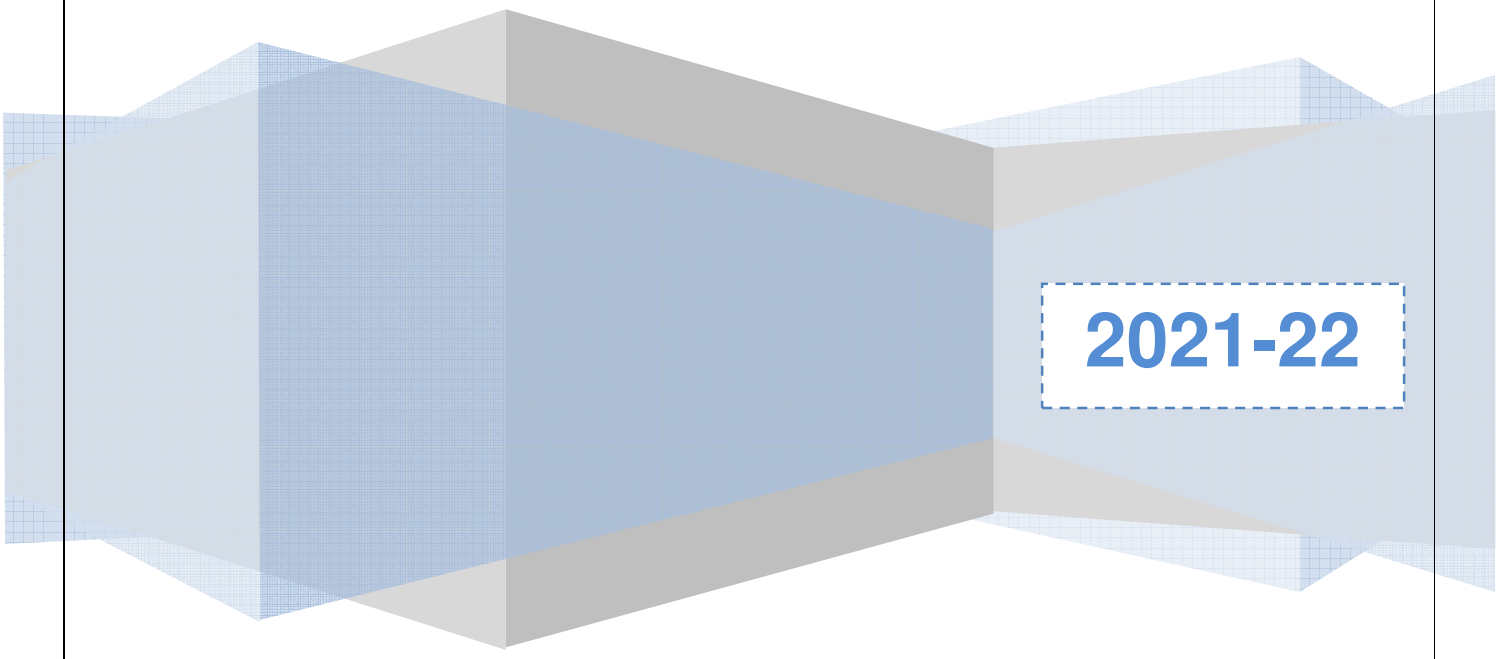
APMSIDC

TENDER NO: 130

PROCUREMENT OF HEPATITIS-B VACCINE



2021-22

TENDER NO: -130/APMSIDC/Medicine Wing/2021-22

TENDER FOR SUPPLY OF HEPATITIS-B VACCINE

To

ANDHRA PRADESH MEDICAL SERVICES & INFRASTRUCTURE DEVELOPMENT CORPORATION

(Finalization of Rate Contract for Two years
from the date of Price bid approval)

**ANDHRA PRADESH MEDICAL SERVICES &
INFRASTRUCTURE DEVELOPMENT CORPORATION**

(AN ENTERPRISE OF GOVT. OF A.P.),
Plot No.9, Survey No.49, IT Park, Mangalagiri,
Guntur District – 522 503.
ANDHRA PRADESH
URL: http://msidc.ap.nic.in

ONLINE TENDER FOR THE SUPPLY OF DRUGS TO APMSIDC

S. No	Information	Details
1	Bid Reference	**130/APMSIDC/Medicine Wing/2021-22, (HEPATITIS B VACCINE)**
2	Date and time for downloading bid document	From 04-01-2022,01:30PM
3	Prebid Meeting	Submit your Query through email till 07-JAN-2022 05:00 PM to email **tenders.apmsidc@gmail.com** with subject : Prebid Queries for T NO 127 (HEP-B VACCINE) Prebid Meeting proposed on 07-JAN-2022 at 11:00 AM, Venue: Conference Hall, APMSIDC - Head Office Mangalagiri, Guntur (Dist).
4	Last date and time for uploading Documents	18-JAN-2022 at 5.00 pm
5	Date and time of opening of Online technical bids	18-JAN-2022 at 5.01 pm
6	Last date and time of submission of offline documents	18-JAN-2022 at 5.00 pm
7	Tender Processing Fee	The bidder shall remit processing fee(Non Refundable**Rs. 11,800/- (Rs.10,000+ 18%GST)**in the form of Demand Draft in the name of The Managing Director, APMSIDC, Mangalagiri
8	Earnest Money Deposit (EMD)	The Earnest Money Deposit (EMD) in the form of Demand Draft for **Rs.3,00,000/-** in favour of Managing Director, APMSIDC, Mangalagiri, Guntur district
9	E-mail	tenders.apmsidc@gmail.com, apmsidc.gm@gmail.com
10	Contact number	General Manager- Drugs :8978680705 Pharmacist : 9966878700
11	APMSIDC Bank Details	Account Holder Name: The Managing Director, APMSIDC, Account No :142410011000314,IFSC Code : UBIN0803669, Bank Name : Union Bank (Formerly Andhra Bank), Branch Name : Mangalagiri, Guntur District, Andhra Pradesh.

The tender document can be downloaded free of cost from the e-Procurement Portal https://tender.apeprocurement.gov.in/ and from the website of APMSIDC **www.msidc.ap.nic.in**.

ONLINE TENDER FOR THE SUPPLY OF DRUGS TO APMSIDCFOR 2 YEARS

APMSIDC is responsible for procurement and supply of all essential Medicines & Surgical Consumables to the Government Health facilities of A.P., to ensure availability of medicines on free of cost. The main functions of the Corporation are Construction & Maintenance of Hospital Buildings. Further, the Procurement and distribution of Drugs, Surgicals & Consumable and Equipment is also entrusted to this Corporation by the Government (Medical and Health Department). The Corporation is functioning on No Profit and No Loss basis.

Purchaser/Tender Inviting Authority - Managing Director, APMSIDC, Mangalagiri-522503, Guntur District, Andhra Pradesh (hereinafter referred as Tender Inviting Authority unless the context otherwise requires).

Purchaser/Tender Accepting Authority - Managing Director, APMSIDC, (hereinafter referred as APMSIDC unless the context otherwise requires).
Tender Inviting Authority invites **Tender for the supply of Drugs to APMSIDC.**

1. LAST DATE AND TIME FOR SUBMISSION OF ONLINE TENDERS

a) Online Bids and price bid will be submitted on AP e-procurement portal i.e. https://tender.apeprocurement.gov.in/

b) The price bid shall be valid for a period of 120 days from the date of opening of Technical Bid. Prior to the expiry of the bid validity, the Tender Inviting Authority may request the Tenderers to extend the bid validity for further period as deemed fit on their original quoted prices and all terms &conditions.

2. ELIGIBILITY CRITERIA

(a) Entity of the bidder should be as follows:

i. The Bidder/Tenderer shall be a manufacturer having valid drug manufacturing unit duly licensed by licensing authorities. Manufacturer should have valid **WHO-GMP/GMP** certificate issued by licensing authority.

(OR)

ii. Tenderer shall be direct importer holding valid import license. The manufacturer of foreign supplier should be WHO-GMP certified company. The Importer should have valid sale license and should submit valid WHO-GMP of the manufacturer.

iii. Distributors/Suppliers/Marketer/Agents are not eligible to participate in the Tenders.

(b) An original certificate from C.A. (Chartered Accountant) or Company Secretary that:

I. Average Annual turnover of manufacturer in the lastthree years i.e. 2017-18, 2018-19 and 2019-20 or 2018-19 ,2019-20 and 2020-21shall not be less than Rs.5Crores. In case of Small-scale industries situated in the state of Andhra Pradesh the turnover shall not be less than Rs. 3Crores.

II.(a) Non-conviction Certificate not older than 12 months issued by the licensing authority of the State certifying that the firm/company has not been convicted.
(b)Tenderer should not be submitted for the product(s) for which the firm / company has been blacklisted/debarred/de-registered/banned by any State Government / Central Government / its Drug procurement agencies due to quality failure of the drugs *at the time of submission of online bid.*
(c)Further, quoted drugs have not been failed in house testing or testing by any State Government/Central Government / its Drug procurement agencies/APMSIDC during last two years.
(d)During the validity of the tender, if the firm / Company is blacklisted/debarred/de-registered/banned by any State Government / Central Government / its Drug procurement agencies / convicted by any Court of law in India, it shall be intimated to APMSIDC along with relevant authentic document by the tenderer firm/ company within one month otherwise a penalty of Rs 1,00,000/-shall be imposed on the firm by APMSIDC.
(e)The tenderer should confirm that they have read tender document including Amendment(s)to Tender document (if any) along with terms and condition and these terms and condition of tender document including Amendment(s) to Tender document (if any) are acceptable unconditionally to them.

3. GENERAL CONDITIONS

i. The tender document shall be downloaded from the websites msidc.ap.nic.in; and portal i.e.apeprocurement.gov.in. The bidder shall remit **processing fee (Non Refundable) Rs. 11,800/- (Rs.10,000+ 18%GST)**in the form of Demand Draft in the name of The Managing Director, APMSIDC, Mangalagiri./Online/NEFT/RTGS

ii. The Earnest Money Deposit referred to shall be **Rs. 3 lakh. The Earnest Money Deposit shall be paid in the form of Demand Draft in favour of APMSIDC, payable at Mangalagiri.** APMSIDC will not pay interest on any deposit held in the form of **EMD.**

   a. The tender submitted without sufficient EMD will be summarily rejected.

   b. The Earnest Money Deposit (EMD) of the unsuccessful bidders will be returned after finalization of tender with eligible bidder.

   c. The Earnest Money Deposit (EMD) will be forfeited, if the tenderer withdraws his bid any time after opening of price bid / non submission of Performance security within the period prescribed/non supply of tender items.

   d. The Earnest Money Deposit (EMD) will be forfeited, in case of the lowest bidder, fails to execute the contract or deposit the performance security deposit within the stipulated time. The EMD shall be forfeited if any of the documents found incorrect.

   e. SSI units situated in AP state are exempted from the payment of EMD.(necessary certificates to be submitted).

i. At any time prior to the last date of submission of online bid, Tender Inviting Authority may, for any reason, whether on own initiative or in response to a

clarification requested by a prospective Tenderer, may modify the condition in Tender documents by an amendment uploading on website on **msidc.ap.nic.in;** and AP e-Procurement portal i.e. **apeprocurement.gov.in** will be binding on them. In order to provide reasonable time to take the amendment into account in preparing their bid, Tender Inviting Authority may at discretion, extend the date and time for submission of online bid.

