# TERMS & CONDITIONS FOR RATE CONTRACT OF DRUGS & MEDICAL CONSUMABLES 2012-13

# **DIRECTOR OF HEALTH SERVICES; ODISHA** [HEALTH & F.W. DEPARTMENT, GOVT. OF ODISHA]

Tel No.: 0674 - 2380 749 / 750 Fax: 2380549

#### Bid Reference No. SDMU/ 2012 – 2013 – DMC – 007 (CAT-III)

# TENDER DOCUMENT FOR SUPPLY OF DRUGS AND MEDICAL CONSUMABLES ON RATE CONTRACT FOR A PERIOD OF ONE YEAR FROM THE DATE OF APPROVAL OF TENDER

DATE OF COMMENCEMENT OF SALE OF THE TENDER DOCUMENT: 20.06.2012

(11 A.M to 4 P.M)

PRE BID CONFERENCE : 02.07.2012 at 11:30AM

LAST DATE & TIME FOR SALE OF TENDER DOCUMENT : 19.07.2012 upto 4 PM

LAST DATE & TIME FOR RECEIPT OF TENDER : 20.07.2012 upto 11:30 AM

DATE & TIME OF OPENING OF TENDER (COVER A) : 20.07.2012 at 12 NOON

DATE & TIME OF OPENING OF TENDER (COVER B) : will be intimated later on.

PLACE OF OPENING OF TENDER:

PRE BID CONFERENCE

ADDRESS FOR COMMUNICATION: Joint Director State Drug Management Unit

RECEIPT OF TENDER DOCUMENTS

AND

In-front of Ram Mandir, Convent Square,

Bhubaneswar, Odisha

TEL / FAX - 0674 - 2380 749 / 750 / 549 (F)

Email: sdmuorissa@yahoo.co.in Website: http://www.odisha.gov.in/

OFFICE OF THE DIRECTOR OF HEALTH SERVICES, ODISHA, BHUBANESWAR -751001

### SALE OF TENDER / BID DOCUMENT

A complete set of bidding documents may be purchased by prospective bidders on payment of a non-refundable fee as indicated below in the form of a Demand Draft in favour of Joint Director, State Drug Management Unit, (O) payable at Bhubaneswar from any Nationalised /Scheduled Bank at the office of the Joint Director, State Drug Management Unit, in front of Ram Mandir, Convent Square, Odisha, Bhubaneswar – 1 during office hours from 11 A.M. to 4 P.M. on all working days as mentioned in the tender document either in person or by post.

The Bidders may download the Tender Documents directly from the WEBSITE available at <a href="http://www.odisha.gov.in/portal/default.asp">http://www.odisha.gov.in/portal/default.asp</a>. The Tender Document Cost of Rs.5250- including VAT @ 5% (Non-refundable) by way of separate Demand Draft drawn in favour Joint Director, State Drug Management Unit, (O), Bhubaneswar should be enclosed alongwith the Technical Bid. The Bidders should specifically super-scribe, "DOWNLOADED FROM THE WEBSITE" on the top left corner of the outer envelope containing Technical Bid and Price Bid separately. The Tender Documents Cost (Including taxes) and the EMD amount should be submitted separately in separate demand drafts. In case of any bid amendment and clarification, responsibility lies with the bidders to collect the same from the website or the office notice board on or before the last date for purchase of tender document as mentioned in the Tender Document and the Tender inviting authority shall in no case be held responsible for any such delay or omission on part of the bidder in updating itself.

a) Price of bidding document Rs.5, 250.00 including VAT @ 5%

(Non-refundable)

b) Postal / Courier charges, inland: Rs. 500.00 – (Extra)

#### **Note of Caution:**

The tender paper will be rejected if the bidder changes any clause or Annexure of the bid document downloaded from the website.

TERMS AND CONDITIONS FOR ACCEPTANCE OF TENDER FOR SUPPLY OF DRUGS AND MEDICAL CONSUMABLES TO GOVERNMENT OF ODISHA ON RATE CONTRACT BASIS FOR A PERIOD OF ONE YEAR FROM THE DATE OF APPROVAL BY THE COMPETENT AUTHORITY.

- 1.1 Sealed tenders for the purchase of Drugs and Medical Consumables will be received by the Director of Health Services, Odisha in the office of the Joint Director, State Drug Management Unit, In-front of Ram Mandir, Convent Square, BBSR-751001, Odisha within due date and time for submission of tender document as specified therein i.e. 11.30 AM of 20.07.2012. Any tender received after the due date and time will be rejected and returned unopened to the sender. The Tenders will only be received through Regd. Post / Courier Service / Speed Post.
- 1.2 The sealed tenders 'Cover A' (Technical Bid) submitted by the tenderer will be opened by the Director of Health Services, Odisha at the Office of the Joint Director, State Drug Management Unit (O), in-front of Ram Mandir, Bhubaneswar at 12 Noon on Dt. 20.07.2012. The tenderers or their duly authorised representatives are allowed to be present during the opening of the tenders, if they so desire.
- 1.3 The Bidders may download the Tender Documents directly from the WEBSITE available at <a href="http://www.odisha.gov.in/portal/default.asp">http://www.odisha.gov.in/portal/default.asp</a> (view all tenders). If the Tender Document is downloaded from the website then the Bidders is required to pay the cost of the Tender Document of Rs.5250/- including VAT @ 5% (Non-refundable) by way of separate Demand Draft drawn in favour of Joint Director, State Drug Management Unit, (O), Bhubaneswar which should be enclosed along-with the Technical Bid and in such cases the Bidders should specifically superscribe, "DOWNLOADED FROM THE WEBSITE" on the top left corner of the outer envelope containing Technical Bid and Price Bid separately. The Tender Document Cost and the EMD amount should be submitted separately in two separate demand drafts. In case of any bid amendment and clarification, responsibility lies with the bidders to collect

the same from the website or the office notice board on or before the last date for purchase of tender document as mentioned in the Tender Document and the Tender Inviting Authority shall in no case be held responsible for any such delay or omission on part of the bidder in updating itself.

#### **ELIGIBILITY CRITERIA:**

- 2.1.1 Tenderer shall be either a manufacturer or loan licensee or a direct importer (having valid import license issued by the Drug Controlling Authority of India).
  - a) In case of manufacturer or Loan licensee, it shall have a valid manufacturing license issued by the drug controlling authority.
  - b) In case of direct importer, it shall have a valid import license issued by drug controlling authority, India and the manufacturer should authorize the importer to deal business in India.
- 2.1.2 In case of manufacturer, it shall have valid GMP certificate as per revised schedule M of Drugs & Cosmetics Act 1940 (by & large GMP certificate will not be accepted) or WHO-GMP certificate.
- 2.1.3 Distributors / Suppliers / Agents / C&F Agents / C&A Agents are not eligible to participate in the tender on behalf of any company.
- 2.2 Tenderers (manufacturer/ importer) shall have a minimum turnover ofRs.10 crore or more from pharmaceutical products in each of the year for last three financial years in India.
  - The approved supplier (tenderer) shall have the direct responsibility for supply of stock and who shall only be entitled to raise the bills against such supply. Payments will be made only in favour of the approved supplier (tenderer).
- 2.3. Tenderer / manufacturing unit which has been blacklisted / debarred for any item either by the Tender inviting authority or by any state Govt. or central Govt. Organisation cannot participate in the Tender for that item during the period of blacklisting / debarment.

- 2.4.1 Tenderer shall have a minimum of 3 (three) years of experience in supplying drugs & medical consumables (related to the items quoted in the tender) to the Government / Corporate / PSU Hospitals in India as a manufacturer or otherwise. (Proof of supply to be submitted in "Format T6" duly attested by Notary Public or Gazetted Officer)
- 2.4.2 Tender shall submit a **market standing certificate** issued by the drug licensing authority of the respective state that the quoted product is manufactured/imported and marketed by them since last 3 years.

#### Note:

- A. "A Manufacturer" is defined as an entity (individual, firm or company) having its own or loan manufacturing facility and performs all the manufacturing and processing operations needed to produce drugs in their appropriate dosage forms, including processing, blending, formulating, filling, packing, labeling and quality testing with a valid manufacturing license (including loan manufacturing license) under Drugs & Cosmetics Act, 1940 and Rules.
- **B.** Third party manufacturing units i.e. drugs manufactured by one unit and marketed by another unit / firm will not be allowed to participate in the tender.
- C. The term "Authorised Signatory", means a Proprietor / Proprietress, or a Managing Partner or an whole-time employee, in executive cadre, in a Proprietorship Concern / Partnership Firm or a person who is working as Managing Director / Director Finance / Director Marketing / General Manager / Assistant General Manager / Manager / Company Secretary in the Tenderer Company, who has authority to take decision on the spot with regard to all the aspects of the tender.
- **D.** "Tenderer" means the Manufacturer / Manufacturer with loan license /Importer participating in this tender.
- **E. Valid up-to-date** means the certificate should be valid on the date or beyond the opening of Tender (Cover-A) as per Tender conditions. In case the validity of GMP / manufacturing license has expired on the date of opening of tender and the firm / tenderer has applied for renewal of the

same, a letter from the licensing authority has to be attached alongwith the tender submitted mentioning that the renewal is under process / consideration.

Tender shall be submitted in a single sealed cover containing both Technical Bid (Cover A) and Price Bid (Cover B) separately in two different sealed cover as described hereunder. The content of the technical and price bid shall be put in two separate sealed covers and superscribed as "Cover 'A' (Technical Bid)" and "Cover 'B' (Price Bid)" respectively. Then both the covers should be put into a third Cover, which should be superscribed as "Tender for the supply of Drugs & Medical Consumables to the Govt. of Odisha". "Bid Reference No. – SDMU/ 2012 – 2013 – DMC – 007 (CAT-III)".

Following documents shall be submitted in **Cover-'A'** (Technical Bid) by the tenderer. All the photocopies shall be attested either by a Gazetted Officer or Notary Public.

#### **DOCUMENTS TO BE SUBMITTED TECHNICAL BID (COVER- 'A'):**

- 3.1 Earnest Money Deposit of Rs.1,00,000/- (Rupees One Lakh only).
- 3.2 Checklist with detail of the documents enclosed in Cover 'A' (as per **Format T1**) with page number. The documents should be serially arranged as per this format and should be securely tied or bound.
- 3.3.1 Particulars of the tenderer (Company, Firm and Individual) and its authorized representative (Director/Managing Partner/Proprietor) like; name, address, telephone no., mobile no., fax, e-mail, etc. (As per Format T2).
- 3.3.2 Address, Telephone No., mobile No., e-mail, Fax of the Branch Office /
  Contact Person in Odisha. (As per Format T2)
- 3.4 List of items quoted with strength / specification and packing (Format T4).
- 3.5 Valid up-to-date Manufacturing License (including loan licenses, if any) with **drug endorsement** (i.e. the list of approved items issued at the

time of grant / renewal of the license and it should be a single list) of the items quoted / copy of import license if items quoted are imported / copy of BIS certificate wherever applicable. If the validity of license has expired on the date of bid opening, then letter from the licensing authority is to be attached alongwith the tender submitted mentioning that the tenderer has applied for renewal as per D&C Act.

- In case of manufacturer or loan licensee, the copy of the valid manufacturing license issued by the drug controlling authority with drug endorsement of each item quoted, has to be submitted alongwith the tender.
- ii) In case of importers, copy of the **import license certificate** issued by Drugs Controller General of India, New Delhi will have to be submitted by the tenderer. The importer shall also submit the authorization certificate from the manufacturer to deal business in India.
- 3.6 Valid up-to-date Good Manufacturing Practice (GMP) certificate of the manufacturer as per the revised Schedule M of Drugs & Cosmetics Act 1940 / WHO GMP certificate from the licensing authority. If the validity of license has expired on the date of bid opening, then letter from the licensing authority is to be attached alongwith the tender submitted mentioning that the tenderer has applied for renewal as per D&C Act.
- 3.7 Certificate duly filled by the Auditor / Chartered Accountant (as per **Format T5**) that the annual turnover of pharmaceutical products of the tendering firm is **Rs.10 crore** or more in each financial year (as per clause No. 2.1) for preceding 3 (three) financial years i.e. 2009-10, 2010-11 and 2011-12.
- 3.8.1 **Market Experience** (Performance Statement) towards supply of the quoted pharmaceutical product to Govt./ Corporate Hospitals/ PSU Hospitals in India during the last three financial years (as per **Format T6**)
- 3.8.2 Copies of purchase orders/contract in support of the information provided in the performance statement.
- 3.9 Non Conviction certificate issued by the licensing authority of the state that the manufacturers/importer have not been convicted under the

- provision of D&C Act 1940 by any court of law in contravention to the above Act & Rules.
- 3.10 **Market standing certificate** by the licensing authority that the quoted pharmaceutical product is manufactured and marketed by the tenderer since last three years inside India (applicable both for manufacturer and importer).
- 3.11 An affidavit as per **Format T3** for abiding all the tender terms & conditions and printing of logo / labeling on the carton/ strip/ packets/ foils/ amp./ vial/ bottle as the case may be and put bar coding sticker on secondary & tertiary packing.
- 3.12 Declaration for compliance of GMP as per Format T7.
- 3.13 Sales tax/ VAT clearance certificates till 31.03.2012 (wherever applicable).
- 3.14 The original / downloaded tender book duly signed and sealed in each page with original receipt.

