



**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
AUTOMATIC SIX HEAD LIQUID FILLING & SEALING
MACHINE**

PROTOCOL No.:

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
AUTOMATIC SIX HEAD LIQUID
FILLING & SEALING MACHINE**

EQUIPMENT ID No.	
LOCATION	Filling & Sealing Room
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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1.0 PRE-APPROVAL:

REPAIRED 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 carry out the Installation Qualification of Automatic Six Head Liquid Filling & Sealing machine used in Production, “The process conforming that an item of equipment, or other system, as currently installed, meets its design qualification”.
- To confirm that the equipment and its components are as per the Specifications and Installed as per the Approved Design and complies with GMP practices.
- To prove that each Operation proceeds as per the Design Specification and the tolerances prescribed there in the document, are the same at utmost transparency.
- To ensure that there is sufficient information available to enable the equipment to operate and maintain safely, effectively and consistently.

3.0 SCOPE:

- The Protocol covers all aspects of Installation Qualification of Automatic Six Head Liquid Filling & Sealing machine used in Production.
- To verify that the correct hardware has been installed, system initializes correctly.
- To record the as built drawing numbers of equipment drawing, P & ID and circuit diagram.



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4.0 RESPONSIBILITY:

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

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Review and Approval of the Installation Qualification Protocol.• Co-ordination with Production and Engineering to carryout Installation Qualification.• Monitoring of Installation Process.
Production	<ul style="list-style-type: none">• Giving clearance to install the unit.• Execution of Installation Qualification activity.• Ensure that the equipment is installed as per protocol.• Review and Approval of Protocol cum report.
Engineering	<ul style="list-style-type: none">• To co-ordinate and support Installation Qualification activity.• Calibration of Process instruments.• Ensure that the equipment is installed as per protocol.• Review and Approval of Protocol cum report.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Automatic Six Head Liquid Filling & Sealing machine
Equipment	
Manufacturer's Name	
Model	
Supplier's Name	
Location of Installation	Filling and Sealing Room Liquid Line

6.0 SYSTEM DESCRIPTION:

The Automatic Six Head Filling and Sealing machine is dividing 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, and Control Panel.



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7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Piping and instrumentation diagram (P& ID).
- Electrical circuits diagram.
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction of components.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 General checks and location suitability:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN / DATE
Leveling	Should be properly balanced and Leveled		
Edges of parts	The Metal parts should be properly grounded without any sharp edges		
Welding of Joints	Welding of joints should be without any Welding Burrs		
Place of Installation			
Room Condition	General working condition.		
Illumination in area	Above 300 Lux inside the cubicle.		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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8.2 EQUIPMENT VERIFICATION:

Before the equipment is operated, certain checks are to be completed:

Installation Checks	Acceptance criteria		Observation	Checked By (Engineering)
Equipment	Automatic Six Head Liquid Filling and Sealing Machine			
Model No.				
Capacity	60-80 bottle / Min.			
Filling Accuracy	± 1%			
Direction	Left to Right			
Fill Capacity	10 ml to 200 ml Fill range depending upon bottle opening and bulk density.			
Power Requirement	415 Volts, 3 Phase (4 Wire System), 50 Hz.			
Conveyer	Type	Slat Chain		
	Size	90 mm		
	MOC	SS 304		
Conveyor motor	Make	Rotomotive		
	HP	0.5 HP		
	RPM	1350 RPM		
	Type	71B-4		
	KW	0.37 Kw		
Gear box for Conveyer	Make	Rotomotive		
	Model	Box 040		
	Ratio	i-30		
	S. no.	G02170823		
	PAM	71B14		
VFD for Conveyer Motor	Make	Delta		
	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		
	Frequency Range	1-400 Hz		
	S. No.	004L21A6W16400322		



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Installation Checks	Acceptance criteria		Observation	Checked By (Engineering)
Main Motor	Make	Crompton greaves		
	Frame	ND80		
	KW/HP	0.75/1.0		
	RPM	1410		
	S. No.	PKG 21596		
Main Gear Box	Make	Chamunda		
	Model	2 2017		
	Centre	63 5		
	Ratio	30		
VFD for Main Motor	Make	Delta		
	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		
	MOC	SS316		
	Qty.	06 Nos.		
Filling Nozzles	Type	10, 30 and 60 ml		
	MOC	SS 316		
	Qty.	06 Nos.		
PVC braided Hose For Nozzle	Make	Realon		
	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		
	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		
	Model	IRD 123		
	I/P supply	10-30 V DC		
	Type	PNP + NO		
MCB	Make	Schneider		
	Model	XC60 C16A		
	Rating	16 amps.		



