

### e-TENDER NO:- BPPI/DRUG-064/2018

### 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-064/2018 Dt. 07/06/2018
Date of availability of tender documents on website	07/06/2018 (Thursday)
Time and date and place pre-bid	11:00 AM on
meeting	14/06/2018 (Thursday)
	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	28/06/2018 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	29/06/2018
Time and date of opening of Technical Bid	11:30 AM on 29/06/2018 (FRIDAY)

Place of opening of tender	Bureau of Pharma PSUs of India,		
	8 <sup>th</sup> Floor, Videocon Tower, Block- E1,Jhandewalan Extension, New Delhi-110055		
Address for Communication	Bureau of Pharma Public Sector Undertakings of India,		
	8 <sup>th</sup> Floor, Videocon Tower, Block- E1,Jhandewalan Extension, New Delhi-110055		
Cost of the Tender Document	Free of cost		
Contact Person for clarification if any	1. Mr. Sandeep Sapan Patra, Sr.Executive (Procurement) Phone:- 011-49431858 Mob:- 9090512532 Email:- proc5.bppi@gmail.com		
	2. Mr. P.K.Thakur, Executive (Procurement) Phone:- 011-49431858 Mob:- 9475982561 Email:- proc6@janaushadhi.gov.in 3. Ms. Neha Aggarwal, Executive (Procurement) Phone:- 011-49431859 Mob:- 8447711358		
	Email:- proc5@janausadhi.gov.in  4. Ms. Nisha Kumari, Executive (Procurement) Phone:- 011-49431858 Mob:- 9988290847 Email:- proc7@janausadhi.gov.in		

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

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#### 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 3600 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 AM. up to 28/06/2018** (**THURSDAY**) **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 manufacturer of foreign supplier should be WHO-GMP certified company. The Importer should have valid sale license.
- (iii) Distributors/Suppliers/Marketer/Agents are not eligible to participate in the Tenders.
- (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 average annual turnover of manufacturing unit/ Host Company 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

#### (ONLY in case of Importer)

The supplier have 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	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 months 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) and they are required to submit valid registration certificate from GS1 India for such barcoding.

#### 3. GENERAL CONDITIONS.

- (i) The tender document shall be download from the websites janaushadhi.gov.in; and CPP portal i.e.eprocure.gov.in. Tender Document is free of cost. No tender cost is to be deposited.
- (ii) **EMD** (**Earnest Money Deposit**): EMD of Rs.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 (<b>ANNEXURE III**) to the

- e-Procurement portal. EMD in any other form like *cheque/cash/postal order* etc. will not be accepted. The Bid (in case not exempted for EMD as mentioned in tender document) without EMD shall be summarily rejected.
- (iii) Tenders will be opened online. However, authorized representatives of bidder who like to attend online bid opening on the specified date and time should bring letter of authority authorising to attend online bid opening on the printed letter head of the company. Please also certify in authorisation letter that nominated person of tenderer shall not represent any other tenderer in BPPI.
- (iv) (a) At any time prior to the last date of submission of online bid, Tender Inviting Authority may, for any reason, whether on own initiative or in response to a clarification requested by a prospective Tenderer, may modify the condition in Tender documents by an amendment uploading on website on **janaushadhi.gov.in**; and CPP portal i.e. **eprocure.gov.in** will be binding on them. In order to provide reasonable time to take the amendment into account in preparing their bid, Tender Inviting Authority may at discretion, extend the date and time for submission of online bid.
- (b) Any person who has downloaded the tender document should watch for amendment, if any, on the website **janaushadhi.gov.in**; and CPP portal i.e.**eprocure.gov.in** for which BPPI will not issue any separate communication to them.
- (v) Interested eligible Tenderers may obtain further information in this regard from the office of the Tender Inviting Authority on all working days between 10:00 AM and 5:00 PM.
- (vi) 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 <a href="https://eprocure.gov.in">https://eprocure.gov.in</a>.
- (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 BPPI/Drug-064/2018

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 "Cover A". (Scanned copies of each page of all documents should be uploaded while submitting Technical bid).
- (a) The tenderers are required to upload scanned undertaking on stamp paper duly notarized by authorised signatory (ANNEXURE - II) confirming that they are holding the valid drug license, valid WHO- GMP certificate, 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 Importer). undertaking as per para 2(f) & (h), undertaking to supply the drug with bar code as per ANNEXURE I and as per Annexure XI & XI 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. The original ANNEXURE II 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 III) 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 IV** 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 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 BPPI/Drug-064/2018

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 as well as WHO-GMP certificate of manufacturing company 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/ products manufactured by manufacturing units approved by US FDA, TG Australia, Health Canada, EU approval, MCC South Africa approval, Brazil Anvisa should be uploaded with technical bid.
- (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. Importer should upload WHO-GMP certificate of manufacturer.
- (l)The loan license bidder is required to upload scanned copies of all the documents as per tender requirements including manufacturing unit.
- (m) (i) The tenderers are required to upload copies of the specifications for all quoted drugs and STP (standard testing procedure) for Non- Pharmacopoeia quoted drugs.
- (ii) The bidder shall upload the long term stability data for all quoted drugs with technical bids. If manufacturer has licensed a formula from another company and such licensed formula is used for the product, then the stability data of the licensor should be uploaded alongwith licensing agreement.
- (n) The manufacturer shall declare the polymorphic form of API used in formulation and declare that it is internationally accepted active polymorph. The documented evidence shall be uploaded. The evidence could be pharmacopoeias or journal or certification by any institution like NIPER or any experimental data.
- (o) The bidders shall upload valid GS1 barcoding registration certificate and comply to barcoding requirement as per Annexure I of tender document.
- (p) A Checklist (**ANNEXURE-V**) 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.
- (q) 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 products manufactured by manufacturing units approved by US FDA, TG Australia, Health Canada, EU approval, MCC South Africa approval, Brazil Anvisa, copies of relevant pages of valid document approved by drug authorities of concerned country for imported drug should be uploaded on line with technical bid.

#### (ii) **Determination of L1 bidder:**

- (a) In determining the lowest evaluated price, the rate quoted per unit size inclusive if GST as indicated in column No. 8 of the **BOQ** shall be taken into consideration.
- (b) The Price preference of up to 5% over L1 bidder (if L1 bidder is not offering certificate of pharmaceutical product i.e. **CoPP** issued in the format recommended by the World Health Organization) shall be given to the bidder having CoPP for the particular drugs and shall be awarded contract. Scanned copy of Valid CoPP issued by the Licensing Authority must be uploaded.
- (c) The Price preference up to 10% over L1 bidder (if L1 bidder is not offering products manufactured by manufacturing units approved by from US FDA, TG Australia, Health Canada, EU approval, MCC South Africa approval, Brazil Anvisa) shall be given to the bidder having product manufactured by manufacturing units approved by US FDA. TG Australia, Health Canada, EU approval, MCC South Africa approval, Brazil Anvisa.
- (d)(i) If the participating Micro and Small Enterprises (MSE) meets all the other eligibility criteria and their quoting price is within price band of L1+15 (fifteen) per cent shall also be allowed to supply a portion of requirement by bringing down their price to L1 price in a situation where L1 price is from someone other than a MSE and such MSE shall be allowed to supply up to 20 (twenty) per cent of total tendered value. The 20 (twenty) per cent quantity is to be distributed proportionately among these bidders, in case there are more than one MSMEs within such price band.
- (ii) Within this 20% (Twenty Percent) quantity, a purchase preference of four per cent (that is, 20 (twenty) per cent out of 20 (twenty) per cent) will be reserved for MSEs owned by Scheduled Caste (SC)/Scheduled Tribe (ST) entrepreneurs (if they participate in the tender process and match the L1 price). Provided that, in event of failure of such SC/ST MSE to participate in tender process or meet tender requirements and L1 price, four per cent sub-target shall be met from other MSE. MSEs would be treated as owned by SC/ST entrepreneurs: a) In case of proprietary MSE, proprietor(s) shall be SC/ST b) In case of partnership MSE, the SC/ST partners shall be holding at least 51% (fifty-one percent) shares in the unit c) In case of Private Limited Companies, at least 51% (fifty-one percent) share shall be held by SC/ST promoters.

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

- Note 2:- Later on, if product does not comply CoPP and products manufactured by manufacturing units having approval of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa as declared in tender, the extra price paid to the supplier shall be recovered in addition to other penal action.
- (iii) The rate quoted inclusive of GST in column 8 of **BOQ** should be for a unit size and for the given specification. **The rates quoted should be in rupees and paisa up to 2 digits.** The Tenderer is not permitted to change/alter specification or unit size given in the **ANNEXURE-VII.**

- (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-VI. 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 -VII**. 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 VIII and upload along with technical bid.** In case the bidder is Importer, the importer is required to sign and upload ANNEXURE VIII 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-VII**. 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 products manufactured by manufacturing units having approval of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa. However, to have additional source of supply, the L1 bidder shall be awarded contract/Price agreement for 60% of tender quantity indicated in the tender document. Balance 40% 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 bidder and L2 bidders simultaneously as per discretion of BPPI depending upon requirement. In case, order is placed only on L1 bidder and if 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 if no simultaneously purchase order issued to L2 bidder, 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 CoPP certificate or drug/ Products manufactured by manufacturing units having approval of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa.
- .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 <u>CoPP</u> and 10% for products manufactured by manufacturing units having approval of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa, 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 price 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 for Price Agreement for two years period will be communicated to the Tenderers in writing (ANNEXURE IX).

