PMBI), New Delhi
Tender No. PMBI/SURGICAL/RC-201/2022 dated 07/07/2022)

(1)	(2)	(3)	(4)	(5)	(6)
S. N.	**Item Code**	**Generic Name of Item**	**Unit Size**	**Secondary Pack**	**Indicative Requirement in Unit Size**
1	1460	Reusable Insulin Pen (Suitable for all type of Cartridge)	One in Mono-Pack	One in Mono-Pack X 100	500000.00
2	8128	**Digital Medical Thermometer (100% Mercury Free) with Storage Case:** Temperature measurement range: Dual-mode measurement in Degree Celsius and Fahrenheit (°F & °C), Range; 32 – 43 °C minimum guaranteed. Accuracy: ± 0.1°C in the range specified range Graduation: 0.3°C or better. Display: LCD display for the ease of reading in all levels of light. Designed: Robust design made of ABS Plastic, breck resistance, easy to frequent cleaning and disinfection with hospital-grade products. Power: Battery powered (Coin battery), batteries included in the supply, preferably packed separately. Battery Life: Durable for minimum of 4,000 measurements. Automatic switch-off when not in use. Ready-to-use after switch-on within 10 second. Measurement time: within 90-120 seconds. Indication: Low and high temperature indication. Low battery indicator. Beep audio alert when device is turned on/ready to use or when temperature measurement is complete. Shall be waterproof. Suitably used for taking body temperatures measurements from oral, armpit and rectum. Memory function supported. Warranty: One years. Storage conditions: -20 - 55°C / 85% RH. Operating conditions: 10 - 40°C / 85% RH. Certification: Certified for ISO 13485/ ISO 9001 for Quality management systems and CE certified for Market Clearance and Device Classification. Safety and Product Standards shall be of ISO standard. Note: Hazardous Raw Material shall strictly not be Used.	One in Mono-Pack	One in Mono-Pack X 100	500000.00
3	8130	**Manual Breast Pump:** Body: Screw-fit, graduated bottle includes a cap, screw ring and sealing disk. Equipped with lever to operate the pump, a valve, and diaphragm. Ergonomic design for single-handed operation, with swivel lever for smooth milk extraction. Comes including comfortable breast shield. Low-force operating lever. Allows for complete disassembly. Capacity: 150 ml Bottle. Pumping frequency 30 to 80 cpm and user adjustable. Dust cover protection on breast cup with inserted Cushion inside the cup so that it does not hurt the mother. Suction Pressure 100 to 250 mm Hg; user adjustable Cleaning: Easy to frequent cleaning at a minimum should be able to withstand 5 minutes in boiling water for cleaning. Material: Bottle, pump mechanism, cap and stand: polypropylene, polyethylene or TPE. Membrane and seal: silicone. Storage conditions: -20 - 50°C / 20 – 90 % RH. Operating conditions: 10 - 40°C / 20 - 80% RH. Warranty: One years. Components of Manual Pump: Certification: Certified for ISO 13485/ ISO 9001 for Quality management systems and CE certified for Market Clearance and Device Classification. Safety and Product Standards: shall comply with Regulation on materials and articles intended for food contact for Child use, high grade approved materials and articles intended to come in contact with food. Note: Hazardous Raw Material shall strictly not be Used.	One in Mono-Pack	One in Mono-Pack X 10	300000.00
4	8133	**Digital Blood Pressure Instrument (100% mercury free):** Fully Automated upper arm style with LCD Digital Display/Digital monitor with	One in Mono-Pack	One in Mono-Pack X 10	300000.00

		acrylic panel and 3 colour backlit display for indication on display, Display shall show Numerical Data for reading. Displayed parameters: Unit should display systolic pressure, diastolic pressure, pulse rate and mean arterial pressure. Dimension: Design shall be handy and Portable and as per market standard. Measuring Method: Oscillometric technique. Measurement Range: Pressure- 0mmHg – 300 mmHg (0.00 kPa to 39.9 kPa), Pulse- 30 to 199 Beats/Minute Measurement Accuracy: Pressure- ± 3mmHg Pulse- ± 5%, Measurement time (s): ≤ 60, user selectable. Power supplies: AA / AAA Alkaline Battery and USB operated. Memory: 2 x 99 Memory (90-99 memory). Storage conditions: Temperature range when in use: from 5°C to 40°C. 15% to 90% RH. Storage and transport conditions: - 20°C to 60°C. 10% to 95% RH. Equipment alarms preferred: Hose leak, inflation, or deflation error, Irregular Heartbeat Detection, Low Battery alarm, reading failure alarm. Accessories: High quality Arm Cuff (dimension 22 cm to 32 cm) with tube of suitable length, Protective case. USB Cable, 4 AA / AAA Alkaline battery set, User manual, Warranty Card. Shelf Life and warranty: Five Years with 2-year warranty (from the date of sale at Janaushadhi Kendra) Clinically validated algorithm International Standards: ISO 13485:2016 Certified, FDA Certified, CE certified.			
5	8136	**Electric Nebulizer Machine:** Compressor Nebulizer Machine Motor: Piston Compressor Motor with 25mm Copper binding Body: ABS body Particle Size: < 0.5 um (μm) Sound: 50-55 dB Standards and Safety Certificates: ISO 13485:2016 Certified, WHO-GMP Certified, FDA / CE; ISO 27427-2010. Warranty: 2 Years Weight (Ibs, kg) / Design: <2kg and design shall be handy and Portable. Medication Cup: Shall be scaled for 2-6 ml medication Power Consumption: Product shall be power efficient Knob/Switch: Good quality indicator switch. Storage conditions: Temperature range when in use: from 5°C to 40°C. 15% to 90% RH. Storage and transport conditions: - 20°C to 60°C. 10% to 95% RH. Electric Cable: ISI certified 1.5 meter long, Plug shall be so designed to save from any shock while plugging in. Accessories: Compressor Nebulizer Machine, Adult mask, Child Mask, Mouthpiece, Medicine Cup, Filter (8pcs), Air Tube, Warranty Card, and Pouch. Nebulizer Mask with Tubing: shall be free from any kind of odour, made of clear, Non-toxic PVC, medium concentration, adjustable nose clip & non-autoclave Tube Length: 2-meter, Nebulization rate: 3cc / 10 mins. Packing: All the Accessories shall be supplied with good quality storage pouch (Made of clothing/durable material).	One in Mono-Pack	One in Mono-Pack X 10	150000.00
6	8146	**Baby Feeding Bottle 250 ml**: Material Bottle: Polypropylene Cap: HDPE Nipple: Soft silicone (Medium flow) Key Features: Non – sticky surface easy to sterilize, Wide Neck for easy filling and cleaning Anti-colic system to prevent colic, gas and reflux, Leak free, Ergonomic shape for easy comfort Body: Screw Cap, Bottle Neck Type – Standard, Sterilizer Safe – Yes, BPA Free – Yes, Microwave Safe – Yes, Dishwasher Safe – Yes Product shall confirm IS 10910 Note: Hazardous Raw Material shall strictly not be Used.	One in Mono-Pack	One in Mono-Pack X 100	800000.00
7	8194	**Cotton Balls**: White in colour, Regular size, 100% natural cotton, soft, gentle on skin & absorbent, Hypoallergenic, baby skin friendly, Ideal for delicate application. Zero fragrances and dies used. Weight: 1gm ball	Pack of 100 in a zip lock bag	1's pack X 100	1500000.00
8	8196	**Heating pad (electrical) Automated:** Dimension: Width- 23-25 cm; Length-30-32 cm Body: Outer Part shall be made of high-quality fabric for skin friendly, soft, and comfortable feeling. Stretchable and adjustable straps shall be provided for tighter fitting and compression on any part of the body. Auto cut feature to avoid overheating and shall be provided with ISI marked charging cable and charging port.	One in Mono-Pack	One in Mono-Pack X 100	300000.00