(b) Any person who has downloaded the tender document should watch for amendment, if any, on the website **msidc.ap.nic.in;** and AP e-Procurement Portal i.e.**apeprocurement.gov.in** for which APMSIDC will not issue any separate communication to them.

i. During tender or price agreement period, if L1 bidder is debarred/deregistered/blacklisted/banned by any Central Government or state Government or its procurement agencies due to quality failure or other reasons, APMSIDC may purchase the drugs from L2 bidder who shall match the price of L1 or may go for fresh tender as per discretion of APMSIDC.

3.1 SPECIAL CONDITIONS

(i)Bids shall be submitted online only at procurement portal website:**https://apeprocurement.gov.in**. Manual price bids shall not be accepted except for the original documents/instruments/uploaded copies as mentioned in tender document.

(ii)Bidder shall not modify the downloaded tender form including downloaded price Bid template in any manner. In case any tender form/Price bid template is found to be tampered with/modified in any manner, such bid will be summarily rejected, Bid Security would be forfeited, and bidder is liable to be banned from doing business with APMSIDC.

(iii)Bidders are advised to check the *website of APMSIDC:* ***msidc.ap.nic.in*** and Procurement portal website **https://apeprocurement.gov.in** prior to closing date of submission of tender for any corrigendum, addendum, or amendment to the tender document.

4.TECHNICAL BID

4.1. The Tenderer should upload all documents while submitting technical bid**. (Scanned copies of each page of all documents should be uploaded while submitting Technical bid) by referring them in Index.**

(a) The tenderers are required to upload scanned undertaking on stamp paper duly notarized by authorized signatory **(ANNEXURE - II)** confirming each clause mentioned in Section 2 of eligibility criteria.

(b) In case the bidder is Importer, they may strike the clause or part of clause not applicable in their case. The drugs indicated in this undertaking shall only be considered for evaluation and opening of price bid.

(c) On the basis of such undertaking, the price bid shall be opened within a week after opening of technical bid. However, the bidder is required to upload/submit all the documents along with the technical bid and incase any document is not complying as per undertaking, their contract/Price agreement shall be cancelled with forfeiture of EMD/Performance security deposit.

(d) Offline documents with original ANNEXURE - II in sealed cover should be submitted to APMSIDC, Mangalagiri on or before the scheduled date.

i. The tenderers are required to upload a certificate from the C.A. (Chartered Accountant) or Company Secretary as per **ANNEXURE IV.**

ii. Authorization letter nominating an officer of the Tenderer on the printed letter head of the company to transact the business with the APMSIDC to be uploaded.

(e) The Tenderer should upload Scanned copy of valid drug Manufacturing License for the product, duly approved by the Licensing Authority for each and every product quoted as per specification in the tender. The license must have been duly renewed up to date and the items quoted shall be clearly highlighted in the license. Original documents should be produced for verification when demanded. However, if renewal application for manufacturing license has been filed, Scanned copy of same duly receipted by drug authorities must be uploaded along with the validity certificate from state licensing authority (SLA).

(f) Scanned copy of import license (in Form 10 with Form 41), as per Rule 122A of the Drugs and Cosmetics Act 1940, if the product is imported should be uploaded. The license must have been renewed up to date. A copy of a valid license for the sale of Drugs imported by the firms issued by the State Licensing Authority shall be uploaded. Original documents should be produced for verification when demanded.

(g) The copies of relevant pages approved by drug authorities of concerned country for any quoted Drug/product offering CoPP certificate and quoted drugs/ products manufactured by manufacturing units approved by US FDA, TG Australia, Health Canada, EU approval, MCC South Africa approval, Brazil Anvisa should be uploaded with technical bid.

(h) In case of Imported drugs, labels and product literature of all quoted product(s) must be uploaded COPP certificate as per WHO format of their Principal Manufacturing company/firm.

(i) Documents, if any, to show that the manufacturing unit/importer has been recognized by any other Indian / International Standard Organizations etc. as applicable. Importer should upload WHO-GMP certificate of manufacturer.

(j) A Checklist **(ANNEXURE- V)** shall be uploaded with technical bid. If a company/firm has two or more separate manufacturing units at different sites / States, which are not separate entities then the company will be allowed to submit only one tender for all units but necessary document regarding separate manufacturing units will uploaded as a separate set with the same tender. However, one bidder will be allowed to submit only one offer for one product.

(k) All the documents uploaded should also be signed by the authorized official of the Tenderer.

5.PRICE BID

5.1. Price Bid of the Tenderer.

(i) The Tenderer shall fill in the rate per unit size inclusive of GST in respective column of BOQ for the items quoted.

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

(a) In determining the lowest evaluated price, the rate quoted per unit size inclusive of GST as indicated in price bid shall be taken into consideration and lowest landed price will be taken into consideration for determination of L1 Bidder.

(b) Incase where the tender quantity of certain medicines is high then to keep the drug supplies in track the APMSIDC reserves the right to award the contract to L2 bidder if L2 accepts the L1 bidder price. Local SSI units are also permitted to match the L1 price to the extent of 20% of ordered quantity at the sole discretion of APMSIDC.

(iii) **The rates quoted should be in Indian Rupees.** The Tenderer is not permitted to change/alter specification or unit size given in the **ANNEXURE-VII.**

(iv)In case no information is given on GST, it shall be presumed that rates are inclusive of GST and no GST shall be charged by them under any circumstances.

6.OPENINGOF TENDER

6.1 Technical bid evaluation will be done by the Drug Inspectors, DCA,AP.

6.2 After the completion of Technical evaluation preliminary objections will be published on APMSIDC portal www.**msidc.ap.nic.in** for replies from firms. After scrutiny of these remarks by the technical committee final evaluation will be done.

6.3 Only the technically qualified firms in the bid will be eligible for opening of price bid.

7. EARNEST MONEY DEPOSIT

7.1. The Earnest Money Deposit referred to under Clause 3(ii) & 4.1(a), shall be **Rs. 3 Lakh. The Earnest Money Deposit shall be paid in the form of Demand Draft in favour of APMSIDC, payable at Mangalagiri.** APMSIDC will not pay interest on any deposit held in the form of **Bankers Cheque or Demand Draft.**

7.2. (i) The tender submitted without sufficient EMD will be summarily rejected.

(ii)The Earnest Money Deposit will be refunded to the successful bidders within 30 days from the date of acceptance of rate for price agreement and on the deposit of

Performance security deposit.
(iii)The Earnest Money Deposit (EMD) of the unsuccessful bidders will be returned after finalization of tender with eligible bidder.
(iv)The Earnest Money Deposit (EMD) will be forfeited, if the tenderer withdraws his bid any time after opening of price bid / non submission of Performance security within the period prescribed/non supply of drugs.
(v)The Earnest Money Deposit (EMD) will be forfeited, in case of the lowest bidder, fails to execute the contract or deposit the performance security deposit within the stipulated time. The EMD shall be forfeited if any of the documents found incorrect.
(vi) SSI units situated in AP state are exempted from the payment of EMD.

8. OTHER CONDITIONS

8.1.(i) The details of the required drugs, medicines, etc., are shown in **ANNEXURE -VIII.** ***The tender quantity mentioned herein is not a fixed procurement quantity and it is only a tentative requirement and may be increased or decreased*** by APMSIDC, at its discretion, depending on it is actual need. Though the tentative quantity is indicated in the price agreement, the APMSIDC, will confirm the actual requirement then / there through purchase order/orders. The tenderers shall supply the drugs only on the basis of the purchase order issued time to time within validity of contract period by the APMSIDC. Any supply without a valid purchase order will not be acceptable by APMSIDC and the APMSIDC shall not be responsible for any loss on this account.

(ii) The Tenderer shall fill in manufacturing capacity per year in units, Shelf life in months and manufacturing batch size in units for each quoted drug in required column of **ANNEXURE -X and upload along with technical bid.** In case the bidder is Importer, the importer is required to sign and upload ANNEXURE X on behalf of the exporter which would be supported by documentary evidence provided by the manufacturer.

(iii)However, once the purchase order/orders is/are issued by the APMSIDC, the tenderer shall not renege from the commitment of supplying the quantity mentioned in the acceptance of tender for price agreement.

(iv)The rates quoted shall not be varied with the ordered quantity during the full contract period.

8.2 Tender has been called for in the **Generic name of drugs.** The Tenderers should quote the rates for the generic products only. The composition, strength and packing of each product should be as per specifications given in **ANNEXURE-VIII.** Any variation, if found, will result in rejection of the tender. However, the imported/combination drugs are allowed to quote in trade / brand name.

8.3 Rates (inclusive of Customs duty, packing & forwarding charges, transportation, insurance and any incidental charges, all taxes, GST) should be quoted for each of the

required drugs, medicines etc., separately on door delivery basis to all 13 Central Drug stores located in District headquarters of AP state according to the unit ordered. Tender for the supply of drugs, medicines, etc. with cross conditions like "AT CURRENT MARKET RATES" shall not be accepted. Handling, clearing, transport charges etc., will not be paid separately. The delivery should be made as stipulated in the purchase order placed with Tenderers.

8.4. Each bid must quote not only the unit rate but also the total value of each item quoted for supply in the respective columns. The aggregate value of all the items quoted in the tender shall also be furnished.

8.5. (i) The price quoted by the tenderers shall not, in any case exceed the Drugs Price Control Order (DPCO) controlled price, if any, fixed by the Central/State Government. Tender Inviting Authority at its discretion, may exercise, the right to revise the price at any stage so as to conform to the controlled price as the case may be. This discretion will be exercised without prejudice to any other action that may be taken against the Tenderer.

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

8.6. The rates quoted and accepted will be binding on the Tenderer for the full contract period of two years and any increase in the price will not be entertained till the completion of this contract period and if the tenderer supply lower rates than the APMSIDC to any other agency, the difference amount will be recovered from the supplier. Accordingly, this clause will be applicable for all orders placed during the contract period. **However, Price agreement validity period may be extended for period up to further one year at same rate, terms & conditions with the consent of the supplier.**

8.7. No Tenderer shall be allowed at any time and on any ground, whatsoever it may be, to claim revision or modification in the rates quoted by them. Representation to make correction in the tender documents on the ground of Clerical error, typographical error, etc., committed by the Tenderers in the Bids shall not be entertained after submission of the tenders. Cross Conditions such as "SUBJECT TO AVAILABILITY", "SUPPLIES WILL BE MADE AS AND WHEN SUPPLIES ARE RECEIVED" etc., will not be entertained under any circumstances and the tenders of those who have mentioned

such conditions shall be treated as incomplete and accordingly the Tender will be summarily rejected.

8.8. Supplies should be made directly by the tenderer and not through any other Agency / Dealer / Distributors.

8.9. The Tenderer shall allow inspection of the factory at any time after the opening of technical bid and during the entire contract period by a team of Experts/Officials nominated by the Tender Inviting Authority for the purpose. The Tenderer shall extend necessary cooperation to such team in inspection of the manufacturing process, quality control measures adopted etc., in the manufacture of the items quoted. If Company/Firm does not allow for any such inspection, their tenders will be rejected. If any such situation arises after placement of contract, the same shall be cancelled at the firm's risk cost.

8.10 "AP Govt Supply – Not for Sale" should to be printed on each unit/label by the successful bidders. However, this is exempted for imported items.

