

E-TENDER for urgent requirement of Generic Drugs

TENDER REFERNCE No: BPPI/DRUG- 053/2017 Dated: - 11/08/2017

C.E.O., BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA invites Online Bids for Purchase of Generic Drugs through e-procurement portal https://eprocure.gov.in/eprocure/app

Bidders are advised to note supply schedule of drug under the tender. The quantity of these drugs are to be manufactured as per BPPI Packaging and to be supplied in short period.

BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA

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

IDPL corporate office Complex, Old Delhi-Gurgaon Road, Dundahera, Gurgaon 122016

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BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA (BPPI)

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

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ONLINE TENDER FOR THE SUPPLY OF DRUGS TO BUREAU OF PHARMA PSU OF INDIA FOR THE YEAR 2017

Tender Reference	BPPI/DRUG-053/2017 Dt. 11/08/2017
Date of availability of tender documents on website	12/08/2017 (Saturday)
Last date and time for submission of Online Bid i.e. Bid Submission End Date and time	28/08/2017 upto 11:00 A.M.
Last Date for submission of EMD in physical Form in office of Bureau of Pharma PSUsof India, IDPL corporate office Complex, Old Delhi-Gurgaon Road, Dundahera, Gurgaon- 122016 (Haryana)	29/08/2017
Time and date of opening of Technical Bid	11:30 AM on 29/08/2017 (Tuesday)
Place of opening of tender	Bureau of Pharma PSUs of India,
	IDPL corporate office Complex, Old Delhi-Gurgaon Road, Dundahera, Gurgaon- 122016 (Haryana)
Address for Communication	Bureau of Pharma Public Sector Undertakings of India, IDPL corporate officeComplex, Old Delhi-Gurgaon Road, Dundahera, Gurgaon- 122016 (Haryana)

Cost of the Tender Document	Free of cost
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The tender document can be downloaded free of cost from the CPPP e-Procurement Portal https://eprocure.gov.in and from the website of BPPI: janaushadhi.gov.in.

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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>

PRIME MINISTER BHARTIYA JANAUSHADHI PARIYOJANA(PMBJP) is the initiative of Department of Pharmaceuticals, Ministry of Chemical and Fertilizer, Government of India launching with the noble objective of making quality generic medicines available at affordable prices for all, particularly the poor and disadvantaged, through specialized outlets called Prime Minister Bhartiya 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 PMJAY.

The Bureau has been registered as an independent society under the Societies Registration Act, 1860, in April, 2010. It aims to open more than 3000 stores during current financial year. It is proposed to channelize efforts to popularize PMJAY 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, IDPL Corporate Office, IDPL Complex, Old-Delhi-Gurgaon Road, Dundahera, Gurgaon -122016 (Haryana) (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 urgent requirement of Generic Drugs to BUREAU OF PHARMA PUBLIC SECTOR UNDERTAKINGS OF INDIA.

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

- (a) Online Bids [in two separate Cover {Technical bid ("Cover A") and price bid (Cover "B")}] will be submitted till **11.00 A.M upto 28/08/2017 (Monday) on** CPP portal i.e. eprocure.gov.in.
- (b) The price bid shall be valid for a period of 120 days from the date of opening of Technical Bid. Prior to the expiry of the bid validity, the Tender Inviting Authority may request the Tenderers to extend the bid validity for further period as deemed fit on their original quoted prices and all terms &conditions. However, BPPI reserves the right to place purchase orders at the quoted rate till such period.

2. ELIGIBILITY CRITERIA

- (a) (i) Tenderer shall be a manufacturer having valid drug manufacturing unit duly licensed by licensing authorities. Loan licensee is also eligible.
- (ii) Tenderer shall be direct importer holding valid import license. The Importer should have valid sale license.
- (iii) Tenderer shall be a marketer of manufacturer who have exclusive rights to market the products and manufacturer do not market the products duly supported by valid agreement with the manufacturer and in that case BPPI shall sign tri party agreement for supply of drugs if they are eligible for award of contract. **Distributors/Suppliers/Agents are not eligible to participate in the Tenders.** The Marketer should have valid sale license.
- (b) (i) Manufacturer should have valid WHO-GMP (World Health Organisation-Good Manufacturing Practices) certificate issued by licensing authority.
 - (ii) Average Annual turnover of manufacturer in the last three years i.e.2013-14, 2014-15 and 2015-16 shall not be less than **Rs. 10 Crores.** In case of loan licensees and Marketer, average annual turnover of manufacturer in the last three years i.e. 2013-14, 2014-15 and 2015-16 shall not be less than **Rs. 10 Crores.**
- (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) A certificate from their C.A. (Chartered Accountant) or ICWA that they have manufactured & marketed at least 2 commercial batch in last three years.
- (e) Non-conviction Certificate not older than 6 month issued by the licensing authority of the State certifying that the firm/company has not been convicted.
- (f) A certificate from the C.A. (Chartered Accountant) or ICWA that the bidder 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.
- (g) 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.

- (h) The Tenderer should have not been blacklisted/debarred/de-registered/banned due to quality failure for the quoted product /firm by any State Government / Central Government / 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.
- (i) 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.
- (j) 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.
- (k) Tenderer are required to incorporate bar codes as per GS1 standards at various packaging levels (primary, secondary and tertiary. (ANNEXURE I)

3. GENERAL CONDITIONS.

- (i) The tender document shall be download from the websites janaushadhi.gov.in;and CPP portal i.e.eprocure.gov.in. Tender Document is free of cost. No tender cost is to be deposited.
- (ii) EMD (Earnest Money Deposit): EMD of Rs. 4,00,,000/- (Rupees four 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, Gurgaon on or before the date stipulated against 'Bid opening Date'. Name & full address of the bidder may be written at the back of the Demand Draft/Pay Order. Signed and scanned soft copy of the EMD instrument must be uploaded (ANNEXURE IV) to the e-Procurement portal. EMD in any other form like cheque/cash/postal order etc. will not be accepted. The Bid (in case not exempted for EMD as mentioned in tender document) without EMD shall be summarily rejected.
- (iii) Tenders will be opened online. However, authorized representatives of bidder who like to attend online bid opening on the specified date and time should bring letter of authority authorising to attend online bid opening on the printed letter head of the company.
- (iv) (a) At any time prior to the last date of submission of online bid, Tender Inviting Authority may, for any reason, whether on own initiative or in response to a clarification requested by a prospective Tenderer, may modify the condition in Tender documents by

an amendment uploading on website on **janaushadhi.gov.in**; and CPP portal i.e. **eprocure.gov.in** will be binding on them. In order to provide reasonable time to take the amendment into account in preparing their bid, Tender Inviting Authority may at discretion, extend the date and time for submission of online bid.

- (b) Any person who has downloaded the tender document should watch for amendment, if any, on the website **janaushadhi.gov.in**; and CPP portal i.e. **eprocure.gov.in** for which BPPI will not issue any separate communication to them.
- (v) Interested eligible Tenderers may obtain further information in this regard from the office of the Tender Inviting Authority on all working days between 10:00 AM and 5:00 PM
- (vi) During tender or agreement period, if L1 bidder is debarred/deregistered/blacklisted/banned by any Central Government or state Government or its procurement agencies due to quality failure, BPPI may purchase the drugs from L2 bidder or may go for fresh tender as per discretion of BPPI.
- (vii) The BPPI reserves the right to purchase any drugs full or part quantity from PSU as per discretion of BPPI. In case of emergencies, BPPI may go to PSU and price will be as per negotiation and at the discretion of BPPI.