		An electric hot gel pouch filled & sealed with special gel, used to provide warmth, typically whilst in bed, but also for the application of heat to a specific part of the body, Useful for providing instant relief from pain and treatment of sports injuries, arthritis, sore neck, backache, muscular pains, cramps, hypothermia, sprains, growing pains Heating time: 5 to 10 mins Size: Universal			
9	8197	**Exercise Ball**: Soft sponge stress ball with smiley face printed on it, Compatible for hydro and thermal therapy, Compatible for exercise of forearm, hand, wrist and fingers, non-sticky, Polyurethane Foam, waterproof, non-disintegrating. Size: Universal	One in Mono-Pack	One in Mono-Pack X 250	1000000.00
10	9000	**Reusable Menstrual Cup (non-absorbent bell-shaped hygienic device)-**Small: Medical grade silicone shall be used with medical grade platinum catalyst for polymer cross linkage, FDA/CE Compliance, Shall be Biocompatible. Air holes: At least two air hole of 1 mm size close to the rim covering 2 side. Cup Wall thickness: 2 mm (± 0.3 mm) Pull out stem length: minimum 15 cm Size: Small; Diameter of Outer rim: 36-40 mm Length of the cup excluding pull Out stem: approx. 40-50mm Cup Storage capacity: 15-25 ml Minimum Shelf life: Minimum 5 Years as per ISO-2230:2002 Colour: Colourless/Transparent Testing: Cup shall be tested within International standards i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization). Regulation and Conformity: ISO 9001:2015 or ISO 13485 certified *(shall be supplied with protective textile pouch and user instructions.) Material shall be biocompatible ensuring it no change in performance after multiple uses, good tear strength and endures boiling, cyclic use and pulling out, easy insertion and removal, dimensionally stable.	One in Mono-Pack	One in Mono-Pack X 100	300000.00
11	9001	**Reusable Menstrual Cup (non-absorbent bell-shaped hygienic device)-** Medium: Medical grade silicone shall be used with medical grade platinum catalyst for polymer cross linkage, FDA/CE Compliance, Shall be Biocompatible, Air holes: At least two air hole of 1 mm size close to the rim covering 2 side. Cup Wall thickness: 2 mm (± 0.3 mm) Pull out stem length: minimum 15 cm Size: Small; Diameter of Outer rim: 41-44 mm Length of the cup excluding pull Out stem: approx. 45-55mm Cup Storage capacity: 20-30 ml Minimum Shelf life: Minimum 5 Years as per ISO-2230:2002 Colour: Colourless/Transparent Testing: Cup shall be tested within International standards i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization). Regulation and Conformity: ISO 9001:2015 or ISO 13485 certified * (shall be supplied with protective textile pouch and user instructions). Material shall be biocompatible ensuring it no change in performance after multiple uses, good tear strength and endures boiling, cyclic use and pulling out, easy insertion and removal, dimensionally stable.	One in Mono-Pack	One in Mono-Pack X 100	500000.00
12	9002	**Reusable Menstrual Cup (non-absorbent bell-shaped hygienic device)-**Large: Medical grade silicone shall be used with medical grade platinum catalyst for polymer cross linkage, FDA/CE Compliance, Shall be Biocompatible, Air holes: At least two air hole of 1 mm size close to the rim covering 2 side. Cup Wall thickness: 2 mm (± 0.3 mm) Pull out stem length: minimum 15 cm Size: Small; Diameter of Outer rim: 45-48 mm Length of the cup excluding pull Out stem: approx. 48-58mm Cup Storage capacity: 30-40 ml Minimum Shelf life: Minimum 5 Years as per ISO-2230:2002 Colour: Colourless/Transparent Testing: Cup shall be tested within International standards i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization). Regulation and Conformity: ISO 9001:2015 or ISO 13485 certified * shall be supplied with protective textile pouch and user instructions).	One in Mono-Pack	One in Mono-Pack X 100	500000.00

		Material shall be biocompatible ensuring it no change in performance after multiple uses, good tear strength and endures boiling, cyclic use and pulling out, easy insertion and removal, dimensionally stable.			
13	9003	**Female Natural Latex Condom:** Pouch Dimension: Total Device Length: 125-145 mm Width: 66-77 ± 2 mm Thickness: 0.09 - 0.12 mm External Retainer: Made of High-Grade Polyethylene Diameter: 70-80 mm Thickness (in mm): 1.5 – 2.5 mm width (in mm): 2.0-4.0 mm Colour and Shape: Natural / white and Suitable Internal Retainer: Made of Polyurethane open cell foam Outer diameter (in mm): 47-53 mm Inner diameter (in mm): 7.0 – 13 mm Thickness (in mm): 11.0 – 13.0 mm Colour and Shape: Natural / white and Suitable Lubricant: Silicon Oil, minimum 750mg Colour: Pink / Blue / Green / Yellow / Red / Natural / Brown Flavour: Chocolate / Strawberry / Litchi / Apple Pitch / Fruit Punch / Jasmine / Mango / Banana / Black Grape / Coffee / Hazelnut / Mixed Fruit / Red Bull / Toffee / Bela / Green - apple / Butterscotch / Paan / Rose / Guava / Orange / Pine Apple / Bubble-gum. Testing: Condom shall be tested within International standards i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization), ISO 11737:2018. For protein test: ISO 12243 & For Nitrosamines: ISO 29941. Specification shall comply BIS/ISO 4074:2014 Conforming QMS 13485:2016/NS-EN ISO 13485:2016 Packaging: Shall comply ISO 25841:2017 Hazardous Raw Material shall strictly not be Used. Shelf Life: 3 Years NOTE: Condom shall be free from holes and shall adhere to Schedule R of Drugs and Cosmetics Act 1940 and Rules there under 1945.	Three in Mono-Pack	One in Mono-Pack X 10	500000.00
14	9004	**Male Latex Condom (Plain):** Width: 53 ± 2 mm Length: 180 mm Thickness: 0.060- 0.080 mm Lubricant: Silicon Oil; Not less than 350mg Colour: Pink / Blue / Green / Yellow / Red / Natural / Brown Flavour: Chocolate / Strawberry / Litchi / Apple Pitch / Fruit Punch / Jasmine / Mango / Banana / Black Grape / Coffee / Hazelnut / Mixed Fruit / Red Bull / Toffee / Bela / Green - apple / Butterscotch / Paan / Rose / Guava / Orange / Pineapple / Bubble-gum. Safety and Standards: Condom shall be tested within International standards i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization), ISO 11737. For protein test: ISO 12243 & For Nitrosamines: ISO 29941. Product Shall confirm ISO 25841-2017 Specification shall comply BIS/ISO 4074:2014 Conforming QMS 13485:2016/NS-EN ISO 13485:2016 Packaging: Shall comply ISO 25841:2017 Shelf Life: 3 Years NOTE: Condom shall be free from holes and shall conform Schedule R of Drugs and Cosmetics Act 1940 and Rules there under 1945. Hazardous Raw Material shall strictly not be Used.	Three in Mono-Pack	Three in Mono-Pack X 200	3000000.00
15	9005	**Male Latex Condom (Extra Thin)**: Width: 53 ± 2 mm Length: 180 mm Thickness: 0.040 ± 0.060 mm Lubricant: Silicon Oil; Not less than 350mg Colour: Pink / Blue / Green / Yellow / Red / Natural / Brown Flavour: Chocolate / Strawberry / Litchi / Apple Pitch / Fruit Punch / Jasmine / Mango / Banana / Black Grape / Coffee / Hazelnut / Mixed Fruit / Red Bull / Toffee / Bela / Green - apple / Butterscotch / Paan / Rose / Guava / Orange / Pineapple / bubble-gum. Safety and Standards: Condom shall be tested within International standards i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-	Three in Mono-Pack	Three in Mono-Pack X 200	5000000.00

