OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MEASURING CUP PLACEMENT MACHINE

EQUIPMENT ID. No.	
LOCATION	**Packing Hall**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MEASURING CUP PLACEMENT MACHINE	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MEASURING CUP PLACEMENT MACHINE	PROTOCOL No.:

1.0 PROTOCOL PRE – APPROVAL:

PREPARED 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 Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Measuring Cup Placement machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of **Measuring Cup Placement machine (Make: ……)** Installed in the **Packing Hall, Liquid Line**.
- This Protocol cum Report will define the methods and documentation used to perform OQ activity of Measuring Cup Placement machine.
- Successful completion of this Protocol will verify that Measuring Cup Placement machine meet all acceptance criteria and ready for Performance Qualification.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and compilation of the operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operation Process. • Post approval of Operational Qualification Protocol cum Report after execution.
Production	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Engineering	• Review of Operational Qualification Protocol cum Report. • To co-ordinate and support Operational Qualification Activity.. • Post approval of Operational Qualification Protocol cum Report after execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Measuring Cup Placement machine
Equipment ID.	
Manufacturer's Name	
Model	
Supplier's Name	
Sr. No.	
Location of Installation	Packing Hall

6.0 EQUIPEMENT DESCRIPTION:

Automatic Measuring Cup Placement Machine Model: ……..for measuring cup Placement on the neck of bottle for specific size and shape bottles. The equipment shall be used to linear gripper belt, cup feeder & Cup Placing cylinder on specified size and shape of Bottles. Machine equipped with cup feeder system for continue trouble free cup feeding.

Main Assembly divides in to following section

1. Structure
2. Conveyer Unit
3. Feeder assembly.
4. Vibratory Bowl
5. Cup Placing Cylinder.
6. Control Panel

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- SOP for Operation & Cleaning of Measuring Cup Placement machine.
- SOP for Preventive Maintenance of Measuring Cup Placement machine.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the OQ Protocol cum Report.

7.1.2 Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

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 Measuring Cup Placement machine.			
4.	SOP for Preventive Maintenance Measuring Cup Placement 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 Operational and Functional Checks:

Function	Acceptance Criteria	Observations	Observed By (Engineering) Sign/Date
Starting The Machine			
Check The Power Supply	Power Should be Available.		
Switch ON the mains ON/OFF Switch	The machine Should Start.		
Switch OFF the mains ON/OFF Switch	The machine Should Stop.		
Function of Conveyor Belt Start / Stop Knob/Feeder			
Selector Switch ON (Vibratory Bowl)	The Vibratory Bowl should Start the Vibration		
Selector Switch ON (Conveyer Belt)	Conveyor Belt Should Start.		
Press Push Button (Feeder)	The Measuring Cup Should come from Chute		
Selector Switch OFF (Vibratory Bowl)	The Vibratory Bowl should Stop the Vibration		
Selector Switch OFF (Conveyer Belt)	Conveyor Belt Should Stop.		
Cup pressing Cylinder	When Bottles and Cup come then Cylinder Press The Cup		
No Cup Sensor			
If there is no cup in Vibratory Bowl Chute	The Machine Should Stop.		

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

8.3 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a 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: ……

8.4 Emergency Operation Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
ON/OFF Push button • Press Stop Push Button • Release ON Push Button	Equipment should Stop		
	Equipment should Start		
With the OFF button Pressed in, Try to cause movement of an Operating function.	The Equipment will be inoperative.		

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:

- Design Qualification
- Installation Qualification Protocol
- Operating Manual

10.0 DOCUMENTS TO BE ATTACHED:

- Operation and Maintenance Manual.
- 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 Practices
DQ	:	Design Qualification
HP	:	Horse Power
ID.	:	Identification
IQ	:	Installation Qualification
Kg	:	Kilo Gram
KW	:	Kilo Watt
mm	:	Millimetre
No.	:	Number
OQ	:	Operational Qualification
SS	:	Stainless Steel
WHO	:	World Health Organization

17.0 PROTOCOL POST- APPROVAL:

PREPARED 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)			