3.1 SPECIAL CONDITIONS.

- (i)Bids shall be submitted online only at CPPP website:https://eprocure.gov.in. Manual bids shall not be accepted except for the original documents/instruments as mentioned in tender document.
- (ii) Bidders are advised to follow the 'Special Instructions to the Contractors/Bidders for the e-submission of the bids online' available through the link 'Help for Contractors' at the e-Procurement Portal https://eprocure.gov.in.
- (iii) Bidder shall not modify the downloaded tender form including downloaded price Bid template in any manner. In case any tender form/Price bid template is found to be tampered with/modified in any manner, such bid will be summarily rejected, Bid Security would be forfeited and bidder is liable to be banned from doing business with BPPI.
- (iv)Bidders are advised to check the *website of BPPI: janaushadhi.gov.in* and CPPP website https://eprocure.gov.in at least 3 days prior to closing date of submission of tender for any corrigendum, addendum, or amendment to the tender document.

4. TECHNICAL BID - COVER "A"

4.1. The Tenderer should upload the following documents in while submitting technical bid hereafter called <u>"Cover A"</u>. (Scanned copies of each page of all documents should be uploaded while submitting Technical bid).

- (a) (i) The marketer of manufacturer who have exclusive rights to market the products and manufacturer do not market the products should upload valid agreement with the manufacturer with technical bid (ANNEXURE II) and the original agreement should be submitted on or before the schedule date of technical bid opening. In case, bidder is a marketer of a manufacturer, scanned copy of valid sale license is required to be uploaded. The Importer is also required to upload copy of valid sale license. In case bidder is Importer, it is not mandatory to submit ANNEXURE II but it is advisable to submit the same from their Manufacturer.
- (ii) The tenderers are required to upload scanned undertaking on stamp paper duly notarized by authorised signatory confirming 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, undertaking as per para 2(h) & (j), undertaking to supply the drug with bar code as per ANNEXURE I and as per Annexure XIII & XIII A, undertaking for Clause 7.2 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. 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/agreement shall be cancelled with forfeiture of EMD/Security Deposit/Bank guarantee(ANNEXURE - III). The original ANNEXURE III should be submitted to BPPI, Gurgaon on or before the schedule date of technical bid opening.
- (b) Earnest Money Deposit as indicated in Clause 3(ii) and Clause 7. of the tender document shall be in the form of **Bank Guarantee or Bankers Cheque or Demand Draft** favouring "Bureau of Pharma Public Sector Undertakings of India ", payable at Gurgaon/Delhi. Tender cost and EMD in any other form like *cheque/cash/postal order* etc. will not be accepted. Scanned soft copy of the EMD instrument must be uploaded (ANNEXURE IV) to the e-Procurement portal. and original EMD instrument should be submitted to BPPI, Gurgaon on or before the schedule date of technical bid opening.
- (c) (i) Documentary evidence for the constitution of the Company/Firm such as Memorandum and Articles of Association, Partnership deed, Permanent Registration Number etc. with details of the Name, Address, Telephone Number, Fax Number, email address of the firm and of the Managing Director / Partners / Proprietor. The list of present Directors in the Board of the Company duly certified by a Company Secretary of the Company/Practicing Company Secretary / Chartered Accountant to be uploaded.
- (ii) In case the bidder is MSME, documentary evidence for valid MSME certificate for quoted drugs is required to upload with technical bid failing which the bidder shall be treated as non MSME. Further, MSME unit owned by SC/ST entrepreneurs

if applicable, is also required to upload documentary evidence with techn (d) The instruments such as power of attorney, resolution of board etc., authorizing an officer of the Tenderer as the Authorized signatory of the Company/Firm should be uploaded.

- (e) 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.
- (f) (i) A certificate from the C.A.(Chartered Accountant) or ICWA that the bidder has Production & financial capacity to manufacture (as per format ANNEXURE V) and deliver the drugs quoted by the firm in the tender as per quantity mentioned in tender during contract period. The certificate should be uploaded along with the technical bid. In case the bidder is Importer, a certificate from the C.A.(Chartered Accountant) or ICWA that the bidder has Financial capacity to manufacture (as per format ANNEXURE VA) and deliver the drugs quoted by the firm in the tender as per quantity mentioned in tender during contract period. The certificate should be uploaded along with the technical bid.
- (ii) Average Annual Turnover certificate from Chartered Accountant of manufacturer (in cluding manufacturer of loan licensees and Marketer) in the last three years i.e.2013-14, 2014-15 and 2015-16 certifying not be less than **Rs. 10 Crores is required to upload as per format(ANNEXURE-VI).** The certificate from C.A. (Chartered Accountant) is required to upload as per format(ANNEXURE-VI).
- (g) 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).
- (h) 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.
- (i) MARKET STANDING CERTIFICATE (MSC) ISSUED BY THE STATE LICENSING AUTHORITY UNDER generic or brand name as a Manufacturer for each product quoted in the tender for a minimum 2 years (Certificate should be uploaded with list of items). In case of direct importer, evidence for importing the said items such as bill of landing, bill of entry and certificate of analysis are to be uploaded. MSC issued under brand name or under generic name (by the state licensing authority) will also be accepted but supplies will be accepted as per packing and label by foreign manufacturer in their brand subject to affixing sticker for Logo as approved by BPPI & BPPI MRP. However, for those newly launched drugs whose first product permission to manufacture and sale has been issued within 2 years by the respective country's / state drug authority, MARKET STANDING CERTIFICATE (MSC) issued by the respective country's /STATE LICENSING AUTHORITY under generic or brand name as a Manufacturer for less than 2 years

shall be acceptable to BPPI. In case the bidder is Importer, MARKET STANDING CERTIFICATE (MSC) ISSUED BY THE STATE LICENSING AUTHORITY shall not be applicable.

- (j)The bidder should upload a certificate from their C.A.(Chartered Accountant) or ICWA that they have manufactured & marketed at least 2 commercial batch in last three years. The details of commercial batch no., month of manufacture, batch size in last three years period duly certified by their C.A. or ICWA should be uploaded along with technical bid. In case the bidder is Importer also, a certificate from their C.A.(Chartered Accountant) or ICWA that they have manufactured & marketed at least 2 commercial batch in last three years. The details of commercial batch no., month of manufacture, batch size in last three years period duly certified by their C.A. or ICWA should be uploaded along with technical bid.
- k) The copies of relevant pages approved by drug authorities of concerned country for any quoted Drug/product offering CoPP certificate and quoted drugs/product approved by from US FDA, TG Australia, Health Canada, EU approval, MCC South Africa approval, Brazil Anvisa) should be uploaded with technical bid.
- (1) 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.
- (m) 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.
- (n) a. Scanned copy of GST registration certificate/Latest Sales Tax Clearance certificate/returns are to be uploaded.b. Scanned copy Latest Income tax assessment orders/returns filed are to be uploaded.

In case, bidder is a marketer of a manufacturer, the GST registration certificate/latest Sales Tax Clearance certificate/returns and the latest Income tax assessment orders/returns of bidder as well as of their manufacturer/manufacturers are to be uploaded.

- (o) Documents, if any, to show that the manufacturing unit/importer has been recognized by any other Indian / International Standard Organizations etc. as applicable.
- (p)The loan license bidder are required to upload scanned copies of all the documents as per tender requirements including manufacturing unit.
- (q)List of items quoted (The name & Drug code of the Items quoted as shown in the **ANNEXURE-VII** should be uploaded and **the rate of those items should not_be indicated in this list).**

- (r) A Checklist (ANNEXURE- VIII) shall be uploaded with technical bid. If a company/firm has two or more separate manufacturing units at different sites / States, which are not separate entities then the company will be allowed to submit only one tender for all units but necessary document regarding separate manufacturing units will uploaded as a separate set with the same tender. However, one bidder will be allowed to submit only one offer for one product.
- (s) All the documents uploaded should also be signed by the authorized official of the Tenderer.
- **4.2.** The all documents indicated above should be uploaded and shall be opened at the time of Technical bid opening.