### **COVER - B (PRICE BID):**

- 4.1 The rates offered or quoted by the tenderer for various drugs and medical consumables (item-wise) should be submitted in a separate sealed cover hereafter-called **Cover 'B'** (**Price Bid**). The list of items with specifications for which tenders are invited are in **Annexure-I.**
- 4.2 The Price Bid (price schedule) in the prescribed form (as per Format P1) should be submitted in duplicate inclusive of excise duty, insurance, packing, forwarding and freight (i.e. door delivery) but exclusive of Central Sales Tax / VAT & Entry Tax only. The rate should be quoted for each tablet / capsule / vial / ampoule / bottle / tube etc. i.e. only absolute rate (both in figures and words). But supply will be made in unit pack as per tender specifications. The hard copy of price schedule must be signed and sealed in each page by the tenderer.

- 4.3 If the tenderer has depot. inside Odisha, i.e. VAT is paid to Government of Odisha, then the same has to be clearly mentioned in the top of the price schedule.
- 4.4 The Cover 'B' should contain the price schedule duly signed and stamped (Format P1) by the tenderer along with the C.D. / Pen drive i.e. both soft copy and hard copy (as per the format P1) properly filled in price column both in figures and words.
- 4.5 The "Cover 'B"" of only those tenderers who qualify in technical bid evaluation will be opened at the Office chamber of the Joint Director, State Drug Management Unit, in-front Ram Mandir, Bhubaneswar by the Director of Health Services, Odisha, Bhubaneswar in the presence of the tenderers or their authorised representatives. The date & time to this effect will be intimated later on.

#### NON RESPONSIVE / REJECTION CRITERIA

- 4.6 The tender will be rejected if any one of the following documents is not furnished along with the tender document.
  - i) Earnest Money Deposit (EMD) of Rs.1,00,000/-
  - ii) Attested photocopies of up-to-date valid manufacturing license/ loan license with drug endorsement of the item quoted in case of manufacturer/loan licensee or an attested photocopy of up-to-date valid import license issued by Drugs Controller General, India in case of an importer (as per eligibility criteria at Clause 2.1.1)
  - iii) Any pre-condition by the tenderer contradicting to the tender terms and conditions.
  - iv) Duly attested valid up-to-date Good Manufacturing Practices

    Certificate (GMP) of the manufacturer as per revised Schedule M

    or WHO GMP certificate (as per eligibility criteria at Clause 2.1.2)
  - v) Proof of annual turnover of Rs.10 crore or more in each year during preceding three financial years (ref. Clause No. 2.2) with respect to pharmaceutical products only in India being certified by Auditor / Chartered Accountant (as per Format T5).

- vi) Price Bid / Quotation (hard copy) without signature and seal of tenderer.
- vii) Proof of Market Experience (Performance Statement) of 3 (three) years or more for pharmaceutical products in India by the tenderer (manufacturer or importer).

#### **EARNEST MONEY DEPOSIT (BID SECURITY):**

- 5.1 The earnest money deposit referred to at clause 3.1 will be **Rs. 1,00,000/-** (Rupees One Lakh) only will be submitted by the tenderer irrespective of number of items offered. The earnest money deposit must be paid in the shape of demand draft in favour of the Joint Director, State Drug Management Unit, Odisha from any Nationalised / Scheduled Bank payable at Bhubaneswar which will be deposited in the revolving fund of SDMU(O). This should be submitted with the tender in Cover 'A'. **E.M.D. in shape of Cheque / Cash / Postal Order will not be accepted.**
- 5.2 The E.M.D will be forfeited by the D.H.S. (O), if the tenderer;
  - (a) Withdraws the tender in any respect within the validity of the bid or does not accept the approved rates;
  - **(b)** Fails to furnish the required performance security within the specified period.
- 5.3 The E.M.D of the unsuccessful bidders only will be returned back from the revolving fund of SDMU (O) without interest after publication of the approved list and E.M.D of the successful tenderers will be returned only after deposit of the performance security (security deposit) amount in the manner and within the time limit prescribed in the bid document.
- 5.4 The local micro, small & medium enterprises registered with respective DICs, Khadi, Village, Cottage & Handicraft Industries, OSIC & NSIC shall be exempted from payment of EMD.

#### **PERFORMANCE SECURITY:**

6.1 The successful tenderer shall deposit performance security within 21 days of issue of purchase order in shape of bank draft from any Nationalised/

Scheduled Bank in favour of the Joint Director, State Drug Management Unit, (O), Bhubaneswar only. The amount of performance security shall be determined on the basis of the value of the Purchase Order as detailed under clause no 6.3 which will be deposited in the revolving fund of SDMU (O). In case the firm fails to deposit the performance security in the prescribed manner and within the specified time limit, the Purchase Order shall be cancelled in addition to the forfeiture of EMD amount if not refunded.

- 6.2 The Performance Security will be returned back to the tenderer without interest from the revolving fund of SDMU (O) after expiry of approved list/extended period if any/ completion of the supply against the respective purchase order or completion of the quality testing, whichever is later. Performance Security shall be collected against each Purchase Order separately based on the value of the respective Purchase Order. The previous performance security if any will be adjusted if all the obligations like supply & quality testing against that purchase order have been completed.
- 6.3 The calculation of Performance Security shall be as per the table given below:

Sl. No	Value of Purchase Order	Performance Security (Rs)
a.	Upto 1 lakh	10,000/-
b.	More than Rs.1 lakh and upto Rs.5 lakh	25,000/-
c.	More than Rs.5 lakh and upto Rs.10 lakh	50,000/-
d.	More than Rs.10 lakh and upto Rs.20 lakh	1,00,000/-
e.	More than Rs.20 lakh and upto Rs.50 lakh	2,00,000/-
f.	More than Rs.50 lakh and upto Rs.1Crore	5,00,000/-
g.	More than Rs.1Crore and upto Rs.2 Crore	10,00,000/-
h.	More than Rs. 2 crore and above	20,00,000/-

6.4 The successful local micro, small & medium enterprises registered with respective DICs, Khadi, Village, Cottage & Handicraft Industries, OSIC & NSIC shall pay 25% of the prescribed performance security deposit.

#### **TENDER CONDITIONS:**

- 7.1 The quoted rate shall not vary with the quantum of order placed for destination points.
- A copy of the original tender conditions and the schedules should be signed by the tenderer at the bottom of each page with the official seal duly affixed and returned as a part of the Technical Bid in Cover 'A'. Each and every enclosed document shall be serially numbered with an index page at the front for both Technical and Price Bid separately. The paging must be done on all the documents submitted in "Cover A" & "Cover B".
- 7.3 Tenders shall either be typewritten or machine-written (Computer Printer) and every correction /over-writing in the enclosed document should invariably be attested by the authorized signatory to the tender with date before submission of the tenders. No revision of price (upward or downward) will be allowed once the tender is opened ("Cover B").
- 7.4.1 The Price Bid (Price Schedule) must contain the rate of each Tab. / Cap. / Inj. / Bottle which includes Excise Duty, Transportation (i.e. door delivery), Insurance and all other charges etc. and excludes C.S.T / VAT & Entry Tax only. The absolute rate should be quoted both in figures and words.
- 7.4.2 If there is a discrepancy between words and figures the amount mentioned in words will prevail.
- 7.4.3 If there is discrepancy in absolute and unit rate (which is obtained by multiplying the absolute rate with the total number in a unit pack) the absolute price will prevail and the unit rate will be corrected accordingly.
- 7.5 The price quoted by the tenderers shall not in any case exceed the controlled price, if any, fixed by the Central / State Govt. / N.P.P.A (National Pharmaceutical Pricing Authority) / DGS&D and the Maximum Retail Price (MRP). The Director of Health Services, Odisha

- at his discretion will exercise the right of revising the price at any stage so as to confirm to the controlled price as the case may be.
- To ensure sustained supply without any interruption the Director of Health Services, Odisha reserves the right to split orders for supplying the requirements among more than one tenderer provided that, the rates and other conditions of supply are equal and with sufficient grounds. In case of non-supply of any item by any approved lowest quoted firm, the D.H.S. (O) can ask for willingness to L<sub>2</sub> / L<sub>3</sub> / L<sub>4</sub> firm to supply at L<sub>1</sub> rate (lowest approved rate) and procure the same item in L<sub>1</sub> rate sequentially.

  7.7 The rates quoted and accepted will be binding on the tenderer for a period of one year from the date of publication of the approved list or that of publication of the next approved list whichever is earlier and on no account any increase in the price will be entertained till the completion of this tender period.
- No tenderer shall be allowed at any time on any ground whatsoever to claim revision of or modification in the rates quoted by him. Clerical error, typographical error etc. committed by the tenderers in the tender forms will not be considered after opening of the tenders. Conditions such as "SUBJECT TO AVAILABILITY, SUPPLY WILL BE MADE AS AND WHEN SUPPLIES ARE RECEIVED" etc. will not be considered under any circumstances and the tenders of those who have given such conditions shall be treated as incomplete and for that reason, shall be summarily rejected.
- 7.9 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 Govt. or by the tenderer himself, the tenderer shall be morally and statutorily bound to inform the Director of Health Services, Odisha immediately about such reduction in the contracted prices. The Director of Health Services, Odisha 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. In case of any enhancement in Excise

Duty/Custom Duty due to statutory Act of the Govt. after the date of submission of the tenders and during the tender period, the additional excise duty/custom duty so levied will be allowed to be charged extra as separate item without any change in price structure of the drugs approved under the tender. For claiming the additional cost on account of the increase in excise duty/custom duty, the tenderer should produce letter from the concerned excise authorities indicating his commitment for the supply made to the Director of Health Services, Odisha on account of the increase in excise duty/custom duty.

- 7.10 Preference will be given at the time of evaluation of the Tender to the tenderers / firms having WHO GMP certificate for that item when the price quoted by different firms are equal / same.
- 7.11 The Tax will be charged as per the guidelines issued by the Finance Deptt. from time to time. Only one Sales Tax either C.S.T / VAT will be paid to the supplier. In case of Entry Tax the supplier has to deposit the original receipt to claim it, if finished goods are brought from outside the State. The Sales Tax / VAT & E.T component should be shown separately in the cost price (Price Schedule) (Format P 1).
- 1.5% of the purchase order value will be deposited for all the supplies by the Approved Supplier (Contractor) in the shape of Bank Draft towards Quality Testing, Packaging and Forwarding (sample) charges before issue of Stock Entry Certificate in favour of Joint Director, State Drug Management Unit, (O) to be deposited in the revolving fund. But the supply of each drug / consumable must be in minimum batches. If more than 1.5% of purchase order value is spent towards quality testing due to more number of batches, the extra cost will be collected from the supplier. The balance amount if any remaining due to less batch and bulk supply out of 1.5% will not be returned to the supplier and will be deposited in the revolving fund.

7.13 3% of the purchase order value of the supplies whose place of delivery as per the Purchase Order is at Central Drug Store (Bhubaneswar), will be deposited by the Approved Supplier towards transportation cost (As ultimately the supplies shall be transported to the district and medical college warehouses from the Central Drug Store) in favour of Joint Director, State Drug Management Unit, Bhubaneswar in shape of Bank Draft to be deposited in the revolving fund account. This transportation cost of 3% shall be deposited before issue of the Stock Entry Certificate and processing of bill for payment.

If purchase order is placed for other destinations except Central Drug Store (Bhubaneswar) and the Supplier seeks a permission to supply at Central Drug Store, Bhubaneswar this may only be allowed by the Joint Director, State Drug Management Unit, (O) with 3% transportation charges, if the value of the Purchase Order for a single item is less than Rs. 20,000/- (Rupees twenty thousand) and for all items is less than Rs. 40,000/- (Rupees Forty thousand) per consignee against a particular Purchase Order, subject to the availability of storage space.