		10 (Mucosal Irritation & Sensitization), ISO 11737. For protein test: ISO 12243 & For Nitrosamines: ISO 29941. Product Shall confirm ISO 25841-2017 Specification shall comply BIS/ISO 4074:2014 Conforming QMS 13485:2016/NS-EN ISO 13485:2016 Packaging: Shall comply ISO 25841:2017 Shelf Life: 3 Years NOTE: Condom shall be free from holes and shall conform Schedule R of Drugs and Cosmetics Act 1940 and Rules there under 1945. Hazardous Raw Material shall strictly not be Used.			
16	9006	**Male Latex Condom (Normal Dot)**: Width: 53 ± 2 mm Length: 180 mm Thickness: 0.060- 0.080 mm Lubricant: Silicon Oil; Not less than 350mg Colour: Pink / Blue / Green / Yellow / Red / Natural / Brown Flavour: Chocolate / Strawberry / Litchi / Apple Pitch / Fruit Punch / Jasmine / Mango / Banana / Black Grape / Coffee / Hazelnut / Mixed Fruit / Red Bull / Toffee / Bela / Green - apple / Butterscotch / Paan / Rose / Guava / Orange / Pine Apple / bubble-gum. Safety and Standards: Condom shall be tested within International standards i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization), ISO 11737. For protein test: ISO 12243 & For Nitrosamines: ISO 29941. Product Shall confirm ISO 25841-2017 Specification shall comply BIS/ISO 4074:2014 Conforming QMS 13485:2016/NS-EN ISO 13485:2016 Packaging: Shall comply ISO 25841:2017 Shelf Life: 3 Years NOTE: Condom shall be free from holes and shall conform Schedule R of Drugs and Cosmetics Act 1940 and Rules there under 1945. Hazardous Raw Material shall strictly not be Used.	Three in Mono-Pack	Three in Mono-Pack X 200	5000000.00
17	9007	**Male Latex Condom (1740 Dot):** Width: 53 ± 2 mm Length: 180 mm Thickness: 0.060- 0.080 mm Lubricant: Silicon Oil; Not less than 350mg Colour: Pink / Blue / Green / Yellow / Red / Natural / Brown Flavour: Chocolate / Strawberry / Litchi / Apple Pitch / Fruit Punch / Jasmine / Mango / Banana / Black Grape / Coffee / Hazelnut / Mixed Fruit / Red Bull / Toffee / Bela / Green - apple / Butterscotch / Paan / Rose / Guava / Orange / Pineapple / bubble-gum. Safety and Standards: Condom shall be tested within international standards i.e., i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization), ISO 11737. For protein test: ISO 12243 & For Nitrosamines: ISO 29941. Product Shall confirm ISO 25841-2017 Specification shall comply BIS/ISO 4074:2014 Conforming QMS 13485:2016/NS-EN ISO 13485:2016 Packaging: Shall comply ISO 25841:2017 Shelf Life: 3 Years NOTE: Condom shall be free from holes and shall conform Schedule R of Drugs and Cosmetics Act 1940 and Rules there under 1945. Hazardous Raw Material shall strictly not be Used.	Three in Mono-Pack	Three in Mono-Pack X 200	5000000.00
18	9008	**Male Latex Condom (Ribbed)**: Width: 53 ± 2 mm Length: 180 mm Thickness: 0.060- 0.080 mm Lubricant: Silicon Oil; Not less than 350mg Colour: Pink / Blue / Green / Yellow / Red / Natural / Brown Flavour: Chocolate / Strawberry / Litchi / Apple Pitch / Fruit Punch / Jasmine / Mango / Banana / Black Grape / Coffee / Hazelnut / Mixed Fruit / Red Bull / Toffee / Bela / Green - apple / Butterscotch / Paan / Rose / Guava / Orange / Pineapple / bubble-gum. Safety and Standards: Condom shall be tested within international standards i.e., i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-	Three in Mono-Pack	Three in Mono-Pack X 200	5000000.00

		10 (Mucosal Irritation & Sensitization), ISO 11737. For protein test: ISO 12243 & For Nitrosamines: ISO 29941. Product Shall confirm ISO 25841-2017 Specification shall comply BIS/ISO 4074:2014 Conforming QMS 13485:2016/NS-EN ISO 13485:2016 Packaging: Shall comply ISO 25841:2017 Shelf Life: 3 Years NOTE: Condom shall be free from holes and shall conform Schedule R of Drugs and Cosmetics Act 1940 and Rules there under 1945. Hazardous Raw Material shall strictly not be Used.			
19	9009	**Male Latex Condom (Three in One)**: Width: 53 ± 2 mm Length: 180 mm Thickness: 0.060- 0.080 mm Lubricant: Silicon Oil; Not less than 350mg Colour: Pink / Blue / Green / Yellow / Red / Natural / Brown Flavour: Chocolate / Strawberry / Litchi / Apple Pitch / Fruit Punch / Jasmine / Mango / Banana / Black Grape / Coffee / Hazelnut / Mixed Fruit / Red Bull / Toffee / Bela / Green - apple / Butterscotch / Paan / Rose / Guava / Orange / Pineapple / bubble-gum. Safety and Standards: Condom shall be tested within international standards i.e., i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization), ISO 11737. For protein test: ISO 12243 & For Nitrosamines: ISO 29941. Product Shall confirm ISO 25841-2017 Specification shall comply BIS/ISO 4074:2014 Conforming QMS 13485:2016/NS-EN ISO 13485:2016 Packaging: Shall comply ISO 25841:2017 Shelf Life: 3 Years NOTE: Condom shall be free from holes and shall conform Schedule R of Drugs and Cosmetics Act 1940 and Rules there under 1945. Hazardous Raw Material shall strictly not be Used.	Three in Mono-Pack	Three in Mono-Pack X 200	5000000.00
20	9010	**Medicated Corn Remover:** (Medicated Corn Plaster Strips contains Salicylic Acid 40% w/w ointment) Product shall be so defined to fit on to corn. It shall be provided with good adhesive layer, free form fibre. ISO 13485/ISO 9001, GMP and CE certified	Four strips in mono-pack	One in Mono-Pack X 100	1000000.00
21	9011	**Perforated Plaster**: Contains belladonna extract not less than 0.25% w/w Fabric thickness: not less than 90g/m2 Plaster shall be perforated with protective layer of silicon paper on adhesive surface (with Janaushadhi Art-work printed) Size of plaster is 10cm x 16cm ISO 13485 and CE certified.	Five in mono-pack	One in Mono-Pack X 100	300000.00
22	9012	**Lumbo-Sacral Support Belt (Waist and back support):** For unisex with flexible back splints, Easy to fit body shape for excellent Immobilization, Material: Porous elastic webbing, Heat resistant rubber with high modulus of elasticity Double pull mechanism for secure fitting around the waist, suitably large hook loop panel for controlled compression, and better sizing flexibility. ISO 13485 and CE certified Size: Small 28-32 inch One in mono-pack	One in Mono-Pack	One in Mono-Pack X 50	200000.00
23	9013	**Lumbo-Sacral Support Belt (Waist and back support):** For unisex with flexible back splints, Easy to fit body shape for excellent Immobilization, Material: Porous elastic webbing, Heat resistant rubber with high modulus of elasticity Double pull mechanism for secure fitting around the waist, suitably large hook loop panel for controlled compression, and better sizing flexibility. ISO 13485 and CE certified Size: Medium 32-36 inch One in mono-pack	One in Mono-Pack	One in Mono-Pack X 50	200000.00
24	9014	**Lumbo-Sacral Support Belt (Waist and back support):** For unisex with flexible back splints, Easy to fit body shape for excellent Immobilization, Material: Porous elastic webbing, Heat resistant rubber with high modulus of	One in Mono-Pack	One in Mono-Pack X 50	200000.00