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Installation Checks	Acceptance criteria		Observation	Checked By (Engineering)
	Pole	4 pole		
Variable pot	Make	Potel		
	Qty.	02 nos.		
SMPS	Make	Lubi Electronics		
	Model	LE-A-24-0625		
	Rating	6.25 amp.		
	S. no.	61600947		
Sealing Unit				
Speed	80 Bottle / Min @ 15 ml 60 bottle / min @ 30 ml , 60 ml			
Rotating Direction For Conveyer	Clockwise from Operating panel			
Sealing Head	06 nos.			
Cap Size	25 mm Aluminum Round @ 30 & 60 ml 22 mm Aluminum Round & 15 ml			
Cap Bowl Type	Vibratory Bowl			
Main Motor	Make	Crompton Greaves		
	Frame	GD 90 L		
	KW	1.50		
	V	415 v ± 10 % 3.39 amp.		
	RPM	1420		
	S. No.	ITF2363		
Gear Box	Make	Chamunda		
	Model	3 2017		
	Ratio	50:1		
	Centre	63.5		
	Type	2 ½ NU		
VFD	Make	Delta		
	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		



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Installation Checks	Acceptance criteria		Observation	Checked By (Engineering)
	Freq. Range	0.1-599 Hz		
	S. No.	015EL21AW16360550		
Vibrator Card	Make	Harikrushna		
	Model	HMPL/VC-230		
Relay	Make	Pla		
	Type	MPC-2C, 240A-5		
MCB	Make	HPL		
	Model	Rakshak		
	Rating	C10A		
Timer	Make	Emtech		
	Model	EPT2400		
	Type	Dual Timer		
	I/P supply	230 V AC		
No Cap Sensor	Make	P+F		
	Part Code	4 976 358		
	I/P supply	10-30 V DC		
Push Button	Make	Schneider		
	Qty	03 Nos.		
Selector Switch	Make	Schneider		

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8.3 INSTALLATION VERIFICATION:

The components of the system are inspected so as to verify that they are present and documented properly. Any incorrect installations or any deviations from specification are to be documented.

S.No.	VARIABLE	OBSERVATION
1.	Check the proper mechanical installation of Automatic Six Head Liquid Filling & Sealing machine	
2.	Check the proper alignment of Automatic Six Head Liquid Filling & Sealing machine.	
3.	Check the proper electrical installation of Automatic Six Head Liquid Filling & Sealing machine	
4.	Check the proper Mechanical Safety of Automatic Six Head Liquid Filling & Sealing machine	
5.	Check the proper service connection such as compressed air supply, and illumination of Dry Syrup filling machine	
6.	Check the parts are working properly	
7.	Check the equipment is free from any defects	
8.	Check the finishing of product contact parts	
9.	Check that all parts are getting lubricated	

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Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Sign/Date:



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8.4 VERIFICATION OF MATERIAL OF CONSTRUCTION:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION	OBSERVATION
1.0	Machine shell	SS 304	
2.0	Filling Nozzle	SS316	
3.0	Syringe	SS 316	
4.0	Hose Pipe	PVC Braided	
5.0	Conveyer	SS 304	
6.0	Storage tank	SS316	
7.0	CAM	SS304	
8.0	Conveyor Slats	SS 304	
9.0	Sheet, plate. rods	SS 304	

Checked By
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Inference:

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Manager QA
Sign/Date:



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8.5 SAFETY TESTING:

Item	Acceptance criteria	Observation	Observed by Engineering Sign/date
Well embedded equipment	For proper sifting		
Electrical wiring and Earthing	Electrical wiring should be as per approved drawings. Double external earthing to control machine (panel and motors).		
Guards	Guards for all moving parts		
	Should be provided For Motor safety		
Start On / Off switch: To stop the process immediately	Should be provided For equipment and operator safety		
MCB for electrical overload	Should be properly installed		

**Checked By
 Production
 Sign/Date:**

**Verified By
 Quality Assurance
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Inference:

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 Manager QA
 Sign/Date:**



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9.0 REFERENCES:

- Validation Master Plan
- Schedule M: “Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products.”
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2: Good Manufacturing Practices and Inspection.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificates of MOC.
- Calibration certificates.

11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

- No. : Number
- cGMP : Current Good Manufacturing Practice
- GMP : Good Manufacturing Practice
- WHO : World Health Organization
- P & ID : Piping and Instrumentation diagram
- RH : Relative Humidity
- °C : Degree Centigrade
- DQ : Design Qualification
- mm : Millimetre
- HP : Horse Power
- RPM : Revolution per Minute
- Amp. : Ampere
- SS : Stainless Steel
- Kg : Kilogram
- Hr. : Hour
- MOC : Material of construction
- FDA : Food and Drug Administration
- EU : European Union
- IQ : Installation Qualification
- MCB : Miniature Circuit Breaker
- V : Volts
- IQ : Installation Qualification
- Pvt. : Private
- Ltd. : Limited



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17.0 POST APPROVAL:

REPAIRED 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)			