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Supplier's Copy

USER REQUIREMENT SPECIFICATION

Name of the Company	rara	ozao .
Contact Person		
Address III JaldeT Jabom 913		
Contact Details	didao	
Department of the state of the	A. pa	QCL- First Floor
Equipment and Code No.	2 (1) 2 est	Tablet Disintegration Test Apparatus
Name of work	0.00	Supply, Installation, Commissioning 8 Validation of cGLP model Tablet Disintegration Test Apparatus at M/s. HOMCO -Kerala
Ref. No.		Timer Maximura Interval Serting Temperature Range
Date	0.±	Temperature Resolution
Enclosures	Taci	Display
Quantity See this bortlem steet 20 and		2 Nos.



CONSULTANT: M/S. KNACK TECHNOCRATS

42, AVINASH, 7 BUNGALOWS, J.P. ROAD, ANDHERI (W), MUMBAI – 400 05 TEL. NO.: 022-2636 1629, Email: infoknack@gmail.com

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TABLET DISINTEGRATION TEST APPARATUS

BASIC DETAILS OF THE MACHINE

	DES	CRIPTION		
(To be specifi	ed by th	ne supplier, if any variation)		
Scope		Supply, Installation, Commissioning & Validation of cGLP model Tablet Disintegration Test Apparatus along with connecting accessories cables etc. at M/s. HOMCO –Kerala		
Model		*		
Type 10017 family	15.9	As per USP, IP and BP standard *		
Number of Beakers		2 (1000ml) glass beakers *		
Number of Baskets		2 each containing 6 glass tubes and 6 guided discs, designed as per USP, IP and BP standards*		
Number of Cycles	edalişiy	30 cycles/min. (±1 cycle) *		
Stroke Length	512). -	55 <u>+</u> 2mm*		
Timer Maximum Interval Setting		Up to 4 hrs.*		
Temperature Range		37 ±2 °C *		
Temperature Resolution		± 0.1°C *		
Display	-	LCD Display *		
Input		Tactile keypad + QWERTY /PC keyboard for easy data entry*		
Memory Storage		To store 95 tests method and 48 test reports.		

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



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ANNEXURE - II & III : CGMP AND OPERATIONAL FEATURES

DESCRIPTION

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

MOC

The machine should consist of:

- Unit should be equipped with individual stepper motors to drive baskets up/down independently as well as for parking facility. *
- While one basket is in operation, the other basket should be deactivated. *
- Two different batch products should be analyzed simultaneously. *
- Basket's motor should be validated independently. *
- Unit should support test for enteric-coated tables or delayed release tablets. *
- Should Select of date and product in off line printing. *
- Power failure indication program should be incorporated. *
- Date and time should be password protected. *
- Should be Dual timer. *
- Software as well as hardware protection should be incorporated for over temperature heater. *
- Should be Compatible with DOT Matrix printer *

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

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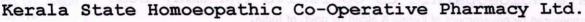
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ANNEXURE - IV : ELECTRICAL DETAILS

		RIPTION
(To be specifie	d by th	e supplier, if any variation)
Standard Operating Frequency	ent ed	50 Hz 2 ed eT)
Standard Operating Voltage		230 / 415V*
Total power consumption	:	The machine should consist of: **
Motor Details with rpm	b viteni	> Unit should be equipped w∗
Gear Box Details (If any)	KING I B	independently as well as for us
PLC and HMI details	io ana ,	While one basket Is in operation ** ** ** ** ** ** ** ** **
VFD details (If any)		Two different batch products at
Tower lamp		& Basket's motor should be valid
Starter	:	* Auft suoma subbott test for en
Major Cabling details		Should Select Or dotte and product
For Main supply (In client's scope)		Power failure malcabon program
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	A JEM I	To be supplied with machine at power supply in point of appropriate capacity by vendor. *
Cable length with equipment	ndane.	* To be specified and confirm by the

Any other detail not mentioned above, also to be included.

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.

