### NOT TRANSFERABLE



### LIMITED TENDER NO. :- BPPI/LTD./DRUG-067/2018 FOR SUPPLY OF DRUGS TO

# Bureau of Pharma Public Sector Undertakings of India (BPPI)



### **BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA**

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

8<sup>th</sup> Floor, Videocon Tower, Block E1, Jhandewalan Extension, New Delhi-110055 Telephone: 011- 49431811/49431824 /49431828/49431829/49431830;

Website: janaushadhi.gov.in

# BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA (BPPI) (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

<u>Telephone</u>: 011-49431811/49431824/49431828/49431829/49431830;

Website: janaushadhi.gov.in

## ONLINE LIMITED TENDER FOR THE SUPPLY OF DRUGS TO BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA IS INVITED FROM FOLLOWING ELIGIBLE BIDDERS OF BPPI: -

- (i) M/S Maxmed Lifesciences Pvt. Ltd.
- (ii) M/S Nestor Pharmaceuticals Limited
- (iii) M/S Theon Pharmaceuticals Limited
- (iv) M/S Rajasthan Drugs and Pharmaceuticals Ltd.

### Note: -The unsolicited bid shall not be accepted.

Tender Reference	BPPI/LTD./DRUG-067/2018
	Dt. 28/08/2018
Date of availability of tender documents on website	28/08/2018 (Tuesday)
Last date and time for submission of Online Bid I.e. Bid Submission End Date and time	06/09/2018 up to 11.00 A.M.
Last Date and time for submission of EMD and Original Annexure-II (Declaration) in physical Form in office of Bureau of Pharma PSUs of India, 8th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055	07/09/2018 up to 11:00 A.M.
Time and date of opening of tender	11:30 AM on 07/09/2018 (Friday)
Place of opening of tender	Bureau of Pharma PSUs of India,  8 <sup>th</sup> Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi- 110055
Address for Communication	Bureau of Pharma Public Sector Undertakings of India,  8 <sup>th</sup> 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. Mr. P. K. Thakur, Executive (Procurement) Phone: - 011-49431858 Mob: - 9475982561 Email: - proc6@janaushadhi.gov.in

	2. Ms. Nisha Kumari, Executive (Procurement) Phone: - 011-49431858 Mob: - 9988290847 Email: - proc7@janaushadhi.gov.in
	3. Ms. Neha Aggarwal, Executive (Procurement) Phone: - 011-49431859 Mob: - 8447711358 Email: - proc5@janaushadhi.gov.in

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

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### BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA

## LIMITED TENDER FOR THE SUPPLY OF DRUGS TO <u>BUREAU OF PHARMA</u> <u>PUBLIC SECTOR UNDERTAKINGS OF INDIA</u>

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

The Bureau has been registered as an independent society under the Societies Registration Act, 1860, in April 2010. BPPI follows the provisions of GFR 2017 as amended from time to time, the CVC guidelines, and instructions from the Department of Pharmaceuticals.

At present, more than 3900 stores are functional. It is proposed to channelize efforts to popularize PMBJP and ensure availability of the complete basket of medicines at affordable prices.

**Tender Inviting Authority** – C.E.O, Bureau of Pharma Public Sector Undertakings of India, 8<sup>th</sup> 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, Bureau of Pharma Public Sector Undertakings of India, (hereinafter referred as **BPPI** unless the context otherwise requires).

Tender Inviting Authority invites Tender for the supply of Drugs to BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA, for the year 2018.

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### 1. LAST DATE AND TIME FOR SUBMISSION OF ONLINE TENDERS.

- (a) Online Bids [in two separate Cover {Technical bid ("Cover A") and price bid (Cover "B")}] will be submitted till **11.00 A.M. up to 06/09/2018 (Thursday) on** CPP portal i.e. eprocure.gov.in.
- (b) The price bid shall be valid for a period of 60 days from the date of opening of Technical Bid. Prior to the expiry of the bid validity, the Tender Inviting Authority may request the Tenderers to extend the bid validity for further period as deemed fit on their original quoted prices and all terms &conditions. However, BPPI reserves the right to place purchase orders at the quoted rate till such period.

### 2. ELIGIBILITY CRITERIA

- (a) (i) Tenderer shall be a manufacturer having valid drug manufacturing unit duly licensed by licensing authorities.
- (ii) Manufacturer should have valid WHO-GMP (World Health Organisation-Good Manufacturing Practices) certificate issued by licensing authority.
- (iii) Distributors/Suppliers/Marketer/Agents are not eligible to participate in the Tenders.
- (b) Non-conviction Certificate not older than 6 months issued by the licensing authority of the State certifying that the firm/company has not been convicted.
- (c) Tenderer should not be submitted for the product(s) for which the firm / company has been blacklisted/debarred/de-registered/banned by any State Government / Central Government / its Drug procurement agencies due to quality failure of the drugs *at the time of submission of online bid.*
- (e) 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 / its Drug procurement agencies at the time of submission of bid. Further, quoted drugs have not been failed in house testing or testing by any State Government/Central Government / its Drug procurement agencies/BPPI during last two years.
- (f) 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.
- (g) Tenderer are required to incorporate bar codes as per GS1 standards at various packaging levels (primary, secondary and tertiary) (**Annexure I**) and they are required to submit valid registration certificate from GS1 India for such barcoding.

### 3. GENERAL CONDITIONS.

- (i) The tender document shall be download from the websites janaushadhi.gov.in; and CPP portal i.e.eprocure.gov. in. Tender Document is free of cost. No tender cost is to be deposited.
- (ii) EMD (Earnest Money Deposit): EMD of Rs.50,000/- (Rupees Fifty thousand only as specified in Clause 7 of the Tender document in the form of Bank Guarantee or Bankers Cheque or Demand Draft from nationalised/Scheduled Bank favouring "Bureau of Pharma Public Sector Undertakings of India ", payable at Gurgaon/Delhi which is to be delivered in original to BPPI, New Delhi on or before the date and time stipulated in bid 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.
- (iii) Tenders will be opened online. However, authorized representatives of bidder who like to attend online bid opening on the specified date and time should bring letter of authority authorising to attend online bid opening on the printed letter head of the company. Please also certify in authorisation letter that nominated person of tenderer shall not represent any other tenderer in BPPI.
- (iv) (a) 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 an amendment uploading on website on **janaushadhi.gov.in**; and CPP portal i.e. **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.
- (b) Any person who has downloaded the tender document should watch for amendment, if any, on the website **janaushadhi.gov.in**; and CPP portal i.e.**eprocure.gov.in** for which BPPI will not issue any separate communication to them.
- (v) Interested eligible Tenderers 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.
- (vi) The BPPI reserves the right to purchase any drugs full or part quantity from PSU as per discretion of BPPI. In case of emergencies, BPPI may go to PSU and price will be as per negotiation and at the discretion of BPPI.

### 3.1 SPECIAL CONDITIONS.

(i)Bids shall be submitted online only at CPPP website: https://eprocure.gov.in. Manual bids shall not be accepted except for the original documents/instruments as mentioned in tender document.

- (ii) Bidders are advised to follow the 'Special Instructions to the Contractors/Bidders for the esubmission of the bids online' available through the link 'Help for Contractors' at the e-Procurement Portal https://eprocure.gov.in.
- (iii) 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 BPPI.
- (iv)Bidders are advised to check the *website of BPPI: janaushadhi.gov.in* and CPPP website <a href="https://eprocure.gov.in">https://eprocure.gov.in</a> at least 3 days prior to closing date of submission of tender for any corrigendum, addendum, or amendment to the tender document.