#### **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 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-X. 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 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. For drug code 574, Rabies Vaccine Inj. 2.5 IU, period shall be 90 days instead of 45 days.
- (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. For drug code 574, Rabies Vaccine Inj. 2.5 IU, period shall be 90 days instead of 30 days.
- (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 days (90<sup>th</sup> days for code 574, Rabies Vaccine Inj. 2.5 IU) for 12.4 (a) &(b) respectively. However, no supplies will be accepted after 75<sup>th</sup> days/ 60th days (120th days for drug code 574, Rabies Vaccine Inj. 2.5 IU) 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 excluding month of manufacture of products having shelf life up to 2 years, (b) within 3 months excluding month of manufacture of products having shelf life more than 2 years & up to 3 years and (c) within 4 months excluding month of manufacture of products having shelf life more than 3 years (d) Within 3.5 months excluding month of manufacture of products for drug code 574, Rabies Vaccine Inj. 2.5 IU. Products beyond the above-mentioned period from the date of manufacture shall not be accepted. For example, product having manufacturing of November 2018 must be supplied by 31<sup>st</sup> January, 2019 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 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.
- 12.12 If BPPI observes some physical defects(like empty blisters, improper labelling) of the supplies during sampling, the batch shall be rejected. If supplier wants to take back the batch for rectification, they can take back at their cost, rectify and send back to BPPI within 10 days otherwise same batch shall not be accepted. Due to rectification, if its shelf life condition as per tender provision does not meet, it shall be discretion of BPPI depending upon requirement to accept the goods with penalty.

#### 13. LOGOGRAMS

Logogram means, wherever the context occurs, the design as specified in ANNEXURE-XI. 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 –XI &XI-A**.
- **13.2.** All dosage form have to be supplied in packing as specified in product list (**ANNEXURE VII**) 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 VII** and **ANNEXURE** -**XII** and the package shall carry the logograms of proportionate size specified in **ANNEXURE** -**XI**, **XI** -**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-XII**. 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 XI and XIA.** 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 BPPI/Drug-064/2018

samples will be sent to different laboratories including Government Drugs Testing Laboratory/NIPER/PSU labs for testing as decided by the BPPI. Handling and testing charges will be deducted by BPPI for the above purpose, as specified in Clause 17.

- **15.1.1** Supplier should send the soft copy of the specifications for all approved drugs and STP (Standard Testing Procedure) for Non- Pharmacopoeia approved drugs by mail to Quality and Regulatory officer of BPPI with art work approval for design of packaging with the logogram as per Clause 14.10; if they failed to upload/submit the same with technical bid.
- **15.2.** The Drugs shall have the active ingredients at the prescribed level as indicated in official compendiums throughout the shelf life period of the drug. The samples will be drawn periodically throughout the shelf life period and if found "Not of Standard Quality", the cost of entire batch paid will be recovered whether consumed fully/partially. Also action will be initiated for blacklisting as per clause No.19 irrespective of the period of supply. The supplies will be deemed to be completed only upon receipt of the quality certificates from the laboratories. Samples which do not meet quality requirement shall render the relevant batches liable to be rejected. If the sample is declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches will be deemed to be rejected goods.
- **15.3.** In the event of the samples of Drugs supplied fails in quality tests or found to be not as per specifications, the BPPI is at liberty to make alternative purchase of the items of drugs for which the Purchase orders have been placed from any other sources or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier and in such cases the BPPI has every right to recover the cost and impose penalty as mentioned in Clause 19.
- **15.4.** The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the commercial final package on request by the BPPI. In case of any complaint in the field, the B.M.R/B.P.R for the particular batch of the product(s) supplied shall be produced when demanded.
- **15.5.** The products should conform to the standards of IP/BP/USP/EP/JP as the case may be. **However, the drugs notified in the IP (amended up to date) shall be accepted only if supplied conforming to the standards outlined in the IP.** In case the product is not included in the any of the said compendiums, the supplier, upon award of the contract, must provide the reference standards and testing protocols for quality control testing. 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 - XIII) 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. BPPI/Drug-064/2018

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

However, if the firm supplies after originally stipulated Delivery period, increase in taxes/GST due to statutory variation in taxes/GST shall be borne by the supplier. In case of decrease in taxes/GST due to statutory variation in taxes/GST, the same shall be passed on by the supplier to the BPPI.

#### 17. HANDLING & TESTING CHARGES:

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

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

- **18.1.** If the supply reaches the designated places or Central Warehouse after 5 PM of **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 (90th days for drug code 574, Rabies Vaccine Inj. 2.5 IU), 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 (90th days for drug code 574, Rabies Vaccine Inj. 2.5 IU) 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

### <u>20.1. BLACKLISTING OF PRODUCT/TENDERER ON WITHDRAWAL OF TENDER</u>

(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 sample passes quality test in all respects, BPPI will instruct its Warehouse to release such items of drugs.
- d. If the sample of any batch fails in quality test and report is received stating "Not of standard quality "in any test the report along with the chromatograms etc. such batch of drugs shall be rejected & no further procurement of that drug from the supplier will be taken for two years from the date of sample being declared not of standard quality.

- (i) If the supplier challenges and request for retesting, the sample shall be tested at government testing laboratory or reputed govt. institute like NIPER. The test report of govt. lab or NIPER will be final and will be binding to the supplier.
- (ii) The cost of such retesting shall be recovered from the supplier.
- (iii) If **2** batches of item/drug supplied by the same supplier is reported to NOT OF STANDARD QUALITY in specification, then the firm shall be blacklisted for 2 years after observing procedure laid down in Para 20.2.3 besides forfeiture of Performance security deposit.
- (iv) The supplier shall give a report of root cause and CAPA taken to prevent the recurrences of such failure within 20 days.

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

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

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

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

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

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

#### 21. SAVING CLAUSE

No suit, prosecution or any legal proceedings shall lie against the Tender Inviting Authority or any person for anything that is done in good faith or intended to be done in pursuance of the tender.

#### **22. RESOLUTION OF DISPUTES**

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

#### **ARBITRATION AND JURISDICTION**

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

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

#### **23. APPEAL:**

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

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

- (i) No bidder shall contact the *BPPI* on any matter relating to its bid, from the time of bid opening to the time the contract is awarded.
- (ii) Any effort by a bidder to influence the *BPPI* in the *Purchaser*'s bid evaluation, bid comparison or contract award decisions may result in rejection of the bidder's bid.
- (ii) The bidder shall not make any attempt to establish unsolicited and unauthorized contact with the Tender Accepting Authority, Tender Inviting Authority or Tender Scrutiny

Committee after opening of the bids and prior to the notification of award and any attempt by any bidder to bring to bear extraneous pressures on the Tender Accepting Authority, Inviting Authority or Tender Scrutiny Committee, shall be sufficient reason to disqualify the bidder.

(iv) Not withstanding anything contained in clause (iii) above the Tender Inviting Authority or the Tender Accepting Authority, may seek bonafide clarifications from bidders relating to the bids submitted by them during the evaluation of bids.

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

#### (1)For bidders:

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

- (a) defines, for the purposes of this provision, the terms set forth below as follows:
- (i) "corrupt practice" is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party ("another party" refers to a public official acting in relation to the procurement process or contract execution]. In this context, "public official" includes staff and employees of other organizations taking or reviewing procurement decisions.
- (ii) "fraudulent practice" is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation (a "party" refers to a public official; the terms "benefit" and "obligation" relate to the procurement process or contract execution; and the "act or omission" is intended to influence the procurement process or contract execution).
- (iii) "collusive practice" is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party ["parties" refers to participants in the procurement process (including public officials) attempting to establish bid prices at artificial, non competitive level].
- (iv) "coercive practice" is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party (a "party" refers to a participant in the procurement process or contract execution).
- (v) "obstructive practice" is (a) deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or acts intended to materially impede the exercise of the purchaser's inspection and audit rights provided for under sub-clause (e) below.
- (b) will reject a proposal for award if it determines that the bidder considered for award has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the contract in question;

- (c) will cancel the contract if the purchaser determines at any time that the bidder, supplier and contractors and their sub contractors engaged in corrupt, fraudulent, collusive, or coercive practices.
- (d) will sanction a firm or individual, including declaring in eligible, either indefinitely or for a stated period of time, to be awarded a contract if it at any time determines that the firm has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for, or in executing, a contract; and
- (e) will have the right to inspect the accounts and records of the bidders, supplier, and contractors and their subcontractors/authorized representatives and to have them audited by auditors appointed by the purchaser.

