



**DESIGN QUALIFICATION PROTOCOL CUM REPORT
FOR
DOUBLE HEAD AUTOMATIC FILLING, CLOSING AND
SEALING MACHINE**

PROTOCOL No.:

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
DOUBLE HEAD FULLY AUTOMATIC
FILLING, CLOSING AND SEALING
MACHINE**

DATE OF QUALIFICATION

SUPERSEDE PROTOCOL No.

NIL



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1.0 PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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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 fully Automatic filling, closing and sealing machine (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.



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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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> ➤ 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.



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5.0 BRIEF EQUIPMENT DESCRIPTION:

The Automatic linear plastic & aluminum tube filling machine is heavy duty machine designed with high speed for filling the plastic as well as aluminum tubes.

The operator has to feed the product inside the jacketed hopper. The tube from the cassette box passes to each and every station for performing the filling operation of filling is described thoroughly.

A separate control and operator panel with HMI screen is supplied with this machine. The panel contains electronic as well as electrical components which are highly rated.

All the safety features are provided in the machine, which are as per the GMP standard and is in compliance with set industrial standards.

FUNCTION DESCRIPTION OF MACHINE:

1. Jacketed Hopper
2. Auto feeding Unit
3. Filters
4. Tube pusher
5. Orientation station
6. Hot air station
7. Sealing unit
8. Trimming unit
9. Ejecting / discharge unit
10. Cam unit
11. Operator panel
12. HMI screen

Components for aluminum Tube filling

1. First Crimping
2. Second Crimping
3. Batch Code

6.0 EQUIPMENT SPECIFICATION:

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



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7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical variables	Acceptance criteria	Reference
Application: Double head fully automatic filling , closing and sealing 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 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Voltage : 415 VAC Phase : 3 Phase Frequency : 50 HZ & 51 Amp.	GMP Requirement
Room Condition	Temperature NMT 25 °C RH : NMT 55 %	Process Requirement
Compressed Air supply	6 Kg/cm ²	Process Requirement



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7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.No.	Critical Variables	Acceptance Criteria
1.	Commercial Data	
•	Model	PK 120 combo linear
•	Manufacturer	Parle Kovai Technologies Pvt. Ltd.
•	Machine name	Double head fully automatic filling , closing and sealing machine
•	Machine Serial No.	
2.	Mechanical Data	
•	Dimensions	2765 mm X 1300 mm X 2480 mm
•	Weight	2500 kg. approx.
3.	Electrical Data	
•	Machine Voltage	415 Voltage AC, Single phase, 50 Hz
•	Power Supply	415 Voltage AC, Single phase, 50 Hz
•	Main cable Size	1.5 mm ² 4 core
4.	Main motor details	
•	Make	M.G.M. motors
•	Model	BA100LA4
•	HP	3 HP
5.	Motor Gear Box	
•	Make	VARVEL
•	Ratio	15
6.	Stirrer Motor Details	
•	Make	ZHEJIANG TAIZHOU
•	Model	Y2-905-6 814
•	HP	1 hp
•	Phase	3
•	RPM	910



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S.No.	Critical Variables	Acceptance Criteria
7.	Motor Gear Box	
•	Make	ZHEJIANG TAIZHOU
•	Ratio	1:10
8.	Pneumatic Pressure	
•	Pneumatic Pressure	5 – 6 kg / cm ²

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



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7.5 SAFETY:

Critical Variables	Specified Function	Reference
Caution labels electrical panel cover on main machine and on accumulator electrical enclosure terminal boxes motor	For Operator Safety.	Safety Requirement
Moving components and drives enclosure for operator safety	For Operator Safety.	Safety Requirement
SS doors on the machine Body	For Motor, equipment protection & Operator Safety	Safety Requirement
Poly Carbonate Door on the machine	For Motor, equipment protection & Operator Safety	Safety Requirement
Proper ferruling's on the cable for proper traceability	For Motor, equipment protection & Operator Safety	Safety Requirement
Emergency stop switch on the operator panel	For Operator Safety.	Safety Requirement
MCB inside the control panel to cut off the power supply if any short circuit occurs.	For Operator Safety	Safety Requirement
Safety labels on the machine to avoid the hazards.	For Motor, equipment protection & Operator Safety	Safety Requirement



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7.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Double head fully automatic filling, closing and sealing machine.	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 fully automatic filling, closing and sealing machine.

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.



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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



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13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			