DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI FILLING LINE

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI	PROTOCOL No.:

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PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI	PROTOCOL No.:

1.0 PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of Double head Tube filling machine GAN Combi (Make: ……..).
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Production	• Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution.
Engineering	• Review of the Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e. ➢ GA Drawing. ➢ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/ brochures. ➢ Details of utilities. ➢ Identification of components for calibration. ➢ Material of construction of all components. ➢ Brief Process Description. ➢ Safety Features and Alarms. • Review of Qualification Protocol after Execution.

5.0 BRIEF EQUIPMENT DESCRIPTION:

Application:

Double Head Tube Filling Machine is used for Filling and Sealing/closing of Lami/Plastic tube of Dia.16-50mm (beyond Ø42 tube machine will operate on single head) with filling variation of 2 cc to 250 cc depending on the material properties.

Major System Components: Tube filling Machines is comprised of following major subassemblies/ Components.

Automatic Tube Loading on Machine:

Consist of Polycarbonate Cassettes with S.S.304frame, Al tube tilter, Cassette motor and S.S.304 Rocker.

Tube Registration Device:

Two Stepper motors attached to Magnetic lifting head, S.S 304 cone, and Color mark Sensors.

Tube Cleaning:

Tube cleaning by means of suction & ionized compressed air by ionized system.

Tube Filling Device.

S.S 316L Jacked Hopper with 75 liters capacity having surface finish of internal 0.5Ra & external 0.9 Ra, mounted on the machine. Jacketed hopper fitted with cover, electrical, digital temperature controller, level sensor, & cream stirring device which stirs the material to make it free flow with separate motor & VFD (Allen Bradley).S.S 316L-make nozzle with air blow off device attached to the reciprocating S.S. pump.

Complete material transfer device (from hopper to filling nozzle) is made of SS 316L.Tubes gets sealed and coated at tubes sealing at coding station and extra sealed tube gets cut and removed at trimming station and required tube length dimension gets maintained. Good fill tubes can be ejected at ejection station.

For Lami /Plastic 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.

DK-20 P&F (Visolex) make photo scanner is provided for ensuring wrong orientation & no Filling of tube (no I-mark no filling), tube automatically gets rejected at rejection side in empty Condition (it is in interlock).

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared for manufacturer of equipment ensures complies with User Requirement Specification.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical variables	Acceptance criteria	Reference
Application: Double head tube filling machine is designed to fill ointment different weights in different sizes of tubes	Should be able to filled weight accurately with minimal spillage.	Process Requirement
Working: The machine works on vacuum filling principle.	Filling of material should be highly accurate.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

7.2 UTILITIY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Voltage : 440 VAC Phase : 3 Phase Frequency : 50 HZ	GMP Requirement
Room Condition	Temperature NMT 25 ºC RH : NMT 55 %	Process Requirement
Compressed Air supply	6 Kg/cm^2 or 650 LPM / 25 CFM	Process Requirement
Chilled Water	Temp. at Lamisealer outlet 8-10ºC or Volume 8 LPM	Process Requirement
Vacuum	650-700 mmHg	Process Requirement

7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.No.	Critical Variables	Details				
GENERAL						
1.	Product can be filled	Cream, Gel, Toothpaste, Ointment, Adhesive				
2.	Viscosity	500 - 3000 CPS				
3.	Packing style	Lami & Metal Tubes				
4.	Filling Range	1 cc to 250 cc with corresponding change of pistons - 15mm (2.5-9cc),30mm(7-72cc) & 45mm (17-150cc), 60mm (31–250cc)				
5.	Tube sizes	**Parameter**	**Lami/Plastic Tubes**		**Aluminium Tubes**	
			Min	**Max**	**Min**	**Max**
		Dia.	16	50	10	50
		Cylindrical length for conical cap or total length including cap for inline cap tube (mm)	80	205	80	205
6.	Machine speed	Machine is designed for dry run of max of 120 Cycles / minute (approx.). Actual output will depend upon the fill weight, product Viscosity, MOC of the tube and skill of the operator. For 15gm - 50gm – 100 tubes / minute (Approx.) Machine speed is controlled through VFD				
7.	Minimum changeover time	Setting & changeover time will be 45 minutes(Approx.), depends On operator skill & degree of change over. This is estimated Without cleaning, drying & other activities.				
8.	Product filling accuracy	±0.5% of fill weight. For 5g ± 3%				
AUTOMATIC DOUBLE HEAD TUBE IN-FEED DEVICE/SYSTEM						
9.	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.				
10.	Cassettes	Qty. : 04 Nos. MOC : Polycarbonate Frame MOC: SS and Aluminium Function : It reserves the tubes where operator loads the tubes from The corrugated box and feeds into the tilter.				

