Kerala State Homoeopathic Co-Operative Pharmacy Ltd.

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

Office:Pathirappally
Alappuzha, India
Pin-688 521

Phone : 0477 2258012
:0477 2258665
Fax : 0477 2258012

Website : www.homcokerala.com | Email : homcokerala@gmail.com

Supplier's Copy

USER REQUIREMENT SPECIFICATION

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

HOMCO

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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 Vertical Autoclave along with connecting accessories, cables etc. at M/s. HOMCO –Kerala	
Machine	:	Vertical Autoclave	
Model	:	*	
Type	:	*	
Capacity (Approximate)	:	200 Liters *	
Doors	:	Swing door with automatic sealing *	
Working Pressure	:	**Chamber**	**Jacket**
		2.2 Kg/cm² *	2.2 Kg/cm² *
Hydro Test Pressure	:	3.3 Kg/cm² *	4.4 Kg/cm² *
Design Temperature	:	134 ºC *	134 ºC *
operating Temperature:	:	Maximum 121 ^{0}C *	

* 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 & Swing Doors	:	SS – 316L *
Jacket & Non-Contact Parts	:	SS – 304 *
Gasket/Seal/'O' ring	:	Food Grade *
Insulation	:	25 mm thick Rockwool by an over cover of SS 304 *
Finish Chamber & Doors Non-Contact Parts	: :	 Better than 0.8 micron Ra value * surface finish better that 180 grit *
Base wheel	:	Bottom should be provided with PU wheel. *

PRINCIPLE OF OPERATION :

The Vertical Autoclave is effective for Sterilization and Decontamination in a Laboratory, Research Center or Testing Facility. The system is designed to perform gravity displacement sterilization cycles and can be optionally fitted with a vacuum system to perform pre-vacuum sterilization cycles thereby offering maximum flexibility to the user. The system is controlled by a PLC and is provided with a user-friendly operator terminal. Wide ranges of options are available for batch documentation, which comply with the recent regulatory requirements. *

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

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DESCRIPTION (To be specified by the supplier, if any variation)
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. * ➢ A removable screen plug to be provided in the drain lines to prevent clogging of the drainpipes and fittings ➢ Chamber should be provided with safety valve and compound gauge.

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

DESCRIPTION (To be specified by the supplier, if any variation)
JACKET : ➢ The jacket should be made of SS 304. * ➢ The jacket should be maintain temperature uniformity in the sterilizing space. * ➢ Jacket should be provided with a steam generator , Electric water immersion heater* ➢ Dozing pump with on off valve along with level switch for automatic water feeding should be provided. ➢ Level switch for low water protection to safeguard heaters should be provided *

- Pressure switches for automatic pressure control should be provided. *

DOORS :

- The chamber should be provided with a swing door with automatic sealing.*
- The door should be fabricated from SS 316L. *
- The door should be insulated with stone wool (Rockwool) insulation held in place by an outer cover of SS 304.

Insulation :

- The sterilizer chamber should be insulated with 25-mm thick stone wool (Rockwool) *

PIPING :

- All process piping in contact with the chamber should be fabricated from SS 316L with argon welding.
- The pipelines should have a 2% slope for full draining to prevent contamination.

VALVES:

- The process valves should be contact with the chamber have SS 316L contact parts with threaded connections.
- All automatic valves should be pneumatically or electrically actuated angle valves.

VALIDATION PORTS:

- For periodic validation and testing of the system, Validation Ports with tri-clamp connections should be provided provided.
- The Validation Port with 6mm holes with special leak tight ferrules for insertion of up to 8 flexible temperature sensors for temperature mapping should be provided.

LOADING SYSTEM:

- For loading 2 Nos. of SS 316L Circular Wire Mesh baskets should be provided for easy loading and unloading accessories.

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DESCRIPTION

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Control System :

- The functioning of the Vertical Autoclave should be automatic and should be controlled by a PLC. The PLC should be operated with the help of a color, touch screen HMI (7”) with user-friendly features
- The PLC, instrumentation and electrical switchgear should house in a SS 304 control panel. *
- System should be 21 CFR compliance with data storage and PDF report storage.

Salient feature of the system are

- 3 level password protection for process security – Operator Level, Supervisor Level and Manager Level
- Ethernet port for data communication. *
- In-built Real Time Clock with date and time function.
- Battery backup for automatic restart in case of power failure.
- Facility to force all field devices via keys on the HMI is provided for manual operation or maintenance.
- F0 for individual probes.
- 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. *

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 Gravity Displacement Sterilization Program.*

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DESCRIPTION

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

TEMPERATURE AND PRESSURE SENSORS:

- For monitoring and controlling the temperature of the system one Class A RTD Pt100 Temperature Sensor should provide in the drain. *
- A pressure transmitter should also provide for measuring the chamber pressure and is connected to the PLC. The pressure signal has a least count of 0.002 bar.

PROCESS RECORDING :

- For process recording a data printer (32 column Thermal printer) should be provided in the control panel or data should be transferred through SCADA software and data need to be stored and printed.
- The printer should be generate a print of critical process parameter, alarms, faults and other relevant information like: -
- Date and time. *
- Temperature & Pressure. *
- 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 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. *
- Power failure alarm. *
- Utility Failure Alarm. *

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

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	:	*
Any other detail not mentioned above, also to be included.		
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.		

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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 **if required** 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 . PQ test should be in the scope of the supplier.** **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.

ANNEXURE - XI : APPROVED MAKES

- All the Component Makes should be a good accreted make. 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	

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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.		
Any other terms, not mentioned above, also to be specified.		

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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.