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Supplier's Copy

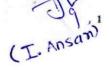
USER REQUIREMENT SPECIFICATION

Name of the Company :	19930
Contact Person	
Address IoR lechanical RolessAddress	
Contact Details	
Department :	Pari and the second of the second of the
Equipment and Code No. :	Mechanical Rotary Shaker (Digital)
: The discs of Staint Arow to ameN	Validation of cGLP model Mechanical Rotar
Robary Knob *	Speed Controller :
to 60 minutes *	Time Range :
Date * Isroid	Display
*sH 02 V0SC 2A	Power - 19won
Enclosures equiparient reques milit	* To be specified and confirmed by the sup
Quantity :	1 No.



CONSULTANT: M/S. KNACK TECHNOCRATS

42, AVINASH, 7 BUNGALOWS, J.P. ROAD, ANDHERI (W), MUMBAI – 400 053 TEL. NO.: 022-2636 1629, Email: infoknack@gmail.com



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MECHANICAL ROTARY SHAKER (DIGITAL)

ANNEXURE - I : BASIC DETAILS OF THE MACHINE

	DES	CRIPTION	
(To be specif	fied by th	e supplier, if any variation)	
Scope		Supply, Installation, Commissioning & Validation of cGLP model Mechanical Rotary Shaker Digital Apparatus along with connecting accessories cables etc. at M/s. HOMCO –Kerala	
Model		*	
Type YooF tasi		Department **	
Platform Size		25 x 25 cm *	
Flask Capacity		250 ml x 9 *	
Platform 2 moitalistent	elegu :	Rubber discs or Stainless steel clamps *	
Speed range		00 to 250 RPM *	
Speed Controller	•	Rotary Knob *	
Time Range		0 to 60 minutes *	
Display		Digital *	
Power		AC 220V 50 Hz*	

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



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ANNEXURE - II & III : CGMP AND OPERATIONAL FEATURES

	(holluinev vno hi it		DESCRIPTION	
			ed by the supplier, if	any variation)
мос	Housing	313	SS *	Standard Operating Freque
	Construction	1	MS *	Serior Supported premuse
Finish		:	Powder Coated *	total power consumption

The machine should consist of:

- > The shaking function should be a rotary shaker. *
- Should have adjustable shaking speed and range. *
- The timer function should be for maximum flexibility. *
- It should be easy to clean and maintain large mounting surfaces with a large load capacity. *
- The shaking motion should be set with a variable speed controller knob. *
- ➤ It should have user-friendly operating and safety features for reliable shaking of Lab glassware. *
- It should be a low-energy, safe, stable, and noiseless apparatus. *

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



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Kerala State Homoeopathic Co-Operative Pharmacy Ltd.

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ANNEXURE - IV : ELECTRICAL DETAILS

	DESC	RIPTION
(To be specified	by the	e 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	:	* nouved addictable over blund?
VFD details (If any)	:	* rol not blueda politanti semit mili
Tower lamp	i de la constante de la consta	* a bac asels of yese oil blundadi
Starter	•	* whene
Major Cabling details		a od blyoda goldosu pableda edi?
For Main supply (In client's scope)	ı	e ou matric trongen primarie on t
For Main drive motor	•	*
End connection details	•	MCB or Socket should be with equipment
Earthing requirement	idens •	Arrangement should be with system
An Isolator Circuit breaker	W2 51	To be supplied with machine at power supply in point of appropriate capacity by vendor. *
Cable length with equipment	:	*

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 confirmed 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 confirmed 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*





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ANNEXURE - VI : UT

UTILITY REQUIREMENT

(To be specified by the supplier, if any variation)				
Vacuum	:	Use of Lubricants :		
Compressed Air		Ordinary * Non-Lubricated *		
If any other utility a manifest and an	7:0	* To be specified and confirmed by the su-		

* 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

(To be specif		SCRIPTION the supplier, if any variation)
Mode of machine cleaning	ne sn	(To be specified */
Use of Lubricants		Vactium

