

### e-TENDER NO:- BPPI/DRUG-055/2017

### TENDER FOR SUPPLY OF DRUGS

TO

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

**For the year 2018-20** 



#### 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: 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

# ONLINE TENDER FOR THE SUPPLY OF DRUGS TO BUREAU OF PHARMA PSU OF INDIA FOR THE YEAR 2018-2020

Tender Reference	BPPI/DRUG-055/2017 Dt. 18/12/2017
Date of availability of tender documents on website	18/12/2017 (Monday)
Time and date and place pre-bid meeting	11:00 AM on 27/12/2017(Wednesday)
	Bureau of Pharma <b>PSUs</b> of India, 8 <sup>th</sup> Floor, Videocon Tower, Block-E1,Jhandewalan Extension, New Delhi-110055
Last date and time for submission of Online Bid i.e. Bid Submission End Date and time	09/01/2018 up to 11:00 A.M.
Last Date for submission of EMD in physical Form in office of Bureau of Pharma PSUs of India, 8 <sup>th</sup> Floor, Videocon Tower, Block-E1,Jhandewalan Extension, New Delhi-110055	10/01/2018
Time and date of opening of Technical Bid	11:30 AM on 10/01/2018 (Wednesday)

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	1. Sh. Ashish Kumar,
any	G.M. (Procurement) Phone:- 011-49431811
	Mob:- 9911028198
	Email: gmproc.bppi@gmail.com
	2.Mr. Sandeep Sapan Patra,
	Sr. Executive (Procurement)
	Phone:- 011-49431830
	Mob:- 9090512532
	Email:- proc5.bppi@gmail.com
	3. Mr. Rupak Kumar,
	Executive (Procurement)
	Phone:- 011-49431829
	Mob:- 7291087675
	Email:- proc3.bppi@gmail.com

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="mailto:janaushadhi.gov.in">janaushadhi.gov.in</a>.

#### TABLE OF CONTENTS Sl.No. **Description** Page No. Last Date and time for submission of ONLINE Tender 7 1. Eligibility Criteria 2. 7 **General Conditions** 3. 8 Technical Bid – Cover "A" 4. 10 Price Bid – Cover "B" 5. 12 Opening of Cover "A" and Cover "B" of Tender 13 6. Earnest Money Deposit 7. 14 Other Conditions 8. 14 Acceptance of Tender 9. 16 Performance security deposit 10. 17 Methodology for placing orders 11. 18 **Supply Conditions** 12. 20 Logograms 13. 22 **Packing** 14. 23 **Quality Testing** 15. 24 **Payment Provisions** 16. 25 Handling & Testing Charges 17. 26 Liquidated Damages and other penalties 18. 26 Deduction and other penalties on account of Quality failure 19. 27 Blacklisting in the event of withdrawal from the tender, and Non-20. 28 Adherence to the Quality Standards and supply schedule Saving Clause 21. 30 Resolution of Disputes 22. 30 Appeal 23. 30 Contacting the Purchaser by the Bidder 24. 31 Fraudulent and Corrupt Practices 25. 31 Jurisdiction 26. 33 ANNEXURE-I 34 27. (BARCODE REQUIREMENTS) ANNEXURE-II (Agreement format with the Manufacturer) 39 28

	ANNEXURE-III	
29.	(Declaration for eligibility in participating the tender)	41
	ANNEXURE –IV	
30.	(Details of EMD submitted)	43
31.	Annexure V – (A certificate from CA or Company Secretary).	44
32.	ANNEXURE -VI (Check List)	46
	ANNEXURE –VII (Bank Guarantee format for submission of	
33.	EMD)	47
34.	ANNEXURE -VIII (Details of requirements for Drugs)	48
35.	ANNEXURE -IX	56
33.	( Details for Shelf Life, Manufacturing Capacity & Batch Size)	30
36.	ANNEXURE -X	62
30.	(Letter of acceptance of tender for price agreement)	62
37.	ANNEXURE -XI	63
37.	(Performance Security Bank Guarantee)	03
38.	ANNEXURE -XII	64
30.	(Declaration for Logogram)	04
39.	ANNEXURE -XIII (Packing Specifications)	71
40.	ANNEXURE –XIV (Mandate Form)	74

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

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

#### **FOR THE YEAR 2018-20**

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 3000 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 2018-2020.

#### 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 09/01/2018(Tuesday) on** CPP portal i.e. eprocure.gov.in.
- (b) The price bid shall be valid for a period of 120 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. Loan licensee is also eligible.
- (ii) Tenderer shall be direct importer holding valid import license. The Importer should have valid sale license.
- (iii) Tenderer shall be a marketer of manufacturer who have exclusive rights to market the products and manufacturer do not market the products duly supported by valid agreement with the manufacturer. **Distributors/Suppliers/Agents are not eligible to participate in the Tenders.** The Marketer should have valid sale license.
- (b) (i) Manufacturer should have valid WHO-GMP (World Health Organisation-Good Manufacturing Practices) certificate issued by licensing authority.
  - (ii) A certificate from their C.A. (Chartered Accountant) or Company Secretary that
  - (i)Average Annual turnover of manufacturer in the last three years i.e.2014-15, 2015-16 and 2016-17 shall not be less than **Rs.10 Crores.** In case of loan licensees and Marketer, average annual turnover of manufacturer in the last three years i.e. 2014-15, 2015-16 and 2016-17 shall not be less than **Rs.10 Crores.**

OR

Manufacturer have invested Rs 10 crores or above for installation of plant and machinery excluding cost towards land, building & other infrastructure to manufacture the drugs.

- (ii) Manufacturer have manufactured & marketed at least 2 commercial batch of quoted drugs in last three years
- or (in case of Importer) marketed at least 2 commercial batch in last three years
- (iii) Manufacturer has Production & financial capacity to manufacture and deliver the drugs quoted by the firm in the tender as per quantity mentioned in tender during contract period.

Or (ONLY in case of Importer)

M/s	has Financial capacity to deliver the drugs quoted by
them	in the tender as per quantity & delivery schedule mentioned in tender. This certificate is
based	d on their marketing experience and financial statement.

- (c) Market Standing Certificate (MSC) issued by the state licensing authority under generic or brand name as a Manufacturer for each product quoted in the tender for a minimum 2 years.
- (d) Non-conviction Certificate not older than 6 month issued by the licensing authority of the State certifying that the firm/company has not been convicted.
- (e) 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.*
- (f) 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.
- (g) During the validity of the tender if the firm / Company is blacklisted/debarred/deregistered/banned by any State Government / Central Government / its Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to BPPI along with relevant authentic document by the tenderer firm/ company within one month.
- (h) 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.
- (i) Tenderer are required to incorporate bar codes as per GS1 standards at various packaging levels (primary, secondary and tertiary). (Annexure I)

#### **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.1,00,000/- (Rupees One Lakh 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 stipulated against 'Bid opening Date'. 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 IV) 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.
- (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) During tender or price agreement period, if L1 bidder is debarred/deregistered/blacklisted/banned by any Central Government or state Government or its procurement agencies due to quality failure, BPPI may purchase the drugs from L2 bidder or may go for fresh tender as per discretion of BPPI.
- (vii) 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 e-submission 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) (i) The marketer of manufacturer who have exclusive rights to market the products and manufacturer do not market the products should upload valid agreement with the manufacturer with technical bid (ANNEXURE II) and the original agreement should be submitted on or before the schedule date of technical bid opening. In case, bidder is a marketer of a manufacturer, scanned copy of valid sale license is required to be uploaded. The Importer is also required to upload copy of valid sale license. In case bidder is Importer, it is not mandatory to submit ANNEXURE II but it is advisable to submit the same from their Manufacturer.
- (ii) The tenderers are required to upload scanned undertaking on stamp paper duly notarized by authorised signatory confirming that they are holding the valid drug license, valid WHO-GMP certificate, 2 years market standing certificate for quoted products issued by licensing authority, a certificate for manufactured & marketed of two batches for quoted drugs within 3 years issued by CA or ICWA, valid Non conviction certificate not older than 6 months issued by licensing authority, valid import license, valid sale license (in case of marketer or Importer). undertaking as per para 2(f) & (h), undertaking to supply the drug with bar code as per ANNEXURE I and as per Annexure XII & XII A, undertaking for Clause 7.2, uploaded 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. In case the bidder is Importer, they may strike the clause or part of clause not applicable in their case. The drugs indicated in this undertaking shall only be considered for evaluation and opening of price bid. On the basis of such undertaking, the price bid shall be opened within a week after opening of technical bid. However, the bidder is required to upload/submit all the documents along with the technical bid and in case any document is not complying as per undertaking, their contract/Price agreement shall be cancelled with forfeiture of EMD/Performance security deposit/Bank guarantee. (ANNEXURE - III). The original ANNEXURE III should be submitted to BPPI, New Delhi on or before the schedule date of technical bid opening.
- (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 IV) to the e-Procurement portal. and original EMD instrument should be submitted to BPPI, New Delhi on or before the schedule date of technical bid opening.
- (c) The tenderers are required to upload a certificate from the C.A.(Chartered Accountant) or Company Secretary as per ANNEXURE V certifying that (i) Constitution of bidding firm with details of PAN no., GST registration no., filed Income tax returned and GST retuned up to date and attested signature of authorised person,(ii) whether the bidder is Micro Small & Medium Enterprises (MSME) and owned/ not owned) by Scheduled Caste (SC)/Scheduled Tribe (ST) entrepreneurs.(iii) Average Annual Turnover certificate of manufacturer/manufacturer of marketer of loan licensee (if applicable) in the last three years i.e.2014-15, 2015-16 and 2016-17 or Manufacturer have invested Rs 10 crores or

above for installation of plant and machinery excluding cost towards land, building & other infrastructure to manufacture the drugs, (iv) Manufacturer have manufactured & marketed at least 2 commercial batch in last three years or (in case of Importer)marketed at least 2 commercial batch in last three years (,(v) Manufacturer has Production & financial capacity to manufacture and deliver the drugs quoted by the firm in the tender as per quantity mentioned in tender during contract period or Importer has Financial capacity to deliver the drugs quoted by them in the tender as per quantity & delivery schedule mentioned in tender.