- The D.H.S. (O) / Joint Director, State Drug Management Unit, (O) has the discretion to grant permission to the Supplier upon a written request made by him taking into consideration the gravity of the situation and availability of space, etc., on a case to case basis..
- 7.14 All the prices quoted should be in Indian Currency only, as the payments will be made in Indian Currency only.
- 7.15 If the Govt. desires, it can extend the period of validity of approved list by mutual consent.
- 7.16 In the event of the date being declared as a holiday for Govt. of Odisha, the due date of submission of bids and opening of bids will be the following working day at the appointed place and time.
- 7.17 All the documents submitted must be in English / Oriya otherwise its attested English version must be attached in the tender document.

- 7.18 A manufacturer / supplier will not be declared as part supplier / non-supplier if he has completed 80% (eighty percent) of the ordered quantity within 70 days or within such extended period with liquidated damage charges.
- 7.19 The selected tenderer shall furnish the source of procurement of raw materials utilised in the formulations and the costing as and when required by the purchasing authority. The Director of Health Services, Odisha / Joint Director, State Drug Management Unit, (O), Bhubaneswar reserves the right to cancel the purchase order in case when asked for verification, the source of procurement of raw material and costing are not furnished.
- 7.20 There will be a **pre-bid conference** prior to submission of Bids for a discussion with the prospective bidders to clarify their doubts in interpreting tender terms and conditions, if any. The prospective bidders are free to put forth points, in writing or otherwise, if they feel it has a bearing in the tendering process. However, it is up to the tender inviting authority to take a final decision.
- 7.21 The Director of Health Services, Odisha reserves the right to reject the tenders or to accept the tenders for the supplies related to all items or of any one or more of the items tendered for without assigning any reason.
- 7.22 The Director of Health Services, Odisha will be at liberty to terminate the contract without assigning any reason thereof either wholly or in part. The tenderer will not be entitled for any compensation whatsoever in respect of such termination.
- 7.23 If the tenderer fails to execute the supply within the stipulated time, the Director of Health Services, Odisha is empowered to make emergency purchases or purchase from  $L_2$ ,  $L_3$  firms if they match the  $L_1$  rate and apply the penal clauses on the defaulting firm.
- 7.24 The purchase order and the payments shall be made directly in the name of the approved supplier through Regd. Post / Speed Post / Courier / e-payment.
- 7.25 The tender document is not transferable.

#### **SUPPLY CONDITIONS:**

- 8.1 The approved supplier will supply as per the technical specification and print the generic name in bold letters and brand name if approved by the licensing authority may be printed in small font in strip / bottle / injection / packing / foil / carton / box, etc. (Annexure III & IV). The supplier will quote in the generic name and once items are approved in generic name, the supplier can supply in brand name mentioning the generic name prominently in bigger font size.
- 8.2 The approved supplier shall deliver the Supplies (Drugs & Consumables) to the different warehouses (**Door Delivery**) of the state as per **Annexure II.** The insurance, storage & transport charges / courier charges if any will be borne by the supplier. The short supply, damage if any at the time of delivery of consignment shall be replaced by the supplier within seven days of the first supply of indented items.
- 8.3 In all the cases the responsibility of the purchaser will start only after receipt and due verification of goods by the receiving authority.
- 8.4 The Composition and strength of each item tendered should be as per the specification given in **Annexure I** (Technical Specification).
- 8.5 All oral liquid preparations will be supplied in non-breakable plastic containers as per standards laid down in I.P 96. The tenderer quoting for oral liquid preparations will have to give an undertaking that the plastic containers are made from materials confirming to Indian Pharmaceutical Specifications standard and a copy of the test report of the plastic container used by them are from an approved laboratory under the Drugs & Cosmetics Act and Rules thereunder. If any of the item (Oral liquid preparation) in the Tender is not permitted to be supplied in non breakable plastic containers as per I.P, the same item can be packed in virgin glass bottle as per I.P.
- 8.6 Supply should be as per technical specification together with a detail label as per rule 96 of D&C Rules 1945.

- 8.7 The D.H.S. (O) can place the purchase order for any item in a phased manner to be supplied within a stipulated time limit depending on the requirements / the scheme / situation.
- 8.8 The supply should be started immediately within 30 days and completed within 70 days from the date of issue of the purchase order. If no supply is received after 30 days or the entire supply is not completed within 70 days from the date of issue of purchase order, the Joint Director, State Drug Management Unit, (O) may cancel the order or allow extension of time applying the liquidated damage clause depending on the situation. The D.H.S. (O) has also the liberty to cancel those orders and purchase the same item from  $L_2 / L_3 / L_4$  firm as the case may be if the other firms agree to supply at  $L_1$  rate. The non-supplier will be penalised as specified at clause 17. He shall also suffer forfeiture of the E.M.D and or security deposit.
- 8.9 The D.H.S. (O) has the liberty to instruct the approved supplier to start the supply immediately and complete within a shorter period, if the situation so demands.
- 8.10.1 Each installment and batch of supply of drugs & medical consumables must be accompanied with a test certificate from a NABL / Government laboratory (like CRL Kasauli in case of Vaccines/ Govt. drug testing laboratory in case of other drugs) that the supplied drugs of the respective batch(s) are of standard quality and as per the pharmacopoeial standard mentioned in the technical specification. The full name and qualification of the certifying Chemist / Analyst should be mentioned with the signature in the test reports. In case of vaccines, if there is 1 3 months delay in getting the test report from Government laboratory like; CRL Kasauli, then the same may be allowed by the Jt. Director (SDMU).
- 8.10.2 The supplier has to submit a copy of the standard quality test report of the batches supplied & a copy of the purchase order to the consignee at the time of supply.
- 8.11 The Drugs and Medical Consumables shall be delivered at the distribution points (warehouse) with **remaining shelf-life** of at least 5/6<sup>th</sup>

- of the stipulated total shelf-life from the date of manufacturing of that product.
- 8.12 The labels in all case of injectables should clearly indicate whether the preparations are meant for INTRA VENOUS, INTRA- MUSCULAR or SUB-CUTANEOUS or INTRA-DERMAL etc.
- 8.13 No item of Drugs and Consumables should bear the price of the item in its Strip / Bottle / Carton / Packet / Box / Vial / Amp. / Than / Foil etc.

#### **AGREEMENT:**

9.1 The successful tenderer shall execute an agreement on a **Rs.100/-** Non Judicial Stamp paper (**stamp duty to be paid by the Tenderer**) with the Joint Director, State Drug Management Unit, Odisha, Bhubaneswar within **21** days from the date of issue of purchase order. The specimen format of the agreement is as per **Annexure – VI**.

## PACKAGING (As per Annexure – III):

- 10.1 All the packaging should be New. The supplier shall provide such packaging of the goods as is required to prevent their damage or deterioration during transit to their final destination. The packaging shall be sufficient to withstand without limitation rough handling during transit and exposure to extreme temperature, salt and precipitation during transit and upon storage. All primary packaging containers, which come in contract with the drug content, should strictly protect the quality & integrity of the drug and medical consumables (as per Annexure III).
- 10.2 The packaging cartons must bear the name of the items (Generic names), strength, total quantity, total weight, name of the manufacturer, month of manufacturing and month of expiry (As per Annexure III).

  The packaging should be as per specification given in Annexure III.
- 10.3 Each Strip / Box / Carton / Bottle / Amp. / Vial / Than / Roll of Gauze and Bandage shall bear the seal of the manufacturer and month of manufacturing, month of expiry & Batch No. and labeling of "ODISHA GOVT. SUPPLY NOT FOR SALE" "ଓଡ଼ିଶା ସର୍କାର୍କ ଯୋଗାଣ ବିକ୍ରୟ ପାଇଁ

ÈềÜi" (As per Annexure – III & IV).

10.4 Labeling and packing of medicines and medical consumables should be as per specification laid down under D&C Act, 1940 and Rules there under made and modified.

#### **LOGOGRAMS, LABELING & BAR CODING:**

- The tenderer should give an undertaking (As per Format T3) that he will print "Odisha Govt. Supply Not For Sale" "ଓଡ଼ିଶା ସରକାର୍କ ଯୋଗାଣ Ì ଣ୍ଡ R ÉaSi ÈàÜi" in bold letters in contrast ink on each unit Strip / Box / carton / Vial / Amp. / Bottle / Pkt. / Tubes / Cotton / Gauze / Bandage / Roller Bandage & Foil etc. All the tablets and capsules have to be supplied in standard packing as per technical / packaging specification enclosed in Annexure III. Affixing of stickers and rubber stamps shall not be accepted except Gauze and Bandage. It is applicable for both SSI Units of state of Odisha as well as other firms uniformly.
- 11.2 2D bar coding should be done on tertiary and secondary packing of the supplies as per the specifications given in **Annexure V.**

#### **QUALITY TESTING:**

- 12.1 The approved supplier shall, furnish a copy of the test report for each batch of items supplied by him specifically issued by NABL accredited testing laboratories / Government testing laboratory (like; CRL Kasauli in case of Vaccine/ Govt. Drug Testing Laboratory) at the time of delivery to the consignee. Basing on the NABL/ Govt. Laboratory standard quality test report, the same batch of drug can be distributed for issue/ consumption at health institutions/facility level.
- 12.2 Random samples from the supplied batches supplied from each item, at the point of delivery/ storage or distribution will be collected by the consignee as a part of standard quality assurance procedure. The samples collected will be forwarded to SDMU who will send the same after coding (except hygroscopic drugs) to different NABL accredited laboratories for appropriate quality testing as decided by the procuring authority. If the outcome of quality testing for a particular batch of a item

is found to be of NSQ (Not of Standard Quality) as per the test report then the supplier shall either replace the entire quantity (100%) of supply of that batch or pay-back the entire cost of it in shape of Bank Draft in favour of Joint Director State Drug Management Unit, (O) / Director of Health Services, Odisha to be deposited in the revolving fund for procurement of other medicines / consumables. In case of a NSQ report the Supplier shall take back the available stock (unused) in different health institutions (facilities) of the State at his own cost within a period of 30 days of the issue of the letter from the Director of Health Services, Odisha / Joint Director State Drug Management Unit, (O).

- 12.3 If the supplier does not take back the NSQ stocks within 30 days of issue of letter by the directorate, the concerned health institution can destroy the NSQ stocks with intimation to the Joint Director, SDMU (O) and concerned Drug Inspector.
- 12.4 If the firm / supplier **challenges the 1st NSQ test report within 15 days** then two separate samples of the same batch will be sent to 2 (two) other NABL drug testing laboratories. The majority opinion of the testing laboratories will be accepted. The expenditure towards packing, forwarding and testing fees for two more additional quality test (as decided by Joint Director, S.D.M.U) will be deposited by the supplier in advance within 15 days of issue of letter by the Directorate for further 2 (two) tests which is in addition to 1.5% testing fees already deposited by the supplier for Quality Testing. The quality testing will be done in different NABL laboratories in rotation basis irrespective of variable quality testing charges.
- 12.5 If either of the test reports of samples drawn from same batch of one drug item by D.C (O) or SDMU (NABL accredited lab) comes out to be NSQ then it would be considered to be of NSQ drug and all provisions as applicable for NSQ drugs shall be applied. If the supplier challenges the test report in the above circumstances then the sample shall be sent to Central Drugs Testing Laboratory, whose report will be final and binding.

- 12.6 If it is found out that one batch of one item has come out to be NSQ two times after challenge then the firm must replace the full supplied quantity of NSQ batch or deposit the cost of it within one month of issue of letter and the firm will also be de-recognised for 3 (three) years from the date of issue of the letter for that item and no further supplies will be accepted from him for that item. The tenderer will also not be eligible to participate in Director of Health Services, Orissa Tenders for that item for supply of Drugs and Consumables for a period of 3 (three) years from the date of issue of letter, no further purchase order will be placed to him & no further supplies will be accepted from him for 3 years. Any amount (price) received by the firm for that product (Not of Standard Quality) must be returned to Director of Health Services, Orissa within 15 days from the date of issue of the order or the amount so received will be adjusted from any other dues payable to him or from the EMD and security money deposited by the firm as the case may be. In case of local SSI Units, if there is no amount to be payable then the amount can be recovered from the concerned firm under the OPDR Act, 1962. No further purchase order will be placed to that firm for that product. Also in case of gross negligencies, where the tenderer is found to have supplied NSQ drugs & medical consumables and fail to comply with the terms & conditions of supply mentioned in the Tender, the security money will be forfeited and the firm will be blacklisted for a period of three years from the date of issue of the letter.
- 12.7 If 2 (two) or more than 2 (two) batches of one item or two (2) times of one batch of drug comes out to be Not of Standard Quality, then the supplier of that item / drug will not be given any purchase order for that item / drug for a period of 3 (three) years and the firm will be blacklisted for a period of 3 (three) years in addition to replacement of the full quantity of that batch of supply within 30 days of issue of letter.
- 12.8 If there is report of any physical changes/deterioration/Not of Standard Quality on visual inspection of any drug from any of the consignee after receipt of Standard Quality analytical test report either from NABL or

from D.C.(O), the technical committee under DHS (O) will take the decision relating to the quantity to be replaced on a case to case basis which will be binding on the supplier.