All contact parts should be easily dismantled and cleanable. *

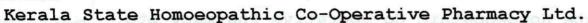
Drain points: Vendor should specify the pipe size and location of drain points **if required** as per their system's drain requirement with pipe, nozzle size, valve etc.*











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ANNEXURE - VIII

MECHANICAL DETAILS

(To be specified by the supplier, if any variation)				
Dimension (In mm) : *				
Net Weight (In Kgs.)		*		
Type of Packing	2 9/3	(To be specified by		
Case Dimension (In mm)	rong b	- Optional Nems (If any, Vendor share		
Gross Weight (In Kgs.)	J. Ali b	If any items required but not include real grandles & Mark & and Start		
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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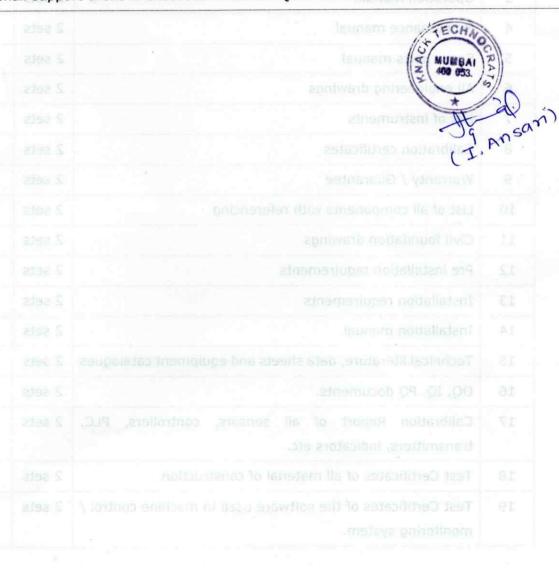
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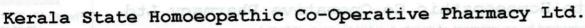
TRAINING REQUIREMENT ANNEXURE - X :

- 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

DOCUMENTATION

Sr. No.	Document to be supplied		Remarks	
HV.	Design and operational qualification	2 sets	> Training to	
2	SAT/FAT procedures	2 sets	of this lab	
3	Operation manual desilification of all the Qualification manual desirable properties of the properties	2 sets	 Vendor sh 	
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 - XII 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 alongwith quotation.

Any other terms, not mentioned above, also to be specified.

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



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ANNEXURE - XIII : ABBREVIATION

1.	URS	:	User Requirement Specification.
2.	номсо	:	Kerala State Homeopathic Co-operative Pharmacy Ltd
3.	DQ		Design Qualification
4.	IQ	1:1	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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USER REQUIREMENT SPECIFICATION

Name of the Company	1.26	ANNEXURE - 1 BASIC
		osao
Address	Supp	(To be specified by the Scope
Contact Details	oto V	
CO - Kerala Cubles etc.		QCL LAB – First Floor
Equipment and Code No.	*1	Digital Water bath
Name of work	3.5	Supply, Installation, Commissioning & Validation of cGLP model Digital Rectangular Water Bath at M/s. HOMCO –Kerala
Ref. No.	ingia.	Temperature controller cum
Date *V0ECU16W	1001	Insurersion Heater Rating ;
Enclosures emqippe riedt reu s	5 : 9i	* To be specified and confirm by the supp
Quantity		1 No.



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WATERBATH RECTANGULAR (DIGITAL) - DOUBLE WALLED (6 HOLES)

ANNEXURE - I : BASIC DETAILS OF THE MACHINE

(To be specif		cription ne supplier, if any variation)
Scope	e: QCL LA	Supply, Installation, Commissioning & Validation of cGLP model microprocessor based Rectangular Water bath Double Walled 6 holes along with connecting accessories, cables etc. at M/s. HOMCO –Kerala
Model		*
Inner Size		14" x 10" x 4" * *
No. of Holes	yltate2	6 holes* Anow to ems/
Hole Size		3.5" DIA. *
Temperature Range		From ambient to 100°C**
Temperature controller cum indicator	:	Digital *
Immersion Heater Rating	1	1000 Watt/230V*