- (d) 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>
- (e) The Tenderer should upload Scanned copy of valid drug Manufacturing Licence for the product, duly approved by the Licensing Authority for each and every 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).
- (f) Scanned copy of import license (in Form 10 with Form 41), as per Rule 122A of the Drugs and Cosmetics Act 1940, if the product is imported should be uploaded. The licence must have been renewed up to date. A copy of a valid licence for the sale of Drugs imported by the firms issued by the State Licensing Authority shall be uploaded. Original documents should be produced for verification when demanded.
- (g) MARKET STANDING CERTIFICATE (MSC) ISSUED BY THE STATE LICENSING AUTHORITY UNDER generic or brand name as a Manufacturer for each product quoted in the tender for a minimum 2 years (Certificate should be uploaded with list of items). In case of direct importer, evidence for importing the said items such as bill of landing, bill of entry and certificate of analysis are to be uploaded. MSC issued under brand name or under generic name (by the state licensing authority) will also be accepted but supplies will be accepted as per packing and label by foreign manufacturer in their brand subject to affixing sticker for Logo as approved by BPPI & BPPI MRP. However, for those newly launched drugs whose first product permission to manufacture and sale has been issued within 2 years by the respective country's / state drug authority, MARKET STANDING CERTIFICATE (MSC) issued by the respective country's /STATE LICENSING AUTHORITY under generic or brand name as a Manufacturer for less than 2 years shall be acceptable to BPPI. In case the bidder is Importer, MARKET STANDING CERTIFICATE (MSC) ISSUED BY THE STATE LICENSING AUTHORITY shall not be applicable.
- (h) The copies of relevant pages approved by drug authorities of concerned country for any quoted Drug/product offering CoPP certificate and quoted drugs/product approved by from US FDA, TG Australia, Health Canada, EU approval, MCC South Africa approval, Brazil Anvisa) should be uploaded with technical bid.
- (i) 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**.

- (j) Scanned copy of Valid WHO-GMP (World Health Organisation-Good Manufacturing Practices) Certificate (for manufacturer only) issued by the Licensing Authority should be uploaded. In case of Imported drugs, labels and product literature of all quoted product(s) must be uploaded COPP certificate as per WHO format of their Principal Manufacturing company/firm.
- (k) Documents, if any, to show that the manufacturing unit/importer has been recognized by any other Indian / International Standard Organizations etc. as applicable.
- (l)The loan license bidder are required to upload scanned copies of all the documents as per tender requirements including manufacturing unit.
- (k) The tenderers are required to upload copies of the specifications for all quoted drugs and STP (standard testing procedure) for Non- Pharmacopoeia quoted drugs.
- (m) A Checklist (**ANNEXURE-VI**) 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.
- (s) 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 Technical bid opening.

#### 5. PRICE BID - 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 product 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 is not offering product 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 approval from 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 product having approval of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa approved product 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-IX**
- (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 % only against the heading of column BOQ 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. (d) are entitled to be present at the time of opening of Technical Bid Cover "A" of the tender submitted by them.
- **6.2** Tenderers, who are found eligible on satisfying the criteria for technical evaluation/based on undertakings & Declaration, will only be informed the time and date of opening of Price Bid Cover "B" of the tender.

6.3 In case, the date for opening of technical bid is declared holiday, the technical bid shall be opened on next working day at 11.30 A.M.

#### 7. EARNEST MONEY DEPOSIT

- 7.1. The Earnest Money Deposit referred to under Clause 3(ii) & 4.1(a), shall be Rs. 1 lakh. 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-VII. 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.

#### **8.OTHER CONDITIONS**

- **8.1**.(i) The details of the required drugs, medicines, etc., are shown in **ANNEXURE -VIII**. The tender quantity mentioned herein is not a fixed procurement quantity and it is only a tentative requirement and may be increased or decreased by the BPPI, at its discretion, depending on it is actual need. Though the tentative quantity is indicated in the price agreement, the BPPI, will confirm the actual requirement then / there through purchase order/orders. The tenderers shall supply the drugs only on the basis of the purchase order issued time to time within validity of contract period by the BPPI. Any supply without a valid purchase order will not be acceptable by BPPI and the BPPI shall not be responsible for any loss on this account.
- (ii) The Tenderer shall fill in manufacturing capacity per year in units, Shelf life in months and manufacturing batch size in units for each quoted drugs in required column of **ANNEXURE IX and upload along with technical bid.** In case the bidder is Importer, the importer is

BPPI/DRUG-055/2017

required to sign and upload ANNEXURE IX on behalf of the exporter which would be supported by documentary evidence provided by the manufacturer.

- (iii) However, once the purchase order/orders is/are issued by the BPPI, the tenderer shall not renege from the commitment of supplying the quantity mentioned in the acceptance of tender for price agreement.
- (iv) The rates quoted shall not be varied with the ordered quantity during the full 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-VIII**. Any variation, if found, will result in rejection of the tender. However, the imported/combination drugs are allowed to quote in trade / brand name.
- **8.3.** Rates (inclusive of Customs duty, packing & forwarding charges, transportation, insurance and any incidental charges, but exclusive **GST** should be quoted for each of the required drugs, medicines etc., separately on door delivery basis according to the unit ordered. Tender for the supply of drugs, medicines, etc. with cross conditions like "AT CURRENT MARKET RATES" shall not be accepted. Handling, clearing, transport charges etc., will not be paid separately. The delivery should be made as stipulated in the purchase order placed with Tenderers.
- **8.4.** Each bid must contain not only the unit rate but also the total value of each item quoted for supply in the respective columns. The aggregate value of all the items quoted in the tender shall also be furnished.
- **8.5.** (i) 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. In case delivery of drugs is not made within delivery period mentioned in Purchase order, the supplier must confirm from BPPI whether BPPI MRP is to be reduced due to changes in DPCO ceiling rate after issue of purchase order.

#### (ii) FALL CLAUSE:

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

- **8.6.** The rates quoted and accepted will be binding on the Tenderer for the full contract period of two years and any increase in the price will not be entertained till the completion of this contract period. Accordingly, this clause will be applicable for all orders placed during the contract period. However, Price agreement validity period may be extended for period up to further one year at same rate, terms & conditions with the consent of the supplier.
- **8.7.** 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.
- **8.8.** Supplies should be made directly by the tenderer and not through any other Agency / Dealer / Distributors.
- **8.9.** 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.
- **8.10** "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 product having approval of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa approved product. However, to have additional source of supply, the L1 bidder shall be awarded contract/Price agreement for 50% of tender quantity indicated in the tender document. Balance 50% of the tender quantity indicated in the tender document shall be awarded to **L2 bidder if they agree to supply the drugs at L1 rates.**
- (ii) In case, L2 bidder does not agree to match L1 rate, 100% tender quantity shall be awarded to L1 bidder. The purchase order shall be issued to L1 bidders and in case they fail to supply in stipulated time or due to quality failure, the purchase order shall be issued to L2 bidder. During the Price agreement period of 2 years, in case L1 bidder completes the supply of drugs for

contracted quantity, next supply shall be taken from L2 bidder accordingly for contracted quantity.

- (iii). The issue of purchase orders in same manner as mentioned above. Negotiation if required will be done at our premises and the same will be done strictly as per Central Vigilance Commission guidelines.
- Note 1.:- No quantity distribution shall be applicable if L1 rates quoted by more than one bidder keeping in view of sharing of quantity as per clause no. 11(c) provided that no L1 bidder has <u>CoPP</u> certificate or drug/product approval of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa.
- Note 2. In case, MSME bidder is not eligible as per clause 5.1(ii)(d) and single bid is available after determination of L1 bidder considering price preference 5% for CoPP and 10% for product having approval of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa approved product, Such bidder shall be awarded 70% of quantity indicated in tender document and balance 30% quantity shall be awarded to lowest bidder at their quoted rates if applicable or L2 bidder at lower rate by 5% over L1 rate in case of CoPP bidder and by 10% over L1 rate in case product having approval of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa approved product.
- **Note 3.** No undue advantage shall be given for additional quantity to L2 Bidders or MSME while matching/reducing the rate with respect to L1 rate.
- **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.
- **9.4.** BPPI also reserves right to place one-time purchase order for certain quantity for any drug without signing agreement for 2 years for such drugs and suppliers are required to pay performance security deposit @ 5 % of value of order of such drug in form DD or Performance Bank Guarantee.
- **9.5.** The acceptance of the tenders Price Agreement for two years period will be communicated to the Tenderers in writing (**ANNEXURE X**).

