DESIGN QUALIFICATION PROTOCOL FOR DOUBLE HEAD TUBE FILLING MACHINE

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL FOR DOUBLE HEAD TUBE FILLING MACHINE	PROTOCOL No.:

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1. SYSTEM AND PROTOCOL INFORMATION :

Equipment	Double Head Tube Filling Machine
Manufacturer	Wimco Limited
Customer	-
P.O. No.	-
Site	-

2. OBJECTIVE:

The purpose of this document is to provide design qualification for Double Head Tube Filling Machine. This document provides evidence that the unit is designed, manufactured and supplied for installation & commissioning as per the user requirement specifications and PO No.:

This also confirms that the equipment shall meet all the requirement of product, process and safety.

3. SCOPE:

This design qualification protocol will define the responsibilities, acceptance criteria, basis of design, technical specifications, list of major bought out parts, utility requirements, safety and documentation requirements.

The protocol also defines the basis of Factory Acceptance Tests.

The design qualification is an essential part of the qualification mechanism and will serve as a basic document for the Validation activity.

4. RESPONSIBILITIES:

CLIENT:

1. To provide Process Description.
2. To provide the URS for the equipment.
3. Room Layout Drawing indicating Machine Position and utility points
4. Sample Tubes (5 Nos. Each) for manufacturing components of Machine, Tubes for Machine Trial & Testing (1000 Nos. of Each Type)
5. To approve Machine Layout Drawing.
6. To verify the Factory Acceptance Test (FAT) and approve it.
7. To ensure the suitability of Equipment installation as per the approved layout.
8. To carry out Equipment validation at site, if required, equipment manufacturer to provide assistance during validation.

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MANUFACTURER:

1. To design, manufacture and provide the complete technical details of the equipment pertaining to its design qualification viz.

   - System Description.
   - Equipment Detail specification with MOC.
   - Specifications of the Accessories/bought out items, and their make, model & quantity, and backup records/brochures.
   - Details of Utilities.
   - Identification of components for calibration/certification.
   - Safety features.
   - Pre-installation requirements.

2. To facilitate the client for the Factory acceptance test of the machine at manufacturing works/site.
3. To submit Qualification Documents with all FAT Records and Manuals.
4. To confirm the safe delivery of the equipment to the user from our factory.
5. To ensure the proper installation and commissioning of the equipment.

5. SYSTEM DESCRIPTION:

Application:

Double Head Tube Filling Machine is used for filling and sealing/closing of Lami tube of Dia.16-40 mm with filling variation of 1 cc to 150 cc depending on the material properties.

Major System Components: Tube filling Machines is comprised of following major sub-assemblies/ components.

- **Automatic Tube Loading on Machine:**
  Consist of Polycarbonate Cassettes with SS/ Al frame, Al tube tilter, Cassette motor and S.S. Rocker.

- **Tube Registration Device:**
  Two Stepper motors attached to Magnetic lifting head, S.S cone, Colour mark Sensors.

- **Tube Filling Device.**
  S.S316 Jacked Hopper with 75 liters capacity supported on the machine.
  S.S 316-make nozzle with air blow off device attached to the reciprocating SS pump. Complete material transfer device (from hopper to filling nozzle) is made of SS 316.

- **Tube Closing Device.**
  Combi Sealer : the system is fitted with aluminum tube folding stations with coding station. Lami tube sealing system is fitted with heating, sealing, coding & trimming stations. Trim collector is used for collecting the trims from the trimming station.

Process:

Empty Tubes from the shipper box are manually loaded in the cassette box. From the cassette box, empty tubes slides to the tilter, then tubes are placed on the tube holder and the holder is carrying the tube to each station. The colour mark sensor at tube registration system senses the 'I' mark of the tube. At tube cleaning station compressed air is blown at bottom of the tube and simultaneously vacuum pump sucks the air and dust particle from the tube. Then tube moves from cleaning station to filling station where the tube is lifted, and set weight of material is filled by the progressive filling method in the tube by the filling nozzle. The entire filling station is also called Pump Housing. Tubes transfers from filling to sealing station,

For Lami tube, tube inner surface is heated by a hot air blowing station then tube is pressed in between two jaws by sealing unit mounted on the sealing station. Then sealed tube is cooled before the trimming operation, which is carried out by the trimming unit.