9. ACCEPTANCE OF TENDER

9.1. (i) Evaluation of the tender and determination of the L1 rate (Lowest rate) will be done based on rate per unit size inclusive of GST as mentioned in column 8 of **BOQ.** However, to have additional source of supply, the L1 bidder shall be awarded contract/Price agreement for 60% of tender quantity indicated in the tender document. Out of remaining 40%, balance 20% of tender quantity shall be provided to the local MSME/SSI bidder and 20% tender quantity to L2 bidder. In case no local MSME/SSI bidder qualifies then the total 40% of the tender quantity indicated in the tender document shall be awarded to **L2 bidder. In either of the above cases, the bidders shall agree to supply the drugs at L1 rates.**

(ii) In case, L2 bidder does not agree to match L1 rate, 100% tender quantity shall be awarded to L1 bidder. The purchase order shall be issued to L1 bidder and L2 bidders simultaneously as per discretion of APMSIDC depending upon requirement. In case, order is placed only on L1 bidder and if they fail to supply in stipulated time or due to quality failure, the purchase order shall be issued to L2 bidder.

(iii). Negotiation if required will be done at APMSIDC premises.

Note 2. No undue advantage shall be given for additional quantity to L2 Bidders or MSME while matching/reducing the rate with respect to L1 rate.

9.2. APMSIDC reserves the right to accept or reject the tender for the supply of all or any one or more items of the drugs tendered for in a tender without assigning any reason.

9.3APMSIDC or its authorized representative(s) has/have the right to inspect the manufacturing premises of Tenderers, before accepting the rate quoted by them or before releasing any purchase order(s) or at any point of time during the continuance of

tender and also has the right to reject the tender or terminate/cancel the purchase orders issued and/or not to place further order, based on adverse reports brought out during such inspections.

9.4APMSIDC also reserves right to place one-time purchase order for certain quantity of any drug even without price agreement, for such drugs suppliers are required to pay performance security deposit @ 5 % (Max of 10 Lakhs) of value of order of such drug in **the form of DD.**

9.5. The acceptance of the tenders for Price Agreement for two years period will be communicated to the Tenderers in writing **(ANNEXURE IX).**

10.PERFORMANCE SECURITY DEPOSIT

10.1 Performance Security Deposit:

On being informed about the acceptance of the tender for 2 years price agreement, the successful tenderer shall be required to pay a Performance Security Deposit of 5% of the contract value subject to a maximum of Rs.10 lakhs per product in the form of ***Demand Draft*** **drawn infavour of MD, APMSIDC Mangalagiri** from any nationalized/scheduled Bank.

10.2. The Tenderer shall not, at any time, assign, sub-let or make over the contract or the benefit thereof or any part thereof to any person or persons whatsoever.

10.3. All notices or communications relating to and arising out of this price agreement or any of the terms thereof shall be considered duly served on or given to the Tenderer if delivered to him or left at the premises, places of business or abode as provided by the tenderer.

10.4. If the lowest selected Tenderer fails to deposit the required Performance Security Deposit (PSD) within the time specified or withdraws the tender, after the intimation of the acceptance of the tender or owing to any other reasons to undertake the contract, the contract will be cancelled and the Earnest Money Deposit deposited by the tenderer along with the tender shall stand forfeited by the APMSIDC and the firm will also be liable for all damages sustained by the APMSIDC apart from blacklisting and other penal actions.

10.5. The performance security deposit of supplier will be returned after the end of rate contract period by APMSIDC only after the supplier has given undertaking to replace supplies and indemnify APMSIDC against any losses on account of quality parameters.

10.6. SSI-units situated in A.P are exempted from payment of Performance Security Deposit provided if submitted MSME certificate.

11.METHODOLOGY FOR PLACING ORDERS

For the above purpose the following procedures will be adopted

(a) After the conclusion of Price Bid opening, the rates offered by tenderers for each product are evaluated and lowest acceptable rate (L1 Rate) arrived at is declared and that tenderer is informed.

(b) The successful Tenderer is eligible for the placement of Purchase Orders only after depositing the required amount as Performance Security.

(c) If two or more Tenderer's are declared as lowest suppliers for the same item(s), such Tenderers are eligible for price agreement and the placement of Purchase Orders for such item(s) for which they are declared as lowest. Placement of order shall be shared equally amongst these bidders' subject to their manufacturing capacity.

(d) In the case of purchase of goods where the quantity offered at the lowest price is less than the total quantity required, the APMSIDC may, after placing orders with the lowest evaluated Tenderer for the entire quantity offered by such Tenderer subject to his ability to supply, require all the other eligible Tenderers who participated in the tender and offered a price higher than that offered by the lowest evaluated Tenderer, to submit sealed offers of the quantity they would be willing to supply at the price quoted by the lowest evaluated Tenderer, and thereafter place orders for the remaining required quantity with all those who match the lowest evaluated price such that those who bid lower prices in the original tender get a higher priority for supply.

(e) If a supplier fails to execute supply order (0% execution) Performance Security Deposit of the product mentioned in purchase order shall be forfeited.

(f) Not with standing anything contained in para (e) above, the supplier, after committing the default in supply either partly or fully, can inform the APMSIDC about his willingness to execute the Purchase Order during the tender period. The MD, APMSIDC at discretion may consider the willingness of the supplier on merit. However, such supplies will be subjected to the levy of Liquidated Damages, unexecuted fine and other penalties as stipulated in the tender document, price agreement and purchase order, at the discretion of MD, APMSIDC.

(g) The supplier shall start supply of the Drugs/Medicines required by APMSIDC at 13 Central Drug Stores (CDS), in Andhra Pradesh or any other place decided by APMSIDC within the stipulated period.

(h) The Drugs/Medicines supplied in excess of the ordered quantity shall not be accepted and the supplier shall take back the excess at their cost. APMSIDC will not be responsible for the loss to the supplier and will not entertain any demand/claim.

(i) After completion of the supplies the documents related to Tax invoice, Analytical test reports of supplied batches or any other document shall be uploaded on

eAushadhi application online for proper acknowledgement of stocks. APMSIDC will not be responsible for any delay in uploading the documents by the supplier which may lead to unforeseen penalties or any wrong entries due to typographical errors, will be allowed for correction within 3 days only.

(j) It is the duty of the supplier to supply Drugs/Medicines at the 13 CDS in AP or any other place decided by APMSIDC and supply shall conform to the conditions mentioned in the provisions of tender documents, viz., logo, nomenclature, specification etc. having a minimum of 3/4th of the shelf life.

(k) APMSIDC reserves the right to place up to 50% additional purchase order of the quantities as contracted within validity of contract.

12. SUPPLY CONDITIONS

12.1. Purchase orders will be issued to the Tenderer(s) at the discretion of the MD, APMSIDC as per actual requirements. All the supplies shall be received at the 13 CDS in AP or any other place decided by APMSIDC.

12.2. Within 4 days from the receipt of purchase orders, the Tenderer should inform APMSIDC through eAushadhi for the receipt of the purchase order.

12.3. The Tenderer should also Communicate and mail the details of supply dates as specified in Annexure, to APMSIDC within 7 days from the receipt of the purchase order. In case, the supply shall not be made by the date as conveyed by the supplier, supply order shall be cancelled at their risk and cost. If no response is received within 7 days from the supplier / tenderer about supply of drugs as per purchase order, it shall be presumed that the supplier/tenderer is not interested to supply the drugs ordered as per purchase order and APMSIDC shall purchase the drugs from alternative sources.

12.4. Supplies against a purchase order shall be completed within 75 days otherwise liquidated damages are levied by APMSIDC as mentioned in clause 18.1.

If the Tenderer fails to execute the supply within the stipulated time, the APMSIDC is at liberty to make alternative arrangement for purchase of the items for which the Purchase orders have been placed, from any other sources or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the defaulted supplier and in such cases the APMSIDC has every right to recover the cost and impose Liquidated Damages as mentioned in Clause 18. In case of any variation in prices during alternative procurement will be charged to L1 bidder or defaulted supplier.

12.5. The liquidated damages as specified in clause 18.1 and 18.2 of the tender conditions will be levied. **However, the supplier must take prior approval from APMSIDC for supply of drugs beyond stipulated delivery period of the Purchase order or in case of special case to proceed with or without penalty will be at the discretion of MD, APMSIDC.**

12.6. The Tenderer must submit an Analysis report for every batch of drug along withinvoice. In case of failure on part of the supplier to furnish such report, the batch of drugs will be returned to the suppliers and he is bound to replenish the same with Govt. approved lab test report. The Drugs supplied by the successful Tenderer shall be of the best quality and shall comply with IP/BP/USP and the specifications, stipulations and conditions specified in the tender.

12.7. Tenderer should supply the product (a) within 2 months excluding month of manufacture of products having shelf life up to 1 or 2 years, (b) within 3 months excluding month of manufacture of products having shelf life more than 2 years & up to 3 years and (c) within 4 months excluding month of manufacture of products having shelf life more than 3 years (d) Within 3.5 months excluding month of manufacture of products for Rabies Vaccine Inj. 2.5 IU. Products beyond the above-mentioned period from the date of manufacture shall not be accepted. For example, product having manufacturing of November 2019 must be supplied by 31stJanuary 2020 in case shelf life less than 2 Years. For imported products, 20 months of shelf life should be available at the time of supply.

12.8. If at any time the Tenderer has, in the opinion of the APMSIDC delayed the supply of drugs due to one or more reasons related to Force Majeure events such as riots, mutinies, wars, fire, storm, tempest, floods or other exceptional events at the manufacturing premises, the time for supplying the drugs may be extended by the MD, APMSIDC at discretion for such period as may be considered reasonable. However, such extension shall be considered only if a specific written request is made by the Tenderer within 20 days from the date of occurrence of such event with necessary documentary evidence. The exceptional events do not include the Increase in the cost of raw material, Electricity failure, Labour disputes/Strikes, Insolvency, and Closure of the Factory/Manufacturing unit on any grounds etc.

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

12.10. Suppliers are required to supply the drugs within the delivery period mentioned in the purchase order. In this regard it is informed to the bidders that their performance shall be considered unsatisfactory in case of delayed supply (beyond delivery period) or non-supply of products. APMSIDC may reject their bid in future tenders considering their unsatisfactory performance of supplies.

12.11. If APMSIDC observes some physical defects(like empty blisters, improper labelling) of the supplies during sampling, the batch shall be rejected. If supplier wants to take back the batch for rectification, they can take back at their cost, rectify and send back to APMSIDC within 10 days otherwise same batch shall not be accepted. Due to rectification, if its shelf life condition as per tender provision does not meet, it shall be discretion of APMSIDC depending upon requirement to accept the goods with or without penalty.

12.12. If the drug is not consumed prior to its expiry date i.e., six months before expiry, the supplier will be notified about the short expiry drugs, upon receipt of such information the supplier should replace (at own cost of supplier to and fro) the short expiry/expired quantity with fresh stock of longer shelf life, otherwise the value of the total expired quantity or 10% of the total PO value whichever is lower will be deducted from the bills or any other amount payable to the firm.

13. LOGOGRAMS

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

13.1. Tenders for the supply for Drugs etc., shall be considered only if the Tenderer gives an undertaking that the product(s) will be prepared as per the specifications such as name, strength, minimum size and packed with appropriate size of the strips/blisters/bottles/tubes etc. as per the design enclosed as per **ANNEXURE -I.**

13.2. All dosage form has to be supplied in packing as specified in product list **(ANNEXURE VIII)** and shall also conform to Schedule P1 of the Drugs & Cosmetics Act &Rules 1940, wherever it applies. Affixing of stickers and rubber stamps shall not be accepted and supplies will be returned at supplier's cost.

13.3. Vials, Ampoules (more or equal than 5 ml) and Bottles containing the items tendered for should also carry the printed AP logogram of proportionate size.