#### **EVALUATION PROCEDURE:**

- 13.1 The rates of each item quoted by the tenderer will be evaluated after taking the following points into consideration:
  - a) Rates will be evaluated / compared after inclusion of the excise duty, transportation, insurance, packing & forwarding.
  - b) Excluding VAT / CST & Entry Tax.
  - c) After giving price preferences to eligible local S.S.I. Units of Odisha. (Ref. Clause 18.6)
  - d) As per the Govt. of Odisha Finance Deptt. Order No. 48317(230)/F dt.23.11.2010, in comparing the cost of an article, if purchased from within the State with the price of similar article if purchased from outside the State, the amount of Odisha Sales Tax (OST) now VAT shall be deducted from the total cost since it accrues back as revenue to the State. If after such deduction, the cost of articles to be purchased within the State is not more than the cost of including Central Sales Tax, transport and other charges of similar articles from outside the State, it would be economical to purchase articles within the State.

#### **ISSUE OF PURCHASE ORDER:**

14. The purchase orders will only be sent to the concerned approved supplier by email and registered post / speed post / courier / fax.

#### **LIQUIDATED DAMAGE:**

15.1 The Joint Director, State Drug Management Unit, (O) may allow extension for a maximum period of 28 days, after the stipulated date of supply, i.e. 70 days from the issue of purchase order, with the penalty of 1% of purchase order value as "Liquidated Damage", for each week upto a maximum of 4% on the value of the goods. So, the firm has to supply

medicines and other consumables without penalty upto 70 days and with penalty of 1% each week for the delayed supplies upto a maximum of 4%.

15.2 The D.H.S. (O) may allow further 4 (four) weeks (28 days) beyond 98 days only on justified grounds with a liquidated damage of 2% per week (7 days) upto a maximum of 12% (4% for first 4 weeks + 8% for additional 4 weeks) of purchase order value as liquidated damage i.e. from 71 days to 126 days from the date of issue of purchase order i.e. 4% from 71 to 98 days, 8% from 99 to 126 days). No firm can claim extension of times for supply beyond 70 days from issue of purchase order. The D.H.S. (O) can apply all the penal clauses for non-supply / part supply beyond 70 days from issue of purchase order. The details of the liquidated damages to be deducted on the purchase order value are as per the followings:

$$(71^{\text{st}} \text{ to } 77^{\text{th}} - 1\%, 78^{\text{th}} \text{ to } 84^{\text{th}} - 2\%, 85^{\text{th}} \text{ to } 91^{\text{st}} - 3\%, 92^{\text{nd}} \text{ to } 98^{\text{th}} - 4\%,$$
  $99^{\text{th}} \text{ to } 105^{\text{th}} - 6\%, 106^{\text{th}} \text{ to } 112^{\text{th}} - 8\%, 113^{\text{th}} \text{ to } 119^{\text{th}} - 10\% \& 120^{\text{th}} \text{ to } 126^{\text{th}} - 12\%).$ 

15.3 If the supplier fails to complete the supply within the extended period, [70 days as per order or 98/126 days if allowed by Joint Director, State Drug Management Unit, (O)/ D.H.S. (O)] i.e., within the period of liquidated damage, no further purchase order will be placed to the firm for the said item and the concerned firm will be blacklisted for that item for three (3) years from the date of issue of letter.

#### TERMS OF PAYMENT:

- 16.1 No advance payments towards cost of Drugs, Consumables etc. will be made to the supplier. The supplier has to submit 4 (four) copies of the bills or invoices with a photocopy of the purchase order and the test certificate (from NABL / Govt. Laboratory) at the place of supply to the consignee for stock entry.
- 16.2 100% (full payment) of the value of the Drugs and Medical Consumables supplied shall be made on receipt of the stock entry certificate on the

body of the bill / invoice from the warehouses. Stock entry bills should be completed and sent to the competent authority for processing the payment within 7 days of receipt of goods if all documents and goods are as per order. All the process for payment should be completed within one month of receipt of stock entry certificates from consignee if all the documents have been submitted.

- Payments will only be released after keeping the security deposit, the quality testing charges, replacement / cost of NSQ items and transportation charges if any from the supplier, if they have not deposited the same before.
- 16.4 **A.** All payments will only be made online (e-payment / e-transfer) or registered post / speed post / courier to the concerned manufacturer / supplier after clearance of all pending dues.
  - **B.** To receive the payment online (e-payment / e-transfer) the selected firm has to open an account in the selected bank as per the guideline of the Joint Director, State Drug Management Unit, (O), Bhubaneswar and submit details of the Bank Account No., other details etc with a sample of cancelled cheque.
- 16.5 No payment will be made to the supplier:
  - (a) if the firm have not replaced the Not of Standard Quality (NSQ) drugs or cost of it.
  - (b) if the firm have not cleared the quality testing or transportation charges and security deposit as per the Tender terms & conditions, the D.H.S (O) / Joint Director, State Drug Management Unit, Bhubaneswar may keep an amount equal or more than the pending dues to be paid by the firm from their payments and may forfeit the same after 30 days notice and the firm will be blacklisted for 3 years (three) as per clause 17. The forfeited amount may be kept in the revolving fund towards purchase of drugs & medical consumables.

16.6 No claims shall be made against the Director of Health Services, Odisha in respect of interest on earnest money deposit or security deposit or delayed payment or any other deposit.

#### **PENALTIES:**

- 17.1 If the successful tenderer fails to execute the purchase order and /or deposit the required performance security deposit and / or quality testing fees or / replacement of full batch of NSQ or cost of it and transportation charges within the time specified or withdraws his tender / unable to undertake the contract or supply as per purchase order, his purchase order will be cancelled and the earnest money deposited and / or performance security deposit by him shall stand forfeited. He will also be liable for the damages sustained by the Director of Health Services, Odisha. Such damages shall be assessed by the Director of Health Services, Odisha, whose decision will be final in the matter. All the forfeited amount (EMD and or Security Deposit) may be deposited in the revolving fund of SDMU (O) and can be utilized for procurement of essential medicines.
- 17.2 If any items (Drugs or Medical Consumables) supplied by the approved supplier are found be in bad order, unsound, inferior in quality or description or otherwise faulty or unfit for consumption, at any time during the shelf life of the product, then the firm has to replace the entire quantity of that batch as per quality testing Rules (12.1 to 12.8) or the cost of total NSQ batch, irrespective of the fact that the supply has been consumed partially/fully.
- 17.3 Non performance of contract provisions, part supply & non supply of purchase order during the validity of the rate contract period will disqualify a firm to participate in the tender for a period of 3 (three) years for that item from the date of issue of order by DHS (O) and the E.M.D & or performance security deposit submitted by the firm for that item will be forfeited and no further purchase order will be placed to that firm for that item.

- 17.4 The Director of Health Services (O) can de-recognise/ blacklist the defaulting firms for that item for a period of three years from the date of issue of letter to the concerned firm for non-supply / part-supply or if two or more than 2 (two) batches of that item or two (2) times of one batch of that item comes out to be Not of Standard Quality.
- 17.5 The tenderer can be blacklisted for a period of 3 years by the tender inviting authority in case it is found at the time of evaluation/ verification/ inspection that the tenderer has furnished forged documents/false information alongwith the tender.
- 17.6 In the event of any litigation arising out of the tender such matters would be subject to the jurisdiction of High Court, Odisha or Civil Courts, Bhubaneswar.

#### CONDITIONS APPLICABLE TO SSI UNITS OF THE STATE:

- 18. The SSI Units of the State of Odisha will be eligible to participate in the tenders and get the price preference provided they produce the attested photocopy of the following documents:
- 18.1 Copy of valid manufacturing license of the quoted products with drug endorsement.
- 18.2 Proof of annual turnover for the last three years as per clause 2.2, 3.7.
- 18.3 Valid up-to-date Good Manufacturing Practice (GMP) certificate as per revised Schedule M or WHO GMP certificate.
- 18.4 Non-conviction certificate for last three years from the licensing authority.
- 18.5 P.M.T Certificate from the Director of Industries, Odisha or General Manager District Industries Centre that it is a SSI Units of the State of Odisha, provided that SSI units has not been derecognised by the Govt. for that specified period.
- 18.6 **A.** Local Micro, Small & Medium Enterprises and Khadi & Village industrial units including coir, handloom and handicrafts will be entitled for a price preference of 10% vis-a-vis local Medium and Large Industries and Industries outside the State (Odisha).

- **B.** Any local micro & small enterprises having valid ISO / ISI certification for their product will get an additional price preference of 3%.
- C. The local micro, small & medium enterprises registered with respective DICs, Khadi, Village, Cottage & Handicraft Industries, OSIC & NSIC shall be exempted from payment of EMD and shall pay 25% of the prescribed performance security.
- 18.7 The supplies will be delivered by the approved SSI Units at the destination points as mentioned in **Annexure II**.
- 18.8 Clause number 1 to 17 are also applicable to the Small Scale Industry Units of the state of Odisha.

# **ANNEXURES**

# **LIST OF ITEM & SPECIFICATIONS**

# ANNEXURE – I As per Clause 4.1 & 8.4

Sl No	Drug Code	Drug Name	Pharmacopoeial Standard.	Specification / Strength	Unit Pack
	Sub-Categ	ory: Anti Leprosy Drugs			
1	D10001	Tab. Dapsone (Aluminium foil/Blister pack)	IP	100 mg/Tab	10 Tabs/Strip 10 Strips/Box
2	D10002	Cap. Clofazimine (Aluminium foil/Blister pack)	IP	100 mg/Cap	10 Caps/Strip 10 Strips/Box
	Sub Categ	ory: Anti- Tubercular Drugs			
3	D11001	Inj. Streptomycin Sulphate (with diluents in plastic container)	IP	0.75 gm/Vial	0.75 gm/Vial 20 Vials/Box
4	D11002	Cap. Rifampicin (Aluminium foil/Blister pack)	IP	150 mg/Cap	10 Caps/Strip 10 Strips/Box
5	D11003	Cap. Rifampicin (Aluminium foil/Blister pack)	IP	450 mg/Cap	10 Caps/Strip 10 Strips/Box
6	D11009	Susp. Rifampicin (Palatable, with measuring cap and plastic container as per I.P)	BP	100 mg/5ml	200 ml/Bottle 20 Bottles/Box
7	D11004	Tab. INH (Coated) (Aluminium foil/Blister pack)	IP	100 mg/Tab	10 Tabs/Strip 10 Strips/Box
8	D11005	Tab. INH (Coated) (Aluminium foil/Blister pack)	IP	300 mg/Tab	10 Tabs/Strip 10 Strips/Box
9	D11007	Tab. Ethambutol (coated) (Aluminium foil/Blister pack)	IP	400 mg/Tab	10 Tabs/Strip 10 Strips/Box
10	D11010	Tab. Pyrazinamide (Coated) (Aluminium foil/Blister pack)	IP	750 mg/Tab	10 Tabs/Strip 10 Strips/Box

