



Kerala State Homoeopathic Co-Operative Pharmacy Ltd.

(sponsored by government of Kerala & aided by govt. of India)

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Website : www.homcokerala.com

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Supplier's Copy

USER REQUIREMENT SPECIFICATION

Name of the Company	:	
Contact Person	:	
Address	:	
Contact Details	:	
Department	:	Micro Biology - First Floor
Equipment and Code No.	:	HPHV Steam Sterilizer Double Door
Name of work	:	Supply, Installation, Commissioning & Qualification of cGMP model HPHV Steam Sterilizer at M/s. HOMCO -Kerala
Ref. No.	:	
Date	:	
Enclosures	:	
Quantity	:	1 No.



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STEAM STERILIZER – DOUBLE DOOR

ANNEXURE - I : BASIC DETAILS OF THE MACHINE

DESCRIPTION			
(To be specified by the supplier, if any variation)			
Scope	:	Supply, Installation, Commissioning & Qualification of Steam Sterilizer –Double Door along with connecting accessories, cables etc. at M/s. HOMCO –Kerala	
Machine	:	Steam Sterilizer-Double Door	
Model	:	*	
Type	:	*	
Capacity (Approximate)	:	324 Liters *	
Doors	:	Double sliding type *	
Chamber Size in mm (inner)	:	600 x 600 x 900mm (W x H x D) *	
Working Pressure	:	Chamber	Jacket
		2.2 Kg/cm ² *	2.2 Kg/cm ² *
Hydro Test Pressure	:	3.3 Kg/cm ² *	4.3 Kg/cm ² *
Design Temperature	:	150 °C *	150 °C *
Sterilizing Temperature:	:	Maximum 121 °C *	
Design standard	:	As per EN 285, USFDA, EU, GMP, PIC/S *	

* To be specified and confirm by the supplier as per their equipment design and requirement



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ANNEXURE – II, III : CGMP FEATURES & OPERATIONAL FEATURES

DESCRIPTION		
(To be specified by the supplier, if any variation)		
MOC		
Chamber & Sliding Doors	:	SS – 316L *
Jacket & Non-Contact Parts	:	SS – 304 *
Gasket/Seal/'O' ring	:	Food Grade *
Insulation	:	50 mm thick Rockwool *
Finish		
Chamber & Doors	:	Better than 0.8 micron Ra value *
Non-Contact Parts	:	surface finish better than 180 grit *
PRINCIPLE OF OPERATION :		
The Steam Sterilizer should use dry and saturated steam as the sterilizing medium usually at a temperature of 121°C. Since steam and air do not mix and form a homogenous mixture all Steam Sterilizers should need a mechanism to remove the air in the chamber and that, which is entrapped in the load to ensure proper penetration of steam and hence effective sterilization. For Gravity Displacement Program of non-porous loads and liquids the air removal should be by gravity. Whereas, in the Pre-Vacuum Sterilization Program the air removal should be achieved with the help of a mechanical vacuum pump. Vacuum drying should also be provided to ensure drying of the load after Sterilization. * Steam Sterilizers should be double-door for pass through operation and should be provided with handling accessories like shelves, carriages and trolleys for easy and safe loading and unloading of the product. *		

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DESCRIPTION

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All product contact parts of the pressure vessel, doors, piping, valves and all instruments should be stainless steel and comply with GMP requirements. *

The system should be controlled by PLC and should be provided with a user-friendly operator terminal. Wide ranges of options should be available for batch documentation, to comply with the recent regulatory requirements. *

The Autoclave should consist of:

PRESSURE VESSEL :-

- The Pressure vessel should consists of chamber and jacket designed in accordance with the applicable standards. *
- The pressure vessel designed should be as per ASME SEC VIII and all welding joints should be radiographed for high security. *

CHAMBER :

