

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

Fax : 0477 2258012

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Supplier's Copy

USER REQUIREMENT SPECIFICATION

Name of the Company	:	
Contact Person	:	
Address	•	
Contact Details	•	
Department	:	Tablet (Second floor)
Equipment and Code No.	=	Supply, Installation, Commissioning & Validation of cGMP Model Tablet Inspection Machine (Manual / Visual) at M/s HOMCO, Kerala
Ref. No.	:	
Date	:	
Enclosures	:	
Qty.:	•	2 Nos.



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TABLET INSPECTION MACHINE (Manual/Visual Inspection)

ANNEXURE - I : BASIC DETAILS OF THE MACHINE

DESCRIPTION (To be specified by the supplier, if any variation)				
Scope	:	Supply, Installation, Commissioning & Validation of cGMP Model Tablet Inspection Machine (Manual / Visual) and any optional item which is required to run the machine along with connecting accessories, cables etc. at M/s HOMCO, Kerala.		
Type of Inspection	:	Manual / Visual		
Model	:	GMP Model		
Capacity	:	75,000 tablets/hr. * Depending upon size and shape of tablets and speed of conveyor belt and inspection of only coulor, or mix or broken tablet to be inspected. If critical inspection e.g. printing defects are to be inspected out put may be less.		
No. of operators	:	2 nos. *		
Height of Inspection	:	900 mm Approx. *		
Working Width Of Belt	:	145 to 150 mm *		
Sides of Tablet Inspection	:	Both sides of tablet		
Room Size Available	-	4.5(L) x 5.4(W) x 3.0(H) mtr.		

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



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ANNEXURE - II : cGMP FEATURES

DESCRIPTION						
(To be sp	(To be specified by the supplier, if any variation)					
MOC	=	Contact Parts	: SS 316			
Hoc	:	Non Contact Parts	: SS 304 or MS parts			
	:	cladded by SS 304				
	:	Conveyor Belt	: Food grade			
		Gasket / Seal / 'O' ring	: Food grade			
Working Area Environment	:	Temperature	: NMT 24 <u>+</u> 2°C			
	:	Relative Humidity	: NMT 65 <u>+</u> 5 %			
Finish	:	Internal	: Mirror Finish			
	:	External	: Matt Finish			
The equipment should be of smooth finish without any sharp edges and crevices						

ANNEXURE - III : PROCESS CONTROL FEATURES

DESCRIPTION				
(To be specified	by the	e supplier, if any variation)		
Variation in speed of the machine		By VFD *		
Control Panel	•	Control Panel location can be decided as per site condition during FAT *		

Following to be provided:

- > Semi automatic control panel to be provided with Non FLP
- > Two different panel i.e. Control panel and power panel which to be machine mounted.
- Common drive for both conveyor belts to be provided with AC motor controlled via AC variable frequency drive. *
- To be specified and confirm by the supplier as per their equipment design (If applicable)



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ANNEXURE - IV : OPERATIONAL FEATURES

DESCRIPTION

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

Following to be provided with the equipment:

- SS 316 feed hopper with height adjustable arrangement. *
- Vibrator plate *
- Magnifying glass with inbuilt lamp with flexible adjustable.
- Vacuum gun / pen for picking of rejected tablets.
- 2 nos. foot switches to be provided so that the operators working can stop the conveyor belt when necessary so as to pick up the rejected tablets/capsules. The switches to be interlocked with each other. *
- ➤ Hopper vibrator to be stopped when the belt is stopped by operator for picking up the defective tablet/capsule.
- > Intensity of vibration to be adjustable by manual speed pot.
- > Inspection height to be fixed.
- > 4 nos. of castor wheels of lockable type to be provided. *
- > Two different panel i.e. Control panel and power panel which to be machine mounted.
- > S.S.304 quality reject tablet collection bin.
- > S.S.316 quality inspected tablet collection bin.

Operation:

Tablets/capsules to be loaded into hopper, which will flow into a vibrating chute. The speed of feeding product to be regulated by electronic regulator. The tablets/capsules to be inspected on both sides and to be automatically rotated on belt or reserved after an interval of time. Two different levels of bets to be provided to inspect the products. The rejected products to be picked manually and passed products to be routed to collection container at the end of the conveyor belt.

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



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ANNEXURE - V : ELECTRICAL DETAILS

DESCRIPTION				
(To be specifie	ed by t	he 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	-	*		
Major Cabling details				
For Main supply (In client's scope)		*		
For Main drive motor	:	*		
Cable length with machine		*		
Any other detail not mentioned above, also to be included.				
		able in to vendor's machine panel. From machine to be supplied and connected by vendor.		

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



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ANNEXURE - VI : 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 *

ANNEXURE - VII : 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)				

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ANNEXURE - VIII : 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)		*	

ANNEXURE - IX : 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 & guoted.
- To be specified and confirm by the supplier as per their equipment design (If applicable)

ANNEXURE - X : TRAINING REQUIREMENT



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- > 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.

ANNEXURE - XI : APPROVED MAKES

Motors: Crompton Greaves / Siemens / Bharat	:	*
Bijlee		
Gear Box: Bonfiglioli / Premium	-	*
VFD: Yaskawa / ABB / Siemens / Delta / Allen		*
Bradley		
Cables: Finolex / Polycab		*
Any other components, not mentioned a	hou	vo to be specified by the yander

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



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ANNEXURE - XII : 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 (G A Drawing)	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	2 sets	
	catalogues		
16	DQ, IQ, PQ documents.	2 sets	
17	Calibration Report of all sensors, controllers, PLC,	2 sets	
	transmitters, indicators etc.		
18	Test Certificates of all material of construction	2 sets	
19	Test Certificates of the software used in machine	2 sets	
	control / monitoring system.		



Delivery Period

Kerala State Homoeopathic Co-Operative Pharmacy Ltd.

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> **ANNEXURE - XIII TERMS AND CONDITIONS**

Payment Terms	:	Payment terms mentioned in the
rayment reims	•	tender document.
Un-loading at site	:	By vendor / Supplier
		(If required, help for the arrangements o
		unloading can be done by client)
		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
Submission of documents and drawings		
Response to URS and submission of	:	Within 1 week
quotation		
Submission of detail functional design	:	Within a week after order finalization
specification and schematic drawings		
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 ad	vance of the beginning of FAT
Catalogue, Equipment drawing, List of clien alongwith quotation.	ıts a	nd year of establishment to be submitted
Any other terms, not mentioned above, also t	to he	specified.
Drawings / diagrams The supplier should notify customer 2 weeks Catalogue, Equipment drawing, List of clien	in adnts a	Within one week of receiving PO Ivance of the beginning of FAT Ind year of establishment to be su Specified.

(If applicable)



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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 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.