5. PRICE BID - COVER "B"

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

(ii) Determination of L1 bidder:

- (a) In determining the lowest evaluated price, the rate quoted per unit landed price as indicated in column No. 6 of the **BOQ** shall be taken into consideration.
- (b) The Price preference of up to 5% over L1 bidder (if L1 bidder is not offering certificate of pharmaceutical product i.e. **CoPP** issued in the format recommended by the World Health Organization) shall be given to the bidder having CoPP for the particular drugs and shall be awarded contract. Scanned copy of Valid CoPP issued by the Licensing Authority must be uploaded.
- (c) The Price preference up to 10% over L1 bidder (if L1 is not offering product approved by from US FDA, TG Australia, Health Canada, EU approval, MCC South Africa approval, Brazil Anvisa) shall be given to the bidder having product approval from US FDA. TG Australia, Health Canada, EU approval, MCC South Africa approval, Brazil Anvisa.
- (d)(i) If the participating Micro and Small Enterprises (MSE) meets all the other eligibility criteria and their quoting price is within price band of L1+15 (fifteen) per cent shall also be allowed to supply a portion of requirement by bringing down their price to L1 price in a situation where L1 price is from someone other than a MSE and such MSE shall be allowed to supply up to 20 (twenty) per cent of total tendered value. The 20 (twenty) per cent quantity is to be distributed proportionately among these bidders, in case there are more than one MSMEs within such price band.
- (ii) Within this 20% (Twenty Percent) quantity, a purchase preference of four per cent (that is, 20 (twenty) per cent out of 20 (twenty) per cent) will be reserved for MSEs owned by Scheduled Caste (SC)/Scheduled Tribe (ST) entrepreneurs (if they participate in the tender process and match

the L1 price). Provided that, in event of failure of such SC/ST MSE to participate in tender process or meet tender requirements and L1 price, four per cent sub-target shall be met from other MSE. MSEs would be treated as owned by SC/ ST entrepreneurs: a) In case of proprietary MSE, proprietor(s) shall be SC /ST b) In case of partnership MSE, the SC/ST partners shall be holding at least 51% (fifty-one percent) shares in the unit c) In case of Private Limited Companies, at least 51% (fifty-one percent) share shall be held by SC/ST promoters.

- Note 1:- (a) Price preference as in Clause 5.1 (ii) (c) will be get preference over the clause 5.1 (ii) (b).
- Note 2:- Later on, if product does not comply CoPP and product having approval of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa approved product as declared in tender, the extra price paid to the supplier shall be recovered in addition to other penal action.
- (iii) The rate quoted in column 6 of **BOQ** should be for a unit and for the given specification. **The rates quoted should be in rupees and paisa up to 2 digits.** The Tenderer is not permitted to change/alter specification or unit size given in the **ANNEXURE-IX**
- (iv) GST (Goods and Services Tax)-The tenderers must indicate the rate of GST applicable and payable by them. In case no information is given, it shall be presumed that no GST shall be charged by them under under any circumstances.

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

- **6.1** Only authorized official as indicated in Clause 4.1. (e) 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. 4 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-X**. 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 signing the contract agreement and on the deposit of Security Deposit.
- (iii) The Earnest Money Deposit (EMD) of the unsuccessful bidders will be returned after finalization of tender/signing of agreement 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 execution of agreement /undertaking within the period prescribed.
- (v) The Earnest Money Deposit (EMD) will be forfeited, in case of the lowest bidder, fails to execute the contract agreement and / or deposit the security Deposit within the stipulated time. The EMD shall be forfeited if the undertaking as Annexure II 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 IX**. The tender quantity mentioned herein is a fixed procurement quantity.
- (ii) The Tenderer shall fill in manufacturing capacity per year in units, shelf-life in month and manufacturing batch size in units for each quoted drugs in required column of **ANNEXURE –XI and upload along with technical bid.**
- **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-IX**. Any variation, if found, will result in rejection of the tender.
- **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.** The price quoted by the tenderers shall not, in any case exceed the DPCO controlled price, if any, fixed by the Central/State Government, the Maximum Retail Price (MRP) and the selling price of the tenderer. Tender Inviting Authority at its discretion, may exercise, the right to revise the price at any stage so as to conform to the controlled price or MRP or the selling price of the tenderer as the case may be. This discretion will be exercised without prejudice to any other action that may be taken against the Tenderer.
- **8.6.** The rates quoted and accepted will be binding on the Tenderer for as per delivery period and any increase in the price will not be entertained till the completion of this contract period.
- 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 the tenders. "SUBJECT submission of Cross Conditions such as 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 before and 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 landed price as mentioned in column 6 of **BOQ** considering

price preference for <u>CoPP</u> and for product having approval of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa approved product. Negotiation if required will be done at our premises and the same will be done strictly as per Central Vigilance Commission guidelines.

- **9.2.** BPPI reserves the right to accept or reject the tender for the supply of all or any one or more items of the drugs tendered for in a tender without assigning any reason.
- **9.3.** BPPI or its authorized representative(s) has/have the right to inspect the manufacturing premises of Tenderers and assess their capability/eligibility before accepting the rate quoted by them or before releasing any purchase order(s).
- **9.4.** The acceptance of the tender by placing purchase order shall be issued to the Tenderers by e-mail and hard copy by post/courier/speed post/Regd. Post.

10. SECURITY DEPOSIT

- 10.1 On being informed about the acceptance of the tender/placement of purchase order, the Tenderer shall pay the Security Deposit @10 % of **value of purchase order** in the form of **Demand Draft or irrevocable Bank Guarantee** in favour of Bureau of Pharma Public Sector Undertakings of India from any scheduled Bank within 7 days. In case the Security Deposit is paid in form of Bank Guarantee, the bank guarantee shall be valid for two years. The format of Bank Guarantee is at **ANNEXURE XII.**
- **10.2**. The security deposit of supplier will be returned by BPPI only after the supplier has given undertaking to replace such medicines and indemnify BPPI against any loses because quality parameters.

11 Methology for placement of Purchase order

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 shall be evaluated. Purchase order shall be placed to the first lowest bidder at L1 rate for offered quantity subject to their manufacturing capacity.
- (b) If two or more than two Tenderer's are found as lowest suppliers for the same item(s), Placement of order shall be shared equally amongst these bidders subject to their manufacturing capacity.
- (c) 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.

- (d) 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.
- (e) All notices or communications relating to and arising out of this contract or any of the terms thereof shall be considered duly served on or given to the Tenderer if delivered to him or left at the premises, places of business or abode as provided by the tenderer.
- (f) If the lowest selected Tenderer fails to supply or to deposit the required security deposit within the time specified or withdraws the tender, after acceptance of the tender/placement of purchase order 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 security deposit shall be forfeited if the undertaking as Annexure II is not found correct.
- (g) If a supplier fails to execute supply order, the 10% value of supply order shall be recovered from pending bill or EMD/Bank Guarantee.
- (h) 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.
- (i) 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.
- (j) The supplier shall supply the Drugs/Medicines at the CWH, Gurgaon or any other place to be mentioned in order along with copy of Purchase order, copy of test reports and 3 original copies of Invoice. No payment will be processed without test reports.
- (k) 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.
- (l) 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.,
- (m) Subject to above, BPPI will process the invoices submitted by the supplier and the payments against supply will be made within 30 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.

