



KERALA MEDICAL SERVICES CORPORATION LTD

(A Government of Kerala Undertaking)

Thycaud P.O, Thiruvananthapuram, Kerala 695 014

e-TENDER DOCUMENT

FOR THE PROCUREMENT OF

ANTI-HAEMOPHILIA DRUGS

(for the year 2019-20)

No: KMSCL/DRGED/HAEM/RC/2019/009 DATED 10.05.2019

<i>Date and time of commencement of the Tender</i>	:	10.05.2019	02.00 pm
<i>Last date and time for the online uploading of Tender</i>	:	10.06.2019	5.00 pm
<i>Date and time of online opening of Technical Bid</i>	:	14.06.2019	11.00 am

For details;

www.kmscl.kerala.gov.in

Email: **edrugs@kmscl.kerala.gov.in**

TABLE OF CONTENTS

Sl. No.	DESCRIPTION	PAGE No.
1.	Section I Introduction	1
2.	Section II General Definitions/Explanations	4
3.	2.27 Pre-tender meeting	7
4.	Section III Tender Schedule	8
5.	3.1 Tender Details	8
6.	3.2 Schedule of dates	8
7.	Section IV Details of Items Tendered	9
8.	4.1 List of items tendered	9
9.	Section V Specific Conditions of Contract	10
10.	5.1 Time Limits Prescribed	10
11.	5.2 Eligibility criteria for participating in the tender	11
12.	5.2.1 Manufacturing license and product permit	11
13.	5.2.2 Average Annual Turnover	12
14.	5.2.3 Special cold storage facilities	12
15.	5.2.4 Market Standing	12
16.	5.2.5 WHO-GMP & COPP	13
17.	5.2.6 Plasma Master File (PMF)	13
18.	5.2.7 Supplies made to other agencies	15
19.	5.2.8 Non-conviction Certificate	15
20.	5.2.9 Minimum Required Shelf Life	15
21.	5.2.10 Blacklisted/Debarred/Rejected by Tender Inviting Authority or other agencies:	15
22.	5.2.11 Inspection of manufacturing premises	16
23.	5.3 Price Preference to PSUs and MSMEs within Kerala	16
24.	Section VI General Conditions of Contract	18
25.	6.2 Responsibility of verification of contents of Tender Document	18
26.	6.3 Tender Document & Earnest Money Deposit	18
27.	6.4 Mode of Payment of Tender Document Cost and EMD	19
28.	6.5 Guidelines for preparation of Tender	22
29.	6.6 Period of Validity of Tender	23
30.	6.7 Amendment of Tender Documents	23

Sl. No.		DESCRIPTION	PAGE No.
31.	6.8	Tendering System	24
32.	6.9	Contents of the Technical Bid	25
33.	6.10	Price Bid (BOQ)	28
34.	6.11	Submission of Tender	29
35.	6.12	Deadline for Submission of Tender	29
36.	6.13	Modification and Withdrawal of Bids	30
37.	6.14	Opening of Tender	30
38.	6.15	Evaluation of Tender	30
39.	6.16	Inspection of Manufacturing Facilities	32
40.	6.17	Acceptance / Rejection of Bids	34
41.	6.18	Other Terms and Conditions	35
42.	6.19	Notices	35
43.	6.20	Award of Contract	36
44.	6.21	Letter of Intent	36
45.	6.22	Signing of Contract	36
46.	6.23	Security Deposit	38
47.	6.24	Purchase Procedures	38
48.	6.25	Supply Conditions	40
49.	6.26	Logograms	45
50.	6.27	Packing and Labeling	45
51.	6.28	Quality Testing, Quality Control Deduction and Penalties	48
52.	6.29	Payment Provisions	50
53.	6.30	Penalties & Deduction in Payments	52
54.	6.31	Saving Clause	54
55.	6.32	Applicable Law & Jurisdiction of Courts	54
56.	6.33	Corrupt or Fraudulent Practices	55
57.	6.34	Code of Contract for Suppliers	56
58.	6.35	Force Majeure	58
59.	6.36	General / Miscellaneous Clauses	58
60.	6.37	Procedure for Blacklisting	59
61.	6.38	Provisions for Appeal	59
62.	6.39	Termination of Contract	59
63.	Annexure I	Check List	62
64.	Annexure II	Bid offer Form	65
65.	Annexure III	Annual Turnover Statement	66
66.	Annexure IV	Performance Statement	67

Sl. No.		DESCRIPTION	PAGE No.
67.	Annexure V	Methods adopted by the bidder for the viral inactivation/purification	68
68.	Annexure VI	Tests performed on viral detection	68
69.	Annexure VII	Purity of the offered products as per the international standards of purity defined by WFH	69
70.	Annexure VIII	Details of testing at NIB	69
71.	Annexure IX	Details of supply made to other agencies	70
72.	Annexure X	Declaration and Undertaking	71
73.	Annexure XI	Packing and Labeling Specification	74
74.	Annexure XII	Details of the Bidder and Manufacturing Unit	76
75.	Annexure XIII	Format of Bank Guarantee of EMD	78
76.	Annexure XIV	Agreement	80
77.	Annexure XV	Format of Bank Guarantee for Security Deposit	83
78.	Annexure XVI	Format of Performance Bank Guarantee	85
79.	Appendix-I	Addresses of the KMSCL Drug Warehouses	87

SECTION I

INTRODUCTION

- 1.1.**The Kerala Medical Services Corporation Limited - KMSCL is a fully owned company of Government of Kerala set up in 2007 and is operational with effect from 1st April 2008 for providing various services to the health care institutions under the Department of Health and Family Welfare, Government of Kerala. One of the key objectives of the KMSCL is to act as the central procurement agency for all essential drugs including Medical devices and other stores and equipments for the health care institutions (hereinafter referred to as user institutions) under the department. The Corporation has also been entrusted with the setting up and running of all kinds of Modern Medical and Paramedical or medical based ancillary facilities such as hospitals, pathological labs, diagnostic centres, x-ray/scanning facilities, ambulance services etc.
- 1.2.**This tender is an e-tender and only on-line bid submission is possible. The e-tender portal (www.etenders.kerala.gov.in) is designed by National Informatics Centre (NIC) and supported by the IT Mission, Kerala.
- 1.3.**Bidders are cautioned that bids devoid of proper documents or adequate information are liable to be rejected. Bids of firms who have furnished all the required documents for each of the product quoted alone will be considered. Utmost care should be taken to see that all the required/proper documents are uploaded.
- 1.4.**All supplies shall be accompanied with the certificates of analysis from the in-house testing laboratory and National Institute of Biologicals (NIB) in respect of each batch supplied. Supplies devoid such reports will not be taken into stock and payments will not be made. Suppliers will be required to take back the supplies and will be deemed as defaulters in respect of the supply and shall be liable for penalties applicable for non-supplies. This test report or the QC approval will not be deemed as a proof of stability of the product during shelf life. The bidders are cautioned that supply of drugs of inferior quality would attract different penal provisions. It is the onus of the manufacturer and supplier under the Drugs and Cosmetics Act and Rules to produce and supply drugs of standard quality and various measures are prescribed in the law to achieve the object. The Corporation would be testing the drugs and other materials at random at different stages, at discretion, and the supplier will have the obligation to pay the cost of the goods found to be

defective and may also be liable for criminal procedures as may be initiated by the Drugs Control department. The bidder will also be liable for disqualification from the tenders of the Corporation.

- 1.5. Inspections of manufacturing units of bidders prior to acceptance of bid or at any stage before or after award of contract will be at the discretion of the Corporation.
- 1.6. A pre-tender meeting will be convened to clarify the doubts of the prospective bidders. The Corporation may amend the terms and conditions as well as technical specifications of the Tender Document after the pre-tender meeting on the basis of feedbacks obtained during such meeting with a view to obtain maximum number of competitive bids and as part of transparency. A pre-bid meeting will be held at Thiruvananthapuram as scheduled in the tender document to inform the requirements of the current year's tender.
- 1.7. Amendments in the terms and conditions of the Tender Documents may be necessitated before the last date of submission of bid on the basis of feedbacks obtained from pre-tender meeting and on expert advice on the feedbacks.
- 1.8. Since the drugs procured are meant for treatment of precious human life in Government hospitals, depended by the poor and downtrodden of the society, it is our endeavor to ensure that only quality drugs are procured and supplied.

If on testing in the laboratory or other verifications the drug is found to be of inferior quality or not complying with the parameters of quality including packaging or any of the provisions of the law the drug supplied will be refused and the supplier will be liable to repay the amount paid and make good the other losses as may be applicable.

- 1.9. Where any drug is found to be Not of standard quality or misbranded or adulterated or spurious or otherwise contravenes the provisions of the Drugs and Cosmetics Act or Rules, the payments for the entire supply of the batch(s) concerned will be withheld or recovered. However, if the Tender Inviting Authority finds the supplier to be an unreliable party by virtue of the violations of the law or of the contract as the case may be, the TIA may terminate the contract and also may blacklist the supplier. Apart from the tests mentioned in the official monographs, additional tests like friability and hardness of the tablets, leak test for primary

packing of the products, freedom from pathogenic organisms etc will be conducted as drug safety depends upon total quality compliance. The suppliers shall be solely responsible for ensuring the quality of the item during transportation and shelf-life. The packaging drugs used for primary and secondary packaging shall be of such nature that the quality of the drug contained is preserved throughout its life period. The storage requirements stated on the labels shall be in accordance with the provisions of the Drugs and Cosmetics Rules only and prescribing cool or cold storage for drugs in respect of which no such stipulation is made in the law will not be acceptable. Quality Assurance goes together with Quality Control and it is the onus of the bidder to ensure not only proper quality control but also total quality assurance.

1.10. The money spent by the Corporation is public money and hence accountable. All decisions will be published from time to time on our website www.kmscl.kerala.gov.in.

10.05.2019

Sd/-
Dr. Dileep Kumar S R
Managing Director i/c, KMSCL &
Tender Inviting Authority

SECTION II

2.General Definitions/Explanations

- 2.1 *Government* means - Government of Kerala, represented by the Secretary to Health & Family Welfare, Thiruvananthapuram.
- 2.2 *Tender Inviting Authority (TIA)* - is the Managing Director of the KMSCL, who on behalf of the User Institution/Government or the funding agencies invites and finalizes bids and ensures supply of the drugs procured under this Tender Document. The term shall include such other officials not below the rank of General Manager of the KMSCL to whom any of the powers of the Managing Director is delegated.
- 2.3 *Tender Document* - means the document published by the Tender Inviting Authority containing the data identifying the article to be purchased, the quantity and delivery, and which includes designs, specifications, quality requirements and general conditions which will govern the contract on acceptance of a bid.
- 2.4 *Running Contract* – means contract for the supply of an approximate quantity of items at a specified price during a certain period.
- 2.5 *e-tender* - The process of notifying/ floating tender and pursuing actions of tender opening online.
- 2.6 *e-Way Bill* - document attached to goods in transit specifying their nature, point of origin, and destination as well as the route to be taken and the rate to be charged.
- 2.7 *Tendered quantity* – means the approximate quantity of items intended for supply to the user institutions as mentioned in Section IV of the Tender Document, in respect of which the rates has to be quoted. Tender Inviting Authority reserves the right to increase or decrease the tendered quantity on the basis of the actual needs or as per the directions of the government, fund availability etc or otherwise, the quantity of goods mentioned under Clause. 4.1, without any increase in the unit price and other terms & conditions quoted by the bidder.
- 2.8 *User Institutions* - are government departments, health care institutions, autonomous bodies, Local self-Government Institutions etc for which the drugs under this tender are procured.
- 2.9 *Funding agencies* - are usually departments like Directorate of Health Services, Directorate of Medical Education, Departments of Ayurveda,

Homoeopathy, Department of Social Welfare etc, and Missions/organizations like National Health Mission (NHM), Institute of Family Health & Welfare, registered societies etc funded by the Government of Kerala, Government of India, UN organizations, World Bank, Government assisted organizations etc who provide funds for the procurement of drugs on behalf of whom the tender is invited by the Tender Inviting Authority.

- 2.10** *Blacklisting/ debarring* – the event occurring by the operation of the conditions under which the bidders will be prevented from participating in the future bids of Tender Inviting Authority for a period up to 3 years, the period being decided on the basis of number/nature of violations in the tender conditions and the loss/hardship caused/likely to be caused to the Tender Inviting Authority on account of such violations, generally relating to supply of substandard, misbranded, adulterated or spurious or any drugs / products manufactured/ imported in contravention of any of the laws of the land and for indulging fraudulent practices or having indulged in fraudulent practices at the time of making the bid or at any time during the validity of the tender or the contract thereof. The term will include, among all other things, making false/ misleading declarations statements, presenting false/ misleading/ fabricated/ forged document(s), trying to influence/affect/ stall the tender/ procurement/ payment processes in any way, making false/ baseless complaints about other bidders or bids or products or any person/ organization/ related to the tender activities etc and such activities as specified in this Tender Document. Blacklisting/debarring etc by other State/Central Government departments/agencies shall also be ground for blacklisting by the TIA.
- 2.11** *Drug* - means and includes, substances defined as drug in the Drugs and Cosmetics act 1940.
- 2.12** *Factory Inspection* - The factory premises and related facilities and documents shall be open for inspection at the discretion of the TIA at any stage after presentation of bid or award of contract.
- 2.13** *Infirmities* - means non-compliance of any of the requirement specified in the Tender Document.
- 2.14** *L1 rate* - means the lowest rate declared by the Tender Inviting Authority for products mentioned in this Tender Document.

- 2.15** *Matched L1 rate* - means the rate of the bidder or bidders who have consented, in writing, to match with the L1 rate for the particular product and agreed to abide by the terms and conditions of the Tender Document.
- 2.16** NPPA - The National Pharmaceutical Pricing Authority is a government regulatory agency that controls the prices of pharmaceutical drugs in India.
- 2.17** *Liquidated Damages* – means penal charges levied by the Tender Inviting Authority for the delay in supply of the products after the expiry of stipulated period mentioned in the supply conditions of the tender at the rate mentioned therein, subject to a maximum of 10% of defaulted value.
- 2.18** *Risk & Cost Value* – is the additional cost incurred by the TIA in making alternate purchases of the quantity defaulted by the supplier from other sources at a higher cost.
- 2.19** *Unexecuted fine* - is the fine imposed for the default committed by the supplier in the form of short-supply or non-supply of the quantity of the product ordered as per the Purchase Order.
- 2.20** *Letter of Intent* – is an intimation informing the successful bidder, the approximate quantity for which the Tender is awarded and requiring the bidder to execute agreement in the prescribed format within a specified time.
- 2.21** *Purchase order* - means the order issued by the Tender Inviting Authority to the supplier informing to supply the required quantity of the Drugs at the contract price and requiring the supplier to supply at the various designated destinations mentioned in the Supply Schedule accompanying the purchase order.
- 2.22** *Supply Schedule* – means the schedule for supply of product which shall be adhered to for supply as per 5.1.2 unless altered with mutual consent on the basis of the movement /consumption of products, exigencies and other reasons suiting the requirements of TIA and not suiting to the requirements of the supplier.
- 2.23** *Basic unit* – means the smallest unit of the drugs to be made available and shall be of form tab/cap/vial etc. The rate to be given on the price bid shall be quoted for the basic unit mentioned in Section IV.

- 2.24** *Supplier* - is a person/firm/company or other(s) to whom Purchase Order is placed on fulfilling the qualification criteria and terms and conditions laid down in the Tender Document.
- 2.25** *'Domestic Micro, Small and Medium Enterprises'* - means industrial units as classified in Clause 7(1) of chapter III of the Micro, Small and Medium Enterprises Development Act, 2006 which manufactures the goods within the state and registered with the competent authority of the Industries and Commerce Department of Govt. of Kerala.
- 2.26** *Empanelled laboratory* - Drug testing laboratory approved under the Drugs and Cosmetics Act, selected by the Tender Inviting Authority either through open tender process or by expression of interest or otherwise for the purpose of conducting analytical testing of drugs listed in Section IV supplied by the suppliers.
- 2.27 Pre-Tender Meeting**
- 2.27.1** Date and venue of pre-tender meeting is mentioned in Section III.
- 2.27.2** Pre-tender meeting is called by the Tender Inviting Authority to explain briefly about the requirements as well as the terms and conditions of the Tender Document and to get the views of the prospective bidders, as part of ensuring transparency in the tender process.
- 2.27.3**It is an opportunity for the prospective bidders to obtain all the details about the tendered items, conditions governing the bids and also to get the explanation of any ambiguous conditions, if any, in the Tender Document.
- 2.27.4**It is also an opportunity for the Tender Inviting Authority to assess the market and obtain feedback on the technical specifications/features etc requested by the User Institution/funding agency, so as to make amendments in the Tender Document on the basis of expert advice.
- 2.27.5**Failure to attend the pre-tender meeting will not be a disqualification, but is an opportunity missed by the prospective bidders to understand the Tender conditions.
- 2.27.6**The bidders are required to upload online bids only after the date of pre-tender meeting.