#### 10.PERFORMANCE SECURITY DEPOSIT

#### 10.1 Performance security deposit:

On being informed about the acceptance of the tender for 2 years price agreement, the Tenderer shall pay the Security Deposit @5% of value of 50% quantity i.e. one year quantity out of 2 years quantity of price agreement 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

BPPI/DRUG-055/2017

guarantee shall be valid for a period beyond **one year of the validity of the price agreement**. The format of Performance Bank Guarantee is at **ANNEXURE-XI**. Due to non-purchase of quantity mentioned in the acceptance letter for 2 years price agreement at later stage, tenderer shall be allowed to replace bank Guarantee with lesser amount fresh Bank Guarantee if tenderer requests for such replacement.

- **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 price agreement 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 selected Tenderer fails to deposit the required performance 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. The performance security deposit shall be forfeited if the undertaking as Annexure II is not found correct.
- **10.5**. The performance 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 the conclusion of Price Bid opening (Cover B), the rates offered by tenderers for each product are evaluated and lowest acceptable rate (L1 Rate) arrived at is declared and that tenderer is informed.
- (b) The Successful Tenderer is eligible for the placement of Purchase Orders only after 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

BPPI/DRUG-055/2017

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), Gurgaon 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, 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 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.
- (n) BPPI reserves the right to place upto 50% additional purchase order of the quantities as contracted within validity of contract.

#### 12. SUPPLY CONDITIONS

- **12.1.** Purchase orders will be issued to the Tenderer(s) at the discretion of the BPPI as per actual requirements. All the supplies shall be received at the central warehouse at Gurgaon or any other place decided by BPPI.
- **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 as specified in Annexure, to BPPI within 7 days from the receipt of the purchase order. In case, the supply shall not be made by the date as conveyed by the supplier, supply order shall be cancelled at their risk and cost. If no response is received within 7 days from the supplier / tenderer about supply of drugs as per purchase order, it shall be presumed that the supplier/tenderer is not interested to supply the drugs ordered as per purchase order and BPPI shall purchase the drugs from alternative sources.
- **12.4**. (a) For the first purchase order, the supplier must supply the ordered quantity within 45 days from the date of Purchase Order.
- (b) For Subsequent purchase orders, the supplier shall complete the supply within 30 days from the date of purchase order at the destinations mentioned in the purchase order.
- (c) If the above day for 12.4 (a) &(b) above happened to be a holiday for BPPI, the supply should be completed by 5.00 PM on the next working day.
- (d) In case of Non- execution of the order, BPPI reserves the right to place purchase orders (partially/fully) on alternate source at the risk and cost of the default tenderer(s) without any notice/Information.

- (e) 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.
- (f) The liquidated damages as specified in clause 18.1 and 18.2 of the tender conditions will be levied on the quantity supplied after the 45<sup>th</sup>day and 30th day for 12.4 (a) &(b) respectively. However, no supplies will be accepted after 75<sup>th</sup> days/ 60th days for 12.4 (a) &(b) respectively 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 including month of manufacture of products having shelf life up to 2 years, (b) within 3 months including month of manufacture of products having shelf life more than 2 years & up to 3 years and (c) within 4 months including 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 March 2018 must be supplied by 31<sup>st</sup> May,2018 in case shelf life less than 2 Years.

For imported products, 60% of shelf life should be available at time of supply.

**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 does not include the Scarcity of raw BPPI/DRUG-055/2017

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-XII. 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 –XII &XII-A**.
- **13.2.** All dosage form have to be supplied in packing as specified in product list (**ANNEXURE VIII**) 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.

**13.5.** For imported Drugs, the supplies will be accepted as per packing and label by foreign manufacturer in their brand subject to affixing sticker for Logo as approved by BPPI & BPPI MRP.

#### 14. PACKING

- **14.1.** The drugs shall be supplied in the package specified in **ANNEXURE VIII** and **ANNEXURE** -**XIII** and the package shall carry the logograms of proportionate size specified in **ANNEXURE** -**XII**, **XII** -**A**. 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 18.5.
- **14.3.** The packing in each carton shall be strictly as per the specification mentioned in **Annexure-XIII**. 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 3 days 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 XII and XIIA.** 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.
- **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. For imported drugs, respective Country's Pharmacopoeia standards shall be acceptable (even if the product is official in IP).

**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 XIV**) 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:

No handling & testing charges shall be applicable.

#### 18. LIQUIDATED DAMAGES AND OTHER PENALTIES:

- **18.1.** If the supply reaches the designated places or Central Warehouse after 5 PM of **45th day** from the date of issue of the Ist purchase order and after 5 PM of the **30th day** from the date of issue of the subsequent purchase order, a liquidated damages 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 45<sup>th</sup>/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 without any intimation.
- **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 the 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 such sample passes quality test in all respects, BPPI will instruct its Warehouse to release such items of drugs.
- d. If the sample fails in quality test and report is received certifying that sample is "NOT OF STANDARD QUALITY" then supplies will 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. If the supplier challenges and request for re-testing, the rejected supply shall be tested in two labs simultaneously at the cost of supplier. The cost of testing shall be recovered from the supplier.
- (i) If such sample passes the quality test in both laboratories, the drugs representing the sample shall be qualified for issue to various Institutions.
- (ii) If the sample passes in one laboratory and fails in other laboratory or fails in both laboratories, the supply shall be rejected. No further procurement of said drug shall be made from such supplier.
- (iii) If **3** 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.

#### **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 BPPI/DRUG-055/2017

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;

. JURISDICTION	<u>JN</u>			
	oute arising out of the	tender such disput	e would subject to	he jurisdiction of the
vil Court within the o	ity of Delhi only.			

#### ANNEXURE I

### (BARCODE REQUIREMENTS)

Reference clause 2(k)

# 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	2	Fixed	Numeric

	barcode			
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	Batch No / Lot No	20	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				1

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	Description	Length	Nature	Data Type
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

500	Quantity/Units in Secondary pack	Upto 8	Variable	Alphanumeric
(37)	Brackets not encoded in the barcode	2	<i>г</i>	Ivumeric
(27)	Application Identifier to indicate serial number	2	Fixed	Numeric
RNBXY0514	Batch No / Lot No	Upto 20	Variable	Alphanumeric
(10)	Application identifier to indicate Lot/batch Brackets not encoded in the barcode	2	Fixed	Numeric
180815	Expiry Date in YYMMDD format	6	Fixed	Date
	Brackets not encoded in the barcode			
	indicate Expiry date			

Recommended Barcode depending upon the space available – GS1 Data matrix

Or

GS1-128



(02) 1 8901072 00253 6 (17) 180815 (10) RNBXY0514 (37) 500

or



(02) 1 8901072 00253 6 (17) 180815 (10) RNRXY0514 (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	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** +91-11-42890890, (D) +91-11-42890846

**F** +91-11-26168730

E ankit@gs1india.org

W http://www.gslindia.org

### **ANNEXURE-II**

{ Clause 4.1(a)(i)}

#### MANUFACTURER'S AGREEMENT WITH MARKETER

To The CEO Bureau of Pharma PSUs of India, 8<sup>th</sup> Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055

VV L	7 TO 055,
ar S	ir,
1.	We who are established and reputable manufacturer of Drugs having factory/factories atand hereby declare that we do not market our products. Therefore, we authorize M/S (Name and address) to bid, negotiate and contract with your tender No. BPPI/Drug-055/2017 dated 18/12/2017 for supply of drugs manufactured by us.
2.	No company of the firm or individual other than M/Sauthorised to bid, negotiate and conclude the contract in regard to this business against this specific tender as also for a business in the entire territory of India.
3.	This agreement is valid from(This period will be the date of opening tender till valid beyond shelf life of the drugs or period of contract/ price agreement whichever is more.
4.	The ex-factory cost of the Drugs being quoted will be provided by us whenever called for. We also undertake that we will not quote a price higher than supplied to any institute in last 6 months. In case our submission is found wrong, we undertake to be liable for punitive action in the form of recovery of excess amount/ withholding of payment/ any other action as deemed appropriate by department.
5.	An marketing commission of% is included in the gross ex-works price is applicable of
M	1/s

- 6. We hereby extend our full guarantee and warrantee as per relevant conditions of contract for the goods offered for supply against this invitation for bid by the above firm. In the event of failure by authorized marketer in honouring the contract, we undertake to provide remedial action at the earliest without any additional charges.
- 7. Our other responsibilities include.

