

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

Email : homcokerala@gmail.com

USER REQUIREMENT SPECIFICATION

Name of the Company	:	
Contact Person	:	
Address	:	
Contact Details	:	
Department	:	QCL- First Floor
Equipment and Code No.	:	Conductivity Meter (Digital)
Name of work	:	Supply, Installation, Commissioning & Validation of cGLP model Digital Conductivity Meterat M/s. HOMCO –Kerala
Ref. No.	:	
Date	:	
Enclosures	:	
Quantity	:	1 No.

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CONDUCTIVITY METER (Micro-Controller based)

ANNEXURE – I : BASIC DETAILS OF THE MACHINE

DESCRIPTION		
(To be specified by the supplier, if any variation)		
Scope	:	Supply, Installation, Commissioning & Validation of cGLP model microcontroller-based ConductivityMeter along with connecting accessories, cables, etc. at M/s. HOMCO – Kerala
Model	:	*
Type	:	Microcontroller based*
Complies	:	USP and DIN standards*
Conductivity Measuring Range	:	Auto-ranging from 0.01 μ S/cm to 199.9mS/cm. (Depending on the cell used 0.1/1.0/10. K)*
Resolution	:	0.01 μ S/cm to 0.1 mS*
Accuracy	:	$\pm$ 1% full scale *
Input	:	2 – Banana socket for conductivity electrode*
	:	1-ATC-PT100 / 8 pin mini-DIN *
Report Format	:	a) Calibration report*
	:	b) Report of all selected Conductivity, TDS & Salinity readings *
Calibration Point	:	5 points *

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

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DESCRIPTION		
(To be specified by the supplier, if any variation)		
Temperature		
Temperature Range	:	0 to 100°C *
Resolution	:	0.1°C *
Relative Accuracy	:	± 0.1°C*
Sensor	:	RTD Pt100 *
Display	:	20 x 2 line back-lit LCD Display*
Keyboard	:	Alphanumeric splash water-proof polyester soft keys*
Environmental Operating Conditions		
Operation	:	Indoor*
Temperature	:	Ambient to 45°C*
Relative Humidity	:	5 to 90% non-condensing*
TDS Mode		
Range	:	0.01 ppm to 100 ppt @0.5 TDS factor * up to 200 ppt @ 1.0 TDS factor *
Resolution	:	0.01 ppm; 0.1 ppm; 1 ppm; 0.01 ppt; 0.1 ppt*
Accuracy	:	±1 % *
TDS Factor	:	0.01 to 100 ppt @ 0.5 TDS * Up to 200 ppt @ 1.0 TDS factor *

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DESCRIPTION

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Electrode	:	Included, 2 cell conductivity /ATC electrode, 0.1 cell constant, SS sensor, Epoxy-Body, 1 m cable *
Power	:	Included, a 100 / 240V AC SMPS power Adapter with US/UK/EUR/Japan plug. 9V. 6W, center +ve*
Necessary standard	:	NIST traceable necessary standards for calibrating the equipment.*

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ANNEXURE – II & III

: cGMP FEATURES AND OPERATIONAL FEATURES

DESCRIPTION

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

MOC

:

*

The machine should consist of:

- It Should have an advanced microcontroller. *
- Calibration data and stored readings should be password-protected. *
- Should have User interactive software in dialogue mode for ease of operation with protection against invalid entries.*
- Conductivity and temperature should be measured simultaneously. *
- Calibration data should be authenticated with date and time stamps.*
- It Should have a calibration reminder alarm. *
- Alphanumeric entries of sample name, and identification number for authentication. *
- Input stability indicators should have reproducible results. *
- Built-in real-time clock (RTC) should have for time display and on report printout. *
- It Should have an error indication for the user to trace the problem. *
- Audible beep indication should be during valid key operation. *
- RTD for temperature sensors – 1no. *
- Electrode stand*
- Electrode conductivity cell 0.1 constant*

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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	:	*
Major Cabling details		
For Main supply (In client's scope)	:	
For the Main drive motor	:	*
End connection details	:	MCB or Socket should be with equipment
Earthing requirement	:	Arrangements should be with the system
An Isolator Circuit breaker	:	To be supplied with the machine at the power supply in point of appropriate capacity by the vendor. *
Cable length with equipment	:	*
<i>Any other detail not mentioned above is also to be included.</i>		
<i>The client will provide & connect the required cable to the vendor's panel. From machine panel to machine and its other accessories to be supplied and connected by the vendor at the site.</i>		

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DESCRIPTION

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Miscellaneous:

- ❖ Wiring between the Panel and the Machine should be in the Scope of the 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 the Operating Panel to the Machine shall be done as per cGMPi.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 the Installation of the Machine, without which the Installation is deemed incomplete. All the Certificates should be Traceable to National / International Standards. *
- ❖ The Validity of Calibration shall be a minimum of 9 months and a maximum of 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 equipments 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. *
Equipments should not restart without human intervention. *
Equipments should indicate fault through audio / visual signal with details on Control panel (Failure mode detection) *
An easily accessible emergency stop 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 confirmed 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. *		
Easy washing and cleaning facility should be available. *		
Drain points: Vendor should specify the pipe size and location of drain points <u>if required</u> as per their system's drain requirement with pipe, nozzle size, valve, etc.*		

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ANNEXURE – VIII

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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) *
- Recommended Spares along with list & quantity (Vendors should submit with tender) *
- 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)

Optional: To be quoted by the bidder with specification

- TDS & Salinity Mode*

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

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ANNEXURE – X

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TRAINING REQUIREMENT

- Training to all concerns of M/s. HOMCO, Kerala for the Installation, commissioning , and validation of this lab item should be provided by vendor and training record will be documented.
- shall support the client in the execution of all the Qualification Phases.

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ANNEXURE – XI

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APPROVED MAKES

Approved Manufactures		Horriba, Thermofisher, Metler Toledo
Stainless Steel Sheet & Pipe: Tata / Jindal	:	*
PLC: Siemens / Allen Bradely / Delta	:	*
HMI: Siemens / Allen Bradely / Delta / Exor	:	*
Cables: Finolex / Polycab	:	*
❖ <i>Any other components, not mentioned above, to be specified by the vendor.</i> ❖ <i>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.</i>		

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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	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, PQ documents.	2 sets	
17	Calibration Report of all sensors, controllers, PLC, transmitters, indicators, etc.	2 sets	
18	Test Certificates of all materials 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.