SECTION III

3. TENDER SCHEDULE

3.1. Tender Details

1.	<i>Tender No.</i>	KMSCL/DRGED/HAEM/RC/2019/009
2.	<i>Cost of Tender Document</i>	29,500/- (Inclusive of GST@ 18%)
3.	<i>Earnest Money Deposit</i>	Shall be as specified in Clause 4.1 and 6.4. The minimum EMD of Rs.2,47,500/- shall be submitted online along with cost of tender document
4.	<i>Validity of EMD</i>	8 months from the date of opening of Technical Bid.
5.	<i>Security Deposit</i>	5% of the total value (including GST) of the LOI
6.	<i>Validity of Security Deposit</i>	18 months from the date of LOI or 3 months after successful completion of supply whichever is later.
7.	<i>Factory re-inspection fee as per clause 6.16..2</i>	Rs. 1,00,000 as Demand Draft

3.2. Schedule of Dates

Sl. No.	Particulars	Date and time
1.	<i>Date and time of commencement of downloading (by bidders) of Tender Document</i>	10.05.2019 02.00 pm
2.	<i>Date and time of pre-tender meeting</i>	23.05.2019 (11.00 am to 1.00 pm) Venue: Head Office of KMSCL, Thycaud, Trivandrum
3.	<i>Last date and time of uploading (by bidders) of tender</i>	10.06.2019 05.00 pm
4.	<i>Date & time for receipt of sealed cover containing (a.)Balance EMD by way of DD/BG (b.)Factory re-inspection fee by way of DD (if applicable) (c.)Factory inspection fee for additional units by way of DD (if applicable) (d.)Notary attested copy of Plasma Master File (PMF) for all the quoted items.</i>	11.06.2019 10.00 am to 13.06.2019 05.00 pm
5.	<i>Date and time of opening of the Technical Bid</i>	14.06.2019 11.00 am
6.	<i>Date of opening of the price bid</i>	To be informed to the bidders qualifying in the Technical Evaluation

SECTION IV

4. DETAILS OF ITEMS TENDERED

Category	Particulars	No of items in each Category	Sl. No. in the list of items quoted (Section 4.1)
Anti Haemophilia Drugs	Drugs	3	1-3

4.1. List of items Tendered

ANTI HAEMOPHILIA DRUGS							
SL No	Drug Code	Drug Name	Strength	Unit	Tender Quantity 2019-20	Minimum Shelf life required (in months)	Required EMD (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
1	D12025	FACTOR VIII INHIBITOR BYPASSING AGENT (FEIBA)	500 IU	1 No	1118	24	2,87,700
2	D12024	HUMAN ANTI HAEMOPHILIC FACTOR IX	600 IU	1 No	2732	24	3,41,500
3	D12023	HUMAN ANTI HAEMOPHILIC FACTOR VIII	250 IU	1 No	8462	24	2,47,500

SECTION V

5. SPECIFIC CONDITIONS OF CONTRACT

5.1. Time Limits prescribed

Sl. No	Activity	:	Time Limit	
1	<i>Schedule of dispatch details</i>			
	<i>0th day</i>	:	Letter of Intent (LOI)/Purchase Order or both	
	<i>Within 21 days of LOI</i>	:	The supplier shall submit agreement, copy of LOI duly signed and sealed on all pages in token of acceptance, required Security Deposit and other documents specified in clause 6.22.2 & 6.22.3 as applicable.	
	<i>Within 10 days of Purchase order</i>	:	The supplier shall furnish confirmed dispatch schedule. If the confirmed dispatch schedule is not received on or before the specified period, the purchase order is liable to be cancelled and arrangement for alternate purchases will be done at the risk and cost of the supplier.	
2	<i>Schedule of purchase order and Supply</i>	:	The first set of purchase orders will be up to 50% of the LOI quantity. Subsequent purchase orders will be issued for 25% of the LOI quantity.	
		:	The schedule of supply drugs will be as follows;	
		1	No of days from purchase order	%
1	Within 90 days	100%		
3	<i>Payments against supplies</i>	:	The Payments against invoices will be initiated on receipt and acceptance of 50% of the ordered quantity as per clause detailed in 6.29.	
4	<i>Cancellation schedule of purchase orders/unexecuted portion of LOI/PO</i>	:	<i>Cancellation of purchase orders/unexecuted portion of LOI/PO</i> in the event of failure to supply the ordered quantity shall be as under:	
		:	If the supplied quantity is less than 50% of the ordered quantity on the stipulated day, the remaining unexecuted portion of the order and the remaining part of the LOI are liable to be cancelled without notice and the contract with respect to the product(s) is liable to be terminated. Alternate purchase will be made at the risk and cost of the supplier.	
5	<i>Penal provisions for supply inefficiency</i>	1	Delayed supply	A penalty of 0.5% per day of the delayed supply up to a maximum of 10%.

Sl. No	Activity	:	Time Limit
		2	Unexecuted Supply Procedure for alternate supply as mentioned in Clause 6.25.22. A penalty of 10% of the value of unexecuted quantity or the extra expenditure incurred for the alternate purchase of the item, whichever is higher will be levied from the defaulted supplier.
6	<i>Release of EMD</i>	1	Unsuccessful bidders EMD submitted online will be discharged/ refunded automatically to the bidders account after finalizing the tender. In the case of EMD remitted in excess of Rs.2,47,500/- paid by way of DD/BG, the amount will be refunded within 30 days on finalization of the bid.
		2	Successful bidders EMD submitted online/DD/BG will be released on signing the contract and after furnishing of required Security Deposit. EMD submitted online/DD may also be adjusted towards Security Deposit on request of the bidder.
7	<i>Release of security deposit / Performance Guarantee</i>		18 months from the date of LOI or 3 months after successful completion of supply whichever is later.

5.2. Eligibility criteria for participating in the tender

5.2.1. Manufacturing license and product permit:

5.2.1.1. The Bidder shall be the manufacturer/loan licensee having valid manufacturing license for the item(s) quoted /direct importer holding valid import license. Importers shall possess the valid sale license also, as applicable.

- 5.2.1.2. The bidder should hold product permit duly approved by the Licensing Authority for all the products quoted. Bids/offer should not be submitted for the product for which the product permit differs with regards to any of the tendered specification.
- 5.2.1.3. The bidders are permitted to offer one item from more than one manufacturing unit. In such circumstances an inspection fee of Rs. 50,000/- for each additional manufacturing unit should be remitted to KMSCL, if the additional manufacturing unit has not been inspected by the Tender Inviting Authority for the past 3 years, in the dates specified in clause 3.2.

Distributors/agents/contract manufacturers are not eligible to participate in the tender

5.2.2.Average annual turnover:

- 5.2.2.1 Average Annual turnover in the last three years (2015-16, 2016-17 and 2017-18) shall not be less than **Rs. 50 Crores**.
- 5.2.2.2 In case of Micro, Small and Medium Enterprises (here in after referred as MSME) located in Kerala State, the average annual turnover for the last three year shall not be less than Rs.50 Lakhs. The bidder shall submit proof of the same (notary attested copy of audited accounts, balance sheet, annual report etc).

5.2.3.Special cold storage facilities:

- 5.2.3.1. Those bidders offering the items requiring special cold storage condition should either have their own cold chain transporting system or should have proper contract with a transporting agent having facilities to transport the drugs under cold chain norms from the manufacturing unit to the respective warehouses of the Corporation by complying cold chain norms.
- 5.2.3.2. The containers of these items should be provided with temperature variation indicators like vaccine vial monitors or the consignment should be provided with data loggers for recording the temperature conditions during transit, the software of which also should be provided to all the warehouses.

5.2.4.Market Standing:

- 5.2.4.1. The Bidder should have at least 3 (three) years Market Standing as a manufacturer / importer/ for each drug quoted in the tender.

5.2.4.2. The bidder should also have manufactured/imported and supplied at least 5 commercial batches of the offered drug in the last 3 consecutive years (total 5 batches in 3 years) in respect of which the bidder shall furnish the statements of all batches manufactured year wise in the format given as **Annexure-IV**.

5.2.5.WHO-GMP and COPP:

5.2.5.1. The bidder should hold valid WHO-GMP Certificate (WHO-Good Manufacturing Practices) in respect of the production units and the products quoted. If the offered products are manufactured from more than one unit, all the units shall be WHO-GMP certified.

5.2.5.2. The bidder should hold valid Certificate of Pharmaceutical Product (COPP) issued by the Licensing Authority for the items quoted.

5.2.6.Plasma Master File(PMF)

5.2.6.1. The quality and safety of products derived from human plasma rely both on the source plasma material and the manufacturing processes. The manufacturers of plasma derived medicinal products shall possess a Plasma Master File (PMF) which is a compilation of all the required scientific data on the quality and safety of human plasma relevant to the medicines, medical devices and investigational products that use human plasma in their manufacture. The Plasma Master File (PMF) shall cover all aspects of the use of plasma, from collection of human plasma to the finished plasma-derived medicinal products. The PMF shall be approved by the Central License Approving Authority and currently valid. The bidder shall furnish a notary attested copy of **Plasma Master File approval certificate** issued by the Central License Approving Authority, along with the online bid.

5.2.6.2. The viral inactivation/purification and validation methods adopted by the bidder shall be approved by the Central License Approving Authority. The bidder shall furnish notary attested copy of all the relevant pages in the Plasma Master File (PMF) on viral inactivation/purification methods. The bidders should mandatorily adopt (1) Solvent-Detergent treatment or Heating Methods, (2) **Any of the Chromatographic Methods specified in Annexure V** for viral inactivation/purification during the manufacturing process. The items manufactured without adopting less than the above two viral inactivation/purification methods are ineligible to participate in the

tender. All the methods adopted for the purpose shall be noted in the format given in **Annexure V**.

- 5.2.6.3. Factor concentrate should be prepared from well verified source plasma, which is individually Nucleic Acid Amplification Test (NAT) performed & found to be Negative. The bidder shall furnish notary attested copy of all the relevant pages on viral detection tests performed in the source plasma, during manufacturing process and the finished products available in the Plasma Master File (PMF), along with the online bid and also the details in the format as in **Annexure-VI**.
- 5.2.6.4. The Factor concentrates offered shall be not less than High purity (100 to 1000 IU of factor per mg of protein **before addition of any protein stabilizer**) as defined by the WFH (World Federation of Hemophilia). The bidder shall furnish notary attested copy of documents to prove to purity of the offered products and the details in the format as in **Annexure-VII**.
- 5.2.6.5. The bidder should have the system which enables each donation to be traced from the donor to finished product and vice versa. All the measures taken to ensure traceability from different plasma collection centers shall be documented. The bidder shall furnish notary attested copy of all the relevant documents on donor traceability along with the online bid.
- 5.2.6.6. **The bidder shall also submit copy of the entire set of PMF of the all the items quoted at the head office of the Corporation on the dates specified in Section III.**
- 5.2.6.7. The products offered shall conform to the standards specified in the Indian Pharmacopoeia (IP). Where the standards of any products are not specified in the IP or the offered product is imported, the item shall conform to the standards specified in the other official monographs (USP/BP/EP etc).
- 5.2.6.8. Tender should not be submitted for a bidder, if any one of their manufactured/imported batches tested in National Institute of Biologicals (NIB), Ministry of Health & Family Welfare, Govt. of India during the past years since 2016-17 (2016-17, 2017-18 and 2018-19) is rejected/declared as Not of Standard Quality by the NIB. The bidder shall give the details of batches tested in NIB in the format as in **Annexure VIII** together with notary attested copy of test reports from NIB of all the batches manufactured from 2016-17 onwards.

5.2.7. Supplies made to other agencies

5.2.7.1. The bidder shall be the current supplier of the quoted products atleast in any three of the below listed organizations or has supplied the quoted items in any three of the organizations during the past three years.

(All India Institute of Medical Sciences (AIIMS), Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER) Pondichery, Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS) Lucknow, King Edward Memorial Hospital (KEM) Mumbai, Christian Medical College and Hospital (CMC) Vellore, Vardhman Mahavir Medical College & Safdarjung Hospital New Delhi, Central Government Health Scheme (CGHS), Other State Medical Services Corporations/Central Procurement agencies.)

5.2.7.2. The bidder shall furnish the statement of supply made to these organizations in the format given in **Annexure IX** and should also furnish the notary attested copy of documentary proof such as Letter of intent/ purchase order /performance certificate etc issued by the above organizations.

5.2.8. Non-conviction Certificate:

5.2.8.1. The bidder shall not be convicted under the Drugs and Cosmetics Act and other laws administrated by the department and no prosecution actions shall be in progress or pending against the licensee and the license of the firm shall not be cancelled or suspended for non compliance of provisions of Drugs and Cosmetics Act 1940 and the rules 1945.

5.2.9. Minimum Required Shelf Life:

5.2.9.1. Tender should not be submitted for a product with shelf life lesser than that specified in Section IV (List of items Tendered) of the tender document.

5.2.10. Blacklisted/Debarred/Rejected by Tender Inviting Authority or other agencies:

5.2.10.1. Tender should not be submitted for the Firms /Concern/Company or for any product(s) which stand(s) blacklisted by KMSCL for any reason.

- 5.2.10.2. Tender should not be submitted for the Firms/Concern/Company which has/have been blacklisted/debarred by any State/Central Government organization for reason of Quality Non-compliances, GMP Non-compliance, Major violation of D&C Act and Rules and furnishing forged/fabricated/false documents, during the period of blacklisting/debarring.
- 5.2.10.3. Tender should not be submitted for the product(s) for which the Firms/Concern/Company stands blacklisted/debarred by the State/Central Government organization for reason of Quality Non-compliances, GMP Non-compliance, Major violation of D & C Act and Rules and furnishing forged/fabricated/false documents, during the period of blacklisting/debarring.
- 5.2.10.4. If Product(s)/Bidder/Supplier is blacklisted/debarred by another state/Central Government agency for the reason of Quality non-compliances, GMP Non-compliance, major violation of D&C Act and Rules and furnishing forged/fabricated/false documents, after bid submission/award of contract/execution of agreement, the product(s)/bidder/supplier will be liable for Blacklisting/Termination of contract/cancellation of purchase order/Letter of Intent etc. The product(s)/bidder/supplier will be liable for such action in the event of any conviction/initiation of prosecution under the D & C Act any stage after submission of bid.

5.2.11. Inspection of manufacturing premises:

- 5.2.11.1. Those firms which were disqualified in factory inspection conducted by KMSCL as part of tenders for the years 2016-17 and 2017-18 are permitted to participate in this tender only on remittance of Rs. 1,00,000, extra towards re-inspection fee as detailed in Clause 6.16. Participation of such firms without remittance of re-inspection fee will lead to summarily rejection of their bids.

The firms/manufacturing units rejected in factory inspection as part of the tenders for the year 2018-19 and 2019-20 will not be eligible for participation in this tender.

5.3. Price Preferences to PSUs and MSMEs within Kerala.

- 5.3.1. Price preference not exceeding 10% for Domestic MSME and 15% for State Public Sector Undertakings shall be available only for products manufactured by them within the State of Kerala.

- 5.3.2. State PSUs & MSMEs manufacturing products within the State of Kerala are exempted from remitting the Tender Document fee and EMD.

SECTION VI

6. GENERAL CONDITIONS OF CONTRACT

6.1. This section deals with the general conditions of contract and contains the following terms & conditions.

6.2. Responsibility of verification of contents of Tender Document:

6.2.1. Bidders shall examine all instructions, forms, terms and specifications in the Tender Document and confirm that the required documents as in Clause 6.9 are duly uploaded in the e-bid.

6.2.2. Failure to furnish any information required by the Tender Document and submission of an offer not substantially responsive to it in every respect shall result in the summary rejection of bids, without any notice.

6.3. Tender Document and Earnest Money Deposit

6.3.1. The specifications and terms and conditions governing the supply of drugs are contained in this “Tender Document”

6.3.2. The Tender Document is to be downloaded from the e-Procurement portal www.etenders.kerala.gov.in. The Tender Document is also available in the official website of the Corporation.

6.3.3. The Tender Document fee and the EMD required for this tender are as specified in Section III and the payment shall be as specified in Clause 6.4 below. The EMD payable for each item is as specified in Section IV. Where the total of the EMD payable is more than Rs.2,47,500/-, Rs.2,77,000/- (Minimum EMD Rs.2,47,500+Tender document cost Rs.29,500) shall be paid online and the balance amount shall be submitted by DD/BG within the dates specified in Section III.

6.3.4. State Public Sector Undertakings and MSMEs registered within the State are exempted from remittance of EMD and Tender Cost subject to submission of valid documents, provided all the offered products shall be manufactured within the State of Kerala.

6.3.5. None of the bidders other than those specified in Clause 6.3.4 above, are exempted from the remittance of EMD, in any case.

6.3.6. Non-payment of Tender cost and EMD (except in cases where payment of Tender Cost and EMD are specifically exempted) will result in summary rejection of the bid.

6.3.7. No interest will be paid for the EMD furnished.

- 6.3.8. The EMD will be forfeited, if a bidder/ successful bidder;
- 6.3.8.1. Misrepresents facts or submit false/fake documents during the tender process.
 - 6.3.8.2. Violates any terms and conditions of the Tender Document.
 - 6.3.8.3. Withdraws its bid after the opening of Technical Bid;
 - 6.3.8.4. Fails to produce hard copies of the documents as specified or to sign the contract after issuance of letter of intent.
 - 6.3.8.5. Fails to furnish security deposit after issuance of letter of intent.