<ol> <li>Provision of requisite inspection and testing fa</li> </ol>	acilities at our works in respect of
supply order placed on our agent.	
ii	
{Here specify in detail manufacturers responsibiliti	ies]
The services to be rendered by the marketer, Nas under:-	<i>N</i> /sare
i	
ii	
{Here specify the services to be rendered by t	he agent}
8. We certify that neither we, nor our agent is blacklis by any Govt. agency.	sted/ debarred/de-registered/banned
9.We jointly agree to abide by the following clauses in	the contract:
<ul><li>a) Penalty for use of undue influence.</li><li>b) Access to books of accounts.</li></ul>	
10. We undertake that GST registration number (PAN), last three years Bank Statement of Accounts, agent/ distributor will be provided as and when deman	, Banker details of our authorized
Yours faithfully,	
(Name, Signature & Stamp)	(Name, Signature & Stamp)
(Name of Authorized Marketer)	(Name of Manufacturer)
Date:	Date:
NOTE: THIS LETTER OF AUTHORIZATION SHOULD BE OF MANUFACTURING CONCERN AND SHOULD BE INK MANUFACTURERE & THE AUTHORIZED MARKETER, BY	SIGNED BY BOTH THE ORIGINAL

NOTE: THIS LETTER OF AUTHORIZATION SHOULD BE ON THE ORIGINAL LETTER HEAD OF THE MANUFACTURING CONCERN AND SHOULD BE INK SIGNED BY BOTH THE ORIGINAL MANUFACTURERE & THE AUTHORIZED MARKETER, BY A PERSON WHO IS COMPETENT AND HAVING THE POWER OF ATTORNEY TO BID THE MANUFCTURER, A COPY OF NOTARIZED POWER OF ATTORNEY SHOULD ALSO BE FURNISHED, NAME, SIGNATURE AND OFFICAL STAMP OF MANUFACTURER AND MARKETER TO BE APPENDED.

#### **ANNEXURE –III**

### (On nonjudicial Stamp Paper)

Ref. Clause No. 4.1(a)(ii)

### **DECLARATION**

(NOTE:-In case Bid is submitted by the Marketer, this declaration is to be signed by Marketer as well as Manufacturer)

represented by its Proprietor/Managing Partner /Managing Director

do hereby declare as under:-
(I) that I/we have carefully read all the terms and conditions of tender in ref. no. BPPI/Drug-
055/2017 dated 18/12/2017 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) a certificate manufactured & marketed two batches within 3 years
issued by C.A. for quoted drugs, (d) valid non conviction certificate not older than 6 months,(e)
Valid Import license (If applicable),(f) the copies of the specifications for all quoted drugs and
STP (standard testing procedure) for Non- Pharmacopoeia quoted drugs and also enclosed all
undertaking/declaration as per Annexure mentioned in the tender document On the basis of
such undertaking, the price bid shall be opened within a week after opening of technical bid
However, any document uploaded with technical bid is not complying as per undertaking, the
contract/Price agreement shall be cancelled with forfeiture of EMD/Performance Security

(III) I/We declare that we possess the valid drug manufacturing licence and 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.

Deposit/Bank guarantee against tender no. BPPI/Drug-055/2017 dated 18/12/2017 along with

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 will supply the drug with bar code as per ANNEXURE I and as per the design as per enclosures to ANNEXURE XII enclosed with tender document as well as other instruction given in this regard.

other action.

I/We M/s. ....

- (b) Further, I / we do hereby declare that I will supply the drugs by affixing logo on Primary/Secondary/ Tertiary packing for the imported items along with the generic name as per the designs given in enclosures to Annexure XII A as well as other instructions given in this regard.
- (c) 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 approved product, (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	Name of the Drug	Unit Size	Whether COPP certificate(Yes/No)	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 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. We are eligible to participate in the tender ref. No. BPPI/Drug-055/2017 dated 18/12/2017 for the following quoted products:-

S. No.	Drug Code	Name of the Drug	Unit Size

			Signed	•
			Name	
			Designation	n
			(Company Seal	)
Witne	ss:-(1)			
	(2)			
To be	attested by	the Notary		

BPPI/DRUG-055/2017

# **ANNEXURE-IV**

**Ref. Clause No. 7.1 & 3(ii)** 

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

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

### **ANNEXURE- V**

### Ref. Clause No.

[]	Format for a	certificate	from the	C.A.	Chartered	Accountant)	or Com	nanv	Secretary	7
ľ		••••••		· · · · · · ·	(	1 10 0 0 00111001110	,		~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	/ 1

(I)	Ltd./Lt no Income compar	certified that M/s. d./Proprietorship/Partnersand GST registration tax returned and GST representation of the control o	hip company/fon no eturned up to dat	irm and they 	have PAN They have filed signatory of the				
(II)	(II) The annual Turnover of $M/s$ for the past three years are given below and certified that the statement is true and correct.								
		Sl.No.	Financial Year	Turnover in Lakl	ns(Rs.)				
		1.	2014-15						
		2.	2015-16						
		3.	2016-17	D	T 11				
		Average Turneyer nor	annual		Lakhs Lakhs				
		Average Turnover per	aiiiuai	185	Lakiis				
OR									
	It is certified that M/S (Name of company and								
a	address) ł	naving factory at	• • • • • • • • • • • • • • • • • • • •	(ad	dress of factory)				
ł	nave inve	sted Rs 10 crores or abov	e for installation	of plant and mac	hinery excluding				
		rds land, building & othe							
		_			Grago. It is also				
C	certified ti	hat the statement is true a	nd correct.						
(III)	It is cer	rtified that M/s		has Prod	luction &				
	financial capacity to manufacture and deliver the drugs quoted by them in the tender								
	as per o	quantity & delivery sched	ule mentioned in t	tender. This certif	icate is based on				
	their Manufacturing capacity, inventory of raw Material and financial statement.								

Or (ONLY in case of IMPORTER)

BPPI/DRUG-055/2017

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

- (V) They have manufactured & marketed 2 or more commercial batches of each quoted drugs in last three years/ They have marketed 2 or more commercial batches of each quoted drugs in last three years( In case of IMPORTER)

Date

(Name, Signature & Stamp) Registration no.

### **NOTE**

- (i) Strike which is not applicable in above certificate.
- (ii) MSEs would be treated as owned by SC/ ST entrepreneurs: a) In case of proprietary 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.

### ANNEXURE – VI

Ref. Clause 4.1 (r)

## **CHECK-LIST( Whether Uploaded the documents)**

### COVER - A

S.No.	Check List	YES	NO
1	Check list - ANNEXURE – VI		
	EMD Rs.100,000/- in the form of <b>Bank Guarantee or Bankers</b>		
	Cheque or Demand Draft uploaded as per ANNEXURE-IV DD		
	NoDatedissued by		
	(name of bank) and <b>delivered to BPPI</b> .		
2	Uploaded NSIC certificate for exemption if any.		
	Scanned copy of WHO-GMP(World Health Organisation-		
3	Good Manufacturing Practices) Certificate.		
	Scanned copy of License for the Product duly approved by		
4	the Licensing Authority for each and every product quoted		
_	Scanned copy of Import License, if Imported and whole		
5	sale Drug license		
_	Scanned copy of Non Conviction Certificate issued by the		
6	licensing authority not older than 6 months.		
_	Scanned copy of Market Standing Certificate issued by the		
7	Licensing Authority		
0	COPP certificate as per WHO format of their Principal		
8	Manufacturing company including Imported drugs.		
	Copies of <b>approval of the any agency like</b> US FDA, TG Australia, Health Canada, EU, MCC South Africa		
9	approval, Brazil Anvisa <b>approved product</b> , if any.		
	Scanned copies of the specifications for all quoted drugs		
	and STP (standard testing procedure) for Non-		
10	Pharmacopoeia quoted drugs.		
	Authorization letter nominating a responsible Person of the		
	tenderer to transact the business with the Tender inviting		
11	Authority.		
	Scanned copy of ANNEXURE-II		
	(Agreement with Manufacturer) if any , original ANNEXURE II		
12	delivered to BPPI.		
	Scanned copy of ANNEXURE –III (Declaration for eligibility in		
	participating the tender) original Annexure II delivered to		
13	BPPI.		
	Scanned copy of ANNEXURE V{certificate from the		
14	C.A.(Chartered Accountant) or Company Secretary.		
	Scanned copy of ANNEXURE-XI		
15	(Details for Manufacturing Capacity & Batch Size)		
16.	Scanned copy of ANNEXURE—XV (Mandate form)		

NOTE:-EMD instrument, ANNEXURE II (if applicable) and ANNEXURE III are to be delivered in original to BPPI, New Delhi on or before 'Bid opening date.