- The chamber should be fabricated with SS 316L with high quality inert gas argon welded. *
- All nozzles and connections should be fabricated from tubes for best hygiene and pressure security. *
- The chamber thickness should be 6mm and provided with round corners for easy cleaning and at least 2% slope for full draining of the condensate. *
- A removable screen plug should be provided in the drain lines to prevent clogging of the drain pipes and fittings. *
- A steam baffle should be provided at the top of the chamber. *
- The chamber should be provided with a safety valve, pressure switch, pressure transmitter and compound gauge (on both sides). *

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DESCRIPTION

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JACKET :

- The jacket should be made of SS 304, 4mm thick dimple plate. *
- The jacket should be maintain temperature uniformity in the sterilizing space. *
- The steam line to the jacket should be provided with an on-off valve and steam trap for condensate removal. *
- The Jacket should be fitted with a pressure switch for automatic pressure control, high-pressure safety valve and vacuum breaker to prevent creation of accidental vacuum in the chamber. *

DOORS :

- The sterilizer should be provided with two automatic sliding doors. *
- The door should be move vertically by a pneumatic cylinder. *
- The door function should be controlled automatically to ensure the safety of the operator and the equipment during the entire operation. *
- Compound gauges for gasket pressure, with door status indications should be provided on Unloading side. *
- The following door safety features should be provided for maximum operator safety. *
 - The door should have interlock to prevent simultaneous opening of both doors. *
 - It should have process-lock to prevent opening of the door during the process. *
 - It should have process-lock to prevent the opening of the non-sterile door after successful completion of the cycle. *
 - It should have door obstruction safety. *

CABINET ENCLOSURE :

- The Cabinet Enclosure should be designed to enclose the pressure vessel, piping system, electrical systems and facia panels of the unit. *

*** To be specified and confirm by the supplier as per their equipment design**

DESCRIPTION

(To be specified by the supplier, if any variation)

- SS 304 fascia panels should be cover the loading/unloading end of the Sterilizer. *



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- The Cabinet Enclosure should be provided with service doors on the sides for maintenance and cleaning. *

BIO SEAL :

- The cross-contamination seal should be provided at the clean side for double door units to separate the clean and unclean sides. *
- The seal should prevent the flow of the air from the clean area. *

VACUUM SYSTEM :

VACUUM PUMP:

- A water ring vacuum pump with mechanical seal should be provided along with the system. *
- This Vacuum pump should remove mechanical air from the chamber prior to sterilization and subsequently for post sterilization vacuum drying. *

STEAM CONDENSOR:

- Condenser should be shell and tube type and fabricated from SS 304 fit in the exhaust /vacuum line to condense the steam before entering the vacuum pump. *

VENT FILTER :

- Vent filter should be 0.2μ bacteria retentive, vacuum break filter (hydrophobic type) on the unloading side for pressure equalization after vacuum creation. *

PIPING & VALVE PACKAGE :

PIPING:

- All process piping in contact with the chamber should be fabricated from SS 316L with argon welding. *
- All connections and fittings used should be sanitary tri-clamp with silicone seals. *
- All other piping should be fabricated with argon welding and all connections and fittings should be threaded. *

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- The piping should be designed to ensure that a single point can be used as utility connection. *
- All drain lines and exhausts should be connected to a drain manifold. *
- The pipelines should also have at least 2% slope for full draining to prevent contamination. *
- All pneumatic lines should be of polyurethane with push in connectors. *

VALVES :

- The process valves in contact with the chamber should have SS 316L contact parts and tri-clamp connections. *
- All other valves should be threaded connections. *
- All automatic valves should be angle valves. *
- The valves should be actuated by instrument air controlled via solenoid valves. *

VALIDATION PORT:

- For periodic validation and testing of the system, Validation Ports with tri-clamp connections should be provided. *
- The Validation Port should have 6mm holes with special leak tight ferrules for insertion of up to 16 flexible temperature sensors for temperature mapping. *

LOADING SYSTEM :

