



Kerala State Homoeopathic Co-Operative Pharmacy Ltd.
Office: Pathirappally
(sponsored by government of Kerala & aided by govt. of India)

Alappuzha, India
Pin-688 521

Phone : 477 2258012
:477 2258665

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Email : cpo.homco@kerala.gov.in
homcokerala@gmail.com

Website : www.homcokerala.com

Supplier's Copy

USER REQUIREMENT SPECIFICATION

Name of the Company	:	
Contact Person	:	
Address	:	
Contact Details	:	
Department	:	Tablet – Second floor Granulation
Equipment and Code No.	:	Fluid Bed Dryer (FBD)
Ref. No.	:	
Date	:	
Enclosures	:	
Quantity	:	1 Nos.



CONSULTANT : M/S. KNACK TECHNOCRATS

111, AVINASH, SEVEN BUNGALOWS, JAY PRAKASH ROAD, ANDHERI (W), MUMBAI – 400 053
TEL. NO. : 022-2636 1629, Email : infoknack@gmail.com



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FLUID BED DRYER (FBD)

ANNEXURE - I : BASIC DETAILS OF THE MACHINE

DESCRIPTION	
(To be specified by the supplier, if any variation)	
Machine	: Fluid Bed Dryer (FBD)
Model	: *
Capacity	: Working : 250 KG
Bulk Density	: *
Volume	: 780 liters
Thickness	: 3mm
PLC monitor	: Touch screen
Solid flow monitor	: Broken bag detector with sensor
Silencer	: SS 304 for exhaust blower with 20 micron washable filter
Filter housing	: 10 micron washable filter 5 micron & 3 micron filters HEPA filter of 0.3 micron efficiency 99.97%
VFD	: For blower motor

*** To be specified by the supplier**



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ANNEXURE - II : cGMP FEATURES

DESCRIPTION	
(To be specified by the supplier, if any variation)	
MOC	: Contact Parts : SS 316 : Non-Contact Parts : SS 304 : Any MS parts : SS 304 cladded : Gasket /Seal/ 'O' Ring : Food Grade
Working Area Environment	: Temperature : $24 \pm 2^{\circ} \text{C}$: Relative Humidity : $65 \pm 5\%$
Finish	: Internal : Mirror Finish : External : Matt Finish
All welds should be ground finished and properly passivated.	
The equipment should be smooth finished without any sharp edges and crevices.	
Any lubricant, used in the equipment must be of food grade and non-toxic.	
Specification of lubricants used	: *

*** To be specified by the supplier**



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ANNEXURE - III : PROCESS CONTROL FEATURES

DESCRIPTION
(To be specified by the supplier, if any variation)
Specification for major components:
Product Container :
➤ Bottom Screen : 24 x 220 mesh double woven and supported with tie rod frame / perforated screen
➤ Viewing window : 8" dia with toughened glass
➤ Sampling port : For inline checking
➤ Container sealing : Silicon inflatable tube to achieve leak proof operation
➤ Trolley : SS Tubular frame with PU wheels
➤ Sensor : Product temperature sensor
➤ Extra one product container with trolley and features shall be provided along with equipment. (Total 2 Nos)
Expansion Chamber
➤ MOC : SS 316
➤ Thickness : 3 mm
➤ Viewing window : 8" dia with toughened glass
➤ Gasket : Lower end flange , Silicon /Neoprene rubber gasket



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Finger Bag Chamber

- MOC: SS316
- Thickness : 3 mm
- Filter media : PP Filter Bag of 5 micron – 5 Nos.
- Pressure Flap: To release excess pressure developed, made of rubberized champion sheet or Aluminium.
- Bag Shaking : Auto bag shaking arrangement
- Bag washing and drying facility inside the chamber

Top Dish

- MOC: SS316
- Thickness : 3 mm

Blower assembly

- Type : Centrifugal
- MOC : SS 304
- Thickness : 2.5 mm
- Motor : Approximate 30 HP , 3000 RPM
- Mounting : On top dish
- Damper : Between top dish and blower assembly with manual operation, Pneumatic operation with auto bag shaking
- Blower to be fitted with silencer to reduce noise.
- 20 micron filter to be fitted on the exhaust duct for exhaust air purity.