### 4. TECHNICAL BID - COVER "A"

- **4.1.** The Tenderer should upload the following documents in while submitting technical bid hereafter called <u>"Cover A"</u>. (Scanned copies of each page of all documents should be uploaded while submitting Technical bid).
  - (a) The tenderers are required to upload scanned undertaking on stamp paper duly notarized by authorised signatory (ANNEXURE II) confirming that they are holding the valid drug license, valid WHO- GMP certificate, valid Non conviction certificate not older than 6 months issued by licensing authority, undertaking as per para 2(e) & (f) and undertaking to supply the drug with bar code as per ANNEXURE I and as per Annexure IX, undertaking for Clause 7.2, The original ANNEXURE II should be submitted to BPPI, New Delhi before stipulated time and date.
  - (b) Earnest Money Deposit as indicated in Clause 3(ii) and Clause 7. of the tender document shall be in the form of **Bank Guarantee or Bankers Cheque or Demand Draft** favouring "Bureau of Pharma Public Sector Undertakings of India "payable at Gurgaon/Delhi. Tender cost and EMD in any other form like *cheque/cash/postal order* etc. will not be accepted. Scanned soft copy of the EMD instrument must be uploaded (ANNEXURE III) to the e-Procurement portal. and original EMD instrument should be submitted to BPPI, New Delhi on or before the schedule date of tender opening.
  - (c) Authorization letter nominating an officer of the Tenderer on the printed letter head of the company to transact the business with the BPPI to be uploaded. <u>Please also certify in authorisation letter that nominated person of tenderer shall not represent any other tenderer in BPPI.</u>
  - (d) The Tenderer should upload Scanned copy of valid drug Manufacturing Licence for the product, duly approved by the Licensing Authority for the product quoted as per specification in the tender. The licence must have been duly renewed up to date and the items quoted shall be clearly highlighted in the licence. Original documents should be produced for verification when demanded. However, if renewal application for manufacturing licence has been filed, Scanned copy of same duly receipted by drug authorities must be uploaded along with the validity certificate from state licencing authority (SLA).
  - (e) The copies of relevant pages approved by drug authorities of concerned country for any quoted Drug/product offering CoPP certificate and quoted drugs/products manufactured by manufacturing units approved by US FDA, TG

Australia, Health Canada, EU approval, MCC South Africa approval, Brazil Anvisa should be uploaded with technical bid.

- (f) Scanned copy Non-Conviction Certificate issued by the licensing authority of the State certifying that the firm/company has not been convicted should be uploaded. The certificate should not be more than 6 months old at the time of submission of technical bid.
- (g) **Scanned** copy of Valid WHO-GMP (World Health Organisation-Good Manufacturing Practices) Certificate (for manufacturer only) issued by the Licensing Authority should be uploaded.
- (h) The tenderers are required to upload copies of the specifications for all quoted drugs and STP (standard testing procedure) for Non- Pharmacopoeia quoted drugs.
- (i) The bidders shall upload valid GS1 barcoding registration certificate and comply to barcoding requirement as per Annexure I of tender document.
- (j) A Checklist (ANNEXURE- IV) shall be uploaded with technical bid. If a company/firm has two or more separate manufacturing units at different sites / States, which are not separate entities then the company will be allowed to submit only one tender for all units but necessary document regarding separate manufacturing units will uploaded as a separate set with the same tender. However, one bidder will be allowed to submit only one offer for one product.
- (k) All the documents uploaded should also be signed by the authorized official of the Tenderer.
- **4.2.** The all documents indicated above should be uploaded and shall be opened at the time of tender opening.

### 5. PRICE BID(BOQ) - COVER" B"

- **5.1.** Cover "B" contains the Price Bid of the Tenderer.
- (i) The Tenderer shall fill in the rate per unit size, % age rate of GST and total rate inclusive of GST in respective column of BOQ for the items quoted. In case, any bidder offers CoPP or offers products manufactured by manufacturing units approved by US FDA, TG Australia, Health Canada, EU approval, MCC South Africa approval, Brazil Anvisa, copies of relevant pages of valid document approved by drug authorities of concerned country for imported drug should be uploaded on line with technical bid.

### (ii) Determination of L1 bidder:

(a) In determining the lowest evaluated price, the rate quoted per unit size inclusive if GST as indicated in column No. 8 of the BOQ shall be taken into consideration.

- (b) The Price preference of up to 5% over L1 bidder (if L1 bidder is not offering certificate of pharmaceutical product i.e. **CoPP** issued in the format recommended by the World Health Organization) shall be given to the bidder having CoPP for the particular drugs and shall be awarded contract. Scanned copy of Valid CoPP issued by the Licensing Authority must be uploaded.
- (c) The Price preference up to 10% over L1 bidder (if L1 bidder is not offering products manufactured by manufacturing units approved by from US FDA, TG Australia, Health Canada, EU approval, MCC South Africa approval, Brazil Anvisa) shall be given to the bidder having product manufactured by manufacturing units approved by US FDA. TG Australia, Health Canada, EU approval, MCC South Africa approval, Brazil Anvisa.
- (d)(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 20 (twenty) per cent of total tendered value. The 20 (twenty) per cent quantity is to be distributed proportionately among these bidders, in case there are more than one MSMEs within such price band.
- (ii) Within this 20% (Twenty Percent) quantity, a purchase preference of four per cent (that is, 20 (twenty) per cent out of 20 (twenty) 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 MSE to participate in tender process or meet tender requirements and L1 price, four per cent 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.

Note 1: - (a) Price preference as in Clause 5.1 (ii) (c) will be get preference over the clause 5.1 (ii) (b).

- Note 2: Later on, if product does not comply CoPP and products manufactured by manufacturing units having approval of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa as declared in tender, the extra price paid to the supplier shall be recovered in addition to other penal action.
- (iii) The rate quoted inclusive of GST in column 8 of **BOQ** should be for a unit size and for the given specification. **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-VI.**
- (iv) GST (Goods and Services Tax)-<u>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 are inclusive of GST and no GST shall be charged by them under any circumstances.</u>
- (v) The bidder is required to indicate GST (%) in digit only in column 7 column of BOQ without suffixing % sign and not to indicate amount of GST in Rs. at particular cell of excel sheet of BOQ.

### 6. OPENING OF COVER "A" AND COVER "B" OF TENDER

- **6.1** Only authorized official as indicated in Clause 4.1. are entitled to be present at the time of opening of Tender Cover "A & B" of the tender submitted by them.
- **6.2**. In case, the date for opening of bid is declared holiday, the technical bid shall be opened on next working day at 11.30 A.M.

### **7. EARNEST MONEY DEPOSIT**

- 7.1. The Earnest Money Deposit referred to under Clause 3(ii) & 4.1(a), shall be Rs. Fifty thousand. The Earnest Money Deposit shall be paid in the form of Bank Guarantee or Bankers Cheque or Demand Draft in favour of BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA, payable at Gurgaon/Delhi. In case EMD in form of Bank Guarantee, Irrevocable Bank Guarantee in favour of Bureau of Pharma Public Sector Undertakings of India from any Nationalised/scheduled Bank should be valid for a period beyond 270 days/9 months from the date of tender opening. The format of Bank Guarantee is at ANNEXURE-V. BPPI will not pay interest on any deposit held in the form of Bankers Cheque or Demand Draft.
- **7.2**. (i) The tender submitted without sufficient EMD will be summarily rejected.
- (ii) The Earnest Money Deposit will be refunded to the successful bidders within 30 days from the date of acceptance of rate for price agreement and on the deposit of Performance security deposit.
- (iii) The Earnest Money Deposit (EMD) of the unsuccessful bidders will be returned after finalization of tender with eligible bidder.
- (iv) The Earnest Money Deposit (EMD) will be forfeited, if the tenderer withdraws his bid any time after opening of price bid / non-submission of Performance security within the period prescribed/non supply of drugs.
- (v) The Earnest Money Deposit (EMD) will be forfeited, in case of the lowest bidder, fails to execute the contract or deposit the performance security deposit within the stipulated time. The EMD shall be forfeited if the undertaking as Annexure III is not found correct.
- (vi) 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.** (vii) PSUs are exempted from the payment of EMD.
- (vii) PSUs are exempted from the payment of EMD.