Sl No	Drug Code	Drug Name	Pharmacopoeial Standard.	Specification / Strength	Unit Pack
	Sub Categ	ory: Anti- Malarial Drugs	,		
11	D14002	Syp. Chloroquin Phosphate (Palatable, with measuring cap and plastic container as per I.P)	IP	80 mg of Chloroquin phosphate/5ml (with measuring cap & palatable) OR Chloroquine 50mg/5ml	60 ml/Bottle 20 Bottles/Box
12	D14003	Inj. Chloroquin Phosphate	IP	54.5 mg of chloroquin sulphate equivalent to 40 mg/ml of chloroquin or, 64.5 mg chloroquin phosphate equivalent to 40 mg of chloroquine / ml	5 ml/Amp 20 Amps/Box
13	D14004	Tab. Quinine Sulphate (coated) (Aluminium foil/Blister pack)	IP	300 mg/Tab	10 Tabs/Strip 10 Strips/Box
14	D14005	Inj. Quinine Di-Hydrochloride	IP	300 mg/ml	2 ml/Amp 20 Amps/Box
15	D14006	Tab. Primaquin Phosphate (coated) (Aluminium foil/Blister pack)	IP	7.5 mg/Tab,13 mg of primaquin phosphate equivalent to 7.5 mg of primaquin	10 Tabs/Strip 10 Strips/Box
16	D14017	Tab. Primaquin Phosphate (coated) (Aluminium foil/Blister pack)	IP	4.35 mg of primaquin phosphate equivalent to 2.5 mg primaquin	10 Tabs/Strip 10 Strips/Box
17	D14018	Inj. Artesunate		60 mg/Vial (with sodium Bi-carbonate 1ml+5ml NaCl)	7 Vials/Box
18	D14007	Tab. Artesunate (Aluminium foil/Blister pack)	EP	50 mg/Tab	4 Tabs/Strip 10 Strips/Box
19	D14008	Inj. Arteether (a:β)	EP	150 mg/2 ml	2 ml/Amp 20 Amps/Box
20	D14019	Tab. Sulphadoxine + Pyrimethamine (Aluminium foil/Blister pack)	IP	Sulphadoxine 500mg + Pyrimethamine 25mg / Tab.	2 Tabs/Strip 10 Strips/Box

Sl No	Drug Code	Drug Name	Pharmacopoeial Standard.	Specification / Strength	Unit Pack
	Category:	Anti- Filarial Drugs	,		,
21	D09097	Syp. Diethylcarbamazine Citrate (Palatable, with measuring cap and plastic container as per I.P) Amber colour bottle		100mg / 5ml	100 ml/Bottle 20 Bottles/Box
	Sub Catego	ory: Anti HIV Drugs	<u> </u>		
22	D32001	Tab. Zidovudine (Aluminium foil/Blister pack)	EP	300 mg/Tab	10 Tabs/Strip 10 Strips/Box
23	D32020	Zidovudine Oral Solution (Palatable, with measuring cap and plastic container as per I.P)	IP	50mg / 5ml	100 ml/Bottle 20 Bottles/Box
24	D32002	Tab. Lamivudine (Aluminium foil/Blister pack)		150 mg/Tab	10 Tabs/Strip 10 Strips/Box
25	D32021	Lamivudine Oral Solution (Palatable, with measuring cap and plastic container as per I.P)	IP	150mg / 5ml	100 ml/Bottle 20 Bottles/Box
26	D32003	Tab. Nevirapine (Aluminium foil/Blister pack)	EP	200 mg/Tab	10 Tabs/Strip 10 Strips/Box
27	D32022	Nevirapine Oral Suspension (Palatable, with measuring cap and plastic container as per I.P)	IP	50mg (as nevirapine hemihydrate) / 5ml	240 ml/Bottle 20 Bottles/Box
28	D32005	Cap. Stavudine (Aluminium foil/Blister pack)	EP	30 mg/Cap	10 Caps/Strip 10 Strips/Box
29	D32023	Stavudine Oral Solution (Palatable, with measuring cap and plastic container as per I.P)	IP	5mg / 5ml	60 ml/Bottle 20 Bottles/Box

Sl No	Drug Code	Drug Name	Pharmacopoeial Standard.	Specification / Strength	Unit Pack
30	D32006	Cap. Indinavir (Aluminium foil/Blister pack)		400 mg/Cap	10 Caps/Strip 10 Strips/Box
31	D32024	FDC - 6 (Triple) Disp. Tablet		Each Disp. Tab. Contains Lamivudine 30mg + Nevirapine 50mg + Stavudine 6mg	25 FDCs / Box
32	D32025	FDC - 6 (Dual) Disp. Tablet		Each Disp. Tab. Contains Lamivudine 30mg + Stavudine 6mg	25 FDCs / Box
33	D32026	FDC - 10 (Dual) Disp. Tablet		Each Disp. Tab. Contains Lamivudine 40mg + Stavudine 10mg	25 FDCs / Box
34	D32027	FDC - 10 (Triple) Disp. Tablet		Each Disp. Tab. Contains Lamivudine 40mg + Nevirapine 70mg + Stavudine 10mg	25 FDCs / Box
35	D32028	Tab. Efavirenz (Top Up) (Scored) (Aluminium foil/Blister pack)		200mg/Tab.	10 Tabs/Strip 10 Strips/Box
36	D32007	Tab. Efavirenz (HIV+TB) (Aluminium foil/Blister pack)		100 mg/Tab	10 Tab/Strip 10 Strips/Box
	Category:	Anti- Neoplastic Drugs			
37	D33004	Inj. Cyclophosphamide	IP	1gm/vial	1gm/Vial 20 Vials/Box
38	D33002	Inj. Cyclophosphamide		200mg/vial	200mg/Vial 20 Vials/Box
39	D33009	Tab. Methotrexate(coated) (Aluminium foil/Blister pack)	IP	2.5 mg/Tab	10 Tabs/Strip 10 Strips/Box
40	D33051	Tab. Methotrexate(coated) (Aluminium foil/Blister pack)	IP	5 mg/Tab	10 Tabs/Strip 10 Strips/Box
41	D33011	Inj. Methotrexate	IP	25 mg/ml LRC	2 ml/ Amp 20 Amps/Box
42	D33012	Inj. Fluorouracil	IP	25 mg / ml	5 ml / Amp 20 Amps/Box

Sl No	Drug Code	Drug Name	Pharmacopoeial Standard.	Specification / Strength	Unit Pack
43	D33017	Inj. Vincristine Sulphate	IP	1 mg / ml	1ml / Amp 20 Amps/Box
44	D33052	Inj. Vincristine Sulphate	IP	2mg / ml	1ml / Amp 20 Amps/Box
45	D33024	Inj. Cisplatin	IP	50 mg/Vial	50 mg / Vial 20 Vials/Box
46	D33045	Tab. Busulphan(coated) (Aluminium foil/Blister pack)	IP	2 mg/Tab	10 Tabs/Strip 10 Strips/Box
47	D33046	Inj. Doxorubicin HCl	IP	2 mg/ml	5 ml/Vial 20 Vials/Box
48	D33049	Tab. Cyclophosphamide (coated) (Aluminium foil/Blister pack)		25 mg/Tab	10 Tabs/Strip 10 Strips/Box
49	D33053	Inj. L-Asperginase (Powder form) (with diluents in plastic container)		10,000 IU / Vial	10,000 IU / Vial 20 Vials/Box
50	D33015	Inj. Adriamycin	IP	2 mg/ml	5 ml / Vial 20 Vials/Box
51	D33054	Inj. Adriamycin	IP	10 mg / ml	5 ml / Vial 20 Vials/Box
52	D33055	Inj. Carboplatin		10 mg / ml	15 ml / Vial 20 Vials/Box
53	D33056	Inj. Carboplatin		10 mg / ml	45 ml / Vial 20 Vials/Box
54	D33057	Inj. 5 Fluorouracil	IP	250 mg / 5ml	5 ml / Amp 20 Amps/Box
55	D33058	Inj. 5 Fluorouracil	IP	500 mg / 5ml	10 ml / Amp 20 Amps/Box

Sl No	Drug Code	Drug Name	Pharmacopoeial Standard.	Specification / Strength	Unit Pack
56	D33059	Inj. Epirubicin		10mg / Vial	10mg / Vial 20 Vials/Box
57	D33060	Inj. Epirubicin		50mg / Vial	50mg / Vial 20 Vials/Box
58	D33061	Inj. Epirubicin		100mg / Vial	100mg / Vial 20 Vials/Box
59	D33062	Inj. Actinomycin D		500 mcg / Vial	500mcg / Vial 20 Vials/Box
60	D33032	Inj. Vinblastine		10mg / Vial	10mg / Vial 20 Vials/Box
61	D33063	Tab. 6 - Mercaptopurine	IP	50 mg/Tab	10 Tabs/Strip 10 Strips/Box
62	D33035	Cap. Etoposide (Aluminium foil/Blister pack)	USP	50 mg/Cap	10 Caps/Strip 10 Strips/Box
63	D33064	Inj. Daunorubicin	USP	20mg/vial	20mg/Vial 20 Vials/Box
64	D33065	Inj. Arabinocide	BP	1gm/vial	1gm/Vial 20 Vials/Box
65	D33066	Inj. Arabinocide	BP	100mg/vial	100mg/Vial 20 Vials/Box
66	D33067	Cap. Cyclosporine (Aluminium foil/Blister pack)	USP	100 mg/Cap.	10 Caps/Strip 10 Strips/Box
67	D33048	Tab. Allopurinol (Aluminium foil/Blister pack)	IP	100 mg/Tab	10 Tab/Strip 10 Strips/Box

Sl No	Drug Code	Drug Name	Pharmacopoeial Standard.	Specification / Strength	Unit Pack
	Category:	Psycho Therapeutic Drugs			
68	D07006	Inj. Diazepam	IP	5mg/ml	2ml/Amp 20 Amps/Box
69	D27006	Tab. Haloperidol (Aluminium foil/Blister pack)	IP	5 mg/Tab	10 Tabs/Strip 10 Strips/Box
70	D27018	Tab. Haloperidol (Aluminium foil/Blister pack)	I.P	0.25 mg /Tab.	10 Tabs/Strip 10 Strips/Box
71	D27019	Tab. Haloperidol (Aluminium foil/Blister pack)	IP	10 mg / Tab	10 Tabs/Strip 10 Strips/Box
72	D27005	Tab. Haloperidol (Aluminium foil/Blister pack)	IP	1.5 mg / Tab	10 Tabs/Strip 10 Strips/Box
73	D27012	Inj. Haloperidol	IP	5 mg/ml	1 ml/Amp 20 Amps/Box
74	D27020	Inj. Haloperidol L.A.	IP	50 mg/ml	1 ml/Amp. 20 Amps/Box
75	D27021	Haloperidol Drops (Palatable, with dropper and plastic container as per I.P)	I.P.	2 mg/ml	20ml/Bottle 20 Bottles/Box
76	D27008	Tab. Trifluoperazine HCl (Aluminium foil/Blister pack)	IP	5 mg/Tab	10 Tabs/Strip 10 Strips/Box
77	D27010	Tab. Thioridazine (Aluminium foil/Blister pack)	BP	50 mg/Tab	10 Tabs/Strip 10 Strips/Box
78	D27013	Tab. Lorazepam (Aluminium foil/Blister pack)	BP	2 mg/Tab	10 Tabs/Strip 10 Strips/Box
79	D27014	Tab. Clonazepam (Aluminium foil/Blister pack)	USP	2 mg/Tab	10 Tabs/Strip 10 Strips/Box

Sl No	Drug Code	Drug Name	Pharmacopoeial Standard.	Specification / Strength	Unit Pack
80	D27015	Tab. Risperidone (Aluminium foil/Blister pack)		2 mg/Tab	10 Tabs/Strip 10 Strips/Box
81	D27017	Tab. Fluoxetine (Aluminium Foil/Blister pack)		20 mg/Tab	10 Tabs/Strip 10 Strips/Box
82	D27004	Tab. Amitriptyline HCl (Aluminium Foil/Blister pack)	IP	25 mg / Tab	10 Tabs/Strip 10 Strips/Box
83	D27022	Inj. Flupenthixol Decanoate	BP	20mg/1ml	1 ml/Amp. 20 Amps/Box
84	D27023	Inj. Zuclopenthixol Decanoate	BP	200 mg/1ml	1 ml/Amp. 20 Amps/Box
85	D27024	Inj. Zuclopenthixol Acitate	BP	50 mg/ ml	1 ml/Amp. 20 Amps/Box
86	D27025	Inj. Olanzapine	USP	10 mg /Ampl	1 ml/Amp. 20 Amps/Box
87	D27026	Inj. Resperidone L.A.	USP	25 mg/ml / Ampl	1 ml/Amp. 20 Amps/Box
88	D27027	Tab. Amisulpiride (Aluminium foil/Blister pack)	BP	100 mg /Tab.	10 Tabs/Strip 10 Strips/Box
89	D27028	Tab. Amitriptyline + Chlordiazepoxide (Aluminium foil/Blister pack)	USP	Amitriptyline 25 mg + Chlordiazepoxide 10 mg / Tab	10 Tabs/Strip 10 Strips/Box
90	D27029	Tab.Carbamazepine CR (Aluminium foil/Blister pack)	IP	400 mg / Tab	10 Tabs/Strip 10 Strips/Box
91	D27030	Tab. Chlorpromazine + Thrihexyphenidyl (Aluminium foil/Blister pack)	USP	Chlorpromazine 100 mg + Thrihexyphenidyl 2 mg / Tab	10 Tabs/Strip 10 Strips/Box
92	D27031	Tab. Clozapine (Aluminium foil/Blister pack)	IP	100 mg / Tab	10 Tabs/Strip 10 Strips/Box