For Metal tubes folding is done three stations (Flattening, 1st Fold & 2nd Fold) which are placed adjacent to each other in sealing station. Tube is transferred after filling to the flattening station. In case of a combi sealer lami sealing units will be idle during sealing however they will be placed in the same location.

For switching from Lami tube to Metal Tube or Vice-Versa, the machine requires some change over, Hence either of the tube can only manufacture in each batches. Change over should be done by Standard tooling.

In the ejection station, lifting ejection pin should be set proper, so that the tube lifted entirely clear of the holder and is then rolled down into the chute.

6. DESIGN QUALIFICATION

6.1 TECHNICAL SPECIFICATIONS:

6.1.1 GENERAL

S.No.	Design Features	Details
1.	**Products can be filled**	Cream, Gel, Toothpaste, Ointment, Adhesive
2.	**Viscosity**	20K – 300K CPS
3.	**Packing style**	Lami & Metal Tubes
4.	**Filling Range**	**1 cc to 200 cc with corresponding change of pistons** – 15 mm (1-6cc), 30 mm (6-72cc) & 45 mm (20-150cc), 60 mm (25 – 200 cc)
5.	**Tube sizes**	Refer the below matrix – A
6.	**Machine speed**	Machine is designed for dry run of max of 120 tubes/minute (approx.). Actual output will depend upon the fill weight, product viscosity, MOC of the tube and skill of the operator. For 15gm/30gm – 100 tubes/minute (Approx.) Machine speed is controlled through VFD
7.	**Minimum change-over time**	Setting & changeover time will be 45 minutes (Approx.)
8.	**Product filling accuracy**	±1% of fill weight

Min & Max Range for Tube Sizes – **Matrix A**

Parameters	Lami/Plastic Tubes		Aluminium Tubes	
	Min	Max	Min	Max
Diameter (mm)	16	50	10	50
Cylindrical length for conical cap or total length including cap for inline cap tube (mm)	80	205	80	205

6.1.2 AUTOMATIC DOUBLE HEAD TUBE IN-FEED DEVICE/SYSTEM

Design Features	Details
Description	This device automatically inserts the empty tubes in the holder. After insertion it also presses the tube in the holder to ensure firm hold. The system consists of rocker, motor, tilter etc. Empty tubes have to be loaded in the cassettes manually.
Cassettes	
Quantity	02 nos.
MOC	Polycarbonate
Frame MOC	Stainless Steel and Aluminum
Function	It reserves the tubes where operator loads the tubes from the corrugated box and feeds into the tilter.
Tube Tilter	
Quantity	2 Nos
MOC	Aluminum
Function	Tilter inserts the tubes in the machine holder.
Rocker	
Quantity	2 Nos
MOC	S.S.
Function	It rocks the tubes if the tubes get seized inside the cassette box.
Tube Holders	
Function	Holders with nylon grippers & stainless steel springs are used for holding tubes
No. of stations	54Nos., extra 5 Nos. is free supply
MOC	Anodized Aluminum
Ferguson Drive	
Description	This is indexing mechanism, which provides indexing motion to the tube holder chain for performing the machine operations in different stations.
Specifications	Input – 120 Degree Output – 90 Degree
Cassette Motors	
Make	Associate
Quantity	02Nos.

Design Features	Details
Specifications	Rating –220V, 50Hz, 0.22A, NFLP, 0.06 W
Function	When the machine is in running in production, Cassette loaded tubes should not come more than one on the tilter. This avoids damage or breakage of tilter.

6.1.3 TUBE REGISTRATION DEVICE

Design Features	Details
Description	Consists of two Stepper motors attached to Magnetic lifting head, S.S cone, Colour mark Sensors
I-Mark/Orientation Sensor	
Description	This device ensures the correct printed panel of tube is always visible. The device is fitted with optical sensors, controller (It's a inbuilt device comes along with the sensor) & stepper motor. Optical sensor senses the eye mark printed on the tube & passes the signal to the motor.
Quantity	02Nos.
Make	P &F (visuolx)
Model	DK 20
Specifications	24 vdc PNP, NO
Stepper Motors	
Quantity	02 Nos.
Make	Gennext Control
Rating	6vdc, 1.4Amp.
Function	It orients the tubes for correct positioning of the "I" mark.