6.4. Mode of payment of Tender Document Cost & EMD

- 6.4.1. For submitting the bid online, bidders are required to make online payment using electronic payment gateway service provided in Govt. of Kerala's e-Procurement website (www.etenders.kerala.gov.in)
- 6.4.2. The bidders while participating online tenders published in Government of Kerala's e-Procurement website (www.etenders.kerala.gov.in) should ensure the following:
- 6.4.2.1. **Single transaction for remitting Tender Document fee and EMD:** Bidder should ensure that Tender Document fees and EMD are remitted **as single transaction and not separate**. Separate or split remittance for Tender Document fee and EMD shall be treated as invalid transactions.
Where the EMD to be paid is more than Rs.2,47,500/- the excess amount shall be paid by way of DD/BG.
 - 6.4.2.2. **State Bank of India Multi Option Payment System (SBI MOPS Gateway):** Bidders are required to avail Internet Banking Facility in any of the listed banks for making the remittances in e-procurement System.
 - 6.4.2.3. During the online bid submission process, bidder shall select **SBI MOPS** option and submit the page, to view the Terms and Conditions page. On further submitting the same, the e-Procurement system will re-direct the bidder to MOPS Gateway, where two options namely **SBI and Other Banks** will be shown. Here, Bidder may proceed as per below:
 - a) **SBI Account Holders** shall click **SBI** option to proceed with its Net Banking Facility, where bidder can enter their internet

banking credentials and transfer the Tender Fee and EMD amount.

b) Other Bank Account Holders may click Other Banks option to view the bank selection page. Here, bidders can select from any of the listed Banks to proceed with its Net Banking Facility, for remitting the payments.

6.4.2.4. Transaction Charges for Other Banks is fixed, vide SBI Letter No. LHO/TVM/AC/2016-17/47 – 1% of transaction value subject to a minimum of Rs. 50/- and maximum of Rs. 150/-

6.4.2.5. Any transaction charges levied while using any of the above modes of online payment has to be borne by the bidder. The supplier's bid will be evaluated only if payment status against bidder is showing "Success" during bid opening.

6.4.2.6. **It is necessary to click on "Freeze bid" link / icon** to complete the process of bid submission otherwise the bid will not get submitted online and the same shall not be available for viewing / opening during bid opening process.

6.4.2.7. **One Remittance form per bidder and per bid:** The remittance form provided by e-Procurement system shall be valid for that particular bidder and bid and should not be re-used for any other tender or bid or by any other bidder.

6.4.2.8. The bids will not be considered for further processing if bidders fail to comply on Clauses 6.4.2.1 to 6.4.2.7 above and tender fees and EMD will be remitted back to the account from which it was received.

6.4.2.9. The Earnest Money Deposit required for each item tendered is specified in Clause 4.1 in Section IV. The amount of EMD to be submitted by the bidder shall be the total of EMD required for each of the item quoted by the bidder, subject to minimum of Rs.2,47,500/-. If the total EMD required for a bidder is above Rs.2,47,500/-, Rs.2,47,500/- shall be paid online along with the cost of tender document fee and the balance of EMD shall be submitted at the Head Office of the Corporation by way of DD/BG drawn in favour of Managing Director, KMSCL. for eg: for a bidder quoting 4 items, the EMD to be submitted is calculated by adding the value of EMD mentioned against each item in Clause 4.1. If

the value thus arrived is 2,47,500/-, the minimum required amount of EMD of Rs.2,47,500/- shall be paid together with Tender Document cost of Rs.29,500/- as single online transaction of Rs.2,77,000/- in the manner specified in Clause 6.4 If the total EMD required is more than Rs. 2,47,500/-, the amount of Rs. 2,47,500/- shall be paid together with the tender document fee as single transaction of Rs. 2,77,000/- [Rs. 2,47,500/- + Rs.29,500/- = Rs. 2,77,000/-] as specified in Clause 6.4.

- 6.4.3.** The balance amount of EMD shall be submitted at the Head Office of the Corporation as DD drawn in favour of Managing Director, KMSCL payable at Thiruvananthapuram or as BG as per the format in **Annexure XIII**, valid for a minimum period of 8 months from the date of opening Technical Bid.

The balance EMD in the form DD/BG shall be submitted in a sealed cover super scribing, “**Earnest Money Deposit for E-Tender No. KMSCL/DRGED/HAEM/RC/2019/009 dated 10.05.2019 for the procurement of Anti Haemophilia Drugs for the year 2019-20**”. The sealed cover shall be addressed to:-

The Managing Director
Kerala Medical Services Corporation Ltd
Thycaud P.O, Thiruvannathapuram-695014
Kerala.

- 6.4.4.** In case of EMD submitted by the bidder is not sufficient to meet the EMD requirement of all the items quoted, the available EMD will be adjusted for the items first in the ascending order of category and then in the Sl. Nos. as per the list given by the bidder in **Annexure-II** along with the technical bid, till the EMD is exhausted. Further, the tender of such bidder for the remaining items, out of the quoted items, will be treated as non-responsive for want of the EMD. Any part value of EMD remaining unadjusted will be treated as an excess value furnished. There will not be any provision to re-submit the balance EMD amount after the date and time specified in Clause 3.2 of tender document.
- 6.4.5.** All the prospective bidders on their own interest are requested to avoid last minute rush in making payment and online Bid submission. Non receipt of payment before online opening of the Technical Bid will lead to automatic rejection of the bid.

6.5. Guidelines for preparation of Tender

- 6.5.1. The bidder shall bear all costs associated with the preparation and submission of its bid and Tender Inviting Authority will in no case be responsible or liable for these costs, regardless of the conduct or outcome of the bidding process.
- 6.5.2. It is compulsory on the part of bidders to provide a check list as per **Annexure-I** at the time of uploading the documents so as to enable the Tender Inviting Authority to prima facie verify the compliance of all tender conditions.
- 6.5.3. *Language of Bid:* - All the documents submitted by the bidder shall be in English or in Malayalam. Supporting documents furnished in other languages shall be accompanied by an authenticated (by the authority concerned) accurate translation of the relevant passages in English or Malayalam. Failure to submit authentic translation of documents would be deemed as “Not Submitted” and will result in rejection of offer.
- 6.5.4. The documentary evidences submitted shall be those duly attested by the bidder on every page and serially numbered. Notary attestation wherever specified will be in addition to the attestation of the bidder as above.
- 6.5.5. The person signing the documents shall have due Power of Attorney/resolution of Board made by the Board of Directors/Partnership/Proprietor etc in cases where person other than the Managing Director/Managing Partner or sole Proprietor signs the document. The photo of the person authorized to sign the document shall be affixed to the Power of Attorney with due authentication. Where the Managing Director/Managing Partner or sole Proprietor signs the tender and accompanying documents a notarized document attesting the signature of the person shall be furnished. The Power of Attorney shall be in non-judicial stamp paper duly attested by notary public.
- 6.5.6. The bidder shall carefully read and understand all the terms and conditions in the tender document including the amendments, if any. The bidder shall furnish an undertaking/declaration as in **Annexure-X** of having read and accepted the contents of the Tender Document in full. The plea of ignorance or failure to understand the terms and condition of the tender will not be acceptable.

- 6.5.7. All clauses of the Tender Document shall be duly filled up before submission. Any clause left unfilled or improperly filled will lead to rejection of the bid.
- 6.5.8. An offer submitted in vague/ambiguous terms and the like, shall be termed as non-responsive and will be summarily rejected.
- 6.5.9. All the bid documents submitted shall be legible and be clearly readable. Illegible documents uploaded, along with the bid if any, will not be considered and the bid will be subject to rejection.
- 6.5.10. A prospective bidder requiring any clarification of the Tender Documents may notify the Tender Inviting Authority in writing by email or fax at the Tender Inviting Authority's mailing address/fax number indicated in this Tender Document. Clarifications to specific requests shall be responded through e-mail and general clarifications, affecting all the bidders will be published in the official website of the Tender Inviting Authority. 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.

6.6. Period of Validity of Tender

- 6.6.1 The tender must remain valid for minimum 180 days from the date of opening of Price Bid. A bid valid for a shorter period shall be rejected by the Tender Inviting Authority as non-responsive.
- 6.6.2 Prior to the expiration of the bid validity the Tender Inviting Authority may with the consent of the bidder, extend the bid validity for another period of 30 days.
- 6.6.3 The bidder who has extended the bid validity is not required or permitted to modify its bid.
- 6.6.4 The bidder cannot withdraw the bid within the minimum price firmness period of 180 days from the date of opening of price bid.
- 6.6.5 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 blacklisting of the successful bidder as per the procedure detailed in Clause 6.37.

6.7. Amendment of Tender Documents:

- 6.7.1 Also at any time prior to the last date of submission of Tender, Tender Inviting Authority may, for any reason, or as per directions of the Government, modify the condition in Tender Documents by an

amendment. All amendments will be notified through the Corporation's website. The Tender Inviting Authority may, at his discretion, extend the date and time for submission of bids.

- 6.7.2 Bidders/ Prospective bidders are advised to browse the website of the Tender Inviting Authority for information/ general notices/ amendments to Tender Document etc on a day to day basis till the tender is concluded.

6.8. Tendering System

- 6.8.1 The Bids are to be submitted in two Parts i.e. Technical Bid & Price Bid.
- 6.8.2 The TECHNICAL BID shall contain the complete technical details of the firm and the documents to prove the eligibility and competency of the bidder and shall be submitted in the manner prescribed in Clause 6.9.
- 6.8.3 The Tender has been called for in the generic names of drugs. The bidders should quote the rates for the drugs in generic names. The products offered shall comply with the tender specifications given in **Section IV**. Any variation found will result in the rejection of the tender.
- 6.8.4 Bids with cross conditions like *“offering different strength/specification/unit and lower shelf life other than tendered”* shall not be made by the bidder. Such attempts to mislead the TIA will be treated as violation of tender condition and the offer will be rejected. If such violation is noticed even after the award of contract, agreement for the product will be terminated and the alternate purchase will be made at risk and cost of the supplier.
- 6.8.5 Bid offer for the supply of drugs with cross conditions like “AT CURRENT MARKET RATES”, “SUBJECT TO AVAILABILITY OF RAW MATERIALS” “SUPPLIES WILL BE MADE AS AND WHEN SUPPLIES ARE RECEIVED” etc., will not be accepted.
- 6.8.6 The Price Bid (BOQ) in the prescribed proforma shall be submitted online only. Submission of price bid (BOQ) in any other form will lead to rejection of bids.
- 6.8.7 The price shall be quoted on basic units mentioned in price bid format and not in respect of any other supply units.

- 6.8.8 The price quoted by the bidders shall not, in any case, exceed the controlled price, if any, fixed by the Central/State Government/NPPA and/or the Maximum Retail Price (MRP). Tender Inviting Authority at its discretion, will exercise, the right to revise the price at any stage so as to conform to the controlled price or MRP as the case may be. This discretion will be exercised without prejudice to any other action that may be taken against the bidder.
- 6.8.9 The rates quoted and accepted will be binding on the bidder during validity of the bid and any increase in the price will not be entertained till the completion of the contract period except statutory levies as may be applicable.
- 6.8.10 Supplies should be made directly by the bidder and not through any other agency and the invoice should be in the name of the bidder.
- 6.8.11 The bidder shall allow inspection of the factory at any time by an expert or team of Experts/Officials of the Tender Inviting Authority. The bidder shall extend all assistance and co-operation to the team to enable to inspect the manufacturing unit, quality control measures adopted etc., in the manufacture of the drugs. Photographs of the key manufacturing areas shall be permitted to be taken.
- 6.8.12 Complaints, if any, should be submitted to the Managing Director in writing. Complaints with ulterior motives will be deemed as fraudulent practice and will be dealt with accordingly.

6.9. Contents of the Technical Bid:

6.9.1 The following documents shall be uploaded online in PDF format along with the Technical Bid. The bid offer form as per Annexure II shall be submitted in PDF as well as in Excel Format.

Sl. No.	Document to be uploaded
1.	Check list in Annexure-I .
2.	Documentary proof that the firm is registered with the Industries department/Directorate of Industries and Commerce of the State of Kerala, if the firm has claimed for exemption from submitting EMD & Tender document cost.
3.	List of item(s) offered in the format prescribed in Annexure II .
4.	Annual turnover statement for last 3 years in the format given in Annexure III certified by the Auditor.
5.	Notary attested photocopy of Manufacturing License and Certificate of renewal/current validity certificate along with the product permit duly approved by the Licensing authority for the product(s) quoted. Items quoted along with specifications shall be clearly highlighted in the product

Sl. No.	Document to be uploaded
	permit and respective drug code of the item shall be noted in the product permit.
6.	Notary attested photocopies of valid import license in Form 10 and previous import licenses issued 3 years prior to the date of notification of the tender, if the product(s) are imported.
7.	Notary attested copy of product wise Market Standing Certificate issued by the Licensing Authority to prove 3 years Market Standing for all the items quoted. In case of imported drugs, bill of lading/sales invoices/market standing certificate to prove that the product is being imported/marketed by the bidder in last 3 years.
8.	Notary attested copy of valid license for the sale of Drugs imported by the firms issued by the licensing authority, in the case of imported products.
9.	Notarized copy of valid WHO-GMP Certificate in respect of the production units and the products quoted.
10.	Notary attested copy of valid COPP issued by the Licensing Authority for the items quoted.
11.	Notary attested copy of PMF Approval Certificate issued by the Central License Approval Authority.
12.	Notary attested copy of all the relevant pages in PMF on viral inactivation/purification processes adopted for the manufacture of Factor VIII.
13.	Notary attested copy of all the relevant pages in PMF on viral inactivation/purification processes adopted for the manufacture of Factor IX.
14.	Notary attested copy of all the relevant pages in PMF on viral inactivation/purification processes adopted for the manufacture of FIEBA.
15.	Statement on the methods adopted for viral inactivation/purification in the format as given in Annexure V .
16.	Notary attested copy of all relevant pages in PMF on viral detection tests performed in the source plasma, during manufacturing process and in finished product for Factor VIII.
17.	Notary attested copy of all relevant pages in PMF on viral detection tests performed in the source plasma, during manufacturing process and in finished product for Factor IX.
18.	Notary attested copy of all relevant pages in PMF on viral detection tests performed in the source plasma, during manufacturing process and in finished product for FIEBA.
19.	Statement on the viral detection tests in the format as given in Annexure VI .
20.	Documents to prove the purity of the offered product as defined by the WFH for Factor VIII.
21.	Documents to prove the purity of the offered product as defined by the WFH for Factor IX.
22.	Statement on purity of the offered product in the format as given in Annexure VII .
23.	Notary attested copy of all the relevant documents on donor traceability for Factor VIII.
24.	Notary attested copy of all the relevant documents on donor traceability for Factor IX.

Sl. No.	Document to be uploaded
25.	Notary attested copy of all the relevant documents on donor traceability for FIEBA.
26.	Details of batches tested in NIB since 2016-17 as in the format given in Annexure VIII .
27.	Notary attested copy of reports of all the batches tested in NIB since 2016-17 for Factor VIII.
28.	Notary attested copy of reports of all the batches tested in NIB since 2016-17 for Factor IX.
29.	Notary attested copy of reports of all the batches tested in NIB since 2016-17 for FIEBA.
30.	Statement of supply of Factor VIII made to the organizations listed in Annexure IX .
31.	Statement of supply of Factor IX made to the organizations listed in Annexure IX .
32.	Statement of supply of FIEBA made to the organizations listed in Annexure IX .
33.	Notary attested documents to prove the supply of Factor VIII made to the organizations (listed in Annexure IX) such as LOI / PO/ Performance Certificate etc issued by the above organization.
34.	Notary attested documents to prove the supply of Factor IX made to the organizations (listed in Annexure IX) such as LOI / PO/ Performance Certificate etc issued by the above organization.
35.	Notary attested documents to prove the supply of FIEBA made to the organizations (listed in Annexure IX) such as LOI / PO/ Performance Certificate etc issued by the above organization.
36.	Notary attested copy of current Non-conviction Certificate issued by the licensing authority of the concerned state.
37.	Notary attested statement of manufacture/imported and sale of the quoted drugs in the last 3 years shall be furnished in the Performance Statement given in the Annexure IV .
38.	Notary attested copy of Power of Attorney/Resolution of Board.
39.	Undertaking/declaration in the format prescribed in Annexure X .
40.	Notarized copy of Audited Balance Sheets and Profit and Loss statement for three years from 2015-16 to 2017-18.
41.	Notary attested details of technical personnel employed in the manufacture and testing of items (Employees' Name(s), Qualification(s), and Experience).
42.	Notary attested details of the bidder and manufacturing unit in the format prescribed in Annexure XII .