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





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ANNEXURE - II, III : CGMP & OPERATIONAL FEATURES

		DESCRIPTION				
(To be specified by the supplier, if any variation)						
мос	3VE 3VV	SS 304* egatiov politage brabhati				
Finish		Mirror finish. *				

The equipment should consist of:

- Design should be double walled in construction. *
- Gap between the walls should be filled with high density insulation glass wool to minimize the heat loss. *
- Lid should be provided with holes of 3" dia. and SS rings. *
- Unit should be with Digital Temperature Controller cum Indictor with a suitable sensor
- Immersion heater should be provided. *









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ANNEXURE - IV : ELECTRICAL DETAILS

(To be specified by the supplier, if any variation)					
Standard Operating Frequency		50 Hz			
Standard Operating Voltage	es de	230 / 415V*			
Total power consumption	tell ion	Finish			
Motor Details with rpm	:	* The equipment should consist of:			
Gear Box Details (If any)	ntenio	* Design should be double walled in			
PLC and HMI details	# h h h h	* Gap between the walls should be in			
VFD details (If any)		the heat loss. • *			
Tower lamp again 22 bus .s	t "E to	* Lid should be provided with ho*			
Starter diw rotifed mus religions	pulsa:	✓ Unit should be with Digital Ter*i			
Major Cabling details					
For Main supply (In client's scope)	ded.				
For Main drive motor		* To be specified and confirm by the s			
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	:	*			

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. *







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ANNEXURE - V : SAFETY FEATURES

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(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. * should be applied to be a possible to be a

Wherever possible, warning symbols should be provided. * diagram and a 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		Made of machine deaning : *			
Compressed Air	nesto b	Ordinary *			
*	oldstie.	Non-Lubricated * prince but painted year			
Water	:	Purified*			
r their equipment design		WFI*			
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

(notified (To be spe	SCRIPTION the supplier, if any	variation)
Mode of machine cleaning	* 4	Vacuum -
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 **if required** as per their system's drain requirement with pipe, nozzle size, valve etc.*







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ANNEXURE - VIII

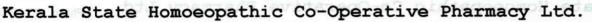
MECHANICAL DETAILS

(To be specif		SCRIPTION the supplier, if any variation)
Dimension (In mm)	dis sui	(To be specified b)
Net Weight (In Kgs.)	DEFENO.E	S Optional Items (if any, Vendor should
Type of Packing	TELID E	Kecommended Spares elong with list ** ** ** ** ** ** ** ** **
Case Dimension (In mm)	ad in i	* 15 any items required but not include: * Trails and mainthy * (And it can be use
Gross Weight (In Kgs.)	a liting	* Cotional: To be quoted by the bidder
Foundation details (If required)		* *ahoM ottalis2 & 201









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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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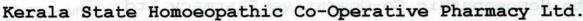
ANNEXURE - X TRAINING REQUIREMENT

- > 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	:	E Training to all conce
PLC: Siemens / Allen Bradely / Delta	:	documented. *
HMI: Siemens / Allen Bradely / Delta / Exor	e <u>i</u>	* shall support chent
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 (As mentioned in tender.	Qty	Remarks
1	Design and operational qualification	2 sets	Packseing an
2	SAT/FAT procedures nev v8	2 sets	ta enthad-rit
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 ad oT) * : thether	2 sets	i mi IshadaM
8	Calibration certificates V viii principal	2 sets	s nonstatant
9	Warranty / Guarantee applicable bus stress	2 sets	Submission
10	List of all components with referencing	2 sets	Response to
11	Civil foundation drawings	2 sets	Submission e
12	Pre installation requirements	2 sets	AUGGERUNGS
13	Installation requirements	2 sets	
14	Installation manual	2 sets	5.1.281(100)(A
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	Catalogue, E
18	Test Certificates of all material of construction	2 sets	Any other to
19	Test Certificates of the software used in machine control / monitoring system.	2 sets	* To be speci