#### (2) For suppliers:

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

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

#### 26. JURISDICTION

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

#### **ANNEXURE I**

### (BARCODE REQUIREMENTS)

Reference clause 2(i)

## 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				

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

	Identifier to indicate Expiry date  Brackets not encoded in the barcode			
180815	Expiry Date in YYMMDD format	6	Fixed	Date
(10)	Application identifier to indicate Lot/batch Brackets not encoded in the barcode	2	Fixed	Numeric
RNBXY0514	Batch No / Lot No	Upto 20	Variable	Alphanumeric
(37)	Application Identifier to indicate serial number Brackets not encoded in the barcode	2	Fixed	Numeric
500	Quantity/Units in Secondary pack	Upto 8	Variable	Alphanumeric
Recommended Barcode depending upon the space available – GS1 Data matrix Or		(17) 1 (10) RN (37)	072 00253 6 80815 BXY0514 ) 500	

*GS1-128* 

### 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 8901072 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.gs1india.org

#### **ANNEXURE -II**

### (On nonjudicial Stamp Paper)

Ref. Clause No. 4.1(a)

### **DECLARATION**

represented by its Proprietor/Managing Partner /Managing Director

	and its factory premises at
BPPI/DRUG-064/2018 dated 07/06/2018 incl any) issued by Bureau of pharma public sector	erms and conditions of tender in ref. no. uding Amendment(s) to Tender document (if undertakings of INDIA, New Delhi,122016 and of tender document including Amendment(s) to
WHO-GMP certificate, (c) a certificate manufissued by C.A. for quoted drugs, (d) valid non of	(a) valid drug license for quoted drugs,(b) valid factured & marketed two batches within 3 years conviction certificate not older than 6 months,(e) ies <b>of</b> the specifications for all quoted drugs and

- 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 Deposit/Bank guarantee against tender no. BPPI/DRUG-064/2018 dated 07/06/2018 along with other action.
- (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.
- 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 XI enclosed with tender document as well as other instruction given in this regard.
- (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

I/We M/s. ....

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, (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( <b>Yes/No</b> )	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-064/2018 dated 07/06/2018 for the following quoted products:-

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

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

# **ANNEXURE-III**

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

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

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

### **ANNEXURE- IV**

### Ref. Clause No. 4.1(b)

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

(I)	Income tax returned and GST r	chip company/f.con no returned up to dat						
(II)	The annual Turnover of M/s		for the past three years are given					
	below and certified that the state	ment is true and c	orrect.					
	Sl.No.	Financial Year	Turnover in Lakhs(Rs.)					
	1.	2014-15						
	2.	2015-16						
	3.	2016-17						
	TOTAL		RsLakhs					
	Average Turnover per	annual	RsLakhs					
	OR							
	It is certified that M/S		(Name of company and					
	address) having factory at		(address of factory)					
	have invested Rs 10 crores or above	e for installation	of plant and machinery excluding					
	cost towards land, building & othe	r infrastructure t	o manufacture the drugs. It is also					
	certified that the statement is true a	nd correct						
	continue that the statement is true a	na correct.						
(III)	It is certified that M/s		has Production &					
	financial capacity to manufacture	e and deliver the d	lrugs quoted by them in the tender					
	as per quantity & delivery sched	ule mentioned in t	tender. This certificate is based on					
	their Manufacturing capacity, inventory of raw Material and financial statement.							

#### Or (ONLY in case of IMPORTER)

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 based on their Manufacturing capacity, inventory of raw Material and financial statement.

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

#### Or (ONLY in case of IMPORTER)

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

Date

(Name, Signature & Stamp) Registration no.

#### NOTE

- (i) Strike which is not applicable in above certificate.
- (ii) MSEs would be treated as owned by SC/ ST entrepreneurs: 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 – V

### Ref. Clause 4.1 (p)

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

### COVER – A

S.N	Check List	YES	NO
•	Cl. 11' ( ANNEWINE V		
1	Check list - ANNEXURE – V		
	EMD Rs. 100,000/- in the form of Bank Guarantee or Bankers Cheque or Demand		
	Draft uploaded as per ANNEXURE-III DD NoDatedDated by		
	(name of bank) and <b>delivered to BPPI</b> .Uploaded NSIC or MSME		
2	certificate for exemption if any.		
	Scanned copy of Valid WHO-GMP (World Health Organisation-Good Manufacturing		
	Practices) Certificate of manufacturing company. In case of imported drugs, scanned		
_	copy Valid WHO-GMP (World Health Organisation-Good Manufacturing Practices)		
3	Certificate of manufacturing company of foreign company.		
_	Scanned copy of Valid License for the Product duly approved by the Licensing		
4	Authority for each and every product quoted		
5	Scanned copy of valid GS1 registration certificate for bar coding		
6	Scanned copy of Valid Import License, if Imported and whole sale Drug license		
7	Scanned copy of Non Conviction Certificate issued by the licensing authority not older than 6 months.		
8	Scanned copy of Market Standing Certificate issued by the Licensing Authority		
0	Valid COPP certificate as per WHO format of their Principal Manufacturing company		
9	including Imported drugs, if any.		
	Copies of approval of Manufacturing Unit of the any agency like US FDA, TG		
10	Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa, if any.		
	Scanned copies of the specifications for all quoted drugs and STP (standard testing		
11	procedure) for Non- Pharmacopoeia quoted drugs.		
	Scanned copy of long term stability data for all quoted drugs. If manufacturer has		
	licensed a formula from another company and such licensed formula is used for the		
	product, then the stability data of the licensor should be uploaded alongwith licensing		
12	agreement.		
	Declaration of the polymorphic form of API used in formulation and declare that it is		
	internationally accepted active polymorph. The documented evidence shall be		
13	uploaded.		
	Authorization letter nominating a responsible Person of the tenderer to transact the		
14	business with the Tender inviting Authority.		
	Scanned copy of ANNEXURE –II (Declaration for eligibility in participating the tender)		
15	original Annexure II delivered to BPPI.		
1.0	Scanned copy of ANNEXURE IV{certificate from the C.A.(Chartered Accountant) or		
16	Company Secretary .		
	Scanned copy of ANNEXURE-VIII		
17	(Details for Shelf life, Manufacturing Capacity & Batch Size)		
18	Scanned copy of ANNEXURE—XIII (Mandate form)		

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

Name and signature	of authorised	d signatory	(with com	oany seal	·

# **ANNEXURE -VI** ( Ref:-Clause 7.1)

### MODEL BANK GUARANTEE FORMAT FOR FURNISHING EMD

Whereas (h	ereinafter called the
"tenderer") has submitted their offer datedsupply	for the
Of Drugs (hereinafter called the "tender") against the purc BBPI/DRUG-064/2018 KNOW ALL MEN by thes	e presents that WE aving our registered office at
Undertakings of India New Delhi(hereinafter called the "Purchas only for which payment will and truly to be made to the said Pu its successors and assigns by these presents. Sealed with the Cothis	ser) in the sum of Rs. One lakh rchaser, the Bank binds itself,
THE CONDITIONS OF THIS OBLIGATION ARE:	
(1) If the tenderer withdraws or amends, impairs or derogates for within the period of validity of this tender.	rom the tender in any respect
(2) If the tenderer having been notified of the acceptance of during the period of its validity:-	his tender by the Purchaser
a) If the tenderer fails to furnish the Performance Securithe contract.	ty for the due performance of
b) Fails or refuses to accept/execute the contract.	
WE undertake to pay the Purchaser up to the above amount udemand, without the Purchaser having to substantiate its didemand the Purchaser will note that the amount claimed by occurrence of one or both the two conditions, specifying the occurrence of the occurrence occurrence of the occurrence o	emand, provided that in its it is due to it owing to the
This guarantee will remain in force up to 15.05.2019 and ar should reach the Bank not later than the above date.	ny demand in respect thereof
(Signature of the authorized officer of the Bank)	
Name and designation of the officer	
BPPI/Drug-064/2018	

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

### **Annexure -VII**

### Clause 8.1 &8.2

### Bureau of Pharma Public Sector Undertakings of India, New Delhi Tender for supply of drugs (Tender No. BPPI/DRUG-064/2018 dated 07/06/2018)

(1)	(2)	(3)	(4)	(5)	(6)	(7)
Sr. No.	Drug Code	Generic name of Drugs	Unit Size	Pack Size	Packing per Carton (Shipper Pack)	Tender quantity in unit size
1.	1	Aceclofenac + Paracetamol (100 mg + 325mg) Tablets	10's	10's x10	(10's x10x10)x10	1500000
2.	6	DICLOFENAC 50 mg+ PARACETAMOL 325 mg+ CHLORZOXAZONE 500 mg Tablets	10's	10's x10	(10's x10x10)x10	1500000
3.	22	Paracetamol Syrup IP 125mg/5ml	60 ml	1'S X10	(1'sX10X5)x10	1500000
4.	24	Pentazocine Injection IP 30mg/ml	1 ml	1 ml x 10	1 ml x 10 x10	1000000
5.	30	Amikacin Injection IP 100mg/2ml	2ml Vial	2ml x 20	2mlx20x5	2000000
6.	44	Amoxycillin Capsules IP 250mg	10's	10's x10	(10's x10x10)x10	2000000
7.	45	Amoxycillin Capsules IP 500mg	10's	10's x10	(10's x10x10)x10	2000000
8.	51	Cefadroxil Dispersible Tablets 250mg	10s	10's x10	10's x10 x10	1500000
9.	52	Cefadroxil 500mg Film Coated Tablet	10's	10's x10	10's x10 x10	3000000
10.	70	Ceftriaxone 1000mg+ Sulbactam 500 mg Inj.	Vial & wfi	1'sx10	(1'sx10x10)x10	2500000
11.	74	Ceftriaxone 500mg with Sulbactum 250mg Injection	Vial with WFI	1'sx10	(1'sx10x10)x10	1500000

