INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
SIX HEAD LOTION FILLING MACHINE

EQUIPMENT ID No.	
LOCATION	
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

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)			

2.0 OBJECTIVE:

- To carry out the Installation Qualification of Six Head Lotion Filling 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 Six Head Lotion Filling 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.

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	• Preparation, Review and Approval of the Installation Qualification Protocol. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Process.
Production	• 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	• 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.

5.0 EQUIPMENT DETAILS:

Equipment Name	Six Head Lotion Filling machine
Equipment	
Manufacturer's Name	GMP India Pvt. Ltd.
Model	cGMP
Supplier's Name	GMP India Pvt. Ltd.
Location of Installation	

6.0 SYSTEM DESCRIPTION:

It is a Fully Automatic Volumetric Filling machine. A Square fabricated out of SS 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 SS 304/SS316 sheets/plates/rods. All product contact parts are in SS 316 and filling bowl in SS 316L to make the machine chemically inert.

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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Reviewed By
Manager QA
Sign/Date: …….

8.2 EQUIPMENT VERIFICATION:

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

Installation Checks		Acceptance criteria	Observation	Checked By (Engineering)
Equipment		Six Head Lotion Filling Machine		
Model No.		cGMP Model.		
Capacity		4500 Bottles/hr. (For 10 ml to 200 ml)		
Direction		Left to Right		
Fill Capacity		10 ml to 200 ml Fill range depending upon bottle opening and bulk density.		
Electrical Supply		3.0 HP		
Power Requirement		415 Volts, 3 Phase (4 Wire System), 50 Hz.		
Conveyor motor	Make	SMPS		
	HP	1.0 HP		
	RPM	1300 RPM		
	Type	Flanged		
Geared Motor	Make	SMPS		
	HP	1 HP		
	RPM	1360 RPM		
Cylinder	50 ml	06 Nos.		
	100 ml	06 Nos.		
	200 ml	06 Nos.		
Pneumatic Valve	Festo	02 Nos.		
Storage Tank	Propack Technology	01 Nos. SS 316		
ELECTRICAL INSTALLATION:				
Electrical Supply		3 Phase Voltage- 415 V (± 6%) Frequency- 50 Hz		
Compressed Air		6 kg/cm^2 (bar)		
Electrical connections have been provided and secured.		Should be provided & secured		
All components in the panel are properly		Should be secured		

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR SIX HEAD LOTION FILLING MACHINE	PROTOCOL No.:

Installation Checks	Acceptance criteria	Observation	Checked By (Engineering)
secured			
All terminals are tightened	Should be tightened		

Checked By
Production
Sign/Date: …….

Verified By
Quality Assurance
Sign/Date: …….

Inference:

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Reviewed By
Manager QA
Sign/Date: …….

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 Six Head Lotion Filling machine	
2.	Check the proper alignment of Six Head Lotion Filling machine.	
3.	Check the proper electrical installation of Six Head Lotion Filling machine	
4.	Check the proper Mechanical Safety of Six Head Lotion Filling 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	

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign / Date: ……

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	Conveyer	SS 304	
4.0	Storage tank	SS316	
5.0	Cylinder	SS316	
6.0	Conveyor Slats	SS 304	
7.0	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: ……

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
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign / Date: ……

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
^{o}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

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
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