



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 : 477 2258012
:477 2258665

Website : www.homcokerala.com

Email : homcokerala@gmail.com

Supplier's Copy

USER REQUIREMENT SPECIFICATION

Name of the Company	:	
Contact Person	:	
Address	:	
Contact Details	:	
Department	:	<i>(Raw Material Store)- Ground Floor</i>
Equipment and Code No.	:	<i>SS 304 Sampling Booth (Reverse Air Flow Unit)</i>
Scope	:	<i>Supply, Installation and commission of SS 304 Sampling Booth including all aids & accessories required to install, at site of M/s. Homco -Kerala RM store at ground floor.</i>
Ref. No.	:	
Date	:	
Enclosures	:	
Qty.	:	1 No.



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Sampling booth (REVERSE AIR FLOW UNIT)

ANNEXURE - I : BASIC DETAILS OF THE MACHINE

DESCRIPTION	
(To be specified by the supplier, if any variation)	
Scope	: Supply, Installation, Commissioning & Validation of cGMP model SS 304 Sampling booth (Reverse Air flow unit) along with filters, SS table ,connecting accessories, cables etc. at M/s. HOMCO –Kerala
Machine	: Sampling booth (Reverse Air Flow Unit-Open front)
Type	: GMP *
Model	: Open fronted Containment Station (OFCS) *
Workspace (In mm)	: 1220 x 915 x 2135 mm (W x D x H) *
Safe Working Zone for Product and Operator (In mm)	: 1220 x 610 x 2135 (W x D x H) *
Overall Dimensions (In mm)	: 1350 x 1625 x 2475 (W x D x H) *
Stand Alone SS Perforated Platform (In mm)	: 600 x 500 x 800 (W x D x H) *
Air Cleanliness	: ISO Class 4.8 (ISO 14644-1:2015 (E)) *
Air Flow	: Vertically *
Room dimension	: 3.5 x 4.7 meter
False ceiling	: 2.6 meter (false ceiling thickness 50 mm)

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



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ANNEXURE - II : cGMP FEATURES

DESCRIPTION	
(To be specified by the supplier, if any variation)	
MOC	: Contact parts : SS 304 * : Gasket: Food grade * Horizontal & vertical Coving : SS 304 * Protective grill: SS 304 * Fan assembly : In generic execution *
SS sheet thickness	16 swg*
Working Area Environment	: Temperature : 22±2°C : Relative Humidity : 65±5%
Air Cleanliness	: ISO Class 4.8 (ISO 14644-1:2015 (E)) *
Air Flow	: Vertical – Re-circulatory *
Air Velocities	: 0.45 ± 0.05mps @ 6 inch below HEPA terminal *
Noise level	: Less than 75dB *
The equipment should be smooth finished without any sharp edges and crevices.	

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ANNEXURE - III : PROCESS CONTROL FEATURES

DESCRIPTION

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

Custom built direct drive type AC fan that should be statically and dynamically balanced electronically. *

Designed with custom built in scavenging arrangement that should draws particulates away from the operator and the operating environment, protecting product and personnel, as well as surrounding environment. *

The equipment should be provided with the following:

- Audio-visual alarm as a safety measures*
- Soft touch keypads*
- Digital Pressure Transmitter with display and with high and low alarm*
 - 0-25 mm to indicate differential pressure across HEPA filter with respect to ambient*
 - 0-10 mm to indicate differential pressure across Scavenging Prefilter with respect to ambient *
 - 0-10 mm to indicate differential pressure across Intermediate Prefilter with respect to ambient *
- Air sampling port at the downstream side of the scavenging Pre-filter and intermediate pre-filter*
- POA test port at the upstream side of the HEPA filter. *
- SS 304 stand-alone perforated platform on vibration isolation with lockable castor wheels*
- Covings on the inner side of the unit along the floor so as to avoid dust collection on all three sides. *