		elasticity Double pull mechanism for secure fitting around the waist, suitably large hook loop panel for controlled compression, and better sizing flexibility. ISO 13485 and CE certified Size: Large 36-40 inch One in mono-pack			
25	9015	**Lumbo-Sacral Support Belt (Waist and back support):** For unisex with flexible back splints, Easy to fit body shape for excellent Immobilization, Material: Porous elastic webbing, Heat resistant rubber with high modulus of elasticity Double pull mechanism for secure fitting around the waist, suitably large hook loop panel for controlled compression, and better sizing flexibility. ISO 13485 and CE certified Size: Extra Large 40-44 inch One in mono-pack	One in Mono-Pack	One in Mono-Pack X 50	200000.00
26	9016	**Lumbo-Sacral Support Belt (Waist and back support):** for unisex with flexible back splints, Easy to fit body shape for excellent Immobilization, Material: Porous elastic webbing, Heat resistant rubber with high modulus of elasticity Double pull mechanism for secure fitting around the waist, suitably large hook loop panel for controlled compression, and better sizing flexibility. ISO 13485 and CE certified Size: Double Extra Large 44-48 inch One in mono-pack	One in Mono-Pack	One in Mono-Pack X 50	200000.00
27	9017	**Anklet (Tubular Support):** Four way stretchable, bi-layered fabric (outer layer made of nylon and inner layer made of fine grade cotton), Heat resistant rubber with high modulus of elasticity. Hypoallergenic, uniform compression, simple pull-on application. To provide mild compression, warmth & support to the ankle joint. Suitable for pain and inflammation associated with old age arthritis support etc. One in mono-pack. Size: Small (18-21 Inch)	Pair in Mono-Pack	Pair in Mono-Pack X 100	300000.00
28	9018	**Anklet (Tubular Support):** Four way stretchable, bi-layered fabric (outer layer made of nylon and inner layer made of fine grade cotton), Heat resistant rubber with high modulus of elasticity. Hypoallergenic, uniform compression, simple pull-on application. To provide mild compression, warmth & support to the ankle joint. Suitable for pain and inflammation associated with old age arthritis support etc. One in mono-pack Size: Medium (21-24 Inch)	Pair in Mono-Pack	Pair in Mono-Pack X 100	300000.00
29	9019	**Anklet (Tubular Support)**: Four way stretchable, bi-layered fabric (outer layer made of nylon and inner layer made of fine grade cotton), Heat resistant rubber with high modulus of elasticity. hypoallergenic, uniform compression, simple pull-on application. To provide mild compression, warmth & support to the ankle joint. Suitable for pain and inflammation associated with old age arthritis support etc. One in mono-pack Size: Large (24-27 Inch)	Pair in Mono-Pack	Pair in Mono-Pack X 100	300000.00
30	9020	**Anklet (Tubular Support):** Four way stretchable, bi-layered fabric (outer layer made of nylon and inner layer made of fine grade cotton), Heat resistant rubber with high modulus of elasticity. hypoallergenic, uniform compression, simple pull-on application. To provide mild compression, warmth & support to the ankle joint. Suitable for pain and inflammation associated with old age arthritis support etc. One in mono-pack Size: Extra Large (27-30 Inch).	Pair in Mono-Pack	Pair in Mono-Pack X 100	300000.00
31	9021	**Elbow Support:** Material: Breathable, hypoallergenic, dual-stretch power knit material made of cotton, nylon. Easy to put on and take off; use on left or right elbow Helps provide compression, relief, and protection. Dimensionally fit to provide uniform compression. Heat resistant rubber with high modulus of elasticity. Size: Small 18-25 cm	Pair in Mono-Pack	Pair in Mono-Pack X 100	300000.00
32	9022	**Elbow Support:** Material: Breathable, hypoallergenic, dual-stretch power knit material made of cotton, nylon. Easy to put on and take off; use on left or right elbow Helps provide compression, relief, and protection. Dimensionally fit to provide uniform compression. Heat resistant rubber with high modulus of elasticity. Size: Medium 25-30 cm	Pair in Mono-Pack	Pair in Mono-Pack X 100	300000.00

33	9023	**Elbow Support:** Material: Breathable, hypoallergenic, dual-stretch power knit material made of cotton, nylon. Easy to put on and take off; use on left or right elbow, Helps provide compression, relief, and protection. Dimensionally fit to provide uniform compression. Heat resistant rubber with high modulus of elasticity. Size: Large 30-35 cm	Pair in Mono-Pack	Pair in Mono-Pack X 100	300000.00
34	9024	**Elbow Support:** Material: Breathable, hypoallergenic, dual-stretch power knit material made of cotton, nylon. Easy to put on and take off; use on left or right elbow Helps provide compression, relief, and protection. Dimensionally fit to provide uniform compression. Heat resistant rubber with high modulus of elasticity. Size: Extra Large 35-40 cm	Pair in Mono-Pack	Pair in Mono-Pack X 100	300000.00
35	9025	**Combined Dressing Pad** Each sterile dressing pad consist of highly absorbent layer of fleece enclosed in a soft and comfortable non-woven fabric to prevent pressure areas forming. Absorbent Pad made from cotton surrounded by absorbent gauze, sterile, free from any brightener. Properly Wrapped. Size: 10x10 cm	Five in mono-pack X 100	Five in mono-Pack X 100	1000000.00
36	9026	**Combined Dressing Pad** Each sterile dressing pad consist of highly absorbent layer of fleece enclosed in a soft and comfortable non-woven fabric to prevent pressure areas forming. Absorbent Pad made from cotton surrounded by absorbent gauze, sterile, free from any brightener. Properly Wrapped. Five in mono-pack Size: 10x20cm	Five in mono-pack	Five in mono-Pack X 100	1000000.00
37	9027	**Microfine/Hypodermic Needle for Insulin Pen** Sterile Single-Use Needle for Insulin Pen Needles measurement: 32G 5 needles in a Pack Certified as per ISO 9001/ ISO 13485 and CE	Ten in Mono-Pack	Five in mono-Pack X 100	500000.00
38	9028	**Medical Steam Vaporizer:** Model: Sleek style Tank Capacity: 400-500ml Comfortable to use in Cough Sinus Nose Console, Steamer for Facial, Cold and Cough, Steam Machine for Face (vaporizer) Steam Vaporizer, Nose Steamer, Cough Steamer, Nozzle Inhaler & Nose vaporizer machine for cold and cough Body / Material: 100% high grade plastic body with double wall protection to prevent shocks and heat injury. Sufficient space for easy cleaning. Electric Cable: ISI certified 1.5 meter long, Plug shall be so designed to save from any shock while plugging in. Water boiling time: 3-5 minutes Warranty: One year Accessory: Vaporizer with nasal aspirator and steaming mask. Product shall be CE/ISO/FDA approved.	One in Mono-Pack	One in Mono-Pack X 10	500000.00
39	9029	**Digital Weighing Scale:** LCD: Large Digital display to facilitate easy reading. Technology: Smart Sensor Technology Weighing Capacity: 2 kg to 180 kg Warranty: 2 Years Body: ABS body Suitability: scale shall be suitable for measuring and displaying body weight, body fat (in %), body hydration, skeletal muscle, body bone mass, and body calories, Overload safety indicator etc. Dimension: As per Market standard Storage: Suitable to store Profile of 10-12 users Power Consumption: Product shall be power efficient with Auto on/off Function and shall be supplied with Alkaline battery. Standards and Safety Certificates: ISO/CE/FDA Approved.	One in Mono-Pack	One in Mono-Pack X 10	150000.00

Note:

i. ***Bidders shall consider the specification confirming all the quality parameters, Safety and Product Standards.***

ii. ***Colour and flavours of Male and Female condom shall be flexible as mentioned in the detailed specification and PMBI may place purchase order based on demand of various Colour and flavours. Bidders shall consider all Colour and flavours while bidding.***

iii. ***Bidder must comply ISO 10993, bioburden test, ISO 11737, ISO 12243, ISO 29941, ISO 25841 etc.***