S.No.	Critical Variables	Details
11.	Tube Tilter	Qty. : 02 Nos. MOC : Aluminium Function : Tilter inserts the tubes in the machine holder.
12.	Rocker	Qty. : 02 Nos. MOC : SS 304 Function : It rocks the tubes if the tubes get seized inside the cassette Box.
13.	Tube Holders	Station : 59Nos. (54nos with machine & extra 5 Nos. is free supply) MOC : Anodized Aluminum Function : Holders with nylon grippers & stainless steel springs are used for holding tubes
14.	Ferguson Drive	Description : This is indexing mechanism, which provides indexing motion to the tube holder chain for performing the machine operations in different stations Specification: Input – 120 Degree Output – 90 Degree
15.	Cassette Motors	Make : Associate Qty. : 02 Nos. 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. Specification: Rating –220V, 50Hz, 0.22A, NFLP, 0.06 W,80RPM
TUBE REGISTRATION DEVICE		
16.	Description	Consists of two Stepper motors attached to Magnetic lifting head, S.S304 cone, Colour mark Sensors

S.No.	Critical Variables	Details
17.	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. Qty. : 02 Nos. Make : P & F (Visulax) Model : DK-20 Specification: 24 vdc PNP, NO
18.	Stepper Motors	Qty. : 02 Nos. Make : Gennext Control Rating : 6vdc, 1.4Amp. Function : It orients the tubes for correct positioning of the "I" mark.
TUBE CLEANING DEVICE		
19.	Description	Tube cleaning is carried out by means of ionized compressed air purged into the tube, after purging the suction cup provided inside the Cleaning unit sucks the waste particles from the tube.
20.	Quantity	01No.
TUBE FILLING DEVICE/SYSTEM		
21.	Description	S.S 316L-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.
22.	Filling System	This assembly contains main pump housing, sleeve (Nylon), valve & piston rod. Pump size depends upon the fill weight of the tube. The size of the pump is15mm (1-6cc), 30mm (6-72cc) & 45mm (20-150cc).
23.	Filling Mechanism	Cam operated progressive filling with mechanical adjustment provided for fine setting of fill weight.

S.No.	Critical Variables	Details
24.	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. Qty. : 02 Nos. Make : P & F Model : NBB5 Specification : 10-40 v dc, PNP NO, 0-200mm
25.	Hopper	Description : 75 liters SS – 316L jacketed hopper with cover fitted With electrical heater. Qty. : 01 Nos. Type : Jacketed
26.	Level Sensor for Hopper	Make : Carlogavazzi Model : UA18CLD09K Range : 100-600mm Voltage : 18-30 v dc O/P : 0 to 10 v analogue Qty : 01 Nos.
27.	Jacket Heater	Make : Girish Specification : Rating – 230V A.C.750W, Qty : 01 Nos.
28.	Temperature Sensor in Hopper	Type : PT 100, 3 Wire type, 'K' Type RTD Qty : 01 Nos. MOC : Thermo well SS316L Sensor SS 316L End Conn. : ½" BSP Range : 0º to 400ºC Specification: Class 'A'
29.	Cream Stirring Device	Description : Stirrs the material to make it free flow with separate motor with VFD

S.No.	Critical Variables	Details
30.	Stirrer Motor	Make : Bonifiglioli Quantity : 01 Nos. Power : 0.5 HP Voltage : 415V RPM : N1-1380, N2- 40 RPM IP Class : IP55 Type : NFLP
31.	A.C. Drive for Stirrer	Make : Allen Bradley Quantity : 01 Nos. Model : Power flex 4 M Specification : 1.0 HP, 415V, 50 Hz
32.	Shut off nozzle	Description : Pneumatic operated blow off pipe is used inside the filling Nozzle for tail free dozing. MOC : SS 316L
TUBE CLOSING DEVICE (COMBI SEALER)		
33.	Description	Can seal both Lami /plastic & 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.(One set of 2mm coding punches 0-9 & A-Z is Provided with the machine).
34.	Heaters	Make : Lister Quantity : 02Nos. Specification : Rating – 230v, 3.3 kw
35.	Hot Air Blower	Make : Lister Quantity : 01Nos. Specification : Rating –415v, 50HZ, 0.33kw, 2850rpm, 1200 liters/min.