Name and signature of authorised signatory (with company seal)	
BPPI/DRUG-055/2017	

# ANNEXURE -VII( Ref:-Clause 7.1)

### MODEL BANK GUARANTEE FORMAT FOR FURNISHING EMD

Whereas		(hereinafter called	l the
"tenderer") has submitted their offer supply	dated		for the
Of Drugs (hereinafter called the "tend BBPI/DRUG-055/2017 KNOW ALL of	MEN by	these presents having our regist	that WE
Undertakings of India New Delhi(herein only for which payment will and truly to its successors and assigns by these pres this	be made to the sa	aid Purchaser, the Bar	nk binds itself,
THE CONDITIONS OF THIS OBLIGATION A	RE:		
(1) If the tenderer withdraws or amends within the period of validity of this tende		ates from the tender	in any respect
(2) If the tenderer having been notified during the period of its validity:-	d of the acceptan	ce of his tender by	the Purchaser
a) If the tenderer fails to furnish the contract.	the Performance S	Security for the due p	erformance of
b) Fails or refuses to accept/execu	ite the contract.		
WE undertake to pay the Purchaser u demand, without the Purchaser having demand the Purchaser will note that t occurrence of one or both the two condit	to substantiate he amount claime	its demand, provide ed by it is due to it	d that in its owing to the
This guarantee will remain in force u should reach the Bank not later than the		and any demand in re	espect thereof
(Signature of the authorized officer of	the Bank)		
Name and designation of the officer			
Seal, name & address of the Bank and ad	dress of the Branch	ı	

### **Annexure -VIII**

### Clause 8.1 &8.2

### Bureau of Pharma Public Sector Undertakings of India, New Delhi Tender for supply of drugs (Tender No. BPPI/Drug-055/2017 dated 18/12/2017)

(1)	(2)	(3)	(4)	(5)	(6)	(7)
Sr. No.	Drug Code	Generic name of Medicines	Unit Size	Pack Size	Packing per Carton (Shipper Pack)	Tender quantity in unit size
1	5	Asprin 150 mg Tab	14's	14x10	14's X 10 x10	5000000
2	16	Ibuprofen Tablets IP 400mg	15's	15's x 10	15's x10x10	3000000
3	21	Diclofenac Sodium 50 mg and Paracetamol 325 mg Tablet 10's	10's	10's x10	10's x10 x10	2000000
4	22	Paracetamol 125 mg / 5 ml Syrup	60 ml bottles	1 X10	1'sX10X5	1300000
5	24	Pentazocine 30 mg/ ml Inj. IP	1 ml	1 ml x 10	1 ml x 10 x10	1000000
6	30	Amikacin 100mg inj.	2ml Vial	2ml x 20	2mlx20x5	2000000
7	38	Amoxycillin + Clavulanic acid (500 mg + 100mg) Inj.	Vial with WFI	1 x 10	1 × 10 × 10	300000
8	40	Amoxycillin + Cloxacillin (250 mg + 250 mg) Caps	10's	10'sx10	10'sx10 'sx 10	1000000
9	44	Amoxycillin 250 mg Caps IP	10's	10's x10	10's x10 x10	2000000
10	45	Amoxycillin 500 mg Caps IP	10's	10's x10	10's x10x10	2000000
11	50	Azithromycin 500 mg film coated Tablets IP	10's	10's x10	10's x10 x10	5000000
12	51	Cefadroxil 250 mg dispersible Tablets	10s	10's x10	10's x10 x10	1500000
13	52	Cefadroxil film coated Tablets IP 500mg	10's	10's x10	10's x10 x10	3000000

14	53	Cefixime oral suspension 50mg/5ml 30 m	30 ml bottles	1'sX10	1'sx10x10	1000000
15	66	Cefpodoxime 200 mg film coated Tablets IP	10's	10's x10	(10's x10x10)x10	500000
16	69	Ceftazadime 500 mg Injection	Vial & wfi	1 x10	1×10 × 10	500000
17	74	Ceftriaxone +Sulbactam (500 mg + 250 mg)	Vial & wfi	1 x 10	1 × 10 × 10	1000000
18	94	Gentamycin Sulphate 80 mg/ 2ml Inj. IP	2 ml	2 ml x 20	2mlx20x5	1000000
19	112	BECLOMETHASONE IP 0.025% w/w+ CLOTRIMAZOLE IP 1% w/w+ GENTAMYCIN IP 0.1% w/w CREAM	15 GM	1'sX200	1'sX200	2000000
20	150	Metformin (SR) 500mg + Pioglitazone 15mg Tablets	10's	10'sx10	10'sx10 'sx10	1000000
21	152	Bleomycin Sulphate Inj. IP 15 Unit	Vial	1 x 10	1 × 10 × 10	10000
22	164	Tamoxifen Citrate 20 mg Tab	10's	10's x10	10's x10 x10	500000
23	176	Sterile Water for Injection	5ml Amp	5ml X10	5ml X10 X10	500000
24	186	Domperidone Tablets IP 10mg	10's	10'sx10	10's x 10x 10	3000000
25	191	FAMOTIDINE TABLETS IP 20 MG	14's	14'sX10	14's x 10X 10	3000000
26	218	RANITIDINE Tablets IP 300 mg FILM COATED	10's	10's x10	10'sX10X10	5000000
27	220	calcium carbonate 500 mg calcium (1,250 mg) tablet + Vitamin D <sub>3</sub> 500iu film coated Tablets	10's	10's x10	10's X10X10	5000000
28	226	Iron(carbonil Iron)100 mg+Folic Acid 1.5 mg+Zinc Capsules )	15's	15'sX10	15'sx10 x10	2000000
29	233	Vitamin-C Chewable 100mg Tablet IP	10's	10's x10	10's x10 x10	1000000
30	239	Cetrizine (5 mg/ 5 ml) Syrup	60 ml bottles	60 ml X 10	60 ml x 10 x 5	1000000

31	250	Montelukast Sodium 5 mg Tab IP	10's	10'sX10	10'sX10X100	1000000
32	254	Promethazine(5mg/5ml) solution IP	100ml bottles	100ml x 10	100ml x 10 x 5	500000
33	255	Salbutamol 100 mcg/puff Inhaler	200 mdi	1's X10	1's X10 X10	1000000
34	260	Salbutamol 4mg Tabs IP	10's	10's x10	10's x 10 X10	2000000
35	278	Frusemide (10 mg/ ml)	2ml	2ml X 10	(2X10)X10	1000000
36	281	Heparin Sodium 5000iu/ ml Inj. IP	5 ml	5 ml x 10	5 ml x 10 x 10	500000
37	311	Disodium hydrogen Citrate (Alkalyser) 1.4 gm/5ml Syrup 100 ml	100ml bottles	1's x 10 Bottles	1's x 10 Bottles X 10	1000000
38	317	Carbamazepine 100mg Tabs IP	10's	10's x10	10X10X10	1000000
39	327	Phenytoin Sodium 100 mg Tabs	100's in bottle	1 bottle X10	1'sX10X10	1000000
40	343	Chloramphenicol 1%w/v Eye Applicaps , 250 mg each.	50 Applica ps	1's X10	1'sX10X10	200000
41	379	RIFAMPICIN and ISONIAZIDE TABLETS IP (450 MG+300 MG)	10's	10's x10	10's x10 x5	1000000
42	382	LINEZOLID TABLETS IP 600 MG	10's	10'sX10	(10's x 10x 10)x10	2000000
43	385	CEFIXIME 200 MG + CLAVULANIC ACID 125 MG TABLETS	10's	10'sx10	10'sX10x10	1500000
44	424	CARVEDILOL TABLETS IP 3.125 MG	10's	10'sx10	10'sX10X100	1500000
45	437	NIFEDIPINE PROLONGED RELEASE Tablets IP 20 mg	10's	10'sx10	10'sX10X200	1500000
46	507	CARBIMAZOLE TABLETS IP 5 MG	10's	10'sx10	(10'sx10x10)	2000000
47	512	ACECLOFENAC 100 mg + PARACETAMOL 325 mg + SERRATIOPEPTIDASE 15 mg Tablets	10's	10'sx10	10'sX10X100	1500000

48	513	PIROXICAM Capsules IP 20 mg 10's	10's	10's x10	10's x10x10	700000
49	515	MEFENAMIC ACID SUSPENSION 100 MG/5 ML	60 ML	60 ML x 10	60ml X 10 X10	1000000
50	516	ACECLOFENAC Tablets SR/CR 200 mg	10's	10'sx10	10'sX10X200	1000000
51	531	GUAIFENESIN 100 MG+ TERBUTALINE 2.5 MG+ BROMHEXINE 8 MG /10 MLSYRUP	100 ML	100 ML X6	100 ml X 6 X10	1000000
52	555	DOXOFYLLINE TABLETS IP 400 MG	10's	10'sx10	10'sX10X10	1500000
53	560	FLUTICASONE PROPIONATE 50 MCG PER PUFF NASAL SPRAY	120 MD	120 MDX10	1'sx20x10	100000
54	562	LORATIDINE TABLETS BP 10 MG	10's	10'sx10	10'sX10X10	1000000
55	574	VACCINE RABIES INJECTION 2.5	1 ML	1 MLX10	1'sx10x10	2000000
56	581	CALCIUM CARBONATE 500 MG + CALCITRIOL 0.25 MCG + ZINC 7.5 MG Tablets	10's	10'sx10	10'sx10 x10	1500000
57	585	VITAMIN-D (CHOLECALCIFEROL) 60000 IU /1 GM SACHET	1 SACHE T	1 GMX25	1 GMX25X50	5000000
58	587	APPETITE ENHANCER (PEPTONE, MINERALS, VITAMINS )SYRUP	300 ML	1'sX5	300 ML X5X7	1000000
59	589	CALCIUM 500 MG+ CALCITRIOL 0.25 MG TABLETS	15's	15'S X 10	(15'sx10) x 10	1000000
60	596	ZINC SULPHATE 20 MG/ ML ORAL SOLUTION	15 ML	1's x20	15 ML x20X10	500000
61	597	VITAMIN B6 TABLETS IP 50MG (Pyridoxine HCl Tablets IP 50mg)	10's	10'sx10	10'sx10 x10	500000
62	627	Etophylline IP 115mg + Theophylline 35mg Tablet	10's	10's x10	10's x10 x10	3000000
63	629	Inhalent Softgel Caps. (Camphor 25 mg + Clorothymol 5 mg + Eucalyptol 130 mg + Menthol 55 mg + Terpineol 110 mg	10's	10's x10	10's x10 x10	1000000

