



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
SIX HEAD LOTION FILLING MACHINE**

**PROTOCOL No.:**

**DESIGN QUALIFICATION  
PROTOCOL  
CUM REPORT  
FOR  
SIX HEAD LOTION FILLING MACHINE**

**DATE OF QUALIFICATION**

**SUPERSEDES PROTOCOL No.**

**NIL**



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**1.0 PROTOCOL 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 document for Premix Filling machine on basis of URS and information given by Supplier.
- To ensure that all Critical Aspects of Process / Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

**3.0 SCOPE:**

- The Scope of this Qualification Document is limited to the Design Qualification for Premix Filling machine with cGMP Model procured.
- The drawings and P & IDs provided by Vendor shall be verified during Design Qualification.



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**4.0 RESPONSIBILITY:**

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

DEPARTMENTS	RESPONSIBILITIES
<b>Quality Assurance</b>	<ul style="list-style-type: none"> <li>• Preparation, Approval and Authorization of the Protocol cum Report.</li> <li>• Assist in the verification of Critical Process Parameters &amp; Drawings as per the Specification.</li> <li>• Post Approval of Qualification Protocol cum Report after Execution.</li> <li>• Co-ordination with Production and Engineering to carryout Design Qualification.</li> <li>• Monitoring of Design Qualification Activity.</li> </ul>
<b>Production</b>	<ul style="list-style-type: none"> <li>• Review of the Protocol cum Report.</li> <li>• Assist in the verification of Critical Process Parameters &amp; Drawings as per the Specification.</li> <li>• Post Approval of Qualification Protocol cum Report after Execution</li> </ul>
<b>Engineering</b>	<ul style="list-style-type: none"> <li>• Review of the Protocol cum Report.</li> <li>• Assist in the Preparation of the Protocol cum Report.</li> <li>• To co-ordinate and support the Design Qualification Activity.</li> <li>• To assist in Verification of Critical Process Design Feature &amp; Drawings as per the Specification.</li> <li>• Specification of the sub-components/ bought out items, their Make, Model, Quantity and backup records / brochures.</li> <li>• Details of utilities</li> <li>• Material of construction of all components</li> <li>• Brief Process Description</li> <li>• Safety Features and Alarms</li> <li>• Post Approval of Qualification Protocol cum report after Execution</li> </ul>



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**5.0 BRIEF ABOUT EQUIPMENT:**

It is a Fully Automatic Volumetric Filling machine. A Square fabricated out of S.S.316L imported sheet is provided at the center of filling section at both side of which 6equidistant piston- Cylinder assemblies are mounted. The volume in all the cylinders can be adjusted by adjusting the ring. Also, micro settings up to ½ ml can be done by turning the knob of square guide blocks in desired direction. The complete machine has been constructed in ASTM and AISI grade S.S.304/SS316sheets/plates/rods. All product contact parts are in S.S.316 and filling bowl in S.S316L to make the machine chemically inert.

**6.0 EQUIPMENT SPECIFICATION:**

Equipment Specification document is provided to manufacturer for engineering equipment & Some critical variables to be met during designing the equipment.

**7.0 CRITICAL VARIABLES TO BE MET:**

**7.1 PROCESS PARAMETERS:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
<b>Application:</b> Conveyer Speed	Conveyor Speed Should be facillate the easy and efficient as per product requirement i.e.4500 bottles/Hr.	Process Requirement
<b>Working:</b> Working on Six Head Lotion Filling Machine	Six Head Lotion Filling Machine should be facillate the easy & efficient working during the course of the filling operations.	Process Requirement
<b>Electrical Control Panel</b>	The system should have Electrical Control Panel.	Approved Design Requirement
<b>Safety Feature</b>	Various Safety Features Should be provided to the equipment	Process Requirement



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**7.2 UTILITY REQUIREMENTS / LOCATION SUITABILITY :**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
Utility connections should be available as per the specification.		
Electrical Supply	The electrical system of the equipment shall be housed as per the cGMP and cGEP standards, with adequate safety. Electrical panel and electro pneumatic panel is to be installed in the service area.	Approved Design Requirement
Compressed air supply	Should be oil & dust free.	As Per Approved Design Requirement
Room Condition	Temperature : NMT 25°C RH : NMT 55%	Process Requirement