Annexure – XIII

{Ref:- clause 19(K)}

(1)	(2)	(3)	(4)	(5)	(6)
S. N.	**Item Code**	**Generic Name of Item**	**Unit Size**	**Minimum Shelf Life** *(Must not be less than warranty period in specification)*	**HSN Code of item**
1	1460	Reusable Insulin Pen (Suitable for all type of Cartridge)	One in Mono-Pack		
2	8128	**Digital Medical Thermometer (100% Mercury Free) with Storage Case:** Temperature measurement range: Dual-mode measurement in Degree Celsius and Fahrenheit (°F & °C), Range; 32 – 43 °C minimum guaranteed. Accuracy: ± 0.1°C in the range specified range Graduation: 0.3°C or better. Display: LCD display for the ease of reading in all levels of light. Designed: Robust design made of ABS Plastic, breck resistance, easy to frequent cleaning and disinfection with hospital-grade products. Power: Battery powered (Coin battery), batteries included in the supply, preferably packed separately. Battery Life: Durable for minimum of 4,000 measurements. Automatic switch-off when not in use. Ready-to-use after switch-on within 10 second. Measurement time: within 90-120 seconds. Indication: Low and high temperature indication. Low battery indicator. Beep audio alert when device is turned on/ready to use or when temperature measurement is complete. Shall be waterproof. Suitably used for taking body temperatures measurements from oral, armpit and rectum. Memory function supported. Warranty: One years. Storage conditions: -20 - 55°C / 85% RH. Operating conditions: 10 - 40°C / 85% RH. Certification: Certified for ISO 13485/ ISO 9001 for Quality management systems and CE certified for Market Clearance and Device Classification. Safety and Product Standards shall be of ISO standard. Note: Hazardous Raw Material shall strictly not be Used.	One in Mono-Pack		
3	8130	**Manual Breast Pump:** Body: Screw-fit, graduated bottle includes a cap, screw ring and sealing disk. Equipped with lever to operate the pump, a valve, and diaphragm. Ergonomic design for single-handed operation, with swivel lever for smooth milk extraction. Comes including comfortable breast shield. Low-force operating lever. Allows for complete disassembly. Capacity: 150 ml Bottle. Pumping frequency 30 to 80 cpm and user adjustable. Dust cover protection on breast cup with inserted Cushion inside the cup so that it does not hurt the mother. Suction Pressure 100 to 250 mm Hg; user adjustable Cleaning: Easy to frequent cleaning at a minimum should be able to withstand 5 minutes in boiling water for cleaning. Material: Bottle, pump mechanism, cap and stand: polypropylene, polyethylene or TPE. Membrane and seal: silicone. Storage conditions: -20 - 50°C / 20 – 90 % RH. Operating conditions: 10 - 40°C / 20 - 80% RH. Warranty: One years. Components of Manual Pump: Certification: Certified for ISO 13485/ ISO 9001 for Quality management systems and CE certified for Market Clearance and Device Classification. Safety and Product Standards: shall comply with Regulation on materials and articles intended for food contact for Child use, high grade approved materials and articles intended to come in contact with food. Note: Hazardous Raw Material shall strictly not be Used.	One in Mono-Pack		
4	8133	**Digital Blood Pressure Instrument (100% mercury free):** Fully Automated upper arm style with LCD Digital Display/Digital monitor with acrylic panel and 3 colour backlit display for indication on display, Display shall show Numerical Data for reading. Displayed parameters: Unit should display systolic pressure, diastolic pressure,	One in Mono-Pack		

		pulse rate and mean arterial pressure. Dimension: Design shall be handy and Portable and as per market standard. Measuring Method: Oscillometric technique. Measurement Range: Pressure- 0mmHg – 300 mmHg (0.00 kPa to 39.9 kPa), Pulse- 30 to 199 Beats/Minute Measurement Accuracy: Pressure- ± 3mmHg Pulse- ± 5%, Measurement time (s): ≤ 60, user selectable. Power supplies: AA / AAA Alkaline Battery and USB operated. Memory: 2 x 99 Memory (90-99 memory). Storage conditions: Temperature range when in use: from 5°C to 40°C. 15% to 90% RH. Storage and transport conditions: - 20°C to 60°C. 10% to 95% RH. Equipment alarms preferred: Hose leak, inflation, or deflation error, Irregular Heartbeat Detection, Low Battery alarm, reading failure alarm. Accessories: High quality Arm Cuff (dimension 22 cm to 32 cm) with tube of suitable length, Protective case. USB Cable, 4 AA / AAA Alkaline battery set, User manual, Warranty Card. Shelf Life and warranty: Five Years with 2-year warranty (from the date of sale at Janaushadhi Kendra) Clinically validated algorithm International Standards: ISO 13485:2016 Certified, FDA Certified, CE certified.			
5	8136	**Electric Nebulizer Machine:** Compressor Nebulizer Machine Motor: Piston Compressor Motor with 25mm Copper binding Body: ABS body Particle Size: < 0.5 um (μm) Sound: 50-55 dB Standards and Safety Certificates: ISO 13485:2016 Certified, WHO-GMP Certified, FDA / CE; ISO 27427-2010. Warranty: 2 Years Weight (Ibs, kg) / Design: <2kg and design shall be handy and Portable. Medication Cup: Shall be scaled for 2-6 ml medication Power Consumption: Product shall be power efficient Knob/Switch: Good quality indicator switch. Storage conditions: Temperature range when in use: from 5°C to 40°C. 15% to 90% RH. Storage and transport conditions: - 20°C to 60°C. 10% to 95% RH. Electric Cable: ISI certified 1.5 meter long, Plug shall be so designed to save from any shock while plugging in. Accessories: Compressor Nebulizer Machine, Adult mask, Child Mask, Mouthpiece, Medicine Cup, Filter (8pcs), Air Tube, Warranty Card, and Pouch. Nebulizer Mask with Tubing: shall be free from any kind of odour, made of clear, Non-toxic PVC, medium concentration, adjustable nose clip & non-autoclave Tube Length: 2-meter, Nebulization rate: 3cc / 10 mins. Packing: All the Accessories shall be supplied with good quality storage pouch (Made of clothing/durable material).	One in Mono-Pack		
6	8146	**Baby Feeding Bottle 250 ml**: Material Bottle: Polypropylene, Cap: HDPE, Nipple: Soft silicone (Medium flow) Key Features: Non – sticky surface easy to sterilize, Wide Neck for easy filling and cleaning Anti-colic system to prevent colic, gas and reflux, Leak free, Ergonomic shape for easy comfort Body: Screw Cap, Bottle Neck Type – Standard, Sterilizer Safe – Yes, BPA Free – Yes, Microwave Safe – Yes, Dishwasher Safe – Yes Product shall confirm IS 10910 Note: Hazardous Raw Material shall strictly not be Used.	One in Mono-Pack		
7	8194	**Cotton Balls**: White in colour, Regular size, 100% natural cotton, soft, gentle on skin & absorbent, Hypoallergenic, baby skin friendly, Ideal for delicate application. Zero fragrances and dies used. Weight: 1gm ball	Pack of 100 in a zip lock bag		
8	8196	**Heating pad (electrical) Automated:** Dimension: Width- 23-25 cm; Length-30-32 cm Body: Outer Part shall be made of high-quality fabric for skin friendly, soft, and comfortable feeling. Stretchable and adjustable straps shall be provided for tighter fitting and compression on any part of the body. Auto cut feature to avoid over heating and shall be provided with ISI marked charging cable and charging port. An electric hot gel pouch filled & sealed with special gel, used to provide warmth, typically whilst in bed, but also for the application of heat to a specific	One in Mono-Pack		