Sl No	Drug Code	Drug Name	Pharmacopoeial Standard.	Specification / Strength	Unit Pack
93	D27032	Tab. Dothiepin HCl (Aluminium foil/Blister pack)	ВР	25 mg / Tab	10 Tabs/Strip 10 Strips/Box
94	D27033	Tab. Dothiepin HCl (Aluminium foil/Blister pack)	BP	75 mg / Tab	10 Tabs/Strip 10 Strips/Box
95	D27034	Tab. Divalproex Sodium (Aluminium foil/Blister pack)	IP	250 mg / Tab	10 Tabs/Strip 10 Strips/Box
96	D27035	Tab. Divalproex Sodium (Aluminium foil/Blister pack)	IP	500 mg / Tab	10 Tabs/Strip 10 Strips/Box
97	D27036	Tab. Escitalopram (Aluminium foil/Blister pack)	IP	5 mg / Tab	10 Tabs/Strip 10 Strips/Box
98	D27037	Tab. Escitalopram (Aluminium foil/Blister pack)	IP	10 mg / Tab	10 Tabs/Strip 10 Strips/Box
99	D27039	Tab. Flupenthixol + Melitracin (Aluminium foil/Blister pack)	BP	Flupenthixol 0.5 mg + Melitracin 10 mg / Tab	10 Tabs/Strip 10 Strips/Box
100	D27040	Tab. Imipramine (Aluminium foil/Blister pack)	IP	25 mg / Tab	10 Tabs/Strip 10 Strips/Box
101	D27041	Tab. Loxapine (Aluminium foil/Blister pack)	USP	10 mg / Tab	10 Tabs/Strip 10 Strips/Box
102	D27042	Tab. Loxapine (Aluminium foil/Blister pack)	USP	25 mg / Tab	10 Tabs/Strip 10 Strips/Box
103	D27043	Tab. Lithium Carbonate (Aluminium foil/Blister pack)	IP	300 mg / Tab	10 Tabs/Strip 10 Strips/Box
104	D27044	Tab. Lithium Carbonate - SR (Aluminium foil/Blister pack)	USP	400 mg / Tab	10 Tabs/Strip 10 Strips/Box

Sl No	Drug Code	Drug Name	Pharmacopoeial Standard.	Specification / Strength	Unit Pack
105	D27045	Tab. Nitrazepam (Aluminium foil/Blister pack)	IP	10mg / Tab	10 Tabs/Strip 10 Strips/Box
106	D27046	Tab. Olanzapine (Aluminium foil/Blister pack)	IP	5 mg / Tab	10 Tabs/Strip 10 Strips/Box
107	D27047	Tab. Olanzapine (Aluminium foil/Blister pack)	IP	7.5 mg / Tab	10 Tabs/Strip 10 Strips/Box
108	D27048	Tab. Olanzapine (Aluminium foil/Blister pack)	IP	10 mg / Tab	10 Tabs/Strip 10 Strips/Box
109	D27049	Tab. Oxcarbazepine (Aluminium foil/Blister pack)	IP	300 mg / Tab	10 Tabs/Strip 10 Strips/Box
110	D27050	Tab. Prochlorperazine (Aluminium foil/Blister pack)	IP	25 mg / Tab	10 Tabs/Strip 10 Strips/Box
111	D27051	Tab. Procyclidine (Aluminium foil/Blister pack)	IP	2.5 mg / Tab	10 Tabs/Strip 10 Strips/Box
112	D27052	Tab. Procyclidine (Aluminium foil/Blister pack)	IP	5 mg / Tab	10 Tabs/Strip 10 Strips/Box
113	D27053	Tab. Propranolol HCL (Aluminium foil/Blister pack)	IP	40 mg / Tab	10 Tabs/Strip 10 Strips/Box
114	D27054	Tab. Quetiapine (Aluminium foil/Blister pack)	IP	100 mg / Tab	10 Tabs/Strip 10 Strips/Box
115	D27055	Tab. Risperidone (Aluminium foil/Blister pack)	BP	3 mg / Tab	10 Tabs/Strip 10 Strips/Box
116	D27056	Tab. Sertraline (Aluminium foil/Blister pack)	BP	50 mg / Tab	10 Tabs/Strip 10 Strips/Box
117	D27057	Tab. Sertraline (Aluminium foil/Blister pack)	BP	100mg / Tab	10 Tabs/Strip 10 Strips/Box

Sl No	Drug Code	Drug Name	Pharmacopoeial Standard.	Specification / Strength	Unit Pack
118	D27058	Tab. Sodi-Valporate CR (Aluminium foil/Blister pack)	USP	300 mg / Tab	10 Tabs/Strip 10 Strips/Box
129	D27059	Tab. Sodi-Valporate CR (Aluminium foil/Blister pack)	USP	500 mg / Tab	10 Tabs/Strip 10 Strips/Box
120	D27060	Tab. Trihexyphenidyl (Aluminium foil/Blister pack)	IP	2 mg / Tab	10 Tabs/Strip 10 Strips/Box
121	D27061	Tab. Trifluperazine + Thrihexyphenidyl (Aluminium foil/Blister pack)	IP	5 mg +2 mg / Tab	10 Tabs/Strip 10 Strips/Box
122	D27062	Tab. Lamotrigine (Aluminium foil/Blister pack)	IP	50 mg / Tab	10 Tabs/Strip 10 Strips/Box
123	D27063	Tab. Desvenlafaxine (Aluminium foil/Blister pack)	IP	50 mg / Tab	10 Tabs/Strip 10 Strips/Box
124	D27064	Tab. Miznacepam (Aluminium foil/Blister pack)	IP	25 mg / Tab	10 Tabs/Strip 10 Strips/Box
125	D27065	Tab. Paroxetine (Aluminium foil/Blister pack)	IP	20 mg / Tab	10 Tabs/Strip 10 Strips/Box
126	D27066	Tab. Paliperidone (Aluminium foil/Blister pack)	IP	3 mg / Tab	10 Tabs/Strip 10 Strips/Box
127	D27067	Tab. Iloperidone (Aluminium foil/Blister pack)	IP	4 mg / Tab	10 Tabs/Strip 10 Strips/Box
128	D27068	Tab. Donepezil (Aluminium foil/Blister pack)	IP	5 mg / Tab	10 Tabs/Strip 10 Strips/Box
139	D27069	Tab. Donepezil +Mimintine. (Aluminium foil/Blister pack)	IP	10 mg / Tab	10 Tabs/Strip 10 Strips/Box
130	D27070	Tab. Levetiracetain (Aluminium foil/Blister pack)	IP	500 mg. / Tab	10 Tabs/Strip 10 Strips/Box

Sl No	Drug Code	Drug Name	Pharmacopoeial Standard.	Specification / Strength	Unit Pack
131	D27071	Tab. Chlorodiazepoxide (Aluminium foil/Blister pack)	IP	25 mg / Tab	10 Tabs/Strip 10 Strips/Box
132	D27072	Tab. Zolpidem (Aluminium foil/Blister pack)	IP	10 mg / Tab	10 Tabs/Strip 10 Strips/Box
133	D27073	Tab. Oxazepam (Aluminium foil/Blister pack)	IP	10 mg/Tab.	10 Tabs/Strip 10 Strips/Box
134	D27074	Tab. Alprazolam (Aluminium foil/Blister pack)	IP	0.5 mg / Tab.	10 Tabs/Strip 10 Strips/Box
135	D27075	Tab. Baclofen (Aluminium foil/Blister pack)	I.P.	10 mg /Tab.	10 Tabs/Strip 10 Strips/Box
136	D27076	Tab. Disulfiram (Aluminium foil/Blister pack)	I.P.	25 mg /Tab.	10 Tabs/Strip 10 Strips/Box
137	D27077	Tab. Buprenorphine + Nalaxone (Aluminium foil/Blister pack)	U.S.P.	2  mg + 0.5  mg / Tab.	10 Tabs/Strip 10 Strips/Box
138	D27078	Tab. Clonidine (Aluminium foil/Blister pack)	I.P.	100 mg. / Tab.	10 Tabs/Strip 10 Strips/Box
139	D27079	Tab. Tetra Benazine (Aluminium foil/Blister pack)	I.P.	25 mg /Tab.	10 Tabs/Strip 10 Strips/Box
140	D27080	Tab. Amantadine (Aluminium foil/Blister pack)	I.P.	100 mg / Tab.	10 Tabs/Strip 10 Strips/Box
141	D27081	Tab. Aripiprazole (Aluminium foil/Blister pack)	I.P.	10 mg / Tab.	10 Tabs/Strip 10 Strips/Box
142	D27082	Tab. Aripiprazole (Aluminium foil/Blister pack)	I.P.	15 mg / Tab.	10 Tabs/Strip 10 Strips/Box
143	D27083	Tab. Asenapine (Aluminium foil/Blister pack)	U.S.P.	5 mg / Tab.	10 Tabs/Strip 10 Strips/Box

Sl No	Drug Code	Drug Name	Pharmacopoeial Standard.	Specification / Strength	Unit Pack
144	D27084	Tab. Asenapine (Aluminium foil/Blister pack)	U.S.P.	10 mg / Tab.	10 Tabs/Strip 10 Strips/Box
145	D27085	Tab. Tetrahydrofolate (Aluminium foil/Blister pack)	U.S.P.	7.5 mg /Tab.	10 Tabs/Strip 10 Strips/Box
146	D27086	Sodium Valproate Syrup. (Palatable, with measuring cap and plastic container as per I.P)	I.P.	200 mg /5 ml	100ml/Bottle 20 Bottles/Box
147	D27087	Tab. Atomoxetine (Aluminium foil/Blister pack)	I.P.	10 mg/Tab.	10 Tabs/Strip 10 Strips/Box
148	D27088	Tab. Atomoxetine (Aluminium foil/Blister pack)	I.P.	18 mg/Tab.	10 Tabs/Strip 10 Strips/Box
149	D27089	Tab. Atomoxetine (Aluminium foil/Blister pack)	I.P.	25 mg/Tab.	10 Tabs/Strip 10 Strips/Box
150	D27090	Inj. Procyclidine	IP	5 mg /Ampl.	1 ml/Amp. 20 Amps/Box
151	D27091	Tab. Methyl Phenidate (Aluminium foil/Blister pack)	I.P.	5 mg/Tab.	10 Tabs/Strip 10 Strips/Box
152	D27092	Tab. Methyl Phenidate (Aluminium foil/Blister pack)	I.P.	10 mg/Tab.	10 Tabs/Strip 10 Strips/Box

#### **INSTRUCTION FOR PACKAGING OF DRUGS & MEDICAL CONSUMABLES**

- 1. Every Consignment of Blood and related products should be certified to be
  - (a) AIDS Free (b) Hepatitis B Free
- 2. Strips of Aluminium foils refer to gauge 04.
- 3. Aluminium foils as back material for blisters refer to gauge 025.
- 4. The rigid PVC used in blister packing should be of not less than 250 micron
- 5. All plastic / glass bottles should be new / virgin neutral glass as per I.P.
- 6. Ointments should be packed in liquidized Aluminium Tubes.
- 7. LVP Fluid bottles should be FFS / BFS Plastic Bottle as per revised Schedule M and Eye / Ear Drops should be of FFS plastic bottles.
- 8. Small Tablets packed in blisters should be packed to facilitate easy removal of the tablet without breaking / crushing.
- 9. Specification of outer cartons are as given in the Schedule (Annexure-IV)
- 10. In case of any conflict between Carton specifications and packets per carton specification (Last column of this table), the specification of the packets / carton shall prevail.
- 11. All tablets should have a score line.
- 12. All liquid orals should be provided with a measuring device.
- 13. All plastic containers should be made of virgin grade plastics as per I.P.
- 14 Injection in vials should have a snap of seals.
- 15. Bioavailability report should be submitted in the case of the following drugs
  - (1) Tab Lithium Carbonate
- 16. The strips shall be aluminium strip / blisters with aluminium foil back.
- 17. All injectables (Ampoules) should have are lutter in each unit box.
- 18. All hygroscopic drugs and sugar coated tablets should be stripped in Aluminium foil / Blister pack.

## I. SCHEDULE FOR PACKAGING OF DRUGS AND MEDICAL CONSUMABLES

#### **GENERAL SPECIFICATIONS**

- 1. No corrugate package should weigh more than 15 Kgs (ie., product + inner carton + corrugated box).
- 2. All Corrugated boxes should be of `A' grade paper i.e., Virgin.
- 3. All items should be packed only in first hand boxes only.