6.1.4 TUBE FILLING DEVICE/SYSTEM

Design Features	Details
Description	S.S 316-make nozzle (2 Nos) with air blow off device attached to the reciprocating S.S. pump, which fills the material into the tube, by a CAM operated system. Blow off pipe and compressed air cuts the tail of the filling material from the nozzle.
Filling system (Progressive Filling System)	This assembly contains main pump housing, sleeve (Nylon), valve & piston rod. The size of the pump is 15mm (1-6cc), 30mm (6-72cc) & 45mm (20-150cc) All 2 nos.
Filling Mechanism	Cam operated progressive filling with mechanical adjustment provided for fine setting of fill weight
No Tube No Fill Device (Proximity Sensors)	
Description	This is built-in feature provided in the machine with the feedback from proximity sensor. And a pneumatic cylinder disengages the filling valve from the operation.
Quantity	02 Nos.
Make	Carlo Gavazzi

Design Features	Details
Model	PA18CDPASA
Specifications	10-40 v dc, PNP NO, 0-200 mm
Hopper	
Description	75 litres SS – 316 double jacketed hopper with cover fitted with electrical heater.
Quantity	01
Capacity	75 liters (approx.)
Type	Double Jacketed
MOC	SS 316
Level Sensor for Hopper	
Make	Carlogavazzi
Model	UA18CLD064K
Range	100-600mm
Voltage	18-30 v dc
o/p	0 to 10 v analogue
Quantity	01 Nos.
Jacket Heater	
Quantity	01Nos.
Make	Girish
Specifications	Rating – 230V A.C.750W,
Temperature Sensor in Hopper	
Quantity	01Nos.
Make	
Type	PT 100, 3 Wire type
MOC	Thermo well SS316L Sensor SS 316
End connection	½" BSP
Range	0º to 400ºC
Specifications	Class 'A'
Cream Stirring Device	
Description	Stirrs the material to make it free flow with separate motor with VFD
Stirrer Motor	
Make	Bonfiglioli
Quantity	01 Nos.
Power	0.5 HP
Voltage	415V
RPM	N1-1380, N2- 40 RPM
IP Class	IP55
Type	NFLP
A.C. Drive for Stirrer	

Design Features	Details
Make	Allen Bradley
Quantity	01 Nos.
Model	Power flex 4 M
Specifications	1.0 HP, 415V, 50 Hz
Shut off nozzle	
Description	Pneumatic operated blow off pipe is used inside the filling nozzle for tail free dozing.
MOC	SS 316

6.1.5 TUBE CLOSING DEVICE (COMBI SEALER)

Design Features	Details
Description	Can seal both lami & metal tubes. The system is fitted with aluminum tube folding stations with coding station. Lami tube sealing system is fitted with heating, sealing, Online Cooling with compressed air, coding & trimming stations. Trim collector is used for collecting the trims from the trimming station.
Heaters	
Make	Lister
Quantity	02Nos.
Specifications	Rating – 415v, 3.3 kw
Hot Air Blower	
Make	Lister
Quantity	01Nos.
Specifications	Rating –230v, 50HZ, 0.33kw, 2850rpm, 1200 liters/min.
Temperature Sensors in Hot Air Nozzle / Controller	
Make	Microcon
Quantity	02Nos.
Type	2 Wire type, Thermocouple‘K’type
MOC	Thermo well SS316 Sensor SS 316
End connection	½” BSP
Range	0º to 800ºC
Specifications	Class ‘A’
Coding Unit	
Description	One set of each Alfa/numeric coding punches (0-9 and A-Z) is provided with the machine to punch in the product as per the user defined code.