		part of the body, Useful for providing instant relief from pain and treatment of sports injuries, arthritis, sore neck, backache, muscular pains, cramps, hypothermia, sprains, growing pains Heating time: 5 to 10 mins Size: Universal			
9	8197	**Exercise Ball**: Soft sponge stress ball with smiley face printed on it, Compatible for hydro and thermal therapy, Compatible for exercise of forearm, hand, wrist and fingers, non-sticky, Polyurethane Foam, waterproof, non-disintegrating. Size: Universal	One in Mono-Pack		
10	9000	**Reusable Menstrual Cup (non-absorbent bell-shaped hygienic device)-** Small: Medical grade silicone shall be used with medical grade platinum catalyst for polymer cross linkage, FDA/CE Compliance, Shall be Biocompatible. Air holes: At least two air hole of 1 mm size close to the rim covering 2 side. Cup Wall thickness: 2 mm (± 0.3 mm) Pull out stem length: minimum 15 cm Size: Small; Diameter of Outer rim: 36-40 mm Length of the cup excluding pull Out stem: approx. 40-50mm Cup Storage capacity: 15-25 ml Minimum Shelf life: Minimum 5 Years as per ISO-2230:2002 Colour: Colourless/Transparent Testing: Cup shall be tested within International standards i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization). Regulation and Conformity: ISO 9001:2015 or ISO 13485 certified *(shall be supplied with protective textile pouch and user instructions.) Material shall be biocompatible ensuring it no change in performance after multiple uses, good tear strength and endures boiling, cyclic use and pulling out, easy insertion and removal, dimensionally stable.	One in Mono-Pack		
11	9001	**Reusable Menstrual Cup (non-absorbent bell-shaped hygienic device)-** Medium: Medical grade silicone shall be used with medical grade platinum catalyst for polymer cross linkage, FDA/CE Compliance, Shall be Biocompatible, Air holes: At least two air hole of 1 mm size close to the rim covering 2 side. Cup Wall thickness: 2 mm (± 0.3 mm) Pull out stem length: minimum 15 cm Size: Small; Diameter of Outer rim: 41-44 mm Length of the cup excluding pull Out stem: approx. 45-55mm Cup Storage capacity: 20-30 ml Minimum Shelf life: Minimum 5 Years as per ISO-2230:2002 Colour: Colourless/Transparent Testing: Cup shall be tested within International standards i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization). Regulation and Conformity: ISO 9001:2015 or ISO 13485 certified * (shall be supplied with protective textile pouch and user instructions). Material shall be biocompatible ensuring it no change in performance after multiple uses, good tear strength and endures boiling, cyclic use and pulling out, easy insertion and removal, dimensionally stable.	One in Mono-Pack		
12	9002	**Reusable Menstrual Cup (non-absorbent bell-shaped hygienic device)-** Large: Medical grade silicone shall be used with medical grade platinum catalyst for polymer cross linkage, FDA/CE Compliance, Shall be Biocompatible, Air holes: At least two air hole of 1 mm size close to the rim covering 2 side. Cup Wall thickness: 2 mm (± 0.3 mm) Pull out stem length: minimum 15 cm Size: Small; Diameter of Outer rim: 45-48 mm Length of the cup excluding pull Out stem: approx. 48-58mm Cup Storage capacity: 30-40 ml Minimum Shelf life: Minimum 5 Years as per ISO-2230:2002 Colour: Colourless/Transparent Testing: Cup shall be tested within International standards i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization). Regulation and Conformity: ISO 9001:2015 or ISO 13485 certified * shall be supplied with protective textile pouch and user instructions). Material shall be biocompatible ensuring it no change in performance after multiple uses, good tear strength and endures boiling, cyclic use and pulling out,	One in Mono-Pack		

		easy insertion and removal, dimensionally stable.			
13	9003	**Female Natural Latex Condom:** Pouch Dimension: Total Device Length: 125-145 mm Width: 66-77 ± 2 mm Thickness: 0.09 - 0.12 mm External Retainer: Made of High-Grade Polyethylene Diameter: 70-80 mm Thickness (in mm): 1.5 – 2.5 mm width (in mm): 2.0-4.0 mm Colour and Shape: Natural / white and Suitable Internal Retainer: Made of Polyurethane open cell foam Outer diameter (in mm): 47-53 mm Inner diameter (in mm): 7.0 – 13 mm Thickness (in mm): 11.0 – 13.0 mm Colour and Shape: Natural / white and Suitable Lubricant: Silicon Oil, minimum 750mg Colour: Pink / Blue / Green / Yellow / Red / Natural / Brown Flavour: Chocolate / Strawberry / Litchi / Apple Pitch / Fruit Punch / Jasmine / Mango / Banana / Black Grape / Coffee / Hazelnut / Mixed Fruit / Red Bull / Toffee / Bela / Green - apple / Butterscotch / Paan / Rose / Guava / Orange / Pine Apple / Bubble-gum. Testing: Condom shall be tested within International standards i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization), ISO 11737:2018. For protein test: ISO 12243 & For Nitrosamines: ISO 29941. Specification shall comply BIS/ISO 4074:2014 Conforming QMS 13485:2016/NS-EN ISO 13485:2016 Packaging: Shall comply ISO 25841:2017 Hazardous Raw Material shall strictly not be Used. Shelf Life: 3 Years NOTE: Condom shall be free from holes and shall adhere to Schedule R of Drugs and Cosmetics Act 1940 and Rules there under 1945.	Three in Mono-Pack		
14	9004	**Male Latex Condom (Plain):** Width: 53 ± 2 mm Length: 180 mm Thickness: 0.060- 0.080 mm Lubricant: Silicon Oil; Not less than 350mg Colour: Pink / Blue / Green / Yellow / Red / Natural / Brown Flavour: Chocolate / Strawberry / Litchi / Apple Pitch / Fruit Punch / Jasmine / Mango / Banana / Black Grape / Coffee / Hazelnut / Mixed Fruit / Red Bull / Toffee / Bela / Green - apple / Butterscotch / Paan / Rose / Guava / Orange / Pineapple / Bubble-gum. Safety and Standards: Condom shall be tested within International standards i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization), ISO 11737. For protein test: ISO 12243 & For Nitrosamines: ISO 29941. Product Shall confirm ISO 25841-2017 Specification shall comply BIS/ISO 4074:2014 Conforming QMS 13485:2016/NS-EN ISO 13485:2016 Packaging: Shall comply ISO 25841:2017 Shelf Life: 3 Years NOTE: Condom shall be free from holes and shall conform Schedule R of Drugs and Cosmetics Act 1940 and Rules there under 1945. Hazardous Raw Material shall strictly not be Used.	Three in Mono-Pack		
15	9005	**Male Latex Condom (Extra Thin)**: Width: 53 ± 2 mm Length: 180 mm Thickness: 0.040 ± 0.060 mm Lubricant: Silicon Oil; Not less than 350mg Colour: Pink / Blue / Green / Yellow / Red / Natural / Brown Flavour: Chocolate / Strawberry / Litchi / Apple Pitch / Fruit Punch / Jasmine / Mango / Banana / Black Grape / Coffee / Hazelnut / Mixed Fruit / Red Bull / Toffee / Bela / Green - apple / Butterscotch / Paan / Rose / Guava / Orange / Pineapple / bubble-gum. Safety and Standards: Condom shall be tested within International standards i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization), ISO 11737. For protein test: ISO 12243 & For Nitrosamines: ISO 29941. Product Shall confirm ISO 25841-2017 Specification shall comply BIS/ISO 4074:2014	Three in Mono-Pack		