		5 5 5 7 5	I	I	1	
64	655	Enyme Syrup Mix Fruit Flavour Pepsin 7.5 mg + Fungal Diastase 12.5 mg / 5 ml	200 ml	1'sX6	200 ml X 6 X10	1000000
65	656	Enzyme Drops Pepsin (1:3000) 5 mg + Fungal Diastase (1:1200) 33.33 mg/ml	15ML	1'sX20	15 MLX20	500000
66	664	Mouth Ulcer Gel (Choline Salicylate sodium 9% w/v, Benzalkonium Chloride 0.01% w/w)	10 gm	1'sX200	1'sX200	500000
67	665	B Complex with vitamin C Each capsule contains - Thiamine mononitrate IP-10mg,Riboflavin IP -10 mg,Pyridoxine HCI IP-3mg,Vitamin B 12 IP -5mcg,Niacimnamide IP -50mg,Calcium Pantothenate IP-12.5mg,Folic Acid IP -1mg, Ascorbic Acid IP-150mg	10's	10's x10	10's x10	2000000
68	671	Diacerein 50 mg + Glucosamine Sulphate 500 mg Tablets	10's	10'sx10	10'sx10x 10	500000
69	673	Biotin 10 mg Tablet	10's	10'sx10	10'sx10 x10	1000000
70	685	Pantoprazole 40mg + Itopride 150mg S.R. Capsules.	10's	10'sx10	10'sX 10X 100	500000
71	706	Cefpodoxime proxetil 50 mg DS dry syrup	30ml	30ml X 10	30ml X 10 X 50	500000
72	713	Glibenclamide 5mg + MetforminHcl 500 mg tab	10's	10's x10	10's x10	5000000
73	725	Dextrose Injection IP 5 %, iv fluid plastic container using FFS/ BFS technology	500ml	1's	1's x50	300000
74	726	Dextrose Injection IP 10 %, iv fluid plastic container using FFS/ BFS technology	500ml	1's	1's x50	300000
75	728	Sodium Chloride (0.9% W/V) and Dextrose 5% w/v Injection IP, i.v fluid plastic container using FFS/BFS Technology	500ml	1's	1's x50	300000
76	741	Cefpodoxime Proxetil dispersible tablet 50 mg	10's	10's x10	(10's x10x10)x20	500000
	_	EF/2017				

		Alpha Lipoic acid 100mg, Vit. D3 1000 IU, Folic acid 1.5mg,				
77	779	Pyridoxine 3mg, Methylcobalamin 1500mcg Tablets	10's	10'sx10	10'sx10x10	1000000
78	804	Betamethasone Inj. I.P 4 mg/ml	1ml	(1ml x10)	1mlx10x10	500000
79	811	Bromfenac Sodium Eye Drop 0.09%	5ml	1x10	1x10 x10	500000
80	818	Calcium Gluconate Injection I.P 10 %	10ml	1's x5	1's x5x10	500000
81	821	Carvedilol Tablets IP 6.25mg	10's	10'sx10	10'sx10 x10	1500000
82	840	Citicoline Tabs 500 mg	10's	10'sx10	(10'sx10x10)	500000
83	850	Cyclosporin Soft Gelatin Capulses IP 50mg	5's	5's x10	5's x10x10	500000
84	864	Dextrose Injection IP 25%w/v	25ml	1's	1mlx10x10	300000
85	865	Diacerein Capsules IP 50mg	10's	10'sx10	10'sx10 x10	1000000
86	881	Ebastine Film Coated Tablets 10mg	10's	10'sx10	10'sx10x10	500000
87	926	Ketoconazole Cream 2%w/w	15gm Tube	1 x 25	(1 x 25) x 20	1000000
88	938	Levocarnitine Injections 1gm	5ml	1's x10	1mlx10x10	500000
89	939	Levocarnitine Tablets 500mg	10's	10'sx10	(10'sx10x10)x10	500000
90	1024	Promethazine Injection I.P 25 mg/ml	2ml	(2ml x10)	2ml x10 x 5	500000
91	1072	Tamsulosin Modified-Release Capsules 0.4 mg	10's	10'sx10	10'sx10 x10	1500000
92	1074	Telmisartan 80mg, Hydroclorthiazide 12.5mg Tablets	10's	10'sx10	(10'sx10x10)x20	5000000
93	1091	Vecuronium Bromide Injection I.P 4mg	Vial	1x10	1×10 × 10	50000
94	1099	Voglibose 0.3 mg, Metformin 500mg Tablets SR	10's	10'sx10	10'sx10x 10	1000000
95	1107	Pregabalin Capsules 75mg	14's	14x10	14's X 10 x10	2000000
				•		

96	1111	Gabapentin+Nortriptyline(400/10 mg) Tablets	10's	10x10	10'sx10x10	1500000
97	1153	Carbamazepine 400mg Tabs CR/SR	10's	10'sx10	10'sx10x10	1000000
98	1163	BETAMETHASONE 0.05 % w/w CREAM	20 GM	1 x10	1×10 × 10	500000
99	1185	Cycloserine 250mg Capsules	6's	6'sx10	6'sx10 x10	300000
100	1187	Cyclosporin Capulses IP 100mg	5's	5'sx10	5'sx10 x10	500000
101	1221	Thyroxine Sodium 50mcg Tabs	100's in bottle	1 bottle X10	(1's x10x10)	500000
102	1222	ARTEMETHER 80 MG + LUMEFANTRINE 480 MG TABLETS	6's	6's X 10	6's X 10 x 10	500000
103	1223	Iron(carbonil Iron) 50mg+Folic Acid 0.5mg+Zinc 61.8mg Capsules	15's	15'sX10	15'sX10X10	1000000
104	1224	Povidone-lodine 10% antiseptic paint	50 ml	50 ml x 10	50 ml x 10 ml	500000
105	1225	Orlistat 120mg capsule	10's	10'sx10	10'sx10 x10	750000
106	1226	Triamcinolone 40mg/ml inj.	1 ML	1X10	10'sx10 x10	1000000
107	1227	Triamcinolone 4mg tabs	10's	10'sx10	10'sx10 x10	500000
108	1228	Gabapentin+Amitriptyline(300/1 0mg) Tablets	10's	10'sx10	10'sx10 x10	1500000
109	1229	Levosalbutamol+Ipratropium(2.5 +500)mcg Respules	2.5 ml	2.5ml X10	10'sx10 x10	1000000
110	1230	Levosalbutamol+Ipratropium(100 +20)mcg INHALER	200MD I	1X10	10'sx10 x10	1000000
111	1231	Levocarnitine+VitaminE(150+200 )mg Tab.	10's	10'sx10	10'sx10 x10	500000
112	1232	Noscapine 1.83mg/5ml Syp	50ml	1X10	10'sx10 x10	1000000
113	1233	Valethamate 8mg inj.	1ml	1X10	10'sx10 x10	500000

114	1234	GLIMEPIRIDE 2 mg + METFORMIN 500mg + PIOGLITAZONE 7.5mg Tab SR	10'S	10'sx10	10'sx10 x10	2000000
115	1235	GLIMEPIRIDE 1 mg + METFORMIN 500mg + PIOGLITAZONE 7.5mg Tab SR	10'S	10'sx10	10'sx10 x10	2000000
116	1236	Albendazole 400mg Tabs IP	1's	1's X10X10	1's X10X10X10	10000000
117	1237	Methyldopa tabs 500mg	10's	10'sx10	10'sx10 x10	500000
118	1238	Prazosin Tablets 2.5mg "SR" Tab	30's	30's X10	30'sx10 x10	1000000

