



**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
MEASURING CUP PLACEMENT MACHINE**

PROTOCOL No.:

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
STICKER LABELLING MACHINE**

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



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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)			



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2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Measuring Cup Placement Machine Liquid Line.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of Measuring Cup Placement Machine to be installed in packing hall, Liquid Line.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Measuring Cup Placement Machine



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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	<ul style="list-style-type: none">• Preparation, Review, Authorization and Compilation of the Installation Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Installation Qualification.• Monitoring of Installation Qualification Activity.• Post approval of Installation qualification Protocol cum Report after execution.
Production	<ul style="list-style-type: none">• Review & Pre Approval of Installation Qualification Protocol cum Report.• To Co-ordinate and support for Execution of Qualification study as per Protocol.• Post Approval of Installation Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Installation Qualification Protocol cum Report.• Co-ordination, Execution and technical support in Installation Qualification Activity.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Installation Qualification Protocol cum Report after Execution.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Measuring Cup Placement Machine
Equipment ID.	
Manufacturer's Name	
Machine No.	
Model No.	
Capacity	80 bottle per Minute
Supplier's Name	
Location of Installation	Packing Hall

6.0 SYSTEM DESCRIPTION:

Automatic Measuring Cup Placement Machine Model: HMPL/MCP 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



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7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Technical specification of equipment.
- MOC Certificate of components.

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 IQ Protocol cum Report.

7.1.2 Acceptance Criteria:

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



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Grouting and Mounting	Should be properly grouted and mounted.		
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly ground without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Packing Hall Liquid Line		
Room Condition	General Room Conditions.		
Illumination	NLT 300 Lux		
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:

Reviewed By
Manager QA
Sign/Date:



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8.2 Technical Specification :

Critical variables	Acceptance criteria	Observation	Checked By Engineering Sign / Date
Make	Harikrushna Machinery Pvt. Ltd.		
Model	HMPL/MCP		
Sr. No.		
Dimensions	1525 x 660 x 1470 mm		
Working Height	850 ± 5 mm		
Speed	80 bottles/minute		
Design	Left → Right		
Conveyer Motor	Make : Rotomotive Type : Squarrel cage Induction Motor RPM : 1380 Sr. No.: M02174528		
Conveyer Gear Box	Make : Rotomotive Model: Box 030 PAM : 63B14 Sr. No.: G03170846		
Feeder Motor	Make : Rotomotive Type : Squarrel cage Induction Motor RPM : 1380 Sr. No.: M02177400		
Feeder gear Box	Make : Rotomotive Model: Box 040 PAM : 71B14 Sr. No.: G02170822		



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Critical variables	Acceptance criteria	Observation	Checked By Engineering Sign / Date
VFD	Make : Delta Model: Kw/Hp: 0.18/0.5 Sr. No.: Qty : 02 Nos.		
Contactora	Make : Telemacaneque Model : LC1D093		
Vibrator Card	Make : Harikrushna Model :		
Relay	Make : Pla Type : MPC-2C, 240A-5		
MCB	Make : Schneider Model : HPL Rating : C10A		
Timer	Make : Emtech Model : EPT2400 Type : Dual Timer		
SMPS	Make : Del Model : ME-50W		
No cup Sensor	Make : Leuze Electronics Model : D-7327 & LV461.1/P2 Sr. No. : 50118398		
Emergency Switch	Make : Schneider Model : ZBE-102N		
Push Button	Make : Schneider Model : Green, Yellow, Red		
Selector Switch	Make : Schneider Qty : 04 Nos.		



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Critical variables	Acceptance criteria	Observation	Checked By Engineering Sign / Date
Indication Light	Make : Jigo Model : AD18-22D/S Qty : 01 Nos.		
Variable Pot	Make : Pankaj Model : RW-3		
FRL	Make : Genetics		
Coil & Valve Set	Make : Genetics		
Cup Pressing Cylinder	Make : Genetics Model : A810200250 Max. Pr.: 10 Bar		

**Checked By
Production
Sign/Date:.....**

**Verified By
Quality Assurance
Sign/Date:.....**

Inference:

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.....
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**Reviewed By
Manager QA
Sign/Date:.....**



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8.3 MATERIAL OF CONSTRUCTION:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION	OBSERVATION	CHECKED BY ENGINEERING SIGN/DATE
Main Body & Product Conveyor				
1.	Main Body & Top plate	SS304		
2.	Conveyer	SS304		
3.	Conveyor slide chain	SS304		
4.	Sprockets	EN 24 Duly Hardened		
5.	Fixing Space	SS304		
6.	General Nut & Bolt	SS/MS, Duly Chrome Pleated		
7.	Guide Bracket	SS304/ Aluminum /Nylon		
8.	Cup bowl	SS304		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:.....

Inference:

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.....
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Reviewed By
Manager QA
Sign/Date:.....



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8.4 Safety Feature:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Joints	Welding of joints without any welding burrs.		
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.		
Leveling and Balancing	Equipment should be properly balanced & leveled.		
Earthing	Proper Earthing should be provided.		
Emergency Switch	For Immediately Stop the machine		
No Cup Sensor	No cup available in Chute Machine should Stop		
Rotating Parts	Covered with SS cover		

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:.....

Inference:

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Reviewed By
(Manager QA)
Sign/Date:.....



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9.0 REFERENCES:

- Validation Master Plan
- Design Qualification Documents
- P & ID , Utility , and GA Drawing
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2-Good Manufacturing Practices and Inspection.

10.0 DOCUMENTS TO BE ATTACHED:

- Certificate of MOC.
- Any other Relevant Document

11.0 DEVIATION FROM PRE-DEFINED 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
- CI. : Cast Iron
- MMI : Man Machine Interface
- MOC : Material of Construction
- MS : Mild Steel
- No : Number
- RPM : Revolution per minute
- SS : Stainless steel
- VFD : Variable Frequency Drive
- WHO : World Health Organization



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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)			