		Conforming QMS 13485:2016/NS-EN ISO 13485:2016 Packaging: Shall comply ISO 25841:2017 Shelf Life: 3 Years NOTE: Condom shall be free from holes and shall conform Schedule R of Drugs and Cosmetics Act 1940 and Rules there under 1945. Hazardous Raw Material shall strictly not be Used.			
16	9006	**Male Latex Condom (Normal Dot)**: Width: 53 ± 2 mm Length: 180 mm Thickness: 0.060- 0.080 mm Lubricant: Silicon Oil; Not less than 350mg Colour: Pink / Blue / Green / Yellow / Red / Natural / Brown Flavour: Chocolate / Strawberry / Litchi / Apple Pitch / Fruit Punch / Jasmine / Mango / Banana / Black Grape / Coffee / Hazelnut / Mixed Fruit / Red Bull / Toffee / Bela / Green - apple / Butterscotch / Paan / Rose / Guava / Orange / Pine Apple / bubble-gum. Safety and Standards: Condom shall be tested within International standards i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization), ISO 11737. For protein test: ISO 12243 & For Nitrosamines: ISO 29941. Product Shall confirm ISO 25841-2017 Specification shall comply BIS/ISO 4074:2014 Conforming QMS 13485:2016/NS-EN ISO 13485:2016 Packaging: Shall comply ISO 25841:2017 Shelf Life: 3 Years NOTE: Condom shall be free from holes and shall conform Schedule R of Drugs and Cosmetics Act 1940 and Rules there under 1945. Hazardous Raw Material shall strictly not be Used.	Three in Mono-Pack		
17	9007	**Male Latex Condom (1740 Dot):** Width: 53 ± 2 mm Length: 180 mm Thickness: 0.060- 0.080 mm Lubricant: Silicon Oil; Not less than 350mg Colour: Pink / Blue / Green / Yellow / Red / Natural / Brown Flavour: Chocolate / Strawberry / Litchi / Apple Pitch / Fruit Punch / Jasmine / Mango / Banana / Black Grape / Coffee / Hazelnut / Mixed Fruit / Red Bull / Toffee / Bela / Green - apple / Butterscotch / Paan / Rose / Guava / Orange / Pineapple / bubble-gum. Safety and Standards: Condom shall be tested within international standards i.e., i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization), ISO 11737. For protein test: ISO 12243 & For Nitrosamines: ISO 29941. Product Shall confirm ISO 25841-2017 Specification shall comply BIS/ISO 4074:2014 Conforming QMS 13485:2016/NS-EN ISO 13485:2016 Packaging: Shall comply ISO 25841:2017 Shelf Life: 3 Years NOTE: Condom shall be free from holes and shall conform Schedule R of Drugs and Cosmetics Act 1940 and Rules there under 1945. Hazardous Raw Material shall strictly not be Used.	Three in Mono-Pack		
18	9008	**Male Latex Condom (Ribbed)**: Width: 53 ± 2 mm Length: 180 mm Thickness: 0.060- 0.080 mm Lubricant: Silicon Oil; Not less than 350mg Colour: Pink / Blue / Green / Yellow / Red / Natural / Brown Flavour: Chocolate / Strawberry / Litchi / Apple Pitch / Fruit Punch / Jasmine / Mango / Banana / Black Grape / Coffee / Hazelnut / Mixed Fruit / Red Bull / Toffee / Bela / Green - apple / Butterscotch / Paan / Rose / Guava / Orange / Pineapple / bubble-gum. Safety and Standards: Condom shall be tested within international standards i.e., i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization), ISO 11737. For protein test: ISO 12243 & For Nitrosamines: ISO 29941. Product Shall confirm ISO 25841-2017 Specification shall comply BIS/ISO 4074:2014 Conforming QMS 13485:2016/NS-EN ISO 13485:2016 Packaging: Shall comply ISO 25841:2017 Shelf Life: 3 Years NOTE: Condom shall be free from holes and shall conform Schedule R of Drugs and Cosmetics Act 1940 and Rules there under 1945. Hazardous Raw Material shall strictly not be Used.	Three in Mono-Pack		

19	9009	**Male Latex Condom (Three in One)**: Width: 53 ± 2 mm Length: 180 mm Thickness: 0.060- 0.080 mm Lubricant: Silicon Oil; Not less than 350mg Colour: Pink / Blue / Green / Yellow / Red / Natural / Brown Flavour: Chocolate / Strawberry / Litchi / Apple Pitch / Fruit Punch / Jasmine / Mango / Banana / Black Grape / Coffee / Hazelnut / Mixed Fruit / Red Bull / Toffee / Bela / Green - apple / Butterscotch / Paan / Rose / Guava / Orange / Pineapple / bubble-gum. Safety and Standards: Condom shall be tested within international standards i.e., i.e., ISO 10993-1 (Biological evaluation), ISO 10993-3 (potential genotoxicity, carcinogenicity, or reproductive toxicity), ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Mucosal Irritation & Sensitization), ISO 11737. For protein test: ISO 12243 & For Nitrosamines: ISO 29941. Product Shall confirm ISO 25841-2017 Specification shall comply BIS/ISO 4074:2014 Conforming QMS 13485:2016/NS-EN ISO 13485:2016 Packaging: Shall comply ISO 25841:2017 Shelf Life: 3 Years NOTE: Condom shall be free from holes and shall conform Schedule R of Drugs and Cosmetics Act 1940 and Rules there under 1945. Hazardous Raw Material shall strictly not be Used.	Three in Mono-Pack		
20	9010	**Medicated Corn Remover:** (Medicated Corn Plaster Strips contains Salicylic Acid 40% w/w ointment) Product shall be so defined to fit on to corn. It shall be provided with good adhesive layer, free form fibre. ISO 13485/ISO 9001, GMP and CE certified	Four strips in mono-pack		
21	9011	**Perforated Plaster**: Contains belladonna extract not less than 0.25% w/w Fabric thickness: not less than 90g/m2 Plaster shall be perforated with protective layer of silicon paper on adhesive surface (with Janaushadhi Art-work printed) Size of plaster is 10cm x 16cm ISO 13485 and CE certified.	Five in mono-pack		
22	9012	**Lumbo-Sacral Support Belt (Waist and back support):** For unisex with flexible back splints, Easy to fit body shape for excellent Immobilization, Material: Porous elastic webbing, Heat resistant rubber with high modulus of elasticity Double pull mechanism for secure fitting around the waist, suitably large hook loop panel for controlled compression, and better sizing flexibility. ISO 13485 and CE certified Size: Small 28-32 inch One in mono-pack	One in Mono-Pack		
23	9013	**Lumbo-Sacral Support Belt (Waist and back support):** For unisex with flexible back splints, Easy to fit body shape for excellent Immobilization, Material: Porous elastic webbing, Heat resistant rubber with high modulus of elasticity Double pull mechanism for secure fitting around the waist, suitably large hook loop panel for controlled compression, and better sizing flexibility. ISO 13485 and CE certified Size: Medium 32-36 inch One in mono-pack	One in Mono-Pack		
24	9014	**Lumbo-Sacral Support Belt (Waist and back support):** For unisex with flexible back splints, Easy to fit body shape for excellent Immobilization, Material: Porous elastic webbing, Heat resistant rubber with high modulus of elasticity Double pull mechanism for secure fitting around the waist, suitably large hook loop panel for controlled compression, and better sizing flexibility. ISO 13485 and CE certified Size: Large 36-40 inch One in mono-pack	One in Mono-Pack		
25	9015	**Lumbo-Sacral Support Belt (Waist and back support):** For unisex with flexible back splints, Easy to fit body shape for excellent Immobilization, Material: Porous elastic webbing, Heat resistant rubber with high modulus of elasticity Double pull mechanism for secure fitting around the waist, suitably large hook loop panel for controlled compression, and better sizing flexibility. ISO 13485 and CE certified Size: Extra Large 40-44 inch	One in Mono-Pack		

		One in mono-pack			
26	9016	**Lumbo-Sacral Support Belt (Waist and back support):** for unisex with flexible back splints, Easy to fit body shape for excellent Immobilization, Material: Porous elastic webbing, Heat resistant rubber with high modulus of elasticity Double pull mechanism for secure fitting around the waist, suitably large hook loop panel for controlled compression, and better sizing flexibility. ISO 13485 and CE certified Size: Double Extra Large 44-48 inch One in mono-pack	One in Mono-Pack		
27	9017	**Anklet (Tubular Support):** Four way stretchable, bi-layered fabric (outer layer made of nylon and inner layer made of fine grade cotton), Heat resistant rubber with high modulus of elasticity. Hypoallergenic, uniform compression, simple pull-on application. To provide mild compression, warmth & support to the ankle joint. Suitable for pain and inflammation associated with old age arthritis support etc. Pack: One in mono-pack. Size: Small (18-21 Inch)	Pair in Mono-Pack		
28	9018	**Anklet (Tubular Support):** Four way stretchable, bi-layered fabric (outer layer made of nylon and inner layer made of fine grade cotton), Heat resistant rubber with high modulus of elasticity. Hypoallergenic, uniform compression, simple pull-on application. To provide mild compression, warmth & support to the ankle joint. Suitable for pain and inflammation associated with old age arthritis support etc. Pack: One in mono-pack Size: Medium (21-24 Inch)	Pair in Mono-Pack		
29	9019	**Anklet (Tubular Support)**: Four way stretchable, bi-layered fabric (outer layer made of nylon and inner layer made of fine grade cotton), Heat resistant rubber with high modulus of elasticity. hypoallergenic, uniform compression, simple pull-on application. To provide mild compression, warmth & support to the ankle joint. Suitable for pain and inflammation associated with old age arthritis support etc. Pack: One in mono-pack Size: Large (24-27 Inch)	Pair in Mono-Pack		
30	9020	**Anklet (Tubular Support):** Four way stretchable, bi-layered fabric (outer layer made of nylon and inner layer made of fine grade cotton), Heat resistant rubber with high modulus of elasticity. hypoallergenic, uniform compression, simple pull-on application. To provide mild compression, warmth & support to the ankle joint. Suitable for pain and inflammation associated with old age arthritis support etc. Pack: One in mono-pack Size: Extra Large (27-30 Inch).	Pair in Mono-Pack		
31	9021	**Elbow Support:** Material: Breathable, hypoallergenic, dual-stretch power knit material made of cotton, nylon. Easy to put on and take off; use on left or right elbow Helps provide compression, relief, and protection. Dimensionally fit to provide uniform compression. Heat resistant rubber with high modulus of elasticity. Size: Small 18-25 cm	Pair in Mono-Pack		
32	9022	**Elbow Support:** Material: Breathable, hypoallergenic, dual-stretch power knit material made of cotton, nylon. Easy to put on and take off; use on left or right elbow Helps provide compression, relief, and protection. Dimensionally fit to provide uniform compression. Heat resistant rubber with high modulus of elasticity. Size: Medium 25-30 cm	Pair in Mono-Pack		
33	9023	**Elbow Support:** Material: Breathable, hypoallergenic, dual-stretch power knit material made of cotton, nylon. Easy to put on and take off; use on left or right elbow, Helps provide compression, relief, and protection. Dimensionally fit to provide uniform compression. Heat resistant rubber with high modulus of elasticity. Size: Large 30-35 cm	Pair in Mono-Pack		
34	9024	**Elbow Support:** Material: Breathable, hypoallergenic, dual-stretch power knit material made of cotton, nylon. Easy to put on and take off; use on left or right elbow Helps provide compression, relief, and protection. Dimensionally fit to provide uniform compression. Heat resistant rubber with high modulus of elasticity.	Pair in Mono-Pack		