## Annexure – IX

{Ref:- clause 8.1(ii)}

	(2)	(3)	(4)	(5)	(6)	(7)
Sr. No.	Drug Code	Generic name of Drug	Unit Size	Shelf Life in months	Manufacturing Capacity per year in Units	Manufacturi ng Batch Size in Units
1	5	Asprin 150 mg Tab	14's			
2	16	Ibuprofen Tablets IP 400mg	15's			
3	21	Diclofenac Sodium 50 mg and Paracetamol 325 mg Tablet 10's	10's			
4	22	Paracetamol 125 mg / 5 ml Syrup	60 ml bottles			
5	24	Pentazocine 30 mg/ ml Inj. IP	1 ml			
6	30	Amikacin 100mg inj.	2ml Vial			
7	38	Amoxycillin + Clavulanic acid (500 mg + 100mg) Inj.	Vial with WFI			
8	40	Amoxycillin + Cloxacillin (250 mg + 250 mg) Caps	10's			
9	44	Amoxycillin 250 mg Caps IP	10's			
10	45	Amoxycillin 500 mg Caps IP	10's			
11	50	Azithromycin 500 mg film coated Tablets IP	10's			
12	51	Cefadroxil 250 mg dispersible Tablets	10s			
13	52	Cefadroxil film coated Tablets IP 500mg	10's			
14	53	Cefixime oral suspension 50mg/5ml 30 m	30 ml bottles			
15	66	Cefpodoxime 200 mg film coated Tablets IP	10's			
16	69	Ceftazadime 500 mg Injection	Vial & wfi			
17	74	Ceftriaxone +Sulbactam (500 mg + 250 mg)	Vial & wfi			
18	94	Gentamycin Sulphate 80 mg/ 2ml Inj. IP	2 ml			
19	112	BECLOMETHASONE IP 0.025% w/w+ CLOTRIMAZOLE IP 1% w/w+ GENTAMYCIN IP 0.1% w/w CREAM	15 GM			
20	150	Metformin (SR) 500mg + Pioglitazone 15mg Tablets	10's			
21	152	Bleomycin Sulphate Inj. IP 15 Unit	Vial			
22	164	Tamoxifen Citrate 20 mg Tab	10's			

BPPI/DRUG-055/2017

23	176	Sterile Water for Injection	5ml Amp		
24	186	Domperidone Tablets IP 10mg	10's		
25	191	FAMOTIDINE TABLETS IP 20 MG	14's		
26	218	RANITIDINE Tablets IP 300 mg FILM COATED	10's		
27	220	calcium carbonate 500 mg calcium (1,250 mg) tablet + Vitamin D <sub>3</sub> 500iu film coated Tablets	10's		
28	226	Iron(carbonil Iron)100 mg+Folic Acid 1.5 mg+Zinc Capsules )	15's		
29	233	Vitamin-C Chewable 100mg Tablet IP	10's		
30	239	Cetrizine (5 mg/ 5 ml) Syrup	60 ml bottles		
31	250	Montelukast Sodium 5 mg Tab IP	10's		
32	254	Promethazine(5mg/5ml) solution IP	100ml bottles		
33	255	Salbutamol 100 mcg/puff Inhaler	200 mdi		
34	260	Salbutamol 4mg Tabs IP	10's		
35	278	Frusemide (10 mg/ ml)	2ml		
36	281	Heparin Sodium 5000iu/ ml Inj. IP	5 ml		
37	311	Disodium hydrogen Citrate (Alkalyser) 1.4 gm/5ml Syrup 100 ml	100ml bottles		
38	317	Carbamazepine 100mg Tabs	10's		
39	327	Phenytoin Sodium 100 mg Tabs	100's in bottle		
40	343	Chloramphenicol 1%w/v Eye Applicaps, 250 mg each.	50 Applicaps		
41	379	RIFAMPICIN and ISONIAZIDE TABLETS IP (450 MG+300 MG)	10's		
42	382	LINEZOLID TABLETS IP 600 MG	10's		
43	385	CEFIXIME 200 MG + CLAVULANIC ACID 125 MG TABLETS	10's		
44	424	CARVEDILOL TABLETS IP 3.125 MG	10's		
45	437	NIFEDIPINE PROLONGED RELEASE Tablets IP 20 mg	10's		

46	507	CARBIMAZOLE TABLETS IP 5 MG	10's	
47	512	ACECLOFENAC 100 mg + PARACETAMOL 325 mg + SERRATIOPEPTIDASE 15 mg Tablets	10's	
48	513	PIROXICAM Capsules IP 20 mg 10's	10's	
49	515	MEFENAMIC ACID SUSPENSION 100 MG/5 ML	60 ML	
50	516	ACECLOFENAC Tablets SR/CR 200 mg	10's	
51	531	GUAIFENESIN 100 MG+ TERBUTALINE 2.5 MG+ BROMHEXINE 8 MG /10 MLSYRUP	100 ML	
52	555	DOXOFYLLINE TABLETS IP 400 MG	10's	
53	560	FLUTICASONE PROPIONATE 50 MCG PER PUFF NASAL SPRAY	120 MD	
54	562	LORATIDINE TABLETS BP 10 MG	10's	
55	574	VACCINE RABIES INJECTION 2.5 IU	1 ML	
56	581	CALCIUM CARBONATE 500 MG + CALCITRIOL 0.25 MCG + ZINC 7.5 MG Tablets	10's	
57	585	VITAMIN-D (CHOLECALCIFEROL) 60000 IU /1 GM SACHET	1 SACHET	
58	587	APPETITE ENHANCER (PEPTONE, MINERALS, VITAMINS )SYRUP	300 ML	
59	589	CALCIUM 500 MG+ CALCITRIOL 0.25 MG TABLETS	15's	
60	596	ZINC SULPHATE 20 MG/ ML ORAL SOLUTION	15 ML	
61	597	VITAMIN B6 TABLETS IP 50MG (Pyridoxine HCl Tablets IP 50mg)	10's	
62	627	Etophylline IP 115mg + Theophylline 35mg Tablet	10's	
63	629	Inhalent Softgel Caps. (Camphor 25 mg + Clorothymol 5 mg + Eucalyptol 130 mg + Menthol 55 mg + Terpineol 110 mg	10's	

64	655	Enyme Syrup Mix Fruit Flavour Pepsin 7.5 mg + Fungal Diastase 12.5 mg / 5 ml	200 ml	
65	656	Enzyme Drops Pepsin (1:3000) 5 mg + Fungal Diastase (1:1200) 33.33 mg/ml	15ML	
66	664	Mouth Ulcer Gel (Choline Salicylate sodium 9% w/v, Benzalkonium Chloride 0.01% w/w)	10 gm	
67	665	B Complex with vitamin C Each capsule contains - Thiamine mononitrate IP- 10mg, Riboflavin IP -10 mg, Pyridoxine HCl IP- 3mg, Vitamin B 12 IP - 5mcg, Niacimnamide IP - 50mg, Calcium Pantothenate IP-12.5mg, Folic Acid IP - 1mg, Ascorbic Acid IP- 150mg	10's	
68	671	Diacerein 50 mg + Glucosamine Sulphate 500 mg Tablets	10's	
69	673	Biotin 10 mg Tablet	10's	
70	685	Pantoprazole 40mg + Itopride 150mg S.R. Capsules.	10's	
71	706	Cefpodoxime proxetil 50 mg DS dry syrup	30ml	
72	713	Glibenclamide 5mg + MetforminHcl 500 mg tab	10's	
73	725	Dextrose Injection IP 5 %, iv fluid plastic container using FFS/ BFS technology	500ml	
74	726	Dextrose Injection IP 10 %, iv fluid plastic container using FFS/ BFS technology	500ml	
75	728	Sodium Chloride (0.9% W/V) and Dextrose 5% w/v Injection IP, i.v fluid plastic container using FFS/BFS Technology	500ml	
76	741	Cefpodoxime Proxetil dispersible tablet 50 mg	10's	

77	779	Alpha Lipoic acid 100mg, Vit. D3 1000 IU, Folic acid 1.5mg, Pyridoxine 3mg, Methylcobalamin 1500mcg Tablets	10's		
78	804	Betamethasone Inj. I.P 4 mg/ml	1ml		
79	811	Bromfenac Sodium Eye Drop 0.09%	5ml		
80	818	Calcium Gluconate Injection I.P 10 %	10ml		
81	821	Carvedilol Tablets IP 6.25mg	10's		
82	840	Citicoline Tabs 500 mg	10's		
83	850	Cyclosporin Soft Gelatin Capulses IP 50mg	5's		
84	864	Dextrose Injection IP 25%w/v	25ml		
85	865	Diacerein Capsules IP 50mg	10's		
0.0	001	Ebastine Film Coated	1010		
86	881	Tablets 10mg	10's		
07	026		15gm		
87	926	Ketoconazole Cream 2%w/w	Tube		
88	938	Levocarnitine Injections 1gm	5ml		
89	939	Levocarnitine Tablets 500mg	10's		
90	1024	Promethazine Injection I.P 25 mg/ml	2ml		
91	1072	Tamsulosin Modified- Release Capsules 0.4 mg	10's		
92	1074	Telmisartan 80mg, Hydroclorthiazide 12.5mg Tablets	10's		
93	1091	Vecuronium Bromide Injection I.P 4mg	Vial		
94	1099	Voglibose 0.3 mg, Metformin 500mg Tablets SR	10's		
95	1107	Pregabalin Capsules 75mg	14's		
96	1111	Gabapentin+Nortriptyline(4 00/10mg) Tablets	10's		
97	1153	Carbamazepine 400mg Tabs CR/SR	10's		
98	1163	BETAMETHASONE 0.05 % w/w CREAM	20 GM		
99	1185	Cycloserine 250mg Capsules	6's		
100	1187	Cyclosporin Capulses IP 100mg	5's		
101	1221	Thyroxine Sodium 50mcg Tabs	100's in bottle		