S.No.	Critical Variables	Details
36.	Temperature Sensors in Hot Air Nozzle / Controller	Make : Microcon Quantity : 02Nos. Specification : Class 'A' Type : 2 Wire type, Thermocouple 'K' type MOC : Thermo well ,SS316L Sensor SS 316L End Conn. : ½" BSP Range : 0º to 800ºC
37.	Coding Unit	Description : One set of each Alfa/numeric coding punches 2 mm (0-9 and A-Z) is provided with the machine to punch in the product as per the user defined Code.
CENTRAL LUBRICATION SYSTEM		
38.	Description	It lubricates to the moving parts of the entire machine periodically
39.	Lubrication Pump	Make : Dropco Quantity : 02Nos. Specification: Rating –230V, 50 HZ, 2.3 Amp., 1350 RPM. IP55, NFLP, 90W
CONTROL DEVICES/SYSTEMS		
40.	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 : 01Nos. Power : 1.5 HP Voltage : 415V,50Hz RPM : 1440 RPM Current : 2.5Amp. Type : TEFC type
41.	Encoder	Make : Kubler Quantity : 01Nos. Specification: Rating – 10-30 vdc, 100 mA,360 ppr

S.No.	Critical Variables	Details
42.	Gear Box for Main Motor	Make : Greaves Reduction Ratio : 15:1
43.	A.C. Drive for Main Motor	Make : Allen Bradley Quantity : 01Nos. Specification : 2.0 HP, 415V, 50 Hz Model : Power flex 4 M Location : Control Panel Function : To control the main motor speed
44.	PLC	Make : Allen Bradley Quantity : 01Nos. Specification : 19 Input & 11Output AI4 Model : Micrologix 1400 B x BA
45.	MMI	Make : Allen Bradley Quantity : 01Nos. Specification : 24 vdc Model : Component C600
46.	Electronic product counter & time Totaliser	Provided (Product counting is based on filling stroke. After pressing machine start push button time totaliser starts)
47.	Power Supply	Description : Provided in electrical panel provided for giving supply to PLC & HMI Make : Shavison Quantity : 01Nos. Specification : Input-230v A.C. O/P- 24v D.C Model : G31-120-24
48.	Home Position	Description : Provided on main shaft for insuring machine home position Make : P & F Quantity : 01Nos. Specification : 10-40 v dc, PNP NO Model : NBBS
49.	Jogging device	Description : One Machine Jogging switch with cable is provided for Easy machine maintenance & set-up.

S.No.	Critical Variables	Details
50.	Indicator Tower Lamp	Description : Electrical Indicator for stop/ready/run status is provided on the machine as tower lamp Specification : 24 V DC
51.	Machine Guards	Tubular covers provided made of SS 304 sheets with matt finish & square Profile members & also fitted with polycarbonate sheets.
52.	Mechanical overload clutch	Machine stop if get jam for any reason with help of self-centering over load clutch.
53.	Hand Wheel	Provided for manual settings for CAM orientation / Check Machine load.
54.	Pneumatic System for No Tube No Fill (solenoid)	Make : Festo Quantity : 02Nos. Specification : 24 vdc 4.5w, 50/60 Hz Model : MSFG-24 Location : Pneumatic panel. Function : To ensure the filling material does not come out of the Nozzle when there is no tube present.
55.	Pneumatic System for Trimming	Make : Festo Quantity : 02Nos. Specification : 24 vdc 4.5w, 50/60 Hz Model : MSFG-24 Function : It blows the trimming chip of the sealed tube to the Trimming chute. Further the chip sucks to the trim collector box by a vacuum extractor.
56.	Pneumatic System for Hot Air Sealing	Make : Festo Quantity : 02Nos. Specification : 24 vdc 4.5w, 50/60 Hz Model : MSFG-24 Function : It provides the continue air to the hot air unit which heats The tube before sealing.

