

(sponsored by government of Kerala & aided by govt. of India) Office: Pathirappally, Alappuzha, Kerala, India. Pin-688 521 Phone: 477 2258012 :477 2258665

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Supplier's Copy

USER REQUIREMENT SPECIFICATION

Name of the Company	:	
		DESCRI (To be specified by the s
Address aninolasimmoo molfalletan model Digital Ultrasonic	oGLF	guz () Sup
Contact Details	icato is et	(se)
Department	The second secon	QCL-FIRST FLOOR
Equipment and Code No.	₹ .	Digital Ultrasonic Cleaner (Sonicator)
Name of work	:	Supply, Installation, Commissioning & Validation of cGLP model Digital Ultrasonic Cleaner (Sonicator) at M/s. HOMCO –Kerala
Ref. No.	i.i.elel	Display Dig
Date	:	Olej i jednemy (mednemy)
Enclosures	36 7	* Fo be specified and confirm by the suppli-
Quantity		01 No.



CONSULTANT: M/S. KNACK TECHNOCRATS

42, AVINASH, 7 BUNGALOWS, J.P. ROAD, ANDHERI (W), MUMBAI - 400 053

TEL. NO.: 022-2636 1629 / 2631 4010, Email: infoknack@gmail.com





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DIGITAL ULTRASONIC CLEANER (SONICATOR)

ANNEXURE - I BASIC DETAILS OF THE MACHINE

(To be spe	-	the supplier, if any variation)
Scope		Supply, Installation, Commissioning & Validation of cGLP model Digital Ultrasonic Cleaner (Sonicator) along with connecting accessories, cables etc. at M/s. HOMCO –Kerala
Model		*
Tank Capacity	#	3.0 L TO 4.0 L *
Tank Size (mm)		300 x 150 x 100 *
Ultrasonic Power		100 Watt *
Time Setting	*	1-15 minutes *
Heating Temperature		0-60°C *
Display		Digital LED *
Frequency	*	40 kHz *

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

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ANNEXURE - II & III : CGMP AND OPERATIONAL FEATURES

(To be	zn ve i		Standard Operating Frequency any variation)
мос	:		Standard Operating Voltage
Lid Material		SS 204 *	Total power construction
Inner Tank Material	-6. •	SS 304 *	PLC and HMI details
Outer Tank Material		SS 304 *	(one W) Shakeb CW/
Finish		*	(Aug II) supportation

The equipment should consist of:

- Bench top ultrasonic Cleaner for laboratory use*
- SS Lid for low noise. *
- Digital LED display should be provided. *
- Should have intense cleaning action, self-tuning, simple to operate. *
- Should have SMPS power source to ensure amazing > 90° C efficiency compared to modula enidosem disable beliegue ad other forms of conventional linear source.
- Water drainage valve should be provided. *

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

rovide & connect the required cable in to yendor's panel. From machine pain it's other accessories to be supplied and connected by vendor at site. cified and confirm by the supplier as per their equipment design





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ANNEXURE - IV : ELECTRICAL DETAILS

(To be specifi		cription he supplier, if any variation)
Standard Operating Frequency	19138	50 Hz
Standard Operating Voltage		230 / 415V*
Total power consumption		*
Motor Details with rpm		*
PLC and HMI details		*
VFD details (If any)		* Paris Marcellai
Starter		*
Major Cabling details		The equipment should be a second
For Main supply (In client's scope)		* anion wat to ki 1.22
For Main drive motor		* This and blunds velocib GR Lietleid
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	• , Jeen	

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

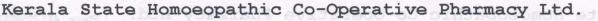


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DESCRIPTION

(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) * book between the

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

(notished year) (To be spec		DESCRIPTION ed by the supplier, if any variation)
Vacuum	:	Use of Lubricants : *
Compressed Air	sel	Ordinary * mails visee as bluoris shart samo IIA
		Non-Lubricated * April 19 Apri
If any other utility	ą e	* To be specified and confirm by the supplier