13.4. Failure to supply Drugs etc., with the printed logogram of proportionate size will be treated as breach of the terms of price agreement / violation of tender conditions. The purchase order shall be cancelled at the risk and cost of the supplier. However, if such failure continuous despite notice, will be viewed as a serious lapse and APMSIDC will initiate suitable action.

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

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

14.PACKING

14.1. The drugs shall be supplied in the package specified in ANNEXUREVII and ANNEXURE -XII and the package shall carry the logograms of proportionate size specified in ANNEXURE -XI, XI -A. Non-printing of logograms will be treated as violation of tender conditions and fine of 0.5% of the value of Purchase Order will be deducted from the amount payable as per conditions. In case of emergency to meet the short fall

of drugs exemption can be given on penalty of 0.5% with the prior approval of MD, APMSIDC.

14.2. The minimum size of each tablet should be 6.4 mm in diameter and the minimum size of the blister packing/strip packing/Alu-alu packing should be 80mm x 35mm/50mm x 130mm/45mm x 110mm respectively. The drugs in any dosage form to be supplied by the supplier should not be embossed indicating any code no./logo or name of the company. Failure to comply with this shall lead to non-acceptance of the goods besides imposition of penalties.

14.3. The packing in each carton shall be strictly as per the specification mentioned in Annexure-XII. The outer carton/secondary packaging should be of pearl white duplex board (off white/grey is not acceptable) with a minimum of 350 GSM with Gloss laminated packing for the strips, blisters, ointments, creams etc. and for ampoules and vials should be with pearl white board of 350 GSM (off white/grey is not acceptable). The material to be used for carton should be from virgin chemical pulp. Failure to comply with this shall lead to non-acceptance of the goods besides imposition of penalties. Storage conditions must be indicated on outer label.

14.4. The cap of bottle should be of Aluminum and preparations should not carry the name of the supplier.

14.5. The labels in the case of Injectable preparations should clearly indicate whether the preparations are meant for Intravenous (IV), Intramuscular (IM), Intra Dermal (ID), Subcutaneous (SC) administration etc.

14.6. It should be ensured that only first-hand virgin packaging material of uniform size, including bottle and vial, is used for packing.

14.7. All primary packing containers should be strictly conforming to the specification included in the relevant pharmacopoeia.

14.8. Packing should be able to prevent damage or deterioration during transit.

14.9. In the event of items of drug supplied found to be not as per specifications in respect of their packing and logogram, the APMSIDC is at liberty to make alternative purchase of the items of drugs for which the Purchase orders have been placed from any other sources or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier. In such cases the APMSIDC has every right to recover the cost and impose penalty as mentioned in Clause 18 & 19.

14.10. Designs of packaging with the logograms shall be subject to approval by APMSIDC within 3 days of receipt of purchase order. Text matter of all type of label must be checked and responsibility shall be of manufacturer. In case of failure of APMSIDC to do so, the supplier may go ahead with the design as per the specification in ANNEXURE XI and XIA.

14.11. The color of the strength must be different from the color of the generic name of the drug on primary and secondary packaging and the approval for the same should be taken from the quality/regulatory department while taking artwork approval. The printing ink used should be of good quality (clarity, brightness, contrast) which is easily readable.

15. QUALITY TESTING

15.1. Samples of supplies from each batch will be chosen at the point of dispatch at supplier's site or receipt of supply or distribution/storage points for testing at discretion of APMSIDC. The samples will be sent to different laboratories including Government Drugs Testing Laboratory/NIPER/PSU labs for testing as decided by the APMSIDC. Handling and testing charges will be borne by APMSIDC for the above purpose.

15.1.1 Supplier should send the soft copy of the specifications for all approved drugs and STP (Standard Testing Procedure) for Non- Pharmacopoeia approved drugs by mail to Quality and Regulatory officer of APMSIDC with art work approval for design of packaging with the logogram as per Clause 14.10.

15.2. The Drugs shall have the active ingredients at the prescribed level as indicated in official compendiums throughout the shelf life period of the drug. The samples will be drawn periodically throughout the shelf life period and if found "Not of Standard Quality", the cost of entire batch paid will be recovered whether consumed fully/partially. Also, action will be initiated for blacklisting as per clause No.19 irrespective of the period of supply. The supplies will be deemed to be completed only upon receipt of the quality certificates from the laboratories. Samples which do not meet quality requirement shall render the relevant batches liable to be rejected. If the sample is declared to be "Not of Standard Quality" or spurious or adulterated or misbranded, such batch/batches will be deemed to be rejected goods.

15.3. In the event of the samples of Drugs supplied fails in quality tests or found to be not as per specifications, the APMSIDC is at liberty to make alternative purchase of the items of drugs for which the Purchase orders have been placed from any other sources or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier and in such cases the APMSIDC has every right to recover the cost and impose penalty as mentioned in Clause 19.

15.4. The supplier shall furnish evidence of the basis for shelf life and other stability data concerning the commercial final package on request by the APMSIDC. In case of any complaint in the field, the B.M.R/B.P. R for the particular batch of the product(s) supplied shall be produced when demanded.

15.5. The products should conform to the standards of IP/BP/USP as the case may be. **However, the drugs notified in the IP (amended up to date) shall be accepted only if supplied conforming to the standards outlined in the IP.** In case the product is not included in the any of the said compendiums, the supplier, upon award of the contract, must provide the reference standards and testing protocols for quality control testing.

For imported drugs, respective Country's Pharmacopoeia standards shall be acceptable (even if the product is official in IP).

15.6. The case of admixture of drugs will be treated as a violation of tender conditions and fine will be levied as per clause 19. If such lapses happen more than twice in a tender period such cases will be treated as "Misbranded Drugs".

16. PAYMENT PROVISIONS

16.1. No advance payments towards costs of drugs, medicines etc., will be made to the Tenderer.

16.2. Payments towards the supply of drugs will be made within 60 days from the date of receipt of goods, strictly as per the tender terms and condition. The payment will be made through AP Government Finance portal CFMS / RTGS (Real Time Gross Settlement System)/Core Banking/NEFT. The Tenderer shall furnish the relevant details in original **(MANDATE FORM)** to make the payment through CFMS/RTGS/Core Banking/NEFT.

16.3. All bills/Invoices should be raised in duplicate and the bills should be drawn as per GST Rules in the name of MD, APMSIDC. Mangalagiri, Andhra Pradesh.

16.4. (i) Payment will be paid after completion of 95% of supplies. In case any purchase order is executed partially beyond 75% up to 95% remaining bills will be processed at the discretion of APMSIDC by imposing a penalty of 10% on unexecuted quantity value only.

(ii) The payment for part supply if any will subject to the deduction of liquidated damages, penalty towards unexecuted quantity, risk and cost etc., as per the tender conditions.

16.5. If at any time during the period of contract, the price of tendered items is reduced or brought down by any law or Act of the Central or State Government or by the Tenderer himself, the Tenderer shall be bound to inform the APMSIDC immediately about such reduction in the contracted prices. Tender Inviting Authority is empowered to unilaterally effect such reduction as is necessary in rates in case the Tenderer fails to notify or fails to agree for such reduction of rates.

16.6. In case of any increase of decrease in the GST after the date of submission of tenders and during the tender period, such variation in the GST will be to the account of the APMSIDC. For claiming the additional cost on account of the increase in GST, the Tenderer should produce the proof of having paid additional amount on this account on the goods supplied to APMSIDC from the concerned authorities and also must claim the same in the invoice separately.

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

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

Subject to the conditions mentioned in the Purchase Order, Tender Document, Price Agreement and here under, the Supplier is entitled for the payment against supply. In case of any discrepancy in levy of LD, Penalty, Unexecuted Fine, Short Passing of Bills, such discrepancy shall be intimated within 30 days from the date of receipt of payment, failing which APMSIDC will not entertain any claim thereafter.

17.TESTING CHARGES

In all supplies, testing charges will be borne by APMSIDC.

18.LIQUIDATED DAMAGES AND OTHER PENALTIES

18.1. Liquidated damages and penalties -

Sr. No.	Penalty	Action
1	Supply period without penalties	Upto 75 days from the date of issue of PO, supplies shall be started by 45th day from the date of issue of Po
2	0.5% per day	For 76thday to 120th days, not exceeding to 5% of the PO value for the Small Scale Industries located in state of Andhra Pradesh and not exceeding to 10% of the PO value for all other firms
3	PO Cancellation	Beyond 120 days PO will be cancelled and stocks will not be accepted. PSD will be forfeited. Alternate Procurement will be done from the other bidders matching with L1 price or at their quoted price or from the other open sources procurement and difference in procurement will be charged to the L1 supplier
4	Other penalties	If two POs were not executed, the firm will be declared as "Undependable" for the product and the action will be taken as per clause 20.3 of this tender.

18.2 If the supply is received in damaged condition, open delivery of the supplies shall be received, wherein it is possible to physically inspect the shipment, damaged products shall not be accepted.

18.3 All the Tenderers are required to supply the product(s) with printed “Andhra Pradesh Govt. Supply – Not for Sale” and logogram of appropriate size on the strips, blisters, vials, ampoules& bottles and with prescribed packing specification. If there are any deviations in these Tender conditions, action will be taken to blacklist the product and/or a separate damage will be levied @ 0.5% of value of the defaulted quantity irrespective of the Tender Inviting Authority having actually suffered any damage/loss or not, without prejudice the rights of alternative purchase specified in Clause No.14.11 and 13.4.

19.DEDUCTION& OTHER PENALTIES ON ACCOUNT OF QUALITYFAILURE:

19.1. If the samples do not conform to statutory standards, the Tenderer will be liable for relevant action under the existing laws and the entire stock in such batch has to be taken back by the Tenderer within a period of 30 days of the issue of the letter from the APMSIDC Such stock shall be taken back at the expense of the Tenderer. Further, actual testing charges (including handling charges for conducting those tests) shall be paid to APMSIDC by the supplier otherwise these charges shall be recovered from their pending bill/EMD/performance security deposit. The APMSIDC has the right to destroy such "NOT OFSTANDARD QUALITY DRUGS" if the Tenderer does not take back the goods within the stipulated time. The APMSIDC will arrange to destroy the "NOT OF STANDARD QUALITY DRUGS" after the expiry of 30 days mentioned above without further notice and shall also collect demurrage charges calculated at the rate of 2% per week on the value of those drugs which are of “NOT OF STANDARD QUALITY” rejected till such time stipulated. Further, the cost of disposal shall be recovered from the supplier.

19.2. If any items of Drugs/Medicines supplied by the Tenderer have been partially or wholly used or consumed after supply and are subsequently found to be in bad odour, unsound, inferior in quality or description(Adulterated/Spurious/Misbranded) or otherwise faulty or unfit for consumption, then the contract price or prices of total such batches supplied will be recovered from the Tenderer, if payment had already been made to him. In other words, the Tenderer will not be entitled to any payment whatsoever for Items of drugs found to be of "NOT OF STANDARD QUALITY" whether consumed or not consumed and the Tender Inviting Authority is entitled to deduct the cost of such batch of drugs from any amount payable to the Tenderer. On the basis of the nature of failure, action will be initiated to blacklist the product/supplier.

19.3. The Tenderer shall furnish the source of procurement of raw material utilized in the formulations, if required by the APMSIDC. The APMSIDC reserves the right to cancel the purchase orders, if the source of supply is not furnished.

19.4. The decision of the APMSIDC or any officer authorized by him, as to the quality of the supplied drugs, medicines etc., shall be final and binding. In such cases, the APMSIDC will be at liberty to terminate, the contract either wholly or in part on 30 days' notice. The Tenderer will not be entitled for any compensation whatsoever in respect of such termination besides forfeiture of Performance Security Deposit.

