



Kerala State Homoeopathic Co-Operative Pharmacy Ltd.

(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

Website : www.homcokerala.com

Email : homcokerala@gmail.com

Supplier's Copy

USER REQUIREMENT SPECIFICATION

Name of the Company	:	
Contact Person	:	
Address	:	
Contact Details	:	
Department	:	<i>Ointment – Ground Floor</i>
Equipment and Code No.	:	<i>Automatic Tube Filling Sealing machine</i>
Name of Work	:	Supply, Installation, Commissioning & Validation of cGMP model Single Head Linear type Automatic Tube Filling, Sealing Machine for Plastic, Laminates & Aluminium tubes at M/s. HOMCO – Kerala
Ref. No.	:	
Date	:	
Enclosures	:	
Quantity	:	<i>1 No.</i>



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SINGLE HEAD LINEAR TYPE AUTOMATIC TUBE FILLING SEALING MACHINE FOR PLASTIC, LAMINATES & ALUMINIUM TUBES

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 Single Head Linear Type Automatic Tube Filling, Sealing Machine for Plastic, Laminates & Aluminium Tubes and all the items which is required to run the plant along with connecting accessories, cables etc. at M/s. HOMCO -Kerala
Machine	:	Single Head Linear Type Automatic Tube Filling, Sealing Machine for Plastic, Laminates & Aluminium Tubes
Model	:	*
Type	:	Linear Type, Fully Automatic*
Output (Max.)	:	60 tubes/min of 10 gm filling * (Output may vary depends upon the viscosity of the filling material and the fill volume)
Number of Stations	:	8 *
Tube Types	:	Plastic / Laminated / Aluminium Tubes *

* 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)		
Tube Diameter Lami / PL	:	Min 12 mm, Max. 50 mm *
Tube Diameter Aluminium	:	Min 12 mm, Max. 35 mm *
Tube Height	:	PL – 75mm – 200 mm * (PL= Plastic,laminated)
	:	AL – 80mm – 200 mm * (Aluminum)
Filling Range	:	3 gm–250 gm * (With interchangeable syringe pumps)
Syringe Pump Size range	:	3 gm – 30 gm*
	:	30 gm – 100 gm*
	:	100 gm – 250 gm*
Filling Accuracy	:	\pm 0.5 gm of fill weight *
Fill Material	:	Cream, Gel, Ointment, Paste
Hopper Capacity	:	40 Liters *

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



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ANNEXURE - II : cGMP FEATURES

DESCRIPTION	
(To be specified by the supplier, if any variation)	
MOC	: : Contact Parts: SS 316 * including the following <ul style="list-style-type: none">• Shut-off body• Filling nozzle• Filling block• Siring and piston• Hopper and Lid cover Non-Contact Parts: SS 304 * Any gasket: Food grade *
Finish	: Matt Finish
<ul style="list-style-type: none">▪ The equipment should be smooth finished without any sharp edges and crevices.▪ The body is fully enclosed from all sides.	

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ANNEXURE - III : OPERATIONAL FEATURES

DESCRIPTION

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

The machine should be consist of:

- No Tube No fill *
- No Tube – No closing system *
- Indexer *
- Machine consist of PLC & Touch screen HMI*
- Daily production log to be maintained in HMI*
- Machine speed indication and changing the speed using VFD*
- Hopper level indication*
- Batch coding unit*
- Tube counter*
- Easy adjustable sealing head*
- Automatic discharge of tube*
- 0% possibility of reverse tube feeding at the time of tube loading, tube getting jammed with nozzle during filling & lifting*
- Safety interlocks for *
 - Emergency stop – Machine stop*
 - Low air pressure – Machine stop*
 - Tube not ejected – Machine stop*
 - Indexer clutch overload – Machine stop*
 - Motor overload – Machine stop*

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DESCRIPTION

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

Machine operational description

Station 1: Auto Tube Feeding

Empty tubes to be loaded automatically into the in-feed device.

Empty tubes to come down from cassette on a slider plate.

The tilter to hold the tube by vacuum loads and lodges it into the tube holders with a centering / pressing cone.