### **8. OTHER CONDITIONS**

**8.1**. (i) The details of the required drugs, medicines, etc., are shown in **ANNEXURE -VI**. *The tender quantity mentioned herein is fixed procurement quantity* 

- (ii) The Tenderer shall fill in manufacturing capacity per year in units and Shelf life in months quoted drugs in required column of **ANNEXURE** –**VII** and **upload along with technical bid.**
- (iii.) The rates quoted shall not be varied during contract period.
- **8.2.** Tender has been called for in the <u>Generic name of drugs</u>. 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 -VI**. Any variation, if found, will result in rejection of the tender.
- **8.3.** The price quoted by the tenderers shall not, in any case exceed the DPCO controlled price, if any, fixed by the Central/State Government, the Maximum Retail Price (MRP) and the selling price of the tenderer. Tender Inviting Authority at its discretion, may exercise, the right to revise the price at any stage so as to conform to the controlled price or MRP or the selling price of the tenderer as the case may be. This discretion will be exercised without prejudice to any other action that may be taken against the Tenderer.
- **8.4.** The rates quoted and accepted will be binding on the Tenderer and any increase in the price will not be entertained till the completion of this contract period.
- **8.5.** 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.
- **8.6.** Supplies should be made directly by the tenderer and not through any other Agency / Dealer / Distributors.
- **8.7.** The Tenderer shall allow inspection of the factory at any time after the opening of technical bid and during the entire contract period by a team of Experts/Officials nominated by the Tender Inviting Authority for the purpose. The Tenderer shall extend necessary cooperation to such team in inspection of the manufacturing process, quality control measures adopted etc., in the manufacture of the items quoted. If Company/Firm does not allow for any such inspection, their tenders will be rejected. If any such situation arises after placement of contract, the same shall be cancelled at the firm's risk cost.
- **8.8** "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.

### 9. ACCEPTANCE OF TENDER

- **9.1.** (i) Evaluation of the tender and determination of the L1 rate (Lowest rate) will be done based on rate per unit size inclusive of GST as mentioned in **column 8** of **BOQ considering price preference for <u>CoPP</u> and for products manufactured by manufacturing units having approval of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa.**
- (ii). Negotiation if required will be done at our premises and the same will be done strictly as per Central Vigilance Commission guidelines.
- **9.2.** BPPI reserves the right to accept or reject the tender for the supply of all or any one or more items of the drugs tendered for in a tender without assigning any reason.
- **9.3.** BPPI 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.

### 10. SECURITY DEPOSIT

### **10.1 Security Deposit:**

On being informed about the acceptance of the tender and the Tenderer shall pay the Security Deposit @ 5% of the value of order in the form of *Demand Draft or irrevocable Bank Guarantee* in favour of Bureau of Pharma Public Sector Undertakings of India from any scheduled Bank. In case the Security Deposit is paid in form of Bank Guarantee, the bank guarantee shall be valid for two years. The format of Bank Guarantee is at **ANNEXURE-VIII.** 

- **10.2.** The Tenderer 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 what so ever.
- **10.3.** All notices or communications relating to and arising out of this contract or any of the terms thereof shall be considered duly served on or given to the Tenderer if delivered to him or left at the premises, places of business or abode as provided by the tenderer.
- **10.4.** If the lowest Tenderer fails to execute the contract and/or to deposit the required security deposit within the time specified or withdraws the tender, after the intimation of the acceptance of the tender or owing to any other reasons to undertake the contract, the contract will be cancelled and the Earnest Money Deposit deposited by the tenderer along with the tender shall stand forfeited by the BPPI and the firm will also be liable for all damages sustained by the BPPI apart from blacklisting and other penal actions.
- **10.5**. The security deposit of supplier will be returned by BPPI only after the supplier has given undertaking to replace such medicines and indemnify BPPI against any loses on account of quality parameters.

### 11.METHODOLOGY FOR PLACING ORDERS

For the above purpose the following procedures will be adopted

- (a) After Bid opening, 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) The Successful Tenderer is eligible for the placement of Purchase Order with provision of depositing the required amount as Performance Security.
- (c) If two or more than two Tenderer's are declared as lowest suppliers for the same item(s), such Tenderers are eligible for price agreement and the placement of Purchase Orders for such item(s) for which they are declared as lowest. Placement of order shall be shared equally amongst these bidders subject to their manufacturing capacity.
- (d) In the case of purchase of goods where the quantity offered at the lowest price is less than the total quantity required, the BPPI may, after placing orders with the lowest evaluated Tenderer for the entire quantity offered by such Tenderer subject to his ability to supply, require all the other eligible Tenderers who participated in the tender and offered a price higher than that offered by the lowest evaluated Tenderer, to submit sealed offers of the quantity they would be willing to supply at the price quoted by the lowest evaluated Tenderer, and thereafter place orders for the remaining required quantity with all those who match the lowest evaluated price such that those who bid lower prices in the original tender get a higher priority for supply.
- (e) If a supplier fails to execute supply order, the 5% value of supply order shall be recovered from pending bill or EMD/Bank Guarantee and their bad performance shall be kept in record of BPPI for future dealing as considered appropriate by BPPI.
- (f) Notwithstanding anything contained in para (e) above, the supplier, after committing the default in supply either partly or fully, can inform the BPPI about his willingness to execute the Purchase Order during the tender period. The BPPI at discretion may consider the willingness of the supplier on merit. However, such supplies will be subjected to the levy of Liquidated Damages, unexecuted fine and other penalties as stipulated in the tender document, price agreement and purchase order.
- (g) The supplier shall start supply of the Drugs/Medicines required by BPPI at Central Ware House (CWH), Bilaspur, Haryana or any other place decided by BPPI within the stipulated period.
- (h) The Drugs/Medicines supplied in excess of the ordered quantity shall not be accepted and the supplier shall take back the excess at their cost. BPPI will not be responsible for the loss to the supplier and will not entertain any demand/claim.

- (i) The supplier shall supply the Drugs/Medicines at the CWH, Bilaspur, Gurgaon (or any other place decided by BPPI) along with copy of Purchase order, copy of test reports and 3 original copies of Invoice, original label and aluminium sheet (if applicable) sample of primary label. No payment will be processed without test reports.
- (j) The supplier shall take utmost care in supplying the quality Drugs/Medicines and ensure that the batch number mentioned in the packages of the Drugs/Medicines tally with the batch number mentioned in the Invoice produced to BPPI for payment. Also, the supplier shall ensure the quantity relevant to the Batch Number of the Drugs/Medicines is mentioned in the invoice. Drugs to be supplied of any batch shall not be accepted with different MRP.
- (k) It is the duty of the supplier to supply Drugs/Medicines at the CWH Bilaspur, Gurgaon or any other place decided by BPPI and supply shall conform to the conditions mentioned in the provisions of tender documents, viz., logo, nomenclature, specification etc.,
- (l) Subject to above, BPPI will process the invoices submitted by the supplier and the payments against supply will be made within 60 days from the date the Drugs/Medicines supplied has been declared of STANDARD QUALITY, by the Empanelled laboratory of BPPI subject to various terms and conditions of the tender.
- (m) Subject to the conditions mentioned in the Purchase Order, Tender Document, Price Agreement and here under, the Supplier is entitled for the payment against supply. In case of any discrepancy in levy of LD, Penalty, Unexecuted Fine, Short Passing of Bills, such discrepancy shall be intimated within 30 days from the date of receipt of payment, failing which BPPI will not entertain any claim thereafter.

### 12. SUPPLY CONDITIONS

- **12.1.** Purchase orders will be issued to the Tenderer(s) at the discretion of the BPPI. All the supplies shall be received at the central warehouse at Bilaspur, Gurgaon.
- **12.2.** Within 3 days from the receipt of purchase orders the Tenderer should inform BPPI through fax and mail the confirmation for the receipt of the purchase order.
- **12.3.** The Tenderer should also fax and mail the details of supply dates to BPPI within 7 days from the receipt of the purchase order.
- **12.4**. (a) The supplier must supply the ordered quantity CWH Bilaspur, Gurgaon within 30 days from the date of Purchase Order.
- (b) If the Tenderer fails to execute the supply within the stipulated time, the BPPI 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 BPPI has every right to recover the cost and impose Liquidated Damages as mentioned in Clause 18.

