OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
SIX HEAD LOTION FILLING MACHINE

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

PROTOCOL CONTENTS

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 verify that the equipment operates in accordance with the design and user requirements as defined by set of Acceptance Criteria and comply with relevant GMP Requirements.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To verify the Operational features of Six Head Lotion filling machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user friendly point of view of the Equipment, Cleaning Procedure, start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The Protocol covers all the aspects of Operation Qualification for Six Head Lotion filling machine used in packing area.
- This Protocol defines the methods and documents to be used to qualify the Six Head Lotion filling machine for OQ.
- Successful completion of this Protocol will verify that the Six Head Lotion filling machine meets all acceptance criteria and is ready for Performance Qualification.

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, Approval and Compilation of the Operation Qualification Protocol. • Co-ordination with Production and Engineering to carryout Operation Qualification. • Monitoring of Operation Process.
Production	• Review of Operation Qualification Protocol. • To Co-ordinate and support for execution of Operation Qualification study as per Protocol.
Engineering	• Review & Pre Approval of Operational Qualification Protocol. • Co-ordination, Execution and technical support in Six Head Lotion filling machine Operational Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution).

5.0 EQUIPMENT DETAILS:

Equipment Name	Six Head Lotion filling machine
Equipment ID.	
Manufacturer's Name	
Supplier's Name	
Location of Installation	

6.0 SYSTEM DESCRIPTION:

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.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design and Installation 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 VERIFICATION OF THE DOCUMENT:

S.No.	Document Name	Document/SOP No	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By QA Officer/Exe. Sign/Date
1.	DQ Protocol Cum Report				
2.	IQ Protocol Cum Report				
3.	SOP for Operation & Cleaning of Six Head Filling machine				

Checked By
Production
Sign/Date:……

Verified By
Quality Assurance
Sign/Date:……

Inference:……..

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Reviewed By
Manager QA
Sign/Date:…….

8.2 TEST EQUIPMENT CALIBRATION:

Instruments Name	Instrument ID	Calibration On	Due On	Observed By Sign / Date

Checked By
Production
Sign / Date:……

Verified By
Quality Assurance
Sign / Date:……

Inference:……..

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Reviewed By
Manager QA
Sign / Date:…….

8.3 OPERATIONAL AND FUNCTIONAL CHECKS:

Operate the Lotion Filling machine as per Manufacturer's Manual / SOP and Check for the following functions of the Equipment. The Equipment should function as desired

Operation	Acceptance criteria	Observation
Check correct working of Machine	The machine should be operational	
Press Start Switch	Machine should started by pressing the orange switch push button	
Press Stop Switch	Machine should stop by pressing the Red switch push button.	
UP / DOWN Button	Air for the machine ON/OFF	
Press Push Button start conveyor	Conveyor start by pressing green push button.	

Checked By
Production
Sign / Date:……

Verified By
Quality Assurance
Sign / Date:……

Inference:……..

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Reviewed By
Manager QA
Sign / Date:…….

8.4 Power Failure Verification

ITEM	RESULTS	OBSERVATION	OBSERVED BY ENGINEERING SIGN / DATE
Main Power shut down	Equipment stops in safe and secure condition		
Main Power Restored	Equipment can be restarted with no problems or adverse		

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:

- Any other Relevant Documents

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:

cGMP	:	Current Good Manufacturing Practice
GMP	:	Good Manufacturing Practice
WHO	:	World Health Organization
P & ID	:	Piping and Instrumentation diagram
RH	:	Relative Humidity
^{0}C	:	Degree Centigrade
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
SOP	:	Standard Operating Procedure
PU	:	Polyurethane
AC	:	Alternating Current
mm	:	Millimetre
HP	:	Horse Power
RPM	:	Revolution Per Minute
Amp.	:	Ampere
SS	:	Stainless Steel
Hr.	:	Hour
MOC	:	Material of construction
FDA	:	Food and Drug Administration
EU	:	European Union

17.0 PROTOCOL POST 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)			