* 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. ECM







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ANNEXURE - VII

CLEANING TECHNIQUE

	DE	SCRIPTION	
(To be sp	ecified by	the supplier, if any variation	n)
Mode of machine cleaning	supplifier,	ent vo beinbege ed oi)	
Use of Lubricants	. :	*	Vacuum

All contact parts should be easily dismantled and cleanable. *

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

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ANNEXURE - VIII : MECHANICAL DETAILS

(To be specifie	No. of Contract of	CRIPTION he supplier, if any variation)
Dimension (In mm)		*
Net Weight (In Kgs.)		ı ≛ ig
Type of Packing (notished yes 1) Tell	101-2 9	(To be specified by*
Case Dimension (In mm) W 32 add 1		> Optional Items (If any, Vendor shoul*
Gross Weight (In Kgs.)		> If any items required but not include:
Foundation details (If required)	:	rate and quantity * (And it can be indic







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ANNEXURE - IX : LIST OF ANCILLARY / ACCESSORIES

OPTIONAL ITEMS

DESCRIPTION

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

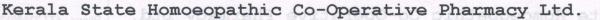
- Optional Items (If any, Vendor should provide the list with rate) * notational description.
- If any items required but not included in URS, to be mentioned and submitted with unit rate and quantity * (And it can be indicated during pre-bid meeting)

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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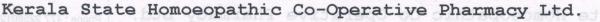
ANNEXURE - XI : APPROVED MAKES

Stainless Steel Sheet & Pipe: Tata / Jindal	193	validation of this lab
PLC: Siemens / Allen Bradely / Delta	i	decumented. *
HMI: Siemens / Allen Bradely / Delta / Exor	1:	> Vendor shall support *.
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.







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ANNEXURE - XII

DOCUMENTATION

Sr. No.	Document to be supplied	Qty	Remarks
1	Design and operational qualification	2 sets	ing griggstag
2	SAT/FAT procedures to be very very	2 sets	ta palbaol-at
e31ep	Operation manual besiuper 11)	2 sets	
4 ^(th)	Maintenance manual ibsolut to	2 sets	
5	Spare parts manual	2 sets	
6	All engineering drawings	2 sets	
7	List of instruments	2 sets	Waterlaitfor
8	Calibration certificates nev ya	2 sets	is consistant
9	Warranty / Guarantee epniws/b bns ein	2 sets	e moleaimilu2
10	List of all components with referencing offstoup to notes and	2 sets	Response to U
11	Civil foundation drawings (1974)	2 sets	o noissimdud
12	Pre installation requirements	2 sets	Tantes Toeus
13	Installation requirements	2 sets	0.01012010101440
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.		Catalogue, Equalogue, along with quo
18	Test Certificates of all material of construction od benoting	2 sets	Any other ratif
19	Test Certificates of the software used in machine control / monitoring system.	2 sets	TECHA



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ANNEXURE - XIII : **TERMS AND CONDITIONS**

Delivery Period boile	iluė s	Sr. Document to b
Payment Terms	:	As mentioned in tender.
Packaging and forwarding		By Vendor de la
Un-loading at site	:	By vendor /Supplier AANAA
		(If required, help for the arrangements
		of unloading can be done by client)
2 sets *		Installation in position by the vendor under the client's supervision
Excise / Taxes /GST		* All engineering drawings
Material for Trial arrangement		* (To be arranged by client)
Installation and Commissioning		By Vendor Solida en alle Solida en a
Submission of documents and drawings		9 Warranty / Guarantee
Response to URS and submission of quotation	entions	Within 1 week amou ile lo leld 01
Submission of detail functional design	:	Within a week after order finalization
specification and schematic drawings		12 Pre installation requirements
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. The local section of the local se

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



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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	# 1	Right Hand Side
9.	MOC	# 1	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		Singl 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.	SÁT		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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