



**DESIGN QUALIFICATION PROTOCOL CUM REPORT  
FOR  
AUTOMATIC SIX HEAD LIQUID FILLING AND SEALING  
MACHINE**

**PROTOCOL No.:**

**DESIGN QUALIFICATION  
PROTOCOL  
CUM REPORT  
FOR  
AUTOMATIC SIX HEAD LIQUID  
FILLING AND SEALING MACHINE  
LIQUID LINE**

**DATE OF QUALIFICATION**

**SUPERSEDES PROTOCOL No.**

**NIL**



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**1.0 PROTOCOL 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)			



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**2.0 OBJECTIVE:**

- To prepare the Design Qualification document for Automatic Six Head Liquid Filling and Sealing 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 Automatic Six Head Liquid Filling and Sealing Machine with cGMP Model procured.
- The drawings and P & ID's 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, Review 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 and Approval 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:**

The Automatic Six Head Filling and Sealing machine is divide into two Parts.

**Filling Process:**

The Six Head Automatic Filling machine Shall be Used to Filling by six head also work on Volumetric filling Principal, Whom fills with the help of vacuum and maintain the level of liquid in bottles on specified size and shape of bottles.

It is Comprises of Main Electric Panel with VFD, Relay, Operating panel, emergency switch & Push buttons, Nozzles Drive Assembly, Mechanical Stoppering System & Mechanical operation with motor gear box, cam, gears etc.

**Sealing Process:**

The Equipment shall be used to sealing with die by six head on specified size & shape of Bottle. Machines are equipped with cap feeder system for Continuous trouble free cap feeding.

It Comprises of Conveyer unit , Worm Assy, Star plate set sealing head Assy, Vibrator Bowl, Control Panel.

**6.0 EQUIPMENT SPECIFICATION:**

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



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**7.0 CRITICAL VARIABLES TO BE MET:**

**7.1 PROCESS PARAMETERS:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
<b>Application:</b> Conveyer Speed	Conveyor Speed Should be facilitate the easy and efficient as per product requirement i.e.40-80 bottles/min.	Process Requirement
<b>Working:</b> Working on Automatic Six Head Liquid Filling and Sealing Machine	Automatic Six Head Liquid Filling and Sealing Machine should be facilitate the easy & efficient working during the course of the filling and Sealing 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

**7.2 UTILITY REQUIREMENTS / LOCATION SUITABILITY :**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
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 65%	Process Requirement



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

CRITICAL VARIABLES		ACCEPTANCE CRITERIA	REFERENCE
<b>Filling Unit</b>			
Equipment		Automatic Six Head Liquid Filling and Sealing Machine	.....
Model No.			As Per Approved Design Requirement
Capacity		40-80 bottle / Min.	As Per Approved Design Requirement
Filling Accuracy		± 1%	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
Power Requirement		415 Volts, 3 Phase (4 Wire System), 50 Hz.	As Per Approved Design Requirement
Conveyer	Type	Slat Chain	As Per Approved Design Requirement
	Size	90 mm	
	MOC	SS 304	
Conveyor motor	Make	Rotomotive	As Per Approved Design Requirement
	HP	0.5 HP	
	RPM	1350 RPM	
	Type	71B-4	
	KW	0.37 Kw	
Gear box for Conveyer	Make	Rotomotive	As Per Approved Design Requirement
	Model	Box 040	
	Ratio	i-30	
	S. no.	G02170823	
	PAM	71B14	
VFD for Conveyer Motor	Make	Delta	As Per Approved Design Requirement
	Model	VFD004L21A	
	KW/HP	0.4/ 0.5	
	I/P	1Ø -6.5 Amps. , 3Ø -2.7 amp., 200-240V , 50/60 Hz	
	O/P	3Ø, 0-240V, 2.5 amps. 1.0 KVA -0.5 HP	





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CRITICAL VARIABLES		ACCEPTANCE CRITERIA	REFERENCE
	Frequency Range	1-400 Hz	
	S. No.	004L21A6W16400322	
Main Motor	Make	Crompton greaves	As Per Approved Design Requirement
	Frame	ND80	
	KW/HP	0.75/1.0	
	RPM	1410	
	S. No.	PKG 21596	
Main Gear Box	Make	Chamunda	As Per Approved Design Requirement
	Model	2 2017	
	Centre	63 5	
	Ratio	30	
VFD for Main Motor	Make	Delta	As Per Approved Design Requirement
	Frame	VFD007EL43A	
	KW/HP	0.75 kw/1.0 Hp	
	I/P	3 Phase , 380-480V AC 50-60 Hz 3.2 A	
	S. No.	007EL43AW16360099	
Syringe	Type	50-250 ml	As Per Approved Design Requirement
	MOC	SS316	
	Qty.	06 Nos.	
Filling Nozzles	Type	10, 30 and 60 ml	As Per Approved Design Requirement
	MOC	SS 316	
	Qty.	06 Nos.	
PVC braided Hose For Nozzle	Make	Realon	As Per Approved Design Requirement
	Type	ID: 8mm, OD: 14 mm @ 10-30 ml ID: 12 mm, OD: 19 mm @ 50-250 ml	
PVC braided Hose For Syringe	Make	Realon	As Per Approved Design Requirement
	Type	ID: 15 mm, OD: 23 mm @ 10-30 ml ID: 20 mm, OD: 27 mm @ 50-250 ml	
No Bottle Sensor	Make	ESPL NASIK	As Per Approved Design Requirement
	Model	IRD 123	
	I/P supply	10-30 V DC	
	Type	PNP + NO	