12.	75	Ceftriaxone Injections IP 1g	Vial & wfi	1'sx10	(1'sx10x10)x10	1500000
13.	94	Gentamycin Sulphate 80 mg/ 2ml Inj.	2 ml	2 ml x 20	2mlx20x5	1000000
14.	98	Norfloxacin 400 mg + Tinidazole 600 mg film coated Tablet	10's	10's x10	(10's x10x10)x10	150000
15.	99	Norfloxacin 400 mg film coated Tablet	10's	10's x10	(10's x10x10)x10	150000
16.	103	Piperacillin 4gm + Tazobactum 0.5 gm Inj.	Vial & wfi	1'sx10	(1'sx10x10)x10	1800000
17.	115	Calamine Lotion	100 ml	100ML x 6	(100ML x 6)x10	350000
18.	143	INSULIN INJECTION (INSULIN HUMAN SOLUBLE 30% & ISOPHANE 70%) 40 IU/ML 10ml Vial	10 ml Vial	1'sx10	(1'sx10x10)x10	5000000
19.	153	Cisplatin Injection IP10 mg	vial	1'sx10	(1'sx10x10)x10	150000
20.	164	Tamoxifen Citrate 20 mg I.P Tablets	10's	10's x10	(10's x10x10)x10	3000000
21.	177	Albendazole Suspension IP 200 mg/ 5ml	10 ml	1'sx10	(1'sx10x10)x10	10000000
22.	183	Dicyclomine Tablets IP 10mg	10's	10's x10	(10's x10x10)x10	60000
23.	185	Diethylcarbamazine citrate 100 mg film coated Tablets	10's	10'sx10	(10's x10x10)x10	500000
24.	206	Omeprazole 20mg + Domperidone 10 mg Caps	10's	10's x10	(10's x10x10)x10	10000000
25.	215	Rabeprazole Gastro- resistant Tablets IP 20mg	10's	10's x10	(10's x10x10)x10	10000000
26.	218	Ranitidine HCl film coated Tablets 300mg	10's	10's x10	10'sX10X10	5000000
27.	229	Haematinic syrup of Iron,Folic acid and Vitamin B12	100 ml	1'sx10	1's x10x10	2500000
28.	231	VITAMIN B1 10mg, B2 10mg, B3 45mg, B5 50mg, B6 3mg, B12 15mcg	10's	10'sx10	(10's x10x10)x10	5000000

		Tablets				
29.	232	Vitamin B-Complex Syrup	200 ML	200MLx6	200MLx6x10	600000
30.	252	Levocetrizine 5mg and Montelukast Sodium 10mg film coated Tablet	10's	10's x10	(10's x10x10)x10	30000000
31.	254	Promethazine (5mg/5ml) syrup	100 ml	100ml x 10	100ml x 10 x 5	500000
32.	255	Salbutamol 100 mcg/puff Inhaler	200 mdi	1's X10	1's X10 X10	1000000
33.	260	Salbutamol 4 mg tablets	10's	10's x10	10's x 10 X10	2000000
34.	275	Enalapril 5 mg Tablets	10's	10's x10	(10's x10x10)x10	4000000
35.	278	Frusemide (10 mg/ ml)	2ml	1'sx10	(1's x10x10)x10	3000000
36.	281	Heparin Sodium 5000iu/ ml Inj.	5 ml	1'sx10	(1'sx10x10)x10	500000
37.	311	Disodium hydrogen Citrate (Alkalyser) 1.4 gm/5ml Syrup	100 ml	100MLx6	100ML x 6x10	300000
38.	327	PHENYTOIN Tablets IP 100 mg	100's in bottle	1 bottle X10	1'sX10X10	1000000
39.	328	Prochlorperazine Tablets IP 5mg	10's	10's x10	(10's x10x10)x10	2000000
40.	343	Chloramphenicol 1%w/v Eye Applicaps, 250 mg each.	10's	10's x10	(10's x10x10)x10	300000
41.	345	Gentamycin 0.3% w/v Eye Drop	10 ML	10ml x 10	(10ml x 10x10)x10	700000
42.	351	Xylometazoline Nasal Drop IP 0.1%w/v	10 ML	10ml x 10	(10ml x 10x10)x10	1100000
43.	356	Lignocaine Injection IP 2%w/v	30 ml Vial	1's x 10	(1'sx10x10)x10	2000000
44.	357	Lignocaine 1% + Adrenaline 2%w/v Inj.	30 ml Vial	1'sx10	(1's x10x10)x10	200000

45.	359	Tetanus Toxoid 40 IU Inj.	0.5 ml Amp.	1'sx10	(1's x10x10)x10	2000000
46.	363	GLARGINE 100 IU / ml INJECTION Cartridge 3 ml	CARTR IDGE/ vial 3 ML	1's x 10	(1'sx10x10)x10	5000000
47.	379	RIFAMPICIN and ISONIAZIDE TABLETS IP (450 MG+300 MG)	10's	10's x10	(10's x10x10)x10	1000000
48.	416	PRAZOSIN TABLETS IP 5 MG	15's	15's x10	(15's x10x10)x10	3000000
49.	425	DILTIAZEM TABLETS SR 90 MG	10's	10'sx10	(10's x10x10)x10	500000
50.	446	AMLODIPINE 5 MG + HYDROCHLOROTHIAZIDE 12.5 MG TABLETS	10's	10'sx10	(10's x10x10)x10	1500000
51.	450	LABETALOL TABLETS IP 100 MG	10's	10'sx10	(10's x10x10)x10	400000
52.	488	LANSOPRAZOLE CAPSULES IP 15 MG	10's	10's x10	(10's x10x10)x10	100000
53.	508	LEVETIRACETAM Tablets 500 mg	10's	10's x10	(10's x10x10)x10	15000000
54.	525	DICLOFENAC 1.16 w/w+ LINCEED OIL3% w/w+ METHYL SALICYLATE 10% w/w+MENTHOL 5% w/w GEL	30 GM	30 GMX20	(30 GMX20x10)x10	2000000
55.	535	TERBUTALINE 2.5 MG + BROMHEXINE 8 MG syrup	100 ML	100 ML X6	100 ML X6x10	5000000
56.	555	DOXOFYLLINE TABLETS IP 400 MG	10's	10'sx10	(10'sX10X10)x10	1500000
57.	560	FLUTICASONE PROPIONATE 50 MCG PER PUFF NASAL SPRAY	120 MD	1'sX20	(1'sx20x10)x10	1000000
58.	563	OXYMETAZOLINE 0.5 MG /ML NASAL DROPS	10 ML	10 MLX10	(10 MLX10x10)10	10000000
59.	574	VACCINE RABIES INJECTION 2.5 IU	1 ML	1'sx10	(1's x10x10)x10	1000000
60.	581	CALCIUM CARBONATE 500MG+CALCITRIOL 0.25 MCG + ZINC 7.5 MG	10's	10'sx10	(10's x10x10)x10	800000

		Capsules				
61.	587	APPETITE ENHANCER (PEPTONE, MINERALS, VITAMINS )SYRUP	300 ML	1'sX6	1's X6X6	1000000
62.	591	METHYLCOBALAMIN 500 MCG INJECTION	1 ML	1 MLX10	(1 MLX10x10)10	500000
63.	626	Ketoconazole Shampoo 2% W/V	100 ML bottle	1's X6	1's x 6x10	150000
64.	627	Etophylline IP 115mg + Theophylline 35mg Prolonged Release Tablet	10's	10's x10	10's x10 x10	3000000
65.	646	Diclofenac diethylamine BP 1.116% (equivalent to diclofenac sodium 1.0%, Linseed oil BP 3.0% + Methyl Salicylate IP 10.0%, Capsiacin USP 0.025%, Menthol IP 0.025%, Benzyl alcohol IP 1.0% (as preservative) In a gel base q.s.	30GM	1'sX20	(1'sX20x10)x10	6000000
66.	656	Enzyme Drops Pepsin (1:3000) 5 mg + Fungal Diastase (1:1200) 33.33 mg/ml	15ML	1'sX20	1'sX20x10	500000
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	10's x10	(10's x10x10)x10	2000000
68.	672	Mometasone Furoate 0.1%w/w cream	15GM	1'sx20	(1'sX20x10)x10	600000
69.	698	Sulfacetamide eye drop 20 %	20 ml	1'sx10	(1's x10x10)x10	700000
70.	710	Piroxicam 40 mg with bezyl alcohol injection	2ml	1'sx10	(1's x10x10)x10	1500000