6.1.6 CENTRAL LUBRICATION SYSTEM

Design Features	Details
Description	It lubricates to the moving parts of the entire machine periodically.
Lubrication Pump	
Make	Dropco

Quantity	01Nos.
Specifications	Rating –230V, 50 HZ, 2.3 Amp., 1350 RPM. IP55, NFLP, 90W

6.1.7 CONTROL DEVICES/SYSTEMS

Design Features	Details
Main Motor	
Description	Crompton make motor is used to drive the mechanism. A worm reduction gearbox of greaves make is used to reduce the speed & a chain sprocket transfers this motion to the machine main shaft.
Make	Crompton, NFLP, IP 55
Quantity	01 Nos.
Power	1.5 HP
Voltage	415V
RPM	1440 RPM
Current	2.5Amp.
Type	TEFC type
Encoder	
Make – Kubler, 1 Nos	
Specification –Rating – 10-30 vdc, 100 mA,360 ppr	
Gear Box for Main Motor	
Make	Greaves
Reduction Ratio	15:1
A.C. Drive for Main Motor	
Make	Allen Bradley
Quantity	01 Nos.
Model	Power flex 4 M
Specifications	2.0 HP, 415V, 50 Hz
Location	Control Panel
Function	To control the main motor speed
PLC	
Make	Allen Bradley
Quantity	01 Nos.
Model	Micrologix 1400 B x BA
Specifications	IO 32 on base module/Add on IO 32
MMI	
Make	Allen Bradley
Quantity	01 Nos.
Model	Component C600
Specifications	24 vdc
Electronic product counter & time totaliser	Provided (Product counting is based on filling stroke. After pressing machine start push button time totaliser starts)
Power Supply	
Description	Provided in electrical panel provided for giving supply to PLC & HMI

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Design Features	Details
Make	Shavison
Model	G31-120-24
Quantity	01Nos.
Specification	Input-230v A.C. O/P- 24v D.C.
Home Position	
Description	Provided on main shaft for insuring machine home position.
Make	P & F
Model	NBBS
Quantity	01Nos.
Specification	10-4- v dc, PNP NO
Jogging device	
Description	One Machine Jogging switch with cable is provided for easy machine maintenance & set-up.
Indicator Tower Lamp	
Description	Electrical Indicator for stop/ready/run status is provided on the machine as tower lamp
Specification	24 V DC, LED type Lamp
Machine Guards	
Description	Tubular covers provided made of SS 304 sheets with matt finish & square profile members & also fitted with polycarbonate sheets.
Mechanical overload clutch	
Description	Machine stop if get jam for any reason with help of self-centering over load clutch.
Hand Wheel	
Description	Provided for manual settings for CAM orientation / Check Machine load.
Safety Switches	
Make	Telemechnic
Model	XCS
Quantity	07 Nos.
Type	Potential free contact
Function and Location	To stop the machine during Auto RUN If frame doors open. These switches are mounted on frame & actuator fitted on doors.
Limit Switch	
Make	Jai Balaji
Model	BC9
Quantity	01 Nos.
Type	Potential free contact
Function and Location	This switch gives signal to stop the machine if one of Unejected tubes comes to in-feed station. It is fitted after center ejection on machine.
Micro Switch for machine O/L Sensor	
Make	P & F
Model	N BB 5
Quantity	01 Nos.

Design Features	Details
Type	Potential free contact
Function and Location	This machine is equipped with center overload clutch system, which in turn switches off the machine in case of any overload. This avoids damages or breakdown of components.
Air pressure switch	
Make	Festo
Model	Pev ¼ B
Quantity	01Nos.
Type	Potential free contact
Function and Location	During Auto Run If Air pressure drops below set point Machine gets stop by getting signal from this pressure switch. It is present in the pneumatic panel, which is mounted on the rear side of the machine.
Earthing	
Description	Provided in electrical panel.
Machine Extension - Standard	
Description	Extension with 14 links with holders & necessary attachments is included in the machine. Also side tube ejection system is provided to hook-up the tube-filling machine with automatic Cartooning Machine with the help of conveyor.

After sealing but before ejection of filled tube there should be a provision of supply for attachment of Printer head for printing UIN code on the tube

6.1.8 Change Parts and Tooling

- First aid spares with toolbox shall be provided for quick change over. This kit of spares includes toolbox with spanners, Allen keys, oilcan, hammer, O-rings, chain links etc.
- Basic machine includes a set of change part for one tube size & one product – 30gm (Tube Holder, Tilter, Cone, Pump Set, Nozzle, Blow off Pipe & Fix Set Assembly.