#### **FLUTE**:

4. The corrugated boxes should be of narrow flute.

#### **JOINT**:

5. Every box should be preferably single joint and not more than two joints.

#### **STITCHING:**

6. 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.

#### FLAP:

7. The flaps should uniformly meet but should not over lap each other. The flap when turned by  $45 - 60^{\circ}$  should not crack.

#### **TAPE:**

8. Every box should be sealed with gum tape running along the top and lower opening.

#### **CARRY STRAP:**

9. Every box should be strapped with two parallel nylon carry straps (they should intersect).

#### **LABEL:**

- 10. Every corrugated box should carry a large outer label clearly indicating that the product is for "Odisha Govt. supply Not for sale".
- 11. The product label on the cartoon should be large atleast 15cms x 10cms dimension. It should carry the correct technical name, strength or the product, date of manufacturing, date of expiry, quantity packed and net weight of the box.

#### **OTHERS:**

12. No box should contain mixed products or mixed batches of the same product.

## II. SPECIFICATION FOR 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 5 ply with Bursting strength of 9 Kg/ Cm2

## III. SPECIFICATION FOR LARGE VOLUME BOTTLE i.e., ABOVE 100 ml. AND BELOW 1 LIT.

- (1) All these bottles should be packed only in single row with partition between each and also with top and bottom pad of 3 ply.
- (2) Grammage : Outer box should be 150 gsm inside

partition/lining should be 120 gsm

(3) Ply : 7 Ply.

(4) Bursting Strength : Not less than 12 Kg/Cm<sup>2</sup>

#### IV. SPECIFICATION FOR IV FLUIDS

(1) Each corrugated box may carry a maximum of only 20 bottles of 500 ml in a single row or 50 bottles of 100 ml in 2 rows with individual sealed polythene cover and centre partition pad, top and bottom pads of 3 ply.

(2) Grammage : Outer box should be 150 gsm inside

partition/lining should be 120 gsm

(3) Ply : 5 or 7

(4) Bursting Strength : Not less than 12 Kg/Cm<sup>2</sup>

#### V. SPECIFICATIONS FOR LIQUID ORALS

50ml to 120 ml bottles.

- (1) 100 bottles of 50ml or 60ml may be packed in a single corrugated in 2 rows with top, bottom and centre pad of 3 ply.
  - 50 bottles of 100 ml 120 ml may be packed in a similar manner in a single corrugated box.
- (2) If the bottles are not packed in individual carton, 3 ply partition should be provided between each bottle. The measuring device should be packed individually.

(3) Grammage : Outer box should be 150 gsm inside

partition / lining should be 120 gsm

(4) Ply : 7 ply

(5) Bursting Strength : Not less than 12 Kg/Cm<sup>2</sup>

(6) In case the box is heavier than 7 Kg but less than 10 kg, the grammage may be 150 gsm (outer 150 gsm and others 120 gsm) 5 ply and bursting strength should not be less than 9 Kg/Cm<sup>2</sup>.

# VI. SPECIFICATIONS 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 cartoon and then packed in 20's in a grey board box, which may be packed in a corrugated box.
- (3) Grammage : Outer box should be 150 gsm inside partition / lining should be 120 gsm

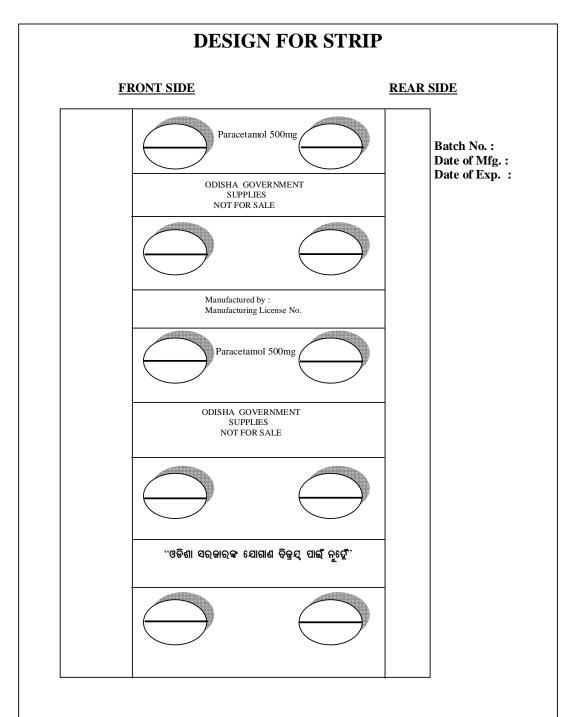
#### VII. SPECIFICATIONS FOR INJECTABLE (IN VIALS AND AMPOULES)

- (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 5 ply.
- (3) Bursting strength for CB boxes for

a. Vials
 b. Amp
 c. Note less than 13 Kg/Cm<sup>2</sup>
 d. Note less than 9 Kg/Cm<sup>2</sup>

- (4) In the case of 10 ml Ampoules 100 or 50 ampoules may be packed in a grey board box. Multiples of grey 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 cartoon, there is no necessity for grey board box packing. The individual cartoon may be packed as such in the CB with centre pad.
- (6) In case of ampoules every grey board box should carry 5 amps. Cutters placed in a polythene bag.
- (7) Vials of eye and eardrops should be packed in an individual cartoon with a dispensing device. If the vial is of FFS technology, they should be packed in 50's in a grey board box.

NB: If there are differences in packing between Annexure I and Annexure III, then the packing & unit pack mentioned in Annexure I will be applicable.



 ${\rm N.B.:M.R.P}$  OF THE DRUG SHOULD NOT BE PRINTED ANY WHERE THE GENERIC NAME SHOULD BE PRINTED IN BOLD LETTER.

#### **SPECIMEN LABEL FOR OUTER CARTON**

Name of the Consignee:

# ODISHA GOVERNMENT SUPPLY NOT FOR SALE

"ଓଡିଶା ସରକାରଙ୍କ ଯୋଗାଣ ବିକ୍ରସ୍ ପାଇଁ ନୁହେଁ"

# PARACETAMOL I.P - 500mg

Mfg. Date :	Exp. Date:
Batch No.:	
<b>Total Quantity:</b>	
Net Weight of the Carton:	
Supply Head: "CENTRAL	PURCHASE"
Purchase Order No.:	Date:
Manufactured By:	

#### ANNEXURE – V Refer Clause No. 11.2

## **BAR CODING DETAILS**

Box No. :

P.O. No. :

Supplier Name :

Drug Code :

Drug Name :

Batch No :

Expiry Date :

Batch Qty :

Invoice No :

D.C. No.

#### **AGREEMENT**

THIS AGREEMENT made the Day of, 20Between
of the purchaser) of (address of the Purchaser) (hereinafter "the Purchaser") of the one
part and
(hereinafter called "the <b>Supplier</b> ") of the other part:
WHEREAS the Purchaser has invited tenders for the Supply of Drugs and Consumables in
tender reference No The supplier has submitted the technical &
price bid as contained in the tender document. The purchaser has finalized the tender in favour
of the supplier for the supply of drugs specified in the Schedule attached hereto at the prices
noted against each item on the terms and conditions set forth in the agreement.

#### NOW THIS AGREEMENT WITNESSTH AS FOLLOWS:

- 1. In this agreement words and expression shall have same meanings as are respectively assigned to them in the tender document referred to.
- 2. The following documents shall be deemed to form and be read and constructed as part of this Agreement, viz; :
  - a. The purchase order.
  - b. The Notice inviting Tender.
  - c. The suppliers bid including enclosures, Formats, Annexures etc.
  - d. The Terms and Conditions of the tender document referred above.
  - e. The list of items & Specification
  - f. The Specification and quality parameters mentioned in the tender document referred above.
  - g. Any other document listed in the supplier's bid and replies to queries, clarifications issued by the purchaser, such confirmations given by the bidder which are acceptable to the purchaser and all the addendum issued as forming part of the contract.
- 3. In consideration of the payments to be made by the purchaser to the supplier as hereinafter mentioned, the Supplier hereby covenants with the purchaser to supply the drugs confirming in all respects with the provision of the contract.

- 4. The purchaser hereby covenants to pay the supplier in consideration of the provision of the tender, the Contract Price or such other sum as may become payable under the provisions of the contracts at the times and in the manner prescribed by the Contract.
- 5. The supplier has to deposit the performance security as mentioned in the purchase order from time to time for due & faithful performance of the provisions of this agreement. Such performance security deposit made by the supplier is liable to be forfeited by the Purchaser in the event of the supplier failing duly & faithfully to perform any one or more or any part of any one of the said provisions.

#### **SCHEDULE**

Sl.	Drug Code	Name	Strength	Unit Pack	Absl. Rate	Unit Pack Rate	Tax
No.		of Drug	Specification		(Rs.)	(Rs.)	

#### **DELIVERY SCHEDULE:**

Supply shall commence within 30 days and shall be completed within 70 days from the date of issue of purchase order (at the consignee places mentioned in the purchase order)

Signed, Sealed and Delivered by the
Said (For the Purchaser)
In the presence of
(Signature, Name, Designation & Address with Office Seal)
Signed, Sealed and Delivered by the
Said
1) (signature, Name & Address of Witness)
2) (signature, Name & Address of Witness)

IN WITNESS whereof the parties hereto have caused this Agreement to be executed in

accordance with their respective laws the day and year first above written.

## **FORMATS FOR**

## **TECHNICAL BID**

(Cover A)

**FORMAT – T 1** Ref. Clause: 3.2

<u>CHECK LIST</u> (to be submitted in Technical Bid – Cover A)

Note: The documents has to be arranged serially as per the order

mentioned in the check list

DOCUMENTS: SUBMITTED OR NOT (Please put in the respective box)

Sl. No.	Details	Provided or not	If provided mention page No.(s)
1.	Earnest Money Deposit	Yes / No	
2.	Tenderer paper with Original receipt or cost in shape of BD	Yes / No	
3.	Details of Manufacturing Unit / contract person / local office in Odisha ( <b>Format –T2</b> )	Yes / No	
4.	Declaration form ( <b>Format–T3</b> ) signed by the Tenderer & affidavit before Notary Public	Yes / No	
5.	List of items ( <b>Format–T4</b> ) being quoted with specification and strength	Yes / No	
6.	Photo copy of valid manufacturing license /Loan License / Import license for each and every product quoted	Yes / No	
7.	Valid Drug Endorsement for each quoted product	Yes / No	
8.	Photocopy of the authorization by the manufacturer to the importer (In case of importer only)	Yes/No	
9.	Valid up-to-date WHO GMP certificate	Yes / No	
10.	Valid up-to-date Good manufacturing practice certificate as per revised schedule-M, (GMP)	Yes / No	
11.	Annual Turnover statement for preceding 3 years signed by Auditor / CA (Format – T5)	Yes / No	
12.	Market Experience (Performance Statement) of the bidder towards supply of the quoted pharmaceutical product to Govt./Corporate/ PSU hospitals during the last three years (Format – T6)	Yes / No	
13.	Market Standing Certificate from <b>licensing authority</b> (Drug Controller) regarding manufacturing & marketing of the quoted product for last 3 (three) years	Yes / No	
14.	Non Conviction certificate issued by the licensing authority(Drugs Controller)	Yes / No	
15.	Declaration for Compliance of Good Manufacturing Practices properly filled ( <b>Format –T7</b> )	Yes / No	
16.	Attested Photocopy of Sales Tax / VAT clearance Certificate / TIN No. (whenever applicable)	Yes / No	
17.	ISO/BIS Certificate (if any)	Yes / No	
18.	Copy of original / downloaded Tender and schedules, duly signed by the	Yes / No	
19.	Cover 'B' with price schedule (both hard copy & soft copy) in <b>Separate Envelop</b>	Yes / No	

<u>FORMAT – T2</u> (Refer Clause No. 3.3.1 & 3.3.2)

#### (To be submitted with Cover A – Technical Bid)

### DETAILS OF THE TENDERER & LOCAL CONTACT PERSON

	Corporate Office (The address in which the purchase orders and payment details will be communicated)	Local Contact Person / Branch Office / Zonal Office / if any.
Name & Full	,	
Address		
1 Iddi C55		
Telephone Nos., landline		
Mobile		
Fax		
E – Mail		
Date of Inception		
Manufacturing License Nos. & Date		
Loan License Nos. & Date (If any)		
Name of the issuing authority		
Manufacturing License		
valid up to Import License Details		
(if any)		
GMP /WHO GMP valid		
up to		
Whether ISO /BIS		
Certified Organization		