(n) Subject to the conditions mentioned in the Purchase Order, Tender Document, 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.

(o) Tolerance Clause

- (a) At the time of issue of Purchase order, the purchaser reserves the right to increase or decrease up to twenty five (25) per cent, the quantity of drugs/items mentioned in tender without any change in the unit price and other terms & conditions quoted by the Bidder.
- (b) If the quantity have not been increased at the time of placing order, BPPP reserves the right to increase up to twenty five (25) per cent, the quantity of drugs/Items mentioned in the contract (rounded off to next whole number) without any change in the unit price and other terms and conditions mentioned in the contract, during the currency of the contract frame.

12. SUPPLY CONDITIONS

12.1. The Tenderer should inform BPPI through fax and mail the confirmation for the receipt of the purchase order and also the details of supply dates to BPPI within 3 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 3 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.

12.2. Delivery Period

- (a) The supplier is required to supply the ordered quantity of (a) drugs in form of Tablets and capsules within 15 days (b) drugs in remaining formulations within 30 days from the date of Purchase Order to CWH Gurgaon or any other place decided by BPPI. The date of delivery of drug/item stipulated in the purchase order shall be deemed to be the essence of the contract and delivery must be completed within stipulated Date of Delivery which is 15 days in case of tablets & capsules and 30 days in case of other formulations of drugs.
- (b) If the above day for 12.3 (a) above happened to be a holiday for BPPI, the supply should be completed by 5.00 PM on the next working day.

- (c) 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.
- (d) 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.
- (e) 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 15th day in case of tablets & capsules and 30th day in case of other formulations of drugs. However, BPPI reserves right of discretion to accept/reject supplies after 15th day in case of tablets & capsules and after 30th day in case of other formulations of drugs from the date of issue of purchase order and in case of rejection of supplies the purchase order shall be cancelled at the risk and cost of the supplier.
- 12.3. 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.
- **12.4.** 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 the specifications, stipulations and conditions specified in the tender.
- **12.5.** Tenderer should supply the product within 2 months including month of manufacture of products. Products beyond the above-mentioned period from the date of manufacture shall not be accepted. For example, product having manufacturing of November, 2017 must be supplied before December 31, 2017.

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

12.6. (i)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.

(ii) The supplier shall not be liable to pay LD and forfeiture of security deposit for the delay in executing the contract on account of the extension of supply period on the ground of force majeure events.

13. LOGOGRAMS

Logogram means, wherever the context occurs, the design as specified in ANNEXURE-XIII. The name of the drug shall be mentioned in English and Hindi.

- **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 XIII&XIII-A**.
- **13.2.** All tablets and capsules have to be supplied in packing as specified in product list (**ANNEXURE IX**) 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 Jan Aushadhi 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 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 IX** and **ANNEXURE** -**XIV** and the package shall carry the logograms of proportionate size specified in **ANNEXURE** -**XIII**, **XIII** -**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-XIV**. The outer carton/secondary packaging should be of pearl white duplex board (**off white/grey is not acceptable**) with a minimum of 350 GSM with **Gloss laminated** packing for the strips, blisters, ointments, creams etc. and for ampoules and vials should be with pearl white board of 350 GSM(**off white/grey is not acceptable**). **The material to be used for carton should be from virgin chemical pulp.** Failure to comply with this shall lead to non-acceptance of the goods besides imposition of penalties as per clause 18.5. Storage conditions must be indicated on outer label.
- **14.4.** The cap of bottle preparations should not carry the name of the supplier.
- **14.5.** The labels in the case of Injectable preparations should clearly indicate whether the preparations are meant for Intravenous (IV), Intra Muscular (IM), Intra Dermal (ID), Subcutaneous (SC) administration etc.
- **14.6.** It should be ensured that only first-hand virgin packaging material of uniform size, including bottle and vial, is used for packing.
- **14.7.** All primary packing containers should be strictly conforming to the specification included in the relevant pharmacopoeia.
- **14.8.** Packing should be able to prevent damage or deterioration during transit.
- **14.9.** In the event of items of drug supplied found to be **not as per specifications in respect of their packing and logogram**, the BPPI is at liberty to make alternative purchase of the items of drugs for which the Purchase orders have been placed from any other sources or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier. In such cases the BPPI has every right to recover the cost and impose penalty as mentioned in Clause 18 & 19.
- **14.10.** Designs of packaging with the logograms shall be subject to approval by BPPI within one day of receipt of the same from the supplier, as per the specifications with soft copy of STP(standard testing procedure) for Non- Pharmacopoeil drugs as per clause

- 15.1.1. In case of failure of BPPI to do so, the supplier may go ahead with the design as per the specification in **ANNEXURE XIII and XIV.**
- 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 despatch at supplier's site or receipt of supply or distribution/storage points for testing at discretion of BPPI. The samples will be sent to different laboratories including Government Drugs Testing Laboratory 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** For Non- Pharmacopoeil drugs, supplier should send soft copy of STP(standard testing procedure) 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.
- 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. 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 Pharmacopeial 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 happens 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 -XV) 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. IDPL Complex, Dundahera, Gurgaon 122016 or in the name of any other authority as may be designated.
- **16.4.** (i) Payments for supply will be considered only after supply of minimum 50% of Drugs ordered in the individual Purchase Order PROVIDED reports of Standard Quality on samples testing are received from Government Analyst or Approved Laboratories of BPPI.
- (ii) However, in case of cancellation of a particular purchase order due to failure in delivery, payment for part supplies less than 50% of the purchase order quantity on the date of cancellation of the purchase order may be considered for release of payment subject to the following:
- (a) If the Tenderer have supplied at least 50% of the quantity ordered in the subsequent purchase order within delivery period stipulated in purchase order from the issue of such purchase order.
- (b) If further purchase order is not placed with the supplier due to any reason, not attributable to the supplier, the amount eligible will be paid within 60 days from the date of last supply.
- (c) The payment for part supply as mentioned above will subject to the deduction of liquidated damages, penalty towards unexecuted quantity, risk and cost etc., as per the tender conditions.

- **16.5.** If at any time during the period of contract, the price of tendered items is reduced or brought down by any law or Act of the Central or State Government or by the Tenderer himself, the Tenderer shall be bound to inform the BPPI immediately about such reduction in the contracted prices. Tender Inviting Authority is empowered to unilaterally effect such reduction as is necessary in rates in case the Tenderer fails to notify or fails to agree for such reduction of rates.
- **16.6.** In case of any increase of decrease in the taxes/GST after the date of submission of tenders and during the tender period, such variation in the taxes/GST will be to the account of the BPPI. For claiming the additional cost on account of the increase in taxes/GST, the Tenderer should produce the proof of having paid additional amount on this account on the goods supplied to BPPI from the concerned authorities and also must claim the same in the invoice separately. However, the basic price structure and the price of the Drugs approved under the tender shall not be altered. Similarly, if there is any reduction in the taxes/GST and statutory levies as notified by the Govt., after the date of submission of tender, the Tenderer will be paid based on the unit rate worked out on the basis of the reduced taxes/GST/statutory levies without any change in the basic price or the price structure of the drugs approved under the tender. Any increase or decrease in taxes/GST and statutory levies will be considered based on the notification issued by the Government.

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

17. HANDLING & TESTING CHARGES:

No handling & testing charges shall be applicable.