Note: - *The certificates of WHO-GMP, non-conviction, market standing etc produced shall be either for production before KMSCL or in general terms and shall be currently valid or issued within one year prior to the date of notification of the tender.*

6.10 Price Bid(BOQ)

- 6.10.1 The Price Bids of those firms qualified in the technical evaluation will be opened for evaluation.
- 6.10.2 The PRICE BID will contain only the "Price Bid Form" (BOQ) and every bidder shall submit their rates in the prescribed proforma attached to the Bid document. The price bid submitted in any other format will be treated as non-response and not considered for tabulation and comparison.
- 6.10.3 The price bid (BOQ) file shall be downloaded from the e-tender portal and quote the prices on respective fields before uploading it. **The bidders shall not rename the BOQ files downloaded.**
- 6.10.4 The bidder shall quote prices in all necessary fields in the available format. 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. Bidders are allowed to enter the bidder name & values only.
- 6.10.5 The Price Bid shall be submitted online in the format given in this document as Price Bid Form. The Price Bids submitted in any other format or as hard copy will be treated as non-responsive and not considered for tabulation and comparison.
- 6.10.6 The rate quoted shall be per unit and shall be landed price inclusive of all taxes, packing, freight, Insurance, loading & unloading, handling charges at various heads etc.,
- 6.10.7 The total of rates quoted in column No. 11 of BOQ (Landed price) will be considered for bid ranking.
- 6.10.8 The bidder shall necessarily quote the total GST% and its values (IGST/CGST/SGST as applicable) for all the items offered in the price bid.
- 6.10.9 The price bid (BOQ) once quoted is not permitted to change the rate/amount unless such change is supported by the notification issued by the Government of India or by the order of the court, after submission of Tender.
- 6.10.10 If there is an error in the total amount obtained by the addition of sub totals, the sub-totals shall prevail and the total will be corrected. If the bidder does not accept the correction of errors, the bid will be disqualified and the EMD will be forfeited.

6.11 Submission of Tender

- 6.11.1** The Tender shall be submitted online only. Bidders shall upload all necessary Technical bid documents mentioned in Clause 6.9.1 in the e-tender portal.
- 6.11.2** In the event of any document submitted along with the bid or thereafter by the bidder or his representative, found fabricated / forged / tampered / altered / manipulated during verification, the bid will stand rejected and the EMD of the bidder shall be forfeited and the bidder is liable to be blacklisted as per clause 6.37.
- 6.11.3** Both Technical Bid and Price Bid are to be submitted concurrently duly digitally signed in the website at "etenders.kerala.gov.in".
- 6.11.4** If a particular document/certificate to be uploaded as specified in Clause 6.9.1, is not applicable for a bidder, to avail such claim the bidder shall attach a scanned copy of declaration in the official letter head stating as to why the specific document is not applicable/exempted/not available for the bidder in connection to this tender. Failure to attach any of the documents specified in the Technical Bid requirement of the e-procurement portal will lead to rejection of the bid automatically.
- 6.11.5** Tender by any other means is void.

6.12. Deadline for submission of Tender

- 6.12.1** The electronic bids of the bidders who have submitted their digitally signed bids within the stipulated time, as per the tender schedule (Section III) alone will be accepted by the system. Online bids/balance EMD not submitted within the stipulated time scheduled in Section III will not be accepted.
- 6.12.2** In the event of the date specified in Section III for submission of EMD for the amount in excess of Rs.50,000/-, is declared as a holiday under Negotiable Instruments Act, it will be received up to the appointed time on the next working day.
- 6.12.3** If the date set for submission of online tender is declared as a holiday under Negotiable Instruments Act, the tender can be uploaded till 5.00 PM on the next working day. Consequently the date and time of opening of the Technical Bid will also be extended.

6.13. Modification and Withdrawal of Bids

- 6.13.1** The bidder may modify or withdraw its bid after the bid submission before last date and time of submission of online Tender.
- 6.13.2** No bid will allowed to be withdrawn in the interval after the last date & time of submission of online Technical Bids and the expiration of the period of bid validity specified in the Tender Document. Withdrawal of a bid during this interval will result in the forfeiture of its EMD and may lead to blacklisting of the bidder for a period up to 3 years from the date of issue of such order and the bidder shall be ineligible to participate in any of the bids of the Tender Inviting Authority for that period.

6.14. Opening of Tender

- 6.14.1** The opening of the Technical Bid and the Price Bid will be done online as notified. The date of opening of price bid will be announced only after the opening and evaluation of Technical bid. The date and time of price bid opening will be published on the website of the Corporation along with the list of qualified bidders in technical evaluation.
- 6.14.2** In the event of the specified date for opening of Tender being declared holiday, the Tender shall be opened at the appointed time on the next working day.
- 6.14.3** The bidder shall be solely responsible for properly super scribing and sealing the envelope submitting DD/BG for EMD in excess of the amount paid online. The Tender Inviting Authority shall not be held liable for accidental opening of the envelopes before the time appointed for opening of the technical bid.

6.15. Evaluation of Tender

- 6.15.1** The findings as to whether the bids are responsive or non-responsive will be published in the website of the Corporation.
- 6.15.2** Bids of firms who have furnished all the required documents for each of the product quoted alone will be considered. A firm quoting for more than one product and if the required/proper document is not furnished for any of the product then offer of that product will be

rejected. Utmost care should be taken to see that all the required/proper documents are uploaded.

- 6.15.3 Bid offer form (**Annexure-II**) in PDF format submitted online alone will be considered for bid evaluation. If any discrepancy found with excel format, details submitted in the PDF format will prevail.
- 6.15.4 The status of bidders/products after technical bid evaluation will be published in the website of the Tender Inviting Authority, inviting complaints / suggestions from the bidders / public.
- 6.15.5 The complaints/ suggestions/ comments received will be scrutinized and their findings along with the list of bidders qualified for Price Bid opening along with the date of opening of the Price Bids will be published in the Corporation's website.
- 6.15.6 The Price Bids will be scrutinized and the provisional drug wise rate list of all the accepted products of the eligible bidders will be published in the website of the Tender Inviting Authority inviting complaints / suggestions/comments from the bidders / public.
- 6.15.7 The status of the bidders after the opening of the price bid available in the e-tender web-site of the NIC will be a provisional one. The final product wise status will be published in the official web-site of the Corporation.
- 6.15.8 The complaints / suggestions/ comments received will be scrutinized and the findings along with the rank list (L1, L2, L3 etc) will be published in the website of the Corporation.
- 6.15.9 Final rate list of L1 bidders will be published in the website of the Corporation.
- 6.15.10 All the other bidders in the bid status will be permitted to match their offered rate with the final L1 rate published.
- 6.15.11 Where the production facilities of the bidder or the level of compliance of WHO-GMP requirements are found to be not satisfactory after acceptance of the Bid or the Award of Contract, the TIA shall have the right to terminate the Contract and to make alternate purchase of the tendered quantity at the risk and cost of the supplier.

6.15.12A bidder, at any stage of tender process or thereafter, in the event of being found after verification by the Tender Inviting Authority/award of contract, to indulge in fraudulent practices or concealment or misrepresentation of facts, in respect of the claims of the offer, shall be rejected, the agreement will be terminated and the bidder is liable to be blacklisted. The alternate purchase of the contract quantity will be made at the risk and cost of the supplier.

6.15.13The Tender Inviting Authority's decisions on the tender submitted may be based on the recommendations made by the various technical committees or otherwise as per the clauses as mentioned above.

6.16. Inspection of Manufacturing Facilities

6.16.1 Inspections of the production and related facilities of bidders/suppliers will be at the discretion of the Tender Inviting Authority. Such inspection may be at any stage before or after acceptance of the Bid or Award of Contract.

6.16.2 Re-inspection of manufacturing units of bidders disqualified in factory inspection as part of the tenders for the year 2016-17 and 2017-18 will be conducted on remittance of re-inspection fee of Rs 1,00,000/- extra, which is not refundable.

The re-inspection fee shall be submitted as separate Demand draft drawn in favour of **The Managing Director, KMSCL payable at Thiruvananthapuram** as specified in Section III of tender document.

6.16.3 Where inspections are conducted as above, all parts of the manufacturing units including the quality control section will be subjected to rigorous inspection/auditing, irrespective of the items quoted. The bidder/ supplier will have to provide necessary arrangements for the conduct of inspection of all the sections and failure to co-operate with the inspection of the different facilities or in providing information as per the details in the standard inspection report format, will lead to disqualification. However, undue demands, beyond the scope of the standard inspection report format etc made by the members of the inspector(s) shall be immediately notified to the Tender Inviting Authority by the manufacturer by fax/e-mail, so that the disputes could be resolved before the Inspector(s) leave(s) the manufacturing facilities. The decisions of the Inspector(s) will not be

communicated to the bidder at their site and shall only be published on the website later.

- 6.16.4** Entry to all the areas of production including sterile products manufacturing/filling areas shall be facilitated.
- 6.16.5** The availability of plant & machinery, technical experts, analytical facilities of quality control lab etc as claimed in the documents submitted along with the compliance of standard operating procedures adapted for the production of quality assured products, and in case of drugs, all other parameters mentioned in the Schedule M of the Drugs and Cosmetics Rules shall be evaluated by the team for considering the eligibility of the firm. Claim of holding the valid GMP certification/valid license will be of no avail for eligibility, if the procedures as stipulated in the schedule M of the Drugs and Cosmetics Rules are not duly complied with, or if the available plant/machinery are not in working condition at the time of inspection. Tender offer will be rejected/ contract will be terminated with due notice in such cases.
- 6.16.6** Control samples and batch manufacturing records for the products offered/ supplied will be checked during inspections. Failure to produce even one batch of the control samples will result in the rejection of that product from the Tender offer as the situation shows lack of proper controls over the quality of the products.
- 6.16.7** Copy of one full set of the documents submitted for the bid should be made available at the time of inspection.
- 6.16.8** Originals of all the documents uploaded/submitted in the Technical Bids should be produced for verification during inspection. Failure to produce any of the original documents will result in the rejection of the tender offer deeming that the supplier had made false statement at the time of the bid, as the case may be.
- 6.16.9** Key manufacturing areas will be photographed by the inspection team, as part of transparency and cross verification. Denial of permission for photographing may result in the rejection of tender offer deeming that the supplier had made false statement at the time of the bid, as the case may be.

- 6.16.10** Failure to observe any of the conditions of the licenses issued under the Drugs and Cosmetics Act, by the manufacturer, if reported by the inspection team will result in the rejection of the Tender offer deeming that the supplier had made false statement at the time of the bid, as the case may be.
- 6.16.11** Any firms during the inspection/re-inspection, found non complying with the requirements, will be rejected. In such case an amount of Rs.50,000/- will be deducted from the EMD/SD/any money due to the supplier. Further, alternate arrangements will be made for the procurement of the item from any other bidder willing to supply the product within the minimum delivery period, irrespective of the Bid status, or from the open market and the additional expenditure incurred will also be recovered from any money due to the supplier.

6.17. Acceptance/Rejection of bids

- 6.17.1** The Tender Inviting Authority reserves the right to accept/reject/cancel or defers the Tender submitted for any or all items. Price, which is a relevant factor, is not the only criteria in accepting/rejecting/cancelling/deferring Tender for any or all items without assigning any reason. The other criteria to be considered will be quality, capacity to deliver the quantity required etc. Decision taken will be at the best interest of the Tender Inviting Authority, user institution, State Government and above all, in public interest.
- 6.17.2** The Tender Inviting Authority attaches prime importance to the quality of the product supplied and the competency of the bidder to supply the products in the quantity and quality specified and as per the supply schedule in addition to looking at the prices of the products offered.
- 6.17.3** Proper packing, transport and other factors that could affect the quality and shelf life of the items would also be considered. Usually the lowest offers of bidders qualified for the Price Bid opening shall be accepted, unless one sided conditions unacceptable to the Tender Inviting Authority are made in the Price Bid.
- 6.17.4** At any point of time, the Tender Inviting Authority reserves the right to cancel or modify the supply order for the supply of all items or for any one or more of the items in a tender even after it is awarded to the successful bidder for breach of terms and conditions of the tender

document and agreement. Contraventions of the Drugs and Cosmetics Act and Rules as noticed by the TIA will also amount to breach of the terms and conditions of the Tender Document and the Contract.

6.17.5 The Tender Inviting Authority, or his authorized representative(s) has/have the right to inspect the factories of bidders, before releasing any purchase order(s) or at any point of time during the continuance of the tender and also has the right to reject the tender or terminate / cancel the purchase orders issued and or not to re-order, based on adverse reports brought out during such inspections.

6.18. Other terms and Conditions

6.18.1 The bidder will be responsible for making all statutory payments such as Income Tax and other statutory levies. If it is found that some statutory deduction is to be made at the source, the Tender Inviting Authority will have the authority to do so from the value payable for the goods supplied or from any amount due or becoming due to the supplier.

6.19. Notices

6.19.1 The Tender Inviting Authority will publish the following information on its website at the appropriate time as part of ensuring transparency in the tender process;

6.19.2 The tender notices, documents, amendments, corrigendum, addendum etc, if any, at any stage of the tender process.

6.19.3 Results of the responsiveness of the Technical Bids.

6.19.4 List of bidders qualified for Price Bid opening and reasons for rejection of unqualified bidders.

6.19.5 Product wise rate list with the bid ranking status.

6.19.6 L1 rate list/ bid ranking status.

6.19.7 Final rate list.

6.19.8 Such other information which the Tender Inviting Authority desires to notify the stakeholders.

6.19.9 All notices or communications relating to or arising out of this tender or any of the terms there of shall be considered duly served on or given to the bidder/supplier if published in the website of the Corporation/e-mail/fax/post/courier or left at the premises, places of business or abode/communicated in any other manner.

6.19.10 The effective date of a notice shall be the date on which the notice is published in the website or when delivered to the recipient by e-mail/fax or the effective date specifically mentioned in the notice whichever is earlier.

6.20. Award of Contract

6.20.1 *Criteria:* - *The subject tender is a running contract.* The contract will be awarded to the lowest evaluated responsive bidder qualifying to the final round after Technical and Price Bid evaluation subject to the reservations and preferences to the state MSMEs/PSUs.

6.20.2 *Variation of quantities during currency of Contract:* - The quantity of the requirement stated in this Tender Document is an estimated one for the purpose of the contract. The variations as noted above will be $\pm 25\%$ without any change in the agreed rate and other terms & conditions.

6.21. Letter of Intent

6.21.1 The Tender Inviting Authority shall issue Letter of intent/ Purchase Order in respect of the drugs selected. Communication by email will be deemed as valid communication.

6.22. Signing of Contract

6.22.1 The successful bidder, upon receipt of the Letter of intent / Purchase Order, shall communicate the acceptance of the Letter of Intent/Purchase order in the copy of the Letter of Intent/Purchase order, furnish the required Security Deposit, furnish the documents required to be furnished and also submit an agreement in the prescribed format as given in **Annexure-XIV** within 21 days, in a non-judicial Kerala stamp paper of value of Rs.200/- (stamp duty to be paid by the bidder).

6.22.2 The successful bidder at the time of submission of the agreement shall furnish copy of notary attested Documentary evidence for the

constitution of the company /concern such as Memorandum and Articles of Association, along with notary attested copies of Form 32 whenever there is a change of Directors, Latest Partnership deed (Notary attested copy) etc. with details of the Name, Address, Telephone Number, Fax Number, e-mail address of the firm and of the Managing Director / Partners / Proprietor. The list of present MD & Directors of the firm shall also be furnished separately.

- 6.22.3** The bidders shall submit notary attested Documents to prove that they are having own cold chain transporting system or copy of the contract agreement made with a transporting agent having facilities to transport the drugs under cold chain norms within 48 hours from the manufacturing unit to the warehouses of the corporation, at the time of submission of agreement or before execution of supply of the item upon request of the supplier.
- 6.22.4** The purchase order will be placed after the issuance of Letter of Intent, pending execution of agreement and the supplier shall execute the supply as per the terms & conditions in the tender.
- 6.22.5** If the successful bidder fails to furnish the documents sought and/or, execute the agreement and/ or to deposit the required security deposit within the time specified or withdraws the tender, the award will stand cancelled and the Earnest Money Deposit deposited along with the tender shall stand forfeited without any notice and the bidder shall also be liable to be blacklisted as specified in Clause 6.37.
- 6.22.6** If the withdrawal is in respect of particular product/products under the circumstances or the situations as above, the EMD will stand forfeited in respect of that/those product(s) and the product(s) will also be liable to be blacklisted as per Clause 6.37.
- 6.22.7** Withdrawal after award of contract will necessitate alternate purchase at the risk and cost of the bidder and the additional cost over and above the accepted price will be recovered from payments due/deposits/BG/by the way of revenue recovery.
- 6.22.8** Non-compliances in any of the contract provisions will lead to the termination of contract and will be liable for blacklisting as per Clause 6.37.

6.22.9 The bidder shall not, at any time, assign, sub-let or make over the contract or the benefit thereof or any part thereof to any person or persons what so ever. Such practices will be deemed as fraudulent practices and also as breach of terms of contract. All penal provisions such as blacklisting, termination of contract etc will apply. LOI/PO is liable to be cancelled at the risk and cost of the supplier. Product(s), if any, supplied in such manner will be disqualified and rejected summarily.

6.23. Security Deposit

6.23.1 There will be a Security Deposit amounting to 5% of the total value of the awarded items as per Letter of Intent including taxes, which shall be furnished by the successful bidder to the Tender Inviting Authority within 21 days from the date of communication of LOI.

6.23.2 The Security Deposit should be paid upfront along with each contract on or before the due date fixed in the LOI/PO by Tender Inviting Authority in the form of Demand Draft drawn in favour of the Managing Director, Kerala Medical Services Corporation Limited payable at Thiruvananthapuram / Bank Guarantee in the format as given in **Annexure - XV** for a period of 18 months from the date of Letter of Intent.

6.23.3 The Security Deposit shall be denominated in Indian Rupees and shall be in any one of the forms namely Account Payee Demand Draft or Bank Guarantee issued by a Scheduled / Nationalized bank in India and endorsed in favour of the Tender Inviting Authority.

6.23.4 In the event of any failure /default/deviations from the tender agreement of the successful bidder with or without any quantifiable loss to the Tender Inviting Authority, the amount of the Security Deposit is liable to be forfeited.

6.23.5 The Bank Guarantee submitted in place of EMD/Security Deposit shall be in the prescribed format as in the Annexures to this document. Bank Guarantee in no other form will be accepted and will be liable for rejection of the same.

6.24. Purchase Procedures

6.24.1 After the conclusion of Price Bid opening, the lowest offer (after giving preferences to MSMEs and State PSUs) is declared as L1 rate

and the bidder offering the L1 rate for the item for which the tender has been invited shall be called as the L1 bidder.

- 6.24.2** The Tender Inviting Authority will publish the bid status and L₁ rate in the website of the Corporation permitting the other eligible bidders to match with the lowest rate for the item quoted by them and the bidder, who has given consent, in writing, will be considered as Matched L₁ bidder. The bidders agreeing for matching with lowest rate shall furnish the revised rate breakup details of their final rate in the price bid format. The matched L1 bidder, on placement of LOI will be deemed as L1 rate supplier for the purpose of the tender and all provisions of the tender documents applicable to the L1 bidder will apply to the matched L1 supplier.
- 6.24.3** The L₁ bidder is eligible for placement of Purchase Orders for the item and if there is more than one L₁ supplier, the purchase orders for the requirement of items will be placed among them in equal/appropriate proportions.
- 6.24.4** The Corporation reserves the right to split the order with two or more suppliers willing to match with L₁ rate as per the tendered quantity, criticality of the item and the past performance of the suppliers and preferences applicable to state PSUs/MSMEs. The division will be according to the bid ranking status. Where other eligible bidder match with the L1 rate, the award will be as follows:
- i.If L₂ bidder matches with the lowest rate then the quantity will be ordered in the ratio 70:30 between L₁ & L₂ bidders.
 - ii.In case of bulk quantity, if L₂ & L₃ bidder's match with the lowest rate then the ratio will be 60:20:20.
 - iii.In case L₂ / L₃ bidder has not matched with the lowest rate then the share of the order will be given to the next matched bidder according to the bid ranking status.
- 6.24.5** The division of quantity to State MSMEs is as follows;
- 6.24.5.1 If the MSME has quoted the lowest rate, the quantity will be ordered as per Clause 6.24.3 and Clause 6.24.4 above. The offer of other MSMEs coming within the price preference of 10% will not be considered.
- 6.24.5.2 If the rate quoted by one MSME is not L1 but comes within the price band of L1+10%, then orders will be placed for 30% or the quantity offered by the MSME whichever is

lesser. The orders for the remaining quantity will be placed with the L1/other matched bidders as specified in Clause 6.24.4.

6.24.5.3 If two or more MSMEs comes within the price band of L1 + 10%, then the 30% quantity eligible to State MSMEs will be divided in the ratio specified in Clause 6.24.3 & 6.24.4 provided the second MSME matches with the lowest quoted MSME.

6.24.5.4 If State MSMEs matches with the lowest rate then the quantity will be ordered in the ratio 50:50 between L1 & MSMEs, irrespective of the bid ranking status of MSMEs.

6.24.6 If the L₁ supplier has failed to supply the required items in full/in part within the stipulated time, the Tender Inviting Authority will cancel the unexecuted quantity of purchase orders. On such cancellation, the Tender Inviting Authority will place purchase orders with the Matched L₁ bidder or to the next bidder(s) according to the bid ranking status at the risk and cost of defaulted supplier.

6.25. Supply Conditions

6.25.1 Purchase orders will be placed with the successful bidder based on the existing stock, availability of funds, directions of the Government and/or at the discretion of the Tender Inviting Authority. The bidder shall furnish the delivery schedule as stipulated in Section V.

6.25.2 The drugs supplied by the successful bidder shall be of the best quality and shall comply with the specifications, stipulations and conditions specified in Section IV. Drugs supplied in contravention to the specification, condition in Section IV will be summarily rejected.

6.25.3 The items supplied in violation of above condition will not be accepted. In such cases the bidder shall take back the items from the warehouse premises at his own expenses within twenty (20) days from the date of intimation from the TIA. If the bidder fails to take back the items; TIA at its discretion shall collect demurrage charges of the value of such drugs from any money due/becoming due to the supplier.

6.25.4 The supplier shall supply the drugs required by the Tender Inviting Authority at the destination(s) within the period stipulated in the purchase order.

- 6.25.5 The bidders offering drugs requiring special cold storage conditions should have their own cold chain transporting system or contract agreement had been made with a transporting agent having facilities to transport the drugs under cold chain norms within 48 hours from the manufacturing unit to the depot at any one point in the state and such facilities to distribute it to the warehouses of the corporation complying cold chain norms.
- 6.25.6 Maintenance of cold chain conditions shall apply to all drugs requiring such conditions irrespective of the fact whether they are included in the specific group of drugs requiring cold storage or not. Proof of availability and adherence to such conditions shall be furnished as stipulated by the TIA. Non-adherence to the conditions shall result in summary rejection of the goods supplied. It would be deemed as non-supply and the supplier will be solely responsible for his own losses and the penalties that would be attracted.
- 6.25.7 More than one product shall not be included in one invoice. Supplies relating to more than one purchase order shall not be included in one invoice. Where more than one batch is supplied under an invoice, the quantity supplied under each batch shall be stated in the Invoice.
- 6.25.8 The supplier shall intimate the ambiguity, if any w.r.t the pack size/production capacity etc. in the purchase orders issued to them within 10 days from the date of purchase order. Beyond 10 days, it would be deemed that the supplier has accepted the purchase order and supplies shall be executed as per the terms & conditions in the order.
- 6.25.9 The quantity supplied in excess of the total ordered quantity will not be accepted. The Tender Inviting Authority will not be responsible for the loss to the supplier and will not entertain any demand/claim.
- 6.25.10 **The labeled shelf life of drugs supplied should be not less than the period mentioned against each item in list of Drugs Tendered (Section IV). Only those bidders who can manufacture and supply the product with the required shelf life shall only quote the product. The product of labeled shelf life lesser than required shelf life will not be accepted.**
- 6.25.11 The bidder/supplier shall not have two different shelf life for the same product, either supplied to the KMSCL and open market or other agencies. Where it is found that the bidder has a longer shelf-life for a product supplied to the open market or to other agencies and has

adopted a reduced shelf-life for supplies to the KMSCL, it will be deemed as a fraudulent practice and non-compliance of GMP norms and appropriate penal actions will be taken.

- 6.25.12 All items supplied should retain prescribed Quality & maximum potency throughout the shelf life and should have minimum 75% shelf life from the date of manufacture when supplied to the Corporation. It is imperative that the drugs supplied are in proper packaging capable of protecting the drug throughout their shelf life. Any drug supplied without following the above conditions will be rejected.
- 6.25.13 The bidder shall submit the certificate of analysis from NIB with necessary protocols for every batch of items supplied along with the consignment. The bidder shall furnish a notary attested declaration in this regards as specified in **Annexure-X** along with the technical bid.
- 6.25.14 Before the shipment of the items against the purchase orders, the supplier shall furnish the copy of the invoices, **test reports from NIB and In-house test reports** of all the batches in the invoice to the Quality Control Division of the Corporation through e-mail (qcapproval@gmail.com). The Quality Control Division will verify the test reports and confirm that the test report is complete and covering all the parameters as prescribed in the official monograph or other standards for the item and will update the status as **“Accepted”** or **“Rejected”** in DDMS software against each batch.
- 6.25.15 The drugs/items supplied at the warehouses will be accepted and taken into stock based on the approval status available in DDMS software. In case, if the test report is found **“Rejected”**, the entire quantity of the batch will not be accepted.
- 6.25.16 Bidder shall supply the product at the Drugs Warehouses of the Kerala Medical Service Corporation Limited located at various places in Kerala and/ or the places/ points specified in purchase orders, by door delivery. Locations of present warehouses are mentioned on **Appendix -I**. Wrong delivery at a different place will not form ground for claim of ‘on time delivery.’ The consignment should be delivered at the destination on the scheduled date and mere dispatch on or before the scheduled date of delivery will not be deemed as compliance of the delivery schedule.
- 6.25.17 The suppliers have to furnish the details of consignment in advance, while the goods are loaded in the vehicle for obtaining the e-token.

The condition of submitting e-token for all goods moving into/out from the State is as follows;

6.25.17.1 *Those consignments requires e-token through Roadways/Airport/Railways shall forward the request to edtoken@kmscl.kerala.gov.in with the copy of invoice, Expected Check post and date of arrival, Vehicle No. and copy of relevant documents having details of quantity and weight. KMSCL will prepare the e-token and forward to the consignee. The Corporation will not be responsible, if any delay in the preparation of e-token occurred due to errors in invoice, change in arrival Check post/date, incomplete details of vehicle etc.*

6.25.17.2 *E-way bill are governed by the commercial taxes department of Kerala. Time to time changes published by the Government shall be applicable in the process of e-token. Issue of e-tokens shall be in adherence to the directions of Government of Kerala.*

6.25.18 The supplier shall, after supply of drugs at the specified destinations, submit Invoice (original) certificate of analysis of each batch tested **in in-house testing laboratory in addition to the NIB, as the case may be,** at the Head Office, KMSCL claiming payment for the supply made.

6.25.19 The supplier shall supply the drugs at the specified destination(s) and submit the copy of invoice, copy of the Purchase order, Test Reports from NIB, as the case may be, Delivery Chelan and other relevant documents at the destinations. The invoice shall specify the generic name of the drugs as tendered together with brand name if any. Where more than one batch of the drug is supplied under one invoice, the quantities of each batch supplied shall be clearly specified. The date of manufacture, the date of expiry of each batch shall be specified in the invoices and the test report. The quantity supplied shall be in terms of the units mentioned in the tender document. The suppliers are cautioned that the variation in the description of product/batch no. in the invoice/analysis report and actual supplies will be considered as improper invoicing and such supplies will not be accepted.

6.25.20 The supplier shall take utmost care in supplying quality drugs and ensure that the batch number(s) mentioned in the packages of the items tally with the batch number(s) mentioned in the Invoice produced to the Tender Inviting Authority for payment. Also the supplier shall

ensure the quantity relevant to the Batch Number(s) of the drugs mentioned in the invoice. Where variations are noticed the supplier shall furnish proper document detailing each batch supplied together with quantities there off in each batch. The supplier will not be eligible for payments without furnishing proper document.

- 6.25.21** It is the onus of the supplier to supply drugs to the destinations mentioned in the purchase order and supply shall conform to the condition mentioned in the Tender Document, packing and labeling requirements as per **Annexure-XI**. Delivery of goods shall be made as stipulated in the purchase order and deviations will be deemed as non-deliveries and liable for penalties as provided.
- 6.25.22** In the case of failure to supply by a bidder, the Tender Inviting Authority can procure the defaulted quantity from other bidder whom so ever agrees to supply within the prescribed time schedule at the risk and cost of the default bidder. If no other bidders are available or no other bidders are offering the defaulted quantity within the prescribed time schedule, Tender Inviting Authority at its discretion may procure the defaulted quantity of drugs from any other sources or from open market at the risk & cost of the defaulted supplier. A penalty of 10% of the value of unexecuted quantity or the extra expenditure incurred for the alternate purchase of the item, whichever is higher will be levied from the defaulted supplier.
- 6.25.23** The bidder will be responsible for any shortages/damage at the time of receipt in Warehouse. Tender Inviting Authority is also not responsible for the excess quantity of drug received, for which no order is placed. In such cases, the bidder shall take back the excess quantity supplied at his own expenses within 15 days from the date of such intimation from the Tender Inviting Authority. If the supplier has not taken back the item even after the intimation, the excess quantity supplied will be disposed at the discretion of the TIA, without consideration for any payment to the supplier in lieu of that quantity.
- 6.25.24** In respect of the firm supplying more than one item during the contract period, if purchase orders for three or more than 50% of the items, whichever is less are cancelled due to default, then the firm is liable to be blacklisted for a period of 24 months from the date of such order and the firm will be ineligible to participate in any of the tenders floated by the TIA during the period of blacklisting. If in any case such practice of default supply is repeated, the firm will be blacklisted for further three years.

6.26. Logograms

6.26.1 Logogram means, wherever the context occurs, the design as specified in **Annexure-XI**. The name of the drug stated in logogram shall be mentioned in English. Logogram and “KERALA GOVERNMENT SUPPLY – NOT FOR SALE” shall appear in primary, secondary and tertiary packing of all products.

Affixing of stickers printed with indelible ink will be permitted only in case of imported products. Imported products are exempted from affixing of Logogram and “KERALA GOVERNMENT SUPPLY – NOT FOR SALE” in the primary packing.

6.26.2 Bidders for the supply of drugs shall be considered only if the bidder gives undertaking as in **Annexure-X** in this tender that the supplies will be prepared and packed with the logogram either printed or embossed as per the design specified in **Annexure-XI**.

6.26.3 The items quoted are to be supplied in standard packing with logogram and “KERALA GOVERNMENT SUPPLY – NOT FOR SALE” shall also conform to Schedule P1 of the Drugs & Cosmetics Rules, 1945 and other statutory requirements wherever apply. Affixing of stickers printed with **indelible** ink will be permitted on request only in case of imported products on merits.

6.26.4 Supply of items without the logogram and/or “KERALA GOVERNMENT SUPPLY – NOT FOR SALE” will be treated as breach of the terms of agreement and penalties will be levied as per Clause 6.30.6. Repeated breach of contract on the above condition will result in termination of contract and other penal provisions are applicable.

6.26.5 The items supplied shall not be printed with Maximum Retail Price (MRP) on their primary/secondary/ tertiary packing.

6.27. Packing and Labeling

6.27.1 The items shall be supplied in the packages with logograms and printings as specified here under and in **Annexure-XI**. The drugs shall also be supplied with bar coding conditions. (For details visit website www.gs1india.org)

6.27.2 2D/1D bar coding as per GS1 standard should be done on primary, secondary and tertiary packing of the supplies as per the specifications given in **Annexure-XI**. Supply of items without specified bar coding as per GS1 standards will not be accepted.

- 6.27.3** The packing in each carton shall be strictly as per the specification. Supplier shall follow the general requirement that the size of the labels indicating the name and other details of the drugs supplied shall not be less than 30% of the area of the side of the carton. Affixing of labels of primary containers on the outer cartons will also result in the rejection of the consignment. This may result in the termination of the contract and blacklisting of the firm. Failure to comply with these provisions shall lead to non-acceptance of the goods besides imposition of penalties at the rate of 5% of the total value of items supplied in this manner.
- 6.27.4** The labels of two or more drugs/materials supplied by the same supplier shall not be identical or resemble in any form especially in colour and markings leading to confusion in identifying the items. Similarly if the Tender Inviting Authority informs that the labels of a relatively new supplier resemble same or another item of another supplier, the new supplier shall change their labels immediately. For non-compliance of this provision even after the notice, the penalty of 15% of the total value of drug(s) in question will be levied and such drug(s) are liable to be rejected.
- 6.27.5** The cap of vials/bottles should not carry any logo/marks of the supplier. Failure to comply with this provision would attract penalty @ 5% of value of such supply.
- 6.27.6** Damaged/Mutilated labels due to spillage, breakage or poor quality of containers, closures, packing materials etc would attract penalty @ 5% of value of such supply.
- 6.27.7** The labels in the case of injectables should clearly indicate that the preparation is meant for IM, IV, ID, SC etc.
- 6.27.8** The label of the primary packing of the external liquid preparations affixed in the bottle shall be in yellow background and shall carry horizontal red color band of minimum 5 mm width extending from top left to right corners of the label, as identification mark. Failure to comply with this provision will attract penalty @ 5% of value of such supply.
- 6.27.9** It should be ensured that only first hand fresh packaging materials of uniform size are used for Packing. Packing of recycled paper or packages of different products/companies are prohibited. The penal charges for usage of packets of other products shall be 5% of the total value of item (s) in question after notice.

- 6.27.10** All primary packing containers should be strictly conforming to the specification included in the relevant pharmacopoeia or other official monograph or other requirements relevant to the drugs concerned.
- 6.27.11** The secondary/tertiary packaging in master carton shall be in 5 ply carton cardboard box made of virgin craft paper (120gsm) and minimum bursting strength of 7kg/cm² and not more than 15kg. Where heavier packaging is required 7-ply cardboard (minimum 120gsm) and minimum bursting strength of 7kg/cm² shall be used. Failure to comply with the packaging requirement would attract penalty @ 5% on the value.
- 6.27.12** Strip packs shall be packed in plastic covers and sealed air tight first before packing in unit cartons.
- 6.27.13** The primary, secondary units, bottles and packing materials should be of sufficient strength to withstand the weight of other boxes stacked on it, (as per stacking norms) while on transit and on storage and also should be able to prevent damage or deterioration during transit and storage in the climatic conditions of the Kerala throughout shelf life of items. The tertiary carton of every dispatch should be minimum 5 ply cardboard made of virgin craft paper (120gsm) and minimum bursting strength of 7kg/cm² in order to prevent damage during transit. The Tender Inviting Authority shall arrange for the repacking of drugs, if it is found that the packing materials are damaged or deteriorated during storage in the warehouses or user institutions, and such additional cost shall be deducted from the amount payable to the default supplier.
- 6.27.14** In the event of items supplied is found to be not as per specifications in respect of their packing/labeling, the Tender Inviting Authority is at liberty to make alternative purchase of the items for which the Purchase orders have been placed from any other sources or from the open market or from any other bidder who might have quoted higher rates at the risk and the cost of the supplier and in such cases the Tender Inviting Authority has every right to recover the cost and impose penalty as mentioned in Clause 6.30.8.
- 6.27.15** The packing's/labels of two different products of a same supplier should be clearly distinct from each other. Supply of products with packing's/labels of same design, color etc by which the products cannot be easily distinguishable, penalty at the rate of 15% will levied for all the items in question/ the items are liable to be rejected.

6.28. Quality Testing, Quality Control Deduction and Penalties

- 6.28.1 All the batches of the drugs supplied shall be supported by test/analysis reports from NIB. The TIA has the right to get the drugs tested at the laboratories of his choice for further verifications, though this is not a pre-condition for acceptance of goods.
- 6.28.2 The decisions of the TIA based on the reports of the Drugs Control Department of the State on the quality of the drugs will be conclusive. If any of the item cannot be tested in the Government Drugs Testing Laboratory, due to any reasons, the test results of the Drug Testing Laboratories empanelled by the Corporation will be final and conclusive.
- 6.28.3 Drugs failing in descriptions 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 make the drug unfit for use and hence will be deemed as Not of Standard Quality summarily for the purposes of the tender and all clauses applicable to Not of Standard Quality Drugs shall apply to such drugs even if the drug has not been tested in the laboratory. Use of primary and secondary packaging material not suitable or appropriate or adequate enough to preserve the properties of the drug during its entire shelf life period will also cause the drug to be deemed as Not of Standard Quality for the purpose of the tender.
- 6.28.4 The drugs shall be of standard quality throughout the shelf life period of the item. Samples will be drawn for quality testing periodically throughout the shelf life period either on complaint or *suo motto*.
- 6.28.5 In case of any complaint received from the institutions, public, Doctors, Medias etc, the available stock will be frozen, payment will be with held and samples of the batch drawn from the point of complaint will be tested for quality.
- 6.28.6 If a sample is found as not of standard quality by the Tender Inviting Authority, the available stock of the batch will be frozen pending decision on mode of disposal. The bidder will be liable for appropriate action as per the tender conditions and also for other legal actions under the Drugs & Cosmetics Act & Rules as may be initiated by the regulatory department in the case of drugs. The Tender Inviting Authority, at his discretion may terminate the Contract and in case of such termination, the Supplier shall be liable for all losses sustained by the Tender Inviting Authority in consequence of such termination,

which may be recovered from the Security Deposit made by the Supplier and / or any other money due or becoming due to him. In the event of such amounts being insufficient, the balance may be recovered from the Supplier or from his properties as per the provisions of Law.

- 6.28.7** In the event the drugs supplied is rejected based on report of analysis, the Tender Inviting Authority is at liberty to make alternative purchase of the items for which the Purchase orders will be placed with any other sources or from the open market or from any other bidder who might have quoted higher rates at the risk and the cost of the supplier, and in such cases the Tender Inviting Authority has every right to recover the cost and to impose penalty.
- 6.28.8** Where a drug/ material is declared as not of standard quality by the Government Analyst or approved laboratory the supplier will not be eligible for any payment of the cost of the entire batch of the material/ drug irrespective of the fact whether the same has been partially or fully consumed.
- 6.28.9** Where a second batch of the same drug/ material supplied is also declared as NSQ for reasons as above, the supplier will be liable for a penalty equivalent to 50 percent of the value of the batch supplied in addition to the value of respective batch.
- 6.28.10** Where a third batch of the same drug/ material supplied is also declared as NSQ for reasons as above, the supplier will be liable for a penalty equivalent to 100 percent of the value of the batch supplied in addition to the value of the respective batch.
- 6.28.11** If any three batches of the particular item supplied by the firm during the contract period, fail in any of the quality tests conducted by the Tender Inviting Authority and/or by the Drugs Control Department, then that particular product of that firm will be blacklisted for a period up to 3 years.
- 6.28.12** In the case of the bidder supplying more than one item during the contract period, and if two or more items supplied by the supplier are blacklisted based on the above process, then the firm itself will be blacklisted as per the procedure detailed in Clause 6.37.
- 6.28.13** The unused portion of a batch of item declared as Not of Standard Quality shall not be returned to the supplier while such batches will be destroyed and the cost incurred for this purpose will be recovered from the supplier from any money due/becoming due to the supplier.

- 6.28.14 Drugs supplied in contravention to any of the provisions of the Drugs & Cosmetics Act and Rules made there under will be rejected.
- 6.28.15 In the case of any drug being spurious or adulterated or misbranded or otherwise contravening the provisions of the law, the company will be blacklisted as detailed in Clause 6.37.
- 6.28.16 The supplier shall furnish Bioavailability/Bioequivalence data or evidence of basis of fixing expiry date and other stability data of items, if so required by the Tender Inviting Authority.
- 6.28.17 The bidder shall furnish the source of procurement of raw materials utilized in the formulations if required by Tender Inviting Authority. Tender Inviting Authority reserves the right to cancel the purchase orders, if the source of supply is not furnished.
- 6.28.18 The decision of the Tender Inviting Authority or any officer authorized by him as to the quality of the supplied items shall be final and binding.

6.29. Payment Provisions

- 6.29.1 No advance payments towards costs of drugs will be made to the supplier.
- 6.29.2 Payments for supply will be considered only after supply of 50% of the quantity ordered is completed, provided reports of Standard Quality of the batch tested at third party independent NABL accredited laboratory/CDL/NIB together with in-house test report are furnished along with the invoice in respect of each batch supplied. The NABL test report must be complete and covering all parameters specified in the official monographs. Where it is observed that for any batch of the supplies the report as above is not furnished, payment of the entire consignment would be withheld pending verifications and the entire consignment would be liable to be rejected.
- 6.29.3 95% Payments towards the supply of items will be made as per terms and conditions laid down in the Tender Document. In such cases, balance 5% would be retained as performance security.

100% payment towards the supply will be released to those suppliers who have furnished an additional Performance Guarantee for 5% of the total LOI value along with Security Deposit.

The performance guarantee shall be furnished in form of bank guarantee as in **Annexure–XVI** valid for a period of 18 months from

the date of LOI or Demand Draft drawn in favour of the Managing Director, KMSCL. Refund of the retention amount/performance guarantee will be made only after 18 months from the date of execution of agreement or 3 months after satisfactory completion of supply, whichever is later.

- 6.29.4** All the suppliers can access the updates of their supply and invoice wise payments status by logging in to the online DDMS software linked with the official website of the Corporation (www.kmscl.kerala.gov.in) with their respective user name and password allotted to each supplier. If any discrepancies found with the submitted documents, the Corporation will update the details in online DDMS software. The Suppliers have to verify DDMS software and to re-submit the short fall documents, if any, recommended by the Corporation.
- 6.29.5** The supplier shall desist from deputing their representatives to the head office of the Tender Inviting Authority for follow up for payments. All communications in this regard shall be in writing and the Tender Inviting Authority discourages the visits, phone calls etc as part of transparency policy.
- 6.29.6** All bills/invoices should be raised in duplicate and should be drawn as per the rules and regulations in force and provisions in this tender in the name of **Managing Director, Kerala Medical Services Corporation Ltd., Thiruvananthapuram**. The original invoice along with the certificates of analysis from the in-house testing laboratory and NABL accredited laboratory/Central Drug Testing Laboratory/NIB in respect of every batch supplied shall be submitted to the Headquarters. The duplicate invoices along with test reports from NABL accredited laboratory/Central Drug Testing Laboratory/NIB shall be submitted at the District Drug Warehouses/scheduled delivery points along with the supply. No payment will be effected if the above provisions are not complied with.
- 6.29.7** Subject to the conditions mentioned in the purchase order, Tender Document, Agreement executed by the supplier and this Policy, the Supplier is entitled for the payment against supply. In case of any discrepancy in levy of LD, Penalty, Unexecuted Fine, Short Passing of Bills, such discrepancy shall be intimated within 15 days from the date of receipt of payment, failing which the Tender Inviting Authority will not entertain any claim thereafter.

- 6.29.8** If at any time during the period of contract, the price of tendered items is reduced or brought down by any law or Act or Notification of the Central or State Government or NPPA or by the bidder himself, below the contracted rate, their contracted rate will stand reduced automatically to reduce the level. Failure to supply at the reduced rate will be deemed as withdrawal from the contract and alternate purchase of the item will be made at risk and cost of the supplier. If supplies are made at higher rates after the rate of reduction, payments will be eligible at the reduced rates only.
- 6.29.9** In case of any enhancement in GST by notification of the Government after the date of submission of bids and during the tender period, the quantum of additional GST so levied will be allowed to be charged without any change in price structure of the items approved under the tender provided the supply is made on time. If the supplier has failed to supply the items as scheduled in the purchase order and any delay has occurred in the part of the supplier in supplying the item and if such the enhancement in statutory levies occurred in this delayed period then such enhancement will not be given by the TIA and the supplier has to bear the cost of such extra levies. For claiming the additional cost on account of the increase in GST, the bidder should produce proof of payment of additional GST on the goods supplied to Tender Inviting Authority. If the documentary evidence for increase in GST is produced, then the invoice amount with the enhanced rates of GST will be admitted, after due verification.

6.30. Penalties & Deduction in Payments

- 6.30.1** All supply should be made within the stipulated time and as per the scheduled quantity as mentioned in Section V/purchase order.
- 6.30.2** If the supply reaches the District Drug Warehouses beyond the stipulated time as mentioned in Section V, liquidated damages will be levied at the rates mentioned therein for the delayed supplies, irrespective of the Tender Inviting Authority having actually suffered any damage/loss or not, on account of delay in effecting supply.
- 6.30.3** Purchase orders will be cancelled under the conditions mentioned in Section V after levying penalties at the rates mentioned therein and such penalty is recoverable from any amount payable to the supplier.
- 6.30.4** However, the Tender Inviting Authority may receive supply even after expiry of the scheduled date from the date of purchase order, at its

discretion, considering the urgency of the essential item for the user Institutions and in such case, liquidated damages will be levied at 0.5% per day of the value of the delayed supply subject to a maximum of 10% percent.

- 6.30.5** If the supply is received in damaged condition it shall not be accepted. In case of damage in the tertiary packing only, the supply will be accepted only after levying penalty @ 5% on the total value of supply to that destination. Continuance of supply in damaged packages will lead to termination of contract. The supplier shall have to replace the goods with damage in primary or secondary packing and the penalty equal to the penalty for unexecuted supplies will be levied for the damaged goods and payments will be withheld till proper replacement.
- 6.30.6** All the bidders are required to supply the product with logogram and with prescribed packing specifications. The label of the primary packing of the external liquid preparations affixed in the bottle shall be in yellow background and shall carry horizontal red color band of minimum 5 mm width extending from top left to right corners of the label, as identification mark. If there is any deviation in these Tender conditions a penalty will be levied @ 5% irrespective of the Tender Inviting Authority having actually suffered any damage/loss or not.
- 6.30.7** The supplies shall not be printed with MRP on their primary/secondary/ tertiary packing. If there is any deviation in these Tender conditions a penalty will be levied @ 5% irrespective of the Tender Inviting Authority having actually suffered any damage/loss or not, without prejudice to the rights for alternative purchase specified in Clause 6.30.8.
- 6.30.8** In the event of making alternate purchase, the excess expenditure over and above contracted prices incurred by the Tender Inviting Authority in making such purchases from any other sources or in the open market or from any other bidder who has quoted higher rates and other losses sustained in the process, shall be recovered from the Security Deposit or Performance Guarantee or from any other money due and become due to the supplier and in the event of such amount being insufficient, the balance will be recovered personally from the supplier.
- 6.30.9** If LOI/purchase order is cancelled or agreement is terminated/blacklisted, the Corporation is at liberty to purchase the

entire tendered quantity of the item from any other sources at the risk and cost of the defaulted bidder.

6.30.10 In all the above conditions, the decision of the Tender Inviting Authority shall be final and binding.

6.31. Saving Clause

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

6.32. Applicable Law & Jurisdiction of Courts

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

6.32.2 Any bidder who had accepted the Tender Terms and Conditions of previous bids floated by the Corporation and had given a declaration of acceptance but had subsequently violated any of the said Terms and Conditions and for which no other penalty is specified in the Tender Terms and Conditions will be deemed to have indulged in unacceptable/unfair tender practices and the breach of tender/contract terms and will be liable for termination of contract and blacklisting.

6.32.3 Any and all disputes arising out of this tender will be subject only to the jurisdiction of courts of law / tribunals situated in Thiruvananthapuram City or normally having territorial jurisdiction over Thiruvananthapuram City only, or the High Court of Kerala as applicable. It is possible that jurisdiction to file disputes may be available before courts of law, including High Courts, or tribunals situated elsewhere. However, considering the limited resources of the Corporation, the bidders should specifically agree and covenant not to file any legal proceedings before any such courts of law/tribunals and should undertake and bind themselves to initiate and carry on legal proceedings in respect of this Tender exclusively before the courts of law/tribunals situated in or normally having territorial jurisdiction over Thiruvananthapuram City, or the High Court of Kerala as applicable. Any bidder who violates these conditions will be held to have indulged in an unacceptable/unfair tendering practice and will be deemed ineligible to participate in any of the bids of the Corporation for a period of three years from the date of the breach/violation of the aforesaid conditions.

6.32.4 The suppliers are also required to abstain from printing the words “subject to jurisdiction of Delhi Courts only” etc on the invoices submitted, which may force the Tender Inviting Authority to entertain the payment only after the supplier undertakes in writing his/her agreeing to the conditions above in respect of the jurisdiction of the courts of Kerala.

6.33. Corrupt or Fraudulent Practices

6.33.1 It is required that all concerned namely the 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:

6.33.1.1 “Corrupt practice” means the offering, giving, receiving or soliciting of anything of value to influence the action of any person in the procurement process or in contract execution and related activities of the Corporation.

6.33.1.2 Without prejudice to the provision of Clause 2.10 of this Tender Document “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 tender submission) designed to establish tender prices at artificial non-competitive levels and to deprive the Tender Inviting Authority of the benefits of free and open competition. Suppression of facts such as blacklisting of the product/bidder elsewhere for reason of failure in quality / conviction under Drugs and Cosmetics Act/submission of fake document will be deemed as fraudulent practices. Making false/incorrect statement will also be treated as fraudulent practice.

6.33.1.3 In case Product(s)/Bidder/Supplier is blacklisted/debarred by another state/Central Government agency for the reason of Quality non-compliances, GMP Non-compliance, major violation of D&C Act and Rules and furnishing forged/fabricated/false documents, after bid submission/award of contract/execution of agreement, the bidder shall intimate the TIA in writing within 14 days from

the date of such order. If fails to, it will be treated as fraudulent practice and concealment of facts.

- 6.33.2** Government/ 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.
- 6.33.3** 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 tender in writing, with an intention to influence the members of various committees or officials of Tender Inviting Authority or any person associated with KMSCL. Any such effort by a bidder to influence the Tender Inviting Authority/ factory inspection team/ sample evaluation committee/ bid comparison or contract award decisions may result in rejection of the bid.
- 6.33.4** The supplier shall not be in any way interested in or concerned directly or indirectly with, any of the officers, subordinates or servants of the Tender Inviting Authority in any trade or business or transactions nor shall the supplier give or pay promise to give or pay any such officers, subordinates or servants directly or indirectly any money or fee or other considerations under designation of “Custom” or otherwise, nor shall the supplier permit any person or persons whom so ever to interfere in the management or performance hereof under the power of attorney or otherwise without the prior consent in writing of the Tender Inviting Authority. Any such effort by the supplier to influence the Tender Inviting Authority or its officers may result in rejection of the bid.

6.34. Code of Conduct for Suppliers

- 6.34.1** The following principles are expected to be adopted by the manufacturers as part of quality assurance norms and also as commitment towards the welfare of the workers.

A. Labour:

- i. Workers shall be sufficiently literate to know and understand the nature and precise requirements of the works entrusted to them and the risks involved therein.
- ii. Workers shall also be literate enough to read and understand the instructions relating to a work and perform the work exactly as per the needs without any deviation. They should also be literate enough to maintain the records of the works performed.
- iii. Workers shall be well informed, and in needed trained, in safety measures and procedures in the work area.
- iv. The work places, machineries and equipments, chemicals, reagents and materials, the environment in general and the in the workplaces in particular, shall be safe without any risk to the general health or life of the workers.
- v. Monitoring the health of the personnel handling cytotoxic substances and other drugs of hazardous nature is very important. Norms, if any, prevailing in such matters shall be properly adhered to. If no norms prescribed by statutory agencies are available, own norms shall be developed and implemented.
- vi. Personnel attending to works that cause strain to the eyes shall be given sufficient rest in between.
- vii. The hours of working shall not be unreasonable as extended work hours could affect the quality of work.
- viii. Waste of human hours shall also be avoided.
- ix. Wastage of all types including water, energy are to be reduced.

B. Unethical practices: Unethical practice of any form will be least tolerated. These include:

- Contacting KMSCL officials or persons associated with its activities for no specific reason,
- giving gifts, providing hospitality, invitations for cultural/ scientific/ social events, offer of holidays, free goods or services etc;
- trying to influence officials or the associates of the Corporation under the cover of region, religion, political consideration, language, relationship etc;
- offer of employment to any of the employee' relative or associate of the employee of the Corporation etc. KMSCL will not tolerate any such activity on the part of the suppliers and such norms apply to the employees of the Corporation also.

6.35. Force Majeure

- 6.35.1 For purposes of this clause, Force Majeure means an event beyond the control of the successful bidder and not involving the successful bidder's fault or negligence and which is not foreseeable and not brought about at the instance of , the party claiming to be affected by such event and which has caused the non – performance or delay in performance. Such events may include, but are not restricted to, acts of the Tender Inviting Authority either in its sovereign or contractual capacity, wars or revolutions, hostility, acts of public enemy, civil commotion, sabotage, fires, floods, explosions, epidemics, quarantine restrictions, strikes excluding by its employees, lockouts excluding by its management, and freight embargoes. **Scarcity of raw materials and power cut are not considered as force majeure.**
- 6.35.2 If a *Force Majeure* situation arises, the successful bidder shall promptly notify the Tender Inviting Authority in writing of such conditions and the cause thereof with satisfactory documentary proof, within twenty one days of occurrence of such event. The time for making supply may be extended by the Tender Inviting Authority at its discretion for such period as may be considered reasonable.
- 6.35.3 In case due to a *Force Majeure* event the Tender Inviting Authority is unable to fulfill its contractual commitment and responsibility, the Tender Inviting Authority will notify the successful bidder accordingly and subsequent actions taken on similar lines described in above subparagraphs.

6.36. General/ Miscellaneous Clauses

- 6.36.1 Any failure on the part of any Party to exercise right or power under this Contract shall not operate as waiver thereof.
- 6.36.2 The Successful bidder shall, at all times, indemnify and keep indemnified the Tender Inviting Authority 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.
- 6.36.3 All claims regarding indemnity shall survive the termination or expiry of the contract.

6.37. Procedure for Blacklisting

- 6.37.1 The Tender Inviting Authority may blacklist any drug, bidder/supplier for reason specified in tender document. Blacklisting shall be done after giving an opportunity to the bidder/supplier to show cause in writing. **Blacklisting shall be for a maximum period of three years from the date of such order.** The product(s)/bidder/ supplier will not be eligible to be considered in any of the tender/quotations floated by the Tender Inviting Authority during the period of blacklisting.
- 6.37.2 For blacklisting a product(s)/firm as noted in the tender, a registered notice shall be issued to the firm/supplier calling for explanation in writing within 15 days from the date of receipt of notice. The TIA will examine the reply furnished by the firm, if any, and will pass appropriate orders on blacklisting of the product(s)/firm, based on merits of the case. If no reply is received from the firm within the stipulated period, it will be presumed that the firm has no valid reason to adduce as to why the product(s)/firm should not be blacklisted as per the tender conditions.
- 6.37.3 Blacklisting of a particular firm or product is without prejudice to other penalties stipulated in the terms & conditions of the tender document.

6.38. Provisions for Appeal

- 6.38.1 A bidder/supplier who whose product has been blacklisted or whose contract has terminated or against whom any other penalty has been imposed by the Tender Inviting Authority may, within 15 days from the date of receipt of such order, appeal to the State Government. The State Government after such enquiry into the matter, as is considered necessary and after giving the said supplier an opportunity for representing his views, may pass such order in relation thereto as it thinks fit.

6.39. Termination of Contract

- 6.39.1 The contract will be liable for termination for any breach of contract at the discretion of Tender Inviting Authority.
- 6.39.2 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/User Institution.

- 6.39.3** In the event of the TIA terminates the contract of a supplier in whole or in part, the Corporation is at liberty to purchase the entire tendered quantity of the item(s) from any other sources and the extra expenditure incurred by the TIA will be realized from the supplier.
- 6.39.4** Unless otherwise instructed by the Tender Inviting Authority, the successful bidder shall continue to perform the contract to the extent not terminated.
- 6.39.5** 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.
- 6.39.6** 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 date with effect from which such termination will become effective.
- 6.39.7** In case, any item(s) supplied by the bidder are reported to be inferior in performance/description/safe usage, the TIA at liberty to reject such items and terminates the contract of the product/supplier.
- 6.39.8** Tender Inviting Authority will be at liberty to terminate the contract either wholly or in part on 15 days notice. The bidder will not be entitled for any compensation whatsoever in respect of such termination.
- 6.39.9** Termination of contract of a contract with a supplier in whole or in part is without prejudice to any other penalties stipulated in the tender condition.

- 6.39.10** For infringement of the stipulations of the contract or for other justifiable reasons, the contract may be terminated by the Tender Inviting Authority, and the bidder shall be liable for all losses sustained by the Tender Inviting Authority, in consequence of the termination which may be recovered personally from the bidder or from his properties, as per rules.
- 6.39.11** No compensation is payable to the supplier in the event of any termination of contract.

Sd/-

Dr. Dileep Kumar S R
Managing Director i/c, KMSCL &
Tender Inviting Authority

CHECK LIST

TENDER NO. KMSCL/DRGED/HAEM/RC/2019/009

DATED 10.05.2019

NAME OF THE BIDDER:.....

Sl. No.	Document to be uploaded
1.	Check list in Annexure-I .
2.	Documentary proof that the firm is registered with the Industries department/Directorate of Industries and Commerce of the State of Kerala, if the firm has claimed for exemption from submitting EMD & Tender document cost.
3.	List of item(s) offered in the format prescribed in Annexure II .
4.	Annual turnover statement for last 3 years in the format given in Annexure III certified by the Auditor.
5.	Notary attested photocopy of Manufacturing License and Certificate of renewal/current validity certificate along with the product permit duly approved by the Licensing authority for the product(s) quoted. Items quoted along with specifications shall be clearly highlighted in the product permit and respective drug code of the item shall be noted in the product permit.
6.	Notary attested photocopies of valid import license in Form 10 and previous import licenses issued 3 years prior to the date of notification of the tender, if the product(s) are imported.
7.	Notary attested copy of product wise Market Standing Certificate issued by the Licensing Authority to prove 3 years Market Standing for all the items quoted. In case of imported drugs, bill of lading/sales invoices/market standing certificate to prove that the product is being imported/marketed by the bidder in last 3 years.
8.	Notary attested copy of valid license for the sale of Drugs imported by the firms issued by the licensing authority, in the case of imported products.
9.	Notarized copy of valid WHO-GMP Certificate in respect of the production units and the products quoted.
10.	Notary attested copy of valid COPP issued by the Licensing Authority for the items quoted.
11.	Notary attested copy of PMF Approval Certificate issued by the Central License Approval Authority.
12.	Notary attested copy of all the relevant pages in PMF on viral inactivation/purification processes adopted for the manufacture of Factor VIII.
13.	Notary attested copy of all the relevant pages in PMF on viral inactivation/purification processes adopted for the manufacture of Factor IX.
14.	Notary attested copy of all the relevant pages in PMF on viral inactivation/purification processes adopted for the manufacture of FIEBA.
15.	Statement on the methods adopted for viral inactivation/purification in the format as given in Annexure V .
16.	Notary attested copy of all relevant pages in PMF on viral detection tests performed in the source plasma, during manufacturing process and in finished product for

Sl. No.	Document to be uploaded
	Factor VIII.
17.	Notary attested copy of all relevant pages in PMF on viral detection tests performed in the source plasma, during manufacturing process and in finished product for Factor IX.
18.	Notary attested copy of all relevant pages in PMF on viral detection tests performed in the source plasma, during manufacturing process and in finished product for FIEBA.
19.	Statement on the viral detection tests in the format as given in Annexure VI .
20.	Documents to prove the purity of the offered product as defined by the WFH for Factor VIII.
21.	Documents to prove the purity of the offered product as defined by the WFH for Factor IX.
22.	Statement on purity of the offered product in the format as given in Annexure VII .
23.	Notary attested copy of all the relevant documents on donor traceability for Factor VIII.
24.	Notary attested copy of all the relevant documents on donor traceability for Factor IX.
25.	Notary attested copy of all the relevant documents on donor traceability for FIEBA.
26.	Details of batches tested in NIB since 2016-17 as in the format given in Annexure VIII .
27.	Notary attested copy of reports of all the batches tested in NIB since 2016-17 for Factor VIII.
28.	Notary attested copy of reports of all the batches tested in NIB since 2016-17 for Factor IX.
29.	Notary attested copy of reports of all the batches tested in NIB since 2016-17 for FIEBA.
30.	Statement of supply of Factor VIII made to the organizations listed in Annexure IX.
31.	Statement of supply of Factor IX made to the organizations listed in Annexure IX.
32.	Statement of supply of FIEBA made to the organizations listed in Annexure IX.
33.	Notary attested documents to prove the supply of Factor VIII made to the organizations (listed in Annexure IX) such as LOI / PO/ Performance Certificate etc issued by the above organization.
34.	Notary attested documents to prove the supply of Factor IX made to the organizations (listed in Annexure IX) such as LOI / PO/ Performance Certificate etc issued by the above organization.
35.	Notary attested documents to prove the supply of FIEBA made to the organizations (listed in Annexure IX) such as LOI / PO/ Performance Certificate etc issued by the above organization.
36.	Notary attested copy of current Non-conviction Certificate issued by the licensing authority of the concerned state.
37.	Notary attested statement of manufacture/imported and sale of the quoted drugs in the last 3 years shall be furnished in the Performance Statement given in the Annexure IV .

Sl. No.	Document to be uploaded
38.	Notary attested copy of Power of Attorney/Resolution of Board.
39.	Undertaking/declaration in the format prescribed in Annexure X .
40.	Notarized copy of Audited Balance Sheets and Profit and Loss statement for three years from 2015-16 to 2017-18.
41.	Notary attested details of technical personnel employed in the manufacture and testing of items (Employees' Name(s), Qualification(s), and Experience).
42.	Notary attested details of the bidder and manufacturing unit in the format prescribed in Annexure XII .
Note:	
<p>If a particular document/certificate to be uploaded as specified in the above check list is not applicable for a bidder, to avail such claim the bidder shall attach a scanned copy of declaration in the official letter head stating as to why the specific document is not applicable/exempted/not available for the bidder in connection to this tender. Failure to attach any of the documents specified in the Technical Bid requirement of the e-procurement portal will lead to rejection of the bid automatically.</p>	

Place:

Signature:

Date:

Name in Capital Letters:

Seal:

Designation:

BID OFFER FORM

I/We M/s have examined and accepted the conditions of the tender document No. **KMSCL/DRGED/HAEM/RC/2019/009** dated 10.05.2019, hereby submit this offer for the supply of the following items conforming to the specification, shelf life and all other parameters mentioned in Section IV of the tender document.

Sl No	Drug Code	Drug Name	Strength	Unit	Name & Location of the Mfg unit	* Whether own Mfg/Loan Licensee /Imported.	Mfg/loan/Import License no: and Date	Date of issue of product approval	Required EMD as per clause 4.1 (in Rs)
1									
2									
3									
4									
5									
Total Amount:									

*Loan licensee shall specify the name & address of manufacturing unit of the item.

Place:Signature:

Date :Name in Capital Letters:

Designation:

Seal:

ANNUAL TURN OVER STATEMENT

I hereby certify that M/s _____ (Name & address _____) who is a prospective bidder for the Tender **KMSCL/DRGED/HAEM/RC/2019/009 DATED 10.05.2019** of KMSCL is having the following annual turnover and the statement is true and correct.

Sl. No.	Year	Turnover in Crores(Rs.)
1.	2015 – 2016	
2.	2016 – 2017	
3.	2017 – 2018	
Total (Rs.)		
Average turnover per annum (Rs.)		

Date:

Signature of Auditor/

Chartered Accountant

(Name in Capital):

Name of firm:

Reg. No.:

Seal:

PERFORMANCE STATEMENT

(ATTACH SEPARATE SHEET FOR EACH PRODUCT QUOTED)

Name of firm
Name of the productDrug code
Tendered Quantity (in units)..... Offered Quantity (in units).....

Production Capacity	
No. of days	Quantity in tendered units
30 days	
70 days	
90 days	
365 days	

Production details for three years:**Year:2016-17/ 2017-18/2018-19****Furnish statement of all batches produced including rejected batches, if any**

Sl. No	Total No. of Batches Mfd.	Individual Batch Numbers mfd during the year	Date of mfg	Qty mfd	Max capacity per single batch production	Qty sold	Date / Month of sales	Quantity returned/ rejected	Reason for return /rejection
2016-17									
2017-18									
2018-19									

Certified true statement of productions

Signature and seal of the Tenderer Attested by notary public

METHODS ADOPTED BY THE BIDDER FOR THE VIRAL INACTIVATION/PURIFICATION

Sl. No.	Viral inactivation methods	Whether the bidder is performing the procedure during mfr of the item.			Documentary proof submitted in the bid
		HUMAN AHF VIII	HUMAN AHF IX	FEIBA	
1.	Solvent - Detergent Treatment				
2.	Heating (Dry heat/Vapour heat)				
3.	Nanofiltration (<20nm)				
4.	Immunoaffinity chromatography using recombinant monoclonal antibody				
5.	Anion exchange chromatography				
6.	Size exclusion gel chromatography				

Drug Code & Drug Name:

TESTS PERFORMED ON VIRAL DETECTION

Sl no	Tests	Individual Donation	Plasma Pool	Finished Product
1.	HIV 1			
2.	HIV 2			
3.	Hepatitis A Virus			
4.	Hepatitis B Virus			
5.	Hepatitis C Virus			
6.	Parvovirus B19			
7.	Other tests, <i>specify</i>			

ANNEXURE-VII		
Purity of the offered product as per the International standards of purity defined by WFH (World Federation of Haemophilia).		
Factor concentrate	Purity of the offered product	Details of documentary proof submitted in the bid
HUMAN AHF VIII		
HUMAN AHF IX		

ANNEXURE-VIII					
Drug Code & Drug Name:					
DETAILS OF TESTING AT NIB					
Year	Total no of batches mfd/ imported by the bidder.	Number of batches sent to NIB for QC analysis	Number of batches Approved by NIB for sale	Number of batches Rejected by NIB	Reasons for Rejection
2015-16					
2016-17					
2017-18					
2018-19					

ANNEXURE – IX

Details of Supply made to other agencies					
Drug Code & Drug Name:					
Sl. No.	Name of Institution	Quantity supplied in nos.			
		2015-16	2016-17	2017-18	2018-19
1.	All India Institute of Medical Sciences (AIIMS)				
2.	Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER) Pondichery				
3.	Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS) Lucknow				
4.	King Edward Memorial Hospital (KEM) Mumbai				
5.	Christian Medical College and Hospital (CMC) Vellore				
6.	Vardhman Mahavir Medical College & Safdarjung Hospital New Delhi				
7.	Central Government Health Scheme (CGHS)				
8.	Other State Medical Services Corporations/Central procurement agencies				
	a.				
	b.				
	c.				

DECLARATION AND UNDERTAKING
(Non-judicial stamp paper of Rs.200)

I/We, Sole Proprietor/Managing Partner/Managing Director/Power of Attorney holder of M/s. _____ having its Registered Office/ Place of business at _____ and having Factory Premise(s) at _____ & _____ do hereby declare on oath as follows;

- 1.that I/we have carefully read all the conditions of tender **KMSCL/DRGED/HAEM/RC/2019/009 dated 10.05.2019 for the procurement of Anti Haemophilia Drugs for the period of 2019-20** floated by the Kerala Medical Services Corporation Ltd., Thiruvananthapuram and I/we do accept(s) all the terms and conditions of the Tender document including amendments of the tender published by the Corporation.
- 2.that I/we declare that we possess all the legal license(s)/permits for manufacture and supply of the material(s) bided and that we possess the necessary facilities for the production, have adopted proper procedures for control of all activities to ensure proper quality of the product(s) during its/their shelf-life and we shall maintain all documents including raw data records and will produce to the TIA, on demand. I/we understand and agree that in the event of I/we failing to provide such facilities, we will be liable for the penal actions such as rejection of bid, termination of contract and blacklisting.
- 3.that I/we possess the valid manufacturing licenses and WHO-GMP Certificate and COPP issued by the Competent Authority for all the quoted products and complies and shall continue to comply with the conditions of WHO-GMP criteria together with the standards laid in Schedule M of Drugs & Cosmetics Act 1940 and the Rules made there under. I/we will manufacture/supply items from the WHO-GMP certified plants as mentioned in our bid. I/we do hereby understand and agrees that in the event of I/we failing to adhere to the WHO-GMP norms and or any of the standards laid in Schedule M of Drugs & Cosmetics Act 1940 and the Rules made there under at any stage when the contract is in operation, the bid will be rejected/contract will be liable to be terminated and I/we will be liable to pay for the additional cost incurred for the alternate purchase of the contract quantity. Where the failure is observed after the conclusion of the contract, we will be liable for blacklisting according to the provision of this tender.
- 4.that I/we possess valid COPP issued by the Licensing Authority for the quoted items.