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**7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:**

CRITICAL VARIABLES		ACCEPTANCE CRITERIA	REFERENCE
Equipment		Six Head Lotion Filling Machine	Hari Krushna. Engineering
Model No.		cGMP Model.	As Per Approved Design Requirement
Capacity		4500 Bottles/hr. (For 10 ml to 200 ml)	As Per Approved Design Requirement
Direction		Left to Right	As Per Approved Design Requirement
Fill Capacity		10 ml to 200 ml Fill range depending upon bottle opening and bulk density.	As Per Approved Design Requirement
Electrical Supply		3.0 HP	As Per Approved Design Requirement
Power Requirement		415 Volts, 3 Phase (4 Wire System), 50 Hz.	As Per Approved Design Requirement
Conveyor motor	Make	SMPS	As Per Approved Design Requirement
	HP	1.0HP	
	RPM	1300 RPM	
	Type	Flanged	
Geared Motor	Make	SMPS	As Per Approved Design Requirement
	HP	1 HP	
	RPM	1360 RPM	
Cylinder	50 ml	06 Nos.	As Per Approved Design Requirement
	100 ml	06 Nos.	As Per Approved Design Requirement
	200 ml	06 Nos.	As Per Approved Design Requirement
Pneumatic Valve	Festo	02 Nos.	As Per Approved Design Requirement
Storage Tank	Propack Technology	01 Nos. SS 316	As Per Approved Design Requirement



**7.4 MATERIAL OF CONSTRUCTION :**

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Machine shell	SS 304
2.	Filling Nozzle	SS316
3.	Conveyer	SS 304
4.	Storage tank	SS316
5.	Cylinder	SS316
6.	Conveyor Slats	SS 304
7.	Sheet, plate. rods	SS 304

**Checked By**  
**Production**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:** .....

**Inference:**

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 .....  
 .....

**Reviewed By**  
**Manager QA**  
**Sign / Date:** .....

**7.5 SAFETY:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
MCB	MCB should be provided so that when there is an overload in current or any short circuit then the MCB trips.	Safety Requirement
Mechanical Guard	Mechanical guard for all rotating parts should be provided	Safety Requirement
Joints	Welding of joints should be Leaving without any welding burrs.	Safety Requirement
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.	Safety Requirement
Leveling And Balancing	Equipment should be Properly balanced & leveled.	Safety Requirement
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine (panel and motors) and operator should be provided.	Safety Requirement
Noise Level	Below 80 db.	cGMP Requirement
Emergency Switch	Provided easy access position.	Safety Requirement

**Checked By**  
**Production**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:** .....

**Inference:**

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**Reviewed By**  
**Manager QA**  
**Sign / Date:** .....

**7.6 VENDOR SELECTION:**

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for supplying the Premix Filling 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, feed back from market (customers already using the equipment)	Process Requirement

**Checked By**  
**Production**  
**Sign / Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign / Date:** .....

**Inference:**


.....  
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**Reviewed By**  
**Manager QA**  
**Sign / Date:** .....

**Reference:** (1) the equipment shall confirm to the specifications and requirement as specified in PO and URS  
 (2) Operating and service manual for Premix Filling 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 THE FORMALLY AGREED PARAMETERS:**

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**11.0 RECOMMENDATION:**

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**12.0 ABBREVIATION:**

URS	:	User Requirement specification
DQ	:	Design Qualification
PO	:	Purchase Order
cGMP	:	Current Good Manufacturing Practice
cGEP	:	Current Good Engineering Practice
Ltd.	:	Limited
QA	:	Quality Assurance
PO	:	Purchase Order
Kg	:	Kilogram
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
P & ID	:	Piping and Instrumentation Diagram
Db	:	Deci bel



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**13.0 REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (ENGINEERING)</b>			

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			