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



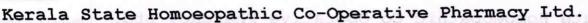
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DESCRIPTION

(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



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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) *

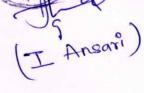
An easily accessible emergency stops to be provided on main control panel door. *

Lubricant should not come in product contact. *

Wherever possible, warning symbols should be provided. *

Electrical wiring must be concealed *

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



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ANNEXURE - VI

UTILITY REQUIREMENT

(nodens (To be	e specifie	DESCRIPTION ed by the supplier, if any variation)
Vacuum		Mode of machine cleaning
	d ceanal	Ordinary * Non-Lubricated * princeto bus guidase year
Any other utility	1:	Drain points: Vendor-should specify the pipe a

* 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

(noitsha (To be spe		SCRIPTION the supplier, if any variation)
Mode of machine cleaning		* secucia
Use of Lubricants	•	*
All contact parts should be easily	dismantle	ed and cleanable. *
Easy washing and cleaning facilit	y should b	be available. *
Drain points: Vendor should spe per their system's drain requiren		ipe size and location of drain points if required pipe, nozzle size, valve etc.*

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









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ANNEXURE - VIII

MECHANICAL DETAILS

DESCRIPTION (To be specified by the supplier, if any variation)					
Dimension (In mm)	idas emp	(To be specified by			
Net Weight (In Kgs.)	E kong	Optional Items (If any, Vendor should *			
Type of Packing	THE MAP ES	Recommended Spares along with list			
Case Dimension (In mm)		B any items required but not included * Cate and quantity * (And it can be income.)			
Gross Weight (In Kgs.)	a diiw	* Optional: To be quoted by the pidder			
Foundation details (If required)		* TDS & Sallouty Mode*			

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

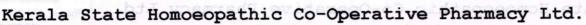


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ANNEXURE - IX : LIST OF ANCILLARY / ACCESSORIES / OPTIONAL ITEMS

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.

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









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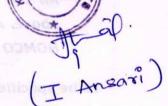
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ANNEXURE - X : TRAINING REQUIREMENT

- Training to all concern 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 client in execution of all the Qualification Phases.



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ANNEXURE - XI : APPROVED MAKES

Stainless Steel Sheet & Pipe: Tata / Jindal	:	Training to all congr
PLC: Siemens / Allen Bradely / Delta	:	documented.
HMI: Siemens / Allen Bradely / Delta / Exor	d	d. A. shall support client in
Cables: Finolex / Polycab	:	*

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









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ANNEXURE - XII

DOCUMENTATION

Sr. No.	Document to be supplied As mentioned in tender.	Qty	Remarks	
1	Design and operational qualification	2 sets	Packaging an	
2	SAT/FAT procedures and yell	2 sets	Un-loading at	
3	Operation manual	2 sets		
4	Maintenance manual	2 sets		
5	Spare parts manual	2 sets		
6	All engineering drawings	2 sets	Excise / Taxe	
7	List of instruments ad oT) *	2 sets	Material for	
8	Calibration certificates V va	2 sets	a netalistani	
9	Warranty / Guarantee egniwarb bna einen	2 sets	Submission	
10	List of all components with referencing	2 sets	Response to	
11	Civil foundation drawings	2 sets		
12	Pre installation requirements	2 sets	HODESHIESE	
13	Installation requirements	2 sets		
14,9	Installation manual	2 sets	2 Zielweig .	
15	Technical literature, data sheets and equipment catalogues	2 sets		
16	DQ, IQ, PQ documents.	2 sets	Legisla March 25, 14	
17	Calibration Report of all sensors, controllers, PLC, transmitters, indicators etc.	2 sets	Catalogue, in with quotatio	
18	Test Certificates of all material of construction	2 sets	Any other ter	
19	Test Certificates of the software used in machine control / monitoring system.	2 sets	* To be specif	

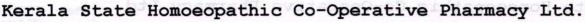


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ANNEXURE - XIII : TERMS AND CONDITIONS

Delivery Period	he s	Sr. Document to	
Payment Terms	:	As mentioned in tender.	
Packaging and forwarding	013.60	By Vendor 1940 bns agreed 1	
Un-loading at site	:	By vendor /Supplier ARVIAGE S	
		(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	:	o All engineering drawings *	
Material for Trial arrangement	:	* (To be arranged by client)	
Installation and Commissioning	:	By Vendorition certification 8	
Submission of documents and drawings		9 Warranty / Guarantee	
Response to URS and submission of quotation	1919)	Within 1 week not lis to tall of	
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	1:	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.	номсо		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.



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