- (c) The supplier may continue the supply of unexecuted quantity after 30th day in case of 12.4(a) above, however Liquidated Damages as specified in clause 18.1 and 18.2 of the tender conditions will be levied on the quantity supplied after the 60<sup>th</sup> day. However, no supplies will be 60 days from the date of issue of purchase order and the purchase order shall be cancelled at the risk and cost of the supplier. **However, the supplier must take prior approval from BPPI for supply of drugs beyond stipulated delivery period in Purchase order.**
- 12.5. 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.
- 12.6. The supplied Drugs (covered in SCHEDULE "P" of Drugs and Cosmetics Act) should have the prescribed potency throughout the shelf life period as prescribed in the Drugs and Cosmetics Act 1940 and rules there under and in relevant Pharmacopoeias. However, in case of thermolabile drugs not covered in SCHEDULE "P" of Drugs and Cosmetics Act, the minimum shelf life should be 2 years from the date of manufacture.
- **12.7.** The Tenderer must submit an Analysis report for every batch of drug along with invoice. In case of failure on part of the supplier to furnish such report, the batch of drugs will be returned to the suppliers and he is bound to replenish the same with Govt. approved lab test report. The Drugs supplied by the successful Tenderer shall be of the best quality and shall comply with IP/BP/USP and the specifications, stipulations and conditions specified in the tender.
- 12.8. Tenderer should supply the product (a) within 2 months excluding month of manufacture of products having shelf life up to 2 years, (b) within 3 months excluding month of manufacture of products having shelf life more than 2 years & up to 3 years and (c) within 4 months excluding month of manufacture of products having shelf life more than 3 years. Products beyond the above-mentioned period from the date of manufacture shall not be accepted. For example, product having manufacturing of November 2018 must be supplied by 31st January 2019 in case shelf life less than 2 Years.
- 12.9. If at any time the Tenderer has, in the opinion of the BPPI delayed the supply of drugs due to one or more reasons related to Force Majeure events such as riots, mutinies, wars, fire, storm, tempest or other exceptional events at the manufacturing premises, the time for supplying the drugs may be extended by the BPPI 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 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.

- **12.10**. The supplier shall not be liable to pay LD and forfeiture of performance security deposit for the delay in executing the contract on account of the extension of supply period on the ground of force majeure events.
- 12.11. Suppliers are required to supply the drugs within the delivery period mentioned in the purchase order. In this regard it is informed to the bidders that their performance shall be considered unsatisfactory in case of delayed supply (beyond delivery period) or non-supply of products. BPPI may reject their bid in future tenders considering their unsatisfactory performance of supplies.

### 13. LOGOGRAMS

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

- **13.1.** Tenders for the supply for Drugs etc., shall be considered only if the Tenderer gives an undertaking that the product(s) will be prepared as per the specifications such as name, strength, minimum size and packed with appropriate size of the strips/blisters/bottles/tubes etc as per the design enclosed as per **ANNEXURE IX**.
- **13.2.** All dosage form has to be supplied in packing as specified in product list (**ANNEXURE VI**) and shall also conform to Schedule P1 of the Drugs & Cosmetics Act & Rules 1945, wherever it applies. Affixing of stickers and rubber stamps shall not be accepted and supplies will be returned back at supplier's cost.
- **13.3.** Vials, Ampoules (more or equal than 5 ml) and Bottles containing the items tendered for should also carry the printed PMBJP logogram of proportionate size.
- **13.4.** Failure to supply Drugs etc., with the printed logogram of proportionate size will be treated as breach of the terms of price agreement / violation of tender conditions. The purchase order shall be cancelled at the risk and cost of the supplier. However, if such failure continuous despite notice, will be viewed as a serious lapse and initiate blacklisting of the supplier.

Tenderers who are not willing to agree to conditions above will be summarily rejected.

### 14. PACKING

- **14.1.** The drugs shall be supplied in the package specified in **ANNEXURE VI** and **ANNEXURE** -**X** and the package shall carry the logograms of proportionate size specified in **ANNEXURE IX**. 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 18.5
- **14.2.** The minimum size of each tablet should be 6.4 mm in diameter and the minimum size of the blister packing/strip packing/Alu-alu packing should be 80mm x 35mm/50mm x 130

mm/45mm x 110mm respectively. The drugs in any dosage form to be supplied by the supplier should not be embossed indicating any code no./logo or name of the company. Failure to comply with this shall lead to non-acceptance of the goods besides imposition of penalties as per clause 18.3.

- **14.3.** The packing in each carton shall be strictly as per the specification mentioned in **Annexure-X**. The outer carton/secondary packaging should be of pearl white duplex board (**off white/grey is not acceptable**) with a minimum of 350 GSM with **Gloss laminated** packing for the strips, blisters, ointments, creams etc. and for ampoules and vials should be with pearl white board of 350 GSM (**off white/grey is not acceptable**). **The material to be used for carton should be from virgin chemical pulp.** Failure to comply with this shall lead to non-acceptance of the goods besides imposition of penalties as per clause 18.5. Storage conditions must be indicated on outer label.
- **14.4.** The cap of bottle preparations should not carry the name of the supplier.
- **14.5.** The labels in the case of Injectable preparations should clearly indicate whether the preparations are meant for Intravenous (IV), Intra Muscular (IM), Intra Dermal (ID), Subcutaneous (SC) administration etc.
- **14.6.** It should be ensured that only first-hand virgin packaging material of uniform size, including bottle and vial, is used for packing.
- **14.7.** All primary packing containers should be strictly conforming to the specification included in the relevant pharmacopoeia.
- **14.8.** Packing should be able to prevent damage or deterioration during transit.
- **14.9.** In the event of items of drug supplied found to be **not as per specifications in respect of their packing and logogram**, the BPPI is at liberty to make alternative purchase of the items of drugs for which the Purchase orders have been placed from any other sources or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier. In such cases the BPPI has every right to recover the cost and impose penalty as mentioned in Clause 18 & 19.
- **14.10.** Designs of packaging with the logograms shall be subject to approval by BPPI within one day of receipt of purchase order. Text matter of all type of label must be checked and responsibility shall be of manufacturer. In case of failure of BPPI to do so, the supplier may go ahead with the design as per the specification in **ANNEXURE IX**. The specifications for all quoted drugs and STP (Standard Testing Procedure) for Non- Pharmacopoeia drugs in form of soft copy are to be uploaded with technical bid.
- 14.11. The colour of the strength must be different from the colour of the generic name of the drug on primary and secondary packaging and the approval for the same should be taken from the quality/regulatory department while taking artwork approval. The printing ink used should be of good quality (clarity, brightness, contrast) which is easily readable.
- 14.12. WHO-GMP certified, Therapeutic code & NABL lab tested shall be indicated on the primary and secondary packaging and shall be incorporated as per the approval from the quality/regulatory department while taking artwork approval.

### 15. QUALITY TESTING

- **15.1.** Samples of supplies from each batch will be chosen at the point of dispatch at supplier's site or receipt of supply or distribution/storage points for testing at discretion of BPPI. The samples will be sent to different laboratories including Government Drugs Testing Laboratory/NIPER/PSU labs for testing as decided by the BPPI. Handling and testing charges will be deducted by BPPI for the above purpose, as specified in Clause 17.
- **15.1.1** Supplier should send the soft copy of the specifications for all approved drugs and STP (Standard Testing Procedure) for Non- Pharmacopoeia approved drugs by mail to Quality and Regulatory officer of BPPI with art work approval for design of packaging with the logogram as per Clause 14.10; if they failed to upload/submit the same with technical bid.
- **15.2.** The Drugs shall have the active ingredients at the prescribed level as indicated in official compendiums throughout the shelf life period of the drug. The samples will be drawn periodically throughout the shelf life period and if found "Not of Standard Quality", the cost of entire batch paid will be recovered whether consumed fully/partially. Also, action will be initiated for blacklisting as per clause No.19 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.
- **15.3.** In the event of the samples of Drugs supplied fails in quality tests or found to be not as per specifications, the BPPI is at liberty to make alternative purchase of the items of drugs for which the Purchase orders have been placed from any other sources or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier and in such cases the BPPI has every right to recover the cost and impose penalty as mentioned in Clause 19.
- **15.4.** The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the commercial final package on request by the BPPI. 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.
- **15.5.** The products should conform to the standards of IP/BP/USP/EP/JP as the case may be. **However, the drugs notified in the IP (amended up to date) shall be accepted only if supplied conforming to the standards outlined in the IP.** In case the product is not included in the any of the said compendiums, the supplier, upon award of the contract, must provide the reference standards and testing protocols for quality control testing.
- **15.6.** The case of admixture of drugs will be treated as a violation of tender conditions and fine will be levied as per clause 19. If such lapses happen more than twice in a tender period such cases will be treated as "Misbranded Drugs".

### 16. PAYMENT PROVISIONS

- **16.1.** No advance payments towards costs of drugs, medicines etc., will be made to the Tenderer.
- **16.2.** Payments towards the supply of drugs will be made within 60 days from the date of receipt of goods, strictly as per the tender terms and condition. The payment will be made either

by means of a/c payee Cheque or through RTGS (Real Time Gross Settlement System)/Core Banking/NEFT. The Tenderer shall furnish the relevant details in original (ANNEXURE - XI) to make the payment through RTGS/Core Banking/NEFT.

