



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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Website : www.homcokerala.com

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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.	:	Blister Packing Machine
Ref. No.	:	
Date	:	
Enclosures	:	
Quantity	:	1 Nos.



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 : infknack@gmail.com



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BLISTER PACKING MACHINE

ANNEXURE - I : BASIC DETAILS OF THE MACHINE

DESCRIPTION	
(To be specified by the supplier, if any variation)	
Machine	: Blister Packing Machine
Type	: Automatic , Thermo-formed blister
Model	: *
Working Principle	: Intermittent * (Flat forming & Flat sealing)
Product	: Tablet.
Output	: 400 to 450 packs / minute of 10 tablets *
Forming material	: Thermo-formable Nontoxic PVC, PVC /ACLAR, PVC/ PVDC
Lidding material	: Hard tempered aluminium foil with heat –sealable coating or Paper
Product	: 6 mm & 9 mm dia tablets
Available Room size	: 6000 x 4500 x 3000 mm

*** 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 : Gasket / Seal / 'O' ring : Food grade
Safety Guard	: Polycarbonate
Working Area Environment	: Temperature : NMT $24 \pm 2^\circ \text{C}$: Relative Humidity : NMT $60 \pm 5 \%$
Finish	: Internal : Mirror Finish : External : Matt Finish
<ul style="list-style-type: none">➤ The equipment should be smooth finished without any sharp edges and crevices.➤ All welds should be ground finished and properly passivated.	



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ANNEXURE - III : PROCESS CONTROL FEATURES

DESCRIPTION		
(To be specified by the supplier, if any variation)		
Variation in speed of the machine	:	By VFD & Servo Drive
Machine Operation Control	:	Servo control operation
Machine Operational Interface	:	By Pre-programmed HMI screen with function keys.
Control Panel	:	On rear side of machine , and HMI on swivel as per operator's convenience with colour HMI screen
Following features to be provided :		
➤ Feeding system with hopper, linear vibrator and feeding channel or universal brush box depending upon the product		
➤ Film Unwinding Station <ul style="list-style-type: none">• Roll core diameter: 72-76mm. (Maximum roll diameter 440mm)		
➤ Forming Station <ul style="list-style-type: none">• Film heating roller with teflon coating for thermo-forming. Separate temperature controller for forming.		
➤ Lidding Foil Unwinding Station <ul style="list-style-type: none">➤ Roll diameter: 72-76mm. (Maximum roll diameter 220mm)		
➤ Inspection system should be capable of detecting missing product/broken or crushed product.		
➤ Safety Flap for product out of pocket: SS 316 Flap to be mounted after product feeding zone. The flap is continuously sensed by a safety magnetic sensor. If product does not seat correctly in to the blister cavity, then machine will stop with alarm.		



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DESCRIPTION

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

- Sealing Station
 - Filled web to pass over counter sealing roller, thereby pressed by pressure sealing roller. Pressure sealing roller to include knurling and heaters so as to seal the filled web with ALU lidding foil.
- Film Presence
 - Film presence sensor for an interlock function for stopping the machine when base foil/lidding foil has exhausted to be included.
- Separate perforation and embossing with facility for hot embossing/perforation to be provided.
- No Form No Fill: If cavities are not being well formed, sensor to be available to sense and reject those blisters.
- Print Registration Control
 - Edge to edge print registrations
 - Batch details printing

Safety Devices for :

- No Base Material – Machine stop
- No Lidding material – Machine stop

Alarms and Warnings for the following processes :

- Sealing Temperature Low
- Cooling Water Pump Trip
- Low Chilled Water Flow Rate / Pressure
- Motor overload
- Heaters OFF



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- Door guards open / close
- PLC Battery Low Warning
- Operating Air Pressure Low
- Vacuum Pump ON/OFF
- Low Temperature – Forming top plate / Forming bottom plate / Sealing / Cooling water / Perforation blade
- High Temperature – Forming top plate / Forming bottom plate / Sealing / Cooling water / Perforation blade

ANNEXURE - IV : OPERATIONAL CONTROL

DESCRIPTION

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

The following minimum options available in the machine but not limited to

- ON / OFF button
- Form bottom plate temperature – Set and Actual
- Form top plate temperature – Set and Actual
- Sealing heater temperature – Set and Actual
- Perforation heater temperature – Set and Actual
- Chiller temperature – Set and Actual
- Machine speed strokes per minute – Set and Actual
- Cutting station delay timer
- Display the total time for which the machine has run up to till time



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ANNEXURE - V : OPERATIONAL FEATURES

