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

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

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR AUTOMATIC SIX HEAD LIQUID FILLING & SEALING MACHINE	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR AUTOMATIC SIX HEAD LIQUID FILLING & SEALING MACHINE	PROTOCOL No.:

1.0 PRE APPROVAL:

REPARED 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)			

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 Automatic Six Head Liquid Filling & Sealing 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 Automatic Six.
- This Protocol defines the methods and documents to be used to qualify the Automatic Six Head Liquid Filling & Sealing machine for OQ.
- Successful completion of this Protocol will verify that the Automatic Six Head Liquid Filling & Sealing 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, Authorization and Compilation of the Operation Qualification Protocol. • Co-ordination with Production and Engineering to carryout Operation Qualification. • Monitoring of Operation Process.
Production	• Review & Approval 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 Automatic Six Head Liquid Filling & Sealing machine Operational Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution).

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR AUTOMATIC SIX HEAD LIQUID FILLING & SEALING MACHINE	PROTOCOL No.:

5.0 EQUIPMENT DETAILS:

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

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.

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	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By QA Sign/Date
1.	DQ Protocol Cum Report			
2.	IQ Protocol Cum Report			
3.	SOP for Operation & Cleaning of Automatic Six Head Filling & Sealing 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
Filling Unit		
Check correct working of Machine	The machine should be operational	
Press Start Switch	Machine should started by pressing the switch push button	
Press Stop Switch	Machine should stop by pressing the Red switch push button.	
Diving Mechanism	The machine should be up & down Without any Jerk	
Noise level of Filling unit	Should be Normal	
Vibration of Filling unit	Should be Normal	
Dropping & leakage from Nozzles	No leakage should be Observed and Dropping should be Bottom to top	
Bottle Stoppering Assembly	Should work without any jerking and to perform its function Properly	
Foaming in Container during the filling	The Foaming should not Observe	
Product Sensor Device	No container no filling should be Done	
Sealing Unit		
Sealing of Caps	Should be Sealed all around of cap	
Vibration of cap Feeder	Should be As per the Cap run in the machine	
Set Chain Drive Mechanism	Should work without any jerking	
Interlocking	No cap -Machine Should stop	

Checked By
Production
Sign / Date:……

Verified By
Quality Assurance
Sign / Date:……

Inference:……..

……

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:……..

……

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:

REPARED 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)			