- **16.3.** All bills/Invoices should be raised in triplicate and the bills should be drawn as per GST Rules in the name of Bureau of Pharma Public Sector Undertakings of India. 8<sup>th</sup> Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055or in the name of any other authority as may be designated.
- **16.4.** (i) Payments for supply will be considered only after supply of minimum 50% of Drugs ordered in the individual Purchase Order provided reports of Standard Quality on samples testing are received from Government Analyst or Approved Laboratories of BPPI.
- (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.
- **16.5.** 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 BPPI 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.
- **16.6.** In case of any increase of decrease in the taxes/GST after the date of submission of tenders and during the tender period, such variation in the taxes/GST will be to the account of the BPPI. 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 BPPI from the concerned authorities and also must claim the same in the invoice separately.

However, the basic price structure and the price of the Drugs approved under the tender shall not be altered. Similarly, if there is any reduction in the taxes/GST and statutory levies as notified by the Govt., after the date of submission of tender, the Tenderer will be paid based on the unit rate worked out on the basis of the reduced taxes/GST/statutory levies without any change in the basic price or the price structure of the drugs approved under the tender. Any increase or decrease in taxes/GST and statutory levies will be considered based on the notification issued by the Government.

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 BPPI.

### 17. HANDLING & TESTING CHARGES:

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

### 18. LIQUIDATED DAMAGES AND OTHER PENALTIES:

- **18.1.** If the supply reaches the designated places or Central Warehouse after 5 PM of **30th day** from the date of issue of the purchase order and after 5 PM of the **30th day**, a liquidated damage will be levied at 2% per week or part thereof, subject to maximum of 10% irrespective of the fact that whether the BPPI has suffered any damage/loss or not, on account of delay in effecting supply. If the 30<sup>th</sup> day happens to be a holiday the supply will be accepted on the next working day without any penalty.
- **18.2.** If the supply is received in damaged condition, open delivery of the supplies shall be received, wherein it is possible to physically inspect the shipment. Damaged products shall not be accepted.
- **18.3.** All the Tenderers are required to supply the product(s) with printed MRP as per purchase order and logogram of appropriate size on the strips, blisters, vials, ampoules& bottles and with prescribed packing specification. If there are any deviation in these Tender conditions, action will be taken to blacklist the product and/or a separate damages will be levied @ 5% of value of the defaulted quantity irrespective of the Tender Inviting Authority having actually suffered any damage/loss or not, without prejudice the rights of alternative purchase specified in Clause No.14.11 and 13.4.

## 19. DEDUCTION & OTHER PENALTIES ON ACCOUNT OF QUALITY FAILURE:

19.1. 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 BPPI Such stock shall be taken back at the expense of the Tenderer. Further, actual handling and testing charges shall be paid to BPPI by the supplier otherwise these charges shall be recovered from their pending bill/EMD/performance security deposit. The BPPI has the right to destroy such "NOT OF STANDARD QUALITY DRUGS" if the Tenderer does not take back the goods within the stipulated time. The BPPI will arrange to destroy the "NOT OF STANDARD QUALITY DRUGS" after the expiry of 30 days mentioned above without further notice, and shall also

collect demurrage charges calculated at the rate of 2% per week on the value of the drugs rejected till such time stipulated. Further, the cost of disposal shall be recovered from the supplier.

- 19.2. If any items of Drugs/Medicines supplied by the Tenderer have been partially or wholly used or consumed after supply and are subsequently found to be in bad odour, unsound, inferior in quality or description(Adulterated/Spurious/Misbranded) or otherwise faulty or unfit for consumption, then the contract price or prices of total such batches supplied will be recovered from the Tenderer, if payment had already been made to him. In other words, the Tenderer will not be entitled to any payment whatsoever for Items of drugs found to be of "NOT OF STANDARD QUALITY" whether consumed or not consumed and the Tender Inviting Authority is entitled to deduct the cost of such batch of drugs from any amount payable to the Tenderer. On the basis of the nature of failure, action will be initiated to blacklist the product/supplier.
- 19.3. For the supply of Adulterated/Spurious/Misbranded, as defined in the Drugs and Cosmetics Act, 1940, to BPPI, BPPI reserves the right to blacklist the supplier. No further supplies shall be accepted from the firm/company. If the tenderer is blacklisted, the tenderer shall also not be eligible to participate in tenders of Tender Inviting Authority of BPPI for supply of Drugs for a period of 5 years from the date of blacklisting. In case of supply of NOT OF STANDARD QUALITY drug(s) to BPPI, the product shall be blacklisted by BPPI and no further supplies shall be accepted for the particular drug(s). The Tenderer shall also not be eligible to participate in tenders of BPPI for supply of such Drugs for a period of 2 years from the date of blacklisting. In addition, the Director of Drugs Control of concerned State will be informed for initiating necessary action on the Tenderer in their state. Performance security deposit will also be forfeited.
- **19.4.** The Tenderer shall furnish the source of procurement of raw material utilized in the formulations, if required by the BPPI. The BPPI reserves the right to cancel the purchase orders, if the source of supply is not furnished.
- **19.5.** The decision of the BPPI or any officer authorized by him, as to the quality of the supplied drugs, medicines etc., shall be final and binding. In such cases, the BPPI 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.
- **19.6.** For contravention of the stipulations of the contract or for other justifiable reasons, the contract may be terminated by the BPPI, and the Tenderer shall be liable to pay for all losses sustained by the BPPI in consequence of the termination which may be recovered from the Tenderer, as per rules besides forfeiture of Performance security deposit.
- **19.7.** Non-performance of any of the contract conditions and provisions will disqualify a firm from participating in the tender for the next 2 years besides forfeiture of Performance security deposit.
- **19.8.** In the event of making Alternative Purchase, as specified in Clause 12.4 (a), Clause 14.11 and in Clause 15.3 penalty will be imposed on the supplier. The excess expenditure over

and above contracted prices incurred by the BPPI 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.

**19.9.** In all the above conditions, the decision of the BPPI shall be final and binding.

## 20. BLACK LISTING IN THE EVENT OF WITHDRAWL FROM THE TENDER, AND NON-ADHERENCE TO THE QUALITY STANDARDS AND SUPPLY SCHEDULE

### 20.1. BLACKLISTING OF PRODUCT/TENDERER ON WITHDRAWAL OF TENDER

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

### **BLACKLISTING FOR QUALITY FAILURE**

### 20.2.1. Quality Test by the Empanelled Laboratories of BPPI

- a. Each batch of drugs/medicines shall be subjected to quality test by the Empanelled laboratories.
- b. The samples collected from each batch of supply of each drugs will be sent to the empanelled testing laboratories for testing the quality of drugs. In addition to the above BPPI shall also draw the samples of products supplied in the market place and get the same tested, to make sure the products are conforming to quality requirements.
- c. If sample passes quality test in all respects, BPPI will instruct its Warehouse to release such items of drugs.
- d. If the sample of any batch fails in quality test and report is received stating "Not of standard quality " in any test the report along with the chromatograms etc. such batch of drugs shall be rejected & no further procurement of that drug from the supplier will be taken for two years from the date of sample being declared not of standard quality.
- (i) If the supplier challenges and request for retesting, the sample shall be tested at government testing laboratory or reputed govt. institute like NIPER. The test report of govt. lab or NIPER will be final and will be binding to the supplier.
- (ii) The cost of such retesting shall be recovered from the supplier.
- (iii) If 2 batches of item/drug supplied by the same supplier is reported to NOT OF STANDARD QUALITY in specification, then the firm shall be blacklisted for 2 years

- after observing procedure laid down in Para 20.2.3 besides forfeiture of Performance security deposit.
- (iv) The supplier shall give a report of root cause and CAPA taken to prevent the recurrences of such failure within 20 days.