19.5. For contravention of the stipulations of the contract or for other justifiable reasons, the contract may be terminated by the APMSIDC, and the Tenderer shall be liable to pay for all losses sustained by the APMSIDC in consequence of the termination which may be recovered from the Tenderer, as per rules besides forfeiture of Performance Security Deposit.

19.6. Non-performance of any of the contract conditions and provisions will disqualify a firm from participating in the tender for the next 2 years besides forfeiture of Performance Security Deposit.

19.7. In the event of making Alternative Purchase, as specified in Clause 12.4 (a), Clause 14.11 and in Clause 15.3 penalty will be imposed on the supplier. The excess expenditure over and above contracted prices incurred by the APMSIDC in making such purchases from any other sources or in the open market or from any other Tenderer who has quoted higher rates and other losses sustained in the process, shall be recovered from the Performance Security Deposit or from any other money due and become due to the supplier and in the event of such amount being insufficient, the balance will be recovered personally from the supplier as per rules.

19.8. In all the above conditions, the decision of the MD, APMSIDC shall be final and binding.

20. BLACKLISTING CRITERIA

20.1. BLACKLISTING OF PRODUCT/TENDERER ON WITHDRAWAL OF TENDER

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

20.2. BLACKLISTING FOR QUALITY FAILURE

20.2.1. Quality Test by the Empanelled Laboratories of APMSIDC/Govt Labs

a. Each batch of drugs/medicines shall be subjected to quality test by the empanelled laboratories.

b. The samples collected from each batch of supply of each drug will be sent to the empanelled testing laboratories for testing the quality of drugs. In addition to the above, APMSIDC shall also draw the samples of products supplied to the health facilities and get the same tested, to make sure the products are conforming to quality requirements.

c. If sample passes quality tests in all aspects, APMSIDC will instruct its CDS(Central Drugs Stores) to release such items of drugs.

d. If the sample of any batch fails in quality test and report is received stating Not of Standard Quality such batch of drugs shall be unutilized.

e. If the supplier challenges and requests for retesting after an NSQ is received from empanelled laboratory (other than Government Laboratories), the other portion of the same batch shall be sent to State Drugs Control Laboratory, AP or any other Government testing laboratory or NABL accredited laboratory as decided by APMSIDC. The test report received from any of these laboratories (second opinion) will be final for any decision and will be binding on the supplier. The cost of such retesting shall be recovered from the supplier.

   If one or more batches of item/drug supplied by the same supplier is reported to be NOT OF STANDARD QUALITY (NSQ) in specifications as given in table under clause 20.2.2(b), then the product of the firm shall be blacklisted for 2 years.

20.2.2 Quality Test by Statutory Authorities:

a. If any drug is declared "NOT OF STANDARD QUALITY", by any of the Government testing laboratory (DCL, AP or CDTLs or NIB, Noida or any other Government labs), the issue of available stock of the particular item will be stopped. Further, the available stock of the product in hospitals will be retrieved.

b.

S. No (A)	Formulation (B)	Test Parameters in which sample fails (C)	No. of Batches that fail the test (D)
1	Tablets/Capsules or Other formulations	Assay for Active Pharmaceutical ingredients or Dissolution test	02
2	Liquid preparations	Showing Presence of Fungus, Foreign matter, Non-Dispersible Lump or Cake formation	01
3	Parenteral preparations	Failing in Test for Sterility, Test for Pyrogen / Endotoxin or undue Toxicity	01
4	Sera / Vaccines	Failing in Test for Sterility, Toxicity, Moisture Content	01
5	Ophthalmic preparation	Failing in test for Sterility, Fungal Growth, Foreign Matter	01
6	Powders	Fungal Growth	01

As per the above table if number of batches of same drug (shown in column D) of a particular firm are declared as then that particular drug of the firm will be blacklisted against the firm for a period of 2 years.In case the supplier challenges the statutory test report as defined in the Drugs and Cosmetics Act, 1940 and Rules made there under1945, issued by any Government Analyst then the test report issued by Central Drugs Laboratory, Kolkata shall be treated as final.

c. In case of other parameters (excluding those given in above table), if 3 batches are declared as NSQ then the item of the firm will be blacklisted against the firm for 2 years.

d. The amount of the NSQ batch shall be deducted/ withheld from the amount payable to the firm or from the performance security deposit of the firm. No purchase orders will be placed for the blacklisted item of the firm.

e. In case a firm is supplying more than one product and one of the products is declared as NSQ, in such case, in addition to the measure suggested above, 10% of total bill amount submitted by the firm will be withheld for a period of four months and will be paid after monitoring satisfactory supply of all other products.

f. If two or more items/products of any firm are blacklisted, then the entire firm will be blacklisted, and it will not be allowed to participate in tender for 2 consecutive years from the date of blacklisting

g. If any batch of any product(s) supplied by the company/firm declared, NOT OF STANDARD QUALITY in specification by the Government Authorities during the relevant tender period or during quality check within shelf life period, suitable action will be taken for blacklisting of the product/ firm.

20.2.3 Procedure for Blacklisting:

(i) On receipt of complaint from CDS or report from Govt. Analyst/Drug Testing Laboratory indicating that a particular Item/Drug is **"NOT OF STANDARD QUALITY/ ADULTERATED/ SPURIOUS/ MISBRANDED"** (As the case may be), a show cause notice shall be issued to the supplier calling for explanation within 7 days from the date of notice. On receipt of explanation from the supplier, the MD, APMSIDC may take appropriate action on merits of the case and impose penalty or the blacklisting of the product/company or both as deemed fit besides forfeiture of Performance Security Deposit.

(ii)If a particular drug has been blacklisted according to the procedure stated above, the supplier is not eligible to participate in any of the tenders for that particular item floated by the APMSIDC until the period of blacklisting is over.

(iii)If a supplier / firm is blacklisted according to the procedure stated above, such supplier is not eligible to participate in any of the tenders floated by the APMSIDC until the period of blacklisting is over.

20.3 BLACKLISTING FOR NON-SUPPLY

Due to non-supply of item against any purchase order, 5 % value of purchase order shall be recovered from the supplier in addition of other penal like risk purchase. In case of repeated circumstances of non-supply of items i.e. 3 times, the supplier/firm may be blacklisted for 2 years in addition of forfeiture of Performance Security Deposit/ EMD and other penal action.

20.4. For the supply of Adulterated/Spurious/Misbranded items as defined in the Drugs and Cosmetics Act, 1940, to APMSIDC, APMSIDC reserves the right to blacklist the supplier/firm. No further supplies shall be accepted from the firm/firm. If the tenderer is blacklisted, the tenderer shall also not be eligible to participate in tenders of Tender Inviting Authority of APMSIDC for supply of Drugs for a period of 2 years from the date of blacklisting. In case of supply of NOTOF STANDARD QUALITY drug(s) to APMSIDC, the product shall be blacklisted by APMSIDC and no further supplies shall be accepted for the particular drug(s). The Tenderer shall also not be eligible to participate in tenders of APMSIDC for supply of such Drugs for a period of 2 years from the date of blacklisting. In addition, the Director of Drugs Control of concerned State will be informed for initiating necessary action on the Tenderer in their state. Performance security deposit will also be forfeited without any intimation.

20.5 APPEAL (s) IN CASE OF BLACKLISTING:

I. A supplier/firm whose product or the supplier/firm, itself have been blacklisted by the corporation which is displayed in the corporation website i.e.://msidc.ap.nic.in//, within 15 days from the date of display, may appeal to the Director General, Drug Control Administration, A.P.

The Director General, Drug Control Administration, A.P., after such enquiry into the matter, as it is considered necessary and after giving the said supplier an opportunity for representing his views and may pass such order in relation thereto, as he thinks fit.

II. If the firm is not satisfied with the outcome of appeal, within 15 days from the date of appeal order, the firm may file review petition before the Principle Secretary, Health, Medical & Family Welfare, A.P. The State Government after such enquiry into the matter, as is considered necessary and after giving the said supplier an opportunity for representing his views, may pass such order in relation thereto, as it thinks fit.

21.SAVING CLAUSE

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

APMSIDC reserves the right to make modification, alteration or relaxation in any of the clauses or conditions given in this tender document.

For contravention of the stipulations of the contract or for other justifiable reasons, the contract may be terminated by the APMSIDC. The decision of the MD, APMSIDC shall be final and binding.

22.RESOLUTION OF DISPUTES

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

23. FRAUDULENT AND CORRUPT PRACTICES:

(1) For bidders:

If the APMSIDC determines that a Supplier has engaged in corrupt, fraudulent, collusive, coercive or obstructive practices, in competing for or in executing the Contract, then the APMSIDC may, after giving 7 days' notice to the Supplier, terminate

the Supplier's engagement under the Contract and cancel the contract, and the procurement will be made at the risk and cost of the supplier besides blacklisting the bidder for 2 years with forfeiture of Performance security deposit apart from other penal actions.

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

(a) defines, for the purposes of this provision, the terms set forth below as follows:

i. "corrupt practice" is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party *("another party" refers to a public official acting in relation to the procurement process or contract execution]. In this context, "public official" includes staff and employees of other organizations taking or reviewing procurement decisions.*

ii. "fraudulent practice" is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation (a *"party" refers to a public official; the terms "benefit" and "obligation" relate to the procurement process or contract execution; and the "act or omission "is intended to influence the procurement process or contract execution).*

iii. "collusive practice" is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party *["parties "refers to participants in the procurement process (including public officials) attempting to establish bid prices at artificial, noncompetitive level].*

iv. "coercive practice" is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party (a *"party" refers to a participant in the procurement process or contract execution).*

v. "obstructive practice" is

(a) deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede an investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening, harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or acts intended to materially impede the exercise of the purchaser's inspection and audit rights provided for under sub-clause (e) below.

(b) will reject a proposal for award if it determines that the bidder considered for award has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the contract in question;

(c) will cancel the contract if the purchaser determines at any time that the bidder, supplier and contractors and their sub-contractors engaged in corrupt, fraudulent, collusive, or coercive practices.

(d) will sanction a firm or individual, including declaring in eligible, either indefinitely or for a stated period of time, to be awarded a contract if it at any time determines that the firm has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for, or in executing, a contract; and

(e) will have the right to inspect the accounts and records of the bidders, supplier, and contractors and their subcontractors/authorized representatives and to have them audited by auditors appointed by the purchaser.

24. JURISDICTION

In the event of any dispute arising out of the tender such dispute would subject to the jurisdiction of the Honorable Civil Courts within the city of Vijayawada only.

ANNEXURE -I

DESIGN FOR LOGOGRAMS

INJECTIONS

Injection in ampoule form should be supplied in Double constructed neck ampoules with the label bearing the words “Andhra Pradesh Govt. Supply – Not for sale” over printed and letter containing the logogram No. 1. Which will distinguish them from the normal rate packing.

Logogram No.1

The vials should be supplied with aluminium seals containing the logogram.

In addition to the label bearing the logogram Andhra Pradesh Govt. Supply – Not for sale and the logogram No.1

LIQUIDS

Liquid preparations either be in HDPE bottles/ glass bottles depending on the nature of the product with pilfer-proof caps bearing the logograms:

On the top of the cap and the label to be affixed on the containers should bear a distinct colour different from the colour of the label of the trade packs and they should be over printed in red colour with the words Andhra Pradesh Government Supply -Not For Sale and the logogram above.

Top of the cap

Or

SPECIMEN LABEL FOR OUTER CARTON

Or

A.P. GOVT.

SUPPLY

NOT FOR SALE

(or)

DECLARATION

I do hereby declare that I will supply the drugs and medicines as per the above design.

Signature

ANNEXURE -II
(On nonjudicial Stamp Paper)

Ref. Clause No. 4.1(a)

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 as under: -

(I) that I/we have carefully read all the terms and conditions of tender in ref. no. _____ including Amendment(s) to Tender document (if any) issued by APMSIDC, Mangalagiri and accept unconditionally all terms and condition of tender document including Amendment(s) to Tender document (if any).

(II) I/We hereby declare that all required annexures and documents are uploaded.

(III) Iam / We are aware of the Tender inviting Authority's right to forfeit the Earnest Money Deposit and /or Performance security deposit and blacklist me/us for a period of 2 years if, any information furnished by us proved to be false at time the of inspection and also not complying with any of the tender conditions.

Name of the bidder:

Address:

Name of the authorized signatory:

Sign and Seal:

ANNEXURE-III

DETAILS OF QUOTED PRODUCTS

I _____ Managing Director/Director / Partner / Proprietor of M/s._____ having its manufacturing or import unit / registered office at_____ do hereby declare that the firm & its quoted product have not been blacklisted currently (as on the date of submission of the tender) by Central Government/Central Government Agencies/any state government/any of the state government agencies/any Drug Procurement Agencies or by APMSIDC. We are eligible to participate for the following quoted products.

S.No	Tender S.No	Item Code	Item Name	Whether Manufacturer/Importer	Mfg. /Import License No. And Date	Date of issue of product approval BY licensing authority	Mfg./Import License and product approval valid up to

Date:

Signature Seal:

(Authorised Signatory)
Name and Address of the Bidder

ANNEXURE- IV

Ref. Clause No.4.1(b)

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

(I) It is certified that M/s .... is a Private. /Ltd./Proprietorship/Partnership company/firm and they have PAN no and GST registration no…. They have filed Income tax returns and GST returns up to date. The authorized signatory of the company/firm is Shri ..... and whose signature is attested asunder: .....

(II) The annual Turnover of M/s..... for the past three years i.e. 2017-18, 2018-19 and 2019-20 or 2018-19 ,2019-20 and 2020-21 are given below and certified that the statement is true and correct.

S. No	Financial Year	Turnover in Lakhs (Rs.)
1		
2.		
3.		
TOTAL		Rs ...Lakh
Average Turnover per annum		Rs ....Lakh

(III) ..... It is certified that M/s……. has Production &financial capacity to manufacture and deliver the Medicines quoted by them in the tender as per quantity & delivery schedule mentioned in tender. This certificate is based on their Manufacturing capacity, inventory of raw Material and financial statement.

Or **(ONLY in case of IMPORTER)** It is certified that M/s……. has Financial capacity to manufacture and deliver the surgical consumables quoted by them in the tender as per quantity &delivery schedule mentioned in tender. This certificate is based on their Manufacturing capacity, inventory of raw Material and financial statement.

Or **(ONLY in case of SSI/MSME)**It is certified that M/S _____is Micro and Small Enterprises (MSE)/SSI and registered with Director of Industries appropriate authorities for quoted products against APMSIDC tender No. _____and eligible for exemption of paying EMD.

Date_____

(Name, Signature & Stamp)

Registration no.

ANNEXURE-V

STATEMENT OF CAPACITY OF PRODUCTION

01. Name of the firm:

Address

The installed capacity of this firm is as follows per shift

Name of the product Capacity

S. No	Item Code	Name of the Product	Minimum Batch Size	Manufacturing capacity for 75 days
1				

Signature of the tenderer: _____ Date _____

Full Name (IN BLOCK LETTERS) _____

NOTE: - Details are to be provided for two month's production capacity

Signature and seal of the Tenderer_____

CHECK-LIST

(Documents to be uploaded)

S. N	Check List	YES	NO	PAGE
1	Processing Fee The bidder shall remit processing fee Rs. Rs. 11,800/- (NON REFUNDABLE) in the form of DD in the name of The Managing Director, APMSIDC, Mangalagiri/NEFT/RTGS/Online.			
2	EMD Rs. 3,00,000/- in the form of Demand Draft / NEFT/ RTGS/ Online Uploaded NSIC or MSME certificate of AP state for exemption if any.			
3	Scanned copy of Valid **GMP/WHO-GMP**Certificate of manufacturing company. In case of imported drugs, scanned copy Valid WHO-GMP Certificate of manufacturing company of foreign company.			
4	Scanned copy of Valid License for the Product duly approved by the Licensing Authority for each and every product quoted. Note : Authorization from concerned state authority for retention/renewal of the products to be furnished.			
5	Scanned copy of Valid Import License, if Imported and wholesale Drug license			
6	Scanned copy of valid Non-Conviction Certificate issued by the licensing authority.			
7	Scanned copy of ANNEXURE II (Declaration for eligibility in participating the tender) original Annexure II delivered to APMSIDC**.**			
8	Annexure III, Details of Quoted products			
9	Scanned copy of ANNEXURE IV {certificate from the C.A. (Chartered Accountant)			
10	Details for Manufacturing Capacity and Batch Size Annexure V			
11	Scanned copy of ANNEXURE-VII (Mandate form)			

NOTE: -EMD instrument and Processing Fee are to be delivered in original to APMSIDC, Mangalagiri on or before stipulated dates give in document.

Name and signature of authorized signatory (with company seal).

MANDATE FORM
(ANNEXURE VII)

S.No.	Details Required		
1.	**Company Name**		
	PAN Number		
	TIN Number		
	GST NO.		
	Date of Inception		
	Legal status of the Bidder (Proprietorship/ Partnership/ Pvt. Ltd. Company/ Limited Company)		
	License No. & Date		
	Issued By		
	Valid Up to		
2.	Postal Address of the Company		
	Telephone No.		
	Fax No.		
	E-mail ID		
	Alternate E-mail ID		
3.	Name of the Managing Director / Director / Manager		
	Mobile No. / Phone No		
	E-mail ID		
4.	Name and Designation of the authorized company official	Name:	
		Designation:	
	Mobile No.		
	E-mail ID		
5.	**Bank Details**		
	a) Name of the Bank		
	b) Branch Name & address		
	c) Branch Code No.		
	d) Branch Manager Mobile No.		
	e) Branch Telephone no		
	f) Branch E-mail ID		
	g) 9-digit MICR code number of the bank and branch appearing on the MICR cheque issued by the bank Branch		
	h) Type of Account (Current / Savings)		
	i)Account Number (as appear in cheque book)		

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

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

Date: Place:

Company Seal ..... Signature
(Name of the person signing & designation)

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

TENDER ITEMS
ANNEXURE-VIII

S No	Item Code	Name of the Item	Specification	Unit	Tentative required Doses
1	HBV1	Hepatitis B Vaccine IP	Multi Dose Vails	1	23,87,514

*** Tender Quantity is Tentative and APMSIDC has right to increase or decrease the procurement quantity at any time as per the requirement.**

Detailed Specification:

Hepatitis B Virus Vaccine Specifications
(For NCB/LCB)

A. Specific requirements

Item:

Hepatitis B virus vaccine, shall meet the requirements as per Indian Pharmacopoeia (I.P.) and Rule-122B of Drugs and Cosmetics Act

The vaccine shall be currently registered in the country of manufacture and shall meet all requirements of the licensing authority of the country of manufacture. The vaccine also shall be currently registered in the country of use (India) and shall meet all the requirements of the licensing authority of the country of use.

Description:

Hepatitis B virus vaccine may exist in two forms, i.e. as an inactivated (plasma-derived) vaccine and as a recombinant (DNA) vaccine.
Hepatitis B virus vaccine (Inactivated) is a non-infectious inactivated liquid preparation derived from surface antigen of hepatitis virus (HBsAg). The production of vaccine is based on a virus seed lot system.
Hepatitis B virus vaccine (Recombinant) is a non-infectious preparation containing the purified major surface antigen of hepatitis B virus (HBsAg). The antigen is manufactured by recombinant DNA technology by culturing genetically engineered yeast cells lines which carry the gene that codes for the major surface antigen of the hepatitis B virus as approved by the competent authority.
The purified antigen is finally adsorbed on aluminium hydroxide or aluminium phosphate.
The vaccine must be free from all demonstrable viable microbial agents and found suitable for human immunization. It may contain a suitable stabilizing agent with anti microbial properties.
Hepatitis B vaccine contains not less than 20mcg of hepatitis B surface antigen per ml.

Protocol and testing:

Complete Test Protocol along with samples of all batches should be sent to the Head of the vaccine testing laboratory i.e. Central Drugs Laboratory, Kasauli-173204;
For local manufacturers:
Complete Test Protocol and samples are taken and sent to by the Inspecting Officer duly sealed and signed by him or his authorized representative.

The vaccine should be dispatched to the consignee only on clearance from the Central Drugs Laboratory, Kasauli. The vaccine will be released on the basis of protocol scrutiny and testing of the vaccine by Central Drugs Laboratory, Kasauli.

Each batch should be accompanied with a certificate from the manufacturer that the vaccine meets the I.P. requirements.

Dosage size:

By intramuscular injection (Anterolateral part of thigh); when given as part of a primary immunization starting at 6 weeks of age. Three injections are given at monthly intervals. In all institutional deliveries a dose at the time of birth as early as possible and preferably within 24 hours.

Dose package:

Single-dose; multi-dose vials contain 10 paediatric doses 0.5ml, or 10 adult doses 1 ml.

Filling volume:

Final product should contain 15% overfill.

Storage temperature:

In light-resistant containers between +2 and +8^{0}C;
must not be frozen.

Shelf-life:

At least 24 months from date of manufacture when stored between +2 to +8^{0}C ; at least 20 months must remain after shipment. The supplier will provide manufacturer's stability test data substantiating this 24 month shelf life in the proposed vial. At the time of inspection or acceptance for delivery to the country of destination, no more than 6 months shall have expired since the Date of manufacture (or date of beginning of the last satisfactory test for potency) shown on the Certificate of Analysis.

Labelling:

The label on each vial shall conform to the requirements of I.P. and shall appear in the language of English.
All labelling shall be indelible ink and shall withstand immersion in water and remain intact.
All labels shall state the name of the vaccine, name of the manufacturer, address of manufacturer, lot number, composition, concentration, dose and mode for administration, expiry date, storage temperature and any other marking that is appropriate.

VVM:

The label on each vial should include a Vaccine Vial Monitor (VVM) designed to meet the heat stability curve of the vaccine supplied. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.
The position of the VVM may be on the label or on the neck or on the cap as validated by the supplier
The Vaccine Vial Monitor (VVM) shall be as per WHO Specifications (please refer to Annex I).

Labelling for secondary packaging:
A label must be affixed either to the top and/or front surface of the secondary packages. It should indicate the type of vaccine, the name of the manufacturer, presentation, batch number, date of manufacture, date of expiry, quantity and storage conditions.

Labelling for tertiary packaging (insulated packaging):
The external surface of insulated packages should be either white or in the natural colour of corrugated carton. Dark colours must be avoided. All labels on tertiary packaging must be attached to all four sides.
Vaccine Rush: A label must be affixed to all four sides of the vaccine package in English/Hindi.
"Do not freeze" sticker in English/Hindi should be attached to all four sides of the vaccine package.

Numbering of tertiary packaging:
All boxes should be numbered consecutively. Shipping documents should be included in the box labelled number 1, and this box should be clearly labelled with the words
"**Containing vaccine shipping documents**".

Additional Labelling:
All the containers and other outer containers shall be marked with the statement "CGS NOT FOR SALE" in English.
All labels on containers i.e. vials/ampoules, cartons, tubes etc. as well as outer dropper should be marked with the statement "CGS NOT FOR SALE" in bold red letters in English.

Containers:
IP type 1 amber coloured glass tamper proof ampoule/vial or plastic container for parenteral preparation.

Closures:
Vaccine vials shall be fitted with closures that conform to IP requirements for injectable preparations.

Printed materials:
Two (2) information sheets, printed in English and Hindi, shall be included in each secondary package and shall include information as per Annexure III

B. Quality assurance

Compliance:
The Supplier shall guarantee that the products as packed for shipment (a) comply with all provisions of the specification and related documents; (b) meet I.P/Internationally (WHO as cited above) recognized standard for safety, efficacy and quality; (c) are fit for the purposes made known to the Seller (d) are free from defects in workmanship and in materials and (e), the product has been manufactured cGMP included in Schedule M.

Evidence:

The Supplier shall provide objective evidence, acceptable to the Purchaser, of the satisfaction of the requirements of this document for which no specific inspection has been mentioned.
The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment.
The Supplier shall provide a copy of **Validation record** with regards to process validation demonstrating batch to batch consistency and to confirm that the packaging complies with WHO requirements
The supplier shall provide document that the batch conforms to the WHO requirements of **Shake test.**
The Supplier shall provide a copy of the Certificate of Analysis for each lot intended for shipment.
The Supplier shall provide to the Purchaser a copy of the approval of each source material, constituent material and component for each lot intended for shipment.
The Supplier shall retain a sample of twenty (20) vials from each lot shipped for two years beyond the printed expiration date.
Chemical, physical and biological test data for in-process and finished product testing must be on record for each lot shipped and must be available to Purchaser's representatives when requested.

Inspection:

The Purchaser may inspect and sample, or cause to be sampled, the product at the Supplier's factory and/or warehouse at a mutually agreeable time prior to the shipment of the product.

Testing:

The Purchaser may cause independent laboratory testing to be performed as deemed necessary to assure that the goods conform to the prescribed requirements. The said laboratory testing shall be of the Purchaser's choice if suitably equipped and qualified to conduct quality assurance tests on biological products.

C. Packing

Prior to and at the time of packing, the vaccines must be kept within the storage temperature limits recommended by the manufacturer.

Storage:

Supplier shall state storage volume occupied per infant dose of vaccine (storage volume includes the vaccine vial, packet containing the vaccine vial and any intermediate packaging).

Inner boxes:

_____ (number) individual glass vials or ampoules shall be contained in sturdy white cardboard boxes (of not less than 300 GSM) outfitted with individual segments for protecting and separating each vial.

Temperature monitoring devices:

To be included in all vaccine shipments to document whether temperature limits have been exceeded.
One electronic temperature device is included in each and every vaccine shipping carton
(Please refer to Annex II).
Prior to and at the time of packing, the vaccine must be kept at the storage temperature recommended by the manufacturer.
Vaccine manufacturer is required to validate their packaging twice for a period of 48 hours i) that the warmest temperature inside the insulated packing does not rise above +30^{0}C in the continuous outside ambient temperature of + 43^{0}C and ii) that the coolest storage temperature does not fall below +2^{0}C in the continuous outside temperature of -5^{0}C..

Over packing:

Box shall be over packed so that the vaccine remains refrigerated at between + 2 and +8^{0}C and does not freeze. The containers must be suitable for export shipping in accordance with *WHO guidelines on the international packaging and shipping of vaccines* (WHO/V&B/01.05). The containers must have adequate insulation and or sufficient refrigerant to ensure that the warmest storage temperature of the vaccine does not rise above +30^{0}C in continuous outside ambient temperature of + 43 degrees C nor fall below +2^{0}C in continuous external temperature of -5^{0}C during transit and for a period of at least 48 hours after arrival at the airport of destination[13].
Additional cushioning shall be provided, sufficient to protect the vials from breakage during transit and handling.

Exterior shipping cartons:

Product and printed materials, packaged as specified above, shall be packed in weather-resistant, triple-wall corrugated fibreboard cartons with a bursting test strength of not less than 1900 kPa.The overall dimensions of the exterior shipping cartons should be such that the product does not become damaged during transportation and storage.

Each international shipping carton should weigh less than 50 kg. It is important that individual boxes are not too heavy during transport as they are frequently loaded and offloaded manually at airports and intermediate stores.

[13] When considering "best practices" for transport and storage of vaccines, reference should be made to current recommendations in the appropriate literature.

D. Markings

All containers and invoices must bear the name of vaccine, expiry dates of the vaccine and appropriate storage temperature.

Inner boxes:

The inner boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Purchaser:

- Generic name and trade name of the vaccine
- Manufacturer's name and registered address
- Manufacturer's national registration number
- Lot or batch number
- Composition and concentration
- Number of vials contained in box
- Date of manufacture (month and year)
- Expiration date (month and year)
- Instructions for storage and handling[14]*
- Place of manufacture (Made in_____)

Exterior shipping cartons:

The following information shall be stencilled or labelled on the exterior shipping cartons on two opposing sides in bold letters at least **'Ariel font size 14'** high with waterproof indelible ink in a clearly legible manner which is acceptable to the Purchaser:

- Generic name and trade name of the vaccine
- Lot or batch number
- Date of manufacture (month and year)
- Expiration date (month and year)
- Manufacturer's name and registered address
- Manufacturer's national registration number
- Destination country license or registration number
- Consignee's address and emergency phone number including mobile number
- Destination airport
- Contract number
- Number of vials contained in the carton
- Gross weight of each carton (in kg)
- Carton containing ---------- secondary packages
- Instructions for storage and handling[15]*
- Place of manufacture (Made in_____)

[14] * Markings on inner boxes should state clearly that the reconstituted vaccine is good for 6 hours only; additional text to be provided by Purchaser.

[15] * To be provided by Purchaser.

E. Documentation

Supplier shall provide to Purchaser a copy of the batch record, including all quality assurance documentation for the vaccine being supplied.

Advance notice of arrival and advance shipping documentation:
Copies of the documentation for the goods to be shipped must be sent at least seven days in advance of arrival of the shipment. In the case of an individual contract for a specific destination that requires a longer period of advance notice, a longer period should apply. The consignee(s) should be intimated well in advance by registered letter/telegram telephone, so that vaccines are collected from airport immediately after arrival. Copy of the communication from the supplying firm should be endorsed to the Assistant Commissioner (I) and Deputy Director (UIP), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi for information.

The documentation must include the following:
- Pre-advice defined by the Purchaser
- Airway bill (AWB);
- Supplier's invoice;
- Packing list;
- Lot release certificate (LRC) issued by the national regulatory authority (NRA) of the country of manufacture for each lot of vaccine supplied; and
- Any other document, certificate or instruction specified in the individual order.

The documents should be sent by e-mail and fax by the freight forwarder or the manufacturer to the consignee, the Purchaser, and any other parties specified in the individual contract.

The pre-advice must contain the following information:
- Purchase order reference;
- Consignee requisition reference;
- Number of packages, gross weight (in kilograms) and volume (in cubic meters);
- Type of vaccine, total number of vials and number of doses per vial/ampoule/tube;
- Value of shipment (in Indian Rupees and/or in US $);
- AWB and flight number(s);
- Date and time for place of departure, transit (if applicable), and arrival;
- Instructions for collection;
- Any other information specified in the individual contract must also be included for the consignee.

The following information shall be stated on the airway bill:
- Consignee's name, address, telephone number (including mobile no) and e-mail ID.
- Purchase order reference;
- Consignee's requisition reference;
- Type of vaccine and quantity;
- Instructions to: "Telephone consignee upon arrival *(repeat telephone number)*";
- Handling information: **"Medicines – Vaccine – For human use – Highly perishable – Not to be delayed.**

The following instruction should be stated in the AWB: "Throughout shipment, pending reshipment and prior to collection by the consignee, the vaccine must be stored at +2°C to +8°C.

F. Dispatch

Vaccines should travel by a direct route wherever possible, road transport may be used if accompanied by attendant. Where trans-shipment is unavoidable, the journey should be planned through airports that:
a) have cold storage facilities, and
b) are located in countries with a temperate climate.
The maximum transit time from the manufacturer to arrival at the airport of final destination must not exceed 48 hours.

Shipments should be scheduled to arrive outside weekends and/or public holidays in the recipient country and airline bookings should be made well ahead of the date of departure.

-Vaccines must not be transported with radioactive products, fish or meat;
-Correct cold-chain procedures must be observed during transit, warehousing and shipping (i.e., all vaccines must be kept in temperature-controlled environments at all times throughout the shipment process);
-Reactivation of the refrigeration process of shipments must be performed in accordance with the instructions of the supplier of each shipment whenever deemed necessary;

G. References

1) Indian Pharmacopoeia 2007, Indian Pharmacopoeia Commission, Government of India; Ministry of Health & Family Welfare. Ghaziabad.

2) British Pharmacopoeia 2007, Volume III, page 24

3) Guidelines on the international packaging and shipping of vaccines. WHO 2005; Department of Immunization, Vaccines and Biologicals. WHO/IVB/05.23.

4) Procurement of vaccines for public-sector programmes- A reference manual. WHO/ IVB/03.16; 2004.

Annexure-I
SPECIFICATION FOR VACCINE VIAL MONITORS (VVM)

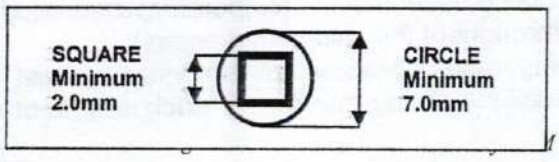
Specification reference : E6/ IN5
Applies to test procedures : E6/ Proc/5

Purpose

Vaccine vial monitors serve primarily to warm health workers when the cumulative heat exposure of a vial of vaccine has exceeded a pre-set limit, beyond which the vaccine should not be used. In addition, changes in the appearance of the VVM before this limit is reached will serve to guide health workers to first use more exposed vials of vaccine.

Format and dimensions:

The VVM is a circle of colour, minimum 7.0mm with a square of colour, Minimum dimension 2.0 x 2.0mm positioned in the centre of the circle (See Figure 1).
The ratio of the area of the square to the area of the circle (including the square) Is at least 0.1, whatever dimensions are chosen.



Design:

The circle of the VVM acts as a static, reference colour and the square is a changing, active colour change device. The colour is limited to a change of shade, from light to dark. Any colour is permitted for the VVM design, but changes in hue are not permitted.

Colour:

The colour density change of the indicator is illustrated in the Figure 2 below. At the start point the colour of the square is lighter than the circle. The end point is indicated when the colour of the square matches the circle. The end point is exceeded when the colour of the square is darker than the circle. The following paragraphs describe the colour change in more detail.

Start point		**Square lighter than circle**
End point		**Square matches the circle**
End point exceeded		**Square darker than the circle**

Figure 2. The colour density change of the indicator (The central square is the active surface)

1 Replaces the previous version of 13 August 1999

Definition of the start-point

The colour of the active surface of the VVM at the time of the vaccine vial is

called the 'start point'.
At the start point, the colour density of the square as measured by a colour Densitometer2 must be lighter than the circle by a difference of at least 0.25 OD Densitometer units.

Definition of the end-point

The colour of the active surface of the VVM at the limit of use of the vaccine vial is called the 'end-point'.

The end point is reached when the difference in the average colour density obtained from readings at least two different points on the circle and the colour density of the square is 0.00 OD, as measured by the densitometer. The end point is exceeded when the colour of the square is darker than the colour of the circle.

Homogeneity of the reference colour

The colour density of one 2mm diameter portion of the circle must be within 0.01 OD of the colour density at any other two 2mm diameter portions of the circle, when measured with a colour densitometer.

VVM reaction rates:

Reaction rates are specific to four different models of VVM, relating to four Of vaccines according to their heat stability at two specific temperature points
(See table 1)

Table 1: VVM reaction rates by category of heat stability

Category: (Vaccines)	No. of days to end point at +37^{0}C	No. of days to end point at +25^{0}C	Time to end point at +5^{0}C
VVM30 HIGH STABILITY	30	193	> 4 years
VVM14 MEDIUM STABILITY	14	90	> 3 years
VVM7 MODERATE STABILITY	7	45	> 2 years
VVM2 LEAST STABLE	2	NA*	225 days

***VVM (Arrhenius) reaction rates determined at two temperature points**

At +37^{0}C, RH 33% +/-5% and RH 75% +/-5%, at least 90% of VVMs tested Should reach the end point within a range of time whose upper limit is shown in Table 1 or a period set by the vaccine manufacturer, based on published vaccine stability data, and whose lower limit is 25% below the
upper limit (See Figure 3).

At +25^{0}C (ambient humidity in submerged plastic/foil pouch) at least 90% of VVMs tested should reach the end point within a range of time whose upper limit is shown in Table 1 for VVM30, VVM14 and VVM7 categories, or a period set by the vaccine manufacturer, based on published vaccine stability data, and whose lower limit is 40% below the upper limit (See Figure 3).

At 5^0C(ambient humidity in submerged plastic/foil pouch), all VVM30, VVM14 and VVM7 samples should reach the end point after the lower time limit specified in Table1. Conformance can be determined by extrapolation from high temperature (25^0C and 37^0C) data. At 5^0C(ambient humidity in submerged plastic/foil pouch), at least 90% of VVM2 samples tested should reach the end point within a range of time whose upper limit is 225 days and whose lower limit is 40% below the upper limit (see Figure 3).

A tolerance is allowed in the above tests for up to 5% of VVM samples tested to reach the end point after the upper limit and 5% before the lower limit (See Figure 3).

The colour change shall be monotonic in its response to cumulative heat exposure within the limits of the allowed variation. The observer shall be able to distinguish between unchanged, 50% and the end point of the indicator.

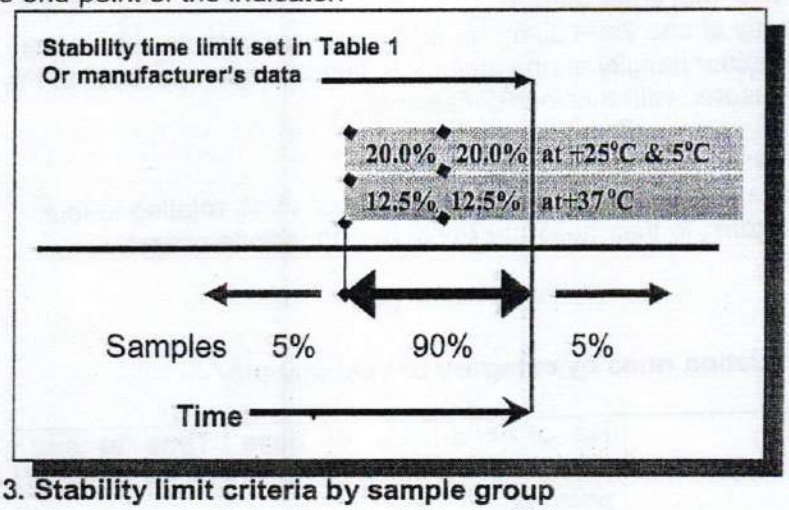


Figure 3. Stability limit criteria by sample group

Global Measurement Accuracy:

The allowable total error for measuring the difference the colour of the circle and Square is ± 0.04OD when using an X-rite 404 GS(X) colour reflectance Densitometer. Major sources of error are instrument error for both the circle and square, repeatability, and variation in end point caused by an allowed temperature variation of ± 0.2^0 C.

Water Bath Precision and Control:

The VVMs should be tested in water baths controlled to within ± 0.2^0C. (Any additional 0.1^0C variation in temperature control requires an allowance for additional measurement error.)

Reversion

The indicator shall not revert to a lighter colour at any point in its life when exposed to conditions likely to be found during normal use. After the endpoint is reached, the square shall remain the same colour as the circle or become darker than the circle.

Integrity of VVMs

The integrity of VVMs depends on the presentation of the vaccine:

For liquid vaccines:

The VVM shall be permanently attached to the vaccine vial, even after the vial has been opened and remain readily observable before, after and during use. Prior to opening, the VVM should not be removable: it should resist removal from the vaccine vial as much as a label meeting current requirements.

For freeze dried vaccines:
The VVM shall be attached to the vaccine vial or ampoule, remaining readily observable until the vial or ampoule is opened but not observable after opening. Prior to opening, the VVM should be removable: it should resist removal from the vaccine vial as much as a label meeting current requirements.

Safety
The performance of the VVM shall not be able to endanger human health. The materials of the VVM shall be non- toxic and non-irritant. The VVM should meet any requirements in force concerning toxicity of labels or packaging in the country of manufacture.

Annex II: Temperature Monitoring Devices

Table 1: Specifications of the electronic devices for all national and international shipments

Storage temperature Range:	-20^{0}C to +70^{0}C
Operating temperature Range:	-20^{0}C to +55^{0}C
Display visibility Range:	-10^{0}C to +55^{0}C
Temperature measuring accuracy	± 0.5^0 C or better
Time measuring accuracy	± 10 seconds per day, or better
Initial delay (see point 2 below)	1 hour
Recording period	10 days
Storage before START	minimum of 18 months
Data retention after STOP	minimum of 6 months

A For specific devices with these features, refer to the WHO web site:
http://www.who.int/vaccines-access/vacman/pis/pqs.htmthe

The electronic devices should, at a minimum, meet the specifications outlined in Table 1 (above) and have the functions outlined below.

1) A "start" function to activate the device at the time the carton is being loaded with vaccine.
2) A "stop" function to allow the recipient to stop the recording when the vaccine arrives at its destination.
3) A one hour "initial delay" function so the device can acclimatize to the temperature inside the shipping carton before it starts recording.
4) A "history" function to provide details of violations of the temperature limit in terms of time, range and duration. This function is primarily to provide information for the use of the procurement agency.
5) A liquid crystal display (LCD) screen to provide a visual display of the information and also to show the symbol that indicates whether the device is functional or not. This symbol, and also the alarm indicator, should be static (i.e. should not flash or blink) so as to be visible when the screen is scanned or photocopied for documentation purposes.
6) An alarm set according to WHO's recommended settings (see Tables 2 and 3 below).

Table 2: WHO-recommended alarm settings for national/international shipments of DTP, DT, TT, HepB and combination vaccines

Temperature	Alarm type	Period for triggering the alarm
45^{0}C	single event	1 hour
30^{0}C	cumulative	10 hours
-0.5^{0}C	single event	1 hour

Table 3: WHO-recommended alarm settings for all national and international shipments of OPV and freeze-dried BCG, measles, MMR vaccines

Temperature	Alarm type	Period for triggering the alarm
45^0C	single event	1 hour
30^0C	cumulative	10 hours
10^0C	cumulative	20 hours

Vaccine manufacturers are required to validate their packaging twice for a period of 48 hours:

i) at ambient temperatures under +43^0Cand

ii) at ambient temperatures under-5^0C.

This validation is critical to ensure that the packaging complies with the above requirements and will not set off an alarm.

Batteries for electronic devices do not perform under extremely cold temperatures, such as when vaccines are being transported with dry ice.

Each electronic device should be attached to a backing card that includes the information outlined below, in the appropriate language.

1. The type of device:

Type 1: for DTP, DT, TT, HepB and combination vaccines

Type 2: for OPV and freeze-dried BCG, measles, MMR vaccines

2. For the person packing/sending the shipment:

a) Instructions on how to activate the device;

b) A reminder that one device must be placed in each shipping carton;

c) Space for the following information to be entered:

- the supplier's name;
- date and time of the packing;
- vaccine purchase order number;
- vaccine type.

3. For the person receiving the shipment:

a) Instructions on how to stop the device;

b) Illustrations to show information on the LCD screen – how it will indicate problems/no problems and the alarm-status display;

c) Tables 4 and 5 (below) showing what to do.

Table 4: Information to be displayed on the backing card of electronic device – Type 1 (for DTP, DT, TT, HepB and combination vaccines)

Alarm temperature	What to do with vaccines
45^0C	Contact Consignee
30^0C	Contact Consignee
-0.5^0C	Conducts shake tests. USE vaccine if passes. Inform Consignee of test results.

Shake test guidelines can be found on Guidelines on the international packaging and shipping of vaccines. WHO 2005; Department of Immunization, Vaccines and Biologicals. WHO/IVB/05.23.

Table 5: Information to be displayed on the backing card of electronic device – Type 2 (for OPV and freeze-dried BCG, measles, MR, MMR, lyophilized Hib, yellow fever and meningitis vaccines)

Alarm temperature	What to do with OPV	What to do with other vaccines
45^0C	Contact Consignee	Contact Consignee
30^0C	Contact Consignee	Contact Consignee
10^0C	Contact Consignee	Accept

SPECIFICATIONS:

Alarm setting	Type 1: for vaccine: DTP,DT, TT, Hep B and combination vaccines		Type 2: for vaccine: OPV, freeze dried BCG, measles and MMR	
	>=+45^0C	1 hour single	>=+45^0C	1 hour single
	>=+30^0C	10 hours cumulative	>=+30^0C	10 hours cumulative
	>=-0.5^0C	1 hour single	>=+10^0C	20 hours cumulative
Initial start delay	1 hour		1 hour	

MODEL INSERT

Hepatitis-B Vaccine

DESCRIPTION:
Hepatitis B virus vaccine may exist in two forms, i.e. as an inactivated (plasma-derived) vaccine and as a recombinant (DNA) vaccine. Hepatitis B vaccine contains not less than 20mcg of hepatitis B surface antigen per ml.

ADMINISTRATION:
The vaccine should be injected intramuscularly. The preferred site of injection is outer mid-thigh (infants)/outer upper arm (children and adults). (An injection into a child's buttocks may cause injury to the sciatic nerve and is not recommended.)

It must not be injected into the skin as this may give rise to a local reaction. 1 dose is 0.5 ml. A sterile needle and sterile syringe should be used for each injection. Once opened multi-dose vials should be kept between $+2^0$C and $+8^0$ C. Opened vials of vaccine may be used in subsequent immunization sessions until, a new shipment of vaccine arrives providing that the conditions described in WHO/EPI/LH15/95.1 are met.

IMMUNIZATION SCHEDULE:
By intramuscular injection (Anterolateral part of thigh); when given as part of a primary immunization starting at 6 weeks of age. Three injections are given at monthly intervals. In all institutional deliveries a dose at the time of birth as early as possible and preferably within 24 hours.

SIDE EFFECTS:
Local soreness and redness, rarely anaphylactic reaction

CONTRAINDICATIONS:
Anaphylactic reaction to a previous dose

STORAGE:
HepB vaccine should be stored and transported between $+2^0$C and $+8^0$C. IT MUST NOT BE FROZEN.

PRESENTATION:
The vaccine comes in vial of 10 doses.