SHELVES (4 Nos. on 2 Layers):

- Loading shelves should be fabricated from SS 316L hollow sections and should have perforation for effective steam penetration. *
- The shelves should be easily removed for easy loading and unloading. *

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Control panel :

- The PLC, instrumentation and electrical switchgear should house in a SS 304 control panel. *

Salient feature of the system are

- The control cabinet should be provided with a main isolator for the three-phase supply and a separate switch for the control supply. *
- All cabling should be flexible and routed via PVC channels mounted in the panel. *
- All cabling for measuring instruments should be shielded for minimum electro-magnetic interference. *
- Necessary relays, contactors, MCB's, etc. should also be mounted in the control panel. *
- The service and maintenance area should be provided with a lighting fixture, plug, and socket. *
- The control system should also have an inbuilt provision to connect a UPS supply to the control circuit. *

TEST AND OPERATIONS PROGRAMS :

- To ensure flexibility, accuracy and highly reliable performance and compliance to regulatory requirements the Steam Sterilizer should be provided with the following programs *

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TEMPERATURE AND PRESSURE SENSORS:

- 6 RTD Pt100 Temperature Sensors should be provided, 4 in the chamber and 2 in drain (one for controlling and other for recording) should be provided for monitoring and controlling the temperature of the system. *
- Temperature sensors should be connected to the PLC and Strip Chart Recorder. *
- For accurate control of temperature it should be controlled on the lowest point. *
- A pressure transmitter should also be provided for measuring the chamber pressure and should connect to the PLC and Strip Chart Recorder. *
- The pressure signal should have a least count of 0.002 bar. *
- All incoming utility lines should be provided with a pressure switch to generate an alarm in case of failure. *

PROCESS RECORDING :

- A Six-Channel Strip Chart Recorder for recording temperature at 5 points and pressure at 1 point should be provided as a watchdog-recording device. *
- A data printer should be provided for process recording in the control panel. *
- The printer should generate a print of critical process parameter, alarms, faults and other relevant information like: -
 - Date and time. *
 - Temperature & Pressure. *

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DESCRIPTION

(To be specified by the supplier, if any variation)

- Operator code. *
- Process status. *
- Alarms and faults. *
- F0 value. *

ALARMS :

- For ease of operation and safety of the operator all critical and non-critical alarms should be displayed on the HMI as a text message and audio signal should also be provided via an audio buzzer. *
- All alarms should be remain active until the alarm condition is resolved and the alarms are acknowledged. *

Following Alarms should be provided:-

- If chamber vacuum leak test is failed. *
- If the chamber temperature overshoots. *
- If chamber temperature falls below specified level & the timer stops counting. *
- If chamber temperature falls further below specified level & the timer resets previously counted time. *
- If chamber pressure is greater than the set value. *
- Too long time for heat up. *
- Too long time for pre vacuum. *
- Too long time for post vacuum. *
- If vacuum pump trips. *
- Door pre condition fails. *
- Chamber temperature sensor probe fail. *
- Chamber Pressure Sensor fail. *
- Power failure alarm. *
- Utility Failure Alarm. *
- Steam Generator Water Level Low. *

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DESCRIPTION

(To be specified by the supplier, if any variation)

Steam Generator (18 KW) :

- The Electric Steam Generator should produces dry and saturated Clean Steam. *
- The pressure vessel should be fabricated from SS 316L with high quality argon welding. *
- The steam generator should be suitably insulated. *
- The system should be provide with the following: -
 - Electric, water immersion heaters. *
 - Dozing pump with on off valve along with level switch for automatic water feeding. *
 - Level switch for low water protection to safe guard heaters. *
 - Pressure switches for automatic pressure control. *
 - Overpressure safety valve. *
 - Level glass for monitoring the water level. *

INDUSTRIAL PC with 21CFR PART 11 COMPLAINT SYSTEM:

- This system should based on a 15" colour touch screen Industrial PC with i5 processor, 8GB RAM, SSD 512 GB, Windows 11. *
- This should include all features according to CFR21 Part 11 such as:
 - User management *
 - Data archival *
 - Audit trails *
 - Traceability and electronic signatures *
- All defined events should be stored with the actual timestamp *
- Following data should be collected :
 - Process data *
 - All alarms *
 - Audit-trails operator actions *
 - Changes of recipe set-points *
 - User changes *
 - Statistics *
- The machine data should share with the PC-Server through Ethernet. *

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ANNEXURE - IV : ELECTRICAL DETAILS

DESCRIPTION		
(To be specified by the supplier, if any variation)		
Standard Operating Frequency	:	50 Hz
Standard Operating Voltage	:	230 / 415V*
Total power consumption	:	*
Motor Details with rpm	:	*
Gear Box Details (If any)	:	*
PLC and HMI details	:	*
VFD details (If any)	:	*
Tower lamp	:	*
Starter	:	*
Major Cabling details		
For Main supply (In client's scope)	:	
For Main drive motor	:	*
End connection details	:	MCB or Socket should be with equipment
Earthing requirement	:	Arrangement should be with system
An Isolator Circuit breaker	:	To be supplied with machine at power supply in point of appropriate capacity by vendor. *
Cable length with equipment	:	*
<i>Any other detail not mentioned above, also to be included.</i>		
<i>Client will provide & connect the required cable in to vendor's panel. From machine panel to machine and its other accessories to be supplied and connected by vendor at site.</i>		

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DESCRIPTION

(To be specified by the supplier, if any variation)

Miscellaneous:

- ❖ Wiring between Panel and the Machine should be in the Scope of Vendor. The exact measurements shall be taken by visiting the site. *
- ❖ The Incomer to the Operating Panel shall be provided by HOMCO, however any Cable Trays or SS 304 Conduits required for the same shall be provided by the Vendor. *
- ❖ Cable routing from Operating Panel to the Machine shall be done as per cGMP i.e., routing through Cable Trays outside Clean Room Areas and SS 304 Conduits inside Clean Room Areas. *
- ❖ All the Component Makes should match the Approved Makes list provided. *
- ❖ Any deviation from this should be documented and communicated to HOMCO. *
- ❖ All Calibration Certificates are to be produced during Installation of Machine, without which the Installation is deemed incomplete. All the Certificates should be Traceable to National / International Standards. *
- ❖ The Validity of Calibration shall be minimum 9 months and maximum 12 months from the date of Installation. *
- ❖ All the Signal Cables should be shielded to avoid interference. *
- ❖ Complete Earthing of Equipment. *
- ❖ Complete covering of Electrical Cables and Other Connections. *

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ANNEXURE - V : SAFETY FEATURES

DESCRIPTION
(To be specified by the supplier, if any variation)
The equipment should be provided with motor overload safety relay. *
In the event of equipment malfunction or stoppage of utilities, the unit must contain all necessary protection devices to ensure that equipment and product remain in safe condition*
Equipment settings should not get disturbed due to power failure. *
Equipment should not restart without human intervention. *
Equipment should indicate fault through audio / visual signal with details on Control panel (Failure mode detection) *
An easily accessible emergency stops to be provided on main control panel door*
Lubricant should not come in product contact. *
Wherever possible, warning symbols should be provided. *
Electrical wiring must be concealed*

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ANNEXURE - VI : UTILITY REQUIREMENT

DESCRIPTION		
(To be specified by the supplier, if any variation)		
Vacuum	:	*
Water	:	*
Cooling	:	*
Process	:	Potable water *
Steam	:	In build steam generation system
	:	*
Compressed Air	:	Ordinary *
	:	Non-Lubricated *
If any other utility required	:	--

*** To be specified and confirm by the supplier as per their equipment's design requirement with pressure and flow rate along with any valve, pipe, nozzles size required and scope of supply.**



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ANNEXURE - VII : CLEANING TECHNIQUE

DESCRIPTION		
(To be specified by the supplier, if any variation)		
Mode of machine cleaning	:	*
Use of Lubricants	:	*
All contact parts should be easily dismantled and cleanable. *		
Drain points: Vendor should specify the pipe size and location of drain points <u>if required</u> as per their system's drain requirement with pipe, nozzle size, valve etc. *		

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ANNEXURE - VIII : MECHANICAL DETAILS

DESCRIPTION		
(To be specified by the supplier, if any variation)		
Dimension (In mm)	:	*
Net Weight (In Kgs.)	:	*
Type of Packing	:	*
Case Dimension (In mm)	:	*
Gross Weight (In Kgs.)	:	*
Foundation details (If required)	:	*

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ANNEXURE - IX : LIST OF ANCILLARY / ACCESSORIES / OPTIONAL ITEMS

DESCRIPTION

(To be specified by the supplier, if any variation)

- Optional Items (If any, Vendor should provide the list with rate) *
- If any items required but not included in URS, to be mentioned and submitted with unit rate and quantity * (And it can be indicated during pre-bid meeting)
- PQ verification need to done with all cycle with 3 run test with high accurate.

Details of Bought out components to be specified.

Any other ancillary or accessories or optional items not mentioned above also to be quoted.

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ANNEXURE - X : TRAINING REQUIREMENT

- Training to all concern of M/s. HOMCO, Kerala for the Installation, commission and validation of this lab item should be provided by vendor and training record will be documented.
- Vendor shall support client in execution of all the Qualification Phases.



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ANNEXURE - XI : APPROVED MAKES

INSTRUMENTATION		STANDARD MAKES
PLC	:	Mitsubisi /Allen Bradely /Siemens *
IPC	:	Siemens / Advantech / Allen Bradely *
SCADA Software	:	Zenon / Wincc / factory talk view*
Strip Chart Recorder	:	Yokogawa / Eurotherm / Honeywell *
Temperature Sensor & Transmitter	:	Radix *
Pressure Transmitter	:	Jumo / wika / vego / honeywell *
Printer	:	Epson / Canon *
D.C. Source	:	Shavison / Schneider *
Photocell sensor	:	P & F/ Optex /Sick *
MECHANICAL		
Stainless Steel Sheet & Pipe	:	Tata / JSW *
Automatic angle Valve (Contact)	:	Forbes Marshal/Avcon *
Automatic angle Valve (Non- Contact)	:	Forbes Marshal/Avcon *
Manual Ball Valves	:	President *
Needle Valve	:	President *
Safety Valve	:	Teleflo / Fainger *
Non Return Valve	:	Modern / Alfa Laval *
Gauges	:	Forbes Marshal *

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Pressure & Vacuum Switch	:	Orion / SMC *
Level Switch	:	Mahalaxmi *
Steam Trap	:	Forbes Marshall *
Vacuum Break Filter	:	Sartorius *
Vacuum Pump	:	Newgenree *
PNEUMATIC		
Pneumatic Door Operating cylinders	:	Janatics / SMC *
Solenoid Valves For Door	:	Janatics / SMC *
Solenoid Valves For Gasket	:	Patcon / SMC *
Filter Regulator Lubricator	:	Janatics / SMC *
ELECTRICAL		
Cables	:	Finolex / Polycab *
Control Panel	:	Machinfabrik *
Limit Switches	:	Bohmen / Schneider / Honeywell *
Switch Gear, MCB, Rotary Switch	:	Siemens / Schneider *
Indication Lamps	:	Siemens / Schneider *
Relays	:	Siemens / Omron / Schneider *
❖ Any other components, not mentioned above, to be specified by the vendor. ❖ All the Component Makes should match with the Approved Makes listed above. Any deviation from this should be documented and communicated to HOMCO and Pharma Consultant.		