S.No.	Critical Variables	Details
57.	Pneumatic System for Tube Ejection	Make : Festo Quantity : 02Nos. Specification : 24 vdc 4.5w, 50/60 Hz Model : MSFG-24 Function : In this station tube gets ejected after sealing or folding. There are 3- Ejection system fitted on the machine. **1. Side ejection –** Good tube will be ejected from this ejection system. It can be used for online cartooning or connecting to the conveyor for Manual packing. **2. Center ejection –** Bad tube will be ejected from this ejection system. SS 304 bin for collecting bad tubes. How the system distinguish b/w good & bad tube? (Tube are sensed at orientation station / Pharma code reader it the feedback given by reader is bad it will go to bad tube or else in good tube) **3.** By pass tube ejection. There should be one more interface b/w Cartoner & tube filling m/c, which stop filling once the Cartoner stops. Utilization of the same can be evaluated once production starts-There are no Provision possible for such interlock. If Cartoner stops the good tubes will Go into by pass ejection. **3.1.** In case if Cartoner stops good tube will be ejected from this side. **3.2.** In case for manual packing we will bypass the system, so as to get good tube from this side ejection
58.	Pneumatic System for Blow Off	Make : Festo Quantity : 02Nos. Specification : 24 vdc 4.5w, 50/60 Hz Model : MSFG-24 Function : To Prevent the material from hanging from the nozzle a Hollow pipe with air blow is fitted inside the nozzle. The Strength of airflow can be adjusted with flow control valve.

S.No.	Critical Variables	Details
59.	Safety Switches	Make : Telemechnic Quantity : 07Nos. Type : Potential free contact Model : XCS Function : To stop the machine during Auto RUN If frame doors Open. These switches are mounted on frame & actuator Fitted on doors.
60.	Limit Switch	Make : Jai Balaji Quantity : 02Nos. Type : Potential free contact Model : BC9 Function : This switch gives signal to stop the machine if one of Unejected tubes come to in-feed station. It is fitted after Center ejection on machine.
61.	Micro Switch for machine O/L Sensor	Make : P & F Quantity : 01Nos. Type : Potential free contact Model : NBB5 Function : 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
62.	Air pressure switch	Make : Festo Quantity : 01Nos Model : Pev ¼ B Type : Potential free contact Function : 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.

7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of construction
1.	Syringe mounting bracket	SS 316
2.	Outlet filling bracket	SS 316
3.	Ring	SS 316
4.	Bearing housing-01	SS 316
5.	Piston (right)	SS 316
6.	Piston (right)	SS 316
7.	Filling block	SS 316
8.	Knurling nut	SS 316
9.	Capillary lock bracket	SS 316
10.	Hopper	SS 316
11.	Tube leveling rod	SS 316
12.	Syringe	SS 316
13.	Nozzle	SS 316

7.5 SAFETY:

Critical Variables	Specified Function	Reference
Machine Overload Clutch	To stop the machine in case of overload.	Safety Requirement
Machine is enclosed with SS 304 structural members with Polycarbonate sheet.	For Operator Safety.	Safety Requirement
Pressure Gauge Make:- Festo Model:- LFR-5D-Mini Range:- 0-16 bar	To Indicate pressure of air.	Safety Requirement
Lock for SS control Panel	For Instruments safety	Safety Requirement
Position stop.	To stop the machine when the tube holder Position is on lower side.	Safety Requirement
Emergency Switch	To stop the machine in case of emergency Stoppage.	Safety Requirement
No Tube no fill Sensor	To give signal to filling station for filling.	Safety Requirement
Safety during tube ejection	Machine stop when not ejected.	Safety Requirement

7.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Double head Tube filling machine GAN combi.	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Reference: (1) Specifications and Requirements as specified in P.O. and URS.

(2) Operating and service manual for Double head tube filling machine GAN combi.

8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy.
- Any other relevant documents.

9.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATIONS:

URS	:	User requirement specification
cGMP	:	Current Good Manufacturing Practice
PO	:	Purchase Order
Kg	:	Kilogram
Hr	:	Hour
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
P & ID	:	Piping and Instrumentation Diagram
MCB	:	Miniature circuit breaker
HMI	:	Human Machine interface
db	:	Decibel
RH	:	Relative Humidity
OFS	:	Double head fully automatic filling, closing and sealing machine
SS	:	Stainless Steel

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY CONTROL)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			