18. LIQUIDATED DAMAGES AND OTHER PENALTIES:

- **18.1.** If the supply reaches the designated places or Central Warehouse after 5 PM of 15th day from the date of issue of purchase order for supply of tablets & Capsules and after 5 PM of 30th day from the date of issue of purchase order for supply of other formulations, a liquidated damages will be levied at 5% per week or part thereof, irrespective of the fact that whether the BPPI has suffered any damage/loss or not, on account of delay in effecting supply. If the 15th/30th day happens to be a holiday the supply will be accepted on the next working day without any penalty.
- **18.2.** If the supply is received in damaged condition, open delivery of the supplies shall be received, wherein it is possible to physically inspect the shipment. Damaged products shall not be accepted.
- **18.3.** All the Tenderers are required to supply the product(s) with printed 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/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. Futher, 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. 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 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 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 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 Security Deposit or from any other money due and become due to the supplier and in the event of such amount being insufficient, the balance will be recovered personally from the supplier as per rules.
- **19.9.** In all the above conditions, the decision of the BPPI shall be final and binding.

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

20.1. BLACKLISTING OF PRODUCT/TENDERER ON WITHDRAWAL OF TENDER

(a) If the Tenderer(s) fails to execute the agreement / 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 Security deposit.

BLACKLISTING FOR QUALITY FAILURE

20.2.1. Quality Test by the Empanelled Laboratories of BPPI

- a. Each and every batch of drugs/medicines shall be subjected to quality test by the Empanelled laboratories.
- b. The samples collected from each batch of supply of the each drugs will be sent to the empanelled testing laboratories for testing the quality of drugs. In addition to the above BPPI shall also draw the samples of products supplied in the market place and get the same tested, to make sure the products are conforming to quality requirements.

- c. If such sample passes quality test in all respects, BPPI will instruct its Warehouse to release such items of drugs.
- d. If the sample fails in quality test and report is received certifying that sample is "NOT OF STANDARD QUALITY" then supplies will be rejected & no further procurement of that drug from the supplier for two years from the date of sample being declared not of standard quality. If the supplier challenges and request for re- testing, the rejected supply shall be tested in two labs simultaneously at the cost of supplier. The cost testing shall be recovered from the supplier.
- (i) If such sample passes the quality test in both laboratories, the drugs representing the sample shall be qualified for issue to various Institutions.
- (ii) If the sample passes in one laboratory and fails in other laboratory or fails in both laboratories, the supply shall be rejected. No further procurement of said drug shall be made from such supplier.
- (iii) If **3** batches of item/drug supplied by the same supplier is reported to NOT OF STANDARD QUALITY in specification, then the firm shall be blacklisted for 2 years after observing procedure laid down in Para 20.2.3 besides forfeiture of Security Deposit.

20.2.2 Quality Test by Statutory Authorities:

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

20.2.3 Procedure for Blacklisting:

(i) On receipt of complaint from Distributer/retailers/customers or report from Govt. Analyst/Drug Testing Laboratory indicating that a particular Item/Drug is "NOT OF STANDARD QUALITY/ ADULTERATED/ SPURIOUS/MISBRANDED" (As the case may be), a show cause notice shall be issued to the supplier calling for explanation within 7 days from the date of notice. On receipt of explanation from the supplier, the CEO, BPPI may take appropriate action on merits of the case and impose penalty including the blacklisting of the item of the product/company or firm as deemed fit besides forfeiture of 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. 3 times, the supplier may be blacklisted for 2 years in addition of forfeiture of 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/agreement.

However, due to various unforeseen reasons, problems may arise during the progress of the contract/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 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(k)

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

These requirements cover medicines/drugs procured by Bureau of Pharma Public Sector Undertakings of India (BPPI), Gurgaon, 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. 1st Barcode: (02)1 8901072 00253 4 (17) 180815 (10) RNBXY0514 (37)5000 2ndBarcode: (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		<u> </u>		1

To,

Warehouse-BPPI, Gurgaon Haryana Mnfd By,

AAA Pharma Company 125, SEZ

Ahmedabad-382213 Gujrat

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





Secondary Level Pack: Data Attributes Captured

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

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

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

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

Primary Level Pack: Data Attributes Captured

GS1-128

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

a. Unique product identification code (GTIN)

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

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

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

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

T +91-11-42890890, (D) +91-11-42890846

F +91-11-26168730

E ankit@gs1india.org

W http://www.gslindia.org

ANNEXURE-II

{ Clause 4.1(a)(i)}

MANUFACTURER'S AGREEMENT WITH MARKETER

To
The CEO
Bureau of Pharma PSUs of India,
IDPL corporate office Complex, Old Delhi-Gurgaon Road,
Dundahera, Gurgaon- 122016 (Haryana),

•	ite office Complex, Old Delhi-Gurgaon Road, Gurgaon- 122016 (Haryana) ,
Dear Sir,	
Drug marl addr	who are established and reputable manufacturer of gs having factory/factories atand hereby declare that we do not ket our products. Therefore, we authorize M/S (Name and ress) to bid, negotiate and contract with your tender No. BPPI/Drug-053/2017 d 11/08/2017 for supply of drugs manufactured by us.
auth	company of the firm or individual other than M/Sorised to bid, negotiate and conclude the contract in regard to this business nst this specific tender as also for a business in the entire territory of India.
the o	agreement is valid fromto(This period will be date of opening tender till valid one year shelf life of the drugs or period of ract/ price agreement whichever is more.
calle any unde	ex-factory cost of the Drugs being quoted will be provided by us whenever ed for. We also undertake that we will not quote a price higher than supplied to institute in last 6 months. In case our submission is found wrong, we ertake to be liable for punitive action in the form of recovery of excess amount holding of payment/ any other action as deemed appropriate by department.
appl	marketing commission of% is included in the gross ex-works price is icable of
M/s	·

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

i. Provision of requisite inspection and	testing facilities at our works in
respect of supply order placed on our a	igent.
ii	
{Here specify in detail manufacturers res	ponsibilities]
The services to be rendered by the ma are as under:-	arketer, M/s
i	
ii	
{Here specify the services to be rend	ered by the agent}
8. We certify that neither we, nor our registered/banned by any Govt. agency.	agent is blacklisted/ debarred/de-
9.We jointly agree to abide by the following of	clauses in the contract:
a) Penalty for use of undue influence.b) Access to books of accounts.	
10. We undertake that GST registration Number (PAN), last three years Bank Statement authorized agent/ distributor will be provided department.	
	Yours faithfully,
(Name, Signature & Stamp)	(Name, Signature & Stamp)
(Name of Authorized Marketer)	(Name of Manufacturer)
Date:	Date:

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

ANNEXURE –III Ref. Clause No. 4.1(a)(ii)

(On non judicial Stamp Paper)

DECLARATION

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

I/We M/s	represented	by its	Proprietor/Managing	Partner /Managing
Director having	its registered office at			and its factory
premises at				
			•	

- (I) that I/we have carefully read all the terms and conditions of tender in ref. no. **BPPI/DRUG-053/2017 Dtd. 11/08/2017** including Amendment(s) to Tender document (if any) issued by Bureau of pharma public sector undertakings of INDIA, GURGAON, 122016 and accept unconditionally all terms and condition of tender document including Amendment(s) to Tender document (if any).
- (II) that I/We are holding and have uploaded (a) valid drug license for quoted drugs,(b) valid WHO-GMP certificate, (c) 2 years market standing certificate for quoted products issued by licensing authority for quoted drugs, (d) a certificate manufactured & marketed two batches within 3 years issued by C.A. for quoted drugs, (e) valid non conviction certificate not older than 6 months,(f) Valid Import license (If applicable) 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/agreement shall be cancelled with forfeiture of EMD/SECURITY DEPOSIT/Bank guarantee against tender no. BPPI/DRUG-053/2017 Dtd. 11/08/2017 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 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 XIII 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 per the designs given in enclosures to Annexure XIII A as well as other instructions given in this regard.