71.	718	Escitalopram 10mg with Clonazepam 0.5mg	10's	10'sx10	(10's x10x10)x10	1500000
72.	725	Dextrose Injection IP 5 %, iv fluid plastic container using FFS/ BFS technology	500ml	1'sx25	1'sx25	300000
73.	726	Dextrose Injection IP 10 %, iv fluid plastic container using FFS/ BFS technology	500ml	1'sx25	1'sx25	300000
74.	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'sx25	1'sx25	300000
75.	739	Cefuroxime Tablets IP 125mg	6's	6's x10	(6's x10x10)x10	2000000
76.	758	Vildagliptin Tablet 50 mg	14's	14's x10	(14's x10x10)x10	5000000
77.	779	Alpha Lipoic acid 100mg, Vit. D3 1000 IU, Folic acid 1.5mg, Pyridoxine 3mg, Methylcobalamin 1500mcg Tablets	10's	10'sx10	10'sx10x10	1000000
78.	811	Bromfenac Sodium Eye Drop 0.09%	5ml	1'sx10	(1's x10x10)x10	700000
79.	817	Calcium Carbonate 1250 Mg, Vitamin D3 250 lu, Magnesium Oxide 40 Mg, Manganese Sulphate 1.8 Mg, Zinc Sulphate 7.5 Mg, Copper Sulphate 1 Mg, Sodium Borate 250 Mcg Film Coated Tablets	10's	10'sx10	(10's x10x10)x10	300000
80.	838	Cilostazol Tablets IP 50mg	10's	10'sx10	(1's x10x10)x10	700000
81.	850	Cyclosporin Soft Gelatin Capulses IP 50mg	5's	5's x10	5's x10x10	500000
82.	881	Ebastine Film Coated Tablets 10mg	10's	10'sx10	(10's x10x10)x10	200000
83.	904	Glimepiride 1mg Metformin SR 500mg Tablets	10's	10'sx10	(10's x10x10)x10	10000000
84.	926	Ketoconazole Cream 2%w/w	15gm Tube	1'sx10	(1'sx10x10)x10	1500000

85.	951	Lycopene 1000 Mcg, Vitamin A Palmitate 2500 Iu, Vitamin E Acetate 10 Iu, Selenium 35 Mcg, Vitamin C 50 Mg, Zinc Gluconate 3 Mg, Manganese Gluconate 2 Mg, Iodine 100 Mcg, Copper 500 Mcg, Thiamine Hydrochloride 2 Mg, Riboflavin 3 Mg, Pyridoxine Hydrochloride 1.5 Mg Syrup	200m 	1'sx6	1's x6x6	500000
86.	975	Nebivolol 5 mg, Hydrochlorothiazide 12.5 mg Tab.	10's	10'sx10	(10's x10x10)x10	300000
87.	1024	Promethazine Injection I.P 25 mg/ml	2ml	(2ml x10)	2ml x10 x 10	500000
88.	1029	Pyrazinamide Tablets I.P 1000mg	10's	10'sx10	(10's x10x10)x10	300000
89.	1080	Ticagrelor Tablets 90mg	14's	14'sx10	14'sx10x10	1000000
90.	1093	Vildagliptin 50mg + Metformin 500mg Tablets	10's	10'sx10	(10's x10x10)x10	10000000
91.	1153	Carbamazepine 400mg Tabs CR/SR	10's	10'sx10	10'sx10x10	1000000
92.	1185	Cycloserine 250mg Capsules	6's	6'sx10	6'sx10 x10	300000
93.	1221	Thyroxine Sodium 50mcg Tabs	100's in bottle	1 bottle X10	(1's ×10×10)	500000
94.	1229	Levosalbutamol+Ipratropiu m(2.5+500)mcg Respules	2.5 ml	(2.5 ml x5 x4)x10	(2.5 ml x5 x4)x10	7500000
95.	1231	Levocarnitine+VitaminE (150+200)mg Tab.	10's	1'sx10	(1's x10x10)x10	1000000
96.	1233	Valethamate 8mg inj.	1ml	1'sx10	(1's x10x10)x10	1000000
97.	1237	Methyldopa tabs 500mg	10's	10'sx10	(10's x10x10)x10	300000
98.	1244	ZINC SULPHATE 20 MG/ 5 ML ORAL SOLUTION	15 ML	15 ML x20	15 ML x20X10	500000
99.	1255	ACEBROPHYLLINE (SR)+ MONTELUKAST TABLET	10's	10'sx10	(10'sx10x10)10	100000

		200/10MG				
100.	1261	AMILORIDE + HYDROCHLORTHIAZIDE TABLET 5/12.5 MG	10's	10'sx10	(10'sx10x10)10	60000
101.	1263	AMPICILLIN 500 MG CAPSULE	10's	10'sx10	(10'sx10x10)10	100000
102.	1267	ATENOLOL + INDAPAMIDE TABLET 50/2.5 MG	10's	10'sx10	(10's x10x10)x10	60000
103.	1268	ATENOLOL + S-AMLODIPINE TABLET 50/2.5 MG	10's	10'sx10	(10's x10x10)x10	250000
104.	1269	BACILLUS CLAUSII + ZINC SACHET	1 GM x10	1'sx10	(10's x10x10)x10	60000
105.	1270	BECLOMETHASONE + FORMETROL ROTACAP 200/6 MCG	30's	30'sx10	(30's x10x10)X10	100000
106.	1271	BENZONATATE CAPSULE 100 MG	12's	12'sx10	(10's x10x10)x10	60000
107.	1272	BENZTHIAZIDE + TRIAMTERENE TABLET 25/50 MG	10's	10'sx10	(10's x10x10)x10	50000
108.	1275	BUCLIZINE TABLET 25 MG	10's	10'sx10	(10's x10x10)x10	100000
109.	1276	CAMYLOFIN + DICLOFENAC INJECTION 25/25 MG	2 ML vial	1'sx10	10's x10x10	100000
	1277	CANAGLIFLOZIN TABLET 100 MG	10's	10'sx10	(10's x10x10)x10	60000
110.	1278	CARBAZOCHROME INJECTION 1 MG	2 ML vial	1'sx10	10x10x10	50000
111.	1279	CEFAZOLIN INJECTION 1000 MG	5 ML vial	1'sx10	(10's x10x10)x10	70000
112.	1282	CHLORPROMAZINE TABLET 100 MG	10's	10'sx10	(10's x10x10)x10	90000
113.	1283	CHLORTHALIDONE 6.25 MG TABLET	10's	10'sx10	(10's x10x10)x10	100000
114.	1284	CILNIDIPINE + TELMISARTAN TABLET 10/40 MG	10's	10'sx10	(10's x10x10)x10	200000

115.	1285	CINITAPRIDE TABLET 1 MG	10's	10'sx10	(10's x10x10)x10	160000
116.	1286	CINITAPRIDE + PANTOPRAZOLE CAPSULE 3/40 MG	10's	10'sx10	(10'sx10x10)10	160000
117.	1290	CYCLOBENZAPRINE GEL	30 GM tube	1'sx10	(10's x10x10)x10	60000
118.	1291	DABIGATRAN TABLET 110 MG	10's	10'sx10	(10's x10x10)x10	200000
119.	1296	INSULIN DETEMIR 100 IU/ml	3 ML CARTR IDGE WITH FLEXP EN	1'sx10	(1'sx10x10)x10	100000
120.	1297	DOMPERIDONE + RANITIDINE TABLET 10/150 MG	15's	15'sx10	(15's x10x10)x10	400000
121.	1299	DORZOLAMIDE EYE DROPS 2 %	5 ML	1'sx10	(1's x10x10)x10	60000
122.	1301	DROTAVERINE + ACECLOFENAC TABLET 80/100 MG	10's	10'sx10	(10's x10x10)x10	350000
123.	1303	EMPAGLIFLOZIN TABLET 10 MG	10's	10'sx10	(10's x10x10)x10	60000
124.	1304	EPLERENONE TABLET 25 MG	10's	10'sx10	(10's x10x10)x10	160000
125.	1308	ETHINYLESTRADIOL + LEVONORGESTREL TABLET 0.03/0.15 MG	21's	21'sx10	(21's x10x10)x10	250000
126.	1311	FENOFIBRATE TABLET 145 MG	10's	10'sx10	(10's x10x10)x10	200000
127.	1312	FLAVOXATE TABLET 200 MG	15's	15'sx10	(15's x10x10)x10	280000
128.	1313	FLUCONAZOLE + IVERMECTIN TABLET 150/6 MG	1's	1'sx10	(1's x10x10)x10	120000
129.	1315	FLUTICASONE FUROATE NASAL SPRAY 27.5 MCG	120 MDI	1'sx10	(1's x10x10)x10	100000
130.	1316	FONDAPARINUX INJECTION	0.5 ML	1'sx10	1'sx10x10	60000

