

## Kerala State Homoeopathic Co-Operative Pharmacy Ltd.

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

Office: Pathirappally, Alappuzha, Kerala, India. Pin-688 521

Phone : 477 2258012

:477 2258665

Fax : 0477 2258012

Website : [www.homcokerala.com](http://www.homcokerala.com)

Email : [homcokerala@gmail.com](mailto:homcokerala@gmail.com)

### Supplier's Copy

## USER REQUIREMENT SPECIFICATION

<b>Name of the Company</b>	:	
<b>Contact Person</b>	:	
<b>Address</b>	:	
<b>Contact Details</b>	:	
<b>Department</b>	:	<b>QCL-First Floor &amp; Production second floor</b>
<b>Equipment and Code No.</b>	:	<b>Vacuum Leak test apparatus</b>
<b>Name of work</b>	:	<b>Supply, Installation, Commissioning &amp; Validation of cGLP model Vacuum Leak test apparatus at M/s. HOMCO –Kerala</b>
<b>Ref. No.</b>	:	
<b>Date</b>	:	
<b>Enclosures</b>	:	
<b>Quantity</b>	:	<b>2 No.</b>

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## VACUUM LEAK TEST APPARATUS

### **ANNEXURE - I : BASIC DETAILS OF THE MACHINE**

<b>DESCRIPTION</b>		
(To be specified by the supplier, if any variation)		
Scope	:	Supply, Installation, Commissioning & Validation of cGLP model Vacuum Leak test apparatus along with connecting accessories, cables etc. at M/s. HOMCO –Kerala
Model	:	*
Range	:	50 to 600 mmHg
Hold Time	:	Up to minimum of 60 minutes
Users	:	1 admin and 10 users.
Operating Environment temperature	:	15° C to 35° C *
Pressure unit setting	:	mmHg / Psi / kPa
Display	:	Touch screen with good graphical interface or soft touch Key pad.
Self-test	:	Facility to scan and check the valves, pump and sensor.
Accessories	:	Polycarbonate desiccator along with connecting tube need be provided.
MOC	:	Machine enclosure should be SS34
Interface port	:	RS 232 , LAN *
Printer	:	Instrument should be supplied with printer.
Desiccator	:	12 inches Dia

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### DESCRIPTION

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Accuracy	:	± 10 mmHg
Calibration standard	:	Required calibration standard need to be provided.

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## ANNEXURE – II & III : CGMP FEATURES AND OPERATIONAL FEATURES

### DESCRIPTION

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

**MOC**

:

\*

Finish

:

\*

The machine should consist of:

- Meets current specification of USP, IP, BP and other Pharmacopoeias. \*
- Specifically designed for use in quality process of packaging of strips, blisters & sachets.\*
- Fully micro controller based equipment\*
- Built in with a rugged oil free vacuum pump. \*
- Should cooperate with printer & computer. \*
- Report should be able to customize as per user requirement.\*
- User-friendly equipment with easy controls. \*

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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	:	*
<b>Major Cabling details</b>		
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 &amp; 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

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#### 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	:	*
Compressed Air	:	Ordinary * Non-Lubricated *
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 - 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 <b><u>if required</u></b> 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)

**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

Approved Make

:

Lab India, Electrolab, Pharmag instruments.

❖ ***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	

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## ANNEXURE - XIII : TERMS AND CONDITIONS

Delivery Period	:	*
Payment Terms	:	As mentioned in tender.
Packaging and forwarding	:	<b>By Vendor</b>
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 <b>supervision</b>
Excise / Taxes /GST	:	*
Material for Trial arrangement	:	* (To be arranged by client)
Installation and Commissioning	:	<b>By Vendor</b>
<b>Submission of documents and drawings</b>		
Response to URS and submission of quotation	:	Within 2 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>		

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