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CRITICAL VARIABLES		ACCEPTANCE CRITERIA	REFERENCE
MCB	Make	Schneider	As Per Approved Design Requirement
	Model	XC60 C16A	
	Rating	16 amps.	
	Pole	4 pole	
Variable pot	Make	Potel	As Per Approved Design Requirement
	Qty.	02 nos.	
SMPS	Make	Lubi Electronics	As Per Approved Design Requirement
	Model	LE-A-24-0625	
	Rating	6.25 amp.	
	S. no.	61600947	
<b>Sealing Unit</b>			
Speed	80 Bottle / Min @ 15 ml 60 bottle / min @ 30 ml , 60 ml		As Per Approved Design Requirement
Rotating Direction For Conveyer	Clockwise from Operating panel		As Per Approved Design Requirement
Sealing Head	06 nos.		As Per Approved Design Requirement
Cap Size	25 mm Aluminum Round @ 30 & 60 ml 22 mm Aluminum Round & 15 ml		As Per Approved Design Requirement
Cap Bowl Type	Vibratory Bowl		As Per Approved Design Requirement
Main Motor	Make	Crompton Greaves	As Per Approved Design Requirement
	Frame	GD 90 L	
	KW	1.50	
	V	415 v ± 10 % 3.39 amp.	
	RPM	1420	
	S. No.	ITF2363	
Gear Box	Make	Chamunda	As Per Approved Design Requirement
	Model	3 2017	
	Ratio	50:1	
	Centre	63.5	
	Type	2 ½ NU	



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CRITICAL VARIABLES		ACCEPTANCE CRITERIA	REFERENCE
VFD	Make	Delta	As Per Approved Design Requirement
	Model	VFD015EL21A	
	KW/HP	1.5/2	
	I/P	1Ø , 200-240V, 50/60 Hz, 15.7 A	
	O/P	3Ø, 0-240V, 7.5 amps. 2.9KVA-2HP	
	Freq. Range	0.1-599 Hz	
	S. No.	015EL21AW16360550	
Vibrator Card	Make	Harikrushna	As Per Approved Design Requirement
	Model	HMPL/VC-230	
Relay	Make	Pla	As Per Approved Design Requirement
	Type	MPC-2C, 240A-5	
MCB	Make	HPL	As Per Approved Design Requirement
	Model	Rakshak	
	Rating	C10A	
Timer	Make	Emtech	As Per Approved Design Requirement
	Model	EPT2400	
	Type	Dual Timer	
	I/P supply	230 V AC	
No Cap Sensor	Make	P+F	As Per Approved Design Requirement
	Part Code	4 976 358	
	I/P supply	10-30 V DC	
Push Button	Make	Schneider	As Per Approved Design Requirement
	Qty	03 Nos.	
Selector Switch	Make	Schneider	As Per Approved Design Requirement



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**7.4 MATERIAL OF CONSTRUCTION :**

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Machine shell	SS 304
2.	Filling Nozzle	SS316
3.	Syringe	SS 316
4.	Hose Pipe	PVC Braided
5.	Conveyer	SS 304
6.	Storage tank	SS316
7.	CAM	SS304
8.	Conveyor Slats	SS 304
9.	Sheet, plate. rods	SS 304

**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
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.	Safety Requirement
No Cap sensor and No fill Sensor	Machine Should Stop	Safety Requirement
Emergency Switch	Provided easy access position.	Safety Requirement



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**7.6 VENDOR SELECTION:**

<b>CRITICAL VARIABLES</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REFERENCE</b>
Selection of Vendor for supplying the Automatic Six Head Liquid Filling 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, feed back from market (customers already using the equipment)	Process Requirement

**Reference:** (1) the equipment shall confirm to the specifications and requirement as specified in PO and URS  
(2) Operating and service manual for Automatic Six Head Liquid Filling 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

**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>			

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

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