### **20.2.2 Quality Test by Statutory Authorities:**

- (a) If any drug is declared "NOT OF STANDARD QUALITY", by any government agencies or drug licensing authority, the issue of available stock of the particular item will be stopped. Further, the available stock of the product in hospitals/JAS will be retrieved.
- (b) If any batch of any product(s) supplied by the company/firm declared, NOT OF STANDARD QUALITY in specification as defined in the Drugs and Cosmetics Act, 1940, by the Government Authorities during the relevant tender period or during quality check within shelf life period, the company/firm shall be blacklisted for a period of 2 **years from the date** of blacklisting after observing procedure laid down in Para 20.2.3.

### **20.2.3 Procedure for Blacklisting:**

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

### **20.3 BLACKLISTING FOR NON-SUPPLY:**

Due to non-supply of item against any purchase order, 5 % value of purchase order shall be recovered from the supplier in addition of other penal like risk purchase. In case of repeated circumstances of non-supply of items i.e. 2 times, the supplier may be blacklisted for 2 years in addition of forfeiture of performance security deposit/ EMD and other penal action.

### **21. 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.

### 22. RESOLUTION OF DISPUTES

(i) The BPPI 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.

### **ARBITRATION AND JURISDICTION**

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

However, due to various unforeseen reasons, problems may arise during the progress of the contract/price agreement leading to disagreement BPPI 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 BPPI 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 President/ CEO of BPPI. The venue of Arbitration Shall be at New Delhi. The award published by the Arbitrator shall be final and binding on the parties.

### **23. APPEAL:**

- (i) Any Tenderer aggrieved by the order passed by the Tender Accepting Authority under section 10 of the said Act, may appeal to the Department of Pharmaceuticals, Ministry of Chemical and Fertilizer, Government of India within ten days from the date of receipt of order and the Department of Pharmaceuticals, Ministry of Chemical and Fertilizer, Government of India shall dispose the appeal within fifteen days from the date of receipt of such appeal.
- (ii) No Appeal shall be preferred while the tender is in process and until tender is finalized and Notification of award is issued by the BPPI.

### 24. CONTACTING THE BPPI BY THE BIDDER:

- (i) No bidder shall contact the *BPPI* on any matter relating to its bid, from the time of bid opening to the time the contract is awarded.
- (ii) Any effort by a bidder to influence the *BPPI* in the *Purchaser*'s bid evaluation, bid comparison or contract award decisions may result in rejection of the bidder's bid.
- (ii) 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.
- (iv) Not withstanding anything contained in clause (iii) 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.

### **25. FRAUDULENT AND CORRUPT PRACTICES:**

### (1) 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.

### (2) For suppliers:

If the BPPI determines that a Supplier has engaged in corrupt, fraudulent, collusive, coercive or obstructive practices, in competing for or in executing the Contract, then the BPPI 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.

### 26. 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

### (BARCODE REQUIREMENTS)

Reference clause 2(g)

## GS1 barcode requirements on Drugs procured by Bureau of Pharma Public Sector undertakings of India (BPPI)

These requirements cover medicines/drugs procured by Bureau of Pharma Public Sector Undertakings of India (BPPI), New Delhi meant for supply and distribution through BPPI regulated distribution channel.

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

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

Suppliers are also required to provide GS1 subscription validity certificate at the time of supply of medicines/drugs issued by GS1 India. For validity certificate suppliers can contact GS1 India at 011-4289-0890

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

### **Technical Specification for GS1 Standards**

### Tertiary Level Pack: Data attributes captured

- *a) Unique product identification code (GTIN Global Trade Identification Number)*
- b) Expiry date
- c) Batch no.
- d) Quantity
- *e)* Serial Shipping Container Code (SSCC)

e.g. 1<sup>st</sup> Barcode: (02)1 8901072 00253 4 (17) 180815 (10) RNBXY0514 (37)5000 2<sup>nd</sup>Barcode: (00) 1 8901072 001234567 6

Attribute Description		Length	Nature	Data Type
(02)	Application Identifier to indicate GTIN-14 Brackets not encoded in the barcode	2	Fixed	Numeric

1 8901072 00253 6	Unique Product Number-GTIN-14	14	Fixed	Numeric
(17)	Application Identifier to indicate Expiry date Brackets not encoded in the barcode	2	Fixed	Numeric
180815	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
RNBXY0514	514 Batch No / Lot No		Variable	Alphanumeric
(37)	Application identifier to indicate Quantity in Outer Carton	2	Fixed	Numeric
5000	Quantity/no of units	Upto 8	Variable	Numeric
(00)	Application identifier to indicate the SSCC Brackets not encoded in the barcode	2	Fixed	Numeric
1 8901072 001234567 6	Unique number of the tertiary pack	18	Fixed	Numeric
Recommended Barcode – GS-128				

To,

Warehouse-BPPI, Gurgaon Haryana Mnfd By,

AAA Pharma Company 125, SEZ

Ahmedabad-382213 Gujrat

Drug Name: Dobucin 500 mg Exp Date: 15 Aug 2018 Batch No: RNBXY0514



### Secondary Level Pack: Data Attributes Captured

- a. Unique product identification code (GTIN)
- b. Expiry date
- c. Batch No.
- d. Qty

e.g. Barcode - (02) 1 8901072 00253 6 (17) 180815 (10) RNBXY0514 (37) 500

Attribute	ribute Description		Nature	Data Type
(02)	Application Identifier to indicate GTIN-14. Brackets not encoded in the barcode	2	Fixed	Numeric
1 8901072 00253 6	GTIN-14- Unique product code with first digit being the packaging indicator	14	Fixed	Numeric
(17)	Application Identifier to	2	Fixed	Numeric

	indicate Expiry date Brackets not encoded in the barcode			
180815	Expiry Date in YYMMDD format	6	Fixed	Date
(10)	Application identifier to indicate Lot/batch Brackets not encoded in the barcode	2	Fixed	Numeric
RNBXY0514	Batch No / Lot No	Upto 20	Variable	Alphanumeric
(37)	Application Identifier to indicate serial number Brackets not encoded in the barcode	2	Fixed	Numeric
500	Quantity/Units in Secondary pack	Upto 8	Variable	Alphanumeric
Recommended Barcode depending upon the space available – GS1 Data matrix Or	(02) 1 8901072	(17) (10) RN (37	1072 00253 6 180815 1BXY0514 7) 500 or	14 (37) 500

Primary Level Pack: Data Attributes Captured

### a. Unique product identification code (GTIN)

### Barcode e.g. - (01) 1 8901072 00253 6

Attribute	Description	Length	Nature	Data Type
(01)	Application Identifier to indicate GTIN-14 Brackets not encoded in the barcode	2	Fixed	Numeric
1 8901072 00253 6	GTIN-14 with first digit being the packaging indicator	14	Fixed	Numeric
Recommended Barcode – GS1 Datamatrix,		(01) 1 89010	<b>2</b> 72 00253 6	

### Please contact GS1 India office for any further assistance – GS1 India

(Under Min. of Commerce, Govt. of India) 330, 2<sup>nd</sup> Floor, 'C' Wing, August Kranti Bhawan, Bhikaji Cama Place, New Delhi - 110066

 $T \;\; +91\text{-}11\text{-}42890890, \, (D) \; +91\text{-}11\text{-}42890846$ 

**F** +91-11-26168730

**E** ankit@gs1india.org

W http://www.gs1india.org

### ANNEXURE -II

### (On nonjudicial Stamp Paper)

Ref. Clause No. 4.1(a)

### **DECLARATION**

I/We M/s	represented by its P	roprietor/Managing	Partner /Managin	g Director
having its registered of	office at		and its factory p	remises at
		do he	reby declare as un	der: -

- (I) that I/we have carefully read all the terms and conditions of tender in ref. no. **BPPI/LTD./DRUG-067/2018 dated 28/08/2018**including Amendment(s) to Tender document (if any) issued by Bureau of pharma public sector undertakings of INDIA, New Delhi,122016 and accept unconditionally all terms and condition of tender document including Amendment(s) to Tender document (if any).
- (II) that I/We are holding and have uploaded (a) valid drug license for quoted drugs, (b) valid WHO-GMP certificate, (c) valid non conviction certificate not older than 6 months and (d) the copies of the specifications for all quoted drugs and STP (standard testing procedure) for Non- Pharmacopoeia quoted drugs and also enclosed all undertaking/declaration as per Annexure mentioned in the tender document. However, any document uploaded with technical bid is not complying as per undertaking, the contract shall be cancelled with forfeiture of EMD/Performance Security Deposit/Bank guarantee against tender no. BPPI/LTD./DRUG-067/2018 dated 28/08/2018along with other action.