Station 2: Tube Cleaning

Tube cleaning to be carried out by the flow of air through nozzle and flask around the nozzle to suck the dust which is deposited inside the tube.

Vacuum to be provided for dust collection through separate vacuum pump.

Station 3: Eye Mark Sensor & Orientation

Eye mark sensor to sense the eye mark printed on the tube and position the tubes accordingly.

Station 4: Filling

Capable of filling liquid, Semi viscous and viscous product.

Tube filling to be done in this station.

No tube- No fill device to prevent the dosing action if tube is not present, to avoid wastage and spillage of cream.

Shut - off nozzle to eliminate product dripping and to maintain high accuracy of filling.

Plunger in the nozzle to help shut-off action.

A blow-off system to be provided to control product stringing.

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

DESCRIPTION

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

Station 6: Sealing & Coding

The sealing unit will be hot air type which can seal lami as well as plastic tubes. The heating



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gun controlled by electronic thermo regulator.

Sealing and coding unit to first seal the heated part of the tube and then to code on the seal with metal stereotypes.

Station 7: Trimming

Pneumatic trimming unit to trim the irregular end portion of the tube. An extractor to be provided for collecting the trimmed chips in a bin by suction.

Station 8: Filled Tubes Discharge Station

Provision of Inkjet printing will be provided before ejecting.

Filled and sealed tubes to be discharged and collected in the collection bin through discharge tray.

For Aluminium Tubes

Station 6: 1st Folding

First crimping unit to consist of two jaws with cam for performing the first crimping operation. Tube gets hold or to be locked in between the two jaws. Cam becomes active and folds the tube – this is first crimping.

Station 6: 2nd Folding

Second folding of the tube to be done on this station, and then tubes to move ahead for reverse folding coding.

Station 7: Batch Coding

This station is individual pneumatic operated batch coding station, where coding to be done on the folded area with metal stereotypes.

Station 8: Discharge Station

Filled and crimped tubes to be discharged and collected in the collection bin through discharge tray.

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

ANNEXURE - V : ELECTRICAL DETAILS

DESCRIPTION

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

Standard Operating Frequency	:	50 Hz
Standard Operating Voltage	:	230V / 415V



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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	:	*
<i>Any other detail not mentioned above, also to be included.</i>		
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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ANNEXURE - VI : SAFETY FEATURES

DESCRIPTION	
(To be specified by the supplier, if any variation)	
In the event of power failure, the PLC will retain all its memory. *	
Emergency stop button to be provided. *	
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 - 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	
Drain points: Vendor should specify the pipe size and location of drain points if required as per any drain requirement *	

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ANNEXURE - VIII : UTILITY REQUIREMENT

DESCRIPTION (To be specified 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.**

Note - 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

DESCRIPTION (To be specified by 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.

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 Ointment Manufacturing Plant shall be provided by vendor and training record will be documented.
- Vendor shall support client in execution of all the Qualification Phases. *

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

ANNEXURE - XI : APPROVED MAKES



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Motor: Mitsubishi / Siemens / Bonfiglioli / M.G.M Varval / Rotomotive / Hindustan	:	*
PLC: Mitsubishi / Siemens / Allen Bradley	:	*
HMI: Mitsubishi / Siemens / Allen Bradley	:	*
Gear Box: Bonfiglioli / MGM Varval / Rotomotive	:	*
Vacuum Pump: Siddhivinayak / Indovac / Promivac / Orion	:	*
Vacuum motor: Hindustan EM / Mitsubishi / Siemens	:	*
Drive: Mitsubishi / Siemens / Allen Bradley	:	*
Indexer : Hadex	:	*
Encoder : Fraba / Kubler / Baumer	:	*
Pneumatics : FESTO / SMC	:	*
Sensor: Panasonic / PEPPERL+FUCHS / 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**

ANNEXURE - XII : DOCUMENTATION



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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 catalogues	2 sets	
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 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	:	Within one week of receiving PO
The supplier should notify the end user 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>		

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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.	NMT	:	Not more than
21.	VFD	:	Variable frequency drive

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