		2.5 MG	PFS			
131.	1317	FOSPHENYTOIN 150 MG INJECTION	2 ML vial	1'sx10	(1's x10x10)x10	120000
132.	1319	GABAPENTIN TABLET 100 MG	10's	10'sx10	(10's x10x10)x10	280000
133.	1320	GABAPENTIN + AMITRIPTYLINE TABLET 300/10 MG	10's	10'sx10	(10's x10x10)x10	200000
134.	1324	HYDROXYPROGESTERONE 500 MG INJECTION	2 ml ampo ules	1'sx10	1'sx10x10	200000
135.	1327	ISOTRETINOIN CAPSULE 20 MG	10's	10'sx10	(10's x10x10)x10	500000
136.	1329	LACTITOL SYRUP 10 GM	200 ML bottle	1's x10	1'sx10x5	100000
137.	1330	LECITHIN CAPSULE 350 MG	10's	10'sx10	(10's x10x10)x10	120000
138.	1336	LINAGLIPTIN TABLET 5 MG	10's	10'sx10	(10's x10x10)x10	250000
139.	1337	LINAGLIPTIN + METFORMIN TABLET 2.5/500 MG	10's	10'sx10	(10's x10x10)x10	250000
140.	1344	MEROPENEM + SULBACTAM INJECTION 1000/500 MG	vial & WFI	1'sx10	1'sx10x10	200000
141.	1345	MEROPENEM INJECTION 500 MG	vial & WFI	1'sx10	1'sx10x10	200000
142.	1347	METHDILAZINE EXPECTORANT	100 ml	1'sx6	1'sx6x12	200000
143.	1350	METOPROLOL + RAMIPRIL TABLET 25/2.5 MG	10's	10'sx10	(10's x10x10)x10	200000
144.	1353	MIRTAZEPINE TABLET 7.5 MG	10's	10'sx10	(10's x10x10)x10	160000
145.	1355	MYO-INOSITOL + D- CHIROINOSITOL + VITAMIN D3 SACHET 2GM/50MG/1000IU	5 GM Sache t	1'sx10	(1's x10x10)x10	160000
146.	1356	MYO-INOSITOL + D- CHIROINOSITOL + VITAMIN D3 + CHROMIUM PICOLINATE CAPSULE	10's	10'sx10	(10's x10x10)x10	120000

		550MG/13.8MG/200IU/100M CG				
147.	1361	NICORANDIL TABLET 5 MG	20's	20'sx10	(20's x10x10)x10	600000
148.	1365	NORFLOXACIN EYE/EAR DROPS 0.30 %	10 ML	1'sx10	(10's x10x10)x10	1000000
149.	1367	OLMESARTAN + AMLODIPINE + HYDROCLORTHIAZIDE TABLET 20/5/12.5MG	10's	10'sx10	(10's x10x10)x10	1000000
150.	1371	ORNIDAZOLE INFUSION 500 MG	100 ML vial	1'sx10	(10's x10x10)x10	200000
151.	1372	PANCREATIN + ORNITHINE TABLET 100/150 MG	10's	10'sx10	(10's x10x10)x10	120000
152.	1386	RAMIPRIL + HYDROCLORTHIAZIDE TABLET 5/12.5 MG	10's	10'sx10	(10's x10x10)x10	350000
153.	1392	ROSUVASTATIN + ASPIRIN CAPSULE 10/75 MG	10's	10'sx10	(10's x10x10)x10	400000
154.	1393	ROSUVASTATIN + CLOPIDOGREL CAPSULE 10/75 MG	10's	10'sx10	(10's x10x10)x10	350000
155.	1395	SENNA TABLET 12 MG	10's	10'sx10	(10's x10x10)x10	50000
156.	1398	SILODOSIN 8 MG TABLET	10's	10'sx10	(10's x10x10)x10	60000
157.	1411	TELMISARTAN + CHLORTHALIDONE TABLET 40/6.25MG	10's	10'sx10	(10's x10x10)x10	280000
158.	1417	THIOCOLCHICOSIDE CAPSULE 4 MG	10's	10'sx10	(10's x10x10)x10	120000
159.	1433	VOGLIBOSE + METFORMIN + GLIMEPIRIDE TABLET SR 0.2/500/2 MG	10's	10'sx10	(10's x10x10)x10	1200000
160.	1437	Cefpodoxime proxetil 50 mg oral Suspension	30ml	1'sx10	(1'sx10x10)x5	5000000
161.	1	Aceclofenac + Paracetamol (100 mg + 325mg) Tablets	10's	10's x10	(10's x10x10)x10	1500000

## Annexure – VIII

{Ref:- clause 8.1(ii)}

(1)	(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.	1	Aceclofenac + Paracetamol (100 mg + 325mg) Tablets	10's			
2.	6	DICLOFENAC 50 mg+ PARACETAMOL 325 mg+ CHLORZOXAZONE 500 mg Tablets	10's			
3.	22	Paracetamol Syrup IP 125mg/5ml	60 ml			
4.	24	Pentazocine Injection IP 30mg/ml	1 ml			
5.	30	Amikacin Injection IP 100mg/2ml	2ml Vial			
6.	44	Amoxycillin Capsules IP 250mg	10's			
7.	45	Amoxycillin Capsules IP 500mg	10's			
8.	51	Cefadroxil Dispersible Tablets 250mg	10s			
9.	52	Cefadroxil 500mg Film Coated Tablet	10's			
10.	70	Ceftriaxone 1000mg+ Sulbactam 500 mg Inj.	Vial & wfi			
11.	74	Ceftriaxone 500mg with Sulbactum 250mg Injection	Vial with WFI			
12.	75	Ceftriaxone Injections IP 1g	Vial & wfi			
13.	94	Gentamycin Sulphate 80 mg/ 2ml Inj.	2 ml			
14.	98	Norfloxacin 400 mg + Tinidazole 600 mg film coated Tablet	10's			
15.	99	Norfloxacin 400 mg film coated Tablet	10's			
16.	103	Piperacillin 4gm + Tazobactum 0.5 gm Inj.	Vial & wfi			
17.	115	Calamine Lotion	100 ml			
18.	143	INSULIN INJECTION (INSULIN HUMAN SOLUBLE 30% & ISOPHANE 70%) 40 IU/ML 10ml Vial	10 ml Vial			
19.	153	Cisplatin Injection IP10	vial			

		mg		
20.	164	Tamoxifen Citrate 20 mg I.P Tablets	10's	
21.	177	Albendazole Suspension IP 200 mg/ 5ml	10 ml	
22.	183	Dicyclomine Tablets IP 10mg	10's	
23.	185	Diethylcarbamazine citrate 100 mg film coated Tablets	10's	
24.	206	Omeprazole 20mg + Domperidone 10 mg Caps	10's	
25.	215	Rabeprazole Gastro- resistant Tablets IP 20mg	10's	
26.	218	Ranitidine HCl film coated Tablets 300mg	10's	
27.	229	Haematinic syrup of Iron,Folic acid and Vitamin B12	100 ml	
28.	231	VITAMIN B1 10mg, B2 10mg, B3 45mg, B5 50mg, B6 3mg, B12 15mcg Tablets	10's	
29.	232	Vitamin B-Complex Syrup	200 ML	
30.	252	Levocetrizine 5mg and Montelukast Sodium 10mg film coated Tablet	10's	
31.	254	Promethazine (5mg/5ml) syrup	100 ml	
32.	255	Salbutamol 100 mcg/puff Inhaler	200 mdi	
33.	260	Salbutamol 4 mg tablets	10's	
34.	275	Enalapril 5 mg Tablets	10's	
35.	278	Frusemide (10 mg/ ml)	2ml	
36.	281	Heparin Sodium 5000iu/ ml Inj.	5 ml	
37.	311	Disodium hydrogen Citrate (Alkalyser) 1.4 gm/5ml Syrup	100 ml	
38.	327	PHENYTOIN Tablets IP 100 mg	100's in bottle	
39.	328	Prochlorperazine Tablets IP 5mg	10's	
40.	343	Chloramphenicol 1%w/v Eye Applicaps , 250 mg each.	10's	
41.	345	Gentamycin 0.3% w/v Eye Drop	10 ML	
42.	351	Xylometazoline Nasal Drop IP 0.1%w/v	10 ML	
43.	356	Lignocaine Injection IP 2%w/v	30 ml Vial	