7. UTILITY DETAILS:

S.No.	Description		Unit	GAN + LS-120
1.	Power, 3 Phase, 440 V, 50 Hz		KW	8.5
2.	**Compressed Air Pressure**		Kg/sq. cm	6
			LPM	650
			CFM	25
3.	**Chilled water**			
		Temp at Lamisealer outlet	deg C	8 - 10
		Volume	LPM	8
4.	**Vacuum**			

		650 - 700 mm Hg		
		Free Air displacement	LPM	N.A.

8. IDENTIFICATION OF COMPONENTS FOR CERTIFICATION/CALLIBRATION:

S.No.	Components	Documents
1.	Motor	Certificate
2.	Vacuum Pump	Certificate
3.	Variable Frequency Drive	Test Certificate
4.	Pressure Gauge	Calibration Certificate
5.	Temperature Sensor and other measuring instruments	Calibration Certificate
6.	All Contact Parts	Metal Test Certificate
7.	Contact part Surface Area Calculation Sheet	Required
8.	Pneumatic Cylinder	Certificate

9. SAFETY FEATURES:

The unit is provided with following safety features.

S.No.	Safety Device	Specified Function
1.	Machine Overload Clutch	To stop the machine in case of overload.
2.	Machine is enclosed with SS 304 structural members with polycarbonate sheet.	For Operator Safety
3.	Pressure Gauge Make:- Festo Model:- LFR-5D-Mini Range:- 0-16 bar	To Indicate pressure of air.
4.	Lock for SS control Panel	For Instruments safety
5.	Position stop.	To stop the machine when the tube holder position is on lower side.
6.	Machine Reverse Lock	To avoid motion in reverse direction for tube holder chain.
7.	No Tube no fill Sensor	To give signal to filling station for filling.
8.	Emergency Switch	To stop the machine in case of emergency stoppage.

9.	Safety during tube ejection	Machine stop when not ejected.

10. LIST OF DOCUMENTS:

M/s. Wimco Ltd. will provide following documents along with the equipment.

S.No.	Document details	Required (✔/✘)	Requirement	Format
1	Design Specification	✔	Before PO	Paper/PDF/CD
2.	Functional Specification	✔	Before PO	Paper/PDF/CD
3.	PLC Alarm/Interlock/ Safety/communication/ power failure test procedures	✔	Before PO	Paper/PDF/CD
4.	Instrument Listing	✔	Before DQ	Paper/PDF/CD
5.	Control Schematics	✔	Before DQ	Paper/PDF/CD
6.	Operator, Maintenance and Service Manuals	✔	During Commissioning	Paper/PDF/CD
7.	Spare Parts List	✔	During Commissioning	Paper/PDF/CD
8.	MOC Certificates	✔	During Commissioning	Paper
9.	Calibration certificates of instruments	✔	During Commissioning	Paper
10.	Test certificates of components/test devices	✔	During Commissioning	Paper
11.	Electrical drawings	✔	During Commissioning	Paper/CD

11. CHANGE CONTROL PROCEDURE PROTOCOL:

Change Control Report:

Description of Change Control	As per enclosed annexure

Change Control Protocol Generation:

Generated by	Name	Designation	Sign	Date
Wimco Ltd.		Design Engineer		

Change Control Protocol Approval:

Approved by	Name	Designation	Sign	Date

Manufacture		**Design Engineer**		

S.No	Page No.	Clouse No.	Original Specification	Revised Specification	Change Proposed by	Reason for Change
1.						
2.						
3.						
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8.						
9.						

Customer				

12. DESIGN QUALIFICATION REPORT:

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Summary

Conclusion

13. DESIGN QUALIFICATION REPORT APPROVAL:

Remark: Approved/Not Approved

Department	Name, Designation	Signature	Date
For, ……..			
For, M/s. Wimco Ltd.			
Design Engineer			

14. APPENDIX:

A) Abbreviations

Abbreviations	Full Form
PO	Purchase Order
MOC	Material of Construction
CIP	Clean in Place
SIP	Sterilization in Place
DQ	Design Qualification
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
FAT	Factory Acceptance Test
Temp.	Temperature
TPM	Tubes per minute.
LPM	Liter per minute
RPM	Revolution per minute
HP	Horse Power
H_Z	Hertz