- (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/deregistered/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-053/2017 Dtd. 11/08/2017 for the following products:-

S.	Drug Code	Name of the Drug
No.		
		Signed
		Name
		Designation
		(Company Seal)
Witnes	ss:-(1)	
	(2)	

To be attested by the Notary

ANNEXURE-IV

Ref. Clause No. 7.1 & 3(ii)

DETAILS OF E.M.D SUBMITTED

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

ANNEXURE-V

Ref. Clause No. 4.1 (f)(i)

(Format for a certificate from the C.A.(Chartered Accountant) or ICWA)

It is certified that M/s	has Production &
financial capacity to manufacture and deliver the d	lrugs 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.
Date	(Name, Signature & Stamp) Registration no.

ANNEXURE-V A

Ref. Clause No. 4.1 (f)(i)

(Format for a certificate from the C.A.(Chartered Accountant) or ICWA)

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 finan	acial statement.
Date	(Name, Signature & Stamp) Registration no.

ANNEXURE -VI

Ref. Clause No. 4.1{f(ii)}

ANNUAL TURNOVER STATEMENT

Sl.No.	Financial Year	Turnover in Lakhs(Rs.)
1.	2013-14	
2.	2014-15	
3.	2015-16	
TOTAL		RsLakhs

Rs.....Lakhs

below and certified that the statement is true and correct.

Average Turnover per annual

The annual Turnover of M/s.for the past three years are given

Date: Signature of Auditor/Chartered Account
Seal: (Name in Capital)
Registration no.

ANNEXURE – VII

Ref. clause 4.1 (q)

LIST OF ITEMS QUOTED

Sl.No.		Detai	ils			
1.	Name of the firm and address					
	(As given in Drug licence)					
2.	Drug Liceno	ce No. in form 2:	5 & 28			
	Or import L	icence No.				
3.	Date of issu	e & validity				
4.	WHO-GMF	(World Health (Organisation-Good			
	Manufactur	ing Practices) Co	ertificate obtained	on		
5.	Non-convic	tion Certificate (Obtained on			
6.	Market stan	ding Certificate	Obtained on			
7.	Details of E	Indorsement for a	all products quoted	1:		
Sl.No.	Drug	Drug Name	Specifications	Date o	f	Whether
	Code	_	IP/BP/USP	Endors	sement	Endorsement
				obtain	ed from	is in Generic
				the Sta	ite Drugs	or Trade
				Contro	oller	Name
1.						
2.						
		Au	thorised signator	v:		
Date:						
İ						

ANNEXURE – VIII

Ref. Clause 4.1 (r)

CHECK-LIST(Whether Uploaded the documents)

COVER – A

S.No.	Check List	YES	NO
1.	Check list - ANNEXURE – VII		
2.	EMD Rs.100,000/- in the form of Bank Guarantee or Bankers		
	Cheque or Demand Draft uploaded as per ANNEXURE-IV DD		
	NoDatedissued by(name of bank) and delivered to BPPI.		
	Uploaded NSIC certificate for exemption if any.		
3.	Documentary evidence for the constitutions of the		
٥.	company / concern		
4.1	Documentary evidence for MSME if applicable		
4.2	In case of MSME, Documentary evidence that unit owned		
	by SC/ST entrepreneurs if applicable		
5.	Scanned copy of License for the Product duly approved by		
	the Licensing Authority for each and every product quoted		
6.	Scanned copy of Import License, if Imported and whole		
	sale Drug license		
7.	COPP certificate as per WHO format of their Principal		
	Manufacturing company including Imported drugs.		
8.	The instruments such as power of attorney, Resolution of		
_	board etc.,		
9.	Authorization letter nominating a responsible Person of the		
	tenderer to transact the business with the Tender inviting		
10	Authority.		
10.	Scanned copy of Market Standing Certificate issued by the		
11.	Licensing Authority A certificate from their C.A.or ICWA that manufactured at		
11.	least 2 commercial batch in last three years.		
12.	Scanned copy of WHO-GMP(World Health Organisation-		
12.	Good Manufacturing Practices) Certificate.		
13.	Scanned copy of Non Conviction Certificate issued by the		
15.	licensing authority not older than 6 months.		
14.	Scanned copy of GST registration certificate/Latest Sales		
	Tax Clearance Certificate/returns filed.		
15.	Scanned copy of Latest income tax assessment		
	orders/returns filed.		
16.	Copies of approval of the any agency like US FDA, TG		
	Australia, Health Canada, EU, MCC South Africa		
	approval, Brazil Anvisa approved product, if any.		
17.	Scanned copy of ANNEXURE-II		
	(Agreement with Manufacturer) if any , original Annexure I		
10	delivered to BPPI.		
18.	Scanned copy of ANNEXURE –III (Declaration for eligibility in		
	participating the tender) and original Annexure II delivered to		

	BPPI.	
18A	Scanned copy of ANNEXURE V{certificate from the	
	C.A.(Chartered Accountant) or ICWA that the bidder has	
	Production & financial capacity }.	
19.	Scanned copy of ANNEXURE V A in case of	
	importer{certificate from the C.A.(Chartered Accountant)	
	or ICWA that the bidder has financial capacity.	
20.	Scanned copy of ANNEXURE -VI (A certificate from CA	
	for Annual Turnover Statement)	
21.	Scanned copy of ANNEXURE - VII(List of Items quoted without	
	rates).	
22.	Scanned copy of ANNEXURE-XI	
	(Details for Manufacturing Capacity & Batch Size)	
23.	Scanned copy of ANNEXURE—XV (Mandate form)	

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

Name an	d signature	of authorised	signatory	(with com	pany seal)

Annexure -IX

Clause 8.1 &8.2

Bureau of Pharma Public Sector Undertakings of India, Gurgaon Tender for supply of drugs (Tender No. BPPI/DRUG-053/2017 Dtd. 11/08/2017)

(1)	(2)	(3)	(4)	(5)	(6)	(7)
Sr. No.	Drug Code	Generic name of Medicines	Unit Size	Pack Size	Packing per Carton (Shipper Pack)	Tender quantity in units size
1	83	CIPROFLOXACIN 250 MG+ TINIDAZOLE 300 MG FILM COATED TABLETS	10's	10's x10	(10's x10x10)x10	50000
2	150	Metformin (SR) 500mg + Pioglitazone 15mg Tablets	10's	10X10	10X10X100	100000
3	192	FAMOTIDINE TABLETS IP 40 MG	14's	14's x10	(14's x 10x 10)x10	25000
4	196	LACTOBACILLUS SPOROGENES 60 MILLION SPORES TABLETS	10's	10's x10	(10's x 10x 10)x10	150000
5	227	Polyvitamin (Prophylactic) NFI film coated Tablets	10's	10's x10	(10's x10x10)x10	100000
6	230	VITAMIN B COMPLEX (B1,B2,B6,B12) & VIT. C WITH ZINC 22.5 MG CAPSULES	10's	10'sx10	(10'sx10x10)x10	1000000
7	244	Theophylline 25.3 mg+ Etophylline 84.7mg /2ml Injections	2ml	2ml x 10	(2mlx10x10) x 10	200000
8	279	Frusemide 40 mg Tabs IP	10's	10'sX10	10X10X200	150000
9	306	PRIMAQUINE TABLETS IP 15 MG	10's	10'sX10	10'sX10X200	10000
10	357	Ligncaine 10mg + Adrenaline 0.005mg/ml inj.	30 ml vial	1's x 5	(1's x5)x 20	11000
11	386	DIETHYLCARBAMAZINE Tablets IP 50 mg	30's	30's x10	(30 x 10 x 10) x 5	30000
12	390	ETHAMBUTOL TABLETS IP 800 MG	10's	10's x10	(10 x 10 x 10) x 5	10000