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ANNEXURE - XII : DOCUMENTATION

List of all Documents to be supplied along with equipment [AS APPLICABLE]

Sr. No.	Document to be supplied	Qty	Remarks
1	Design qualification	2 sets	
2	SAT/FAT procedures	2 sets	
3	Operation manual	2 sets	
4	Maintenance manual	2 sets	
5	Spare parts manual	2 sets	
6	All engineering drawings	2 sets	
7	List of instruments	2 sets	
8	Calibration certificates	2 sets	
9	Warranty / Guarantee	2 sets	
10	List of all components with referencing	2 sets	
11	Civil foundation drawings	2 sets	
12	Pre installation requirements	2 sets	
13	Installation requirements	2 sets	
14	Installation manual	2 sets	
15	Technical literature, data sheets and equipment catalogues	2 sets	
16	DQ, IQ,OQ, PQ documents.	2 sets	
17	Calibration Report of all sensors, controllers, PLC, transmitters, indicators etc.	2 sets	
18	Test Certificates of all material of construction	2 sets	
19	Test Certificates of the software used in machine control / monitoring system.	2 sets	



Kerala State Homoeopathic Co-Operative Pharmacy Ltd.

(sponsored by government of Kerala & aided by govt. of India)

Office: Pathirappally
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Pin-688 521

Phone : 0477 2258012
: 0477 2258665
Fax : 0477 2258012

Website : www.homcokerala.com

Email : homcokerala@gmail.com

ANNEXURE - XIII : TERMS AND CONDITIONS

Delivery Period	:	*
Payment Terms	:	As mentioned in tender.
Packaging and forwarding	:	By Vendor
Un-loading at site	:	By vendor /Supplier (If required, help for the arrangements of unloading can be done by client) Installation in position by the vendor under the client's supervision
Excise / Taxes /GST	:	*
Material for Trial arrangement	:	* (To be arranged by client)
Installation and Commissioning	:	By Vendor
Submission of documents and drawings		
Response to URS and submission of quotation	:	Within 1 week
Submission of detail functional design specification and schematic drawings	:	Within a week after order finalization
Submission of FAT / SAT specification	:	2 weeks before FAT
Submission of IQ AND OQ documents	:	With equipment delivery
Drawings / diagrams	:	Within a week after receiving PO
The supplier should notify customer 2 weeks in advance of the beginning of FAT		
Catalogue, Equipment drawing, List of clients and year of establishment to be submitted along with quotation.		
<i>Any other terms, not mentioned above, also to be specified.</i>		

*** To be specified and confirm by the supplier as per their equipment design**



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ANNEXURE - XIV : ABBREVIATION

1.	URS	:	User Requirement Specification.
2.	HOMCO	:	Kerala State Homeopathic Co-operative Pharmacy Ltd.
3.	DQ	:	Design Qualification
4.	IQ	:	Installation Qualification
5.	OQ	:	Operational Qualification
6.	PQ	:	Performance Qualification
7.	SS	:	Stainless Steel
8.	RHS	:	Right Hand Side
9.	MOC	:	Material of Construction
10.	KW	:	Kilo Watt
11.	HP	:	Horse Power
12.	RPM	:	Rotation Per Minute
13.	FLP	:	Flame Proof
14.	cGMP	:	Current Good Manufacturing Practices
15.	O&M	:	Operation and Maintenance
16.	GA	:	General Arrangement
17.	SLD	:	Single Line Diagram
18.	HOD	:	Head of Department
19.	QA	:	Quality Analysis
20.	MRP	:	Maximum Retail Price
21.	NMT	:	Not more than
22.	VFD	:	Variable frequency drive
23.	FAT	:	Factory Acceptance Test
24.	SAT	:	Site Acceptance Test

Any other details, not mentioned in Annexure I to XIII, to be specified in the quotation/specification by the vendor.