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DESCRIPTION

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

- Multifunction cGMP clean down timer. *
- Anti-drag shield for air flow directing at front side*
- Variable frequency drive for controlling the speed of the fan*
- Trim panel to cover the gap between the unit and the false ceiling*
- Fluorescent lights (in excess of 450 lux) *
- Electrical control panel*

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ANNEXURE - IV : OPERATIONAL FEATURES

DESCRIPTION	
(To be specified by the supplier, if any variation)	
Two stage multi-layer filter assembly for multi –disperse particles predominantly in the range of 5 to 20 micron. *	
Reactive Filters	
Scavenging Prefilter	: Grade : EU-5 rating* : Efficiency : 40 – 60% *
Intermediate Filter	: Grade : EU7 rating* : Efficiency : 80 – 90%*
Final Filters	
HEPA Filter	: Type : Separator-less Mini-pleat* : Grade : EU-14* : Efficiency : 99.999 % on mono-disperseMicron : : 0.3 *
<ul style="list-style-type: none"> ➤ The main HEPA filter bank configured for continuous clean air movement at workspace. * ➤ The bleed HEPA filter bank for 20% of the total air displacement, for slight negative pressure in workspace. * 	

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ANNEXURE - V : 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/Blower Details with rpm	:	*
PLC and HMI details	:	*
VFD details (If any)	:	*
Tower lamp	:	*
Starter/Socket	:	*
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>		

*** 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)

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. *

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



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ANNEXURE - VI : SAFETY FEATURES

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

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



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ANNEXURE - VI : UTILITY REQUIREMENT

DESCRIPTION	
(To be specified by the supplier, if any variation)	
Compressed Air	: Ordinary * Non-Lubricated *
Water	: Purified* Soft water*
Any other utility	: *

*** 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.**

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.	
Easy washing and cleaning facility should be available	
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 : PHYSICAL 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)	:	*

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



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

DESCRIPTION

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

Vendors should provide the following with estimate

- Recommended Spares list to be provided *
- Change parts list with estimate to be provided *
- Optional items (if any , list with estimate to be provided) *
- VFD *
- Glass side view *
- PLC based control panel *
- HMI port with controller with touch screen etc. *
- UV light with hour meter *

*Details of Bought out components to be specified. **

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

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

ANNEXURE - X : TRAINING REQUIREMENT

Training to all concern of M/s. HOMCO, Kerala for Installation, Operation, Maintenance and Cleaning of Sampling booths should be provided by vendor and training record will be documented.



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ANNEXURE - XI : DOCUMENTATION

List of all Documents to be supplied along with equipment [AS APPLICABLE]			
Sr. No.	Document to be supplied	Qty	Remarks
1	Design and operational 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	P& I process flow diagrams	2 sets	
12	Civil foundation drawings	2 sets	
13	Pre installation requirements	2 sets	
14	Installation requirements	2 sets	
15	Installation manual	2 sets	
16	Technical literature, data sheets and equipment catalogues	2 sets	
17	DQ, IQ, PQ documents.	2 sets	
18	Calibration Report of all sensors, controllers, PLC, transmitters, indicators etc.	2 sets	
19	Test Certificates of all material of construction	2 sets	
20	Test Certificates of the software used in machine control / monitoring system.	2 sets	

ANNEXURE - XII : TERMS AND CONDITIONS



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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, PQ, DQ AND OQ documents	:	With equipment delivery
Drawings / diagrams	:	With equipment delivery
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 alongwith 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 and requirement



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ANNEXURE - XIII : 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 Goods Manufacturing Practices
15.	P& ID	:	Piping and instrumentation diagram
16.	O&M	:	Operation and Maintenance
17.	GA	:	General Arrangement
18.	SLD	:	Single Line Diagram
19.	HOD	:	Head of Department
20.	QA	:	Quality Analysis
21.	MRP	:	Maximum Retail Price
22.	NMT	:	Not more than
23.	VFD	:	Variable frequency drive

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