- 5.that I/we possess valid approved Plasma Master File covering all the aspects for the use of plasma from collection point to the finished product.
- 6.that any one of the batches manufactured by us during the last 3 years has not been declared as Not of Standard Quality by NIB for the reason of viral presence or sterility.
- 7.that I/we or any of the product(s) offered in this tender, at present, have not been blacklisted/debarred by the Tender Inviting Authority for any reason or by any State/Central Government organization for reason of Quality Non-compliances, GMP-non compliance, Major violation of D & C Act and Rules and furnishing forged/fabricated/false documents.
- 8.that the quoted rate of any item is not more than the price fixed by the National Pharmaceutical Pricing Authority or by State/central Government, in any means, and, further undertakes that if in future prices of the items offered is reduced by the authorities the same benefit will be transferred to the TIA.
- 9.that I/We will furnish the Certificate of Analysis of each batch of item tested, in National Institute of Biologicals along with the consignment. I/we also undertake that in the event of failing to produce the above Certificate of Analysis or the submitted Certificate found not genuine/forged at any stage, the contract/ such product(s) will be rejected and the contract is liable to be terminated and I/we/such product may be blacklisted according to the provisions in this tender.
- 10.that I/we will supply the Drugs/supplies as per the packing and labeling specifications and with the logograms as per the designs and barcode as specified in the Annexure (packing and labeling specifications) in the Tender Document and as per the instructions given in this regard.
- 11.(a) that I/we will supply drugs strictly under special cold storage conditions (2-8⁰C) so that the items have reached KMSCL warehouses adhering the cold chain norms. The Cold chain products will be provided with temperature variation indicators like vaccine vial monitors or each container of a consignment will be provided with data loggers for recording the temperature conditions during transit, the software of which will be provided to all the warehouses. I/we agree that the Tender Inviting Authority rejecting the consignment, forfeiting the Security Deposit and terminate the contract/blacklisting me/us, if the condition of cold chain transportation is not complied with.

Verification

I(name)_____ (address)_____ (designation) _____ affirm on oath that the contents/information as mentioned above, are true & correct to the best of my knowledge and nothing is hidden. I also declare on oath, that if any information furnished as above is found wrong, false, forged or fabricated; the Corporation will

be at liberty to reject the product(s)/terminate the contract/alternate purchase of the contract quantity at our risk & cost and the firm may be blacklisted/prosecuted for the same.

(Signature, Name & Designation)

Witness :-

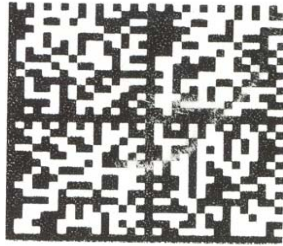
1. (Name, Address & Signature)
2. (Name, Address & Signature)

Seal

Attested by Notary Public

2.BAR CODING DETAILS

BOX NO :
PO NUMBER :
SUPPLIER CODE :
SUPPLIER NAME :
DRUG CODE :
DRUG NAME :
BATCH NO :
MFG DATE :
EXPIRY DATE :
BATCH QUANTITY :



DETAILS OF THE BIDDER AND MANUFACTURING UNITS

I.		Bidder Details	
A	a.	Name of the Bidder	:
	b.	Address for Communication	:
	c.	PIN code	:
	d.	Land Phone No	:
	f.	Mobile No	:
	g.	Fax	:
	h.	Email ID	:
B	a.	Name of the Managing Director/Director/Partner/Proprietor	:
	b.	Land Phone No	:
	c.	Mobile No.	:
	d.	Email ID	:
C	a.	Name of the Authorized contact person	:
	b.	Designation	:
	c.	Land Phone No	:
	d.	Mobile No	:
	e.	Email ID	:
D	a.	Address for return of the supplied item, if such circumstances arise,	:
	b.	PIN code	:
	c.	Landphone No.	:
	d.	Mobile	:
	e.	Fax	:
	f.	Email Id	:
E		GST Registration No. of the bidder	:
F		PAN of the bidder	:
II		Details of Manufacturing Units *	
A	a.	Name of the Manufacturer - I	:

	b.	Address of the manufacturing unit -I	:	
	c.	GST Registration No. of the manufacturing unit -I	:	
	d.	Drugs manufacturing license No. & Date	:	
	e.	Name of Contact person, Contact No, Email ID	:	
B	a.	Name of the Manufacturer - II	:	
	b.	Address of the manufacturing unit - II	:	
	c.	GST Registration No. of the manufacturing unit - II	:	
	d.	Drug manufacturing license No. & Date	:	
	e.	Name of Contact person, Contact No, Email ID	:	
*If the items offered are manufactured in two or more manufacturing units/loan licensee, the above details of all the units shall be furnished.				
III.	Bank Details			
A	Name of the Bank		:	
B	Branch Name & Address		:	
C	Branch Code No.		:	
D	Branch Telephone No.		:	
E	Branch email ID		:	
F	IFS code of the Branch		:	
G	Type of Account (current/savings)		:	
H	Bank Account Number (as appear in the cheque book)		:	

FORMAT OF BANK GUARANTEE OF EARNEST MONEY DEPOSIT

To

The Kerala Medical Services Corporation Limited
(Address)

WHEREAS _____ (Name and address of the Company) (Hereinafter called “the bidder”) has undertaken, in pursuance of tender no _____ dated _____ (herein after called “the tender”) to participate in the tender of The Kerala Medical Services Corporation Limited, (address) with (description of goods and supplies).

AND WHEREAS it has been stipulated by you in the said tender that the bidder shall furnish you with a bank guarantee by a scheduled commercial bank recognised by you for the sum specified therein as Earnest Money Deposit for compliance with its obligations in accordance with the tender;

AND WHEREAS we have agreed to give the bidder ----- (name and address) such a bank guarantee;

NOW THEREFORE we hereby affirm that we are guarantors and responsible to you, on behalf of the bidder, up to a total amount of _____ (Amount of the guarantee in words and figures), and we undertake to pay you, upon your first written demand declaring the bidder to be in default under the tender conditions 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 grounds or reasons for your demand or the sum specified therein.

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

We undertake to pay you any money so demanded notwithstanding any dispute or disputes raised by the bidder(s) in any suit or proceeding pending before any Court or Tribunal relating thereto our liability under these presents being absolute and unequivocal.

We agree that no change or addition to or other modification of the terms of the tender to be performed there under or of any of the Tender 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.

No action, event, or condition that by any applicable law should operate to discharge us from liability, hereunder shall have any effect and we hereby waive any right we may have to apply such law, so that in all respects our liability hereunder shall be irrevocable and except as stated herein, unconditional in all respects.

This guarantee will not be discharged due to the change in the constitution of the Bank or the bidder(s).

We, _____ (indicate the name of bank) lastly undertake not to revoke this guarantee during its currency except with the previous consent, in writing, of The Kerala Medical Services Corporation Limited.

This Guarantee will remain in force up to _____ (Date). Unless a claim or a demand in writing is made against the bank in terms of this guarantee on or before the expiry of -----(Date) all your rights in the said guarantee shall be forfeited and we shall be relieved and discharged from all the liability there under irrespective of whether the original guarantee is received by us or not.

(Signature with date of the authorised officer of the Bank)

.....

Name and designation of the officer

.....

.....

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

AGREEMENT

THIS AGREEMENT made on this..... day of, 2019 between..... Kerala Medical Services Corporation Ltd represented by its Managing Director having its registered office at Thiruvananthapuram (hereinafter “the **Purchaser**”) of one part and M/s. (Name and Address of Supplier)..... (herein after “the **Supplier**”) represented by (Name of the Authorized Signatory and Designation), Aged years, residing at (Full Residential Address of the Signatory) of the other part:

WHEREAS the Purchaser has invited tender for the procurement of drugs vide TENDER NO. **KMSCL/DRGED/HAEM/RC/2019/009 DATED 10.05.2019**. The supplier has submitted technical and Price Bids as contained in the Tender Document. The Purchaser has finalized the tender in favour of the Supplier for the procurement of drugs specified in the schedule attached hereto at the prices noted against each item therein for a total cost of Rs. (Contract Price in Words and Figures) (herein after “the Contract Price”) on the terms and conditions set forth in the agreement.

NOW THIS AGREEMENT WITNESSETH AS FOLLOWS:

1. In this Agreement words and expressions shall have the same meanings as are respectively assigned to them in the Tender Document referred to.
2. The following documents shall be deemed to form and be read and construed as part of this Agreement, viz.:
 - (a) All the documents submitted by the tenderer as part of Technical Bid and Price Bid;
 - (b) The Schedule of Requirements;
 - (c) The Specifications and other quality parameters;
 - (d) The clarifications and amendments issued / received as part of the Tender Document
 - (e) The General Conditions of Contract;
 - (f) The Specific Conditions of Contract; and
 - (g) The Purchaser’s offer Letter
 - (h) All correspondence as part of tender during or after the date of agreement accepted by Tender Inviting Authority
3. This agreement shall deem to extend to such LOIs as may be issued in pursuance and in accordance with the tender.

4. Any supply made on the purchase orders placed against this tender before the execution of this agreement shall deemed to be covered by this agreement and all terms and conditions of the tender applied to such supplies
5. In consideration of the payments to be made by the Purchaser to the Supplier as hereinafter mentioned, the Supplier hereby covenants with the Purchaser to supply drugs conforming in all respects with the provisions of the Contract.
4. The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the tender, the Contract Price or such other sum as may become payable under the provisions of the Contract at the times and in the manner prescribed by the Contract.
5. The Supplier has deposited with the Purchaser an amount of Rs.....(as in Tender condition) as Security Deposit as specified in the Conditions of Tender for due and faithful performance of the provisions of this Agreement. Such Security Deposit made by the Supplier is liable to be forfeited by the Purchaser in the event of the Supplier failing duly and faithfully to perform any one or more or any part of any one of the said provisions. The payment for the supplies made by the Supplier will be paid to him only after he has remitted the required amount of Security Deposit.

SCHEDULE
(Selected L1 items)

Sl.No	Drug Code	Name of the Drug	Strength	Unit	Rate (Rs.)	LOI Quantity	Value (Rs)
Total Value (Rs.)							

IN WITNESS whereof the parties hereto have caused this Agreement to be executed in accordance with their respective laws the day and year first above written.

Signed, Sealed and Delivered by the

said (For the *Purchaser*)

in the presence of

Signed, Sealed and Delivered by the

said(For the Supplier) (Signature, Name,
Designation and Address with Office seal)

in the presence of

1) (Signature, Name and Address of witness)

2)(Signature, Name and Address of witness)

FORMAT OF BANK GUARANTEE FOR SECURITY DEPOSIT

To

The Kerala Medical Services Corporation Limited
(Address)

WHEREAS _____ (Name and address of the supplier) (Hereinafter called “the supplier”) has undertaken, in pursuance of contract no _____ dated _____ (herein after called “the contract”) to supply The Kerala Medical Services Corporation Limited, (address) with (description of drugs).

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 recognised by you for the sum specified therein as security for compliance with its obligations 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 amount 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 grounds 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 undertake to pay you any money so demanded notwithstanding any dispute or disputes raised by the supplier(s) in any suit or proceeding pending before any Court or Tribunal relating thereto our liability under these presents being absolute and unequivocal.

We 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.

No action, event, or condition that by any applicable law should operate to discharge us from liability, hereunder shall have any effect and we hereby waive

any right we may have to apply such law, so that in all respects our liability hereunder shall be irrevocable and except as stated herein, unconditional in all respects.

This guarantee will not be discharged due to the change in the constitution of the Bank or the Supplier(s).

We, _____ (indicate the name of bank) lastly undertake not to revoke this guarantee during its currency except with the previous consent, in writing, of The Kerala Medical Services Corporation Limited.

This Guarantee will remain in force up to (Date). Unless a claim or a demand in writing is made against the bank in terms of this guarantee on or before the expiry of (Date) all your rights in the said guarantee shall be forfeited and we shall be relieved and discharged from all the liability there under irrespective of whether the original guarantee is received by us or not.

(Signature with date of the authorised officer of the Bank)

.....

Name and designation of the officer

.....

.....

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

FORMAT OF PERFORMANCE BANK GUARANTEE

To

The Kerala Medical Services Corporation Ltd

(Address)

Sir,

Bank Guarantee No :
.....

Amount of Guarantee :
.....

Guarantee cover from :
.....

Last date for lodgement of claim :
.....

This deed Guarantee executed by the
.....
.....
.....
.....

(Herein after referred to as the “Bank”) in favour of the Managing Director, Kerala Medical Services Corporation Ltd, Thiruvananthapuram (hereinafter referred to as “the Beneficiary”) for an amount not exceeding ₹ at the request of M/s. (herein after referred to as “ the Contractor”).

This guarantee is issued subject to the condition that the liability of the Bank under this Guarantee is limited to a maximum of Rs. and the guarantee shall remain in full force up to and cannot be invoked otherwise than by a written demand or claim under this Guarantee served on the Bank on or before

Whereas the beneficiary has placed a Letter of Intent with the contractor in terms of the LOI No: dated for drugs/supplies whereas one of the conditions of the agreement made was that the Corporation should make 100% payment of the contract on submission of Performance Bank Guarantee equivalent to 5% contract value valid for 18 months from the date of execution of

agreement or 3 months from the date of satisfactory completion of supply whichever is later.

In consideration of the beneficiary having agreed to pay to the contractor the payment as aforesaid in accordance with the terms of the agreement, we, the hereby undertake that it will in the event of the Contractor, failing to deliver the materials in accordance with the conditions of the agreement, pay to the beneficiary on demand any sum or sums which may from time to time be demanded by the beneficiary after the date there of up to a maximum of Rs.
. being the amount of 5% of the contract value which at the date of the demand by the beneficiary has been paid aforesaid and which has not under the terms of this or any undertaking been reimbursed.

This Guarantee will remain in force up to (Date). Unless a claim or a demand in writing is made against the bank in terms of this guarantee on or before the expiry of (Date) all your rights in the said guarantee shall be forfeited and we shall be relieved and discharged from all the liability there under irrespective of whether the original guarantee is received by us or not.

Notwithstanding anything contained herein:

- i) Our liability under this Bank Guarantee shall not exceed Rs.
.
- ii) The Bank Guarantee shall be valid up to
.
- iii) We are liable to pay the guaranteed amount or any part thereof under this Bank Guarantee only and only if you serve upon us a written claim or demand on or before

Dated on this day of

Witnesses:

- 1.
- 2.

Address of KMSCL Drug Warehouses

SL NO	District Name	Address	E-mail ID	Land line No	Mob No
1	Thiruvananthapuram	District Drug Warehouse, DMO Compound, General Hospital, Palayam, Trivandrum-695035	kmsclwhtrivandrum@gmail.com	0471-2470222 0471- 4015638	9496003900
2	Kollam	District Drug Warehouse, Uliyakovil Nagar, Near Uliyakovil Temple, Kollam - 691019	kmsclwhklm@gmail.com	0474-2731238	9496004500
3	Pathanamthitta Adoor	XV/ 556 (6), 556 (7) & 556(8) K.P Road, Near Malabar Gold, Kannamkode, Adoor (Pathanamthitta) Pin: 691523	kmsclwhpta@gmail.com	04734-223442	9496004600
4	Idukki Painav	District Drug Ware House, Near Idukki Govt. Medical College, Idukki Colony P O, Cheruthoni., Idukki. PIN- 685602	kmsclwhidk@gmail.com	0486-2232228	9496004900
5	Kottayam	District Drug Ware House, Behind District Hospital, Chelliyozhukkam Road, Kottayam-686001	kmsclwhkottayam@gmail.com	0481-2562401	9496004800
6	Alappuzha DDWH	District Drug Ware House, Near General Hospital, Iron Bridge PO, Alappuzha- 688011	kmsclwhalp@gmail.com	0477-2252302	9496004700
7	Ernakulam	District Drug Ware House, Udyogamandal, Near St. Joseph Hospital, Manjummel, Ernakulam-683501	kmsclwhekm2@gmail.com	0484-2555009	9496005400
8	Thrissur	District Drug Ware House, High Road, OPP. Police Officer's Quarters, Thrissur-680001	kmsclwhtrs@gmail.com	0487-2423369	9496005600
9	Palakkad	District Drug Ware House, District Hospital Compound, Court Road, Palakkad-678001	kmsclwhpkd@gmail.com	0491-2533336	9496006200
10	Malappuram Tirur	District Drug Ware House, Near Fire Force Station-Tirur, Tirur(PO), Malapuram-676101	kmsclwhmpm@gmail.com	0494-2426759	9496003914 9995953165

Address of KMSCL Drug Warehouses

SL NO	District Name	Address	E-mail ID	Land line No	Mob No
	Malappuram Manjeri	District Drug Ware House, State WareHousing Corporation Compound, Karuvambram P.O., Cheranni, Manjeri, Malapuram District.-676123	kmsclwhmpm2@gmail.com	0483-2760744	9496005800, 9496003914
11	Kozhikkode	District Drug Warehouse, Karuvannur Post Naduvannur (Via) Kozhikkode, PIN- 673614 Kozhikkode Kuttiady Highway Kerala.	ddwhkkd@gmail.com	0496-2653930	9496006400
12	Kannur	District Drug Warehouse, Harichandra Weaving Mill's compound (HWM), Near lakshmanan kada bus stop Thana Kakkad Road , Kannur-670002	kmsclwhknr@gmail.com	0497-2705046	9496006700
13	Wayanad Kalpetta	State Ware House Building, Near Fathima Hospital, Pinangode Road, Kalpetta, Wayanad -673121	kmsclwhwyd@gmail.com	0493-6202898	9496006500
14	Kasargode	District Drug Ware House, Near Old District Hospital, Kanhangad, Kasaragod-671315	kmsclwhkgd@gmail.com	0467-2206464	9496006900