13	404	LINEZOLID INFUSION 600 MG/300 ML	300 ML	1's x 10	(1's x10)x 20	500
14	407	IVERMECTIN TABLETS 12 MG	10's	10'sX10	10's x 10x 200	10000
15	438	INDAPAMIDE TABLETS IP 1.5 MG	10's	10'sx10	10'sX10X200	40000
16	470	PEPSIN 10 MG+ DIASTASE 50 MG ORAL LIQUID /5 ML	200 ML bott le	1's x 10	(1's x10)x 10	25000
17	472	Domperidone + Esomeprazole(30/40mg) Capsule	10's	10's x9	(10's x10x10)x9	300000
18	501	BETAMETHASONE TABLETS IP 0.5 MG	20's	20'sx10	20'sx10x100	50000
19	504	NANDROLONE DECANOATE INJECTION IP 25MG/ML	1ml amp oule	1ml x 10	(1mlx10x10)x10	20000
20	519	KETOROLAC TABLETS DT 10 MG	10's	10'sx10	(10'sx10x10) x 20	20000
21	563	OXYMETAZOLINE 0.5 MG /ML NASAL DROPS	10 ML	1's x 10	(1's x 10) x 50	5000
22	580	Ginseng extract 42.5 mg, vitamin A 2500 IU, vitamin B1 1 mg, vitamin B2 1.5 mg, vitamin B6 1 mg, vitamin B12 1 mcg, vitamin C 50 mg, vitamin E 5 mg, vitamin D 200 IU, nicotinamide 10 mg, carbohydrates 0.1 g, folic acid 0.15 mg, ferrous fumarate 30 mg, copper 0.5 mg, potassium sulphate 2 mg, manganese 0.5 mg, magnesium sulphate 3 mg, zinc oxide 10 mg, calcium 75 mg, phosphate 58 mg, iodine 0.1 mg, protein 0.2 g, fat 0.38 g	10's	10'sx10	(10'sx10x10) x 20	500000
23	613	Diclofenac Potassium BP 50 mg + Paracetamol 325 mg + Serratiopeptidase 10 mg	10's	10's x10	(10's x10x10)x10	100000

24	621	Iron & Zinc (Carbonyl Iron 50 mg+ Zinc Sulphate Monohydrate USP 61.8 mg equivalent to Elemental Zinc 22.5 mg + Folic Acid IP 0.5mg Capsules	15's	15'sx10	(15'sx10) x 20	300000
25	643	Paracetamol 125mg+ CPM 1 mg + Sodium Citrate 60mg in a flavour syrup base		60ml X 10	60ml X 10 X10	25000
26	652	Dicyclomine 10mg + Mefenamic 250 mg Tablets	10's	10'sx10	10'sx10x100	100000
27	653	Syrup Vitamin D3 200 IU + Vitamin B12 2.5 mcg + Calcium Phosphate eq. to elemental Calcium 82 mg/5 ml	225 ml	1's x 10	(1's x 10)x25	50000
28	655	Enyme Syrup Mix Fruit Flavour Pepsin 7.5 mg + Fungal Diastase 12.5 mg / 5 ml	200 ml	1's x 10	(1's x 10)x25	10000
29	664	Mouth Ulcer Gel (Choline Salicylate sodium 9% w/v, Benzalkonium Chloride 0.01% w/w)	10 gm	1's x 10	(1's x 10)x25	50000
30	669	Cefuroxime 125mg(as Cefuroxime Axetil USP) Syrup	30m I	1's x 10	(1's x 10)x25	25000
31	671	Diacerein 50 mg + Glucosamine Sulphate 500 mg Tablets	10's	10'sx10	10'sX 10X 100	100000
32	676	Trimcelone Acetonide 0.1 % Mouth Ulcer gel	10g m	10gm X 20	10gm X 20X 20	10000
33	712	Paracetamol DS 250 mg/5ml syrup	60m I	1's x 10	(1's x 10)x50	20000
34	915	Hydroxyzine HCl Tablets IP 10mg	10's	10'sx10	(10'sx10x10)x20	50000
35	1142	CALCIUM CARBONATE 500 MG + CALCITRIOL 0.25 MCG + ZINC 7.5 MG Capsule	10's	10'sx10	(10'sx10x10)x10	500000

ANNEXURE -X(Ref:-Clause 7.1)

MODEL BANK GUARANTEE FORMAT FOR FURNISHING EMD

Whereas (hereinafter called the			
"tenderer") has submitted their offer dated for the supply			
Of Drugs (hereinafter called the "tender") against the purchaser's tender enquiry No. BBPI/DRUG-053/2017 KNOW ALL MEN by these presents that WE			
office at			
THE CONDITIONS OF THIS OBLIGATION ARE:			
(1) If the tenderer withdraws or amends, impairs or derogates from the tender in any respect within the period of validity of this tender.			
(2) If the tenderer having been notified of the acceptance of his tender by the Purchaser during the period of its validity:-			
a) If the tenderer fails to furnish the Performance Security for the due performance of the contract.			
b) Fails or refuses to accept/execute the contract.			
WE undertake to pay the Purchaser up to the above amount upon receipt of its first written demand, without the Purchaser having to substantiate its demand, provided that in its demand the Purchaser will note that the amount claimed by it is due to it owing to the occurrence of one or both the two conditions, specifying the occurred condition or conditions.			
This guarantee will remain in force up to 31.05.2018 and any demand in respect thereof should reach the Bank not later than the above date.			
(Signature of the authorized officer of the Bank)			
Name and designation of the officer			
Seal, name & address of the Bank and address of the Branch			

Annexure – XI

{Ref:- clause 8.1(ii)}

(1)	(2)	(3)	(4)	(5)	(6)	(7)
Sr. No.	Drug Code	Generic name of Drug	Unit Size	Manufacturing Capacity per year in Units	Manufactu ring Batch Size in Units	Shelf- life(mont hs)
1	83	CIPROFLOXACIN 250 MG+ TINIDAZOLE 300 MG FILM COATED TABLETS	10's			
2	150	Metformin (SR) 500mg + Pioglitazone 15mg Tablets	10's			
3	192	FAMOTIDINE TABLETS IP 40 MG	14's			
4	196	LACTOBACILLUS SPOROGENES 60 MILLION SPORES TABLETS	10's			
5	227	Polyvitamin (Prophylactic) NFI film coated Tablets	10's			
6	230	VITAMIN B COMPLEX (B1,B2,B6,B12) & VIT. C WITH ZINC 22.5 MG CAPSULES	10's			
7	244	Theophylline 25.3 mg+ Etophylline 84.7mg /2ml Injections	2ml			
8	279	Frusemide 40 mg Tabs IP	10's			
9	306	PRIMAQUINE TABLETS IP 15 MG	10's			
10	357	Ligncaine 10mg + Adrenaline 0.005mg/ml inj.	30 ml vial			
11	386	DIETHYLCARBAMAZINE Tablets IP 50 mg	30's			
12	390	ETHAMBUTOL TABLETS IP 800 MG	10's			
13	404	LINEZOLID INFUSION 600 MG/300 ML	300 ML			
14	407	IVERMECTIN TABLETS 12 MG	10's			
15	438	INDAPAMIDE TABLETS IP 1.5 MG	10's			
16	470	PEPSIN 10 MG+ DIASTASE 50 MG ORAL LIQUID /5 ML	200 ML bott le			
17	472	Domperidone + Esomeprazole(30/40mg) Capsule	10's			
18	501	BETAMETHASONE TABLETS IP 0.5 MG	20's			
19	504	NANDROLONE DECANOATE	1ml			