		Size: Extra Large 35-40 cm			
35	9025	**Combined Dressing Pad** Each sterile dressing pad consist of highly absorbent layer of fleece enclosed in a soft and comfortable non-woven fabric to prevent pressure areas forming. Absorbent Pad made from cotton surrounded by absorbent gauze, sterile, free from any brightener. Properly Wrapped. Size: 10x10 cm	Five in mono-pack X 100		
36	9026	**Combined Dressing Pad** Each sterile dressing pad consist of highly absorbent layer of fleece enclosed in a soft and comfortable non-woven fabric to prevent pressure areas forming. Absorbent Pad made from cotton surrounded by absorbent gauze, sterile, free from any brightener. Properly Wrapped. Five in mono-pack Size: 10x20cm	Five in mono-pack		
37	9027	**Microfine/Hypodermic Needle for Insulin Pen** Sterile Single-Use Needle for Insulin Pen Needles measurement: 32G 5 needles in a Pack Certified as per ISO 9001/ ISO 13485 and CE	Ten in Mono-Pack		
38	9028	**Medical Steam Vaporizer:** Model: Sleek style Tank Capacity: 400-500ml Comfortable to use in Cough Sinus Nose Console, Steamer for Facial, Cold and Cough, Steam Machine for Face (vaporizer) Steam Vaporizer, Nose Steamer, Cough Steamer, Nozzle Inhaler & Nose vaporizer machine for cold and cough Body / Material: 100% high grade plastic body with double wall protection to prevent shocks and heat injury. Sufficient space for easy cleaning. Electric Cable: ISI certified 1.5 meter long, Plug shall be so designed to save from any shock while plugging in. Water boiling time: 3-5 minutes Warranty: One year Accessory: Vaporizer with nasal aspirator and steaming mask. Product shall be CE/ISO/FDA approved.	One in Mono-Pack		
39	9029	**Digital Weighing Scale:** LCD: Large Digital display to facilitate easy reading. Technology: Smart Sensor Technology Weighing Capacity: 2 kg to 180 kg Warranty: 2 Years Body: ABS body Suitability: scale shall be suitable for measuring and displaying body weight, body fat (in %), body hydration, skeletal muscle, body bone mass, and body calories, Overload safety indicator etc. Dimension: As per Market standard Storage: Suitable to store Profile of 10-12 users Power Consumption: Product shall be power efficient with Auto on/off Function and shall be supplied with Alkaline battery. Standards and Safety Certificates: ISO/CE/FDA Approved.	One in Mono-Pack		

ANNEXURE XIV

[Ref. clause no. 4 (C)]

(To be submitted on firm's letterhead duly authorized)

DECLARATION FOR NON-DRUG ITEM(S)

I/we_____, am/are in the capacity of Proprietor/Managing Partner /Managing Director in M/s…… having its registered office at …….....and its factory premises at……..……do hereby declare that the quoted item(s) are neither covered under Drugs & Cosmetics Act 1940 and Rule their under nor Under Medical Device Rule 2017.

That I/we are eligible to participate in the tender no. PMBI/SURGICAL/RC-201/2022 for the following item conforming the terms and conditions laid down in the tender document along with the amendment(s) if any following all the order (s) mentioned by various ministry/department referred in the subject tender:

Sl. No.	Item No.	Specification of the Item	Production Capacity (Per Annum)

That I am / We are aware of the Tender inviting Authority's right to forfeit the Performance Security Deposit and suspending/disqualifying/blacklist me/us for a period of 5 years if, any information furnished by us proved to be false at any time during the contract period.

Signed.....

Name: ……..

Designation…….…….

(Company Seal)

(Above shall be furnished by Authorized Signatory)

ANNEXURE-XV

[Ref. clause no. 3(H)]

(To be submitted on non-judicial stamp paper dully notarized)

DECLARATION FOR NON-BLACKLISTING

I/we_____, am/are in the capacity of Proprietor/Managing Partner /Managing Director in M/s…… having its registered office at …….....and its factory premises at……..……do hereby declare 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.

That I/We are eligible to participate for the following quoted products:

S.N.	ITEM NO.	GENERIC NAME OF ITEM	UNIT SIZE

Signed.....

Name: ……..

Designation…….……

(Company Seal)

(Above shall be furnished by Authorized Signatory)

ANNEXURE- XVI

Enclosure – I

(Ref. Clause No. - 3.U)

(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 of Bidder
1					
2					
3					

That I……..abide by the terms and conditions laid down in guidelines issued by Department of Pharmaceuticals, Ministry of Chemicals & fertilizers, Government of India vide F. No. 31026/36/2016-MD dated 09.11.2020 and DPIIT order no. 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 items are done in accordance with the guidelines laid down in Para 1/2/3/4 of Department of Pharmaceuticals order vide F. No. 31026/36/2016-MD dated 09.11.2020 and I found that items quoted by our firm comes under Class …… local content.

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

Signature.....

Name: ……..

Designation…….……

(Company Seal/Stamp)

(Above shall be furnished by Authorized Signatory)

ANNEXURE- XVII
[Ref. Clause No. 3.1]

Declaration by Authorized Signatory towards the Compliance of Order (Public Procurement No.1, 2 & 3

(On Non-Judicial Paper duly notarized)

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

Signature.....

Name: ……..

Designation…….……

(Company Seal/Stamp)

(Above shall be furnished by Authorized Signatory)

ANNEXURE- XVII
[Ref. Clause No. 4. P (ii)]

SAMPLE RECEIPT

(To be submitted in triplicate on firm's letterhead along with samples)

TENDER NO…… Dated……

Please receive following Samples of Oxo-Biodegradable Sanitary Napkins, Diapers& Other Consumable Items from.

M/s…….....
…….
……..

S.N	Item No.	Product Name	Batch no.	Date of Manufacturing	Date of Expiry	License No	Number of units submitted

Total number of Items submitted: …….

Total number of Boxes submitted: ……

Total Number of signed pages of Pilot studies / Publications: …

Place:

Date:

Signed.....

Name: ……..

Designation…….……

(Company Seal)

(Above shall be furnished by Authorized Signatory)

Yours faithfully,
Sd/-
DGM (Procurement & Quality)
For & on behalf of PMBI
Ph: 011-49431800(811)