OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR AUTOMATIC TWO HEAD CAPPING MACHINE

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

PROTOCOL CONTENTS

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR AUTOMATIC TWO HEAD CAPPING 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 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 Two Head capping 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 Two Head capping machine.
- This Protocol defines the methods and documents to be used to qualify the Automatic Two Head Capping machine for OQ.
- Successful completion of this Protocol will verify that the Automatic Two Head Capping 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 Automatic Two Head Capping machine Operational Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution).

5.0 EQUIPMENT DETAILS:

Equipment Name	Automatic Two Head Capping machine
Equipment ID.	
Manufacturer's Name	Bhawani Engineers Pvt. Ltd.
Supplier's Name	Bhawani Engineers Pvt. Ltd.
Location of Installation	Filling Line

6.0 SYSTEM DESCRIPTION:

The Automatic Two head capping Machine is compact unit totally made of SS structure with height adjustment legs are provided to adjust the machine height and highly efficient machine with elegant look. This multifunctional multi featured machine meets the GMP requirements of labeling for glass and plastic Bottles. The machine requires manual loading and automatic unloading of Bottles.

Two Head capping machine operates in a continuous motion, whereby bottles are fed into the capping area by means of a timing screw, which accelerates and separates the bottles to a pitch which matches the infeed star wheel. Bottles are then transferred through the system from the infeed star wheel via the turret star wheel, onwards to the outfeed star wheel, where they exit the machine. During this process, the caps are simultaneously sorted and fed into the machine along a linear belt into the cap star wheel, where the capping heads descend and picks up the waiting cap and applies it to one of the pre-positioned bottles to a predetermined torque. The whole machine is made of 304 stainless steel and aluminum materials, the standardized design, interchangeable parts, completely according with GMP requirements.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 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 Automatic Two Head Capping Machine				
4.	SOP for Preventive Maintenance of Automatic Two Head Capping Machine				

Checked By
Production
Sign / Date:……

Verified By
Quality Assurance
Sign / Date:……

Inference:……..

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Reviewed By
Manager QA
Sign / Date:…….

7.2 TEST EQUIPMENT CALIBRATION:

Verify that all critical instruments associated with the system will be in a calibrated state. Review the calibration status for the test equipment to be utilized and record the calibration due dates in the table below. All Equipment / Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilized.

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:…….

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Operational and functional checks:

Operate the Automatic Two Head Capping 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	
Operate the machine as per its SOP. Check for proper	these function should be satisfactory	
Check working of and pressure gauges	Displayed pressures should be within the set limits.	
Removal of change parts and product changeover	As per changeover diagram. It should not take more than1 hour	
Removal of product contact parts and cleaning	It should not take more than 1 hour.	
Cap Feeder Empty	When Cap feeder empty Machine should be stop.	
Unsealed Bottle rejection system	Should be Provided and working properly to reject the bottle.	
To check Loose cap fault	When the Cap not fully seated on the container the alarm should indicate and reject container.	
To check the missing foil fault	When the container pass under the sealing coil that did not have a liner installed should not sealed and hooter also indicate	

Checked By
Production
Sign / Date:……

Verified By
Quality Assurance
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Inference:……..

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Sign / Date:…….

8.2 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 conditions		

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
- 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:

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
Pvt.	:	Private
Ltd.	:	Limited

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER / EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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HEAD (PRODUCTION)			
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