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Website: www.homcokerala.com | Email: homcokerala@gmail.com

Supplier's Copy

USER REQUIREMENT SPECIFICATION

Name of the Company	:	
Contact Person	:	
Address	:	
Contact Details	:	
Department	:	Ointment - Ground Floor
Equipment and Code No.	:	Semi-Automatic Cartoning Machine for Ointment
		Summly Installation and Commissioning of
Name of Work	•	Supply, Installation and Commissioning of cGMP model Semi-Automatic Cartoning Machine for ointment at M/s. HOMCO – Kerala
Name of Work Ref. No.	:	cGMP model Semi-Automatic Cartoning
		cGMP model Semi-Automatic Cartoning
Ref. No.	:	cGMP model Semi-Automatic Cartoning





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SEMI-AUTOMATIC OINTMENT CARTONING MACHINE

ANNEXURE - I : BASIC DETAILS OF THE MACHINE

DESCRIPTION				
(To be specified by the supplier, if any variation)				
Scope	•	Supply, Installation and Commissioning of cGMP model Semi-automatic Vertical Rotary Cartoning Machine with all required accessories along with connecting accessories if any, cables, change parts etc. at M/s. HOMCO –Kerala		
Machine Working	:	Semi-Automatic Cartoning Machine		
Model	:	*		
Туре	:	Vertical Rotary Servo Drive*		
Output (Operational)	:	15 to 50 cycles per minute		
Carton Size	:	Width (A): Minimum 20 - Maximum 82 mm * Depth (B): Minimum 15 - Maximum 82 mm * Height (C): Minimum 60 - Maximum 205 mm * (The difference between Width (A) & Depth (B) has to be minimum 2 mm) *		
Leaflet Dimension (Pre-fold)	:	Width: Minimum 20 - Maximum 35 mm * Length: Minimum 60 - Maximum 200 mm * (Fold pattern with respect to the carton dimension) *		

^{*} 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)				
Speed of the Machine		Mechanical Speed: Minimum 5 to Maximum 60 cycles/min * Operational Speed Minimum 15 to Maximum 45 cycles/min*		
Loading of product	:	Manual loading *		
Product loading station	:	3 Station*		
Total station for carton forming and sealing	:	12 station		

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

ANNEXURE - II : cGMP FEATURES

DESCRIPTION				
(To be specified by the supplier, if any variation)				
MOC	: Contact Parts: As per cGMP requirement*			
MOC :	: Non-Contact Parts: SS 304 *			
Finish	: Matt Finish*			
Any gasket:	: Food grade *			
The equipment should be smooth finished without any sharp edges and crevices				

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



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ANNEXURE - III : OPERATIONAL FEATURES

DESCRIPTION

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

The machine to consist of:

- Servo controlled Drive
- Indexer Drive
- Acrylic guard around machine ensure safety of operator*
- PLC control for machine operation*
- Easy & fast change over*
- cGMP -Model
- Safety guards with hardened acrylic glass doors without interlocks. *
- Rapid size changeover from one product to another.
- Tool-less changeover of the carton holding plates, easy mounting of the other change parts.
- No cartons No leaflet
- Cartons without product can be avoided.
- FRL unit to be provided with easy air release mechanism
- Vacuum by means of VAD, so no separate vacuum pump needed.
- Pneumatic air is needed for vacuum generation.
- Machine to mounted on heavy duty castor wheel with locking provision
- Electrical and pneumatic components separated in the control panel for ease of accessing for machine settings.
- Jog & Run mode to be provided.
- HMI display for ease of operation, troubleshooting, error messages and other relevant information's to be displayed

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DESCRIPTION

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The basic machine should design and work ergonomically and operate in a rotary fashion, wherein the cartons should handled vertically.

Process of the machine to be as follows:

Station 1: Carton Forming

Empty cartons stacked in the carton magazine to be picked up by the suction cups, in a vertical manner, so as to form the cartons due to a spring actuated resistance while pick up and thus forming the cartons and placing it on the first station.

Station 2: Bottom Side Flaps Closing

Bottom side flaps to be closed during rotary transit.

Station 3: Bottom Back Flap Closing

Bottom back main flap to be closed in this station.

Intermediate Station 3 – 4 – Glue Application

Glue dispenser assembly to sprinkle the glue on the bottom front flap from back side.

Station 4: Auto Leaflet Insertion

In this station pre-folded leaflets to be inserted into the cartons top opening before manual product insertion.

Station 5 & 6: Product Insertion

After the auto leaflet insertion, product insertion to be done manually by the operator this station.





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DESCRIPTION

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

Station 7: Product Verification

Sensor to be provided to sense the ointment tube which is inserted inside the carton, so as to verify the product insertion. The machined should stop and error message to be displayed on the HMI touch screen, in absence of ointment tube.