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Email: homcokerala@gmail.com

ANNEXURE - XIII : TERMS AND CONDITIONS

Delivery Period	a vid	Sr. Document to
Payment Terms	1	As mentioned in tender.
Packaging and forwarding	00,00	By Vendor
Un-loading at site		By vendor /Supplier ANNAC 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	:	* scurwern bursauldua IV 9
Material for Trial arrangement	:	* (To be arranged by client)
Installation and Commissioning	:	By Vendoritheo heltstidiko 8
Submission of documents and drawings		9 Warranty / Guarantee
Response to URS and submission of quotation	nsiet	Within 1 week not list to real of
Submission of detail functional design specification and schematic drawings	i	Within a week after order finalization
Submission of FAT / SAT specification	1:	2 weeks before FAT
Submission of IQ AND OQ documents	1:	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.

* 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	- I	Performance Qualification
7.	SS		Stainless Steel
8.	RHS		Right Hand Side
9.	MOC		Material of Construction
10.	KW	:	Kilo Watt
11.	НР	:	Horse Power
12.	RPM	1:1	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	- I :	Quality Analysis
20.	MRP		Maximum Retail Price
21.	NMT		Not more than
22.	VFD	:	Variable frequency drive
23	FAT	:	Factory Acceptance Test
24	SAT	- 1	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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Supplier's Copy

USER REQUIREMENT SPECIFICATION

Name of the Company		
Contact Person	12 4	to be specified by the
Address Address Address	19	Scope
Contact Details		
Department	wit	QCL- First Floor
Equipment and Code No.	the sop sop	Digital Automatic Bulk & Tap Density Test Apparatus
Name of work	ded noo	Supply, Installation, Commissioning 8 Validation of cGLP model Digital Automatic Bulk & Tap Density Test Apparatus at M/s HOMCO –Kerala
* IF - 920 Ø T -	USU 	Test Method (
Date * 1010M 1999	912	Drive
Enclosures		3 2 - 980
Enclosures	1.4	Tap Height
Quantity * xoldds suniM\sqaT	300	1 No.



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DIGITAL AUTOMATIC BULK & TAP DENSITY TEST

ANNEXURE

(To be specified by the supplier, if any variation)					
Scope		Supply, Installation, Commissioning & Validation of cGLP model Digital Automatic Bulk and Tap Density Test Apparatus along with connecting accessories, cables etc. at M/s. HOMCO –Kerala			
Model		*			
tel Automatic Bulk & Tap Den aratus piy, Installation, Commissi dation of cGLP model Digital k & Tap Density Test Apparatu		This item should be used to determine the bulk the tapped density of powder samples by tappin the cylinder under specific conditions and can bused for granules, flakes, pellets etc. It should calculate the percentage difference between tapped volumes, Tapped density compressibility index and Housner rational automatically *			
Test Method		USP - I & USP - II *			
Tapping Range		1 - 9999 Taps *			
Drive		Stepper Motor *			
USP - I					
Tap Height		14 mm ± 2 mm*			
Tapping Rate	l. i	300 Taps/Minute approx.*			

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



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Data should be safe by Password protection

HOTTON	JER	CRIPTION
(To be specified	by t	ne supplier, if any variation)
USP - II	:	* 50M
Tap Height	•	3 mm ± 0.3 mm*
Tapping Rate	•	250 Taps/Minute approx.*
Display	* .J	20 x 4 lines, wide angle, alphanumeric backlit LCD*
Keyboard	:	4 x 4 Matrix Feather Touch Keyboard*
Printer show research ablug of as oa	зари	Parallel Port Printer Interface for Dot Matrix Printer*
Validation	*	Built-in validation facility*

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



Validated Measuring Cylinder 250 hilf *

Holder for 250ml cylinder. *



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ANNEXURE - II & III : CGMP AND OPERATIONAL FEATURES

DESCRIPTION

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

MOC

The unit should consist of:

- Advanced Microcontroller.
- Should Support USP 1 & USP II. *
- Should have provision to hold two cylinders *
- Should have alphanumeric display and user-friendly feather touch keypad. *
- Messages Should be displayed promptly so as to guide the user while conducting test. *
- Should display updated test status. *
- Data should be safe by Password protection *
- Non-volatile memory for storage of 24 test method. *
 - Should calculate bulk density, tapped density, compressibility index and Hausner ratio. *
 - Rotating and tapping action of the cylinders should be simultaneous. *
 - Printout should be as per GLP requirements. *
 - Should Compliant with USP specifications. *

Standard Accessories:

The unit should supply with following accessories

- Validated Measuring Cylinder 250 ml. *
- Validated Measuring Cylinder 100 ml. *
- Holder for 250ml cylinder. *
- Holder for 250ml cylinder. *

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



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ANNEXURE - IV : ELECTRICAL DETAILS

(To be specified		CRIPTION
Standard Operating Frequency	by th	50 Hz
Standard Operating Voltage	:	230 / 415V*
Total power consumption	:	*
Motor Details with rpm	1.906	Capic rough con Operating Travs out
Gear Box Details (If any)	:	Clean Room Areas. *
PLC and HMI details	ib3##	All the Component Hakes shou*s
VFD details (If any)	Lione 5	Any deviation from this should*
Tower lamp rodslintent prihub beautin	4.30	* All Calibration Certificates are *
Starter Starter	nean	Which the Installation is deening
Major Cabling details		Lite the months of Continues of the
For Main supply (In client's scope)		the date of Installation. *
For Main drive motor, and blove of I	at el	Ail the Signal Cables should be sn
End connection details	19	MCB or Socket should be with equipment
Earthing requirement	25:41	Arrangement should be with system
An Isolator Circuit breaker	gua	To be supplied with machine at power supply in point of appropriate capacity by vendor. *
Cable length with equipment		*

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 confirmed 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.

ecified and confirmed 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 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

(To be spec	cifie	DESCRIPTION ed by the supplier, if any variation)
Vacuum satety relay.		The equipment should be provided with motor*o
Compressed Air		Ordinary * Upe 16th ensure of environ devices to ensure yesessary
power fallure. *	60)	Non-Lubricated * non-bluoris agnistes memqlupd
Raw material		Equipment should not restart without human int
sual signal with details on Contro	100	Equipment should indicate fault through audio
Any other utility		(Fallure mode detection) * *
s and long london alternation		An easily accessible entergency stop to be provid

* 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

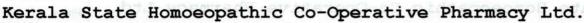
CLEANING TECHNIQUE

(To be spe		the supplier,	if any variation)
Mode of machine cleaning	19.1	*	Olmensión (In mm)
Use of Lubricants	:	*	Net Weight (In Kgs.)
All contact parts should be easily	dismantle	ed and clean	* . Type of Factong
Drain points: Vendor should spe per their system's drain requiren			location of drain points if required as size, valve etc.*









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ANNEXURE - VIII : MECHANICAL DETAILS

(nodshe) (To be specifie		CRIPTION TO SUPPLIE	ON er, if any variation)
Dimension (In mm)	1	*	
Net Weight (In Kgs.)	*:	*	Use of Lubricants
Type of Packing	nis (ver	*Insib	. All contact parts should be easily
Case Dimension (In mm)	s sqiq	*1 (1)	Drain points: Vender should spe
Gross Weight (In Kgs.)		*	per their system's area required
Foundation details (If required)	ggjis	*	* To be specified and confirmed









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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, Operation, Maintenance 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

:	*	
•	besign and opera 🁟	1
	SAT/FAT grocedu *s	S
:	*SEMENT MORRISON	E
	:	Uperanion inanual*

- * 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	PLC: Siemens
2	SAT/FAT procedures	2 sets	HMI: Slemens
3	Operation manual	2 sets	Seria resided
4	Maintenance manual	2 sets	to you de
5	Spare parts manual	2 sets	els NA &
6	All engineering drawings	2 sets	
7	List of instruments January Smith	2 sets	SMOR
8	Calibration certificates	2 sets	To be specif
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	(1)