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Rear Chamber

- MOC: SS 304
- Thickness : 2.5 mm
- Heater : SS 304 finned tube steam radiator (Auto temp. controlled)
- Air filter box : 1.5 mm (16 swg) SS 304
- Filter : 10 micron washable filter
5 micron & 3 micron filters
HEPA filter of 0.3 micron efficiency 99.97%

Plenum Chamber (Bottom Chamber)

- MOC: SS 304
- Thickness : 2.5 mm
- Drain : Drain with taper bottom to drain out wash water
- Digital process timer & temperature controller with indicator
- PT-100 sensors with transmitter and Variation in speed – by providing VFD
- Operation control by PLC and HMI



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ANNEXURE - IV : ELECTRICAL DETAILS

DESCRIPTION		
<i>(To be specified by the supplier, if any variation)</i>		
Standard Operating Frequency	:	50 Hz
Standard Operating Voltage	:	415V
Total power consumption	:	*
RPM	:	*
Motor	:	*
Motor Details	:	*
Gear Box Details	:	*
Blower detail	:	*
Starter	:	*
Major Cabling details		
For Main supply (In client's scope)	:	*
For Main drive motor	:	*
Cable length with equipment	:	*
<i>Any other detail not mentioned above, also to be included.</i>		

*** To be specified by the supplier**



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- ❖ Electrical Control Panel – Control system should include three phase lamps, Ammeter, Voltmeter, Blower ON/OFF, Bag sealing, Bowl sealing, Bag shaking push button, Timer, Emergency push button, Process ON/OFF, Inlet temperature indicator controller, Outlet temperature indicator, Product air temperature, Air pressure.
- ❖ Wiring between Panel and the Machine is 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 machine is to be provided with motor overload safety relay.
In the event of machine malfunction or stoppage of utilities, the unit must contain all necessary protection devices to ensure that machine and product remain in safe condition.
Machine settings should not get disturbed due to power failure. Machine should not restart without human intervention.
On power failure equipment shall come to rest, to protect operator, equipment itself and the product.
The FBD will stop automatically upon loss of electricity, air, or other major utility and will require operator intervention to restart.
An easily accessible emergency stop to be provided on main control panel door.
Wherever possible, warning symbols should be provided.
Electrical wiring must be insulated and concealed
Proposer earthing to be provided
If the unit is not sealed properly, machine should not start.
If air pressure is lower than required, then equipment to be stopped.
Appropriate closure of all the rotating parts.
Noise level below 75 db at a distance of 1mtr from the equipment.
Safe earthing device for static dissipation to be provided.
Anti Vibration mounts.



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ANNEXURE - VI : CLEANING TECHNIQUE

DESCRIPTION

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

Mode of machine cleaning

:

*

All contact parts should be easily dismantled and cleanable.

CIP is required , please provide the details of CIP and water consumption.

Bag washing and drying facility inside the chamber.

Drain points: Please specify the pipe size and location.

All bolt nuts on the exterior parts will be with cap head or cap nuts.

*** To be specified by the supplier**



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ANNEXURE - VII : UTILITY REQUIREMENT

DESCRIPTION (To be specified by the supplier, if any variation)		
Steam	:	*
Vacuum	:	*
Compressed Air	:	*
Water	:	*
Power	:	*
Any other	:	*

*** To be specified by the supplier, if applicable**



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ANNEXURE - VIII : PHYSICAL 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	:	*

*** To be specified by the supplier**



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

DESCRIPTION

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

- Additional Product Container
- Optional Items
- Recommended Spares along with list and quantity

Details of Bought out components to be specified.

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

ANNEXURE - X : TRAINING REQUIREMENT

- Training to all concern of M/s. HOMCO, Kerala for Installation, Operation, Maintenance and Cleaning of Fluid Bed Dryer shall 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

PLC/HMI: Mitsubishi / Siemens / Allen-bradley	:	*
Motors: Crompton Greaves / Siemens / Bharat Bijlee	:	*
Pressure Transmitter: Siemens / Wika	:	*
VFD: Yaskawa / ABB / Siemens / Danfoss / Mitsubishi	:	*
MCB: Siemens / ABB	:	*
Temperature Transmitter/Controller: Radix / Yokagawa / Emerson / Waree	:	*
Air Filter Regulator/Solenoid Valve: Festo / Janitics	:	*
Pressure Gauges: Waree / Forbes Marshall	:	*
Cables: Finolex / Polycab	:	*

*** To be specified by the supplier**



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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 and format	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	:	*
Packaging and Forwarding	:	*
Excise / Taxes / GST	:	*
Material for Trial	:	*
Installation and Commissioning	:	*
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 DQ, IQ, OQ, PQ documents	:	With equipment delivery
Final drawings / diagrams	:	With one week of receiving PO
The supplier should notify customer 2 weeks in advance of the beginning of FAT.		
Catalogue, Equipment drawing (As built), List of clients and year of establishment to be submitted alongwith quotation.		
<i>Any other terms, not mentioned above, also to be specified.</i>		

* To be specified by the supplier



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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 Goods 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

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



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