Station 8: Carton Top Minor Flap Closing

Guide and rotary cylinder to be provided to close the cartons top minor flaps.

Station 9: Top Major Flap Closing & Tuck In

In this station top major flap to be creased, closed and tucked in by operations of pneumatic cylinders.

Station 10: Packed Carton Station

In this station the bottom and top flaps closed and tucked in cartons to be held and transited to the next station

Station 11: Closed Cartons Discharging Station

In this station the cartons that are closed and tucked in to be discharged to the exit channel of the machine, which can be connected to the discharge conveyor or collected in a collection table or bin.

Station 12: Empty Station

This station to be empty so as to make provision to accommodate the cartons which shall be picked and formed during the next operation of the machine.

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



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ANNEXURE - IV : ELECTRICAL DETAILS

	DES	SCRIPTION
(To be specifie	d by t	he supplier, if any variation)
Standard Operating Frequency	:	50 Hz
Standard Operating Voltage	:	230V / 415V
Total Power Consumption	:	*
Motor Details with RPM	:	*
Gear Box Details (If any)	:	*
VFD Details (If any)	:	*
PLC and HMI details	:	*
Tower Lamp	:	*
Starter	:	*
Major Cabling details		
For main supply (In client's scope)		*
For Main drive motor	:	*
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.





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DESCRIPTION

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

- ❖ 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 confirm 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*

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 disr	nantle	d 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 systems drain requirement \ast





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ANNEXURE - VII : UTILITY REQUIREMENT

		DESCRIPTION
(To	be specifie	d by the supplier, if any variation)
Vacuum	:	*
Compressed Air	:	Ordinary *
		Non-Lubricated *
Chilled Water	:	*
Nitrogen	:	*
Cooling water	:	*
Any other	:	*

* To be specified and confirm by the supplier as per their equipment design with pressure and flow rate and pipe size require.

For all required utilities, pipe with fitting (Flexible /SS) valve /nozzles, supports, end connections, pressure gauge, FRL etc., should be supplied along with equipment by the vendor, client will only provide the connections to required utilities at this equipment's end point.

ANNEXURE - VIII : PHYSICAL DETAILS

	DES	SCRIPTION
(To be sp	ecified by t	the supplier, if any variation)
Dimension (In mm)	•	*
Floor Space	•	*
Net Weight (In Kgs.)	=	*
Type of Packing	=	*
Case Dimension (In mm)	.	*
Gross Weight (In Kgs.)	.	*
Foundation Details	:	*, if applicable





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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 include and provide the list with rate during tendering) *
- Recommended Spares along with list & quantity (Vendors should submit with tender) *
- If any items required but not included in URS, should be mentioned and submitted with unit rate and quantity, during tendering (And it can be informed during pre-bid meeting or finalization of bid.) *
- Details of Bought out components to be specified.

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

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

ANNEXURE - X : TRAINING REQUIREMENT

- > Training to all concern of M/s. HOMCO, Kerala for the Installation, Operation, Maintenance and Cleaning of all the Equipment included in the Vertical rotary Cartooning machine shall be provided by vendor and training record will be documented.
- Vendor shall support client in execution of all the Qualification Phases.



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



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ANNEXURE - XI : APPROVED MAKES

		·
Motor: Mitsubishi/Siemens / Bonfiglioli	:	*
PLC: Mitsubishi/Siemens / Allen Bradley	-	*
HMI: Mitsubishi/Siemens / Allen Bradley	-	*
Gear Box: Bonfiglioli / MGM/Varval / Rotomotive	-	*
Vacuum Pump: Siddhivinayak /Indovac / Promivac	-	*
Vacuum motor: Hindustan EM / Mitsubishi / Siemens	-	*
Indexer : Hadex	-	*
Encoder : Fraba/ Kubler / Baumer	:	*
Sensor: Panasonic/ Pepperl / Wenglor Sensors	:	*
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.
- * To be specified and confirm by the supplier as per their equipment design





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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	2 sets		
3	Operation manual	2 sets		
4	Maintenance manual	2 sets		
5	Spare parts manual	2 sets		
6	All engineering drawings (GA 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	IQ, OQ, DQ and PQ documents.	2 sets		





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ANNEXURE - XIII : 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
Taxes / GST	:	*
Material for Trial	:	To be arranged by client
Installation and Commissioning		By Vendor
Submission of documents and draw	ings	i
Response to URS and submission of	ŧ	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 DQ, IQ, OQ, PQ	ŧ	With equipment delivery
documents		
Final Drawings / Diagrams		Within one week of receiving PO
The supplier should notify the end user	2 we	eeks in advance of the beginning of FAT
Catalogue, Equipment drawing, List of	clie	ents and year of establishment to be submitted
alongwith 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	:	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.	NMT	:	Not more than
21.	VFD	:	Variable frequency drive

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