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

Sr. No	Drug Code	Description of Drug as per BPPI Tender	Unit Size	Drug Lic. No.	Date of Issue	Validity of Drug Lic.	Address of Manufacturin g Unit

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

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 as per schedule M of the said Act for a period of five years.

- (IV) (a) I do hereby declare that I have uploaded valid GS1 registration certificate for bar coding and will supply the drug with bar code as per ANNEXURE I and as per the design as per enclosures to ANNEXURE XI enclosed with tender document as well as other instruction given in this regard.
  - (b) We have valid COPP certificate as per WHO format and approval of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa, (if any) only for following quoted drugs and relevant certificate & approval indicating/highlighting drug code have been uploaded with technical bid: -

S. No.	Drug Code	Description of Drug as per BPPI Tender	Unit Size	Whether Valid COPP certificate (Yes/ No)	If Yes, then indicate the validity date of COPP Certificate	Whether approval of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa (yes/No)

(V) that in pursuant to the conditions in Clause No. 7.2 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 of the drugs supplied either by any State government or Central Government Organization or its drug procurement agencies for the following products quoted in the tender at the time of submission of bid. Further, quoted drug have not been failed in house testing or testing by any State Government/Central Government / its Drug procurement agencies/BPPI during last two years. We are eligible to participate in the tender ref. No. **BPPI/LTD./DRUG-067/2018 dated 28/08/2018** for the following quoted products: -

S.	Drug	Description of Drug as per BPPI Tender	Unit Size
No.	Code		

Signed				
				Name
				Designation
				(Company Seal)
Witness:-(1)				
(2)				
To be attested by the Notary				

### **ANNEXURE-III**

Ref. Clause No. 3(ii, 4.1(b) & 7.1

## **DETAILS OF E.M.D SUBMITTED**

UPLOAD THE SCANNED COPY OF DRAFT/ PAY ORDER/BANK GURANTEE

## ANNEXURE – IV

# Ref. Clause 4.1 (j) CHECK-LIST (Whether Uploaded the documents)

### COVER - A

S. N.	Check List		Please indicate
			Page nos.
1	Check list - ANNEXURE – V		11050
	EMD Rs. 50,000/- in the form of <b>Bank Guarantee or Bankers Cheque</b>		
	or Demand Draft uploaded as per ANNEXURE-III DD		
	No		
	(name of bank) and <b>delivered to</b>		
2	<b>BPPI</b> .Uploaded NSIC or MSME certificate for exemption if any.		
	Scanned copy of Valid WHO-GMP (World Health Organisation-Good		
3	Manufacturing Practices) Certificate of manufacturing company.		
	Scanned copy of Valid License for the Product duly approved by the		
4	Licensing Authority for each and every product quoted		
5	Scanned copy of valid GS1 registration certificate for bar coding		
	Scanned copy of Non Conviction Certificate issued by the licensing		
6	authority not older than 6 months.		
7	Valid COPP certificate		
	Copies of approval of Manufacturing Unit of the any agency like US		
	FDA, TG Australia, Health Canada, EU, MCC South Africa approval,		
8	Brazil Anvisa, if any.		
	Scanned copies of the specifications for all quoted drugs and STP		
9	(standard testing procedure) for Non- Pharmacopoeia quoted drugs.		
4.0	Authorization letter nominating a responsible Person of the tenderer to		
10	transact the business with the Tender inviting Authority.		
	Scanned copy of ANNEXURE –II (Declaration for eligibility in		
11	participating the tender) original Annexure II delivered to BPPI.		
1.0	Scanned copy of ANNEXURE-VIII		
12	(Details for Shelf life, Manufacturing Capacity & Batch Size)		
13	Scanned copy of ANNEXURE—XIII (Mandate form)		

NOTE: - (i) Please ensure that page no. for document have been indicated.

(ii)EMD instrument and ANNEXURE II	are to be delivered	in original to	<b>BPPI</b> , New
Delhi before stipulated time and date.			

N	Jame and	signature	of authori	sed signator	y (with com	ipany seal	.)

## **ANNEXURE** –**V** ( Ref:-Clause 7.1)

## MODEL BANK GUARANTEE FORMAT FOR FURNISHING EMD

Whereas (hereinafter called the					•••••			
"tenderer") dated			ıbmitted			their supply	•	offer
Of Drugs (hereinafter BBPI/DRUG-065/2018	8 KNOW	ALL	MEN	by	these	presents	that	WE
having our registered of bound unto Bureau of called the "Purchaser) is to be made to the said presents. Sealed with the 201	Pharma Pub in the sum of Purchaser, the	lic Sector Rs. Fifty he Bank b	Underta thousand inds itse	kings only	s of India for whic	New Delh h payment ors and ass	i (herein will and igns by t	after truly
THE CONDITIONS O	F THIS OBL	IGATION	ARE:					
(1) If the tenderer with within the period of value		-	airs or de	eroga	ites from	the tender i	in any res	pect
(2) If the tenderer having the period of its validity	_	ed of the a	cceptanc	ce of	his tender	by the Pur	chaser du	ıring
a) If the tender the contract.	er fails to fur	nish the P	erforman	ice S	ecurity fo	r the due pe	erforman	ce of
b) Fails or refus	ses to accept/e	execute the	e contrac	t.				
WE undertake to pademand, without the Puthe Purchaser will note one or both the two cor	urchaser having that the amo	ng to subsount claim	tantiate i	ts de is du	mand, pro	ovided that ring to the	in its den	nand
This guarantee will should reach the Bank		_		19 a	nd any de	emand in re	espect the	ereof
(Signature of the aut	horized offic							
Name and designation				•				
Seal, name & address of					1			

### Annexure -VI Clause 8.1 &8.2

## Bureau of Pharma Public Sector Undertakings of India, New Delhi Tender for supply of drugs (Tender No. BPPI/LTD./DRUG-067/2018 dated 28/08/2018)

(1)	(2)	(3)	(4)	(5)	(6)	(7)
Sr. No.	Drug Code	Generic name of Drugs	Unit Size	Pack Size	Packing per Carton (Shipper Pack)	Tender quantity in unit size
1.	40	Amoxycillin 250mg + Cloxacillin 250 mg Caps 10's	10's	10's X 10	[(10's x 10) x 10] x 10	50000

## Annexure - VII

## {Ref:- clause 8.1(ii)}

(1)	(2)	(3)	(4)	(5)	(6)
Sr. No.	Drug Code	Generic name of Drug	Unit Size	Shelf Life in mont hs	Manufact uring Capacity per year in Units
1	40	Amoxycillin 250mg + Cloxacillin 250 mg Caps 10's	10's		

## **ANNEXURE -VIII**

## Ref. Clause No.10.1

## **Performance Security Bank Guarantee**

(unconditional)

Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055
WHEREAS
<b>AND WHEREAS</b> it has been stipulated by you in the said Contract that the Supplie shall furnish you with a Bank Guarantee for the sum specified therein as security for compliance with the Supplier's performance obligations in accordance with the Contract.
AND WHEREAS we have agreed to give the Supplier a Guarantee
THEREFORE WE hereby affirm that we are Guarantors and responsible to you, or behalf of the Supplier, up to a total of
in Words and Figures) and we undertake to pay you, upon your first written demand declaring the Supplier to be in default under the Contract and without cavil or argument., any sum of sums within the limit of
This guarantee is valid until the
Signature and Seal of Guarantors
Date
Address
7 Idd1055

## **ANNEXURE -IX**

Ref. Clause no 13

### **DECLARATION**

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

Signature of the Tenderer

Name

Designation

(Company Seal)

#### Enclosure-1 to <u>ANNEXURE</u> - <u>IX</u>

#### Ref. Clause No. 13

#### **DESIGN FOR:** Foil / blister of tablet and capsule

- 1. Text Matter Printing on Foil /Blister should be in minimum two colour i.e. Black & red. However, colour and design of PMBJP (Pradhan Mantri Bhartiya Janaushadhi Pariyojana) logogram in standard colour format & BPPI Drug code-XXXX as given in PO as per approval at the time of ART WORK approval before supply should be as given below.
- 2. PMBJP Logogram should be placed along with the address as given below.
- 3. BPPI helpline number 1800 180 8080 should be printed.
- 4. Font type should in CALIBIRI format for any type of title name of generic medicines.
- 5. Title name of generic medicine should be **bold** in minimum 12 font size & the strength corresponding to it must be **bold** in minimum 14 font size 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. "Bureau of Pharma PSUs of India" should be running text only and should not be prominent.



