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
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	**:**	Microbiology – First Floor
Equipment and Code No.	**:**	Dynamic Pass box
Scope	**:**	Supply, Installation and commission / Qualification of Dynamic Pass box (Wall mounted) including all aids & accessories required to install, at site of M/s. HOMCO –Kerala.
Ref. No.	**:**	
Date	**:**	
Enclosures	**:**	
Qty.	**:**	**Dynamic Pass box – 2 no's**

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ANNEXURE - I : BASIC DETAILS OF THE MACHINE

DYNAMIC PASS BOX

DESCRIPTION (To be specified by the supplier, if any variation)		
Biosafety cabinet :		
Machine	:	Double walled Dynamic Pass box
MOC	:	SS 304
1. Between Sterility Room -2 to Incubator room 2. Between Incubator room to Corridor		
Internal dimension	:	600 x 600 x 600 (W x D x H)
External dimension	:	760 x 650 x 1100 (W x D x H)
Door Opening type	:	2 way wall mounted , floor supported
Air cleanliness	:	ISO class 5
Air flow	:	Re-circulatory
Gasket	:	Food grade
UV light	:	UV light with timer need to be provided
Coving / cladding internal & external	:	SS 304 with Dynamic pass wall to wall , Dynamic pass box to external clean room panel wall
Return grill on side wall	:	SS304
Door	:	SS 304 door with tempered glass view panel and SS handles
SS sheet thickness	:	16 swg
Support stand for wall mounted dynamic pass box	:	SS 304 to 800 mm / Pass box need to be fixed in clean room PUF panel, hence we need a base support.

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Other requirements :

- LED lights
- Manual regulator for adjusting the speed of the fan
- Digital pressure monitor with high and low alarm
- Differential pressure monitoring across the HEPA filter with respect to ambient
- Electromagnetic interlocking arrangement with adjustable timer setting for door movement
- Audio visual alarm for motor blower tripping
- PAO test port at the upstream side of the HEPA filter
- Fresh air filter required.
- Return air filter required
- HEPA filter H14 with efficiency of 99.999% is required
- Direct drive AC fan with impellers.
- Complete installation is in the scope of vendor

* 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)		
SS sheet thickness		16 swg*
Working Area Environment	: :	Temperature : 22±2°C Relative Humidity : 65±5%
Air Cleanliness	:	ISO Class 5 (ISO 14644) *

The equipment should be smooth finished without any sharp edges and crevices.

PQ test of unit done as per following cycle

- Air velocity
- Filter integrity
- Particle count
- Air flow pattern test.

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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. * ❖ Warranty shall be 1 year from the date of commissioning.

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ANNEXURE - III : 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 - IV : UTILITY REQUIREMENT

DESCRIPTION (To be specified by the supplier, if any variation)		
Compressed Air	:	Ordinary * Non-Lubricated *
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.**

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ANNEXURE - V : 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.*		

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

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ANNEXURE - VI : 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 - VII : LIST OF ANCILLARY / ACCESSORIES / OPTIONAL ITEMS

DESCRIPTION (To be specified by the supplier, if any variation)
➢ Recommended Spares list to be provided * ➢ Change parts list with estimate to be provided* ➢ VFD* ➢ Glass side view* *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 - VIII : TRAINING REQUIREMENT

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

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ANNEXURE - IX : 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	

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ANNEXURE - X : TERMS AND CONDITIONS

Delivery Period	:	*
Payment Terms	:	As mentioned in tender.
Packaging and Forwarding	:	**By Vendor**
Un-loading at site and placing it in the first floor installation area	:	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 DQ ,IQ, OQ, PQ 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 along with quotation.		
Any other terms, not mentioned above, also to be specified.		

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ANNEXURE - XI : 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 XI, to be specified in the quotation/specification by the vendor.