



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

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Supplier's Copy

USER REQUIREMENT SPECIFICATION

Name of the Company	:	
Contact Person	:	
Address	:	
Contact Details	:	
Department	:	QCL- First Floor & Production second floor
Equipment and Code No.	:	Digital Tablet Hardness Tester
Name of work	:	Supply, Installation, Commissioning & Qualification of cGLP model Microcontroller based digital Tablet Hardness Tester at M/s. HOMCO –Kerala
Ref. No.	:	
Date	:	
Enclosures	:	
Quantity	:	QCL – 1 nos. Production compression 1 & 2: 2 no's



Revised URS with approved make

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DIGITAL TABLET HARDNESS TESTER

ANNEXURE - I : BASIC DETAILS OF THE MACHINE

DESCRIPTION		
(To be specified by the supplier, if any variation)		
Scope	:	Supply, Installation, Commissioning & Qualification of cGLP Model Microcontroller based digital Tablet Hardness Tester with connecting accessories, cables etc. at M/s. HOMCO -Kerala
Model	:	*
Type	:	Horizontal loading, to sequentially measure Hardness & other physical parameter of the tablets. *
Measuring Principle	:	Electronic load cell with Solid State Strain Gauge*
Tablet Width / Diameter / Thickness	:	1) 0 - 45 mm* (Lab Model)
Hardness Measuring Range	:	1) Up to 400 N * (Lab Model)
Measuring Units	:	1) Kg, N (Newton) * (Lab Model) 2) N(Newton), KGF (Kilogram Force) Lbf (Low bound force) *
Max. No. of Samples / Batch	:	25 tablets * (Lab Model)
Requirement location	:	QC lab - first floor , Production - second floor (compression 1 & 2).

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



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ANNEXURE - II & III : CGMP FEATURES AND OPERATIONAL FEATURES

DESCRIPTION

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

MOC : SS 304. *

The machine should consist of:

- Unit should be a horizontal loading, mechanical strength testing machine. *
- Should be controlled by Micro-controller-based circuitry to measure physical dimensions of tablet. *
- Should have Tactile keyboard and external QWERTY keyboard / touch screen. *
- Should have high resolution LCD/LED touch display panel. *
- Memory should Store for 25 product names with their expected Boiling Point. *
- Date and time should be password protected. *
- Should have RS232 connectivity for electronic balance interface. *
- Statistical analysis should include Mean and standard deviation. *
- Should have easy validation mode for diameter and weight. *
- Memory should have capacity to store more than 50 test reports and 99 test methods. *
- **Online printer should be available with the equipment.**

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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 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>		

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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. *

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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 *
If 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 <u>if required</u> 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 Manufactures of Disintegration tester	:	Lab India, Electrolab, Veego.
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 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	:	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 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 XIII, to be specified in the quotation/specification by the vendor.