102	1222	ARTEMETHER 80 MG + LUMEFANTRINE 480 MG TABLETS	6's		
103	1223	Iron(carbonil Iron) 50mg+Folic Acid 0.5mg+Zinc 61.8mg Capsules	15's		
104	1224	Povidone-lodine 10% antiseptic paint	50 ml		
105	1225	Orlistat 120mg capsule	10's		
106	1226	Triamcinolone 40mg/ml inj.	1 ML		
107	1227	Triamcinolone 4mg tabs	10's		
108	1228	Gabapentin+Amitriptyline(3 00/10mg) Tablets	10's		
109	1229	Levosalbutamol+Ipratropiu m(2.5+500)mcg Respules	2.5 ml		
110	1230	Levosalbutamol+Ipratropiu m(100+20)mcg INHALER	200MDI		
111	1231	Levocarnitine+VitaminE(150 +200)mg Tab.	10's		
112	1232	Noscapine 1.83mg/5ml Syp	50ml		
113	1233	Valethamate 8mg inj.	1ml		
114	1234	GLIMEPIRIDE 2 mg + METFORMIN 500mg + PIOGLITAZONE 7.5mg Tab SR	10'S		
115	1235	GLIMEPIRIDE 1 mg + METFORMIN 500mg + PIOGLITAZONE 7.5mg Tab SR	10'S		
116	1236	Albendazole 400mg Tabs IP	1's		
117	1237	Methyldopa tabs 500mg	10's	 	
118	1238	Prazosin Tablets 2.5mg "SR" Tab	30's		

#### **ANNEXURE-X**

### Letter of acceptance of tender for price agreement

Ref. No. BPPI/ Drug – 0552017	Date:
To,	
M/S	

Sub: Tender for the Supply of Drugs and Medicines to BPPI for the years 2018-2020: Acceptance tender for price agreement and Deposit of Performance Security Amount. Ref: Your quotation against BPPI e-Tender No. BPPI/DRUG-055/2017 dated: 18.12.2017 opened on ....... (Technical Bid) & on ......(Price bid).

Please refer to your quotation i.e. technical and price bid (BOQ) along with enclosures/Annexure against subject tender read with your subsequent clarification/confirmation for the supply of Drugs to BPPI for the years 2018-2020, the rate offered/accepted by your firm has been approved for price agreement for two years i.e. up to ......as per details below:-

S. N.	Drug Code	Drug Name	Unit Size	Quantity	Rates in Rs. Per unit exclusive of GST	Rate of GST	Rates in Rs. Per unit inclusive of GST	Rs.(including GST)
					Total va	lue of price	agreement	

- 2.You are requested to kindly remit performance security deposit in form of demand draft or irrevocable bank guarantee from scheduled bank which is equivalent to Rs as stipulated in the tender document within 15 days from the date of receipt of this letter for the supply of **Drugs to BPPI**. Format for Bank Guarantee towards performance security deposit shall be as per Annexure X of tender document. Performance security deposit if paid in form of Bank Guarantee should be valid for three years from the date of i.e. Valid till ...../2021.
- 3. The terms and conditions of price agreement shall be applicable as mentioned in tender document. By issue of this acceptance letter, the price agreement is hereby concluded.

Please acknowledge receipt.

Speed post/e-mail

,BPPI

### **ANNEXURE -XI**

### Ref. Clause No.10.1

# **Performance Security Bank Guarantee**

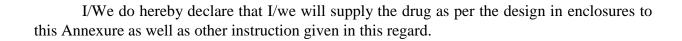
(unconditional)

			etor Undertakings walan Extension, I		(Name of purchaser) 110055	) 8 <sup>th</sup> Floor,
Supplier) her	rein called d. 18/12/	the Suppl	ier" has undertak ply of <b>Drugs for</b>	en, in pur	(Name suance of Tender Bl	PPI/DRUG-
shall furnish	you witl	h a Bank (	Guarantee for the	e sum spe	said Contract that the cified therein as so dance with the Contract	ecurity for
AND	WHERE	<b>AS</b> we have	agreed to give the	Supplier a	Guarantee	
behalf	of	the	Supplier,	upto	fors and responsible a total(Amount of the	of
the Supplier sums within	to be in d the limit figures) as	lefault under ofaforesaid, w	r the Contract and	d without o	r first written demand cavil or argument., a (Amount of the Gu e or to show grounds	any sum or uarantee in
This guarante	ee is valid	until the	day of	f	2021.	
				Sign	ature and Seal of Gua	arantors
				Date	2	2016
				Add	lress	

### **ANNEXURE -X11**

Ref. Clause no 13

# **DECLARATION**



Signature of the Tenderer

Name

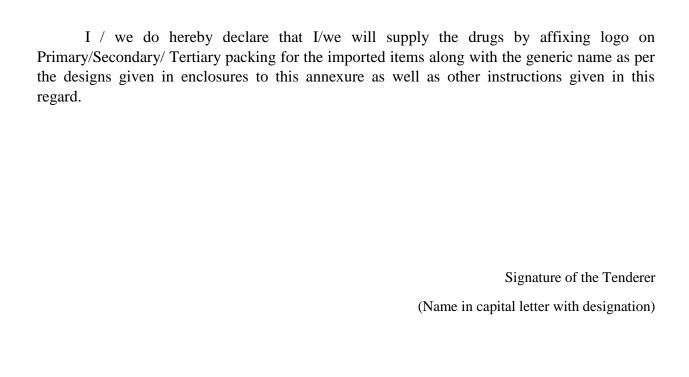
Designation

(Company Seal)

### $\underline{ANNEXURE} - X11(\underline{A})$

Ref. Clause No. 13

## **UNDERTAKING**



### Enclosure–1 to <u>ANNEXURE</u> - <u>X11</u> AND <u>X11 (</u>A)

#### 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>X11</u> & <u>ANNEXURE</u> – <u>X11</u> (A)

#### 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.
- (iii) Font type should in CALIBIRI format for any type of title name of generic medicines.
- (iv) Title name of generic medicine should be minimum 12 font size and it may increase respectively according to size of label.
- (v) "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 JANAUSHADHI or 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.

### Enclosure 3 to <u>ANNEXURE</u> – <u>X11</u> (A)

### SPECIMEN LABEL FOR MONO CARTON (Secondary Packing)

Rx 10 X 10's Tablets

Generic Name of Product



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

For Ampoules/vials :- All secondary packing box/carton should be supplied with printed text matter as per guidelines.

Note: An additional to statuary requirement under Drug & Cosmetic Act 1940 and rules 1945

### **ANNEXURE-XIII**

#### Ref. Clause No.14.1

### SCHEDULE FOR PACKAGING OF DRUGS

#### **GENERAL SPECIFICATIONS**

- 1. Strips of Aluminium foils should be gauge 04.
- 2. Aluminium foils s back material for blisters should be gauge 025.
- 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 lacquerized 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 are 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)

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 over lap each other. The flap when turned
	by 45 - 60° 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 amoules 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 -XIV**

# **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	
	Telephone No.	
	Fax No.	
	E-mail ID	
	Alternate E-mail ID	
3.	Name of the Managing Director /	
	Director / Manager	
	Mobile No. / Phone No	
	E-mail ID	
4.	Name and Designation of the	Name:
	authorized company official	Designation:
	Mobile No.	
	E-mail ID	
5.	Bank Details	
	a) Name of the Bank	
	<ul><li>b) Branch Name &amp; address</li><li>c) Branch Code No.</li></ul>	
	<ul><li>c) Branch Code No.</li><li>d) Branch Manager Mobile No.</li></ul>	
	e) Branch Telephone no	
	f) Branch E-mail ID	
	g) 9 digit MICR code number of	
	the bank and branch	
	appearing on the MICR	
	cheque issued by the bank	
	h) IFSC Code of the Branch	
	i) Type of Account (Current /	
	Savings)	
	j) Account Number (as appear	
1	in cheque book)	

transaction is c would not hole have read the	delayed or not effected at all the delayed or not effected at all the delayed of Pharma Public Seconditions of the tender	lars given above are correct and complete. ne reasons of incomplete or incorrect informate ector Undertakings of India (BPPI) responsion / Price agreement and agree to discharge pany as a tenderer / successful tenderer.	ation, I ible. I
Date:	Company Seal	Signature	
Place:	(1	Name of the person signing & designation)	
	THAT THE PARTICULARS I S PER OUR RECORDS.	FURNISHED ABOVE BY THE COMPANY	Ý ARE
		Signature of the authorized official of th	ie bank

(In lieu of the bank certificate to be obtained, please upload the original cancelled cheque

issued by your bank for verification of the above particulars).

Bank Seal with address: