Odisha State Medical Corporation Limited (OSMCL)

(A Government of Odisha Enterprise)

Website: ***www.osmcl.nic.in,*** **Email:** ***drugs-osmcl@gov.in***

Bid Reference No. OSMCL/2025-26/ BLOOD BANK-SBTC/03

E-TENDER DOCUMENT FOR SUPPLY OF SBTC ITEMS FOR THE YEAR- 2025-26

ON RATE CONTRACT BASIS FOR A PERIOD OF ONE YEAR FROM THE DATE OF APPROVAL OF TENDER

Regd. Office: In front of Ram Mandir, Convent Square, Unit – III, Bhubaneswar -751 001
Tel.: (0674) 2380660

INDEX

NOTICE INVITING BID

Odisha State Medical Corporation Limited (OSMCL)

In front of Ram Mandir, Convent Square, Unit – III, Bhubaneswar -751 001

Tel. : (0674) 2380950, **Website** : *www.osmcl.nic.in* , **Email** : ***drugs-osmcl@gov.in***

Bid Ref. No.: **OSMCL/2025-26/ BLOOD BANK-SBTC/03** Date**: 02/04/2025**

Online Bids through **e-Tender portal** (https://tendersodisha.gov.in) are invited from eligible bidders for **supply of SBTC Items as per the particulars mentioned below:**

Sl. No.	Particulars	Date and time	
1.	*Date & time of release of bid*	***02 /04/2025, 3 PM***	
2.	*Date & time for submission of queries by E-Mail id -* ***drugs-osmcl@gov.in***	***04 /04/ 2025, up to 5:00 PM***	
3.	*Date & time of Online bid submission*	*Start Date & Time*	*End Date & Time*
		08/04/2025, 3 PM	***29/04/2025, 6.00 PM***
4.	*Date & time for submission of Tender Documents, Tender Document Fee and EMD amount as per section-IV of tender document*	*Start Date & Time*	*End Date & Time*
		30/04/2025, 10 AM	***07/05/2025, 11.00 AM***
5.	*Date & time of online Technical bid opening*	***07/05/2025, 11:45 AM***	
6.	*Date of opening of Price Bid*	*To be informed to the qualified bidders*	

The bid document with all information relating to the bidding process including cost of bid document, EMDs, Prequalification criteria and terms & conditions are available in the websites: www.osmcl.nic.in and https://tendersodisha.gov.in The Authority reserves the right to accept / reject any part thereof or all the bids without assigning any reason thereof. All notice will be published in the OSMCL website www.osmcl.nic.in**.** Hence the bidders are requested to visit OSMCL website www.osmcl.nic.in time to time for any published notice against the tender.

SD/-
Managing Director
OSMC Ltd., Odisha

Memo No._____/OSMC Dt._____

Copy submitted to the Commissioner-Cum-Secretary to Govt. H & FW Dept. for kind information.

SD/-
Managing Director
OSMC Ltd., Odisha

Memo No._____/OSMC Dt. _____

Copy forwarded to the MD, NHM (O)/ DHS (O) / DMET (O)/ DPH (O)/DFW (O) for information.

SD/-
Managing Director
OSMC Ltd., Odisha

Memo No._____/OSMC Dt. _____

Copy forwarded to the State Head Portal, IT Cell, Odisha Secretariat, Bhubaneswar / Chief Manager (Technical), State Procurement Cell, Nirman Saudh, Bhubaneswar for information.

SD/-
Managing Director
OSMC Ltd., Odisha

SECTION I

INSTRUCTION TO BIDDERS

1.1 **The Odisha State Medical Corporation Limited - OSMCL** (Tender Inviting Authority) is a Govt. of Odisha Enterprise for providing services to the various health care institutions under the Department of Health & Family Welfare. One of the key objectives of the OSMCL is to act as the central procurement agency for all essential drugs, equipment and other health commodities for all health care institutions (hereinafter referred to as user institutions) under the department.

1.2 This 'Bid Document' contains the following:

Section I: Instruction to bidders

Section II: General Definitions and Scope of Contract.

Section III: Tender Schedule

Section IV: Schedule of Requirement and List of warehouses for delivery.

Section V: Specific Conditions of Contract

Section VI: General Conditions of Contract

Section VII: Formats for bidder for Submission of Bid (Technical bid)

Section VIII: Annexes [Formats for the successful bidder (Supplier) after finalization of bid]

1.3 The bid documents published by the Bid Inviting Officer (Procurement Officer Publisher) in the **e-procurement portal** https://tendersodisha.gov.in will appear in the "**Latest Active Tender**". The Bidders/ Guest Users can download the Bid documents from **02/04/2025, 3PM** and submit it online from **08/04/2025, 3PM** to **29/04 /2025, *6.00 PM* after** which the same will be removed from the list of "**Latest Active Tender**". The bid document is also available at website: *www.osmcl.nic.in*

1.4 **PARTICIPATION IN BID**

1.4.1 **PORTAL REGISTRATION**:

The bidder intending to participate in the bid is required to **register in the e-procurement portal** using an active personal/official e-mail ID as his/her Login ID and attach his/her valid **Digital signature certificate (DSC) - Class II or III** to his/her unique Login ID. He/ She have to submit the relevant information as asked for about the bidder. The portal registration of the bidder

is to be authenticated by the **State Procurement Cell** after **verification** of original valid certificates/documents such as (i) PAN and (ii) Registration Certificate (RC) / GST Certificate (for Procurement of Goods) of the concerned bidder. The time period of validity in the portal is co terminus with validity of RC/ GST. Any change of information by the bidder is to be re-authenticated by the State Procurement Cell. After **successful authentication**, bidder **can participate** in the **online bidding process.**

1.4.2 **LOGGING TO THE PORTAL**:

The Bidder is required to type his/her *Login ID* and password. *The* system *will again ask to* select the DSC and confirm it with the password of DSC as a second stage authentication. For each login, a user's DSC will be validated against its date of validity and also against the **Certificate Revocation List (CRL)** of respective CAs stored in system database. The system checks the unique Login ID, password and DSC combination and authenticates the login process for use of portal.

1.4.3 **DOWNLOADING OF BID**:

The bidder can download the bid of his / her choice and undertake the necessary preparatory work **off-line** and upload the completed bid before the closing date and time of submission.

1.4.4 **CLARIFICATION ON BID**:

The registered bidder can ask questions related to the online bid in the e-procurement portal **before the pre-bid meeting**. OSMC will clarify queries related to the bid. Through e-mail by the e-mail ID: ***drugs-osmcl@gov.in*** and Contact No. 0674-2380660 & 0674-2380950 **or State e-Procurement cell help desk 1800-3456765, 0674-2530998 for assistance in this regard.**

1.4.5 **PREPARATION OF BID**

The detail guideline for preparation of bid is mentioned at General condition of Contract- Section VI (**Clause 6.4 – 6.7 & 6.17**)

1.4.6 **PAYMENT OF EMD AND COST OF BID DOCUMENTS:**

The detail guideline for payment of EMD & Cost of Bid Document is mentioned at General Condition of contract- Section VI (**Clause 6.5 - 6.7**)

1.4.7 **SUBMISSION AND SIGNING OF BID**

The detail guideline for submission of & signing of bid is mentioned at General Condition of Contract- Section VII (**Clause 6.16 - 6.17**)

1.4.8 **TIMELINE FOR DELIVERY OF GOODS AND PAYMENTS**

As mentioned in Section V (5.1).Successful bidders will be provided with online tracking facility for knowing goods delivery status at consignee locations and progress on payment by OSMCL.

Note: (Uploading of files for submission of bid)

For management of space the bidders can serially arrange their scanned documents as per Format T1 (all pages should be signed by authorized signatory with seal and then to be scanned) and create two equal sized PDF files and upload them to avoid any space constraint.

The **BOQ** file (Excel file) is to be uploaded in the **price bid**.

SECTION II
General Definitions & Scope of Contract

2.1 General Definitions

2.1.1 *Department* means Health & Family Welfare Department, Government of Odisha.

2.1.2 *Government* means Government of Odisha.

2.1.3 *Bid / Tender Inviting Authority* is the Managing Director or authorized person of OSMCL by the Managing Director, who on behalf of the User Institution/Government or the funding agencies calls and finalize bids and ensure supply, installation and after sales service of the equipments procured under this bid document.

2.1.4 *Tender Evaluation Committee & Technical Committee* are Committees authorized by the Managing Director of OSMCL to decide on the purchase of the drugs and equipments to be procured by the OSMCL.

2.1.5 *User Institutions* are the Govt. health care institutions under the Health & FW Department, Government of Odisha for which the items under this bid is procured.

2.1.6 *De-recognition/ Debarment* – the event occurring by the operation of the conditions under which the bidders will be prevented for a period of 3 years from participating in the future bids of Tender Inviting Authority, more specifically mentioned in the Specific Conditions of Contract (Section V) and General Conditions of Contract (Section VI) of this bid document, the period being decided on the basis of number of violations in the bid conditions and the loss/hardship caused to the Tender Inviting Authority on account of such violations.

2.2 Scope

2.2.1 The bids are invited for the supply of the items, the details of which are mentioned in Section IV, needed for the government health institutions of Odisha.

2.2.2 **Rate Contract**: This is a **Rate contract Bid**, the rate of which **will be valid** for a period of **1(one) year** from the date of finalization of rate contract or new rate contract which ever is earlier. However, the approx. quantity requirement is

mentioned in the Schedule of Requirement – Section IV, which may increase or decrease substantially as per requirement. The bidders are expected to quote their best rates for the items. The technical specifications, approx. quantity and locations for supply are mentioned in Section IV of this bid document. Only OSMCL is authorized to place purchase orders for the supply of item(s) to be procured under this bid during the validity of the rate contract period.

2.2.3 The bidders can't withdraw their bid after opening of technical bid, within the minimum bid validity period of 180 days & also after accepting the Letter of Intent.

2.2.4 Withdrawal or non-compliance of agreed terms and conditions after the execution of agreement will lead to invoking of penal provisions and may also lead to de-recognition/ debarment.

SECTION III

TENDER SCHEDULE

3.1. Bid Details

1.	*Bid Reference No.*	**OSMCL/2025-26/ BLOOD BANK-SBTC/03**
2.	*Cost of Bid Document (in shape of DEMAND DRAFT) from any nationalized/ scheduled bank in India in favour of Odisha State Medical Corporation Ltd., payable at Bhubaneswar.* *[Local MSME of Odisha exempted for submission of BID COST]*	*Rs.* ***5,900/-*** *(inclusive of GST) for any or all the item(s)*
3.	*Earnest Money Deposit* ***(In shape of DD/e-BG/BC)***	*The bidder has to deposit the required EMD amount as mentioned in Section IV (Schedule of Requirement) for each item quoted by him and it should be reflected in Format-T3. However, maximum capping of EMD amount is fixed to Rupees* ***50 lakhs****. The bidders can participate for all / multiple items by depositing* ***Rs. 50 lakhs*** *towards EMD.*
4.	*Validity of bid*	*180 days from the date of technical bid opening.*
5.	*Performance Security*	*5% of the Total contract value with respect to the Approx. quantity mentioned in Schedule IV excluding taxes (for successful bidders)*
6.	*Validity of Performance Security*	*The performance security (in case of Electronic Bank Guarantee) shall remain valid for a period of minimum* ***(2) two*** *years from the date of LOI or latest expiry date of the batch (es) of a particular item, whichever is later.*

3.2. Important Dates:

Sl. No.	Particulars	Date and time	
1.	*Date & time of release of bid*	***02/04/2025, 3 PM***	
2.	*Date & time for submission of queries by E-Mail id -* ***drugs-osmcl@gov.in***	***04/04/2025, up to 5:00 PM***	
3.	*Date & time of Online bid submission*	*Start Date & Time*	*End Date & Time*
		08/04/2025, 3 PM	***29/04/2025, 6.00 PM***
4.	*Date & time for submission of Tender Documents, Tender Document Fee and EMD amount as per section-IV of tender document*	***30 /04/2025, 10 AM***	***07/05/2025, 11.00 AM***
5.	*Date & time of online Technical bid opening*	***07/05/2025, 11:45 AM***	
6.	*Date of opening of Price Bid*	*To be informed to the qualified bidders*	

SECTION IV
SCHEDULE OF REQUIREMENT

4.1 **Items Tendered with Specification / Strength, Unit Pack, Tentative Quantity (in Absolute) & EMD(s) to be submitted.** *[Qty. in **Absolute** means the **no. of Tab. (not strip)/ Box** (as the case may be) and **not the no. of Unit Pack]***

Hence, the price in the BOQ to be quoted ***per Tab. (Not strip) / Box (as the case may be).***

SDWH- State Drug Warehouse-Bhubaneswar in the Campus of OSMCL as mentioned at CL. No. 4.2 (List of Warehouses).

WH- Drug warehouses at* Supdt. S.C.B Medical College Hospital, Cuttack, Campus of SCB Medical College Hospital *as mentioned at CL. No. 4.2(List of Warehouses).

Note: 1. Drugs which are official in monograph of IP / BP / USP/ EP shall be accepted.
2. The pack size mentioned in column no. 5 Section IV is Preferable Pack Size.
3. Where it mentioned as "measuring cap and plastic container as per I.P" the suppliers should supply the item with measuring cap and plastic container as per I.P/ Glass bottle as per IP.
4. The items which are light / photo / moisture sensitive should be supplied with good quality Amber coloured packing material as per IP / BP / USP/ EP grade.

Sl No.	Drug Code	Name of he Item	Specification / Strength	Mandatory Pack Size	*Approx. Qty Required in Absolute i.e. (No of Piece / Bag/Vial /Amp/Bottle/ Test etc.)	EMD (in Rs.)	Minimum Turnover in Rs.	Remarks
1	2	3	4	5	6	7	8	9
	Blood Collection Bags:							
1	S02166	Blood Collection Bag CPD-A1 100 ml (Single)	AS PER TENDER SPECIFICATION	100 ml / Bag 10 Bags / Packet	**17,470**	**20,000**	5 Crores	
2	S02167	Blood Collection Bag CPD-A1 350 ml (Single)	AS PER TENDER SPECIFICATION	350 ml / Bag 10 Bags / Packet	**385,000**	**437,000**	5 Crores	Bulk Items as per Clause No. 6.23.1.
3	S02170	Blood Collection Bag CPD 350 ml (Triple) with SAGM / SAGM-2 additive solution	AS PER TENDER SPECIFICATION	350 ml / Bag 3 Bags / Packet	**219,000**	**710,000**	5 Crores	Bulk Items as per Clause No. 6.23.1.
4	S02171	Blood Collection Bag CPD 450 ml (Triple) with SAGM / SAGM-2 additive solution	AS PER TENDER SPECIFICATION	450 ml / Bag 5 Bags / Packet	**61,500**	**203,000**	5 Crores	Bulk Items as per Clause No. 6.23.1.
5	S02173	Blood Collection Bag CPD 450 ml (Quadruple) with SAGM / SAGM-2 additive solution (top and bottom)	AS PER TENDER SPECIFICATION	450 ml / Bag 5 Bags / Packet	**3,000**	**15,000**	5 Crores	

6	S02427	Blood Collection Bag CPD 450 ml (Quadruple) with SAGM additive solution (top and top)	AS PER TENDER SPECIFICATION	450 ml / Bag 5 Bags / Packet	**5,030**	**25,000**	5 Crores	
7	S02480	Transfer Bag 100 ml	AS PER TENDER SPECIFICATION	100 ml / Bag 10 Bags / Packet	**25,700**	**26,000**	5 Crores	
	Test Kits:							
8	S02174	HIV (ELISA) TEST KIT	AS PER TENDER SPECIFICATION	96 Test/Kit	**614,400**	**184,000**	2 Crores	
9	S02175	HBV (ELISA) TEST KIT	AS PER TENDER SPECIFICATION	96 Test/Kit	**614,400**	**95,000**	2 Crores	
10	S02176	HCV (ELISA) TEST KIT	AS PER TENDER SPECIFICATION	96 Test/Kit	**614,400**	**799,000**	2 Crores	Bulk Items as per Clause No. 6.23.1.
11	S02177	HIV (I&II) Rapid Diagnostic KIT	AS PER TENDER SPECIFICATION	50 Test/Kit	**51,300**	**36,000**	2 Crores	
12	S02178	HBV Rapid Diagnostic test KIT (Serum based)	AS PER TENDER SPECIFICATION	(25 Tests /50 Tests)/KIT	**564,800**	**66,000**	2 Crores	
13	S02179	VDRL Rapid Diagnostic test KIT	AS PER TENDER SPECIFICATION	(25 Tests /50 Tests)/KIT	**658,000**	**91,000**	2 Crores	
14	S02180	HCV Rapid Test Kit	AS PER TENDER SPECIFICATION	(25 Tests /50 Tests)/KIT	**918,100**	**184,000**	2 Crores	
	Reagents/Antisera							
15	D48001	Anti– D (IgM only) , with dropper	AS PER TENDER SPECIFICATION	10 ml / Vial 6 Vails / Box	**10,512**	**23,000**	50 Lakhs	
16	D48002	Anti- D, IgM and IgG combination, with dropper	AS PER TENDER SPECIFICATION	10 ml / Vial 6 Vails / Box	**9,060**	**24,000**	50 Lakhs	

17	D48003	Anti A Group Sera, with dropper	AS PER TENDER SPECIFICATION	10 ml / Vial 6 Vails / Box	**16,800**	**20,000**	50 Lakhs	
18	D48004	Anti A1 Group Sera, with dropper	AS PER TENDER SPECIFICATION	5 ml / Vial 6 Vails / Box	**3,216**	**14,000**	50 Lakhs	
19	D48005	Anti AB Group Sera, with dropper	AS PER TENDER SPECIFICATION	10 ml / Vial 6 Vails / Box	**3,264**	**5,000**	50 Lakhs	
20	D48006	Anti B Group Sera, with dropper	AS PER TENDER SPECIFICATION	10 ml / Vial 6 Vails / Box	**16,800**	**20,000**	50 Lakhs	
21	D48007	Anti- Human Globulin (Green) polyspecific, with dropper	AS PER TENDER SPECIFICATION	5 ml / Vial 6 Vails / Box	**3,350**	**15,000**	50 Lakhs	
22	D48008	Anti Human Globulin, Monospecific, with dropper	AS PER TENDER SPECIFICATION	5 ml / Vial 6 Vails / Box	**2,862**	**13,000**	50 Lakhs	
23	D48009	Anti Human Globulin, Monospecific, with dropper	AS PER TENDER SPECIFICATION	5 ml / Vial 6 Vails / Box	**744**	**4,000**	50 Lakhs	
24	D48010	Bovine serum Albumin 22%, with dropper	AS PER TENDER SPECIFICATION	10 ml / Vial 6 Vails / Box	**2,340**	**9,000**	50 Lakhs	
25	D48011	Anti –H, with dropper	AS PER TENDER SPECIFICATION	5 ml / Vial 6 Vails / Box	**3,708**	**16,000**	50 Lakhs	
	Leucofilter					**158,000**		
26	S02428	Bedside Leucofilter	AS PER TENDER SPECIFICATION	10 Pcs / Packet	56015	**790,000**	5 Crores	Bulk Items as per Clause No. 6.23.1.
27	S02429	Labside Leucofilter	AS PER TENDER SPECIFICATION	10 Pcs / Packet	74700	**1,494,000**	5 Crores	Bulk Items as per Clause No. 6.23.1.

NB: 1. The Approx. Quantity mentioned at column No. 6 may substantially vary from order quantity. The purchase order shell be issued as per the requirement of the state time to time without considering production capacity.

2. The bidder should ensure the specification in the licence of the quoted item before submitting the bid document. Any deviation may attract penal action like EMD forfeiture etc.

3. The approved Bidder must supply the item as per tender specification, any deviation from tender specification at the time of supply shall not be accepted.

4.2 List of Warehouses for door delivery.

Sl. No	Name of the I.O.	Sl. No	Name of the I.O.	Sl. No	Name of the I.O.	Sl. No	Name of the I.O.
1	**District Drug Warehouse ANUGUL**, Central Warehouse-02, O/O CDM&PHO, Angul Dist. Angul , Odisha Pin-759122 e-mail-osmc.angul@gmail.com Contact no. - 9938151017, 9861471820	2	**District Drug Warehouse-BOLANGIR**, DHH Campus, O/O CDM&PHO, Bolangir, Jail Road, PO / Dist. Bolangir, Odisha Pin-767001 e-mail-osmc.bolangir@gmail.com Contact no.- 8186094241, 9583676455	3	**District Drug Warehouse-GAJAPATI**, Behind Leprosy Office, Treasury Road O/O CDM&PHO, Gajapati ,At/P.O-Paralakhemundi, Gajapati Pin-761200 e-mail-osmc.gajapati@gmail.com Contact no.- 8763389710	4	**District Drug Warehouse-KANDHAMAL**, O/O CDM&PHO, Kandhamal, Medical Square, At / Po - Phulbani, Dist.- Kandhamal, Odisha, Pin-762001 e-mail-osmc.kandhamal@gmail.com Contact no. - 9439396731

5	**District Drug Warehouse –BOUDH** O/O CDM&PHO, Boudh, At/PoBoudh, Dist. Boudh , Odisha Pin-762014 e-mail-osmc.boudh@gmail.com Contact no.- 9040484077	6	**District Drug Warehouse -CUTTACK**, City Hospital Campus, At-Dargha Bazar, Po-Choudhury Bazar, Cuttack Dist. Cuttack, Odisha Pin-753001 e-mail-osmc.cuttack@gmail.com Contact no.- 7205236123, 8895931974	7	**District Drug Warehouse-JAJPUR**, O/O CDM&PHO, Jajpur, DHH Campus, Jajpur Town, Dist. Jajpur , Odisha Pin-755001 e-mail-osmc.jajpur@gmail.com Contact no.- 9439814375	8	**District Drug Warehouse-KEONJHAR**, Near NHM Office Keonjhar, DHH Campus, Keonjhar, Dist. Keonjhar , Odisha, Pin-758001 e-mail-osmc.keonjhar@gmail.com Contact no.- 9937997001
9	**District Drug Warehouse-BALASORE**, O/O CDM&PHO, Balasore Dist. Balasore, Odisha Pin-756001 e-mail osmc.balasore@gmail.com Contact no.- 9439861694, 7873963785	10	**District Drug Warehouse-DEOGARH**, DHH, Deogarh O/O CDM&PHO, Deogarh Dist. Deogarh , Odisha Pin-768108 e-mail-osmc.deogarh@gmail.com Contact no.- 9938665811	11	**District Drug Warehouse-JAGATSINGHPUR**, O/O CDM&PHO, Jagatsinghpur, Jagatsinghpur, Dist. Jagatsinghpur, Odisha Pin-754013 e-mail-osmc.jagatsinghpur@gmail.com Contact no.- 7873366494, 8908618760	12	**District Drug Warehouse-KHURDA**, DHH Campus, O/O CDM&PHO, Khurda, Dist. Khurda , Odisha Pin-752055 e-mail-osmc.khurda@gmail.com 7873150565
13	**District Drug Warehouse-BARGARH**, O/O CDM&PHO, DHH Campus, Baragarh Dist. Baragarh, Odisha Pin-768028 e-mail osmc.baragarh@gmail.com Contact no.- 9439785966	14	**District Drug Warehouse-DHENKANAL**, New Building, Near Kalinga Eye Hospital, Dakhinakali Road, Dhenkanal, Dist. Dhenkanal, Odisha, Pin-759005 e-mail-osmc.dhenkanal@gmail.com Contact no.- 9937657488, 8908362402	15	**District Drug Warehouse-JHARSUGUDA**, O/O CDM&PHO, Jharsuguda Dist. Jharsuguda, Odisha Pin-768201 e-mail-osmc.jharsuguda@gmail.com Contact no.- 9938959204	16	**District Drug Warehouse-KORAPUT**, New Medical, O/O CDM&PHO, Koraput, Janiguda, Koraput, Dist. Koraput, Odisha Pin- 764020 e-mail-osmc.koraput@gmail.com Contact no.- 8763264251
17	**District Drug Warehouse-BHADRAK**, Gabasahi (VIP) colony, Near Collectors Residence, Motel Chhak, Bhadrak Dist. Bhadrak, Odisha Pin-756100 e-mail osmc.bhadrak@gmail.com Contact no.- 9437615473	18	**District Drug Warehouse-GANJAM**, DHH Campus, Berhampur, O/O CDM&PHO, Ganjam, At/P.O – Berhampur Dist. Ganjam,Pin : 760001 e-mail-osmc.ganjam@gmail.com Contact no.- 9861290543, 7978254025	19	**District Drug Warehouse-KALAHANDI**, DHH Campus, Bhawanipatna, O/O CDM&PHO, Kalahandi, At./ P.O-Bhawanipatna Dist. Kalahandi , Odisha Pin-766001 e-mail-osmc.kalahandi@gmail.com Contact no.- 9439695546,	20	**District Drug Warehouse-KENDRAPADA**, DHH Campus, O/O CDM&PHO, Kendrapada, Dist. Kendrapada , Odisha, Pin- 754211 e-mail-osmc.kendrapada@gmail.com Contact no.- 8018469237
21	**District Drug Warehouse-MALKANGIRI**, Medical Road, DNK, O/O CDM&PHO, Malkangiri Dist. Malkangiri , Odisha Pin-764048 e-mail osmc.kandhamal@gmail.com Contact no.- 9439085595	22	**District Drug Warehouse-RAYAGADA**, O/O CDM&PHO, Rayagada, Behind Sri Aurobindo School, Near GIACR Engineering College, Barijhola, Rayagada S.F Dist. Rayagada , Odisha Pin-765002 e-mail-osmc.rayagada@gmail.com Contact no.- 8895108160	23	**Drug Warehouse-VSS MCH, BURLA**, O/O Supdt.VIMSAR, Burla, At./P.O –Burla, Dist – Sambalpur, Odisha Pin-768017 e-mail-osmc.vssburla@gmail.com Contact no.- 8018672325, 9090360980	24	**Drug Warehouse- MHI-CUTTACK**, O/O Director, Mental Health Institute, Cuttack, Campus of SCB Medical College Hospital, Manglabag, Cuttack, Odisha Pin-753001 e-mail-osmc.mhicuttack@gmail.com Contact no.- 9937349885

25	**District Drug Warehouse-MAYURBHANJ**, O/O CDM&PHO, Mayurbhanj At / P.O - Baripada Dist. Mayurbhanj, Odisha Pin-757001 e-mail -osmc.mayurbhanj@gmail.com Contact no.- 9439284408, 9778475682	26	**District Drug Warehouse-SAMBALPUR**, O/O CDM&PHO, Sambalpur, DHH, Sambalpur, Dist. Sambalpur, Odisha Pin-768001 e-mail-osmc.sambalpur@gmail.com Contact no.- 9178834357, 9853116432	27	**State Drug Warehouse (CDS-BBSR),** campus of OSMCL, Convent Square, In front of Ram Mandir, Bhubaneswar Pin-751007 Contact no.- 9853269562, 9778995600, 9861737060 e-mail-osmc.cdsbbsr@gmail.com	28	**District Drug Warehouse-PURI,** O/O CDM&PHO, Puri, DHH Campus, Grand Road, Medical Square, Puri, Dist. Puri , Odisha Pin- 752002 Contact no.: 9439214886, 9778313191 e-mail-osmc.puri@gmail.com
29	**District Drug Warehouse-NUAPADA**, O/O CDM&PHO, Nuapada, DHH Campus, Nuapada, Dist. Nuapada, Odisha Pin- 766105 e-mail-osmc.nuapada@gmail.com Contact no.- 9437631349	30	**District Drug Warehouse-SUNDARGARH**, O/O CDM&PHO, Sundergarh, At/Po-Sundargarh, Dist. Sundergarh , Odisha Pin-770001 e-mail- osmc.sundargarh@gmail.com Contact no.- 8895226184 , 7606846506	31	**Drug Warehouse- RGH- Rourkela** , O/O Director, RGH, Rourkela, Rourkela Govt. Hospital, Near STI Chowk, Rourkela, Sundargarh, Odisha Pin- 769004 e-mail-osmc.rgh@gmail.com Contact no.- 8763142334	32	**Drug Warehouse-MKCG-MCH-BERHUMPUR**, O/O Supt. M.K.C.G Medical College, Berhampur, At/Po- Berhampur Dist – Ganjam, Odisha Pin-760004 e-mail-osmc.mkcg@gmail.com Contact no.- 9861420917, 9938516670
33	**District Drug Warehouse-NAYAGARH** O/O CDM&PHO, Nayagarh, At/Po-Nayagarh, Dist. Nayagarh, Odisha, Pin-752069 e-mail-osmc.nayagarh@gmail.com Contact no.- 9040589024, 9938869261	34	**District Drug Warehouse-SONEPUR**, O/O CDM&PHO, Sonepur, DHH Campus, Sonepur, At / Po- Sonepur, Dist. Sonepur , Odisha Pin- 767017 e-mail-osmc.sonepur@gmail.com Contact no.- 9938025215, 9861353946	35	**Drug Warehouse-CAPITAL HOSPITAL BBSR** , O/O Director, Capital Hospital, Campus of Capital Hospital, Unit-6, Bhubaneswar, Odisha Pin-751009 e-mail-osmc.capitalhospital@gmail.com Contact no.- 9438025079, 9438427391	36	**Drug Warehouse- SISHUBHAWAN-CUTTACK**, O/O Suptd., SVPPGI (Sishubhaban), Cuttack, Campus of Sishubhaban, Cuttack, Chandnichowk, Cuttack, Dist.- Cuttack, Odisha Pin-753002 e-mail-osmc.sishubhawan@gmail.com Contact no.- 9437168806
37	**District Drug Warehouse-NAWARANGPUR** O/O CDM&PHO, Nabarangpur, DHH Campus, Nabarangpur Dist. Nabarangpur, Odisha Pin-764059 e-mail-osmc.nawarangpur@gmail.com Contact no.- 9937221572, 9556659904	38	**Drug Warehouse-SCBMCH-CUTTACK** , O/O Supdt. S.C.B Medical College Hospital, Cuttack, Campus of SCB Medical College Hospital, Manglabag, Cuttack, Odisha, Pin-753001 e-mail-osmc.scbmch@gmail.com Contact no.- 7064323467, 9777915500, 9040093864	39	**Drug Warehouse-AHRCC-CUTTACK (AHPGIC)** , O/O Director, AHRCC(AHPGIC), Cuttack, Manglabag, Cuttack, Odisha, Pin-753001 e-mail-osmc.ahrcc@gmail.com Contact no.- 9438183574, 7735176750 9937484195		

TechnicalSpecificationforBloodBags

1. BloodCollectionBagCPD-A1100ml(Single)(S02166)

GENERALFEATURES

ProductDescription	BloodBags
ClinicalPurpose	Collection,processingandstorageofwhole bloodandbloodcomponents
Disposable	Yes

PRODUCTINFORMATION: -DiversionPouch

ConformitytostandardforBloodBag	ISO3826/IS15102:LatestRevision
Typeofbloodbag	Single
CapacityofbloodBag	100ml
MaterialofBag(Medicalgrade)	DEHPPlasticizedPVC
Blood Collection Bags should be collapsiblenon vented sterile containers complete with collecting tube for completely closed system to avoidthechancesofcontamination	Yes
Flexiblepre-sterilizedandpyrogenfree	Yes
Nontoxic,nonhaemolytic,biocompatible material	Yes
There should be no risk of contamination and air embolism (closed system) with all leak proofseals(Disposablebags)	Yes
Slitonbothsidesofthebagsshouldbeenough toaccommodate5-10mlvolumetesttubes	Yes
The capacity of the bag should be enough to prevent any ballooning/rupture of the bag from the seam when it is filled up with the requisite volume of blood	Yes

TUBINGOFBAG

Flexiblekinkresistanttubing	Yes
Nonsticking	Yes
Transparent	Yes
LeakProof	Yes
Lengthoftubingfromprimarybagtoneedle	≥80Cm
Thetubingshouldhaveuniquelymarked segmentnumbers.	Yes

Thetubesshouldhavemultipleprinted ID/segmentnumbers	Yes
Clampprovidedforclosedsystem	Yes

NEEDLE

NeedleSize	16G
Ultra thin walled and straight to reduce penetration force and enable painless vein puncture	Yes
Sharp,regularandsmoothmarginsand beveledtip	Yes
Rustproof	Yes
Tightlyfixedwithhubcoveredwithsterile guard	Yes
Hermeticallysealed	Yes
The needle should include a needle injury protector which is an additional covering to prevent needle stick injury	Yes
Theneedleshouldnotseparatefromthetubeat any point of time, especially while removing it from the vein for donor safety	Yes
TheneedlemustconfirmtoISO1135-3 standard	Yes

EXTERNALPORT

Tamperproofandshouldnotbere-capped	Yes
Easilyaccessible	Yes

ANTICAOGULANTANDPRESERVATIVESOLUTION

Typeofanticoagulantpresent	CPDA-1
Quantityofanticoagulantsolution	14mlper100mlofblood
Solutionshouldbeclearandcolorless	Yes
Thereshouldbenodiscolorationofsolutionon storageatroomtemperature	Yes
Additivesolutionpresent	No
Typeofadditivesolution	NA
QuantityofAdditivesolution(ml)	NA
Anticoagulantand/oradditivesolutionshould besterileandpyrogenfree	Yes
Availabilityofanticoagulant/additivequality check certificate from manufacture (proof of same to be submitted to buyer)	Yes

LABEL

Non-peeloff	Yes
Heatsealed/Pressureembossedlabel	Yes
The label should remain attached between room temperature to - 80°C with a transparent adhesive	Yes
Dateofmanufacturing,dateofexpiryand batchnumbermustbementionedoneachbag	Yes

RESISTANCETODISTORTION

Bag(Filledtonormalcapacity)shallwithstand	Yes
a acceleration of 5000 g for 30 min at temperature 4°C to 24°C without becoming permanentlydistorted	
Bag (Filled to normal capacity) should be able to withstand temperature upto - 80°C without breakage	Yes

PACKAGING

Individual bag packed in plastic pack and multiple bags packed in moisture proof aluminum foil (Protective dual packaging) eliminating microbial contamination on surface maintainingthecontentsofthebag	Yes
The supplier should ensure proper transportation of the consignment of blood bags in temperature controlled conditions (Storagetemperatureshouldnotexceed30°C)	Yes

CERTIFICATIONS&REPORTS

Availability of valid drug license issued from competent authority defined under Drugs and CosmeticsAct,1940(Proofofthesametobe submittedtobuyerondemand)	Yes
DrugLicenseNumber	Yes
DrugLicenseDate	Yes
Manufacturercertifications(Proofofthesame tobesubmittedtothebuyerondemand)	ISO13485
CertificationNumber	Yes
CertificationDate	Yes
ProductCertifications(Proofofthesametobe submittedtobuyerondemand)	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes

ProductCertificationNumber	Yes
ProductCertificationDate	Yes
CertificateissuingAuthority	Yes
Each batch supplied should be accompanied with quality assurance test report from NABL approved lab/any lab approved from govt of Indiaaswellasinhouselab	Yes
Biocompatibility of the material of the plastic blood bags must be certified by themanufacturer and must be supported by the test reports of cell culture cytotoxicity, hemolysis, systemic infections (acute toxicity), sensitization, Intra-cutaneous injection (irritation), pyrogen test and Sterility (test	Yes
reportforthesametobesubmittedforeach batch)	
Submission of manufacturer's documented evidence of biochemical parameters (plasmapH, ATP % of initial volume, 2-3 DPG % of initial volume, plasma K+ (meq/l), % of viable redcells 24hrs post transfusion,DEHPleachingmg/100ml,DEHPshouldnotbe more than 0.01% w/v in the PVC) of blood stored in CPDA-1containing DEHP plasticized PVCbloodbagsmanufacturedbythecompany on35thdayofstorage	Yes

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	Minimum24months
Stability report from a recognized laboratory mustbesubmittedtothebuyeratthetimeof supply	Yes
The product should have at least 3/4 of the totalshelflifeatthetimeofdispatchtothe consignee	Yes

2.BloodCollectionBagCPD-A1350ml(Single)(S02167)

GENERALFEATURES: -

ProductDescription	BloodBags
ClinicalPurpose	Collection, processing and storage of whole blood and blood components
Disposable	Yes

PRODUCTINFORMATION:-DiversionPouch

ConformitytostandardforBloodBag	ISO3826/IS15102:LatestRevision
Typeofbloodbag	Single
CapacityofbloodBag	350ml
MaterialofBag(Medicalgrade)	DEHPPlasticizedPVC
Blood Collection Bags should be collapsiblenon vented sterile containers complete with collecting tube for completely closed system to avoid the chances of contamination	Yes
Flexiblepre-sterilizedandpyrogenfree	Yes
Nontoxic,nonhaemolytic,biocompatible material	Yes
Thereshouldbenoriskofcontaminationand air embolism (closed system) with all leak proof seals (Disposable bags)	Yes
SlitonbothsidesofthebagsshouldbeenoughtoaccommodateS-10mlvolumetesttubes	Yes
Flexiblepre-sterilizedandpyrogenfree	Yes
Nontoxic,nonhaemolytic,biocompatible material	Yes
Thereshouldbenoriskofcontaminationand air embolism (closed system) with all leak proof seals (Disposable bags)	Yes
SlitonbothsidesofthebagsshouldbeenoughtoaccommodateS-10mlvolumetesttubes	Yes
The capacity of the bag should be enough to prevent any ballooning/rupture of the bag from the seam when it is filled up with the requisite volumeofblood	Yes

TUBINGOFBAG:-

Flexiblekinkresistanttubing	Yes
Nonsticking	Yes
Transparent	Yes
LeakProof	Yes
Lengthoftubingfromprimarybagtoneedle	≥80Cm
Thetubingshouldhaveuniquelymarked segmentnumbers.	Yes
Thetubesshouldhavemultipleprinted ID/segmentnumbers	Yes
Clampprovidedforclosedsystem	Yes

NEEDLE:-

NeedleSize	16G
Ultra thin walled and straight to reduce penetration force and enable painless vein puncture	Yes
Sharp,regularandsmoothmargins, bevelledtip and should not be having barb	Yes
Rustproof	Yes
Tightlyfixedwithhubcoveredwithsterile guard	Yes
Hermeticallysealed	Yes
The needle should include a needle injury protector which is an additional covering to prevent needle stick injury	Yes
The needle should not separate from the tube at any point of time, especially while removing it fromtheveinfordonorsafety	Yes
TheneedlemustconfirmtoISO1135-3 standard	Yes

EXTERNALPORT

Tamperproofandshouldnotbere-capped	Yes
Easilyaccessible	Yes

ANTICAOGULANTANDPRESERVATIVESOLUTION

Typeofanticoagulantpresent	CPDA-1
Quantityofanticoagulantsolution	14mlper100mlofblood
Solutionshouldbeclearandcolorless	Yes
Thereshouldbenodiscolorationofsolutionon storageatroomtemperature	Yes
Additivesolutionpresent	No

Typeofadditivesolution	NA
QuantityofAdditivesolution(ml)	NA
Anticoagulantand/oradditivesolutionshould besterileandpyrogenfree	Yes
Availabilityofanticoagulant/additivequality checkcertificatefrommanufacture(proofof	Yes

LABEL

Non-peeloff	Yes
Heatsealed/Pressureembossedlabel	Yes
The label should remain attached between room temperature to - 80°C with a transparent adhesive	Yes
Dateofmanufacturing,dateofexpiryand batchnumbermustbementionedoneachbag	Yes

RESISTANCETODISTORTION

Bag (Filled to normal capacity) shall withstand a acceleration of 5000 g for 30 min at temperature 4°C to 24°C without becoming permanentlydistorted	Yes
Bag (Filled to normal capacity) should be able to withstand temperature upto - 80°C without breakage	Yes

PACKAGING

Individual bag packed in plastic pack and multiple bags packed in moisture proof aluminum foil (Protective dual packaging) eliminating microbial contamination on surface maintainingthecontentsofthebag	Yes
The supplier should ensure proper transportation of the consignment of blood bags in temperature controlled conditions (Storage temperature should not exceed 30°C)	Yes

CERTIFICATIONS&REPORTS

Availability of valid drug license issued from competent authority defined under Drugs and CosmeticsAct,1940(Proofofthesametobe submittedtobuyerondemand)	Yes

DrugLicenseNumber	Yes
DrugLicenseDate	Yes
Manufacturercertifications(Proofofthesame tobesubmittedtothebuyerondemand)	ISO13485

CertificationNumber	Yes
CertificationDate	Yes
ProductCertifications(Proofofthesametobe submittedtobuyerondemand)	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
ProductCertificationNumber	Yes
ProductCertificationDate	Yes
CertificateissuingAuthority	Yes
EachbatchsuppliedshouldbeaccompaniedwithqualityassurancetestreportfromNABLapprovedlab/anylabapprovedfromgovtof Indiaaswellasinhouselab	Yes
Biocompatibility of the material of the plastic blood bags must be certified by themanufacturer and must be supported by the test reports of cell culture cytotoxicity, hemolysis, systemic infections (acute toxicity), sensitization, Intra-cutaneous injection (irritation), pyrogen test and Sterility (testreport for the same to be submitted for each batch)	Yes
Submission of manufacturer's documented evidence of biochemical parameters (plasmapH, ATP % of initial volume, 2-3 DPG % of initial volume, plasma K+ (m eq/l), % of viable red cells 24 hrs post transfusion, DEHPleaching (mg/100 ml), DEHP should not be more than 0.01% w/v in the PVC) of blood storedinCPDA-1containingDEHP plasticized PVC blood bags manufactured by thecompanyon35thdayofstorage	Yes

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	Minimum24months
Stability report from a recognized laboratory mustbesubmittedtothebuyeratthetimeof supply	Yes

Theproductshouldhaveatleast3/4ofthetotal shelf life at the time of dispatch to the consignee	Yes
sametobesubmittedtobuyer)	

4. Blood Collection Bag CPD 350 ml (Triple) with SAGM /SAGM-2 additive solution (S02170)

GENERALFEATURES

ProductDescription	BloodBags
ClinicalPurpose	Collection,processingandstorageofwhole bloodandbloodcomponents
Disposable	Yes

PRODUCTINFORMATION: -DiversionPouch

ConformitytostandardforBloodBag	ISO3826/IS15102:LatestRevision
Typeofbloodbag	Triple
CapacityofbloodBag	350ml
MaterialofBag(Medicalgrade)	DEHPPlasticizedgood quality PVC
Blood Collection Bags should be collapsiblenon vented sterile containers complete with collecting tube for completely closed system to avoidthechancesofcontamination	Yes
Flexiblepre-sterilizedandpyrogenfree	Yes
Nontoxic,nonhaemolytic,biocompatible material	Yes
There should be no risk of contamination and air embolism (closed system) with all leak proofseals(Disposablebags)	Yes
Slitonbothsidesofthebagsshouldbeenough toaccommodate5-10mlvolumetesttubes	Yes
The capacity of the bag should be enough to prevent any ballooning/rupture of the bag from the seam when it is filled up with the requisite volume of blood	Yes

TUBINGOFBAG

Flexiblekinkresistanttubing	Yes

Nonsticking	Yes
Transparent	Yes
LeakProof	Yes
Lengthoftubingfromprimarybagtoneedle	≥80Cm
Thetubingshouldhaveuniquelymarked segmentnumbers.	Yes
Thetubesshouldhavemultipleprinted ID/segmentnumbers	Yes
Clampprovidedforclosedsystem	Yes

NEEDLE

NeedleSize	16G
Ultra thin walled and straight to reduce penetration force and enable painless vein puncture	Yes
Sharp,regularandsmoothmarginsand	Yes
beveledtip	
Rustproof	Yes
Tightlyfixedwithhubcoveredwithsterile guard	Yes
Hermeticallysealed	Yes
The needle should include a needle injury protector which is an additional covering to prevent needle stick injury	Yes
The needle should not separate from the tube at any point of time, especially while removing it fromtheveinfordonorsafety	Yes
TheneedlemustconfirmtoISO1135-3 standard	Yes

EXTERNALPORT

Tamperproofandshouldnotbere-capped	Yes
Easilyaccessible	Yes

ANTICAOGULANTANDPRESERVATIVESOLUTION

Typeofanticoagulantpresent	CPDwithSAGM/SAGM-2
Quantityofanticoagulantsolution	14mlper100mlofblood(49ml)
Solutionshouldbeclearandcolorless	Yes
Thereshouldbenodiscolorationofsolutionon storageatroomtemperature	Yes
Additivesolutionpresent	Yes
Typeofadditivesolution	SAGM
QuantityofAdditivesolution(ml)	78ml
Anticoagulantand/oradditivesolutionshould besterileandpyrogenfree	Yes
Availabilityofanticoagulant/additivequality check certificate from manufacture (proof of same to be submitted to buyer)	Yes

LABEL

Non-peeloff	Yes
Heatsealed/Pressureembossedlabel	Yes
Thelabelshouldremainattachedbetween room temperature to - 80°C with a transparent adhesive	Yes
Dateofmanufacturing,dateofexpiryand batchnumbermustbementionedoneachbag	Yes

RESISTANCETODISTORTION

Bag (Filled to normal capacity) shall withstand a acceleration of 5000 g for 30 min at temperature 4°C to 24°C without becoming permanentlydistorted	Yes
Bag (Filled to normal capacity) should be able to withstand temperature upto - 80°C without breakage	Yes

PACKAGING

Individualbagpackedinplasticpackand multiplebagspackedinmoistureproofaluminum foil (Protective dual packaging) eliminating microbial contamination on surface maintainingthecontentsofthebag	Yes
The supplier should ensure proper transportation of the consignment of blood bags in temperature controlled conditions (Storagetemperatureshouldnotexceed30°C)	Yes

CERTIFICATIONS&REPORTS

Availability of valid drug license issued from competent authority defined under Drugs and CosmeticsAct,1940(Proofofthesametobe submittedtobuyerondemand)	Yes
DrugLicenseNumber	Yes
DrugLicenseDate	Yes
Manufacturercertifications(Proofofthesame tobesubmittedtothebuyerondemand)	ISO13485
CertificationNumber	Yes
CertificationDate	Yes
ProductCertifications(Proofofthesametobe submittedtobuyerondemand)	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
ProductCertificationNumber	Yes
ProductCertificationDate	Yes
CertificateissuingAuthority	Yes
Each batch supplied should be accompanied with quality assurance test report from NABL approved lab/any lab approved from govt of Indiaaswellasinhouselab	Yes
Biocompatibility of the material of the plastic blood bags must be certified by themanufacturer and must be supported by the test reports of cell culture cytotoxicity, hemolysis, systemic infections (acute toxicity), sensitization, Intra-cutaneous injection (irritation), pyrogen test and Sterility (testreport for the same to be submitted for each batch)	Yes

Submission of manufacturer's documented evidence of biochemical parameters (plasma pH, ATP % of initial volume, 2-3 DPG % of initial volume, plasma K+ (meq/l), % of viable red cells 24hrs post transfusion, DEHPleaching mg/100 ml, DEHP should not bemore than 0.01% w/v in the PVC) of blood stored in CPDA-1-SAGM containing DEHP plasticized PVC blood bags manufactured by thecompanyon42nddayofstorage	Yes

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	Minimum24months
Stability report from a recognized laboratory mustbesubmittedtothebuyeratthetimeof supply	Yes
The product should have at least 3/4 of the totalshelflifeatthetimeofdispatchtothe consignee	Yes

5. Blood Collection Bag CPD450 ml (Triple) with SAGM /SAGM-2additive solution (S02171)

GENERALFEATURES

ProductDescription	BloodBags
ClinicalPurpose	Collection,processingandstorageofwhole bloodandbloodcomponents
Disposable	Yes

PRODUCTINFORMATION:-DiversionPouch

ConformitytostandardforBloodBag	ISO3826/IS15102:LatestRevision
Typeofbloodbag	Triple
CapacityofbloodBag	450ml
MaterialofBag(Medicalgrade)	DEHPPlasticizedgood quality PVC
Blood Collection Bags should be collapsiblenon vented sterile containers complete with collecting tube for completely closed system to avoidthechancesofcontamination	Yes

Flexiblepre-sterilizedandpyrogenfree	Yes
Nontoxic,nonhaemolytic,biocompatible material	Yes
There should be no risk of contamination and air embolism (closed system) with all leak proofseals(Disposablebags)	Yes
Slitonbothsidesofthebagsshouldbeenough toaccommodate5-10mlvolumetesttubes	Yes
The capacity of the bag should be enough to prevent any ballooning/rupture of the bag from the seam when it is filled up with the requisite volumeofblood	Yes

TUBINGOFBAG

Flexiblekinkresistanttubing	Yes
Nonsticking	Yes
Transparent	Yes
LeakProof	Yes
Lengthoftubingfromprimarybagtoneedle	≥80Cm
Thetubingshouldhaveuniquelymarked segmentnumbers.	Yes
Thetubesshouldhavemultipleprinted ID/segmentnumbers	Yes
Clampprovidedforclosedsystem	Yes

NEEDLE

NeedleSize	16G
Ultra thin walled and straight to reduce penetration force and enable painless vein puncture	Yes
Sharp,regularandsmoothmarginsand beveledtip	Yes
Rustproof	Yes
Tightlyfixedwithhubcoveredwithsterile guard	Yes
Hermeticallysealed	Yes
The needle should include a needle injury protector which is an additional covering to prevent needle stick injury	Yes
The needle should not separate from the tube at any point of time, especially while removing it fromtheveinfordonorsafety	Yes
TheneedlemustconfirmtoISO1135-3 standard	Yes

EXTERNALPORT

Tamperproofandshouldnotbere-capped	Yes
Easilyaccessible	Yes

ANTICAOGULANTANDPRESERVATIVESOLUTION

Typeofanticoagulantpresent	CPDwithSAGM/SAGM-2
Quantityofanticoagulantsolution	14mlper100mlofblood(63ml)
Solutionshouldbeclearandcolorless	Yes
Thereshouldbenodiscolorationofsolutionon storageatroomtemperature	Yes
Additivesolutionpresent	Yes
Typeofadditivesolution	SAGM
QuantityofAdditivesolution(ml)	100ml
Anticoagulantand/oradditivesolutionshould besterileandpyrogenfree	Yes
Availabilityofanticoagulant/additivequality check certificate from manufacture (proof of same to be submitted to buyer)	Yes

LABEL

Non-peeloff	Yes
Heatsealed/Pressureembossedlabel	Yes
The label should remain attached between room temperature to - 80°C with a transparent adhesive	Yes
Dateofmanufacturing,dateofexpiryand batchnumbermustbementionedoneachbag	Yes

RESISTANCETODISTORTION

Bag (Filled to normal capacity) shall withstand a acceleration of 5000 g for 30 min at temperature 4°C to 24°C without becoming permanentlydistorted	Yes
Bag(Filledtonormalcapacity)shouldbeable to withstand temperature upto - 80°C without breakage	Yes

PACKAGING

Individualbagpackedinplasticpackand multiple bags packed in moisture proof aluminum foil (Protective dual packaging)eliminatingmicrobialcontaminationon	Yes

surface maintainingthecontentsofthebag	
The supplier should ensure proper transportation of the consignment of blood bags in temperature controlled conditions (Storagetemperatureshouldnotexceed30°C)	Yes

CERTIFICATIONS&REPORTS

Availability of valid drug license issued from competent authority defined under Drugs and CosmeticsAct,1940(Proofofthesametobe submittedtobuyerondemand)	Yes
DrugLicenseNumber	Yes
DrugLicenseDate	Yes
Manufacturercertifications(Proofofthesame tobesubmittedtothebuyerondemand)	ISO13485
CertificationNumber	Yes
CertificationDate	Yes
ProductCertifications(Proofofthesametobe submittedtobuyerondemand)	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
ProductCertificationNumber	Yes
ProductCertificationDate	Yes
CertificateissuingAuthority	Yes
Each batch supplied should be accompanied with quality assurance test report from NABL approved lab/any lab approved from govt of Indiaaswellasinhouselab	Yes
Biocompatibility of the material of the plastic blood bags must be certified by themanufacturer and must be supported by the test reports of cell culture cytotoxicity, hemolysis, systemic infections (acute toxicity), sensitization, Intra-cutaneous injection (irritation), pyrogen test and Sterility (testreport for the same to be submitted for each batch)	Yes

Submission of manufacturer's documented evidence of biochemical parameters (plasma pH, ATP % of initial volume, 2-3 DPG % of initial volume, plasma K+ (meq/l), % of viable red cells 24hrs post transfusion, DEHPleaching mg/100 ml, DEHP should not bemore than 0.01% w/v in the PVC) of blood stored in CPDA-1-SAGM containing DEHP plasticized PVC blood bags manufactured by on42nddayofstorage	Yes

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	Minimum24months
Stability report from a recognized laboratory mustbesubmittedtothebuyeratthetimeof supply	Yes
The product should have at least 3/4 of the totalshelflifeatthetimeofdispatchtothe consignee	Yes

6. Blood CollectionBagCPD450ml(Quadruple)withSAGM/SAGM-2additive solution (top and bottom) (S02173)

GENERALFEATURES

ProductDescription	BloodBags
ClinicalPurpose	Thequadrupletopandbottombagtocollect blood and prepare blood component through buffy coat method
Disposable	Yes

PRODUCTINFORMATION(DiversionPouch)

ConformitytostandardforBloodBag	ISO3826/IS15102:LatestRevision
Typeofbloodbag	Quadruple(topandbottom)
CapacityofbloodBag	450ml
MaterialofBag(Medicalgrade)	DEHPPlasticizedgood quality PVC
Blood Collection Bags should be collapsiblenon vented sterile containers complete with collecting tube for completely closed system to avoidthechancesofcontamination	Yes
Flexiblepre-sterilizedandpyrogenfree	Yes
Nontoxic,nonhaemolytic,biocompatible material	Yes
There should be no risk of contamination and air embolism (closed system) with all leak proofseals(Disposablebags)	Yes
Slitonbothsidesofthebagsshouldbeenoughtoaccommodate5-10mlvolumetesttubes	Yes
The capacity of the bag should be enough to prevent any ballooning/rupture of the bag from the seam when it is filled up with the requisite volumeofblood	Yes

TUBINGOFBAG

Flexiblekinkresistanttubing	Yes
Nonsticking	Yes
Transparent	Yes
LeakProof	Yes
LengthoftubingfromprimarybagtoneedIe	≥80Cm
Thetubingshouldhaveuniquelymarked segmentnumbers.	Yes
Thetubesshouldhavemultipleprinted ID/segmentnumbers	Yes
Clampprovidedforclosedsystem	Yes

NEEDLE

NeedleSize	16G
Ultrathinwalledandstraighttoreduce penetration force and enable painless vein puncture	Yes

Sharp,regularandsmoothmarginsand beveledtip	Yes
Rustproof	Yes
Tightlyfixedwithhubcoveredwithsterile guard	Yes
Hermeticallysealed	Yes
The needle should include a needle injury protector which is an additional covering to prevent needle stick injury	Yes
Theneedleshouldnotseparatefromthetubeat any point of time, especially while removing it from the vein for donor safety	Yes
TheneedlemustconfirmtoISO1135-3 standard	Yes

EXTERNALPORT

Tamperproofandshouldnotbere-capped	Yes
Easilyaccessible	Yes

ANTICAOGULANTANDPRESERVATIVESOLUTION

Typeofanticoagulantpresent	CPDwithSAGM/SAGM-2
Quantityofanticoagulantsolution	14mlper100mlofblood(63ml)
Solutionshouldbeclearandcolorless	Yes
Thereshouldbenodiscolorationofsolutionon storageatroomtemperature	Yes
Additivesolutionpresent	Yes
Typeofadditivesolution	SAGM
QuantityofAdditivesolution(ml)	100ml
Anticoagulantand/oradditivesolutionshould besterileandpyrogenfree	Yes
Availabilityofanticoagulant/additivequality check certificate from manufacture (proof of same to be submitted to buyer)	Yes

LABEL

Non-peeloff	Yes
Heatsealed/Pressureembossedlabel	Yes
Thelabelshouldremainattachedbetween room temperature to - 80°C with a transparent adhesive	Yes
Dateofmanufacturing,dateofexpiryand batchnumbermustbementionedoneachbag	Yes

RESISTANCETODISTORTION

Bag (Filled to normal capacity) shall withstand a acceleration of 5000 g for 30 min at temperature 4°C to 24°C without becoming permanentlydistorted	Yes
Bag(filledtonormalcapacity)shouldbeable to withstand temperature upto - 80°C without breakage	Yes

PACKAGING

Individual bag packed in plastic pack and multiple bags packed in moisture proof aluminum foil (Protective dual packaging) eliminating microbial contamination on surface maintainingthecontentsofthebag	Yes
The supplier should ensure proper transportation of the consignment of blood bags in temperature controlled conditions (Storagetemperatureshouldnotexceed30°C)	Yes

CERTIFICATIONS&REPORTS

Availability of valid drug license issued from competent authority defined under Drugs and CosmeticsAct,1940(Proofofthesametobe submittedtobuyerondemand)	Yes
DrugLicenseNumber	Yes
DrugLicenseDate	Yes
Manufacturercertifications(Proofofthesame tobesubmittedtothebuyerondemand)	ISO13485
CertificationNumber	Yes
CertificationDate	Yes
ProductCertifications(Proofofthesametobe submittedtobuyerondemand)	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
ProductCertificationNumber	Yes
ProductCertificationDate	Yes
CertificateissuingAuthority	Yes

Each batch supplied should be accompanied with quality assurance test report from NABL approved lab/any lab approved from govt of Indiaaswellasinhouselab	Yes
Biocompatibility of the material of the plastic blood bags must be certified by themanufacturer and must be supported by the test reports of cell culture cytotoxicity, hemolysis, systemic infections (acute toxicity), sensitization, Inra-cutaneous injection (irritation), pyrogen test and Sterility (testreport for the same to be submitted for each batch)	Yes
Submission of manufacturer's documented evidence of biochemical parameters (plasma pH, ATP % of initial volume, 2-3 DPG % of initialvolume,plasmaK+meq/l,%ofviable redcells24hrsposttransfusion,DEHP	Yes
leaching mg/100 ml, DEHP should not be more than 0.01% w/v in the PVC) of blood stored in CPDA-1-SAGM containing DEHP plasticized PVC blood bags manufactured by thecompanyon42nddayofstorage	

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	Minimum24months
Stability report from a recognized laboratory mustbesubmittedtothebuyeratthetimeof supply	Yes
The product should have at least 3/4 of the totalshelflifeatthetimeofdispatchtothe consignee	Yes

N.B:i)BloodCollectionBags450mlquadruplewithSAGM/SAGM-2additivesolution (Top and Bottom) should be compatible as per the availability of automated component extractor in the Blood Component Separation Units in the Blood Centres i.e Fresenius and Terumo Penpol machines.

ii)TheresidualRBCwastedshouldbelessthan10ml.

6.BloodCollectionBag CPD450 ml(Quadruple)withSAGMadditive solution (top and top) (S02427)

GENERALFEATURES

ProductDescription	BloodBags
ClinicalPurpose	Thequadrupletopandtopbagtocollectbloodandprepare bloodcomponentthroughPRP method.
Disposable	Yes

PRODUCTINFORMATION(DiversionPouch)

ConformitytostandardforBloodBag	ISO3826/IS15102:LatestRevision
Typeofbloodbag	Quadruple(topandtop)
CapacityofbloodBag	450ml
MaterialofBag(Medicalgrade)	DEHPPlasticized good quality PVC
Blood Collection Bags should be collapsiblenon vented sterile containers complete with collecting tube for completely closed system to avoidthechancesofcontamination	Yes
Flexiblepre-sterilizedandpyrogenfree	Yes
Nontoxic,nonhaemolytic,biocompatible material	Yes
Thereshouldbenoriskofcontaminationand air embolism (closed system) with all leak proof seals (Disposable bags)	Yes
Slitonbothsidesofthebagsshouldbeenough toaccommodate5-10mlvolumetesttubes	Yes
The capacity of the bag should be enough to prevent any ballooning/rupture of the bag from the seam when it is filled up with the requisite volumeofblood	Yes

TUBINGOFBAG

Flexiblekinkresistanttubing	Yes
Nonsticking	Yes
Transparent	Yes
LeakProof	Yes
Lengthoftubingfromprimarybagtoneedle	≥80Cm

Thetubingshouldhaveuniquelymarked segmentnumbers.	Yes
Thetubesshouldhavemultipleprinted ID/segmentnumbers	Yes
Clampprovidedforclosedsystem	Yes

NEEDLE

NeedleSize	16G
Ultra thin walled and straight to reduce penetration force and enable painless vein puncture	Yes
Sharp,regularandsmoothmarginsand beveledtip	Yes
Rustproof	Yes
Tightlyfixedwithhubcoveredwithsterile guard	Yes
Hermeticallysealed	Yes
The needle should include a needle injury protector which is an additional covering to prevent needle stick injury	Yes
The needle should not separate from the tube at any point of time, especially while removing it fromtheveinfordonorsafety	Yes
TheneedlemustconfirmtoISO1135-3 standard	Yes

EXTERNALPORT

Tamperproofandshouldnotbere-capped	Yes
Easilyaccessible	Yes

ANTICAOGULANTANDPRESERVATIVESOLUTION

Typeofanticoagulantpresent	CPDwithSAGM/SAGM-2
Quantityofanticoagulantsolution	14mlper100mlofblood(63ml)
Solutionshouldbeclearandcolorless	Yes
Thereshouldbenodiscolorationofsolutionon storageatroomtemperature	Yes
Additivesolutionpresent	Yes
Typeofadditivesolution	SAGM
QuantityofAdditivesolution(ml)	100ml
Anticoagulantand/oradditivesolutionshould besterileandpyrogenfree	Yes

Availabilityofanticoagulant/additivequality check certificate from manufacture (proof of same to be submitted to buyer)	Yes

LABEL

Non-peeloff	Yes
Heatsealed/Pressureembossedlabel	Yes
The label should remain attached between room temperature to - 80°C with a transparent adhesive	Yes
Dateofmanufacturing,dateofexpiryand batchnumbermustbementionedoneachbag	Yes

RESISTANCETODISTORTION

Bag (Filled to normal capacity) shall withstand a acceleration of 5000 g for 30 min at temperature 4°C to 24°C without becoming permanentlydistorted	Yes
Bag(filledtonormalcapacity)shouldbeable to withstand temperature upto - 80°C without breakage	Yes

PACKAGING

Individualbagpackedinplasticpackand multiple bags packed in moisture proof aluminum foil (Protective dual packaging)	Yes
eliminatingmicrobialcontaminationonsurface maintainingthecontentsofthebag	
The supplier should ensure proper transportation of the consignment of blood bags in temperature controlled conditions (Storagetemperatureshouldnotexceed30°C)	Yes

CERTIFICATIONS&REPORTS

Availability of valid drug license issued from competent authority defined under Drugs and CosmeticsAct,1940(Proofofthesametobe submittedtobuyerondemand)	Yes
DrugLicenseNumber	Yes
DrugLicenseDate	Yes
Manufacturercertifications(Proofofthesame tobesubmittedtothebuyerondemand)	ISO13485

CertificationNumber	Yes
CertificationDate	Yes
ProductCertifications(Proofofthesametobe submittedtobuyerondemand)	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
ProductCertificationNumber	Yes
ProductCertificationDate	Yes
CertificateissuingAuthority	Yes
Each batch supplied should be accompanied with quality assurance test report from NABL approved lab/any lab approved from govt of Indiaaswellasinhouselab	Yes
Biocompatibility of the material of the plastic blood bags must be certified by themanufacturer and must be supported by the test reports of cell culture cytotoxicity, hemolysis, systemic infections (acute toxicity), sensitization, Inra-cutaneous injection (irritation), pyrogen test and Sterility (testreport for the same to be submitted for each batch)	Yes
Submission of manufacturer's documented evidence of biochemical parameters (plasma pH, ATP % of initial volume, 2-3 DPG % of initial volume, plasma K+meq/l, % of viable red cells 24hrs post transfusion, DEHP leaching mg/100 ml, DEHP should not be more than 0.01% w/v in the PVC) of blood stored in CPDA-1-SAGM containing DEHP plasticized PVC blood bags manufactured by thecompanyon42nddayofstorage	Yes

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	Minimum24months
Stability report from a recognized laboratory mustbesubmittedtothebuyeratthetimeof supply	Yes
The product should have at least 3/4 of the totalshelflifeatthetimeofdispatchtothe consignee	Yes

7. Transfer Bag 100 ml (S02480)

General Features

Product Description	Transfer Bag
Clinical Purpose	Transfer Bags are used for preservation andtransfusion of Whole Human Blood or it's Components
Disposable	Yes

PRODUCTINFORMATION: -

Conformitytostandardfor Transfer BloodBag	ISO3826/IS15102:LatestRevision
Typeofbloodbag	Single
CapacityofbloodBag	100ml
MaterialofBag(Medicalgrade)	DEHPPlasticizedPVC
Blood transfer Bags should be collapsible,non-vented, sterile container complete with collecting tube for completely closed system to avoidany chancesofcontamination	Yes
Sterile Nontoxic,non-hemolytic,non-pyrogenic and bio-compatible material	Yes
There should be no risk of contamination and air embolism (closed system) with all leak proofseals(Disposablebags)	Yes
Slitonbothsidesofthebagsshouldbeenough toaccommodate5-10mlvolumetesttubes	Yes

TUBINGOFBAG

Flexiblekinkresistanttubing	Yes
Nonsticking	Yes
Transparent	Yes
LeakProof	Yes
Polycarbonate sharp spike, tightly fixed with tube	Yes
Lengthoftubingfromprimarybagtoneedle	≥80Cm
Thetubingshouldhaveuniquelymarked segmentnumbers.	Yes
Thetubesshouldhavemultipleprinted ID/segmentnumbers	Yes

EXTERNALPORT

Tamperproofandshouldnotbere-capped	Yes
Spike assembly & easilyaccessible	Yes

LABEL

Non-peeloff	Yes
Heatsealed/Pressureembossedlabel	Yes
The label should remain attached between room temperature to - 80°C with a transparent adhesive	Yes
Dateofmanufacturing,dateofexpiryand batchnumbermustbementionedoneachbag	Yes

RESISTANCETODISTORTION

Bag(Filledtonormalcapacity)shallwithstand a acceleration of 5000 g for 30 min at temperature 4°C to 24°C without becoming permanentlydistorted	Yes
Bag (Filled to normal capacity) should be able to withstand temperature up to - 80°C without breakage	Yes

PACKAGING

Individual bag packed in plastic pack and multiple bags packed in moisture proof aluminum foil (Protective dual packaging) eliminating microbial contamination on surface maintainingthecontentsofthebag	Yes
The supplier should ensure proper transportation of the consignment of blood bags in temperature controlled conditions (Storagetemperatureshouldnotexceed30°C)	Yes

CERTIFICATIONS&REPORTS

Availability of valid drug license issued from competent authority defined under Drugs and CosmeticsAct,1940(Proofofthesametobe submittedtobuyerondemand)	Yes
DrugLicenseNumber	Yes
DrugLicenseDate	Yes
Manufacturercertifications(Proofofthesame tobesubmittedtothebuyerondemand)	ISO3826
CertificationNumber	Yes
CertificationDate	Yes
ProductCertifications(Proofofthesametobe submittedtobuyerondemand)	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
ProductCertificationNumber	Yes

ProductCertificationDate	Yes
CertificateissuingAuthority	Yes
Each batch supplied should be accompanied with quality assurance test report from NABL approved lab/any lab approved from govt of Indiaaswellasinhouselab	Yes
Biocompatibility of the material of the plastic blood bags must be certified by themanufacturer and must be supported by the test reports of cell culture cytotoxicity, hemolysis, systemic infections (acute toxicity), sensitization, Intra-cutaneous injection (irritation), pyrogen test and Sterility (test reportforthesametobesubmittedforeach batch)	Yes
Submission of manufacturer's documented evidence of biochemical parameters (plasmapH, ATP % of initial volume, 2-3 DPG % of initial volume, plasma K+ (meq/l), % of viable redcells 24hrs post transfusion,DEHPleachingmg/100ml,DEHPshouldnotbe more than 0.01% w/v in the PVC) of blood stored in CPDA-1containing DEHP plasticized PVCbloodbagsmanufacturedbythecompany on35thdayofstorage	Yes

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	Minimum24months
Stability report from a recognized laboratory mustbesubmittedtothebuyeratthetimeof supply	Yes
The product should have at least 3/4 of the totalshelflifeatthetimeofdispatchtothe consignee	Yes

AdditionaltermsandconditionsForAllBloodBags:

1) **Theproductlabelshouldbebarcodedasper ISBT-128.**
2) **SecondarypackingandshippingcartonsshouldbebarcodedasperGSI-128**

TechnicalSpecificationsforELISAKits

SpecificRequirementalltheKits:-

1. The supplier should supply 600 tests x 2 sets free of cost from each batch for random evaluation at the identified laboratories for pre-dispatch lot verification. Protocol of each batch is to be attached
2. A"ColdChainindicator"istobesuppliedwiththekitswiththefollowingspecification:
    a. Acumulativetime/temperatureindicatorshouldindicatetheexposureto temperature in the range of 2-8 degree C
    b. The cumulative time-temperature indicator technology used should be prequalified by WHO
    c. Theindicatorshouldchangecolouruniformly,irreversiblyandtherateof reaction should be predictable by appropriate kinetic parameters.
    d. Thecolourchangeshouldhaveawell-definedstartpointandendpointthatcan be correlated to the heat stability of the kit.
    e. Eachbatchsuppliedshouldbeaccompaniedwithqualityassurancetestresult from NABL approved Lab as well as in house lab.

8.HIV(ELISA)testKITSpecification(S02174)

GENERALFEATURES

ProductDescription	HIVELISATestingKits
ClinicalPurpose	ToprovidediagnosisofHIVinfection

PRODUCTINFORMATION

TypeofKit	4thgeneration
Detects	HIV1Antibodies, HIV2 Antibodies, HIV1p24Ag
DetectionType	Qualitative

The assay should be solid phase microplate coated HIV 1 and 2 recombinant and/or synthetic peptide antigens and antibody to HIV 1 p24 if the kit detects HIV1p24Ag	Yes
Test can be performed on	WholeBlood/Serum/Plasma
AssayProcedureTime(minutes)	Notmorethan90minutes
TheAssayshouldhavesensitivityof>99%and specificity of >99% (shall be claimed by the manufacturer in the kit literature)	Yes
The assay component should include reactive (for both antigen as well as antibody) and non reactive controls with each kit. The assay component should includesufficientvolumeofcontrolstoperformfor minimumof3batchesasperprotocol.	Yes
Storagetemperature	2°Cto8°C
Thesuppliershouldensuremaintenanceofcoldchain during storage and transportation of Kits at 2°C to 8°C	Yes
ColdChainindicatorprovidedwiththekitsshallbe mountedoncardwithclearinstructionof interpretation	Yes
Cumulative time/temp indicator shall indicate exposure to high temperature above 8°C and indicator changes color uniformly, irreversibly & color change shall have a well defined start & end pointthatcanbecorrelatedtoheatstabilityofthekit	Yes
The cumulative time temperature indicator technology shall be placed on every pack of kits and bepre-qualifiedbyWHO	Yes
Document detailing principle,component,antigendetail for antibody detection of HIV1,2&p24 antigen,biosafety,methodologies,validitycriteria,result interpretation, performance characteristic, assaylimitation,mfg,expdate,storageconditionprovided	Yes
TheKitShouldbecompatibletobothsemi automatedandfullyautomatedElisaanalyzers	Yes
Thevolumeofallthechemicalsusedshouldbe adequate enough for automated Elisa analyze (not less than 1 litre)	Yes
Thevolumeshouldcoverthedeadvolumefor automatedELISAsystem	Yes
ThekitshouldcomplywithallprovisionsofDrugs and cosmentics Act, 1940 and applicable rules there under	Yes

PACKAGING

PackSize	96tests/kit
Thepackingandlabellingofthekitshouldbe as per Drugs and Cosmetics Act, 1940 and applicable rules there under	Yes

CERTIFICATIONS&REPORTS

Thekitshouldhaveapprovalofthestatutory authority in its country of origin and CDSCO/NIB, Noida	Yes
Imported kits shall be registered and licensedin India under the provisions of Drugs and Cosmetics act 1940 and Rules 1945 and/or Medical device rules 2017 as amended till date DCG (I)	Yes
Indigenous manufacturers should be licensedby the competent authority defined underDrugs and Cosmetics act 1940 and Rules 1945 and/or Medical Device Rules 2017 as amended tilldateDCG(I)	Yes
AvailabilityofvaliddruglicensefromcompetentauthoritydefinedunderDrugsandCosmeticsAct,1940(Proofofthesametobe submittedtobuyerondemand)	Yes

DrugLicenseNumber	Yes
DrugLicenseDate	Yes
Manufacturercertifications(Proofofthesame tobesubmittedtothebuyerondemand)	Yes
GMP/WHOGMPCertificationNumber	Yes
GMP/WHOGMPCertificationDate	Yes
ISO13485CertifiedManufacturer(Proofof thesametobesubmittedtobuyerondemand)	Yes
ProductCertifications(Proofofthesametobe submittedtobuyerondemand)	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
CertificationNumber	Yes
CertificationDate	Yes
CertificationIssuingAuthority	Yes

Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specification(proof of the same to be submitted to the buyer on demand)	Yes
Availability of Performance Evaluation Report (Proofofthesametobesubmittedtothebuyer ondemand)	Yes
PerformanceEvaluationReportissuingbody	
NameofthePerformanceEvaluationReport issuingbodyifotherthanspecifiedinstitute	

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	Minimum12months
Thekitshouldhaveminimumremainingshelf life of 5/6th or more of the total shelf life at the time of delivery to the consignees	Yes

9. HBV(ELISA)TESTKITS(S02175)

GENERALFEATURES

ProductDescription	HBsAgELISATestKits
ClinicalPurpose	ToprovidediagnosisofHepatitisBvirus infection

PRODUCTINFORMATION

TypeofKit	3rd generation
Detects	HepatitisBVirusSurfaceAntigen(HBsAg)
DetectionType	Qualitative
TestShouldbeabletodetectall11subtypeof HBV	Yes
MicroplateELISACoatedwithmonoclonal antibodiestoHBsAg	Yes
Testcanbeperformedon	Serum,Plasma
AssayProcedureTime(minutes)	Notmorethan90minutes
TheAssayshouldhavesensitivityof>99% and specificity of > 99% (shall be claimed by the manufacturer in the kit literature)	Yes
Theassayshouldhaveanalyticalsensitivityof detectinglessthan0.1ng/ml	Yes
Theassaycomponentshouldincludepositive andnegativecontrolswitheachkit	Yes
Storagetemperature	2°Cto8°C

The supplier should ensure maintenance ofcold chain during storage and transportation of Kitsat2°Cto8°C	Yes
ColdChainindicatorprovidedwiththekits shall be mounted on card with clear instruction of interpretation	Yes
Cumulative time/temp indicator shall indicate exposure to high temperature above 8°C and indicator changes color uniformly, irreversibly & color change shall have a well defined start & end point that can be correlated to heat stability of the kit	Yes
Thecumulativetimetemperatureindicator technology shall be placed on every box of kits and be pre-qualified by WHO	Yes
Adequate document detailing principle, components, methodologies, validity criteria, interpretation of result, performance characteristic, bio-safety, limitation of assay, storage condition, mfg, exp date & method of disposalprovidedwitheachkit	Yes
TheKitShouldbecompatibletobothsemi automatedandfullyautomatedElisaanalyzers	Yes
Thevolumeofallthechemicalsusedshould be adequate enough for automated Elisa analyze	Yes
ThevolumeshouldcoverthedeadvolumeforautomatedELISAsystem	Yes
The kit should comply with all provisions of Drugs and cosmetics Act, 1940 and applicable rulesthereunder	Yes

PACKAGING

PackSize	96tests/kit
The packing and labelling of the kit should be as per Drugs and Cosmetics Act, 1940 and applicablerulesthereunder	Yes

CERTIFICATIONS&REPORTS

The kit should have approval of the statutory authority in its country of origin and CDSCO/NIBNoida	Yes

Imported kits shall be registered and licensedin India under the provisions of Drugs and Cosmetics act 1940 and Rules 1945 and/or Medical device rules 2017 as amended till date DCG(I)	
Indigenous manufacturers should be licensedby the competent authority defined underDrugs and Cosmetics act 1940 and Rules 1945 and/or Medical Device Rules 2017 as amended tilldateDCG(I)	Yes
Availability of valid drug license from competent authority defined under Drugs and CosmeticsAct,1940(Proofofthesametobe submittedtobuyerondemand)	Yes
DrugLicenseNumber	Yes
DrugLicenseDate	Yes
Manufacturercertifications(Proofofthesame tobesubmittedtothebuyerondemand)	ISO13485
GMP/WHOGMPCertificationNumber	Yes
GMP/WHOGMPCertificationDate	Yes
ISO13485CertifiedManufacturer(Proofof thesametobesubmittedtobuyerondemand)	Yes
ProductCertifications(Proofofthesametobe submittedtobuyerondemand)	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
CertificationNumber	Yes
CertificationDate	Yes
CertificationIssuingAuthority	Yes
Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specification (proofofthesametobesubmittedtothebuyer on demand	Yes
Availability of Performance Evaluation Report (Proofofthesametobesubmittedtothebuyer ondemand)	Yes
PerformanceEvaluationReportissuingbody	
NameofthePerformanceEvaluationReport issuingbodyifotherthanspecifiedinstitute	

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	Minimum12months

The kit should have minimum residual shelflife of 5/6th or more of the total shelf life at the timeofdeliverytotheconsignees	Yes

10. TECHNICAL SPECIFICATIONS FOR HCV (ELISA) TEST KITS(S02176)

GENERALFEATURES

ProductDescription	HCVELISATestKit
ClinicalPurpose	ToprovidediagnosisofHepatitisCvirus infection

PRODUCTINFORMATION

TypeofKit	4th generation
Detects	AntibodiesspecifictoHepatitisCVirus, antigenforNS3,NS5andcore.
DetectionType	Qualitative
Microplate ELISA Coated with recombinant and/or synthetic peptide antigens for core NS3 andNS5.	Yes
Testcanbeperformedon	WholeBlood,Serum,Plasma
AssayProcedureTime(minutes)	Notmorethan90minutes
TheAssayshouldhavesensitivityof>99% and specificity of > 99% (shall be claimed by manufacturer in the kit literature)	Yes
Theassaycomponentshouldincludepositive (for both antibody and antigen) and negative controls with each kit	Yes
Storagetemperature	2°Cto8°C
The supplier should ensure maintenance ofcold chain during storage and transportation of Kitsat2°Cto8°C	Yes
ColdChainindicatorprovidedwiththekits shall be mounted on card with clear instruction of interpretation	Yes
Cumulativetime/tempindicatorshallindicate exposuretohightemperatureabove8°Candindicato r changes color uniformly, irreversibly & color change shall have a well defined start & end point that can be correlated to heat stabilityofthekit	Yes
The cumulative time temperature indicator technology shall be placed on every pack of kitsandbepre-qualifiedbyWHO	Yes

Adequate document detailing principle, components, methodologies, validity criteria, interpretation of result, performance characteristic, bio-safety, limitation of assay, storage condition, mfg, exp date & method of disposalprovidedwitheachkit	Yes
TheKitShouldbecompatibletobothsemi automatedandfullyautomatedElisaanalyzers	Yes
The volume of all the chemicals used should be adequate enough for automated Elisa analyze	Yes
Thevolumeshouldcoverthedeadvolumefor automatedELISAsystem	Yes
The kit should comply with all provisions of Drugs and cosmentics Act, 1940 and applicablerulesthereunder	Yes

PACKAGING

PackSize	96tests/kit
The packing and labelling of the kit should be as per Drugs and Cosmetics Act, 1940 and applicablerulesthereunder	Yes

CERTIFICATIONS&REPORTS

The kit should have approval of the statutory authority in its country of origin and CDSCO/NIB,Noida	Yes
Imported kits shall be registered and licensedin India under the provisions of Drugs and Cosmetics act 1940 and Rules 1945 and/or medical device rules 2017 as amended till date DCG(I)	

Indigenous manufacturers should be licensedby the competent authority defined underDrugs and Cosmetics act 1940 and Rules 1945 and/or Medical Device Rules 2017 as amended till date DCG (I)	

Availability of valid drug license from competent authority defined under Drugs and CosmeticsAct,1940(Proofofthesametobe submittedtobuyerondemand)	Yes
DrugLicenseNumber	Yes
DrugLicenseDate	Yes
Manufacturercertifications(Proofofthesame tobesubmittedtothebuyerondemand)	ISO13485
GMP/WHOGMPCertificationNumber	Yes
GMP/WHOGMPCertificationDate	Yes
ISO13485CertifiedManufacturer(Proofof thesametobesubmittedtobuyerondemand)	Yes
ProductCertifications(Proofofthesametobe submittedtobuyerondemand)	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
CertificationNumber	Yes
CertificationDate	Yes
CertificationIssuingAuthority	Yes
Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specification (proof of the same to be submitted to the buyer ondemand)	Yes
Availability of Performance Evaluation Report (Proofofthesametobesubmittedtothebuyer ondemand)	Yes
PerformanceEvaluationReportissuingbody	
NameofthePerformanceEvaluationReport issuingbodyifotherthanspecifiedinstitute	

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	Minimum12months
The kit should have minimum residual shelflife of 5/6th or moreof the total shelf life at the timeofdeliverytotheconsignees	Yes

N.B:Itistheresponsibleofthebiddertoensuretheprogrammingof HIV,HBV and HCV ELISA kits in the existing ELISA Machines for smooth management ofTTI screening at the respective blood centres.

TECHNICALSPECIFICATIONSFORHCV/HBV/HIV(RAPID)Test Kits/VDRLKits

SpecificRequirement:

1. The supplier should supply 600 tests x 2 sets free of cost from each batch for random evaluation at the identified laboratories for pre-dispatch lot verification. Protocol of each batch is to be attached
2. A"ColdChainindicator"istobesuppliedwiththekitswiththefollowingspecification:
   i. Acumulativetime/temperatureindicatorshouldindicatetheexposureto temperature in the range of 2-8°C.
   ii. The cumulative time-temperature indicator technology used should be prequalified by WHO.
   iii. Theindicatorshouldchangecolouruniformly,irreversiblyandtherateof reaction should be predictable by appropriate kinetic parameters.
   iv. Thecolourchangeshouldhaveawell-definedstartpointandendpointthatcan be correlated to the heat stability of the kit.

HIV(I&II)RapidDiagnosticKit(S02177)

GENERALFEATURES

ProductDescription	HIVRapidTestKit
ClinicalPurpose	ToprovidediagnosisofHIVinfection

PRODUCTINFORMATION

Detects	HIV1Antibodies,HIV2Antibodies
The assay should have solid phase coated HIV 1 and HIV 2 recombinant and/or synthetic peptide antigens for detection of HIV 1 and HIV2.	Yes
Test can be performed on	WholeBlood/Serum/Plasma
Type of Kit	4th Generation
TypeofTest	Qualitative
TestingPrinciple	Immuno-chromatographic
ResultTime(minutes)	Within 30minutes
AbilitytoEvaluateNegativeorPositivetest result	Yes
TheAssayshouldhavesensitivityof≥99.5% andspecificityof≥98%	Yes
Containsaninternalcontrolband/dotforthe confirmation that the test has been performed correctly	Yes
The control dot/band shall be able to detect the presenceofhumanimmunoglobulinand shouldnotbejustaprocedural controlor meant merely for checking the flow of reagents orintegrityoftheantigenexceptinkitsusinglateralflowtechnology	Yes
Storagetemperature	2°Cto30°C
The supplier shall ensure maintenance of cold chain during storage and transportation of Kit at 2°C to 30°C and cumulative time temperature indicator technology shall be placed on every pack of kits and be pre-qualifiedbyWHO	Yes
The kit should comply with all provisions of Drugs and cosmetics Act, 1940 and applicablerulesthereunder	Yes

KITCONTENTS

Mainitemsintestkitforperformingthetest	Card
SampleDropperProvidedwitheachcard/device	Yes
Desiccanttoabsorbmoisturesothatthecarddonot getspoiledprovidedwitheachcard	Yes
SampleDiluent/AssayBufferProvided	Yes
Document detailing principle,component,antigendetail for antibody detection of HIV1,2&p24 antigen,biosafety,methodologies,validitycriteria,result interpretation, performance characteristic, assay	Yes

limitation, mfg,exp date, storage condition provided	
Individuallypackedsteriledisposablelancetsand disposablealcoholswabsprovidedwitheachtestkit	Yes
Otheraccessoriesandsparesprovidedifanyfor standardpackinthekit	50devices,2buffers,50 droppers,1packageinsert

PACKAGING

PackSize	50TestsPack
Thepackingandlabellingshouldbeasper Drugs and Cosmetics Act, 1940 and applicable rules there under	Yes
Eachcard(cassette)shouldhavespacefor patients'particularsanddateofthetest	Yes
The test kit should be packed in such a way that there is provision to conduct single test at atime	Yes
Eachtestkitshouldbeindividuallypackedina hermeticallysealedandnon-permeablepouch	Yes

CERTIFICATIONS&REPORTS

Thekitshouldhaveapprovalofthestatutory authorityinitscountryoforigin	Yes
ImportedkitsshallberegisteredandlicensedinIndiaundertheprovisionsofDrugsandCosmetics act 1940 and Rules 1945 and/or medical device rules 2017 as amended till date DCG(I)	Yes
Indigenous manufacturers should be licensedby the competent authority defined underDrugs and Cosmetics act 1940 and Rules 1945 and/or Medical Device Rules 2017 as amended tilldateDCG(I)	Yes
Manufacturercertifications–ISO13485/ GMP/WHOGMP/QMS/EU-CE	Yes
Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specification(proof of the same to be submitted to the buyer ondemand)	Yes
Availability of Performance Evaluation Report (Proofofthesametobesubmittedtothebuyer ondemand)	Yes

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	24
Thekitshouldhaveminimumresidualshelf life of 5/6th or more of the total shelf life at the time of delivery at the consignee	Yes

12.HBVRapidDiagnostictestKit(Serumbased)(S02178)

GENERALFEATURES

ProductDescription	HepatitisBSurfaceAntigen(HBsAg)Rapid TestKits
ClinicalPurpose	ToprovidediagnosisofHepatitisBVirusinfection

PRODUCTINFORMATION

Detects	HepatitisBSurfaceAntigen(HBsAg)
Shouldbesolidphase/particlecoatedwith monoclonalantibodiestoHBsAg	Yes
TestShouldbeabletodetectall11subtypeof HBsAg	Yes
Testcanbeperformedon	Serum
TypeofTest	Qualitative
Type of Kit	3rd Generation
TestingPrinciple	Immuno-chromatography
ResultTime(min)	Within 30minutes
AbilitytoEvaluateNegativeorPositivetest result	Yes
AssaySensitivity(%)	>99%
AssaySpecificity(%)	>99%
The control dot/band shall be able to detect the presenceofhumanimmunoglobulinand shouldnotbejustaprocedural controlor meant merely for checking the flow of reagents or integrity of the antigen except in kits using lateral flow technology	Yes
Storagetemperature	2°Cto30°C
The supplier shall ensure maintenance of cold chain during storage and transportation of Kit at 2°C to 30°C and cumulative time temperature indicator technology shall be placed on every box of kits and be pre-qualifiedbyWHO	Yes

Thekitshouldcomplywithallprovisionsof Drugs and cosmetics Act, 1940 and applicable rules there under	Yes

KITCONTENTS

Mainitemsintestkitforperformingthetest	Card
SampleDropperProvidedwitheachcard/strip	Yes
Desiccant to absorb moisture so that the Card/Strip do not get spoiled provided with eachcard	Yes
Adequate document detailing principle, components, methodologies, validity criteria, interpretation of result, performance characteristic, bio-safety, limitation of assay, storage condition, mfg, exp date & method of disposal provided with each kit	Yes
Individuallypackedsteriledisposablelancets anddisposablealcoholswabsprovidedwith each test kit	Yes
Otheraccessoriesandsparesprovidedifany forstandardpackinthekit	Yes

PACKAGING

PackSize	50TestsPack
Thepackingandlabellingshouldbeasper Drugs and Cosmetics Act, 1940 and applicable rules there under	Yes
Eachcard(cassette)shouldhavespacefor patients'particularsanddateofthetest	Yes
The test kit should be packed in such a waythat there is provision to conduct single test at atime	Yes
Eachtestkitshouldbeindividuallypackedina hermeticallysealedandnon-permeablepouch	Yes

CERTIFICATIONS&REPORTS

Thekitshouldhaveapprovalofthestatutory authorityinitscountryoforigin	Yes
Imported kits shall be registered and licensedin India under the provisions of Drugs and Cosmetics act 1940 and Rules 1945 and/or medical device rules 2017 as amended till date DCG(I)	NAfordomesticallymanufacturedkits

Indigenous manufacturers should be licensedby the competent authority defined underDrugs and Cosmetics act 1940 and Rules 1945 and/or Medical Device Rules 2017 as amended till date DCG(I)	Yes
Manufacturercertifications–ISO13485/ GMP/WHOGMP/QMS/EU-CE	Yes
Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specification (proof of the same to be submitted to the buyer ondemand)	Yes
Availability of Performance Evaluation Report (Proofofthesametobesubmittedtothebuyer ondemand)	Yes

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	24
Thekitshouldhaveminimumresidualshelf lifeof5/6thormoreofthetotalshelflifeatthe time of delivery at the consignee	Yes

13.VDRLRapidDiagnostictestKit(S02179)

GENERALFEATURES

ProductDescription	SyphilisRapidTestKits
ClinicalPurpose	Fordiagnosisofsyphilisinallstagesof infection by detecting antibodies to Treponema Pallidum

PRODUCTINFORMATION

ResultType	Qualitative
Type of kit	3rd Generation
Detects	Totalanti-treponemalantibody(IgG&IgM)
The assay shall have solid phase coated with syntheticorrecombinanttypeofTreponema Pallidumantigens	Yes
TestingPrinciple	Lateralflowchromatographicimmunoassay
Specimenrequiredfortesting	WholeBlood

ResultTime	Within30minutes
Sensitivity	≥95%
Specificity	≥95%
Containsaninternalcontrollineforthe confirmation that the test has been performed correctly	Yes
The assay calibrated to WHO reference serum and the same shall be supported by statements in kit insert and certificate from the manufacturer	Yes
Storagetemperature	RoomTemperature

KITCONTENTS

Mainitemintestkitforperformingthetest	Card
Desiccanttoabsorbmoisturesothatthe Card/stripdonotgetspoiledprovided	Yes
Disposable sample dropper/capillary pipettefor collection of blood sample and transfer the sample to the test site provided with each card/strip	Yes
SampleDiluent/AssayBufferProvided	Yes
Reactiveandnonreactivecontrolsprovided (minimum10%ofPacksize)	Yes
Eachtestcard/stripsuppliedwithsterileauto retractabledisposablelancet	Yes
Eachtestcard/stripsuppliedwithalcohol soakedswabs	Yes
Adequate literature in English detailing principle, components, methodologies, validity criteria, bio- safety, performancecharacteristics, storage conditions, limitation of assay, manufacture and expiry dates and methodsofdisposaltobeprovided	Yes

PACKAGING

PackSize	50TestsPack
Thetestkitpackedinsuchawaythatthereis provisiontoconductsingletestatatime	Yes
Eachtestcard/stripindividuallypackedina hermeticallysealedandnon-permeablepouch	Yes

CERTIFICATIONS&REPORTS

Kitapprovedfromthestatutoryauthorityinits countryoforigin	Yes

Imported Kits registered and licensed in India by Central Drugs Standard Control Organization(CDSCO)	
Indigenous manufacturers licensed by the competent authority defined under Drugs and Cosmetics Act, 1940 and Rules, 1945 after appropriate evaluation by the centers approved by Central Drugs Standard Control Organization(CDSCO)	
Availability of valid drug license for the product issued from competent authority defined under Drugs and Cosmetics Act, 1940 and Rules, 1945 (Manufacture for sale license in case of OEM or sale license in case of authorizedreseller)	Yes
Manufacturer certifications–QMS/ CE	Yes
Availability of Test report of each batch to be supplied from central GOVT/NABL/ILAC accredited Lab as well inhouse test report from manufacturer to prove conformity to the declaredspecifications	Yes
KitevaluatedfromNationalInstituteof Biologicals(NIB)	Yes
Submission of all necessary certifications, licenses and test reports to the buyer along withsupplies	Yes

SHELFLIFE

Shelflifefromthedateofmanufacture	Minimum12months
The product should have at least5/6thor more ofthetotalshelflifeatthetimeofdeliveryto theconsignees	Yes

ADVANCESAMPLE

Agree to provide advance sample of the Kit for buyer's approval before commencement of bulksupply	Yes

14.HCVRapidTestKit(S02180)

GENERALFEATURES

ProductDescription	HepatitisCVirus(HCV)RapidTestKit
ClinicalPurpose	ToprovidediagnosisofHepatitisCVirus infection

PRODUCTINFORMATION

Detects	AntibodiesspecifictoHepatitisCVirus
TypeofKit	3rd Generation
Should be solid phase / particle coated with recombinant and / or synthetic peptide antigens forCore,NS3,NS4,andNS5	Yes
Testcanbeperformedon	Serum
TypeofTest	Qualitative
TestingPrinciple	Lateralflowchromatographicimmunoassay
ResultTime	20-30 minutes
AbilitytoEvaluateNegativeorPositivetest result	Yes
Sensitivity(%)	>99percent
Specificity(%)	>99percent
The control dot/band shall be able to detect the presence of human immunoglobulin and shouldnotbejustaproceduralcontrolormeant merely for checking the flow of reagents or integrity of the antigen except in kits using lateralflowtechnology	Yes
Storagetemperature	2°Cto30°C
The supplier shall ensure maintenance of cold chain during storage and transportation of Kit at 2°C to 30°C and cumulative time temperature indicator technology shall be placed on every box of kits and be pre-qualifiedbyWHO	Yes
Thekitshouldcomplywithallprovisionsof Drugs and cosmetics Act, 1940 and applicable rules there under	Yes

KITCONTENTS

Mainitemsintestkitforperformingthetest	Card
SampleDropperProvidedwitheachcard/strip	Yes

Desiccanttoabsorbmoisturesothatthe Card/Strip do not get spoiled provided with each card	Yes
SampleDiluent/AssayBufferProvided	Yes
Adequate document detailing principle, components, methodologies, validity criteria, interpretation of result, performance characteristic, bio-safety, limitation of assay, storage condition, mfg, exp date & method of disposalprovidedwitheachkit	Yes
Individually packed sterile disposable lancets and disposable alcohol swabs provided with eachtestkit	Yes
Otheraccessoriesandsparesprovidedifany forstandardpackinthekit	Yes

PACKAGING

PackSize	50TestsPack
Thepackingandlabellingshouldbeasper Drugs and Cosmetics Act, 1940 and applicable rules there under	Yes
Eachcard(cassette)shouldhavespacefor patients'particularsanddateofthetest	Yes
Thetestkitshouldbepackedinsuchaway that there is provision to conduct single test at a time	Yes
Eachtestkitshouldbeindividuallypackedina hermeticallysealedandnon-permeablepouch	Yes

CERTIFICATIONS&REPORTS

Thekitshouldhaveapprovalofthestatutoryauthority initscountryoforigin	Yes
Imported kits shall be registered and licensedin India under the provisions of Drugs and Cosmetics act 1940 and Rules 1945 and/or medical device rules 2017 as amended till date (DCGI)	Yes
Indigenous manufacturers should be licensedby the competent authority defined underDrugs and Cosmetics act 1940 and Rules 1945 and/or Medical Device Rules 2017 as amended tilldate(DCGI)	Yes
Manufacturercertifications–ISO13485/ GMP/WHOGMP/QMS/EU-CE	Yes

Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specification (proof of the same to be submitted to the buyer ondemand)	Yes
Availability of Performance Evaluation Report (Proofofthesametobesubmittedtothebuyer ondemand)	Yes

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	24
The kit should have minimum residual shelflife of 5/6th or more of the total shelf life at the timeofdeliveryattheconsignee	Yes

Inspection&Tests:

Thefollowinginspectionproceduresandtestsarerequiredbythe Purchaser.

a. The supplier should supply 600 tests x 2 sets free of cost from each batch for random evaluationattheidentifiedlaboratoriesforpre-dispatchlotverification.Protocolof each batch is to be attached
b. One set of sealed sample will be sent to an independent laboratory selected by the purchaserfor conductingtherequiredtesttoconfirmwhetherthesamplesconformto the prescribed specification. Another set of sealed sample will be retained with thetesting lab as counter sample till the shelf life.
c. Inspection note will be issued by the inspector on the basis of test report, accepting or rejecting the batch as the case may be.
d. The goods will be dispatched only after the above inspection procedure has beenfollowed and inspection note issued to accept the consignment.
e. After receipt, the consignee shall have the right to draw samples at random from the

consignment and get them retested to satisfy whether the lots conform to the laid down specifications. In the event of the product failing to conform to specifications, the consignee shall reject that batch of supply and inform the supplier for arranging replacement of the rejected batches at supplier's cost.

ProductandPackageSpecifications:

1. The required packing standards and labelling must meet the requirements given in this Technical Specification and Part.
2. Not only the Goods but also the packaging components should also meet specifications suitableforuseinaclimatesimilartothatprevailinginthecountryofthePurchaser. All packaging must be properly sealed and tampered-proof.
3. Alllabelling andpackaginginsertsshallbeinthe languagerequestedby thePurchaser or English if not otherwise stated
4. Goods requiring refrigeration or freezing for stability must specifically indicate storage requirements on labels and containers and be shipped in special containers to ensure stability in transit from point of shipment to port of entry.
5. 1.5.Upon award,thesuccessful Supplier shall,on demand,providea translated version in the language of the bid of the prescriber's information for any specific goods the Purchaser may request

11. ProductInformation:

a. Thefollowing informationwill berequiredfor eachpharmaceutical productofferedby the Bidder:

i. InternationalNon-ProprietaryName(INN),ifapplicable;
ii. BrandName(ifitappearsonlabel);
iii. Nameandaddressofthemanufacturer;
iv. Countryoforigin;and
v. Compendiastandards

b. Uponaward,thesuppliershall,ondemand,provideatranslatedversioninEnglish,o

f the prescriber's information for any specific product, the Purchaser may request.

c. Failure to include any of this information, at the discretion of the Purchaser, may renderthe bid non-responsive.

3. ExpirationDate:

3.1. Allproductsmustindicatethedatesofmanufactureandexpiry

4. Recalls

4.1. If products must be recalled because of problems with product quality as a result of quality check carried out during the life span of the drug or adverse reactions to the pharmaceutical, the supplierwillbeobligatedtonotifythepurchaserprovidingfulldetailsaboutthereasonleading to the recalland shalltakesteps to replace the product in question at its own cost with a fresh batch of acceptable pharmaceuticals, or withdraw and give a full refund if the product has beentake off the market due to safety problems.

5. LabellingInstructions

5.1The label for each Goods shall include: (a) the Purchaser's logo and code number and any specific color coding if required (b) content per pack (c) instructions for use (d) special storage requirements (e) batch number (f) date of manufacture and date of expiry (in clear language, not code) (g) name and address of manufacture with license number (h) any additional cautionary statement.

5.2.Theoutercaseorcartonshouldalsodisplaytheaboveinformation

6. DetailsofPacking/Cases

6.1. Allcasesshouldprominentlyindicatethefollowing:

i) Thegenericnameoftheproduct;

ii) Dateofmanufactureandexpiry(inclearlanguagenotcode);

iii) Batchnumber

iv) Quantitypercase.

6.2. Nocaseshouldcontaindrugsfrommorethanonebatch.

7. UniqueIdentifier

7.1. The Purchaser shall have the right to request the Supplier to imprint a logo on the containers usedforpackagingandincertaindosageformssuchastabletsandthiswillbeindicatedinPart AoftheTechnicalSpecifications.Thedesignofsuchlogoshallbeprovidedtothesupplierat the time of Contract award.

8. QualificationsofManufacturer

8.1. The bidder shall furnish a certificate from the competent FDRA that the manufacturer of thepharmaceutical or vaccine product covered by this

9. StandardsandQualityAssuranceRequirements

9.1. Allproductsmust:

(a) Meet the requirements of manufacturing legislation and regulation of pharmaceuticals or vaccines in the country of origin;

(b) Conformtoallthespecificationscontainedherein;and

(c) Must undergo strict raw material inspection,in process checks, appropriate material handlingto eliminate cross contamination (of molecules) and final product testing to ensure quality and consistency of the products.

9.2. TheBidderisrequiredtofurnishtothePurchaser:

(a) With each consignment, a certificate of quality assurance test results concerning quantitative assay,chemicalanalysisandothertests,asapplicabletotheproductbeingsuppliedandPartA of these Specifications.

(b) Assaymethodologyofanyoralltestsifrequested.

(c) Evidence of basis for expiration dates and other stability data on the offered package (as per climatic conditions prevalentin India) concerning the commercial final packageupon request.

(d) Packageintegritytestresults.

9.3. The Bidder will also be required to provide the purchaser with access to its manufacturing facilities to inspect its facilities, quality control procedures for raw materials, test methods, in-process tests, and finished Goods.

Specificationfor Reagents/Anti-sera

15.D48001-Anti–D(IgMonly)fortubeandslidemethod

GENERALFEATURES

TypeofBloodGroupingSera/Reagent	Anti-DGroupingSeraIgM
ClinicalPurpose	ForRhBloodTyping
AntibodyType	Monoclonal
Suitablefor	SlideMethod,TubeMethod
Anti-Dreagentshouldbecapableofdetecting all weak and partial D	Yes
Titre should be ≥ 1:64 with D positive cell in immediate spin and ≥ 1:128 after 30-40 minutesincubation	Yes
Readytousereagentcontainingantibodies specifictothe'D'antigenonRBC	Yes
DropperProvided	Yes
Reagentshouldhaveavidityless than10 seconds	5-10seconds
Shouldnothaemolyzecellsorproducerouleux	Yes
StorageTemperature	2°Cto8°C
It should give easily observable agglutination reaction with antigen positive cells and clear absence of agglutination reaction in antigen negativecells	Yes
Reagent should meet the standards approved by USFDA/CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity, avidity, affinity and titerstrength	Yes
Reagent should meet the standards mentioned in the technical manual for blood banks approvedbytheMOHFW,GOI	Yes
AllProvisionsofDrugsandCosmeticsAct, 1940 as amended till Date and rules made there under will always be applicable	Yes

CERTIFICATIONS&REPORTS

Availability of valid drug license issued from competentauthoritydefinedunderDrugsand Cosmetics Act, 1940 (copy of the same to be submitted to buyer on demand)	Yes
DrugLicenseNumber	Yes
DrugLicenseDate	Yes
Manufacturercertifications-ISO 13485/GMP/WHOGMP/QMS	Yes
CertificationNumber	Yes
CertificationDate	Yes
ProductCertification(copyofthesametobe submitted to buyer on demand if certification is available)	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
ProductCertificationNumber	Yes
ProductCertificationDate	Yes
CertificateissuingAuthority	Yes
AvailabilityofTestreportfromCentralGOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specifications (copy of the same to besubmittedtothebuyerondemand)	Yes
Evaluated and approved by National Institute of Biologicals (NIB) (copy of the same to be submittedtothebuyerondemand)	Yes

PACKAGINGANDLABELING

PackingType	Vial
Packsize	10ml
NumberofVialsinonepack	1
Packaginginsertprovided	Yes
Each vial should be labeled as per provisions givenforlabelinginDrugsandcosmeticsact 1940andrulesmadethereunder	Yes

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	24
The product should have at least 3/4 of the totalshelflifeatthetimeofdispatchtothe consignee	Yes

16. D48002 - Anti- D, IgM and IgG combination, Monoclonal IgM andIgG

blood typingantibodies for slide and tube method

GENERALFEATURES

TypeofBloodGroupingSera/Reagent	Anti-DGroupingSera(IgM+IgG)
ClinicalPurpose	ForRhBloodTyping
AntibodyType	Monoclonal
Suitablefor	TubeMethod,SlideMethod,Microplate method
Anti-Dreagentshouldbecapableofdetecting allweakandpartialD at 37 degree temperature	Yes
Titreshouldbe≥1:32withDpositivecellin immediate spin and ≥ 1:128 after 30-40 minutes incubation	Yes
Readytousereagentcontainingantibodies specifictothe'D'antigenonRBC	Yes
DropperProvided	Yes
Reagentshouldhaveaviditylessthan10 seconds	10-20seconds
Shouldnothemolyzecellsorproducerouleux	Yes
StorageTemperature	2°Cto8°C
It should give easily observable agglutination reaction with antigen positive cells and clear absence of agglutination reaction in antigen negativecells	Yes
Reagent should meet the standards approved by USFDA/CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity, avidity, affinity and titerstrength	Yes
Reagentshouldmeetthestandardsmentioned in the technical manual for blood banks approved by the MOHFW, GOI	Yes
All Provisions of Drugs and Cosmetics Act, 1940 as amended till Date and rules made there underwillalwaysbeapplicable	Yes

CERTIFICATIONS&REPORTS

Availability of valid drug license issued from competent authority defined under Drugs and Cosmetics Act, 1940 (copy of the same to be submittedtobuyerondemand)	Yes
DrugLicenseNumber	Yes
DrugLicenseDate	Yes
Manufacturercertifications-ISO 13485/GMP/WHOGMP/QMS	Yes
CertificationNumber	Yes
CertificationDate	Yes
Product Certification (copy of the same to be submitted to buyer on demand if certification is available)	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
ProductCertificationNumber	Yes
ProductCertificationDate	Yes
CertificateissuingAuthority	Yes
Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specifications (copy of the same to besubmittedtothebuyerondemand)	Yes
EvaluatedandapprovedbyNationalInstituteofBiologicals(NIB)(copyofthesametobe submittedtothebuyerondemand)	Yes

PACKAGINGANDLABELING

PackingType	Vial
Packsize	10ml
NumberofVialsinonepack	1
Packaginginsertprovided	Yes
Eachvialshouldbelabeledasperprovisions given for labeling in Drugs and cosmetics act 1940 and rules made there under	Yes

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	24
The product should have at least 3/4 of the totalshelflifeatthetimeofdispatchtothe consignee	Yes

17. **D48003-Anti-A,MonoclonalbloodgroupingIgMantibodyforslide and tube method.**

GENERALFEATURES

TypeofBloodGroupingSera/Reagent	Anti-AGroupingSeraIgM
ClinicalPurpose	ForABOBloodGrouping
AntibodyType	Monoclonal
Suitablefor	TubeMethod,SlideMethod,Microplate method
Readytousereagentcontainingantibodies specifictothe'A'antigenonRBC	Yes
Titre	≥1:256withA1cellandnegativewithBCell and O Cell
DropperProvided	Yes
Reagentshouldhaveavidityless than4 seconds	3-4seconds
Shouldnothemolyzecellsorproducerouleux	Yes
StorageTemperature	2°Cto8°C
It should give easily observable agglutination reaction with antigen positive cells and clear absence of agglutination reaction in antigen negative cells	Yes
Reagent should meet the standards approved by USFDA/CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity, avidity, affinity and titer strength	Yes
Reagentshouldmeetthestandardsmentioned inthetechnicalmanualforbloodbanksapprovedbyth eMOHFW,GOI	Yes

All Provisions of Drugs and Cosmetics Act, 1940 as amended till Date and rules made there underwillalwaysbeapplicable	Yes

PACKAGINGANDLABELING

PackingType	Vial
Packsize	10ml
NumberofVialsinonepack	1
Packaginginsertprovided	Yes
Eachvialshouldbelabeledasperprovisions given for labeling in Drugs and cosmetics act 1940 and rules made there under	Yes

CERTIFICATIONS&REPORTS

Availability of valid drug license issued from competent authority defined under Drugs and Cosmetics Act, 1940 (copy of the same to be submittedtobuyerondemand)	ForManufacture
DrugLicenseNumber	Yes
DrugLicenseDate	Yes
Manufacturercertifications-ISO 13485/GMP/WHOGMP/QMS	Yes
CertificationNumber	Yes
CertificationDate	Yes
Product Certification (copy of the same to be submittedtobuyerondemandifcertification isavailable)	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
ProductCertificationNumber	Yes
ProductCertificationDate	Yes
CertificateissuingAuthority	Yes
Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specifications (copy of the same to be submitted to the buyer on demand)	Yes
EvaluatedandapprovedbyNationalInstitute of Biologicals (NIB) (copy of the same to be submitted to the buyer on demand)	Yes

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	24
Theproductshouldhaveatleast3/4ofthe Totalshelflifeatthetimeofdispatchtothe consignee	Yes

18. D48004-Anti-A1,lectinfortubeandslidemethod.

GENERALFEATURES

TypeofBloodGroupingSera/Reagent	Anti-A1(Lectin)
ClinicalPurpose	TodetectA1redcellantigenfromA2 subgroup
Type	Lectin
Suitablefor	TubeMethod,SlideMethod
Titre	≥1:8
Readytousereagent	Yes
DropperProvided	Yes
Reagentshouldhaveavidityless than4 seconds	Yes
Shouldnothemolyzecellsorproducerouleux	Yes
StorageTemperature	2°Cto8°C
It should give easily observable agglutination reaction with antigen positive cells and clear absence of agglutination reaction in antigen negativecells	Yes
Reagent should meet the standards approved by USFDA/CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity, avidity, affinity and titerstrength	Yes
Reagent should meet the standards mentioned in the technical manual for blood banks approvedbytheMOHFW,GOI	Yes
All Provisions of Drugs and Cosmetics Act, 1940 as amended till Date and rules made there underwillalwaysbeapplicable	Yes

CERTIFICATIONS&REPORTS

Availability of valid drug license issued from competent authority defined under Drugs and Cosmetics Act, 1940 (copy of the same to be submittedtobuyerondemand)	Yes
DrugLicenseNumber	Yes
DrugLicenseDate	Yes
Manufacturercertifications(copyofthesame tobesubmittedtothebuyerondemand)	ISO13485,GMP/WHOGMP
CertificationNumber	Yes
CertificationDate	Yes
ProductCertification(copyofthesametobe submittedtobuyerondemandifcertification is available)	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
ProductCertificationNumber	Yes
ProductCertificationDate	Yes
CertificateissuingAuthority	Yes
Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specifications (copy	Yes

of the same to be submitted to the buyer ondemand)	
Evaluated and approved by National Institute of Biologicals (NIB) (copy of the same to be submittedtothebuyerondemand)	Yes

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	24
Theproductshouldhaveatleast3/4ofthe total shelf life at the time of dispatch to the consignee	Yes

PACKAGINGANDLABELING

PackingType	Vial
Packsize	5ml
NumberofVialsinonepack	1
Packaginginsertprovided	Yes
Eachvialshouldbelabeledasperprovisions given for labeling in Drugs and cosmetics act 1940 and rules made there under	Yes

19. D48005 -Anti-AB,MonoclonalIgMantibodyforslideandtubemethod.

GENERALFEATURES

TypeofBloodGroupingSera/Reagent	Anti-ABGroupingSeraIgM
ClinicalPurpose	ForABOBloodGrouping
AntibodyType	Monoclonal
Suitablefor	TubeMethod,SlideMethod,Microplate method
Readytousereagentcontainingantibodies specificto'A'and'B'antigensonRBC and no reaction with O Cell	Yes
Titre	≥1:256withA1cellandBcell and no reaction with O Cell
DropperProvided	Yes
Reagentshouldhaveavidityless than4 seconds	Yes
Shouldnothemolyzecellsorproducerouleux	Yes
StorageTemperature	2°Cto8°C
It should give easily observable agglutination reaction with antigen positive cells and clear absence of agglutination reaction in antigen negativecells	Yes
Reagent should meet the standards approved by USFDA/CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity, avidity, affinity and titerstrength	Yes
Reagentshouldmeetthestandardsmentioned in the technical manual for blood banks approved by the MOHFW, GOI	Yes

All Provisions of Drugs and Cosmetics Act, 1940 as amended till Date and rules made there underwillalwaysbeapplicable	Yes

PACKAGINGANDLABELING

PackingType	Vial
Packsize	10ml
NumberofVialsinonepack	1
Packaginginsertprovided	Yes
Each vial should be labelled as per provisions givenforlabellinginDrugsandcosmeticsact 1940andrulesmadethereunder	Yes

CERTIFICATIONS&REPORTS

Availability of valid drug license issued from competent authority defined under Drugs and Cosmetics Act, 1940 (copy of the same to be submittedtobuyerondemand)	Yes
DrugLicenseNumber	Yes
DrugLicenseDate	Yes
Manufacturercertifications-ISO 13485/GMP/WHOGMP/QMS	Yes
Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specifications (copy of the same to be submittedtothebuyerondemand)	Yes
EvaluatedandapprovedbyNationalInstitute of Biologicals (NIB) (copy of the same to be submitted to the buyer on demand)	Yes

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	24
The product should have at least 3/4 of the totalshelflifeatthetimeofdispatchtothe consignee	Yes

20. D48006-Anti-B,Monoclonalblood groupingIgM antibodyforslide and tube method.

GENERALFEATURES

TypeofBloodGroupingSera/Reagent	Anti-BGroupingSeraIgM
ClinicalPurpose	ForABOBloodGrouping
AntibodyType	Monoclonal
Suitablefor	TubeMethod,SlideMethod,Microplate method
Readytousereagentcontainingantibodies specifictothe'B'antigenonRBC	Yes
Titre	≥1:256withBcellandnegativewithA1cell and O Cell
DropperProvided	Yes
Reagentshouldhaveavidityslessthan4 seconds	Yes
Shouldnothemolyzecellsorproducerouleux	Yes

StorageTemperature	2°Cto8°C
It should give easily observable agglutination reaction with antigen positive cells and clear absence of agglutination reaction in antigen negativecells	Yes
Reagent should meet the standards approved by USFDA/CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity, avidity, affinity and titerstrength	Yes
Reagentshouldmeetthestandardsmentioned in the technical manual for blood banks approved by the MOHFW, GOI	Yes
AllProvisionsofDrugsandCosmeticsAct, 1940 as amended till Date and rules made there under will always be applicable	Yes

CERTIFICATIONS&REPORTS

Availability of valid drug license issued from competent authority defined under Drugs and Cosmetics Act, 1940 (copy of the same to be submittedtobuyerondemand)	Yes
DrugLicenseNumber	Yes
DrugLicenseDate	Yes
Manufacturercertifications-ISO 13485/GMP/WHOGMP/QMS	Yes
CertificationNumber	Yes
CertificationDate	Yes
Product Certification (copy of the same to be submittedtobuyerondemandifcertification isavailable)	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
ProductCertificationNumber	Yes
ProductCertificationDate	Yes
CertificateissuingAuthority	Yes
Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specifications (copy of the same to besubmittedtothebuyerondemand)	Yes
EvaluatedandapprovedbyNationalInstitute of Biologicals (NIB) (copy of the same to be submitted to the buyer on demand)	Yes

SHELFLIFE

ShelfLifefromthedateofmanufacture(in months)	Minimum24months
The product should have atleast 3/4 of the total shelf life at the time of dispatch to the consignee	Yes

PACKAGINGANDLABELING

PackingType	Vial
Packsize	10ml
NumberofVialsinonepack	1
Packaginginsertprovided	Yes
Eachvialshouldbelabeledasperprovisions given for labeling in Drugs and cosmetics act 1940 and rules made there under	Yes

21. D48007 - Anti- Human Globulin (Green), polyspecific, containinganti – IgG and anti C3d to detect IgG Antibodies in DAT and IATtests

GENERALFEATURES

ProductDescription	Anti-HumanGlobulin(AHG)Sera
ClinicalPurpose	ForuseinDirectandIndirectAnti-Human GlobulinTests

PRODUCTION FORMATION

TypeofAntiHumanGlobulin(AHG)Sera	PolyspecificAntiHumanGlobulin(AHG)seraAnti-IgG+AntiC3d
AntibodyType	Monoclonal
Suitablefor	TubeMethod, Micro-plateMethod
DropperProvided	Yes
Shallnothemolyzecellsorproducerouleaux	Yes
Appropriately givesclearpositivereactionswith O Rh D positive sensitizedcells	Yes
Givesclearnegativereactionswith unsensitizedcells	Yes
MinimumTitreforIgG	1:64
MinimumTitreforC3d	1:4
StorageTemperature	2-80C
The supplier shall ensure maintenance of cold chainduringstorageandtransportationofKit atrecommendedtemperature	Yes
Coldchainindicatortobeprovided	Yes

PACKAGING AND LABELING

Packsize	5mlvial
PackaginginsertinEnglishtobeprovided	Yes

CERTIFICATIONS & REPORTS

Availability of valid drug license issued from competent authority defined under Drugs and Cosmetics Act, 1940 (Manufacturing license in case of OEM or sale license in case of AuthorizedReseller)	Yes
DrugLicenseNumber	Yes
OtherProductCertification	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
Manufacturercertifications	ISO:13485
Meets the standards as mentioned in the technical manual for blood banks approved by theMOHFW,GOI	Yes

Meets the standards approved by USFDA/CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity,avidity,affinityandtitrestrength	Yes
Availability of Test report/CoA of each batchof the product to be supplied from Central GOVT/NABL/ILAC accredited Lab as well as inhouse test report to prove the conformity to thedeclaredspecifications	Yes
EvaluatedandapprovedbyNationalInstitute ofBiologicals(NIB)	Yes
Submissionofallnecessarycertifications, licensesandtestreportstothebuyeralong with supplies	Yes

SHELF LIFE

Shelflifefromthedateofmanufacture	24months
The product shall have at least 3/4 of the total shelf life at the time of delivery to the consignee	Yes

ADVANCE SAMPLE

Agree to provide advance sample of the product for buyer's approval before commencementofbulksupply	Yes

22. D48008- Anti HumanGlobulin,Monospecific,containing Anti-IgGto detect IgG antibodies in DAT

GENERAL FEATURES

ProductDescription	Anti-HumanGlobulin(AHG)Sera
ClinicalPurpose	ForuseinDirectAnti-HumanGlobulinTests

PRODUCTION FORMATION

TypeofAntiHumanGlobulin(AHG)Sera	MonospecificAntiHumanGlobulin(AHG) seraAnti-IgG
AntibodyType	Monoclonal
Suitablefor	TubeMethod, Micro-plateMethod
DropperProvided	Yes
Shallnothemolyzecellsorproducerouleaux	Yes
Givesclearpositivereactionswith O Rh D positive sensitizedcells	Yes
Givesclearnegativereactionswith unsensitizedcells	Yes
MinimumTitreforIgG	1:64
MinimumTitreforC3d	NAformono-specificIgGAHGSera
StorageTemperature	2-8^{0}C
Thesuppliershallensuremaintenanceofcold chain during storage and transportation of Kit at recommended temperature	Yes
Coldchainindicatortobeprovided	Yes

PACKAGING AND LABELING

Packsize	5mlvial
PackaginginsertinEnglishtobeprovided	Yes

CERTIFICATIONS & REPORTS

Availabilityofvaliddruglicenseissuedfrom competentauthoritydefinedunderDrugsand	Yes
Cosmetics Act, 1940 (Manufacturing license in case of OEM or sale license in case of AuthorizedReseller)	
DrugLicenseNumber	Yes
OtherProductCertification	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
Manufacturercertifications	ISO:13485
Meets the standards as mentioned in the technical manual for blood banks approved by theMOHFW,GOI	Yes
Meets the standards approved by USFDA/CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity,avidity,affinityandtitrestrength	Yes
Availability of Test report/CoA of each batchof the product to be supplied from Central GOVT/NABL/ILAC accredited Lab as well as inhouse test report to prove the conformity to thedeclaredspecifications	Yes
EvaluatedandapprovedbyNationalInstitute ofBiologicals(NIB)	Yes
Submissionofallnecessarycertifications, licenses and test reports to the buyer along with supplies	Yes

SHELF LIFE

Shelflifefromthedateofmanufacture	24month
Theproductshallhaveatleast3/4ofthetotal shelf life at the time of delivery to the consignee	Yes

ADVANCE SAMPLE

Agreetoprovideadvancesampleofthe product for buyer's approval before commencement of bulk supply	Yes

23. D48009 - Anti Human Globulin, Monospecific, containing Anti-C3dto detect C3d in DAT test.

GENERALFEATURES

ProductDescription	Anti-HumanGlobulin(AHG)Sera
ClinicalPurpose	ForuseinDirectAnti-HumanGlobulinTests

PRODUCTION FORMATION

TypeofAntiHumanGlobulin(AHG)Sera	MonospecificAntiHumanGlobulin(AHG) seraAnti-C3d
AntibodyType	Monoclonal
Suitablefor	TubeMethod, Micro-plateMethod
DropperProvided	Yes
Shallnothemolyzecellsorproducerouleaux	Yes
Givesclearpositivereactionswith appropriatelysensitizedcells	Yes
Givesclearnegativereactionswith unsensitizedcells	Yes
MinimumTitreforIgG	NAformono-specificC3dAHGSera
MinimumTitreforC3d	1:4
StorageTemperature	2-8^{O}C
The supplier shall ensure maintenance of cold chainduringstorageandtransportationofKit atrecommendedtemperature	Yes
Coldchainindicatortobeprovided	Yes

PACKAGING AND LABELING

Packsize	5mlvial
PackaginginsertinEnglishtobeprovided	Yes

CERTIFICATIONS & REPORTS

Availability of valid drug license issued from competent authority defined under Drugs and Cosmetics Act, 1940 (Manufacturing license in case of OEM or sale license in case of AuthorizedReseller)	Yes
DrugLicenseNumber	Yes
OtherProductCertification	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
Manufacturercertifications	ISO:13485
Meetsthestandardsasmentionedinthe technical manual for blood banks approved by the MOHFW, GOI	Yes
Meets the standards approved by USFDA/CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity,avidity,affinityandtitrestrength	Yes
Availability of Test report/CoA of each batchof the product to be supplied from Central GOVT/NABL/ILAC accredited Lab as well as inhouse test report to prove the conformity to thedeclaredspecifications	Yes
EvaluatedandapprovedbyNationalInstitute	Yes

ofBiologicals(NIB)	
Submission of all necessary certifications, licenses and test reports to the buyer along withsupplies	Yes

SHELF LIFE

Shelflifefromthedateofmanufacture	24month
The product shall have at least 3/4 of the total shelf life at the time of delivery to the consignee	Yes

ADVANCE SAMPLE

Agree to provide advance sample of the product for buyer's approval before commencementofbulksupply	Yes

24. D48010-BovineserumAlbuminwithDropper

Packaging

PackagingType	GlassBottle
ManufactureandExpiryDatePrintedonLabel	Yes
Shelflife	24month
Packagingsize	10ml

Physical And Chemical Characteristics

Diffusionconstant,D20,W×10−7cm2/s	5.9
Meanresidueellipticity	21.1[θ]209nm;20.1[θ]222nm
PhysicalState	Liquid
Estimatedb-form,%	18
Intrinsicviscosity,η	0.0413
CASNumber	9048-46-8
Refractiveindexincrement(578nm)10−3	1.9
Isoelectricpointinwaterat25C	4.7
Molecularweight	66,463Da(=66.5kDa)
Albuminpurity	>97%
pHof1%Solution	7.1(±0.2)
Solubility	WaterSoluble
Meanresiduerotation,[m']233	8443
Frictionalratio,f/f0	1.3
Numberofaminoacidresidues	583
Odor	Odorless
Wastetype	Non-Hazardous
Opticalabsorbance,A279nm1g/L	0.667
Overalldimensions,1	40X140
Sedimentationconstant,S20,W1013	4.5(monomer),6.7(dimer)
Appearance	Lightgreen
Bulkdensity,kg/m3	150
OpticalRotation	[alpha]259:-61;[ailpha]264:-63
Estimateda-helix,%	54
Partialspecificvolume,V20	0.733
StokesRadius	3.48nanometer
ProteinConcentration	22%

Disposal Measures

Disposal	Disposeinaccordancewithlocal,state,and federalregulations

Test Reports and Certifications

TestReporttobesubmittedtotheBuyeron Demand	Yes
IsISOCertified	
Availability of Test Report from Central Govt/NABL/ILAC accredited lab to prove conformitytospecification	Yes

25. D48011–Anti–HLectin with Dropper

GENERAL FEATURES

TypeofBloodGroupingSera/Reagent	Anti-Hlectin (Bombay)
ClinicalPurpose	ForDetectionofHAntigenonHumanRed Cell
Type	Lectin
Suitablefor	TubeMethod,SlideMethod,Microplate method
Readytousereagentspecifictothe'H'antigenonRBC	Yes
Titre	Negativereactionwithredbloodcellsof Bombaygroup
DropperProvided	Yes
Reagentshouldhaveaviditylessthan4 seconds	Yes
Shouldnothemolyzecellsorproducerouleux	Yes
StorageTemperature	2°Cto8°C
It should give easily observable agglutination reaction with antigen positive cells and clear absence of agglutination reaction in antigen negativecells	Yes
Reagent should meet the standards approved by USFDA/CDSCO/NIB for blood bank reagents with respect to appearance, color, sensitivity, specificity, avidity, affinity and titerstrength	Yes
Reagent should meet the standards mentioned in the technical manual for blood banks approvedbytheMOHFW,GOI	Yes
AllProvisionsofDrugsandCosmeticsAct, 1940 as amended till Date and rules made there under will always be applicable	Yes

CERTIFICATIONS & REPORTS

Availability of valid drug license issued from competentauthoritydefinedunderDrugsand Cosmetics Act, 1940 (copy of the same to be submitted to buyer on demand)	Yes
DrugLicenseNumber	Yes
DrugLicenseDate	Yes
Manufacturercertifications-ISO13485/ GMP/WHOGMP/QMS	Yes
CertificationNumber	Yes
CertificationDate	Yes

ProductCertification(copyofthesametobe submitted to buyer on demand if certification is available)	Yes
FourdigitnumberofnotifiedbodyIfproduct isEU-CEcertified	Yes
ProductCertificationNumber	Yes
ProductCertificationDate	Yes
CertificateissuingAuthority	Yes
Availability of Test report from Central GOVT/NABL/ILAC accredited Lab to prove the conformity to the declared specifications(copy of the same to be submittedtothebuyerondemand)	Yes
Evaluated and approved by National Institute of Biologicals (NIB) (copy of the same to be submittedtothebuyerondemand)	Yes

SHELF LIFE

ShelfLifefromthedateofmanufacture(in months)	Minimum24months
Theproductshouldhaveatleast3/4ofthetotalshelflifeatthetimeofdispatchtothe consignee	Yes

PACKAGING AND LABELING

PackingType	Vial
Packsize	5ml
NumberofVialsinonepack	1
Packaginginsertprovided	Yes
Eachvialshouldbelabeledasperprovisions given for labeling in Drugs and cosmetics act 1940 and rules made there under	Yes

Technical Specification for Leucofilter

Sl. No. 26 : Bedside Leucofilter. (S02428)

Category	Specification	Requirements
General Features	Product Description	Bed side Leukocyte removal filter for red blood transfusion
	Usage	Disposable
	Sterile	Yes
	Method of Sterilization	ETO/Gamma
Product Information	High efficiency leucocyte removal filter	Yes
	Removes leukocytes and microaggregates from one unit of whole blood or red blood cell concentrate	Yes
	Housing Material	Polyurethane/ Poly Carbonate / PVC Biocompatiable Material.
	Housing Material should be non toxic and biocompatible	Yes
	Filter Media Material	Polyester Media/Polyurethane
	Red Blood Cell recovery	More than 90%
	Percentage of haemolysis	<0.8-1%
	Filter hold up volume after recovery	Less than 35 ml
	Filtering screen size	40 microns or less
	Average residual leucocyte count	$5x10^6$ / unit or less
	Primes directly with red cells	Yes
	Provided with self-leveling drip chamber allowing self-priming of the filter and drip chamber	Yes

Packaging	Type of Packing	Individual moisture proof packing
Certifications and Reports	Product certification	CDSCO
	Imported kits shall be registered and licensed in India under the provisions of Drugs and Cosmetics act 1940 and Rules 1945 and/or Medical device rules 2017 as amended till date DCG (I)	Yes
	Indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 and Rules 1945 and/or Medical Device Rules 2017 as amended till date DCG (I)	Yes
	Four digit number of notified body if product is EU-CE certified	yes
	CM/L Number if Product is BIS marked	Yes
	Valid Drug License approved from CDSCO	Yes
	ISO 13485 or Latest	Yes
	Manufacturer certification	EU-CE (From Notified Body)/US-FDA/BIS
	Submission of all necessary certifications (EU-CE/US-FDA/ISO:13485Latest/BIS and licenses (CDSCO) to the buyer along with supplies and during submission of technical bid	Yes
Shelf Life	Shelf Life from the date of manufacture	24 months
	The product should have at least ¾ of the total shelf life at the time of delivery to the consignee	Yes

Sl. No. 27 : Labside Leucofilter. (S02429)

Category	Specification	Requirements
General Features	Product Description	Lab side Leukocyte removal filter for packed red blood cell transfusion
	Usage	Disposable
	Sterile	Yes
	Method of Sterilization	ETO/Gamma
Product Information	High efficiency leucocyte removal filter	Yes
	Filtration of red cells must be completed for > 95% of bags within 45 minutes from the time at which flow of blood in to the filter is opened	Yes
	Removes leukocytes and microaggregates from one unit of red blood cell concentrate	Yes
	Housing Material	Polyurethane/ Poly Carbonate / PVC Biocompatiable Material.
	Housing Material should be non toxic and biocompatible	Yes
	Filter Media Material	Polyester Media/ Polyurethane
	Red Blood Cell recovery	More than 90%
	Percentage of haemolysis	<0.8-1%
Product Information (contd.)	Filter hold up volume after recovery	Less than 35 ml
	Filtering mechnaism	Selective Adsorption/adhesion of leucocytes
	Average residual leucocyte count	$5x10^6$ / unit or less

	Air vent: Should have sterile air venting Elimination system in the filter housing. The device should be with a by-pass line and one-way valve to remove air inside the bag OR filter should contain air valve to remove air inside the bag.	Yes
	Should have a sampling pouch for air removal and QC sampling	Yes
Packaging	Type of Packing	Individual moisture proof packing
Certifications and Reports	Product certification	CDSCO
	Imported kits shall be registered and licensed in India under the provisions of Drugs and Cosmetics act 1940 and Rules 1945 and/or Medical device rules 2017 as amended till date DCG (I)	Yes
	Indigenous manufacturers should be licensed by the competent authority defined under Drugs and Cosmetics act 1940 and Rules 1945 and/or Medical Device Rules 2017 as amended till date DCG (I)	Yes
	Four digit number of notified body if product is EU-CE certified	yes
	CM/L Number if Product is BIS marked	Yes
	Valid Drug License approved from CDSCO	Yes
	ISO 13485 or Latest	Yes
Certification and reports (Contd.)	Manufacturer certification	EU-CE (From Notified Body)/US-FDA/BIS
	Submission of all necessary certifications (EU-CE/US-FDA/ISO:13485Latest/BIS and licenses	Yes

	(CDSCO) to the buyer along with supplies and during submission of technical bid	
Shelf Life	Shelf Life from the date of manufacture	24 months
	The product should have at least ¾ of the total shelf life at the time of delivery to the consignee	Yes

SECTION V

SPECIAL CONDITIONS OF CONTRACT

5.1 Time Limits Prescribed

Sl. No	Activity	Time Limit
5.1.1	*Delivery period*	**70(Seventy) days** from date of issue of Supply Order.
5.1.2	*Submission of Performance Security.*	**15 days** from the date of issue of Letter of Intent.
5.1.3	*Time for making payments by Tender Inviting Authority*	*The payment will be completed within 60 days from the date of delivery of the last consignment/ successful delivery of the supplied item or batch(s).*

5.2 Pre qualification of Bidders:

5.2.1 Bidder shall only be a manufacturer having valid **own manufacturing license/loan license with product endorsement or direct importer holding valid import license** with product registration certificate issued by the Drugs Controller General of India.

a) In case of manufacturer, it shall have a valid manufacturing drug license or duly acknowledged renewal application with old license issued by the State Licensing Authority / Central Licensing Approving Authority (wherever applicable) **or** copy of original Treasury Challan regarding manufacturing license retention fee **or** Manufacturing license issued by competent authority as per Medical Devices Rules, 2017 .

b) In case of importer, it should have a valid import license and product registration certificate issued by the Drugs Controller General of India.

c) In case of non-drug item(s) the bidder shall have a manufacturing license/ import export certificate (IEC) with an under taking/Self declaration in his letter pad that the item(s) quoted by the bidder is/are non-drug item(s).

5.2.2 In case of manufacturer, it shall have valid **WHO GMP** certificate / COPP (Certificate of Pharmaceutical Products) issued by the concerned licensing authority. In case of items coming under medical devices **WHO GMP** certificate is relaxed as per GOI CDSCO Clarification No. 29/Misc/03/2018-DC(59) particularly Q. No. 62. However, those bidders have to submit compliance to Quality Management System (QMS) as per CDSCO letter dated 08.08.2018.

The MSMEs registered within the state of Odisha shall hold valid **GMP** Certificate issued by the licensing authority for the products manufactured within the State Odisha. **However the MSMEs registered firm of Odisha should submit an affidavit not to claim any further relaxation from WHO GMP to GMP for tender of 2026-2027 and onwards.**

5.2.3 In case of imported items (Drug items), WHO GMP (of Manufacturer) /COPP shall be submitted.

Note: Valid certificate mean the certificates should be valid on the date of opening of technical bid.

5.2.4 Distributors / Suppliers / Agents / C&F Agents / C&A Agents are not eligible to participate in the tender on behalf of any company.

5.2.5 Bidder (manufacturer/ importer) shall have minimum turnover as per **Section IV** Column No. **8** in each of the year for **last 3(three) financial years** in India.

Last **3(three) financial years** means either during ***2021-22, 2022-23 and 2023-24 or 2022-23, 2023-24 and 2024-25***.

However, **50% of stipulated average turnover or a turnover of average 5 Crores, whichever less** for **local MSE Units** registered with respective DICs, Khadi, Village, Cottage & Handicraft Industries, OSIC and NSIC within the state of Odisha.

The proof of turnover is to be furnished in **Format T6** certified by the Chartered accountant & supported by audited annual statements / annual report with the turnover figures highlighted there. **(Provisional statement of account shall not be considered).**

5.2.6 The bidder must be registered under **GST**.

5.2.7 (a) Bidder/ manufacturer who has been de-recognized/ debarred/banned/blacklisted by any other State Government / Central Govt. Organization /State Medical Corporations/ Director Health Services (Odisha) and or convicted by any court of law due to (i) quality failure of the drug(s) supplied (NSQ/ Spurious/ Adulterated/ Misbranded etc.) (ii) Submission of fake or forged documents (iii) Submission of incorrect information / Suppression of vital information & facts can't participate in the tender during the period of de-recognition / debarment/ Banned/blacklisted. Bidder / manufacturing unit which has been de-recognized/ debarred/banned/blacklisted by OSMC for any reasons can't participate in the tender during the period of de-recognition/ debarment/banned.

(b) Any bidder who has been convicted by a competent court of law for supplying (NSQ/ Spurious/ Adulterated/ Misbranded etc.) drugs within a period of last 3 years from the date of floating of tender shall not be eligible to participate in the tender.

5.2.8 Bidder should have experience in supplying quoted item/Same Molecule of Similar Dosages form as per tender specification to the State or Central Government or Government Hospitals / Corporate Hospitals / PSU Hospitals / Municipal Hospitals / Pvt. Hospitals in India / UN agencies / Authorized agency of the State / Central Govt. / PSU/Open Market Supply as a manufacturer or otherwise during **last 3(three) years** in **Format T7**.

5.2.9 Bidder should have at least **3 (three) years market standing** for the quoted item(s) as per tender specification (In **Format T8** / Market standing certificate issued by the licensing authority to establish the 3 years market standing for the quoted item(s) as per tender specification). This certificate is not applicable for non drug items. This would not apply to new drugs; certificate from the Drug Controller General (India) shall be required for all new drug formulations to this effect in **From-46 / Form CT-23** for exemption. **The Market Standing Certificate should not have been issued by licensing authority more than 2 years old as on bid opening date.**

5.2.10 Non Conviction certificate issued by the licensing authority of the state that the manufacturers/importer have not been convicted under the provision of D&C Act 1940 and Rules thereof by any court of law in contravention to the above Act & Rules**. It should be recent and not more than two year old as on bid opening date.**

5.2.11 The bidder have to submit the EMD (s) & the Bid document cost as mentioned in Section-III.

5.2.12 The bidder should have ISO certificate. In case of items required with **ISI Mark** the bidder should furnish valid ISI/BIS certificate for the items as per the technical specification mentioned at Section IV.

5.2.13 The bidder has to submit declaration form as per **Format T5.**

5.2.14 The bidder has to furnish the declaration of Production Capacity for the quoted item(s) as per **Format T10.**

5.2.15 The bidder has to furnish the declaration regarding information of quoted items as per **Format T11.**

SECTION VI

GENERAL CONDITIONS OF CONTRACT

6.1 Contents of the Bid Document:

This 'Bid Document' contains the following:

Section I: Instruction to Bidders

Section II: General Definition & Scope of Contract.

Section III: Tender Schedule

Section IV: Schedule of Requirement and list of warehouse for door delivery.

Section V: Special Conditions of Contract

Section VI: General Conditions of Contract

Section VII: Formats for bidder for Submission of Bid (Technical Bid)

Section VIII: Annexes [Formats for the successful bidder (Supplier) after finalization of bid]

6.2 Bid Document:

6.2.1 The detailed technical specifications and terms and conditions governing the supply and quality related matters are in the "Bid Document".

6.2.2 The bid document shall be made available in the website *www.osmcl.nic.in* and **https://tendersodisha.gov.in** for downloading. Bidder shall submit Bid Document cost (mentioned in Section III) as described in clause 6.5 and non submission of the same shall be one of the primary reasons for rejection of the offer in the first round.

6.2.3 The documents shall be submitted online through the e-Tender portal https://**tendersodisha.gov.in** Bidders have to enroll themselves in the e-procurement portal and digital signature certificate is required.

6.2.4 The **general guidelines** on **e-Tender** process is as mentioned below :

6.2.4.1 Bidders should have a Class II or III Digital Signature Certificate (DSC) to be procured from any Registration Authorities (RA) under the Controller of certifying agency (CCA). Once, the DSC is obtained, bidders have to **register** in the **e-procurement portal https://tendersodisha.gov.in** for participating in this bid. Website registration is a one-time process without any registration fees. However, bidders have to procure DSC at their own cost.

6.2.4.2 Bidders may contact e-Procurement support desk of OSMCL over telephone at 0674 – 2380660 & 2380950, or State e-Procurement cell help desk 1800-3456765, 0674-2530998 for assistance in this regard.

6.2.4.3 The e-Tender process comprises the stages viz. downloading the bid document, pre-bid meeting (as applicable to each bid), bid submission (technical cover and financial cover), opening of technical bid and opening of financial bids for the technically qualified bidders.

6.2.4.4 **Payment of Bid Document Cost & EMD**:

The **details of payment of document cost & EMD** is mentioned at clause 6.5

6.2.4.5 The details of documents (in PDF format) for online submission of technical bid is mentioned at clause 6.17

6.2.4.6 The blank price bid format should be downloaded and saved on bidder's computer without changing file-name (otherwise price bid will not get uploaded). The bidder should fill in the details in the same file and upload the same back on the website.

6.2.4.7 Prices quoted by the Bidder shall be fixed during the bidder's performance of the contract and not subject to variation on any account. However statutory taxes & duties will be paid as per prevailing rates. A bid submitted with an adjustable/variable price quotation will be treated as non - responsive and rejected.

6.3 Responsibility of Verification of Contents of Bid Document:

6.3.1 The purchasers of the bid document shall examine all instructions, forms, terms and specifications in the Bid Document and verify that all the contents mentioned under clause 6.1, are contained in the 'Bid Document'.

6.3.2 Failure to furnish any information required by the bid documents and submission of an offer not substantially responsive to it in every respect shall be at the bidder's risk and may result in the rejection of the bids, without any further notice.

6.4 Guidelines for Preparation of Bid

6.4.1 The Bidder shall bear all costs associated with the preparation and submission of its bid and OSMCL, hereinafter referred to as "Tender Inviting Authority", will in no case be responsible or liable for these costs, and regardless of the conduct or outcome of the bidding process. The **documents to be submitted** online is mentioned in clause 6.17.

6.4.2 In the event of documentary proof as required being not enclosed, the Bid shall be liable to be rejected. All pages of the bid, shall be signed by the authorized person(s) along with the stamp of the bidder.

6.4.3 Language of Bid:- The Bid prepared by the bidder and all correspondence and documents relating to the bid exchanged by the bidder and the Tender Inviting Authority, shall be in English language. Supporting documents and printed literature furnished by the bidder may be written in another language provided they are accompanied by an authenticated accurate translation of the relevant

passages in the English language in which case, for purposes of interpretation of the Bid, the English translation shall govern.

6.4.4 The bid (in English Language only) for the supply of items mentioned in Section IV shall be submitted along with detailed specifications.

6.4.5 The documentary evidence regarding past performance shall be submitted along with the Bid shall be produced duly attested by the bidder on every page and serially numbered. Any interlineations, erasures or over writing shall be valid only if they are initialled by the person (s) signing the offer.

6.4.6 Bidder shall submit a **declaration letter** as per Format T5 signed by the bidder or the authorized representative and shall enclose it as part of the technical bid as a proof of having read and accepted the terms and conditions of the bid document.

6.4.7 An offer submitted in vague /ambiguous financial terms and the like, shall be termed as non-responsive and shall be summarily rejected.

6.4.8 Clarifications to specific requests shall be responded through e-mail and general clarifications, affecting all the bidders shall be published in the official website of the Tender Inviting Authority (*www.osmcl.nic.in*). However, it shall be the duty of the prospective bidder to ensure that the clarifications sought for has been properly received in time by the Tender Inviting Authority.

6.4.9 Any clarification on the e-Tender procedure shall be obtained from OSMCL and the contact numbers are 0674 - 2380660 & 2380950.

6.5 Payment for e-Tenders (Bid document Cost & EMD)

6.5.1 The bid document cost and EMD shall be paid by the bidder in the following manner through the e-Tender system:

i. The Bid document fee/EMD shall have to be furnished in shape of Demand Draft (DD)/Bankers Cheque (BC) from any nationalized/scheduled bank in India in favour of Odisha State Medical Corporation Ltd., payable at Bhubaneswar.

The EMD in Shape of Electronic Bank Guarantee (e-BG) from any of the nationalized/scheduled bank in India authorised by RBI to issue e-BG are also being acceptable. The issuing bank should have branches in Bhubaneswar. OSMCL reseves the rights to reject the e-BG, if the same is not in the specified format of OSMCL. The e stamping should be made in the name of bank executing the e-BG.

The details required for issuance of e-BG are as follows :

1. Beneficiary Name: Odisha State Medical Corporation Ltd.

2. Payble at : Bhubaneswar

3. **Benificiary Email id : faosmcl.od@gov.in**

4. **Bank IFS Code : ICIC0000061**

5. **PAN : AABCO9370P**

6. **GST No : 21AABCO9370P1Z1**

7. **CIN : U74140OR2013SGC017541**

Original e-BG as per format Annexure-IV is mandatory for the bidders to submit before the opening of the online technical bid. e-BG submitted in format other than Annexure- IV will be liable for rejection.

ii. The bidder has to furnish the scan copy (in PDF format) of the Demand Draft (s) / Electronic Bank Guarantee/ Bankers Cheque along with other required document of technical bid through online submission on or before the due date & time of submission of technical bid.

iii. The **original instrument** of the bid document cost & EMD(s) in a sealed envelope must reach the Tender Inviting Authority by post / courier on or before the opening of technical bid, failing which the bid shall be liable for rejection. The sealed envelope containing the bid document cost & EMD should be clearly superscripted as: **Bid document cost & EMD, Bid Reference No. and the name of the bidder**.

6.6 Bid Document Cost

6.6.1 6.6.1 The bidder has to submit the bid document cost as mentioned in Section–III and non-submission of Bid Document Cost as mentioned in Section III shall be one of the primary reasons for rejection of the offer in the first round.

6.6.2 All bidders shall pay bid document cost as per the instructions provided in clause 6.5. Bidders are **liable to pay bid document cost** .

6.6.3. Only **Local MSMEs** registered in **Odisha** with the respective DICs, Khadi, Village, Cottage & Handicraft Industries, NSIC, OSIC are exempted from submission of Bid Document Cost, subject to submission of the valid registration certificate from the concerned authority.

6.7 Earnest Money Deposit (EMD):

6.7.1 The amount of the EMD(s) to be submitted **per item maximum up-to Rs. 50 (Fifty) Lakhs** as mentioned at Section III. The bidders can participate for all / multiple items by depositing **Rs. 50 (Fifty) Lakhs** towards EMD. In case of EMD in shape of e-BG the validity of e-BG Shall be up to **01/04/2026 i.e. 1(one) year from the date of floating of the tender.** Non- submission of EMD as mentioned in Section III shall be one of the primary reasons for rejection of the offer in the first round

6.7.2 Only **Local MSMEs** registered in **Odisha** with the respective DICs, Khadi, Village, Cottage & Handicraft Industries, NSIC, OSIC are exempted from submission of EMD, subject to submission of the valid registration certificate from the concerned authority.

6.7.3 None of the bidders other than those specified in clause 6.7.2, are exempted from the remittance of EMD.

6.7.4 EMD of unsuccessful bidders will be discharged/ returned within 15 days of price bid finalisation.

6.7.5 The successful bidder's EMD will be discharged after furnishing the prescribed performance security.

6.7.6 No interest will be paid for the EMD submitted.

6.7.7 **OSMCL may debar/de-recognize the bidder and EMD will be forfeited, if a bidder;**

6.7.7.1 Misrepresents facts or submit fabricated / forged / tampered / altered / manipulated documents.

6.7.7.2 Withdraws bid after the opening of technical bid;

6.7.7.3 Fails to furnish performance security and agreement within 10 days of issuance of Letter of Intent.

6.8 Deadline for Submission of Bid

6.8.1 Bidders shall upload all the necessary documents in the e-Tender portal before the last date & time for online submission.

6.8.2 The Tender Inviting Authority may, at its discretion, extend the deadline for submission of Bid, in which case all rights and obligations of the Tender Inviting Authority and the bidders shall remain unaffected.

6.9 Modification and Withdrawal of Bids

6.9.1 The bidder can modify or withdraw bids submitted online before the last date & time of online submission.

6.10 Period of Validity of Bid

6.10.1 The bid must remain valid for minimum 180 days (six months) from the date of opening of technical bid. A bid valid for a shorter period shall be rejected by the Tender Inviting Authority as non-responsive.

6.10.2 The bidder can't withdraw their bid within the bid validity period.

6.10.3 Withdrawal or non-compliance of bid terms and conditions after the issuance of Supply Order will lead to de-recognition/ debarment of the successful bidder.

6.11 Rejection of Bids:

6.11.1 The bids shall be rejected in case the bidder fails to meet the pre-qualification criteria as specified in Clause 5.2 of Section V

6.11.2 At any point of time, the Tender Inviting Authority reserves the right to reject the bid if the bidder fails to fulfil the terms & conditions of the bid document including technical specification, factory inspection, furnish of relevant document as per the satisfaction of Tender Inviting Authority.

6.11.3 Any pre-condition by the bidder contradicting to the tender terms & conditions or non-compliance to product specification.

6.11.4 The Tender Inviting Authority reserves the right to cancel the tender for all items or for any one or more of the items tendered without assigning any reasons thereof.

6.12 Notices

6.12.1 The Tender Inviting Authority shall publish the following information on its website or e-Tender portal at the appropriate time as part of ensuring transparency in the bid process;

6.12.1.1 The bid notices, documents, corrigendum, addendum etc if any.

6.12.1.2 Amendments to the bid conditions, if any, especially after the pre-bid meeting.

6.12.1.3 Results of the responsiveness of the technical bids.

6.12.1.4 List of bidders qualified and reasons for rejection of unqualified bidders.

6.12.1.5 Results of the sample verification / factory inspection (if required), reasons for rejection and provisional list of bidders qualified for price bid opening.

6.12.1.6 Final List of technically qualified bidders.

6.12.1.7 Summary of Online price bid opening.

6.12.2 Notice, if any, relating to the contract given by one party to the other, shall be sent in writing by email or fax and confirmed by post. The procedure will also provide the sender of the notice, the proof of receipt of the notice by the receiver. The addresses of the parties for exchanging such notices will be the addresses as incorporated in the contract.

6.12.3 The effective date of a notice shall be either the date when delivered to the recipient or the effective date specifically mentioned in the notice, whichever is later.

6.13 Other Terms and Conditions

6.13.1 Specifications and Standards:- The Goods & Services to be provided by the successful bidder under this contract shall conform to the specifications and quality control parameters mentioned in Section IV of this document.

6.13.2 The bidder shall be responsible for payment of any charges due to any statutory authorities such as Income Tax, GST and Customs Duties etc.

6.13.3 In the event if it found that there is some statutory deduction to be made at the source, the Tender Inviting Authority will have the authority to do so.

6.14 Submission of Queries

6.14.1 Submission of queries regarding tender terms & condition must be reach by E-Mail id ***drugs-osmcl@gov.in*** up to **04/04/2025, 5:00 PM** . The Tender Inviting Authority may or may not amend the terms and conditions as well as technical specifications of the bid document on the basis of feedback obtained with a view to obtain maximum number of competitive bids.

6.14.2 **Online Submission** of bids will be accepted only **after** the last date of Submission of queries.

6.15 Amendment of Bid Documents:

6.15.1 At any time prior to the dead line for submission of Bid, the Tender Inviting Authority may, for any reason, modify the bid document by amendment and publish it in e-tender portal and OSMCL website.

6.15.2 The Tender Inviting Authority shall not be responsible for individually informing the prospective bidders for any notices published related to each bid. Bidders are advised to browse e-Tender portal or website of the Tender Inviting Authority for information/general notices/amendments to bid document etc. on a day to day basis before submission of bid.

6.16 Submission of Bid

6.16.1 The bids are to be submitted **on-line** in two parts in the e-Tender portal. Each process in the e-procurement is time stamped and the system can detect the time of log in of each user including the Bidder.

6.16.2 **PART-I as TECHNICAL BID** shall be submitted **on-line only** in the e-Tender portal with all the required documents as mentioned in **clause 6.17.**

6.16.3 **PART II as PRICE BID** (in the required Format) shall be submitted **online only**. The price bid format (excel sheet available in e-Tender portal) is specific to a bid and is not interchangeable. The price bid format file shall be downloaded from the e-Tender portal and the bidders shall quote the prices in the respective fields before uploading it. All **white** areas of BOQ file shall be filled by the bidder. The **grey areas** of BOQ shall not be modified/ edited by the bidder. The Price bids submitted in **any other formats** will be treated as **non-responsive**. Multiple price bid submission by bidder shall lead to cancellation of bid.

6.16.4 The bidder should **check** the **system generated confirmation statement** on the status of the submission.

6.16.5 **SIGNING OF BID**

The bidder shall sign on all statements, documents, certificates uploaded by him, owning responsibility for their correctness / authenticity. If any of the information furnished by the bidder is found to be false / fabricated / bogus, the EMD/Bid Security shall stand forfeited & his/her name shall be recommended for blocking of portal registration and the bidder is liable to be de-recognition/ debarment.

6.16.6 **SECURITY OF BID SUBMISSION:**

6.16.6.1 All bid uploaded by the bidder to the e-procurement portal will be encrypted.

6.16.6.2 The encrypted bid can only be decrypted / opened by the authorised openers on or after the due date and time.

6.16.7 **RESUBMISSION AND WITHDRAWAL OF BIDS:**

6.16.7.1 Resubmission of bid by the bidders for any number of times before the final date and time of submission is allowed.

6.16.7.2 Resubmission of bid shall require uploading of all documents including price bid a fresh.

6.16.7.3 If the bidder fails to submit his modified bids within the pre-defined time of receipt, the system shall consider only the last bid submitted.

6.16.7.4 The Bidder can withdraw it's bid before the closure date and time of receipt of the bid. The system shall not allow any withdrawal after expiry of the closure time of the bid.

6.16.7.5 The bidder should avoid submission of bid at the last moment to avoid inconvenience.

6.16.7.6 The details of the documents to be uploaded **online** are mentioned in **Clause 6.17.**

6.17 List of Documents in Bid Submission

The list of documents (**Scanned documents** to be **uploaded online** in P**DF format**) as a part of Technical Bid (PART I) is as mentioned below:

6.17.1 Bid Document cost [(Scanned copy of the instrument in PDF)]

6.17.2 Earnest Money Deposit (s) [Scanned copy of the instrument in PDF)]

[**Original instruments** of the bid document cost & EMD(s) in a sealed envelope must reach the Tender Inviting Authority by post / courier after the closing date of online bid submission and within the date and time of opening of online technical bid, failing which the bid shall be rejected]

6.17.3 Format – T1 (Check List)

6.17.4 Format – T2 (Details of Items quoted)

6.17.5 Format – T3 (Details of EMD submitted)

6.17.6 Format – T4 (Details of Bidder)

6.17.7 Format – T5 (Declaration Form)

6.17.8 Format – T6 (Annual Turnover Statement by Chartered Accountant)

6.17.9 Copies of the annual audited statement / Annual Report for ***2021-22, 2022-23 and 2023-24 or 2022-23, 2023-24 and 2024-25***.(Provisional statement of account shall not be considered).

6.17.10 Format–T7 (**Performance Statement** during the last three Years)

6.17.11 Format–T8 (Market Standing Certificate) / Market Standing certificate in the format of the drug licensing authority in case of Drug items.

6.17.12 Format – T9 (Declaration for compliance of WHO GMP/**GMP (**for MSMEs registered within the state of Odisha**)**)

6.17.13 Format- T10 (Declaration of Production Capacity).

6.17.14 Format – T11 (Information regarding Quoted Items)

6.17.15 Photo copy of valid manufacturing license /Loan License / Import license for each product quoted by the drug licensing authority

6.17.16 Valid Drug Endorsement for each quoted product / Product registration certificate (In case of Importer)

6.17.17 Valid up-to-date Good manufacturing practice certificate as per revised schedule-M (WHO GMP) / COPP Certificate by the drug licensing authority/ QMS in case of items under Medical Devices.

6.17.18 Valid up-to-date WHO GMP / COPP certificate/ equivalent (in case of importer) by the drug licensing authority

6.17.19 Valid up-to-date **GMP certificate** for MSMEs registered within the state of Odisha, issued by the licensing authority for the products manufactured within the State Odisha

6.17.20 Non Conviction certificate issued by the licensing authority

6.17.21 Copy of ISO/BIS Certificate (if any)

6.17.22 Copy of the GST registration certificate

6.17.23 Copy of PAN

6.17.24 Copy of IT Returns of the financial years during ***2021-22, 2022-23 and 2023-24 or 2022-23, 2023-24 and 2024-25***.

Copies of all the above documents uploaded in the **technical bid** shall **also to be submitted** along with the original EMD document & Tender document Cost after the closing date of online bid submission and within the date and time of opening of online technical bid, failing which the bid shall be rejected. However, the copy of all documents to be submitted should be **exactly the same** as **uploaded** in **e-tender portal**. Copy of the documents to be submitted shall be only for the purpose of clarity / better visibility of the documents uploaded in case of any scanned documents uploaded (like product catalogues/ information's/ Certificates etc.) is not clear. In that case, the documents shall be considered for evaluation **if the scan copy of the same is uploaded**.

Note: No price information to be furnished in the Technical bid.

6.18 Opening of Technical Bid

6.18.1 The technical bid opening is **online**. The date of technical bid opening is published in advance. The date of opening of price bid will be decided after the technical bid evaluation and those who qualify in the technical bid evaluation shall be informed in advance.

6.18.2 The **on-line opening** of the technical bid and the price bid shall be done by the Tender Inviting Authority or his authorized representatives as per bid schedule. The prospective bidders or his/her representative can access to the on-line bid opening by logging in to the e-Tender portal with the registered digital signature. Bidders or his/her representative may not come to the office of the Tender Inviting Authority for the opening of either technical or price bids.

6.18.3 In the event of the specified date for opening of bid being declared holiday, the Bid shall be opened at the appointed time and venue on the next working day.

6.18.4 In the event of the claims in the on-line documents are materially missing or of substantial error or unqualified for want of required qualifications, the bid shall be rejected. However, minor infirmities in the submission of documents will be allowed to be rectified by obtaining required clarification by the Tender Inviting

Authority so as to ensure qualification of maximum number of competitive offers to the final round.

6.18.5 The bidder shall be **responsible** for **properly uploading** the relevant documents (in the format specified) in the **e-Tender portal** in the specific location and the Tender Inviting Authority shall not be held liable for errors or mistakes done while uploading the on-line bid.

6.18.6 The date and time of Price Bid will be announced only after the opening of the Technical Bid, Technical Evaluation and sample verification of the item(s) offered.

6.19 Evaluation of Bid

6.19.1 The Evaluation will be done by Tender Evaluation Committee.

6.19.1.1 The online documents submitted as part of the technical bids shall be scrutinized by a Tender Evaluation Committee duly appointed.

6.19.1.2 The Tender Evaluation Committee may also verify the veracity of claims in respect of the known performance of the item(s) offered, the experience and reputation of bidder in the field, the financial solvency etc.

6.19.1.3 The decisions of the Tender Evaluation Committee on whether the bidders are responsive or non-responsive or requiring clarifications will be published.

6.19.1.4 The details of price bid evaluation is mentioned at Clause No. 6.22

6.20 Sample Verification of the item(s):

6.20.1 The Tender Inviting Authority's contractual right to inspect, test and, if necessary, reject the goods after the goods' arrival at the final destination shall have no bearing of the fact that the goods have previously been inspected and cleared by Tender Inviting Authority's inspector during sample verification as mentioned above.

6.21 Price Bids Opening

6.21.1 The price bid of the technically qualified bidders shall be opened online by the Tender Inviting Authority or his authorized representative.

6.21.2 Price Offered shall be in **Indian Rupees**.

6.21.3 Fixed price: Prices quoted by the Bidder shall be fixed during the period of the contract and not subject to variation on any account.

6.21.4 There shall also be no hidden costs.

6.21.5 Bidder shall quote prices in all necessary fields in the available format. The price shall be entered separately in the following manner:

6.21.5.1 Basic Price: Basic absolute price includes customs duty, packaging, forwarding, insurance, transportation (Door Delivery) [Price per each Tab/Cap/Amp/Vial/Kit/film etc. as per price bid/BOQ (as the case may be)] should include the cost of all accessories **excluding GST.**

6.21.5.2 Applicable GST shall be quoted in the specified column in numeric values (If the field is left blank, value will be taken as zero) in the BOQ/Price Bid format.

6.21.5.3 The bidders shall offer the price which shall be inclusive of all the accessories (if any) mentioned in the technical specification under Section IV.

6.21.5.4 Bidders in no way can alter/modify the price bid/ BOQ format, if so he is liable for disqualification.

6.21.5.5 No bidder shall be allowed at any time on any ground, whatsoever it may be, to claim revision or modification in the rates quoted by him(Except any change made by the NPPA/Govt.). Representation to make correction in the tender documents on the ground of Clerical error, typographical error, etc., committed by the bidder in the Bids shall not be entertained after submission of the tenders. 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 given such conditions shall be treated as incomplete and accordingly the Tender will be rejected.

6.22 Price Bid Evaluation

6.22.1 The quoted rate should include excise / customs duty, transportation, insurance, packing & forwarding or any other incidental charges for door delivery at the warehouses & excluding GST. The price bid evaluation of an item will be made by comparison of basic quoted prices of each bidder excluding GST. The lowest eligible bidder i.e. (L1) bidder will be the bidder who has quoted the lowest basic price in BOQ, out of the rest bidders for that item.

6.22.2 Deleted.

.

6.22.3 In case of any discrepancy in quoted GST percentage in BOQ by different bidders for a similar item(s). Then price bid evaluation for that item will be finalized after getting clarification from bidders as well as from tax department.

6.22.4 If L1 price for any of the tendered item is found to be more than the price offered by any of the suppliers in GeM at any point of time, then OSMCL reserves the right to cancel the contract for the said item at any point of time during the tender

validity period or the rate contract period and will go for procurement of the said item from GeM.

6.23 Award of Contract

6.23.1 Criteria:- The contract will be awarded to the lowest evaluated responsive (L1) bidder for the entire tendered quantity or part thereof as per the discretion of management. However, empanelment of other technically qualified bidders may be asked through negotiation to match with the L1 price for supply of the **Bulk/ Critical/ Essential/Program** item (s). The ***MD, OSMCL reserves all rights regarding the decision of division of the total order quantity***. In case of splitting in two and three, the ratio of 70:30; 50:30:20, respectively, may be used or a different ratio at the discretion of ***MD, OSMCL***.

In case of failure of any supplier, the non supplied portion of the order quantity can go to the other suppliers who are on the panel for supplying of the said item. If L2 and L3 bidders/suppliers unwilling/failing to supply the item with L1 rate, then purchase orders may be placed to the other qualified bidders who are willing to supply the item at L1 rate. If other technically qualified bidders are not willing to supply the item(s) matching with L1 rate, then the total Tender/Order Quantity shall be supplied by L1 approved bidders / Supplier.

6.23.2 Variation of Quantities at the Time of Award/ Currency of Contract:-At the time of awarding the contract, the Tender Inviting Authority reserves the right to increase or decrease substantially the quantity of goods and services mentioned under Cl. 4.1 (rounded off to next whole number) without any change in the unit price and other terms & conditions quoted by the bidder.

6.24 Notification of Award/Letter of Intent (LOI)

6.24.1 Within the bid validity period, the Tender Inviting Authority will notify the list of successful bidder(s) in tender portal or website of OSMCL before issuing the Letter of Intent (LOI).

6.24.2 The successful bidder(s), upon receipt of the LOI, shall deposit the prescribed performance security within **10 (ten)** days, failing which the EMD will be forfeited and the award will be cancelled.

6.24.3 The Notification of Award shall constitute the formation of the Contract.

6.25 Signing of Contract

6.25.1 The successful bidder shall execute an agreement in a format which will be provided to the successful bidder along with the LOI for ensuring satisfactory supply and after sales support.

6.25.2 The successful bidder shall submit the Electronic bank guarantee in the format as per Annexure IV, or a demand draft as a performance security prescribed under Cl.6.27.

6.25.3 Promptly after notification of award, within ten days from the date of the letter of intent, the successful bidder shall execute the contract (as per agreement) on Rs.100/- stamp paper purchased in the name of the successful bidder, duly signed and dated, to the Tender Inviting Authority by registered / speed post or in person.

6.25.4 Assignment:-The Successful bidder shall not assign, either in whole or in part, its contractual duties, responsibilities and obligations to perform the contract, except with the Tender Inviting Authority's prior written permission.

6.25.5 Sub Contracts:- The Successful bidder shall not sub contract the execution of the contract. Such action, if done without the knowledge of the Tender Inviting Authority prior to the entering of the contract, shall not relieve the Successful bidder from any of its liability or obligation under the terms and conditions of the contract.

6.25.6 Modification of contract:- If necessary, the Tender Inviting Authority may, by a written order given to the successful bidder at any time during the currency of the contract, amend the contract by making alterations and modifications within the general scope of contract in any one or more of the following:

6.25.6.1 Specifications, drawings, designs etc. where goods to be supplied under the contract are to be specifically manufactured for the Tender Inviting Authority,

6.25.6.2 Incidental services to be provided by the successful bidder,

6.25.6.3 Place of delivery

6.25.6.4 Any other term(s) of the contract, as felt necessary by the Tender Inviting Authority depending on the merits of the case.

6.25.7 In the event of any such modification/alteration causing increase or decrease in the cost of goods and services to be supplied and provided, or in the time required by the successful bidder to perform any obligation under the contract, an equitable adjustment shall be made in the contract price and/or contract delivery schedule, as the case may be, and the contract amended accordingly.

6.25.8 If the successful bidder doesn't agree to the adjustment made by the Tender Inviting Authority, the successful bidder shall convey its views to the Tender Inviting Authority within ten days from the date of the successful bidder's receipt of the Tender Inviting Authority amendment / modification of terms of the contract.

6.26 Performance Security

As the tender quantity of some items to be procured is huge, hence purchase orders will be issued in phases/ staggered manner, thus there should be coherence between LoI quantity vis-a-vis purchase order quantity.

6.26.1 Performance Security for an amount equal to 5% of LOI value excluding Taxes shall be paid upfront within **15 days** of issue of LOI in form of Demand Draft drawn in favour of the Managing Director, OSMCL payable at Bhubaneswar/ Irrevocable Electronic Bank Guarantee from any Nationalised / Scheduled Bank in favour of the Odisha State Medical Corporation (O), Bhubaneswar in the format as given in Annexure –V with validity for a period **of 24 months** from the date of

execution of the agreement or latest expiry date of the batch (es) of a particular item, whichever is later .

The Perfernmance security in Shape of Electronic Bank Guarantee (e-BG) from any of the nationalized/scheduled bank in India authorised by RBI to issue e-BG are also being acceptable. The issuing bank should have branches in Bhubaneswar. OSMCL reseves the rights to reject the e-BG, if the same is not in the specified format of OSMCL. The e stamping should be made in the name of bank executing the e-BG.

The details required for issuance of e-BG are as follows :

1. **Beneficiary Name: Odisha State Medical Corporation Ltd.**
2. **Payble at : Bhubaneswar**
3. **Benificiary Email id : faosmcl.od@gov.in**
4. **Bank IFS Code : ICIC0000061**
5. **PAN : AABCO9370P**
6. **GST No : 21AABCO9370P1Z1**
7. **CIN : U74140OR2013SGC017541**

Original e-BG as per format Annexure-V is mandatory for the bidders to submit.

6.26.2 For subsequent order (s)/ emergency situations, the successful supplier shall deposit performance security for an amount equal to 5% of P.O. value excluding Taxes within 15 days of issue of purchase order in shape of Demand Draft / Irrevocable Electronic Bank Guarantee from any Nationalised / Scheduled Bank in favour of the Odisha State Medical Corporation (O), Bhubaneswar valid for a period of 24 months from the date of execution of the agreement.

In case of successful bidders pertaining to Local MSEs registered in Odisha with the respective DICs, Khadi, Village, Cottage & Handicraft Industries, OSIC, NSIC shall be required to furnish 25% of prescribed performance security excluding taxes as mentioned in Section III.

6.26.3 Upon receipt of performance security, the Tender Inviting Authority shall issue the Supply Orders containing the terms and conditions for the execution of the order.

6.26.4 Failure of the successful bidder in providing performance security mentioned in Section III in time shall make the bidder liable for forfeiture of its EMD.

6.26.5 The Performance security shall be denominated in Indian Rupees as detailed below:

6.26.5.1.1 It shall be in any one of the forms namely Account Payee Demand Draft or Bankers Cheque or Electronic Bank Guarantee issued by a Scheduled bank in India, in the prescribed form (Annexure V) as provided in this document endorsed in favour of the Tender Inviting Authority.

6.26.5.2 In the event of any failure /default of the successful bidder with or without any quantifiable loss to the government, the amount of the performance security is liable to be forfeited.

6.26.5.3 In the event of any amendment issued, the successful bidder shall, within ten (15) days of issue of the amendment, furnish the corresponding amendment to the Performance Security (as necessary), rendering the same valid in all respects in terms of the contract, as amended.

6.26.6 Tender Inviting Authority will release the Performance Security without any interest to the successful bidder on completion of 24 months from the date of execution of the agreement.

6.27 Supply Conditions

6.27.1 The tender inviting authority may place the purchase order in a phased manner during the rate contract period. The Purchase orders will be issued through E-mail followed by Speed Post/ Courier.

6.27.2 (a) The successful bidder shall have to supply the item(s) within the **stipulate period (70 days as mentioned in Clause 5.1.1)**, at the warehouses/ Supply points as mentioned in Section IV - Schedule of Requirement.

(b) In case of vaccines, serum, immunoglobulin, blood products like human coagulation factors VII, VIII, IX, etc., which requires quality clearance of the item(s) from CRI Kasauli/ NIB Noida/ Govt. Statutory Laboratories, the items will be accepted based on the above mentioned lab test report only within **90 days** from issue of purchase order. Further the imported items will be accepted within **90 days** from issue of purchase order without LD

(c) In case of emergency, however the limit will be revisited by MD, OSMCL.

6.27.3 In case the supplied item(s) not delivered within the stipulated delivery period, the Tender Inviting Authority shall deduct **Liquidated Damage (LD) charges** as per the bid conditions specified in **clause 6.37.5**

6.27.4 The successful bidder(s) will arrange transportation of the ordered goods as per its own procedure and pay necessary insurance against loss or damage incidental

to manufacture or acquisition, transportation, storage and delivery and pay all incidental charges till it reaches at consignee point. It shall be ensured by the supplier that the item(s) delivered at the destination(s) in good condition as per Bid Document.

6.27.5 All items should have **minimum 5/6th shelf** at the time of supply.

6.27.6 However, in case of small ordered items (i.e. small ordered quantity in comparison to the batch manufacturing size), imported items and in case of vaccines, serums, immunoglobulin's, blood products like human coagulation factors VII, VIII, IX, etc. may be considered for exemption from the above stipulation (Cl. No. 6.27.5) with an undertaking furnished by the supplier that if the item expires not being utilised then the supplier shall replace the whole expired stock of that item with fresh batch(es). However, at the time of supply the item should have **minimum 70% of the remaining shelf life** from the date of manufacture.

6.27.7 The supplier shall submit the copy of the **invoice** along with the copy of the **Standard Quality** certificate of analysis from their **own laboratory / NABL accredited Laboratory / Government approved Laboratory** as applicable with necessary protocols for **every batch of items** supplied. The supplier has to submit all the copies of the test reports to the Quality Assurance Division and copy of the invoice to finance division of OSMCL.

6.27.8 Where more than one batch of the drug is supplied under one invoice, the quantities of each batch with **date of manufacture** and **expiry** shall be clearly specified. The quantity supplied shall be in terms of the units mentioned in the Tender Document. Any variation in the description of product in the invoice, analysis report and actual supplies shall be considered as improper invoicing.

6.27.9 The name of the item shall be mentioned in English. The items quoted are to be supplied in **standard packing** with wordings "**Govt. of Odisha Supply – NOT FOR SALE"** (in Odia and English) and OSMCL logograms as per the design and barcode as specified in the Annexure I–III to legibly appear in primary, secondary and tertiary packing of all products. Affixing of stickers and rubber stamps shall not be accepted except Gauze and Bandage.

6.27.10 No goods shall be received after expiry of the penal period i.e. 30 days after the normal delivery period of **70 days** as per Cl. no. 6.27.2 (a), hence the maximum deliver/supply period is up-to **100 days**.

However, in case of items coming under Cl. no. 6.27.2 (b) i.e. in case of vaccines, serums, immunoglobulin's, blood products like human coagulation factors VII, VIII, IX, etc. which requires quality clearance of the item(s) from CRI Kasauli / NIB Noida / Govt. Statutory Laboratories, the items will be accepted based on the above mentioned lab test report with normal delivery period of **90 days** from the date issue of purchase order. Hence, accordingly the maximum delivery period shall be up-to **120 days** from the date of issue of the purchase order including **30 days** of penal period and the purchase order shall stand automatically cancelled without prejudice to penal action as applicable.

6.27.11 The items requiring special cold storage conditions should either be supplied with cold chain transporting system under cold chain norms from the manufacturing unit to the warehouses of the Corporation (as per section- IV, Clause No. 4.2) complying cold chain norms.

6.27.12 If the consignment arrived at the warehouse on **70th** day or **100th** day of Purchase Order and it will be a holiday then the next working day will be considered as **70th** day or **100th** day. However, in case of items coming under Cl. no. 6.27.2 (b), if the consignment arrived at the warehouse on **90th** or **120th** day of Purchase Order and it will be a holiday then the **next working day** will be considered as **90th** day or **120th** day.

6.27.13 Purchase Order value up to **Rs/- 25,000** will be accepted at CDS with 3% transportation charge with prior approval.

6.28 PACKAGING (As per Annexure – I):

6.28.1 All the packaging materials should be new and as per specification. The packaging shall be sufficient to withstand the hazards of transportation and storage (as per Annexure–I).

6.28.2 The packaging cartons must bear the name of the items (Generic names), strength, total quantity, total weight, name of the manufacturer, month of manufacturing and expiry (As per Annexure – I).

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

6.28.4.2 1D - GS1 bar coding should be done on tertiary and secondary packing of the supplies as per the specifications given in Annexure-III (OPTIONAL)

6.29 Quality Testing

6.29.1 The approved supplier shall furnish a copy of in-house Certificate of Analysis (COA)/Test Report issued by Approved NABL Accredited Laboratory/Central Drug Testing Laboratory i.e. C.R.I. Kasauli in case of Vaccines/N.I.B/other Govt. Testing Laboratories for each batch of items supplied by them.

6.29.2 All the items received shall be quarantined for Quality Testing by OSMCL. Samples from the supplied batches of each item at the point of delivery/storage or distribution will be collected by the consignee as a part of Standard Quality Assurance Procedure and will be sent to QA division of OSMCL. The QA division will send the same to Approved NABL Accredited Laboratory

empanelled by OSMCL/Govt. Testing Laboratories for appropriate quality testing as decided by the procuring authority. The item(s) shall only be allowed for distribution after getting the "Standard Quality" Test Report from the above mentioned laboratories. If the outcome of quality testing for a particular batch of item is found to be of NSQ (Not of Standard Quality) as per the test report, then the supplier shall replace the entire quantity (100%) of supply of that batch. In case of a NSQ report the supplier shall take back the available NSQ stock (unused) in different health institutions (facilities) of the State at his own cost within a period of 60 days of the issue of the letter from OSMC.

6.29.3 **Drugs / Items having 3 (Three) or more empanelled laboratories for test and analysis :**

In case of NSQ report of the sample from the empanelled NABL Accredited Laboratory, two other portions of the sample shall be sent to two different empanelled NABL Accredited Laboratories. In that case, the majority of the status report (out of three laboratory reports) related to NSQ / SQ shall be treated as final report.

6.29.3.1 **Drugs / Items having 1 (one) or 2 (two) empanelled laboratories for test and analysis :**

In case of NSQ report of the sample from the empanelled NABL Accredited Laboratory, the status report related to NSQ / SQ shall be treated as final report.

6.29.4 Quality testing and Handling charges**: 1.5 %** of the purchase order value shall be collected from the approved supplier as the quality testing charges. But the supply of each drug/consumable must be in minimum batches. *If more than **1.5%** of purchase order value is spent towards quality testing due to more number of batches, the extra cost will be collected from the supplier*. The balance amount if any remaining due to less batch and bulk supply out of **1.5%** will not be returned to the supplier.

6.29.5 In case of NSQ, OSMCL reserves the right to instruct the supplier to take back the NSQ batch with replacement of the same at all the warehouse(s) at their own cost **within 60 days of issue of letter from OSMC**, failing which a penalty as per the penalty clause (Cl. No. 6.37.1) would be levied. In the event of non replacement OSMCL reserves the right to destroy the entire NSQ batch (es) of which cost will be recovered from the supplier from any money due/becoming due to the supplier. Further OSMC will not be held responsible for any damage/loss, if there is expiry of the shelf-life of the above item(s) due to efflux of time attributable to the supplier.

6.29.6 Sample can be drawn for re-testing any time during the shelf-life of the item irrespective of the fact that the same batch has already been tested earlier.

6.29.7 If any item(s) supplied has undergone some physical changes and the same is visible to naked eye such as change of colour, chipping, breaking, being/becoming fragile or soft, appearance of spots, being/becoming sticky, presence/appearance of particulate matters/flakes etc., which make the drug unfit for use, no further test and analysis shall be carried out and the same item(s) shall be recalled and replaced by the supplier. However, OSMCL reserves the right to draw sample for Test/Analysis, if felt necessary.

6.29.8 **De-recognition/Debarment** procedures for supply of NSQ item (s) are mentioned in Clause 6.38.1(ii)

6.29.9 In case of non-availability of empanelled NABL laboratories for testing/specific testing of items, OSMC reserves the right to send the sample of the items to any other NABL/Govt. laboratories which have the testing/specific testing facilities for that item(s) and the test report will be treated as final.

6.29.10 After being released for public distribution, if any statutory sample of OSMCL supply drug is drawn by Drugs Control Department of the state on suo-motto basis or on complaint or drawn by officers of CDSCO and if it is declared as Not of Standard Quality (NSQ), the report is conclusive till it is challenged by supplier/ company. If it is challenged, then the report of Director, CDL, Kolkata shall be conclusive and action as contemplated in foregoing paragraphs will be initiated in the matter of debarring of product or company.

6.30 Payment

6.30.1 No advance payments towards cost of items will be made to the bidder.

6.30.2 Payments shall be made after receipt of **standard quality test report** (of the samples of all batches of the quarantined items) from the empanelled NABL Laboratory of OSMC.

6.30.3 Payment for the supplied quantity shall be made in three phases against minimum of 40%, 70% and full supply (delivery & acceptance after QC) of the ordered quantity respectively within a period of 60 days from the date of delivery of the last consignment in each phase.

6.30.4 The original invoice submitted shall be in the name of the Tender Inviting Authority and the name of the consignee shall be mentioned in it.

6.30.5 Where there is a statutory requirement for tax deduction at source, such deduction towards income tax and other taxes as applicable will be made from the bills payable to the Successful supplier at rates as notified from time to time.

6.31 Intellectual Property Rights (IPR)

6.31.1 The successful bidder shall, at all times, indemnify and keep indemnified the Tender Inviting Authority, free of cost, against all claims which may arise in

respect of goods & services to be provided by the successful bidder under the contract for infringement of any intellectual property rights or any other right protected by patent, registration of designs or trademarks.

6.31.2 In the event of any such claim in respect of alleged breach of patent, registered designs, trademarks etc. being made against the Tender Inviting Authority, the Tender Inviting Authority shall notify the successful bidder of the same and the successful bidder shall, at his own expenses take care of the same for settlement without any liability to the Tender Inviting Authority.

6.31.3 The Successful bidder/its Indian Agent shall at all times, indemnify and keep indemnified the Tender Inviting Authority/ Government of India against all claims/ damages etc. for any infringement of any Intellectual Property Rights (IPR) while providing its services.

6.32 Corrupt or Fraudulent Practices

6.32.1 It is required by all concerned namely the User Institution/ Bidders/ Successful bidders etc to observe the highest standard of ethics during the procurement and execution of such contracts. In pursuance of this policy, the Tender Inviting Authority defines, for the purposes of this provision, the terms set forth below as follows:

6.32.2 "corrupt practice" means the offering, giving, receiving or soliciting of anything of value to influence the action of a public official in the procurement process or in contract execution; and

6.32.3 "fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the Tender Inviting Authority, and includes collusive practice among Bidders (prior to or after Bid submission) designed to establish Bid prices at artificial non-competitive levels and to deprive the Tender Inviting Authority of the benefits of free and open competition;

6.32.4 Tender Inviting Authority will reject a proposal for award if it determines that the bidder recommended for award has engaged in corrupt or fraudulent practices in competing for the contract in question; will declare a firm ineligible, either indefinitely or for a stated period of time, to be awarded a contract by the Tender Inviting Authority if it at any time determines that the firm has engaged in corrupt or fraudulent practices in competing for, or in executing the contract.

6.32.5 No bidder shall contact the Tender Inviting Authority or any of its officers or any officers of the government on any matter relating to its bid, other than communications for clarifications and requirements under this bid in writing, with an intention to influence the members of various committees or officials of Tender Inviting Authority. Any such effort by a bidder to influence the Tender Inviting Authority in the Tender Inviting Authority's bid evaluation committee, bid comparison or contract award decisions may result in rejection of the bid.

6.33 Force Majeure

6.33.1 For purposes of this clause, Force Majeure (FM) means extraordinary events or circumstance beyond human control such as an event described as an act of God (like a natural calamity) or events such as a war, strike, riots, crimes (but not including negligence or wrong-doing, predictable/seasonal rain and any other events specifically excluded in the clause).

6.33.2 An FM clause in the contract frees both parties from contractual liability or obligation when prevented by such events from fulfilling their obligations under the contract. An FM clause does not excuse a party's non-performance entirely, but only suspends it for the duration of the FM. The firm has to give notice of FM as soon as it occurs (**within 7 days**) and it cannot be claimed ex-post facto.

6.33.3 There may be a FM situation affecting the purchase organisation only. In such a situation, the purchase organisation is to communicate with the supplier along similar lines as above for further necessary action. If the performance in whole or in part or any obligation under this contract is prevented or delayed by any reason of FM for a period exceeding **60(Sixty)** days, either party may at its option terminate the contract without any financial repercussion on either side. Notwithstanding the punitive provisions contained in the contract for delay or breach of contract, the supplier would not be liable for imposition of any such sanction so long as the delay and/ or failure of the supplier in fulfilling its obligations under the contract is the result of an event covered in the FM clause.

6.34 Resolution of Disputes

6.34.1 If dispute or difference of any kind shall arise between the Tender Inviting Authority and the successful bidder in connection with or relating to the contract, the parties shall make every effort to resolve the same amicably by mutual consultations.

6.35 Applicable Law & Jurisdiction of Courts

6.35.1 The contract shall be governed by and interpreted in accordance with the laws of India for the time being in force.

6.35.2 All disputes arising out of this bid will be subject to the jurisdiction of courts of law in Bhubaneswar / High Court of Orissa.

6.36 General/ Miscellaneous Clauses

6.36.1 Nothing contained in this Contract shall be constructed as establishing or creating between the parties, i.e. the Successful bidder on the one side and the Tender Inviting Authority on the other side, a relationship of master and servant or principal and agent.

6.36.2 Any failure on the part of any Party to exercise right or power under this Contract shall not operate as waiver thereof.

6.36.3 The Successful bidder shall notify the Tender Inviting Authority of any material change that would impact on performance of its obligations under this Contract.

6.36.4 The Successful bidder shall, at all times, indemnify and keep indemnified the Tender Inviting Authority / Government of Odisha against any claims in respect of any damages or compensation payable in consequences of any accident or injury sustained or suffered by its employees or agents or by any other third party resulting from or by any action, omission or operation conducted by or on behalf of the successful bidder/its associate/affiliate etc.

6.36.5 All claims regarding indemnity shall survive the termination or expiry of the contract.

6.37 Penalties for Non-performance

6.37.1 The penalties to be imposed at any stage under this bid are;

6.37.1.1 imposition of liquidated damages,
6.37.1.2 forfeiture of performance security
6.37.1.3 cancelation of Purchase Order and termination of the contract
6.37.1.4 de-recognition/ debarment of the bidder/supplier

6.37.2 Failure to produce the requisite certificates after claiming to possess such certificates or concealment or misrepresentation of facts will not only lead to rejection of bids in the first round itself and/or may lead to forfeiture of performance security as well as result in de-recognition/ debarment of the bidder.

6.37.3 The penalties to be imposed on the bidder, at any stage, will be decided on the basis of the violations of number of bid conditions specifically mentioned in the bid document as that leading to forfeiture of Performance Security or leading to de-recognition/ debarment.

6.37.4 Any unexcused delay by the successful bidder in maintaining its contractual obligations towards delivery of goods and performance of services shall render the successful bidder liable to any or all of the following sanctions:

6.37.5 **Liquidated Damages**:- will be charged for delayed supply as follows –

a) Beyond the normal period of supply as per the purchase order, for immediate **next 15 days** : **@ 0.25% per day**

b) For the **next 15 days** after initial delay of **15 days**: **@0.5% per day**.

6.37.6 *in case of incomplete supply (not completing 100%), penalty equal to 30% of the value of goods not supplied will be imposed subject to a limit of 20% of the Purchase Order value.*

6.37.7 The decision to impose penalties and finally to **de-recognition/debarment** the defaulting firm will be final and shall be binding on all bidders participating in the bid.

6.37.8 The recovery of different penalties from any payable amount of supplier and/or security available with the Corporation under any tender and amount due under one contract can be recovered from available amount of other contract.

6.38 De-recognition/Debarment

6.38.1 OSMCL shall **de-recognize/ debar** the defaulting supplier for any item for a period up-to **3(three) years** from the date of issue of De-recognition/Debarment order on the following grounds:

(i) For non-performance of contract provisions, non-supply / part-supply **(To be decided by the Tender Inviting authority)** as per purchase order during the validity of the rate contract period.

(ii) If **2(two)** or more batches of any item supplied during the contract period declared as **"Not of Standard Quality"** on the basis of quality test report by empanelled Laboratories and/or Regulatory Authority **(both State and Central).**

6.38.2 If **2(two)** or more items supplied by the supplier are declared as **de-recognized/debarred** on **quality grounds**, then the firm **itself will be de-recognized/debarred** by OSMCL.

6.38.3.1 The bidder can be **de-recognized/debarred** by OSMCL up-to a period of **3 years** in case it is found at the time of *evaluation/verification/inspection/at any point of time till the end of contract period,* that the bidder has furnished **forged documents/false information** along with the bid.

6.38.3.2 **De-recognized / Debarred for "Misbranded" Drugs -**

OSMCL shall de-recognize / debar the defaulting supplier for any item for a period of 3 (Three) year from the date of issue of De-recognition / Debarment order on the following grounds :

(a) If 2 (two) or more batches of any item supplied during the contract period declared as "Misbranded", On the basis of quality test report(s) by empanelled laboratories or on physical verification and/or Regulatory Authority (both state and central) then the particular item shall be de-recognized / debarred.

(b) If 2 (two) or more items supplied by the supplier are declared as de-recognized / debarred based on "Misbranded" drug , then the firm itself will be de-recognized / debarred by OSMCL.

6.38.3.3 **De-recognize / Debarred for "Spurious" Drugs -**

OSMCL shall de-recognize / debar the defaulting supplier for any item for a period up to 7 (seven) years From the date of issue of De-recognition / Debarment order on the following grounds :

(a) If 1 (one) or more batches of any item supplied during the contract period declared as "Spurious", On the basis of quality test report(s) by empanelled laboratories and /or

Regulatory Authority (both state and central) then the particular item shall be de-recognized / debarred.

(b) If 2(two) or more items supplied by the supplier are declared as de-recognized / debarred based on "spurious" drug or quality grounds, then the firm itself will be de-recognized / debarred by OSMCL.

6.38.3.4 **De-recognize / Debarred for supply of drugs not as par Purchase Order for human use-**

(a) Bidder supplying item / items not as per tender conditions other than human use shall be derecognized for 7 years for same item/ items.

6.38.4 The de-recognition/debarment provisions will apply *without prejudice to other penal provisions as per the tender terms & conditions*.

6.38.5 The penalties imposed by the Tender Inviting Authority will be published on the website of the Tender Inviting Authority for a period as decided appropriate.

6.39 Termination of Contract

6.39.1 Termination for default:- The Tender Inviting Authority, without prejudice to any other contractual rights and remedies available to it (the Tender Inviting Authority), may, by written notice of default sent to the successful bidder, terminate the contract in whole or in part, if the successful bidder fails to deliver any or all of the goods or fails to perform any other contractual obligation(s) within the time period specified in the contract, or within any extension thereof granted by the Tender Inviting Authority.

6.39.2 In the event of the Tender Inviting Authority terminating the contract in whole or in part, the Tender Inviting Authority may procure goods and/or services similar to those cancelled, with such terms and conditions and in such manner as it deems fit and the successful bidder shall be liable to the Tender Inviting Authority for the extra expenditure, if any, incurred by the Tender Inviting Authority for arranging such procurement.

6.39.3 Unless otherwise instructed by the Tender Inviting Authority, the successful bidder shall continue to perform the contract to the extent not terminated.

6.39.4 Termination for insolvency: If the successful bidder becomes bankrupt or otherwise insolvent, the Tender Inviting Authority reserves the right to terminate the contract at any time, by serving written notice to the successful bidder without any compensation, whatsoever, to the successful bidder, subject to further condition that such termination will not prejudice or affect the rights and remedies which have accrued and / or will accrue thereafter to the Tender Inviting Authority.

6.39.5 Termination for convenience:- The Tender Inviting Authority reserves the right to terminate the contract, in whole or in part for its (Tender Inviting Authority's) convenience, by serving written notice on the successful bidder at any time during the currency of the contract. The notice shall specify that the termination

is for the convenience of the Tender Inviting Authority. The notice shall also indicate inter-alia, the extent to which the successful bidder's performance under the contract is terminated, and the effective date of such termination.

6.40 Fall Clause

The prices charged for the supplies under the contract by successful bidder shall in no event exceed the lowest price at which the successful bidder sells the items/NPPA price of identical description elsewhere in the country during the period of contract. If at any time, during the contract, the bidder reduces the price chargeable under the contract, he shall forthwith notify such reduction to the Tender Inviting Authority and the price payable under the contract of the items supplied after the date of coming into force of such reduction or sale shall stand correspondingly reduced.

6.41 Cross fall Breach Clause

The award of two contracts shall not in any way dilute the responsibility of the Supplier/ bidder for the successful completion of the contract and breach in one Contract shall automatically be constructed as a breach of the other Contract which will confer a right on the Purchaser to terminate the other Contract also at the risk and the cost of the Supplier/ bidder. Both contracts will contain a cross fall breach clause specifying that breach of one will constitute breach of the other.

SECTION –VII

FORMATS FOR SUBMISSION OF BID

(Technical Bid)

FORMAT – T 1

CHECK LIST

(To be submitted in ***Part I -Technical Bid***)

The documents have to be arranged as per the order mentioned in checklist for ease of scrutiny.

The bidder has to **upload the documents** as mentioned in Check list (**in PDF format) online** in the **e-procurement portal,** on or before the due date & time of submission of technical bid.

Copies of the all the documents uploaded in the technical bid shall **also to be submitted** along with the **Original EMD & Tender Document Cost** on or before the online technical bid opening. However, the copy of all documents should be exactly the same as uploaded in e-tender portal.

Name of the Bidder	

Sl. No	**Item**	**Whether included Yes / No**	**Page No.**
1	Format – T1 (Check List)		
2	Bid Document Cost as DD (Rs.5,900/- for any or all the item		
3.	The Earnest Money Deposit(s) as Demand Draft (s) based on no. of items tendered		
3	Format – T2 (Details of Items quoted)		
4	Format – T3 (Details of EMD submitted)		
5	Copy of the GST registration certificate		
6	Copy of PAN (Income Tax)		
7	Copy of IT Returns of the financial years during ***2021-22, 2022-23 and 2023-24 or 2022-23, 2023-24 and 2024-25***.		
8	Format – T4 (Details of Bidder)		
9	Format – T5 (Declaration Form)		
10	Format – T6 (Annual Turnover Statement by Chartered Accountant)		
11	Copies of the annual audited statement / Annual Report for during ***2021-22, 2022-23 and 2023-24 or 2022-23, 2023-24 and 2024-25***. (Provisional statement of account shall not be considered)		
12	Format–T7 (Performance Statement during the last three Years)		
13	Format–T8 (Product Manufacturing Certificate) OR Market Standing certificate by the drug licensing		

	authority in case of Drug items.		
14	Format–**T9** (Declaration of **compliance of WHO GMP/GMP (**for MSMEs registered within the state of Odisha**)**)		
15	Format – **T10** (Declaration Form for Production Capacity)		
16	Format – **T11** (Information regarding Quoted Items)		
17	Photo copy of valid manufacturing license / Import license for each and every product quoted by the drug licensing authority		
18	Valid Drug Endorsement for each quoted item/ Product registration certificate (In case of Importer) by the drug licensing authority		
19	Valid up-to-date Good manufacturing practice certificate as per revised schedule-M (GMP **(**for MSMEs registered within the state of Odisha**)**)/WHO GMP/ COPP Certificate by the drug licensing authority		
20	Valid up-to-date WHO GMP / COPP certificate (in case of importer) by the drug licensing authority		
21	Non Conviction certificate issued by the licensing authority of the state that the manufacturers/importer have not been convicted under the provision of D&C Act 1940 and Rules thereof by any court of law in contravention to the above Act & Rules.		
22	ISO Certificate		
23	BIS/CE Certificate (if any)		
24	Any other document required as per the technical specification (Section-IV)(i.e. Product Brochure/ Catalog/Data Sheet etc.)		

All the documents to be furnished in the checklist has to be page numbered. All the formats (T1 – T10) are to be filled up mandatorily.

Note:

1) Mentioning of Page Nos. in the relevant column as mentioned above is mandatory for ease of scrutiny.
2) No price information (i.e. Scanned copy of the price format etc.) to be uploaded in Technical Bid.
3) After preparation of the all the documents as per checklist, the bidders have to put the page nos. on each page and put the signature of the authorized signatory & seal. Then each page has to be scanned and the scanned document to be uploaded in the e-tender portal before the scheduled date & time.
4) The bidders can find two files [(i) Scan copy of EMD, Tender document cost, VAT, PAN etc. & (ii) All documents as per check list T1] in technical bid for uploading their files.

However, for management of space the bidders can divide their scanned documents in two parts and upload one part in one file and balance document in the second file to avoid any space constraint.

Format - T2

(To be submitted in *Part I -Technical Bid*)

DETAILS OF THE ITEMS QUOTED

(use additional sheets if space provided is not sufficient)

Sl. No.	Item Code	Item Name	Specification / Strength & Unit Pack	Pl. Mention (Item wise) whether participating as a Manufacturer / Importer	* Mfg. / import license number / product registration certificate number	Validity of Mfg. / Import License: Validity of GMP (for MSMEs registered within the state of Odisha) / WHO GMP /COPP:	Page No.(s) of Mfg. License / Import License & GMP (for MSMEs registered within the state of Odisha) /WHO GMP/COPP certificate (of the items quoted)	Shelf life of the quoted item(s)	Standard Batch Size of the quoted item(s)	Monthly Production Capacity of the quoted item(s)	Annual Production Capacity of the quoted item(s)
1	2	3	4	5	6	7	8	9	10	11	12

***Items should be supplied only from the manufacturing unit as per the quoted license no.**

*** Standard Batch Size, Monthly Production Capacity and Annual Production Capacity (**Column No. **9,10 &11** of **T2) of the quoted items must be specified in quantifiable no's i.e. in case of Tabs/Caps it should be in no. of Tabs/Caps, in case of Syrup/Sups'./Solutions/Lotions/Liquid internal or external preparations' it should be in no bottles/Jars etc., in case of Ointments/Semisolid preparations it should be in no. of Tubes/Jars etc., In case of Gauge/bandage/Cotton etc. it should be in no. of Than/KGs/Packets etc. and in case of inject able items/IV fluids it should be in no. of AMP/VIAL/Bottles etc.**

Signature of the Bidder:

Date: Official Seal:

Format – T3

(To be submitted in ***Part I -Technical Bid***)
(In terms of Cl. No**. 5.2.11** of Bid Document)

DETAILS OF EMD SUBMITTED

(Use separate sheet if the space provided is not sufficient)

Sl.	Item Code	Name of Item	D.D/e-BG/BC No. & Date & name of Bank	EMD Amount (Rs.)
		TOTAL (Rs.)		

Note : The bidder may submit one single DD/e-BG/BC of the total amount of the EMD(s) for the item(s) quoted. In case of one single EMD submitted (cumulative EMD amount), **if there is a discrepancy** (for e.g. arithmetical error in summing of the individual EMD values) then the item(s) mentioned in Format–T3 serially from the bottom shall not be considered for evaluation for the unmatched amount.

Signature of the Bidder:

Date:

Official Seal:

Format – T4

(To be submitted in ***Part – I Technical Bid***)

DETAILS OF THE BIDDER

GENERAL INFORMATION ABOUT THE BIDDER				
1	Name of the Bidder			
	Registered address of the firm			
	State		District	
	Telephone No.		Fax	
	Email		Website	
Contact Person Details				
2	Name		Designation	
	Telephone No.		Mobile No.	
Communication Address				
3	Address			
	State		District	
	Telephone No.		Fax	
	Email		Website	

Type of the Firm (Please □ relevant box)						
4	Private Ltd.		Public Ltd.		Proprietorship	
	Partnership		Society		Others, specify	
	Registration No. & Date of Registration.					

Nature of Business (Please □ relevant box)				
5	Manufacturer			
	Direct Importer			

Key personnel Details (Chairman, CEO, Directors, Managing Partners etc.)				
6	in case of Directors, DIN Nos. are required			
	Name		Designation	
	Name		Designation	

Name designation & Address of the person(s) responsible to the company as per Sec. 34 of D & C Act 1940.				
7	Name		Designation	

8	*Whether any criminal case was registered against the company or any of its promoters in the past?*	Yes / No
9	*Other relevant Information*	

9.a	*Furnish the copy of the GST registration certificate*				
9.b	*PAN : Furnish the copy of the PAN*				
10	***Bank Details of the Bidder: The bidders have to furnish the Bank Details as mentioned below for return of EMD / Payment for supply if any (if selected)*** **a. Name of the Bank :** **b. Full address of the Branch concerned :** **c. Account no. of the bidder :** **d. IFS Code of the Bank :**				
Date:		*Office Seal*		*Signature of the bidder / Authorized signatory*	

Format – T5

DECLARATION FORM

(To be submitted in ***Part–I Technical Bid***)
(In terms of Cl. No**. 5.2.13** and **6.38** of Bid Document)

(Affidavit before Executive Magistrate / Notary Public on **10** Rupees non- judicial stamp paper)

I / We ……having My / our registered office at……. & having My / our factory premises at……. do declare that I / We have carefully read all the terms & conditions of bid of OSMCL, Odisha for the supply of …….. (Name of the items). The approved rate will remain valid for a period of one year from the date of approval or new rate contract which ever is earlier . I will abide with **all the terms & conditions** set forth in the **Bid document Reference no. OSMCL/2025-26/ BLOOD BANK-SBTC/03** along with the subsequent amendment, if any.

I/We do hereby declare I/We are not de-recognized / debarred/ banned/ blacklisted/ convicted as a firm or for the quoted item(s) **on or before the date of floating of the tender** by any one or more of the authorities and for one or more of the reasons mentioned in Cl. No. **5.2.7** of the tender document.

I/We agree that the Tender Inviting Authority can forfeit the Earnest Money Deposit and or Performance Security Deposit and de-recognition/ debarment me/us for a period of **3(three)** years if, any information furnished by us proved to be false at the time of inspection / verification and not complying with the Bid terms & conditions. In case I/We are de-recognized / blacklisted/banned/ debarred by any State Govt. / Union Territory / Govt. of India / Govt. Organization / Govt. Health Institutions/ State Medical Corporations and or convicted by any court of law **on and from the date of floating of the tender**, I/We undertake to inform the same to OSMCL. I/we also under take that, I/we are not involved in any unfair/fraudulent practice.

I/ We do hereby declare that I / we will supply the quoted item(s) as per the terms, conditions & specifications of the bid document and hereby further declare that I/We will supply the items /Supplies with packing, logograms as per the design and barcode as specified in the Annexure I–III of the tender under reference.

I/We do hereby declare that I/We have not been convicted by any court of competent jurisdiction for supplying NSQ items within the last 3(three) years from the date of floating of the tender.

Signature of the bidder:

Seal:

Date:

Name & Address of the Firm:

Format – T6

(To be submitted in ***Part – I Technical Bid***)
(In terms of Cl. No**. 5.2.5** of Bid Document)

ANNUAL TURN OVER STATEMENT

(In the letterhead of the Chartered Accountant)

The Annual Turnover for the last 3(three) financial years of M/S_____ _____who is a manufacturer/importer of drugs are given below and certified that the statement is true and correct.

Sl. No.	***Financial Year***	***Turnover in Crores (Rs)*** **both in figures & words**
1	***2021 –2022/ 2022-2023***	
2	***2022-2023/ 2023-2024***	
3	***2023-2024/2024-2025***	

Date:

Signature of Auditor/
Place: Chartered Accountant

(Name in Capital)

Seal

Membership No.

N.B: This turnover statement should also be **supported by** copies of audited **annual statement** of the last three financial years / **Annual Report** and the turnover figures mentioned above should be **highlighted** there.

Format – T7

(To be submitted in ***Part – I Technical Bid***)

(In terms of Cl. No**. 5.2.8** of Bid Document)

PERFORMANCE STATEMENT

(For the period of last three years)

Name of Bidder:

Name of Manufacturer:_____ Name of the Item :_____

Sl.	Order Placed by (Address of purchaser)	Order no. & Date	Item Name with Drug Code.	Specification	Qty	Value of Contract (Rs.)	Date of Completion
1							
2							

(attach separate sheets if the space provided is not sufficient)

I / We ……having My / our registered office at……. and having My / our factory premises at……. do hereby declare that I / We have read and understood all of the terms and conditions of the bidding document under bid reference number ..... and the details furnished are true to the best of my/our knowledge. Further the above declare document will be submitted to the Tender Inviting Authority as and when required during any time of contract period, failing which action will be initited against me/us as per tender terms and condition.

Signature and seal of the Bidder

Format – T8

(To be submitted in ***Part – I Technical Bid***)
(In terms of Cl. No**. 5.2. 9** of Bid Document)

(**In LETTER HEAD OF THE LICENSING AUTHORITY)**

PRODUCT MANUFACTURING CERTIFICATE

MARKET STANDING(In case of Drug)

This is to certify that the following products are being manufactured and marketed BY M/s_____ address_____ _____ as per the details mentioned BELOW:

Sl. No.	Name of the drug	Strength	Name of the official compendia (IP/BP/USP/EP)	Manufacturing and marketing since (month / year)	Manufacturing license number
1.					
2.					
….					

(Attach separate sheets if the quoted items are more in numbers)

Signature:

Name:

Date :

Designation of Licensing Authority:

Seal:

Note : **The bidders may furnish the MARKET STANDING CERTIFICATE AS PER THE FORMAT OF THE CONCERNED DRUG LICENSING AUTHORITY, IF IT IS NOT POSSIBLE TO PROVIDE THE MARKET STANDING IN THE ABOVE FORMAT**

Format – T9

(To be submitted in ***Part – I Technical Bid***)

DECLARATION FOR MANUFACTURING ITEMS AND PRODUCTION CAPACITY AS PER GMP/WHO GMP/COPP

01. Name and Address of the Firm:

02. Name of Proprietor / Partner / Director:

03. Name, Designation and address of Person responsible to the company under Section 34 of D and C Act 1940:

04. GMP Certificate as per Revised Schedule "M"/COPP/WHO GMP/QMS:

o5. Testing Facilities (List of Equipments to be furnished Separately in the format to meet the bench mark vide Annexure/own facility/ name of approved institutions carrying out testing of drugs on behalf of the firm

Chemical Method	:	Yes / No
Instrumental (Type of Instrument Provided as indicated in Annexure)	:	Yes / No
Biological	:	Yes / No
Micro Biological	:	Yes / No
Animal Testing	:	Yes / No

(C) Production Capacity (Section Wise) in detail based on the quoted items.

Signature and Seal of Proprietor / Partner / Director

To be attested by the Notary. / Gazetted Officer / Licensing Authority

FORMAT –T9-A

(To be submitted on the date of sample submission)

Performa for Submission of samples of Blood Bags, Test Kits and Anti Serums

Name of the Bidder:_____

Address: _____

Sl. No	Item Code	Name of the Item	Technical Specification	Qty Submitted

Signature:

Date:

Seal:

FORMAT-T10(A)

DECLARATION FOR PRODUCTION CAPACITY OF THE QUOTED ITEM(S) BY THE MANUFACTURER

(To be submitted in ***Part–I Technical Bid***)
(In terms of Cl. No**. 5.2.14** of Bid Document)

(Affidavit before Executive Magistrate / Notary Public on 10 Rupees non- judicial stamp paper)

I / We ……having My / our registered office at……. & having My / our factory premises at……. do hereby declare that, I/ we have complied the minimum required production capacity for the following items which I /we have quoted in the said tender vide Bid Ref. No. **OSMCL/2025-26/ BLOOD BANK-SBTC/03** (as per format T2 and T3). Again, I/we declare that the Production Capacity which I/we mentioned at Format T2 is true in every sense, which is based on with my declaration at Format T9 (Declaration for manufacturing items and production capacity as per GMP **(**for MSMEs registered within the state of Odisha**)** /WHO GMP/COPP as per item dosages form).

Sl. No.	Item Sl. No. as per Section IV (Cl. No. 4.1)	Item Code	Item Name(s)	Strength / Specification	*Monthly Production Capacity of the Quoted item(s)	*Annual Production capacity of the Quoted item(s)
1						
2						
3						
4						
5						
6						

***N:B:- Monthly Production Capacity and Annual Production Capacity of the quoted items must be specified in quantifiable no's i.e. in case of Tabs/Caps it should be in no. of Tabs/Caps, in case of Syrup/Sups'./Solutions/Lotions/Liquid internal or external preparations' it should be in no bottles/Jars etc., in case of Ointments/Semisolid preparations it should be in no. of Tubes/Jars etc., in case of Gauge/bandage/Cotton etc. it should be in no. of Than/KGs/Packets etc., in case of X-Ray photo films it should be in no. of packets and in case of inject able items/IV fluids it should be in no. of AMP/VIAL/Bottles etc.**

Signature of the bidder:

Seal:

Date:

Name & Address of the Firm:

N:B:- In case of Importer he has to certify by himself based on its original manufactures production capacity.

FORMAT-T10 (B)

DECLARATION FOR PRODUCTION CAPACITY OF THE QUOTED ITEM(S) BY THE MANUFACTURER

(To be submitted in ***Part–I Technical Bid***)
(In terms of Cl. No**. 5.2.13** of Bid Document)

(Affidavit before Executive Magistrate / Notary Public on 10 Rupees non- judicial stamp paper)

I / We ……having My / our registered office at…… & having My / our factory premises at……. do hereby declare that, I/ we have complied the minimum required production capacity for the following items which I /we have quoted in the said tender vide Bid Ref. No. **OSMCL/2025-26/ BLOOD BANK-SBTC/03** (as per format T2 and T3). Again, I/we declare that the Production Capacity which I/we mentioned at Format T2 is true in every sense, which is based on with my declaration at Format T9 (Declaration for manufacturing items and production capacity as per GMP **(**for MSMEs registered within the state of Odisha**)** /WHO GMP/COPP as per item dosages form).

Sl No.	Item Sl. No. as per Section IV (Cl. No. 4.1)	Drug Code	Name of he Item	Specification / Strength	Minimum Required Monthly Production Capacity to Qualify In Technical Bid Evaluation	Whether you Complied the Minimum Required Monthly Production Capacity. (YES/NO)
1	1	S02166	Blood Collection Bag CPD-A1 100 ml (Single)	AS PER TENDER SPECIFICATION	1,747	
2	2	S02167	Blood Collection Bag CPD-A1 350 ml (Single)	AS PER TENDER SPECIFICATION	38,500	
3	3	S02170	Blood Collection Bag CPD 350 ml (Triple) with SAGM / SAGM-2 additive solution	AS PER TENDER SPECIFICATION	21,900	
4	4	S02171	Blood Collection Bag CPD 450 ml (Triple) with SAGM / SAGM-2 additive solution	AS PER TENDER SPECIFICATION	6,150	
5	5	S02173	Blood Collection Bag CPD 450 ml (Quadruple) with SAGM / SAGM-2 additive solution (top and bottom)	AS PER TENDER SPECIFICATION	300	
6	6	S02427	Blood Collection Bag CPD 450 ml (Quadruple) with SAGM additive solution (top and top)	AS PER TENDER SPECIFICATION	503	
7	7	S02480	Transfer Bag 100 ml	AS PER TENDER SPECIFICATION	2,570	
8	8	S02174	HIV (ELISA) TEST KIT	AS PER TENDER SPECIFICATION	61,440	

9	9	S02175	HBV (ELISA) TEST KIT	AS PER TENDER SPECIFICATION	61,440	
10	10	S02176	HCV (ELISA) TEST KIT	AS PER TENDER SPECIFICATION	61,440	
11	11	S02177	HIV (I&II) Rapid Diagnostic KIT	AS PER TENDER SPECIFICATION	5,130	
12	12	S02178	HBV Rapid Diagnostic test KIT (Serum based)	AS PER TENDER SPECIFICATION	56,480	
13	13	S02179	VDRL Rapid Diagnostic test KIT	AS PER TENDER SPECIFICATION	65,800	
14	14	S02180	HCV Rapid Test Kit	AS PER TENDER SPECIFICATION	91,810	
15	15	D48001	Anti– D (IgM only) , with dropper	AS PER TENDER SPECIFICATION	1,051	
16	16	D48002	Anti- D, IgM and IgG combination, with dropper	AS PER TENDER SPECIFICATION	906	
17	17	D48003	Anti A Group Sera, with dropper	AS PER TENDER SPECIFICATION	1,680	
18	18	D48004	Anti A1 Group Sera, with dropper	AS PER TENDER SPECIFICATION	322	
19	19	D48005	Anti AB Group Sera, with dropper	AS PER TENDER SPECIFICATION	326	
20	20	D48006	Anti B Group Sera, with dropper	AS PER TENDER SPECIFICATION	1,680	
21	21	D48007	Anti- Human Globulin (Green) polyspecific, with dropper	AS PER TENDER SPECIFICATION	335	
22	22	D48008	Anti Human Globulin, Monospecific, with dropper	AS PER TENDER SPECIFICATION	286	
23	23	D48009	Anti Human Globulin, Monospecific, with dropper	AS PER TENDER SPECIFICATION	74	
24	24	D48010	Bovine serum Albumin 22%, with dropper	AS PER TENDER SPECIFICATION	234	
25	25	D48011	Anti –H, with dropper	AS PER TENDER SPECIFICATION	371	
26	26	S02428	Bedside Leucofilter	AS PER TENDER SPECIFICATION	5,602	
27	27	S02429	Labside Leucofilter	AS PER TENDER SPECIFICATION	7,470	

Signature of the bidder:

Seal:

Date:

Name & Address of the Firm:

N:B:- In case of Importer he has to certify by himself based on its original manufactures production capacity.

Format – T11

DECLARATION FORM

(To be submitted in ***Part–I Technical Bid***)

(Affidavit before Executive Magistrate / Notary Public on **10** Rupees non- judicial stamp paper)

I / We ……having My / our registered office at……. and having My / our factory premises at……. do hereby declare that I / We have read and understood all of the terms and conditions of the bidding document under bid reference number ..... and I/We have participated in the items listed below. The page number is included in the scanned softcopy of bid document. I/We do hereby declare that I have submitted the required documents with the appropriate page numbers. An item may lead to disqualify if the document is not found in the corresponding page number of the bid document.

Sl No	Drug Code	Name of the item	Manufacture Licence No/Import Licence No with validity (page number)	Drug Endorsement (page number)	GMP **(**for MSMEs registered within the State of Odisha**)** /WHO GMP/ COPP with validity date (Relevant to Mfg./import licence no.) (page number)	DC Market standing certificate (page number)	Declaration format (Format T5) (page number)	Format T7 (page number)	Undertaking regarding production capacity T10 (page number)	Non Conviction certificate (page number)	Turn over (as in T6) (page number)	Format T3 (page number)

Signature of the bidder:

Seal: Date:

Name & Address of the Firm

PRICE SCHEDULE

Price bid format (BOQ) is **not enclosed** in this bid document. It has to be downloaded from the **e-procurement portal** https://tendersodisha.gov.in

PRICE BID (in the ***excel Format***) has to be submitted **online only**. The **price bid format (excel sheet available in e-Tender portal)** is specific to a bid and is not interchangeable. The price bid format file shall be **downloaded from the e-Tender portal** by the bidder and quote the **prices in the respective fields before uploading it**. All **white areas** of BOQ file shall be filled by the bidder. The **grey areas** of BOQ shall not be modified / edited by the bidder. The Price bids submitted in any other formats will be treated as non-responsive. Multiple price bid submission by bidder shall lead to cancellation of bid.

SECTION–VIII

ANNEXES

ANNEXURE – IA

INSTRUCTION FOR PACKAGING OF DRUGS & MEDICAL CONSUMABLES

1. Every Consignment of Blood and related products should be certified to be
   (a) HIV Free (b) Hepatitis Free
2. Strips of Aluminum foils refer to gauge 04.
3. Aluminum foils as back material for blisters refer to gauge 025.
4. The rigid PVC used in blister packing should be of not less than 250 micron
5. All plastic / glass bottles should be new / virgin neutral glass as per I.P.
6. Ointments should be packed in lacquered Aluminum Tubes.
7. LVP Fluid bottles should be FFS / BFS Plastic Bottle as per revised Schedule – M and Eye / Ear Drops should be of FFS plastic bottles.
8. Small Tablets packed in blisters should be packed to facilitate easy removal of the tablet without breaking / crushing.
9. Specification of outer cartons are as given in the Schedule (Annexure-IV)
10. In case of any conflict between Carton specifications and packets per carton specification (Last column of this table), the specification of the packets / carton shall prevail.
11. All liquid orals should be provided with a measuring device.
12. All plastic containers should be made of virgin grade plastics as per I.P.
13. All plastic jars above 450Gms / ml should carry an inner plastic lid.
14. Injection in vials should have a snap of seals.
15. The strips shall be aluminum strip / blisters with aluminum foil back.
16. All hygroscopic drugs and sugar coated tablets should be stripped in Aluminum foil / Blister pack.
17. Bandage, Gauze, Plaster Bandage, Roller Bandage & Cotton should be packed as per B.I.S/IP Specification as applicable.

ANNEXURE – IB

I. SCHEDULE FOR PACKAGING OF DRUGS AND MEDICAL CONSUMABLES

GENERAL SPECIFICATIONS

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

FLUTE:

4. The corrugated boxes should be of narrow flute.

JOINT:

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

STITCHING:

6. Every box should be stitched using pairs of metal pins with an interval of two inches between each pair. The boxes should be stitched and not joined using calico at the corners.

FLAP:

7. The flaps should uniformly meet but should not over lap each other. The flap when turned by 45 - 60° should not crack.

TAPE:

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

CARRY STRAP:

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

LABEL:

10. Every corrugated box should carry a large outer label clearly indicating that the product is for **"Odisha Govt. supply Not for sale"**.

11. The product label on the cartoon should be large at least 15cms x 10cms dimension. It should carry the correct technical name, strength or the product, date of

manufacturing, date of expiry, quantity packed and net weight of the box.

OTHERS:

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

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

(1) The box should not weigh more than 7-8 kgs. The grammage of outer box should be 150 gsm and inside partition / lining should be 120 gsm.

(2) The box should be of 5 ply with Bursting strength of 9 Kg/ Cm2

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

(1) All these bottles should be packed only in single row with partition between each and also with top and bottom pad of 3 ply.

(2) Gramm age :Outer box should be 150 gsm inside partition / lining should be 120 gsm

(3) Ply : 7 Ply.

(4) Bursting Strength : Not less than 12 Kg/Cm^2

IV. SPECIFICATION FOR IV FLUIDS

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

(2) Grammage : Outer box should be 150 gsm inside partition / lining should be 120 gsm

(3) Ply : 5 or 7

(4) Bursting Strength : Not less than 12 Kg/Cm^2

V. SPECIFICATIONS FOR LIQUID ORALS

30ml to 120ml bottles.

(1) 100 bottles of 50ml/60ml/30ml may be packed in a single corrugated in 2 rows with top, bottom and centre pad of 3 ply.

50 bottles of 100 ml - 120 ml may be packed in a similar manner in a single corrugated box.

(2) If the bottles are not packed in individual carton, 3 ply partitions should be provided between each bottle. The measuring device should be packed individually.

(3) Grammage : Outer box should be 150 gsm inside partition / lining should be 120 gsm

(4) Ply : 7 ply

(5) Bursting Strength : Not less than 12 Kg/Cm^2

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

VI. SPECIFICATIONS FOR OINTMENT / CREAM / GELS PACKED IN TUBES:

(1) No corrugate box should weigh more than 7-8 Kgs.

(2) Every Ointment tube should be individually packed in cartoon and then packed in 20's in a grey board box, which may be packed in a corrugated box.

(3) Grammage: Outer box should be 150 gsm inside partition / lining should be 120 gsm

VII. SPECIFICATIONS FOR INJECTABLE (IN VIALS AND AMPOULES)

(1) Vials may be packed in corrugated boxes weighing upto 15 Kgs. Ampoules should be packed in C.B weighing not more than 8 kgs.

(2) C.B. for vials should be of 150 GSM (outer box should be 150 GSM and inside partition / lining should be 120 GSM) and 7 ply, while C.B. for ampoules should be of 150 GSM (outer box should be 150 GSM and inside partition / lining should be 120 GSM) and 5 ply.

(3) Bursting strength for CB boxes for
a. Vials : Note less than 13 Kg/Cm^2
b. Amp : Note less than 9 Kg/Cm^2

(4) In the case of 5/10 ml Ampoules 100 or 50 ampoules may be packed in a grey board box. Multiples of grey board boxes packed in CB. In case of ampoules larger than 10 ml only 25 ampoules may be packed in a grey board box with partition.

(5) If the vial is packed in individual cartoon, there is no necessity for grey board box packing. The individual cartoon may be packed as such in the CB with centre pad.

(6) In case of ampoules every grey board box should carry 5 amps. Cutters placed in a polythene bag.

(7) Vials of eye and ear drop*s should be packed in an individual cartoon with a dispensing device. If the vial is of FFS technology, they should be packed in 50's in a grey board box.

VIII. SPECIFICATION FOR THERMOCOOL BOXES HOLDING TABLETS / CAPSULES / INJECTABLE (IN VIALS AND AMPOULES)

(1) The thermo cool box should be of standard thickness capable of withstanding all types of shock during transportation and to preserve the **cold temperature** throughout the period of transit.

(2) The thermo cool box should be packed with sufficient number of **cold packs** to maintain the desired temperature

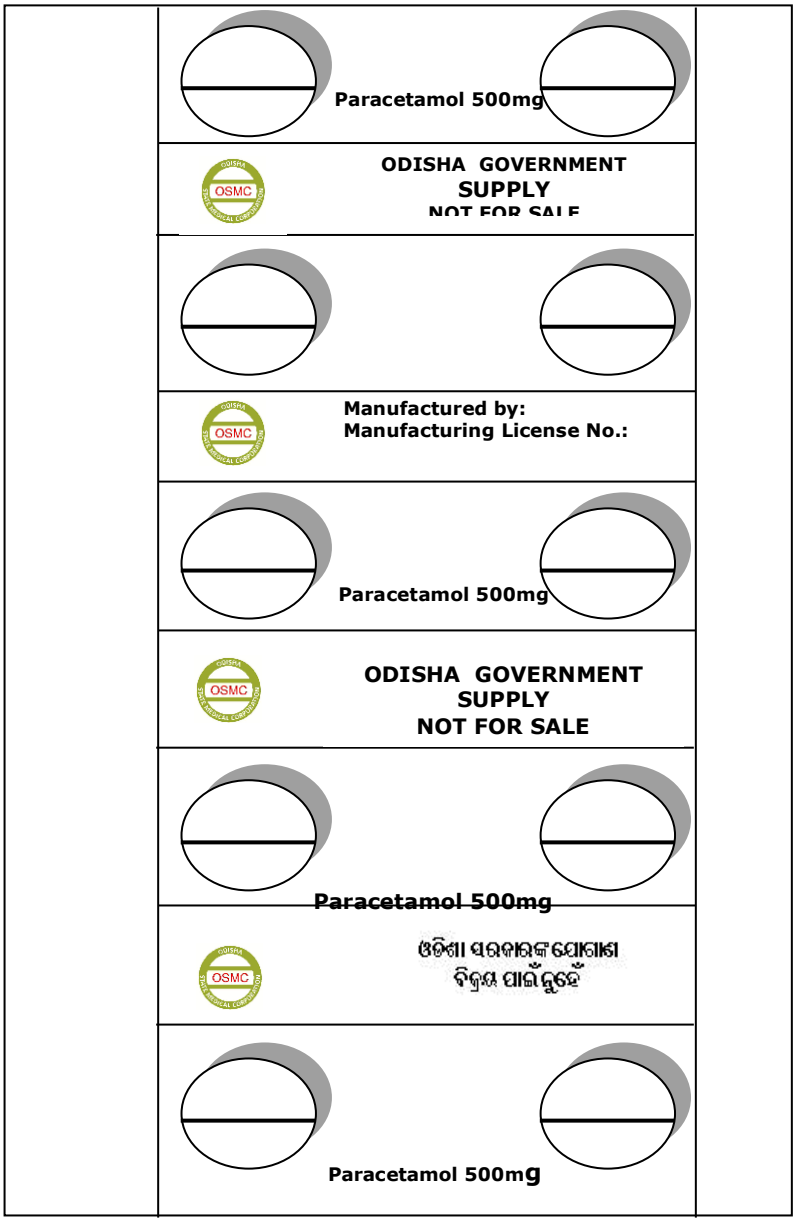
for the entire contents throughout the period of transit. Only first hand thermo cool boxes should be used

NB: If there are differences in packing between Section–IV (Schedule of Requirement) and Annexure I, then the packing & unit pack mentioned in Section – IV will be applicable.

ANNEXURE – I C

DESIGN FOR STRIP

FRONT SIDE **REAR SIDE**



Batch No. :
Date of Mfg.:
Date of Exp.:

N.B: **1.** **MRP OF THE DRUG/ BRAND NAME SHOULD NOT BE PRINTED ANY WHERE ON THE PRIMARY/SECONDARY/TERTIARY PACK.**

2. GENERIC NAME SHOULD BE PRINTED IN BOLD LETTER AS PER THE LATEST GUIDELINE.

ANNEXURE – II

SPECIMEN LABEL FOR OUTER CARTON

Name of the Consignee:

ODISHA GOVERNMENT SUPPLY
NOT FOR SALE
(Both in Odiya and English language)

PARACETAMOL I.P - 500mg

Mfg. Date : **Exp. Date :**

Batch No. :

Total Quantity :

Net Weight of the Carton:

Supply Head: "CENTRAL PURCHASE"

Purchase Order No.: **Date:**

Manufactured By:

ANNEXURE – III

BAR CODING DETAILS

Tertiary Packing

Box No. :
Drug Code:
Drug Name:
Batch No:
MFG. Date:
Expiry Date:
Carton Quantity:

1D - GS1 Bar coding as per the information mentioned above is to be printed on the **tertiary packing**

Secondary Packing

Supplier Name:
Batch No:
MFG. Date:
Expiry Date:

1D - GS1 Bar coding as per the information mentioned above is to be printed on the **secondary packing**

ANNEXES

(TO BE EXECUTED BY THE SUCCESSFUL BIDDER)

Annexure IV

Model Electronic Bank Guarantee Format for furnishing EMD
[Ref. Para 21]

(Electronic Bank Guarantee (e-BG) must be issued from any of the nationalized/scheduled bank in India authorised by RBI to issue e-BG are being acceptable. The issuing bank should have branches in Bhubaneswar. OSMCL reseves the rights to reject the e-BG, if the same is not in the specified format of OSMCL. The e stamping should be made in the name of bank executing the e-BG.)

Whereas..... (herein after called the "tenderer") has submitted their offer dated..... for the supply of ..... (herein after called the "tender") against the purchaser's tender enquiry No.....

KNOW ALL MEN by these presents that we..... of ..... having our registered office at ..... are bound unto ..... (herein after called the "purchaser") in the sum of ..... for which payment will and truly to be made to the said Common

Common Seal of the said Bank this.....day of.....20.....
THE CONDITION OF THIS OBLIGATION ARE:

1. If the tenderer withdraws or amends, impairs or derogates from the tender in any respect within the period of validity of this tender.
2. If the tenderer having been notified of the acceptance of his tender by the purchase during the period of its validity:-
   a) If the tenderer fails to furnish the performance security for the due performance of the contract.
   b) Fails or refuses to accept/execute the contract.

WE undertake to pay the purchase up to the above amount upon receipt of its first written demand, without the purchase having to substantiate its demand, provided that in its demand the purchase will note that the amount claimed by it is due to it owing to the occurrence of one or both two conditions, specifying the occurred condition or conditions.

This guarantee shall be valid until the _____
We the .....Branch.....undertake not to revoke the guarantee during its currency except with the previous consent of the ODISHA STATE MEDICAL CORPORATION in writing.

We the .....Branch..... further agree that a mere demand by ODISHA STATE MEDICAL CORPORATION LTD., is sufficient for us ..... Branch at Bhubaneswar to pay the amount covered by the Bank Guarantee without reference to the Agency and protest by said Agency cannot be a valid ground for us ..... Branch to decline payment to ODISHA STATE MEDICAL CORPORATION LTD.

.....
(Signature of the authorized officer of the Bank)
.....
Name and designation of the officer
.....
.....
Seal, name & address of the Banks and address of the Branch

Annexure V

Model Electronic Bank Guarantee Format for Performance Security

[Ref. Para 22(i)]

(Electronic Bank Guarantee (e-BG) must be issued from any of the nationalized/scheduled bank in India authorised by RBI to issue e-BG are being acceptable. The issuing bank should have branches in Bhubaneswar. OSMCL reseves the rights to reject the e-BG, if the same is not in the specified format of OSMCL. The e stamping should be made in the name of bank executing the e-BG.)

To

The Managing Director,
Odisha State Medical Corporation Ltd.,
Convenient Square-III, Bhubaneswar-751007

WHEREAS.....(name and address of the supplier) (here in after called "the supplier") has undertaking, in pursuance of contact no.....dated..... to supply.....(description of goods and services) (here in after called "the contract").

AND WHEREAS it has been stipulated by you in the said contract that the supplier shall furnish you with a bank guarantee by a scheduled commercial bank recognized by you for the sum specified therein as security for compliance with its obligation in accordance with the contract.

AND WHEREAS we have agreed to give the supplier such a bank guarantee;

NOW THEREFORE we hereby affirm that we are guarantors and responsible to you on behalf of the supplier, up to a total of .....(amount of the guarantee in words and figures), and we undertake to pay you, upon your first written demand declaring the supplier to be in default under the contract and without cavil or argument, any sum or sums within the limits of (amount of guarantee) as aforesaid, without your needing to prove or to show ground or reasons for your demand or the sum specified therein.

We hereby waive the necessity of your demanding the said debt from the supplier before presenting us with the demand.

We further agree that no change or addition to or other modification of the terms of the contract to be Performed there under or of any of the contract documents which may be made between you and the supplier shall in any way release us from any liability under this guarantee and we hereby waive notice of any such change, addition or modification.

This guarantee shall be valid until the .....day of .....20.....

We the .....Branch.....undertake not to revoke the guarantee during its currency except with the previous consent of the ODISHA STATE MEDICAL CORPORATION in writing.

We the .....Branch..... further agree that a mere demand by ODISHA STATE MEDICAL CORPORATION LTD., is sufficient for us ..... Branch at Bhubaneswar to pay the amount covered by the Bank Guarantee without reference to the Agency and protest by said Agency cannot be a valid ground for us ..... Branch to decline payment to ODISHA STATE MEDICAL CORPORATION LTD.

(Signature of the authorized officer of the Bank)
.....
Name and designation of the officer
.....
.....
Seal, name & address of the Banks and address of the Branch