44.	357	Lignocaine 1% +	30 ml	
		Adrenaline 2%w/v Inj.	Vial	
45.	359	Tetanus Toxoid 40 IU Inj.	0.5 ml	
	<u> </u>	, ,	Amp.	
4.0		CLARCINE 400 III / ml	CARTRIDG	
46.	363	GLARGINE 100 IU / ml	E/vial 3	
	363	INJECTION Cartridge 3 ml	ML	
47.	379	RIFAMPICIN and ISONIAZIDE TABLETS IP (450 MG+300	10's	
47.	3/3	MG)	10.5	
48.	416	PRAZOSIN TABLETS IP 5 MG	15's	
40.	410		13.5	
49.	425	DILTIAZEM TABLETS SR 90 MG	10's	
	<u> </u>	AMLODIPINE 5 MG +		
50.	446	HYDROCHLOROTHIAZI	10's	
50.	770	DE 12.5 MG TABLETS	103	
		LABETALOL TABLETS IP		
51.	450	100 MG	10's	
F.2	400	LANSOPRAZOLE CAPSULES	401-	
52.	488	IP 15 MG	10's	
F2	-00	LEVETIRACETAM Tablets 500	4015	
53.	508	mg	10's	
		DICLOFENAC 1.16 w/w+		
		LINCEED OIL3% w/w+	1	
54.	525	METHYL SALICYLATE	30 GM	
		10% w/w+MENTHOL 5%		
		w/w GEL		
		TERBUTALINE 2.5 MG +	1	
55.	535	BROMHEXINE 8 MG	100 ML	
	<del>                                     </del>	syrup	<del> </del> '	
56.	555	DOXOFYLLINE TABLETS IP	10's	
	<u> </u>	400 MG		
F-7	560	FLUTICASONE PROPIONATE	120 MD	
57.	560	50 MCG PER PUFF NASAL SPRAY	120 MD	
	<del> </del>	OXYMETAZOLINE 0.5		
58.	563	MG/ML NASAL DROPS	10 ML	
		VACCINE RABIES		
59.	574	INJECTION 2.5 IU	1 ML	
		CALCIUM CARBONATE		
60	581	500MG+CALCITRIOL	10'6	
60.	201	0.25 MCG + ZINC 7.5 MG	10's	
		Capsules	<u> </u>	
		APPETITE ENHANCER	1	
61.	587	(PEPTONE, MINERALS,	300 ML	
	<u> </u>	VITAMINS )SYRUP	<b> </b> '	
62.	591	METHYLCOBALAMIN	1 ML	
	<u> </u>	500 MCG INJECTION		
63.	626	Ketoconazole Shampoo	100 ML	
C.4	627	2% W/V	bottle	
64.	627	Etophylline IP 115mg +	10's	

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		Theophylline 35mg		
		Prolonged Release Tablet		
		Diclofenac diethylamine BP 1.116% (equivalent to diclofenac sodium 1.0%, Linseed oil BP 3.0% + Methyl		
65.	646	Salicylate IP 10.0%, Capsiacin USP 0.025%, Menthol IP 0.025%, Benzyl alcohol IP 1.0% (as preservative) In a gel base q.s.	30GM	
66.	656	Enzyme Drops Pepsin (1:3000) 5 mg + Fungal Diastase (1:1200) 33.33 mg/ml	15ML	
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.	672	Mometasone Furoate 0.1%w/w cream	15GM	
69.	698	Sulfacetamide eye drop 20 %	20 ml	
70.	710	Piroxicam 40 mg with bezyl alcohol injection	2ml	
71.	718	Escitalopram 10mg with Clonazepam 0.5mg	10's	
72.	725	Dextrose Injection IP 5 %, iv fluid plastic container using FFS/ BFS technology	500ml	
73.	726	Dextrose Injection IP 10 %, iv fluid plastic container using FFS/ BFS technology	500ml	
74.	728	Sodium Chloride (0.9% W/V) and Dextrose 5% w/v Injection IP, i.v fluid plastic container using FFS/BFS Technology	500ml	
75.	739	Cefuroxime Tablets IP 125mg	6's	
76.	758	Vildagliptin Tablet 50 mg	14's	
77.	779	Alpha Lipoic acid 100mg, Vit.	10's	

1	1		1	Г	
		D3 1000 IU, Folic acid			
		1.5mg, Pyridoxine 3mg,			
		Methylcobalamin 1500mcg			
		Tablets			
78.	811	Bromfenac Sodium Eye	5ml		
70.	011	Drop 0.09%	51111		 
79.	817	Calcium Carbonate 1250 Mg, Vitamin D3 250 lu, Magnesium Oxide 40 Mg, Manganese Sulphate 1.8	10's		
		Mg, Zinc Sulphate 7.5 Mg, Copper Sulphate 1 Mg, Sodium Borate 250 Mcg Film Coated Tablets			
80.	838	Cilostazol Tablets IP 50mg	10's		
81.	850	Cyclosporin Soft Gelatin Capulses IP 50mg	5's		
82.	881	Ebastine Film Coated Tablets 10mg	10's		
83.	904	Glimepiride 1mg Metformin SR 500mg Tablets	10's		
84.	926	Ketoconazole Cream 2%w/w	15gm Tube		
85.	951	Lycopene 1000 Mcg, Vitamin A Palmitate 2500 Iu, Vitamin E Acetate 10 Iu, Selenium 35 Mcg, Vitamin C 50 Mg, Zinc Gluconate 3 Mg, Manganese Gluconate 2 Mg, Iodine 100 Mcg, Copper 500 Mcg, Thiamine Hydrochloride 2 Mg, Riboflavin 3 Mg, Pyridoxine Hydrochloride 1.5 Mg Syrup	200ml		
86.	975	Nebivolol 5 mg, Hydrochlorothiazide 12.5 mg Tab.	10's		
87.	1024	Promethazine Injection I.P 25 mg/ml	2ml		
88.	1029	Pyrazinamide Tablets I.P 1000mg	10's		
89.	1080	Ticagrelor Tablets 90mg	14's		
90.	1093	Vildagliptin 50mg + Metformin 500mg Tablets	10's		
91.	1153	Carbamazepine 400mg Tabs CR/SR	10's		
92.	1185	Cycloserine 250mg Capsules	6's		
93.	1221	Thyroxine Sodium 50mcg	100's in		
		,		ı l	

1		Tabs	bottle	
		Levosalbutamol+lpratropi		
94.	1229	um(2.5+500)mcg	2.5 ml	
		Respules		
95.	1231	Levocarnitine+VitaminE	10's	
		(150+200)mg Tab.		
96.	1233	Valethamate 8mg inj.	1ml	
97.	1237	Methyldopa tabs 500mg	10's	
98.	1244	ZINC SULPHATE 20 MG/ 5 ML ORAL SOLUTION	15 ML	
	1255	ACEBROPHYLLINE (SR)+		
99.		MONTELUKAST TABLET	10's	
		200/10MG AMILORIDE +		
100.	1261	HYDROCHLORTHIAZIDE	10's	
100.	1201	TABLET 5/12.5 MG	103	
		AMPICILLIN 500 MG	•	
101.	1263	CAPSULE	10's	
102	1267	ATENOLOL + INDAPAMIDE	1010	
102.	1267	TABLET 50/2.5 MG	10's	
103.	1268	ATENOLOL + S-AMLODIPINE	10's	
105.	1200	TABLET 50/2.5 MG	103	
104.	1269	BACILLUS CLAUSII + ZINC	1 GM x10	
		SACHET		
105.	1270	BECLOMETHASONE + FORMETROL ROTACAP	30's	
103.		200/6 MCG		
		BENZONATATE CAPSULE 100		
106.	1271	MG	<b>12</b> 's	
		BENZTHIAZIDE +		
107.	1272	TRIAMTERENE TABLET	10's	
		25/50 MG		
108.	1275	BUCLIZINE TABLET 25 MG	10's	
109.	1276	CAMYLOFIN + DICLOFENAC	2 ML vial	
		INJECTION 25/25 MG		
110.	1277	CANAGLIFLOZIN TABLET	10's	
		100 MG CARBAZOCHROME		
111.	1278	INJECTION 1 MG	2 ML vial	
		CEFAZOLIN INJECTION	_	
112.	1279	1000 MG	5 ML vial	
112	1282	CHLORPROMAZINE TABLET	10's	
113.	1282	100 MG	10.5	
114.	1283	CHLORTHALIDONE 6.25 MG	10's	
	1200	TABLET		
115.	1284	CILNIDIPINE + TELMISARTAN	10's	
		TABLET 10/40 MG		
116.	1285	CINITAPRIDE TABLET 1 MG	10's	
117.	1286	CINITAPRIDE + PANTOPRAZOLE CAPSULE	10's	
		TANTOFNAZULE CAPSULE		

		3/40 MG			
118.	1290	CYCLOBENZAPRINE GEL	30 GM		
119.	1291	DABIGATRAN TABLET 110	tube 10's		
119.	1291	MG			
120.	1296	INSULIN DETEMIR 100 IU/ml	3 ML CARTRIDG E WITH FLEXPEN		
121.	1297	DOMPERIDONE + RANITIDINE TABLET 10/150 MG	15's		
122.	1299	DORZOLAMIDE EYE DROPS 2 %	5 ML		
123.	1301	DROTAVERINE + ACECLOFENAC TABLET 80/100 MG	10's		
124.	1303	EMPAGLIFLOZIN TABLET 10 MG	10's		
125.	1304	EPLERENONE TABLET 25 MG	10's		
126.	1308	ETHINYLESTRADIOL + LEVONORGESTREL TABLET 0.03/0.15 MG	21's		
127.	1311	FENOFIBRATE TABLET 145 MG	10's		
128.	1312	FLAVOXATE TABLET 200 MG	15's		
129.	1313	FLUCONAZOLE + IVERMECTIN TABLET 150/6 MG	1's		
130.	1315	FLUTICASONE FUROATE NASAL SPRAY 27.5 MCG	120 MDI		
131.	1316	FONDAPARINUX INJECTION 2.5 MG	0.5 ML PFS		
132.	1317	FOSPHENYTOIN 150 MG INJECTION	2 ML vial		
133.	1319	GABAPENTIN TABLET 100 MG	10's	 	
134.	1320	GABAPENTIN + AMITRIPTYLINE TABLET 300/10 MG	10's		
135.	1324	HYDROXYPROGESTERONE 500 MG INJECTION	2 ml ampoules		
136.	1327	ISOTRETINOIN CAPSULE 20 MG	10's		
137.	1329	LACTITOL SYRUP 10 GM	200 ML bottle		
138.	1330	LECITHIN CAPSULE 350 MG	10's		
139.	1336	LINAGLIPTIN TABLET 5 MG	10's		
140.	1337	LINAGLIPTIN + METFORMIN TABLET 2.5/500 MG	10's		