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Email: homcokerala@gmail.com

TERMS AND CONDITIONS ANNEXURE - XIII

Delivery Period	•	2. HOMCO
Payment Terms nollapilities on plant	:	As mentioned in tender.
Packaging and forwarding	:	By Vendor
Un-loading at site qualification	:	By vendor /Supplier
Performance Qualification		(If required, help for the arrangements
Stainless Steet		of unloading can be done by client)
Right Hand Side		Installation in position by the vendor
Material of Construction		under the client's supervision
Excise / Taxes /GST	:	* WN
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.

* 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 render V	•	Installation Qualification D16W01 D16 D11DB0064
5.	y vendar /Supplier QO		Operational Qualification bile is pubsol-nU
6.16	f required, help for thrQq):	Performance Qualification
(7. 9d)	f unloading can be done22) :	Stainless Steel
8.ed	retallation in position2HR	L:	Right Hand Side
9. //	nder the client's supeDOM	:	Material of Construction
10.	KW	:	Excise / Taxes /GST takes / Taxes / Ta
11.	(To be arranged by clic4H)	:	Horse Power management for Trial Interest Miles
12.	RPM robney v	:	Rotation Per Minute loizeimmo bas notisilsteni
13.	FLP	:	Flame Proof
14.	cGMP	<i>;</i> :	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 CAN CAN CAN CAN CAN CAN CAN CAN CAN CA	:	Quality Analysis
20.	MRP 391 Test 8 See Fee MRP		Maximum Retail Price amsigna \ apniwsid
21.	e of the beginning of TMN	nev	Not more than Olega Vitiga bluoda seligous selT
22.	VFD	:	Variable frequency drive
23	FAT A DESIGNATION OF THE TATE	ea/	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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Supplier's Copy

USER REQUIREMENT SPECIFICATION

Name of the Company	9:83	
Contact Person	ni ,y	ggus : /
Address	1	Scope
Contact Details	14:08	HW)
Department	*in	QCL- First Floor
Equipment and Code No.	ir i e	Bunsen Burner (Mared K (edamald) eq.(4)
Name of work		Supply, Installation, Commissioning 8 Validation of cGLP model Bunsen Burner at M/s. HOMCO –Kerala
Ref. No.	:	
Date	•	
Enclosures	:	
Quantity		06 Nos.



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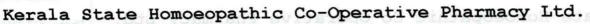
BUNSEN BURNER

BASIC DETAILS OF THE MACHINE

	DESCRIPTI	Name of the Company NO
(To be sp	ified by the suppl	lier, if any variation)
Scope	: Supply, Installation, Commissioning 8 cGLP model Bunsen Burner along with accessories, pipe etc. at M/s. HOMCO (Without 2Kg. mini LPG Cylinder)	
Base Diameter	: 80 mm*	Department
Burner Height	: 150mm App	x.*
Pipe (Diameter x Length)	12mm x 100	Equipment and Code N* mm
Optimum Working Pressure	• 0.035 Kg/cm	1 ² *







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AND OPERATIONAL FEATURES ANNEXURE - II & III FEATURES

	(To be specifi	DESCRIPTION ied by the supplier, if any variation)
мос	1	Base : Cast Iron * Burner Tube : Brass *
Finish		Base : Painted * Tube : Nickel Plated *

The Burner should consist of:

- Should have heavy cast iron base. *
- Should be provided with adjustable air regulator *







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ANNEXURE - IV

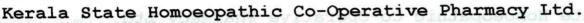
UTILITY REQUIREMENT

(То	DESCRIPTION be specified by the supplier, if any variation)	
Compressed Air	: Ordinary *	
	Non-Lubricated *	30M
LPG	Burner It be : Brass	Finish
Any other utility	rner should consist of:	The Bu