Signature of the Tenderer : with seal
Date:
Official Seal :

#### **DECLARATION**

I/We M/s represented by
its Proprietor / Managing Partner / Managing Director having its Registered Office at
and its Factory Premises at
do hereby declare that I/We
have carefully read all the conditions of tender in Ref. No for
supply of drugs & medical consumables for a period of one year on rate contract basis from
the date of publication of approved list and will abide by with all the terms and conditions of
the Tender referenced above.
I/We declare that we possess the valid license and GMP Certificate (GMP) as per revised Schedule-'M' / WHO GMP issued by the Competent Authority and complies and continue to comply with the conditions laid in revised Schedule M of Drugs & Cosmetics Act, 1940 and the Rules made there under. I/We furnish the particulars in this regard in enclosure to this declaration.
I/We do hereby declare that I/We have not been derecognised / blacklisted / debarred by any State Govt. / Govt. of India / Union Territory / Govt. organization / Govt. Health Institutions / UN Agencies for supply of Not of Standard Quality drugs or medical consumables or for part-supply / non-supply or for fraud / cheating.
I/We declare that we possess valid import license issued by the Drugs Controller, India and have authorization from the manufacturer (In case of Importer)
I/We agree that the Tender Inviting Authority can forfeit the Earnest Money Deposit and or Security Deposit and blacklist me/us for a period of 3 years, if any information furnished by us proved to be false at the time of inspection / verification and not complying with the conditions as per the revised Schedule M of the said Act / not abiding by the tender terms & conditions.
I/We do hereby declare that I will supply the drugs & medical consumables as per the terms & conditions of the tender document, print in bold letters "Odisha Govt. Supply Not For Sale" "3Áଧି

Name & Address of the Firm:

Date

Signature of the bidder

Affidavit before Notary Public

FORMAT – T4 (Refer Clause No. 3.4)

#### (To be submitted with Cover A – Technical Bid)

#### **LIST OF ITEMS QUOTED**

SI.	SI. No. of the Item ( As per Item List at Annexure – I)	Item Code	Item Name	Specification	Pl. Mention (Item wise) whether quoted as a Manufacturer / Manufacturer with loan license / Importer	Page No.(s) of the related document of Manuf. License /Loan license & GMP/WHO GMP (for the item quoted)

Signature & Seal of the Bidder

### ANNUAL TURN OVER STATEMENT

	Annual Turnover for pharmac	who
	ertified that the statement is true and	products for the last three years are given
Sl. No.	Year	Turnover in Crores (Rs) both in words and figures
1	2009 – 2010	, , , , , , , , , , , , , , , , , , ,
2	2010 – 2011	
3	2011 – 2012	
Date:		Signature of Auditor/
Place:		Signature of Auditor/ Chartered Accountant
		(Name in Capital)
		Registration No.

#### N.B:

1. Only turnover of the pharmaceutical products of the original manufacturing unit and the units under loan license / Importer will be taken into account.

Seal

2. The third party manufacturing products (i.e. manufactured by one unit and marketed by another unit) will not be taken into account in annual turnover.

#### FORMAT T-6

(Refer Clause No. 2.4.1, 3.8, 3.9)

(To be submitted with Cover A -Technical Bid)

#### **MARKET EXPERIENCE**

#### (PROFORMA FOR PERFORMANCE STATEMENT)

(For a period of last three financial years)

(ITEM WISE)

Name of the Firm :			Name of the Iten	n :				
*Order Placed By (Full address of the Purchaser)		Description of Ordered Drugs, Medical Consumables and /or	Quantity	Value of order	Date of comple	etion of delivery	Remarks indicating reasons for late	Was the supply of Drugs, Medical Consumables and / or Vaccines satisfactory? (Attach
(Govt./PSU/ UN Agencies/ Corporate Sectors)	Date	Vaccines	quantity	(Rs.)	As per contract	Actual	I If any	certificate from the Purchaser / Consignee)

(Please add separate sheets if the space provided is not sufficient)

\*Furnish purchase order copies in support of the information provided above and arrange the same in the order as mentioned in the statement above.

Signature & Seal of the Bidder

Yes / No

#### **DECLARATION FOR COMPLIANCE OF G.M.P**

01. Name and Address of The Firm 02. Name of Proprietor / Partner / Director 03. Name and Designation of Person Present 04. GMP Certificate As per Revised Schedule "M" 05. Details of Licenses Held With Validity 06. Number of Workers Employed :Ladies Gents 07. Whether Workers Provided with Uniform Yes / No 08. Whether Medical Examination done for the Workers Yes / No 09. **Hygienic Condition** (I) Surrounding Satisfactory / Not Satisfactory (II) **Production Areas** Satisfactory / Not Satisfactory (III) Other Areas Satisfactory / Not Satisfactory Yes / No 10. Provision For Disposal of Waste 11. **Heating System** Yes / No 12. Whether Benches Provided in all Yes / No Working Area **Water Supply** 13. (A) Source (B) Storage Condition : Satisfactory / Not Satisfactory (C) **Testing** (With reference to Pathogenic Organization) Yes / No

Cleaning Schedule In Water Supply

System With Proper Records

(D)

- (E) Type of Machinery installed as to Semiautomatic or Fully Automatic plant for water purification system along with cost and whether this is working, and if so he flow rate of Pharmaceutical water to must the requires preparation
- 14. Air handling system along with list of machine and cost of the unit. Separately for sterile and non sterile preparation
- 15. Whether the pollution control clearance is valid for Air and Water and if so the period upto which valid (copy of the certificate to be enclosed)
- 16. Raw Material Storage Area (Storage Facilities / Hygienic Condition):

(I) Quarantine : Provided / Not Provided

(II) Passed Materials : Provided / Not Provided

(III) Rejected Materials : Provided / Not Provided

17. Finished Product Storage Area

(Hygienic / Storage)

(I) Quarantine : Provided / Not Provided

(II) Released Material : Provided / Not Provided

18. Details of Technical Staff

Name Qualification Experience

For Manufacturing :

For Testing :

## 19. <u>Testing Facilities (List of Equipments to be furnished Separately in the format to meet the bench mark vide Annexure)</u>

Chemical Method : Yes / No

Instrumental : Yes / No

(Type of Instrument Provided as indicated

in Annexure)

Biological : Yes / No

Micro Biological : Yes / No Animal Testing : Yes / No

#### 20. Remarks

- (A) Whether Products Quoted to Health & F.W. Department, Odisha are Endorsed in the Licence : Yes / No
- (B) Whether the drugs Quoted to
  Health & F.W. Department, Odisha have been Manufactured
  Earlier (Last 3 Years) : Yes / No

## If Yes, Details Like

SI.No	Date of Manufacturer	Name of the Drug	Batch No.	Batch Size	Date of Release

(C) Production Capacity (Section Wise)

#### **PRODUCTION CAPACITY:**

#### **Tablet Section**

Type of Equipments  (1)	No. of Equipments (2)	Production Capacity of all the Equipments in column 2 per shift (3)	No of shift (4)	If selected Production Capacity allotted for H&FW Deptt., Odisha
Planatery mixer				
Fluidized bed drier				
Tray drier				
Mechanical shifter				
Multi mill				
Tablet compression				
machine				
1) With				
number of station				
2) With				
number of station				
3) With				
number of station				
4) With				
number of station				

Type of Equipments  (1)	No. of Equipments (2)	Production Capacity of all the Equipments in column 2 per shift (3)	No of shift (4)	If selected Production Capacity allotted for H&FW Deptt., Odisha
Coating pan.				
Blister Packing				
machine				
Strip packing machine				

### **Capsule Section**

Type of Equipments  (1)	No. of Equipments (2)	Production Capacity of all the Equipments in column 2 per shift (3)	No of shift (4)	If selected Production Capacity allotted for H&FW Deptt., Odisha (5)
Double cone blender				
Automatic capsule				
filling machine				
Semi automatic				
Capsule filling				
machine				
Hand filling machine				
Blister packing				
machine				
strip packing				
machine				

### **Parenteral Section**

Type of Equipments	No. of Equipments	Production Capacity of all the Equipments in column 2 per shift	No of shift	If selected Production Capacity allotted for H&FW Deptt.,
(1)	(2)	(3)	(4)	Odisha
				(5)
Small volume				
Parenteral				
Mixing Vessel				
Laminar Flow unit				
Filtration unit				
Ampoule filling				
machine				
(with No of head)				
Vial filling				
Machine				
(with No of head)				
Vial sealing machine				
Powder filling				
machine				
Autoclave for				
terminal Sterilization				
Ampoule labeling				
machine				
Vials labeling				
machine				

### **Large Volume Parenterals**

Type of Equipments  (1)	No. of Equipments (2)	Production Capacity of all the Equipments in column 2 per shift (3)	No of shift (4)	If selected Production Capacity allotted for H&FW Deptt., Odisha
Mixing vessel				
Filtration Unit.				
Filling Machine				
Autoclave for				
terminal Sterilization				
Labeling Machine	_			

#### **Ointment/ Cream**

Type of Equipments	No. of Equipments	Production Capacity of all the Equipments in column 2	No of shift	If selected Production Capacity allotted for H&FW
(1)	(2)	per shift (3)	(4)	Deptt., Odisha (5)
Stream jacket vessel				
for mixing				
Ointment/cream				
filling machine				

### **Liquid Section**

Type of Equipments  (1)	No. of Equipments (2)	Production Capacity of all the Equipments in column 2 per shift (3)	No of shift (4)	If selected Production Capacity allotted for H&FW Deptt., Odisha
Bottle washing machine				
SS tank with capacity				
Filter press			_	
Colloidal mill				
Bottle Filling Machine				
Labeling Machine				

### **External Preparation**

Type of Equipments (1)	No. of Equipments (2)	Production Capacity of all the Equipments in column 2 per shift (3)	No of shift	If selected Production Capacity allotted for H&FW Deptt., Odisha	
				(5)	
Mixing Vessel					
Filling machine					
Labeling machine	· · · · · · · · · · · · · · · · · · ·				

(E) Any, Not Of Standard Quality Reports Of Product Quoted/ Approved By DHS (If Not, Nil Statement)

: Yes / No

(F) Any Prosecution After : Yes / No Submission of Tender Documents.

(If Not, Nil Statement)

(G) Chances of cross contamination : Yes / No

at Raw Materials / In Process /
Finished Product Stages and Steps /

**Facilities** 

(H) Validation of Equipments done : Yes / No

(I) Cleaning Schedule

(I) For Premises :

(II) For Equipments :

(J) Adverse Reaction, If Any and

Reported

SI.No.	Description	Remarks
1	Whether any drug(s) manufactured by the tenderer has / have been recalled during last five years? If yes given details	
2	What are the results of investigations on the recalled drug(s)?	
3	What action have been taken to prevent recurrence of recall of drug(s) on that particular account?	

(K) Complaints Received If Any and Steps taken.

SI. No.	Description	Remarks		
1	Whether any drug(s) manufactured by the tenderer has / have been recalled during last five years? If yes given details			
2	What are the results of investigations on the recalled drug(s)?			
What action have been taken to prevent recurrence of recall of drug(s) on that particular account?				

Signature and Seal of Proprietor / Partner / Director

# FORMATS FOR PRICE BID (Cover B)

#### **FORMAT P 1**

As per Clause - 4.1, 4.2, 7.4 / 7.11

#### **MODEL TENDER FORMAT (PRICE SCHEDULE)**

(To be Submitted with Cover B - Price Bid)

Whether S. S. I. Unit of Odisha: Yes / No

Whether depot. inside Odisha, i.e. VAT paid to Government of Odisha: Yes / No

SI. No.	Drug Code	Generic Name of the Drug	Strength & Composition / Specification	Rates will be quoted for <b>absolute only</b> which <b>includes</b> excise duty, packing, forwarding / transportation & (Door Delivery) and <b>excludes</b> Sales Tax / VAT & Entry Tax but supply will be made in unit pack  Rate for each Tab. / Cap / Amp / Vial / Bottle / Roll etc.  (Absolute rate) in Rs. both in words and figures.	VAT & ET in percentage	Remarks
1	2	3	4	5	6	7
1						1
2						

Seal : Name : Address

Date :

Note: 1. The drug code of each item must be mentioned.

- 2. Only generic names should be quoted. (see clause 8.1 of tender condition ) but supply may be made in brand name mentioning the generic name in bold letter.
- 3. The Page No. of the item endorsement which has been quoted should be indicated in the remark column & should be underlined in the endorsement page.
- 4. This model tender format should also be filled up & submitted in CD/DVD/Pen Drive in Cover 'B' only. This is addition to the hard copy.