		INJECTION IP 25MG/ML	amp	
		V5T0001 40 T4015T6 DT 40	oule	
20	519	KETOROLAC TABLETS DT 10 MG	10's	
21	563	OXYMETAZOLINE 0.5 MG /ML NASAL DROPS	10 ML	
22	580	Ginseng extract 42.5 mg, vitamin A 2500 IU, vitamin B1 1 mg, vitamin B2 1.5 mg, vitamin B6 1 mg, vitamin B12 1 mcg, vitamin C 50 mg, vitamin E 5 mg, vitamin D 200 IU, nicotinamide 10 mg, carbohydrates 0.1 g, folic acid 0.15 mg, ferrous fumarate 30 mg, copper 0.5 mg, potassium sulphate 2 mg, manganese 0.5 mg, magnesium sulphate 3 mg, zinc oxide 10 mg, calcium 75 mg, phosphate 58 mg, iodine 0.1 mg, protein 0.2 g, fat 0.38 g	10's	
23	613	Diclofenac Potassium BP 50 mg + Paracetamol 325 mg + Serratiopeptidase 10 mg	10's	
24	621	Iron & Zinc (Carbonyl Iron 50 mg+ Zinc Sulphate Monohydrate USP 61.8 mg equivalent to Elemental Zinc 22.5 mg + Folic Acid IP 0.5mg Capsules	15's	
25	643	Paracetamol 125mg+ CPM 1 mg + Sodium Citrate 60mg in a flavour syrup base	60 ml Bott le	
26	652	Dicyclomine 10mg + Mefenamic 250 mg Tablets	10's	
27	653	Syrup Vitamin D3 200 IU + Vitamin B12 2.5 mcg + Calcium Phosphate eq. to elemental Calcium 82 mg / 5 ml	225 ml	
28	655	Enyme Syrup Mix Fruit Flavour Pepsin 7.5 mg + Fungal Diastase 12.5 mg / 5 ml	200 ml	
29	664	Mouth Ulcer Gel (Choline Salicylate sodium 9% w/v, Benzalkonium Chloride 0.01% w/w)	10 gm	
30	669	Cefuroxime 125mg(as Cefuroxime Axetil USP) Syrup	30m I	

31	671	Diacerein 50 mg + Glucosamine Sulphate 500 mg Tablets	10's		
32	676	Trimcelone Acetonide 0.1 % Mouth Ulcer gel	10g m		
33	712	Paracetamol DS 250 mg/5ml syrup	60m I		
34	915	Hydroxyzine HCl Tablets IP 10mg	10's		
35	1142	CALCIUM CARBONATE 500 MG + CALCITRIOL 0.25 MCG + ZINC 7.5 MG Capsule	10's		

ANNEXURE -XII

Ref. Clause No.10.1

Performance Security Bank Guarantee

(unconditional)

To: Bureau of Pharma Public Sector Undertakings of India, (Name of purchaser) IDPL Complex, Old-Delhi-Gurgaon Road, Dundehera, Gurgaon 122016 (Haryana)

the Supplier) BPPI/DRUG-0	herein 53/201	called. 7 Dtd.	"the Su	pplier" has u 1017 to suppereinafter calle	ndertaken, i ly of Drug	n purs s for	suance	of Te	
AND WHEREAS it has been stipulated by you in the said Contract that the Supplier shall furnish you with a Bank Guarantee for the sum specified therein as security for compliance with the Supplier's performance obligations in accordance with the Contract.									
AND	WHER	EAS we	e have agr	reed to give the	e Supplier a (Guaran	tee		
on beha		of	the	Firm that we as Supplier,	upto	a	to	tal	you, of the
Guarantee in Words and Figures) and we undertake to pay you, upon your first written demand declaring the Supplier to be in default under the Contract and without cavil or argument., any sum or sums within the limit of									
or the sum spe									
This guarantee is valid until the									
Guarantors									
					Date				2016
					Address				

ANNEXURE -XIII

Ref. Clause no 13

DECLARATION

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

Signature of the Tenderer

Name

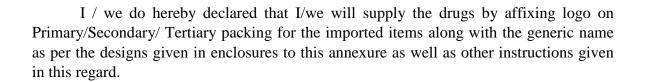
Designation

(Company Seal)

ANNEXURE -XIII(A)

Ref. Clause No. 13

UNDERTAKING



Signature of the Tenderer (Name in capital letter with designation)

Enclosure-1 to **ANNEXURE** -XIII AND XIIIA)

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 from at 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.

Manufactured for:



Bureau of Pharma PSUs of India

IDPL Plant complex, Dundahera, Gurgaon 122016 (Haryana)

BPPI helpline number 1800 180 8080

Or

Manufactured for:



Bureau of Pharma PSUs of India

IDPL Plant complex, Dundahera, Gurgaon 122016 (Haryana)

BPPI helpline number 1800 180 8080

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

Enclosure – 2 to <u>ANNEXURE</u> –XIII & <u>ANNEXURE</u> –XIII(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 **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

IDPL Plant complex, Dundahera, Gurgaon 122016 (Haryana)

BPPI helpline number 1800 180 8080

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 as per approval at the time of ART WORK approval before supply as under (colour should be black)
- (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

IDPL Plant complex, Dundahera, Gurgaon 122016 (Haryana)

BPPI helpline number 1800 180 8080

(vi) 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 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

IDPL Plant complex, Dundahera, Gurgaon 122016 (Haryana)

BPPI helpline number 1800 180 8080

3. OINTMENTS / CREAMS

a) Ointment / Cream /Gel /Glass Jar should bear JANASHADHI or PMJAY logogram as per approval at the time of ART WORK approval before supply as below:

Manufactured for:



Bureau of Pharma PSUs of India

IDPL Plant complex, Dundahera, Gurgaon 122016 (Haryana)

BPPI helpline number 1800 180 8080

- 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 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 ANNEXURE –XIII(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

IDPL Plant complex, Dundahera, Gurgaon 122016 (Haryana)

BPPI helpline number 1800 180 8080

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

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

ANNEXURE-XIV

Ref. Clause No.14.1

SCHEDULE FOR PACKAGING OF DRUGS

GENERAL SPECIFICATIONS

- 1. Strips of Aluminum foils should be gauge 04.
- 2. Aluminum foils s back material for blisters should be gauge 025.
- 3. The rigid PVC used in blister packing should be of not less than 250 micron
- 4. All glass bottles should be new neutral glass. Pet bottles so accepted as per drug laws stipulation.
- 5. Ointments should be packed in lacquerized Aluminum 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 aluminum strip / blisters with aluminum 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.
- 15. All primary/secondary/tertiary packaging should have JA/PMJAY logo.

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

(Schedule)

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

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

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

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

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

Lining should be 120gsm.

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

- (1) Vials may be packed in corrugated boxes weighing upto 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 100 or 50 ampoules may be packed in a grey board box. Multiples of white board boxes packed in CB. In case of ampoules larger than 10 ml only 25 ampoules may be packed in a grey board box with partition.
- (5) If the vial is packed in individual carton, there is no necessity for grey board box packing. The individual carton may be packed as such in the CB with centre pad.
- (6) In case of ampoules every white board box should carry 5 amps. Cutters placed in a polythene bag.
- (7) Vials of eye, ear drops and nasal drops should be packed in an individual 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 -XV

MANDATE FORM

Ref. clause 16.2

Sl.No.	Details Required	
1.	Company Name	
	PAN Number	
	TIN Number	
	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	
1	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</u> <u>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 / agreement entered 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:	