141.	1344	MEROPENEM + SULBACTAM INJECTION 1000/500 MG	vial & WFI	
142.	1345	MEROPENEM INJECTION 500 MG	vial & WFI	
143.	1347	METHDILAZINE EXPECTORANT	100 ml	
144.	1350	METOPROLOL + RAMIPRIL TABLET 25/2.5 MG	10's	
145.	1353	MIRTAZEPINE TABLET 7.5 MG	10's	
146.	1355	MYO-INOSITOL + D- CHIROINOSITOL + VITAMIN D3 SACHET 2GM/50MG/1000IU	5 GM Sachet	
147.	1356	MYO-INOSITOL + D- CHIROINOSITOL + VITAMIN D3 + CHROMIUM PICOLINATE CAPSULE 550MG/13.8MG/200IU/100MC G	10's	
148.	1361	NICORANDIL TABLET 5 MG	20's	
149.	1365	NORFLOXACIN EYE/EAR DROPS 0.30 %	10 ML	
150.	1367	OLMESARTAN + AMLODIPINE + HYDROCLORTHIAZIDE TABLET 20/5/12.5MG	10's	
151.	1371	ORNIDAZOLE INFUSION 500 MG	100 ML vial	
152.	1372	PANCREATIN + ORNITHINE TABLET 100/150 MG	10's	
153.	1386	RAMIPRIL + HYDROCLORTHIAZIDE TABLET 5/12.5 MG	10's	
154.	1392	ROSUVASTATIN + ASPIRIN CAPSULE 10/75 MG	10's	
155.	1393	ROSUVASTATIN + CLOPIDOGREL CAPSULE 10/75 MG	10's	
156.	1395	SENNA TABLET 12 MG	10's	
157.	1398	SILODOSIN 8 MG TABLET	10's	
158.	1411	TELMISARTAN + CHLORTHALIDONE TABLET 40/6.25MG	10's	
159.	1417	THIOCOLCHICOSIDE CAPSULE 4 MG	10's	
160.	1433	VOGLIBOSE + METFORMIN + GLIMEPIRIDE TABLET SR 0.2/500/2 MG	10's	
161.	1437	Cefpodoxime proxetil 50 mg oral Suspension	30ml	

### **ANNEXURE-IX**

Ref: Clause No. 9.5

### Letter of acceptance of tender for price agreement

Ref. No.	Ref. No. BPPI/ Drug – 064/2018						Date:	•••••
Sub: To	nce tender f	the Suppl	y of Drug reement ar	d Deposit o	of Performa	nce Securi	ty Amount.	
Ple against so BPPI for	(Technic rase refer to ubject tende	your quotat r read with 2018-2020,	ion i.e. tech your subsether rate of	ce bid).  hnical and pequent claritefered/accep	orice bid (BC fication/conf oted by you	OQ) along v irmation fo	with enclosu	res/Annexure y of Drugs to ved for price
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)
					0.00.		0.00.	
					Total va	lue of price	agreement	
bank guara within 15 c Guarantee t Performanc	ntee from sc lays from th towards perf	heduled bar he date of recommended by commended by deposit if pa	nk which is eceipt of the curity depos	equivalent to is letter for sit shall be a	to Rs the supply ones per Annex	as stipulate of <b>Drugs to</b> ure X of ten	ed in the tent <b>BPPI</b> . For ader docume	or irrevocable der document mat for Bank ent. ears from the
		_	-		applicable as		l in tender o	document. By
Please ackn	nowledge red	ceipt.						
						,BPPI		

BPPI/Drug-064/2018

Speed post/e-mail

### **ANNEXURE -X**

### Ref. Clause No.10.1

# **Performance Security Bank Guarantee**

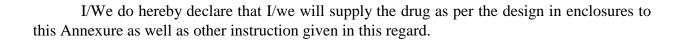
(unconditional)

To: Bureau of Pha Videocon Tower, B			•		of purchaser) 8 <sup>th</sup> l	Floor,
WHEREAS Supplier) herein ca 064/2018 Dtd. 07/0 Services) hereinafte	alled "the Su 06/2018 to sup	oply of <b>Drugs fo</b>	ertaken, i	n pursuance o	of Tender BPPI/D	RUG-
AND WHE shall furnish you compliance with the	with a Ban	k Guarantee for	r the sur	m specified to		
AND WHE	REAS we ha	ave agreed to give	e the Supp	plier a Guarant	ee	
the Supplier to be sums within the li Words and Figures for your demand or This guarantee is va	the res) and we used in default undefault undefault undefault undefault undefault default undefault und eine un	Supplier, undertake to pay nder the Contrac  d, without your neified therein.	up you, upor t and wit eeding to	to(Amount your first with hout cavil or	argument., any sunt of the Guarant now grounds or re	of rantee laring or tee in
				Signature and	d Seal of Guaranto	ors
				Date		.2016
				Address		

### **ANNEXURE -X1**

Ref. Clause no 13

## **DECLARATION**



Signature of the Tenderer

Name

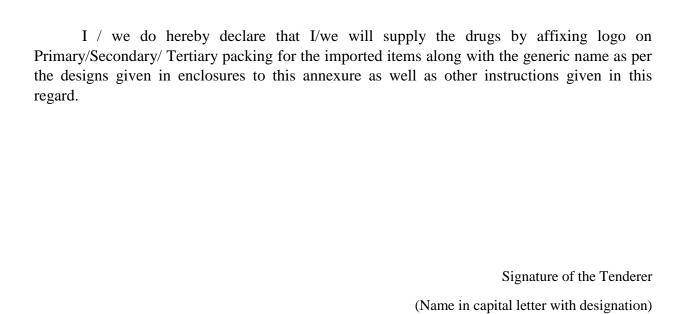
Designation

(Company Seal)

### $\underline{ANNEXURE} - X1(\underline{A})$

Ref. Clause No. 13

## **UNDERTAKING**



### Enclosure–1 to <u>ANNEXURE</u> - <u>X1</u> AND <u>X1 (</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>X1</u> & <u>ANNEXURE</u> – <u>X1</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 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>X1</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: Any additional statuary requirement under Drug & Cosmetic Act 1940 and rules 1945 shall be printed.

### **ANNEXURE-XII**

#### Ref. Clause No.14.1

### SCHEDULE FOR PACKAGING OF DRUGS

#### **GENERAL SPECIFICATIONS**

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

- 16. Two Horizontal/vertical/standing lines in two different colour will be there on Primary and secondary packaging, so as to differentiate therapy groups. The colours of lines will be intimated during Artwork approval.
- 17. The primary packing should be decided by the party depending on the drug category as per D&C act. For e.g if drug is hygroscopic then tablet should be packed in Alu/Alu blister or if it is light sensitive then to be packed in Amber colour PVC e.t.c.

### (Schedule)

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 degree should not crack.
6.	TAPE
	Every box should be sealed with gum tape running along the top and lower opening.
7.	CARRYSTRAP:
	Every box should be strapped with two parallel nylon carry straps (they should intersect).
8.	LABEL
	The product label on the carton should be large at least 15 cms x 10 cms dimension.
	It should carry the correct technical name, strength of the product, date of
	manufacturing, date of expiry, quantity packed and net weight of the box.
9.	OTHERS
	No box should contain mixed products or mixed batches of the same product.

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

- (1) The box should not weigh more than 7-8 kgs. The grammage of outer box should be 150 gsm and inside partition / lining should be 120 gsm.
- (2) The box should be of 7 ply with bursting strength of 9 Kg  $\!\!/$  Cm2 BPPI/Drug-064/2018

# 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 -XIII**

# **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		
	b) Branch Name &		
	address		
	c) Branch Code No.		
	d) Branch Manager		
	Mobile No.		
	e) Branch Telephone no		
	f) Branch E-mail ID		
	g) 9 digit MICR code		
	number of the bank		
	and branch appearing		
	on the MICR cheque		
	issued by the bank		
	h) IFSC Code of the		

Branch	
i) Type of Account	
(Current / Savings)	
j) Account Number (as	
appear in cheque	
book)	

(In lieu of the bank certificate to be obtained, please <u>upload the original cancelled cheque</u> issued by your bank for verification of the above particulars).

I / We hereby declare that the particulars given above are correct and complete. If the transaction is delayed or not effected at all the reasons of incomplete or incorrect information, I would not hold Bureau of Pharma Public Sector Undertakings of India (BPPI) responsible. I have read the conditions of the tender / Price agreement and agree to discharge the responsibility expected of me / from the company as a tenderer / successful tenderer.

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

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

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