DESCRIPTION (To be specified by the supplier, if any variation)	
Base Film	: PVC/ALU : Thermo formable Non toxic PVC, PVC/ACLAR or PVC/PVDC #, If any other Base film is used
Lidding Material	: Hard tempered aluminium foil with heat-sealable : coating or paper : #, If any other Lidding material is used
Format Range (In mm) (# End User to reconfirm)	: Blister Pack size: 212 mm (L) x 110 mm (W) # : PVC Base film Width: 300 mm (maximum) # : PVC Film thickness : 250 to 350 micron # : PVC Reel Dia : 440 mm (maximum) # : Aluminium Foil Width : 300 mm (maximum) # : Aluminium Foil Thickness : 20 to 30 micron # : Aluminium Reel Dia : 220 mm (maximum) # : Total Forming Area : 290 x 120 mm : Advance Length: Max. 120 mm # : Forming Depth : Maximum 16 mm #

To be specified by the end user



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ANNEXURE - VI : FUNCTIONAL REQUIREMENT

DESCRIPTION

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The following minimum options available in the machine but not limited to

- Vacuum – Enable and Disable Key
- Heater – Enable and Disable Key
- Seal – Enable and Disable Key
- Blister – Enable and Disable Key
- Blister Reject – Enable and Disable Key
- Blister Conveyor – Enable and Disable Key
- Perforation – Enable and Disable Key
- Foil Break – Enable and Disable Key



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ANNEXURE - VII : ELECTRICAL DETAILS

DESCRIPTION		
(To be specified by the supplier, if any variation)		
Standard Operating Frequency	:	50 Hz
Standard Operating Voltage	:	415 V
RPM	:	Servo motor for main cam *
Motor Details	:	*
Gear Box Details	:	*
VFD Details	:	*
Programmable Logic Controller	:	*
Major Cabling details		
For Main supply (In client's scope)	:	*
For Main drive motor	:	*
<i>Any other detail not mentioned above, also to be included.</i>		

* To be specified by the supplier

- ❖ Wiring between Panel and the Machine is in the Scope of Vendor. The exact measurements shall be taken by visiting the site.



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- ❖ 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 - VIII : SAFETY FEATURES

DESCRIPTION
(To be specified by the supplier, if any variation)
Safety of machine operation is of utmost importance. To ensure safety, all guards to be fitted with interlock switches.
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.
Condensate to be emptied from Filter Regulator
Electrical wiring must be concealed
Noise level: Below 75 db at a distance of 1 Mtr from the Equipment.



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ANNEXURE - IX : UTILITY REQUIREMENT

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

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

ANNEXURE - X : CLEANING TECHNIQUE

DESCRIPTION (To be specified by the supplier, if any variation)		
Mode of machine cleaning	:	*
Use of Lubricants	:	Any lubricant, used in the Equipment must be of Food Grade and Non-toxic.
Lubricant specification and details	:	*
<ul style="list-style-type: none">All contact parts should be easily dismantled and cleanable.The Equipment shall be easily accessible for Cleaning the Non-product Contact Part at maintenance side of the Equipment.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 - XI : 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 - XII : LIST OF ANCILLARY / ACCESSORIES / OPTIONAL ITEMS

DESCRIPTION

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

- Vertical Feeding Device with bowl dish
- Embossing station
- Perforation station
- Non Fill Detection System
- Print Registration Control system
- On line link up with Cartoning machine
- Water cooler
- Air compressor
- Empty pack rejection system
- Change parts for ALU/PVC
- Batch report and audit trails
- 21 CFR part 11 compatibility
- Essential Spares (For 1 year)

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 - XIII : TRAINING REQUIREMENT

- Training to all concern of HOMCO, Kerala for Installation, Operation, Maintenance and Cleaning of Blister Packing Machine should be provided by vendor and training record will be documented.
- Vendor shall support client in execution of all the Qualification Phases.

ANNEXURE - XIV : APPROVED MAKES

PLC/HMI: Mitsubishi / Siemens / Allen-bradley	:	*
Operational Interface: Mitsubishi / Siemens / Allen-bradley	:	*
Servo Motor: Mitsubishi / Siemens	:	*
Pressure Transmitter: Siemens / Wika	:	*
VFD: Yaskawa / ABB / Siemens / Danfoss	:	*
MCB: Siemens / ABB	:	*
Temperature Transmitter/Controller: Radix / Yokagawa / Emerson / Warea	:	*
Air Filter Regulator/Solenoid Valve: Festo / Janitics	:	*
Pressure Gauges: Warea / Forbes Marshall	:	*
Cables: Finolex / Polycab	:	*

*** To be specified by the supplier**



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ANNEXURE - XV : 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	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 - XVI : TERMS AND CONDITIONS

Delivery Period	:	*
Payment Terms	:	*
Packaging and Forwarding	:	*
Excise / Taxes / Octroi / 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 IQ AND OQ documents	:	With equipment delivery
Final drawings / diagrams	:	Within one week of receiving Purchase order
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 - XVII : 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 XVI, to be specified in the quotation/specification by the vendor.



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