

**Kerala State Homoeopathic Co-Operative Pharmacy Ltd.**

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

Office: Pathirappally
Alappuzha, India
Pin-688 521Phone : 477 2258012
: 477 2258665
Fax : 0477 2258012Website : www.homcokerala.comEmail : homcokerala@gmail.com**Supplier's Copy****USER REQUIREMENT SPECIFICATION**

Name of the Company	:	
Contact Person	:	
Address	:	
Contact Details	:	
Department	:	<i>Production Areas</i>
Equipment and Code No.	:	<i>SS304 Dynamic Pass Box (Floor & Wall mounted)</i>
Scope	:	<i>Supply, Installation and commission of SS304 Dynamic pass boxes (Floor & wall mounted) including all aids & accessories required to install, at site of M/s. HOMCO-Kerala for production areas</i>
Ref. No.	:	
Date	:	
Enclosures	:	
Qty.:	:	12 Nos.



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DYNAMIC PASS BOX (FLOOR & WALL MOUNTED)

ANNEXURE - I : BASIC DETAILS OF THE MACHINE

DESCRIPTION		
(To be specified by the supplier, if any variation)		
Scope	:	Supply, Installation, Commissioning & Validation of SS304 Dynamic pass boxes (Floor & wall mounted) along with connecting accessories, cables etc. at M/s. HOMCO -Kerala
Machine	:	Dynamic Pass Box
Model	:	*
Type	:	Floor Mounted
1) Between RM Day / Tube store to Ointment Manufacturing room (for material transfer) Qty.1 No. ✓ 2) Between Aseptic filling room to labeling room (for transfer of Ophthalmic filled product) Qty.1 No. 3) Between Trituration room to Granulation (for material transfer) Qty.1 No.		
Internal Dimension (In mm)	:	1000 x 1000 x 1000 (W x D x H) *
External Dimension (In mm)	:	1150 x 1075 x 1500 (W x D x H) *
Opening Type	:	2 - Way *
1) Between RM Day / Tube store to Ointment filling room (for packing material transfer) Qty.1 No. ✓ 2) Between RM Day store to compounding room (for material transfer) Qty.1 No.		
Internal Dimension (In mm)	:	750 x 750 x 750 (W x D x H) *
External Dimension (In mm)	:	915 x 825 x 1250 (W x D x H)*
Opening Type	:	2 - Way*

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

CONSULTANT : M/S. KNACK TECHNOCRATS

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DESCRIPTION	
(To be specified by the supplier, if any variation)	
Type	: Wall Mounted (floor support)
1) Between Cooling zone room to sterility room (for spare parts transfer) Qty.1 No.	
2) Between Sterility to Incubator room (for material transfer) Qty.1 No.	
3) Between Incubator to Sterility room (for material transfer) Qty.1 No.	
4) Between Assay test room to Passage (for material transfer) Qty.1 No.	
5) Between Limit test room to Passage (for material transfer) Qty.1 No.	
6) Between Lobby to Under test sample room (for material transfer) Qty.1 No.	
Internal Dimension (In mm)	: 600 x 600 x 600 (W x D x H) *
External Dimension (In mm)	: 760 x 650 x 1100 (W x D x H) *
Door opening Type	: 2 way Wall Mounted, floor supported*
1) Between passage , Media store & Media preparation room – (for material transfer) Qty.1 No.	
Internal Dimension (In mm)	: 600 x 600 x 600 (W x D x H) *
External Dimension (In mm)	: 760 x 650 x 1100 (W x D x H) *
Door opening Type	: 3 way Wall Mounted, floor supported*
<u>Basic details for all pass boxes</u>	:
Air Cleanliness	: ISO Class 5 (ISO 14644-1:1999(E)) *
Air Flow Rate	: 0.45 ± 0.05mps*
Air Flow	: Re-circulatory*

* 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	<ul style="list-style-type: none"> : All contact parts : SS 304 * : Gasket : Food grade* Coving (internal): SS 304 * Return air grill on side wall: SS 304 * Fan assembly : In generic execution* Double walled with base * SS 304 door with tempered glass view panel & SS handles*
SS sheet thickness	: 16 swg*
Support stand for wall mounted dynamic pass box	: SS 304 up to 800 mm*
Cladding	: SS 304 below pass box to cover panel opening*
Removable flange	: SS 304 to cover the hide panel cutout on both entry & exit side. *
Working Area Environment	: Temperature : $24 \pm 2^{\circ}\text{C}$
	: Relative Humidity : $65 \pm 5\%$
Noise level	: Less than 75dB *
The equipment should be smooth finished without any sharp edges and crevices.	

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

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

To be enhanced with fan execution and unique suspension mounting ensures low vibration, low noise levels. *

The equipment should be provided with the following:

- LED lights*
- Manual regulator for adjusting the speed of the fan*
- Digital Pressure Monitor with high and low alarm*
 - 0 – 25 mm to indicate differential pressure across HEPA filter with respect to ambient*
- Electro-Magnetic Interlocking arrangement with adjustable timer setting for delay in door movement*
- Audio-visual alarm for motor blower tripping*
- POA test port at the upstream side of the HEPA filter.*

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

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ANNEXURE - IV : OPERATIONAL FEATURES

DESCRIPTION	
(To be specified by the supplier, if any variation)	
Reactive Filters	
Pre filter	: Grade : EU-6 rating* : Efficiency : 60 – 85%*
HEPA Filter	: Type : Separatorless Minipleat* : Grade : EU14* : Efficiency : 99.999 %*
It should comprise:	
<ul style="list-style-type: none"> ➤ Doubled walled pass box with base – For wall mounted.* ➤ Doubled walled pass box without base – For floor mounted.* ➤ SS 304 door with tempered glass view panel and SS handles and hinges.* ➤ SS 304 support stand up to 800mm.* ➤ SS 304 cladding below the pass box so as to cover the panel openings.* ➤ Removable SS 304 flange to cover the hide, the panel cut-outs on both entry and exit side.* ➤ Re circulatory plenum.* ➤ Return air grills with inbuilt pre filters on side wall.* ➤ Coving at internal workspace.* ➤ Direct drive AC fan with impellers.* 	

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



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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****CONSULTANT : M/S. KNACK TECHNOCRATS**

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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 and requirement



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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**

ANNEXURE - VII : UTILITY REQUIREMENT

DESCRIPTION	
(To be specified by the supplier, if any variation)	
Compressed Air	: *
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 - VIII : 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**

ANNEXURE - IX : 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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(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) *

*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 - XI : TRAINING REQUIREMENT**

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

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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 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 - 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, 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 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 and requirement

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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 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 XIII, to be specified in the quotation/specification by the vendor.

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