



## 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

Phone : 477 2258012  
:477 2258665  
Fax : 0477 2258012

Website : [www.homcokerala.com](http://www.homcokerala.com)

Email : [homcokerala@gmail.com](mailto:homcokerala@gmail.com)

### Supplier's Copy

## USER REQUIREMENT SPECIFICATION

<b>Name of the Company</b>	:	
<b>Contact Person</b>	:	
<b>Address</b>	:	
<b>Contact Details</b>	:	
<b>Department</b>	:	TABLET SECTION - Ground Floor (Existing HOMCO)
<b>Equipment and Code No.</b>	:	<b>Tablet De-dusting Machine (Elevating/Uphill)</b>
<b>Name of work</b>	:	<b>Supply, Installation, Commissioning &amp; Validation of cGMP Model Tablet De-dusting Machine (Elevating/Uphill) at M/s HOMCO, Kerala (Existing Plant)</b>
<b>Ref. No.</b>	:	
<b>Date</b>	:	
<b>Enclosures</b>	:	
<b>Quantity</b>	:	<b>2 Nos.</b>



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### TABLET DE-DUSTING MACHINE (ELEVATING/UPHILL)

#### ANNEXURE – I : BASIC DETAILS.

DESCRIPTION	
( To be specified by the supplier, if any variation)	
Scope	: Supply, Installation, Commissioning and Validation of Tablet De-dusting Machine (Elevating/Uphill) including interconnecting pipes, flexible, cables, stand, with connecting accessories etc., and any optional item which is required for the successful running of the machine at M/s HOMCO, Kerala(Existing Plant).
Type	: Vibro type, Elevating/Uphill - Bottom to Top
Model	: GMP Model
Capacity	: 5,000 to 2,50,000 Tablets/Hour. *
Maximum Tablet Diameter	: 9 mm *
Minimum Tablet Diameter	: 5 mm *
Electric Motor	: 0.25 HP / 1440 RPM / 3 Phase*
Speed	: Adjustable
Charging Height	: 780 mm to 800 mm *
Discharging Height	: 850 mm to 900 mm *
Total Height	: 910 mm to 1000 mm *
De-dusting Distance	: 4 metre *

\* 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 or MS parts cladded by SS 304 : Gasket / Seal / 'O' ring : Food grade
Working Area Environment	: Temperature : NMT $24 \pm 2^{\circ}\text{C}$ : Relative Humidity : NMT $65 \pm 5\%$
Finish	: Internal : Mirror Finish
	: External : Matt Finish
The equipment should be of smooth finish without any sharp edges and crevices	

\* To be specified and confirm by the supplier as per their equipment design (If applicable)



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### ANNEXURE - III : OPERATION

#### DESCRIPTION

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

- De-dusting Machine should have two main functions: Tablet de-dusting and tablet cleaning through compressed air. It should be an ideal pharma machine for fine de-dusting of tablets by means of vibratory effect & upward movement of tablets.
- Tablets are entered to the top of the Tablet De-Dusting Machine and finally passed through elegantly designed perforated spiral which gently vibrated to release the layer of surface dust & remove the edges.
- Dedusting, Deburring and Conveying by Vibration: Tried and tested vibration Basis of the De-Duster. Fine-tuning of the oscillating magnets with the spring assemblies causes the tablet to move forward, turning and rotating along the perforated spiral. This removes the dust and burrs resulting from pressing are gently broken off.
- Adjustable height facility to suit with any Tablet Press machine.
- Simple Disassembly for Cleaning: Loosening a Locking screws allows all the components mounted on a central shaft to be easily removed. The outer cylinder is pulled off after opening a collar. All components may be cleaned dry or wet, allowing optimal cleaning to be achieved in accordance with GMP standards.
- Easy Maintenance and Cleaning: The tablet De-Duster should combines gentle conveying, burring and De-dusting action with very Low noise level, user friendly and low maintenance, and easy cleaning operations as well. Vibration is limited to the spiral only, this allows rigid assembly.
- Castor wheels for free mobility

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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/ 415 V *
RPM	:	*
Motor Details	:	*
Gear Box and Belt Details	:	*
VFD Details	:	*
<b>Major Cabling details</b>		
For Main supply (In client's scope)	:	*
For Main drive motor	:	*
Cable length with machine	:	*
<i>Any other detail not mentioned above, also to be included.</i>		
<i>Client will provide &amp; connect the required cable in to vendor's machine panel. From machine panel to machine and its other accessories to be supplied and connected by vendor.</i>		

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- ❖ 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 should be provided to Equipment.
- ❖ Complete covering of Electrical Cables and Other Connections.

## ANNEXURE - V : SAFETY FEATURES

DESCRIPTION
( To be specified by the supplier, if any variation)
Safety of machine operation is of utmost importance. To ensure safety, all upper guards to be fitted with interlock switches.
The machine 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. *
Machine should indicate fault through audio / visual signal with details on Control panel/PLC (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 : 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.		
Easy washing and cleaning facility should be available (If required)		

## ANNEXURE - VII : PHYSICAL DETAILS

DESCRIPTION		
(To be specified by the supplier, if any variation)		
Dimension (In mm)	:	*
Floor Space (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 - VIII : LIST OF ANCILLARY / ACCESSORIES / OPTIONAL ITEMS

#### DESCRIPTION

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

- Magnifying glass with inbuilt lamp of flexible adjustable arm \*
- Vacuum gun / pen for picking of rejected tablets \*
- Rejection collection bin (2 nos.)
- Inspected collection bin (1 no.)
- Change Parts \*
- Recommended Spares\*
- *Details of Bought out components to be specified.*
- *Any other ancillary or accessories or optional items not mentioned above also to be listed & quoted.*

### ANNEXURE - IX : TRAINING REQUIREMENT

- Training to all concern of M/s. HOMCO, Kerala for Installation, Operation, Maintenance and Cleaning of Multi Mill 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 - X : 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 (GA 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 if required	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, OQ,& 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 - XI : TERMS AND CONDITIONS

Delivery Period	:	*
Payment Terms	:	Payment terms mentioned in the tender document.
Un-loading at site	:	By Vendor. <ul style="list-style-type: none"><li>(If required, help for the arrangements of unloading can be done by client)</li></ul> Installation in position by the vendor under the client's supervision
Taxes / GST	:	*
Material for Trial	:	To be arranged by client
Packaging and Forwarding	:	By Vendor
Installation and Commissioning	:	By Vendor
<b>Submission of documents and drawings</b>		
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 one week of 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.		
<i>Any other terms,not mentioned above, also to be specified.</i>		

**\*To be specified by the supplier**



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### ANNEXURE - XII : 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

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