* 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 - V

CLEANING TECHNIQUE

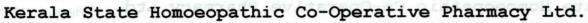
(To be	TOMOTO BETT	SCRIPTIO the supplie	N er, if any variation)
Mode of cleaning		*	Dimension (In min)
Use of Lubricants	*	*	Net Weight (In Kgs.)
All contact parts should be ea	sily dismantle	ed and clea	Type of Packing * .aldana
Easy washing and cleaning fa	cility should l	pe available	Case Dimension (In mm) *.e
			Tank of Assess sand

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.*









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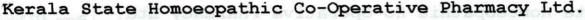
ANNEXURE - VI

MECHANICAL DETAILS

DESCRIPTION (To be specified by the supplier, if any variation)						
Dimension (In mm)		* Mode of cleaning				
Net Weight (In Kgs.)		Use of Lubricants :				
Type of Packing	96 09	All contact parts should be easily dismante				
Case Dimension (In mm)	V6 90	Easy washing and cleaning facility should be				
Gross Weight (In Kgs.)	ie in	Brain points: Vendor should specify the pi				
Foundation details (If required)	e in	per their system's drain requirement with				







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ANNEXURE -

LIST OF ANCILLARY / ACCESSORIES / OPTIONAL ITEMS

VII

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)

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







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ANNEXURE - VIII

DOCUMENTATION

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	TOTAL CONTRACTOR
7	List of instruments state as per their struments and the supplier as per their struments.	2 sets	* To be specif
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	TECH



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ANNEXURE - IX : TERMS AND CONDITIONS

Delivery Period	:	*
Payment Terms	-:	As mentioned in tender.
Packaging and forwarding	:	By Vendor ODMOH .S
Un-loading at site actisoidles of the site	:	By vendor /Supplier
netallation Qualification		(If required, help for the arrangements
Operational Qualification		of unloading can be done by client)
eriumance Qualification		Installation in position by the vendor
Stainless Steel		under the client's supervision
Excise / Taxes /GST	:	* 2 2 2 2 3 3 4 3 4 3 4 3 4 3 4 3 4 3 4 3
Material for Trial arrangement	:	* (To be arranged by client)
Installation and Commissioning	:	By Vendor
Submission of documents and drawings		91
Response to URS and submission of quotation	:	Within 1 week
Submission of detail functional design	:	Within a week after order finalization
specification and schematic drawings		15. O8M
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

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.

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

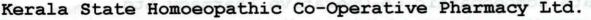


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ANNEXURE - X

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ABBREVIATION

1.	URS 191/16/11 11 USHIGISHIN 2	:	User Requirement Specification.	
2.	HOMCO TOBREST V	6:	Kerala State Homeopathic Co-operative Pharmacy Ltd.	
3.	/ vendor /Supplier QQ	8:	Design Qualification 938 45 pnibsol-nU	
4.	required, help for theQI	0:	Installation Qualification	
5.	unloading can be done 90	0:	Operational Qualification	
6.	stallation in position Q9	H:	Performance Qualification	
7.	nder the client's superv 22ct	u:	Stainless Steel	
8.	RHS	4:	Right Hand Side	
9.	MOC and beginning of of	• :	Material of Construction manage language language	
10.	KW sobsev v	4:	Kilo Watt Commissioning	
11.	HP	•	Horse Power	
12.	RPM desaw to relief to		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 1991950 Instruction 9-121		Single Line Diagram	
18.	HOD 91 1911b 259W 8 HIRE	4:	Head of Department 201519819 \ 2011WLYG	
19.	QA a to equipment of EAA	paley	Quality Analysis	
20.	MRP	:	Maximum Retail Price	
21.	NMT 0 03 3 new middled Suices 10	16,91	Not more than	
22.	VFD	:	Variable frequency drive	
23	FAT beilt	s ; e	Factory Acceptance Test	
24	SAT their squipment device	-:-	Site Acceptance Test	

Any other details, not mentioned in Annexures I to XIII, are to be specified in the quotation/specification by the vendor.



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