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

### Enclosure – 2 to <u>ANNEXURE</u> – <u>IX</u>

#### Ref. Clause No. 13

#### 1. Design for injection for primary packing

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

#### Manufactured for:

Bureau of Pharma PSUs of India



8<sup>th</sup> Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055

BPPI helpline number 1800 180 8080

**BPPI DRUG CODE--XXXX** 

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

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

#### Manufactured for:



Bureau of Pharma PSUs of India

8<sup>th</sup> Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055

BPPI helpline number 1800 180 8080

**BPPI DRUG CODE--XXXX** 

#### (ii) LIQUID:

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

#### Manufactured for:



Bureau of Pharma PSUs of India

8<sup>th</sup> Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055

BPPI helpline number 1800 180 8080

**BPPI DRUG CODE--XXXX** 

#### 3. OINTMENTS / CREAMS

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

Manufactured for:



Bureau of Pharma PSUs of India

8<sup>th</sup> Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055

BPPI helpline number 1800 180 8080

**BPPI DRUG CODE--XXXX** 

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

#### ANNEXURE-X

#### Ref. Clause No.14.1

#### SCHEDULE FOR PACKAGING OF DRUGS

#### **GENERAL SPECIFICATIONS**

- 1. Strips of Aluminium foils should be 0.04 mm thickness.
- 2. Aluminium foils s back material for blisters should be minimum 0.025 mm thickness.
- 3. The rigid PVC used in blister packing should be of not less than 250 micron
- 4. All glass bottles should be new neutral glass. Pet bottles so accepted as per drug laws stipulation.
- 5. Ointments should be packed in lacquer zed Aluminium Tubes or Lami tubes.
- 6. Small Tablets packed in blisters should be packed to facilitate easy removal of the tablet without breaking / crushing.
- 7. Specification of outer cartons are as given in this Schedule.
- 8. In case of any conflict between Carton specifications and packets per carton specification the specification of the packets / carton shall prevail.
- 9. All plastic containers should be made of virgin grade plastics
- 10. Injection in vials should have a flip-off seals.
- 11. The strips shall be aluminium strip / blisters with aluminium foil back.
- 12. The minimum diameters of each tablets should be of 6.4mm
- 13. The outer carton/secondary packaging should be of pearl white duplex board (off white/grey is not acceptable) with a minimum of 350 GSM with Gloss laminated packing for the strips, blisters, ointments, creams etc. and for ampoules and vials should be with pearl white board of 350 GSM (off white/grey is not acceptable). The material to be used for carton should be from virgin chemical pulp.
- 14. All liquid oral preparations to be provided with a measuring plastic cup, fitted over the cap of the bottle in a mono carton. In case of Paediatric Preparation, all liquid oral has to be provided with a measuring plastic cup, dropper fitted over the cap of the bottle in a mono carton.
- 15. All primary/secondary/tertiary packaging should have PMBJP logo and BPPI DRUG CODE—XXXX as per PO.
- 16. Two Horizontal/vertical/standing lines in two different colour will be there on Primary and secondary packaging, so as to differentiate therapy groups. The colours of lines will be intimated during Artwork approval.

17. The primary packing should be decided by the party depending on the drug category as per D&C act. For e.g if drug is hygroscopic then tablet should be packed in Alu/Alu blister or if it is light sensitive then to be packed in Amber colour PVC e.t.c.

#### (Schedule)

-	GODDYG A MED DOVING (A. A. A.)
1.	CORRUGATED BOXES(Liquid)
	1. No corrugate package should weigh more than 15 kgs (i.e. product + inner
	carton + corrugated box).
	2. All Corrugated boxes should be of `A' grade paper i.e. Virgin and 7 Ply.
	3. All items should be packed only in first hand boxes only.
2.	FLUTE
	The corrugated boxes should be of narrow flute.
3.	JOINT
	Every box should be preferably single joint and not more than two joints.
4.	STITCHING
	Every box should be stitched using pairs of metal pins with an interval of two
	inches between each pair. The boxes should be stitched and not joined using
	calico at the corners.
5.	FLAP
	The flaps should uniformly meet but should not overlap each other. The flap when
	turned by 45 – 60 degree should not crack.
6.	TAPE
	Every box should be sealed with gum tape running along the top and lower
	opening.
7.	CARRYSTRAP:
	Every box should be strapped with two parallel nylon carry straps (they should
	intersect).
8.	LABEL
	The product label on the carton should be large at least 15 cms x 10 cms dimension.
	It should carry the correct technical name, strength of the product, date of
	manufacturing, date of expiry, quantity packed and net weight of the box.
9.	OTHERS
	No box should contain mixed products or mixed batches of the same product.

## II. SPECIFICATION OF CORRUGATED BOXES HOLDING TABLETS / CAPSULES / PESSARIES

- (1) The box should not weigh more than 7-8 kgs. The grammage of outer box should be 150 gsm and inside partition / lining should be 120 gsm.
- (2) The box should be of 7 ply with bursting strength of 9 Kg / Cm2

## III. SPECIFICATIONS OF CORRUGATED BOXES FOR OINTMENT / CREAM / GELS PACKED IN TUBES:

- (1) No corrugate box should weigh more than 7-8 Kgs.
- (2) Every Ointment tube should be individually packed in carton and then packed in 20's in a white board box, which may be packed in a corrugated box.
- (3) Grammage: Outer box should be 150 gsm inside partition /

Lining should be 120gsm.

## IV. SPECIFICATIONS OF CORRUGATED BOXESFOR INJECTABLE (IN VIALS AND AMPOULES)

- (1) Vials may be packed in corrugated boxes weighing up to 15 Kgs. Ampoules should be packed in C.B weighing not more than 8 kgs.
- (2) C.B. for vials should be of 150 gsm (outer box should be 150 gsm and inside partition / lining should be 120 gsm) and 7 ply, while C.B. for ampoules should be of 150 gsm (outer box should be 150 gsm and inside partition / lining should be 120 gsm) and 7 ply.
- (3) Bursting strength for CB boxes for

i. Vials : Note less than 13 Kg/Cm2

ii. Amp : Note less than 9 Kg/Cm2

- (4) In the case of 10 ml Ampoules, 20 or 25 ampoules may be packed in a mono carton. Multiples of mono carton boxes should be packed in CB.
- (5) If the vial is packed in individual carton, there is no necessity for grey board box packing. The individual carton may be packed as such in the CB with centre pad.
- (6) In case of ampoules less than 10 ml, every 10 or 5 ampules should be inside the tray with printed white board box.
- (7) Vials of eye, ear drops and nasal drops should be packed in an individual mono carton with a dispensing device. If the vial is of FFS/BFS technology, they should be packed in 50's in a white board box.

## **ANNEXURE -XI**

## **MANDATE FORM**

Ref. clause 16.2

Sl.No.	Details Required		
1.	Company Name		
	PAN Number		
	TIN Number		
	GST NO.		
	Date of Inception		
	Licence No. & Date		
	Issued By		
	Valid Upto		
2.	Postal Address of the Company		
	Company		
	Telephone No.		
	Fax No.		
	E-mail ID		
	Alternate E-mail ID		
3.	Name of the Managing		
	Director / Director /		
	Manager		
	Mobile No. / Phone No		
4	E-mail ID		
4.	Name and Designation of	Name:	
	the authorized company official	Designation:	
	Mobile No.	Designation	
	E-mail ID		
5.	Bank Details	<u> </u>	
J.	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		
1	appearing on the	1	i

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 <u>upload the original cancelled cheque</u> 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 Bureau of Pharma Public Sector Undertakings of India (BPPI) responsible. I have read the conditions of the tender / Price agreement and agree to discharge the responsibility expected of me / from the company as a tenderer / successful tenderer.

Signature

(Name of the person signing & designation)

Company Seal

CERTIFIED THAT THE PARTICULARS ARE CORRECT AS PER OUR RECORDS.	FURNISHED ABOVE BY THE COMPANY
Bank Seal with address:	Signature of the authorized official of the bank

Date:

Place: