



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

PROTOCOL No.:

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MACHINE**

DATE OF QUALIFICATION

SUPERSEDE PROTOCOL No.

NIL



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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 prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of **Measuring Cup Placement Machine (Make:)** to be installed in Packing Hall.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.

4.0 PROJECT REQUIREMENTS:

To confirm that safe delivery of the equipment from the supplier site. To ensure that no un-authorized or unrecorded design modification shall take place.

If at any point in time, any change is desired in the mutually agreed design, change control procedure shall be followed and documented.



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5.0 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 and Authorization of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Design Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity. • Review of Design Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none"> • Review of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Design Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none"> • Review of Design Qualification Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e. <ul style="list-style-type: none"> ➤ GA Drawing. ➤ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/ brochures. ➤ Details of utilities. ➤ Identification of components for calibration. ➤ Material of construction of all components. ➤ Safety Features and Alarms. • Review of Design Qualification Protocol cum Report after Execution.



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6.0 BRIEF EQUIPMENT 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

7.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared for the manufacturer of equipment ensures complies with User Requirement Specification.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS/PRODUCT PARAMETERS:

Critical variables	Acceptance criteria	Reference
Application: Measuring Cup Placement Machine is designed to Placing the measuring cup for different size & shape of Bottles in single straight line operation	Should be able to Placing the Measuring cup..	Process Requirement
Working: The machine product sensor sense the presence of container and Place the Cup	Dispensing of Measuring cup should be immediately done as product container reaches, and should stop as there is no container	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement



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8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria	Reference
Electrical Supply	Voltage : 230 V Phase : Single Phase Frequency : 50 HZ	Process Requirement

8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Make	Harikrushna Machinery Pvt. Ltd.	Design Requirement
Model	Design Requirement
Sr. No.	Design Requirement
Dimensions	1525 x 660 x 1470 mm	Design Requirement
Working Height	850 ± 5 mm	Design Requirement
Speed	80 bottles/minute	Design Requirement
Design	Left → Right	Design Requirement
Conveyer Motor	Make : Rotomotive Type : Squarrel cage Induction Motor RPM : 1380 Sr. No.: M02174528	Design Requirement
Conveyer Gear Box	Make : Rotomotive Model: Box 030 PAM : 63B14 Sr. No.: G03170846	Design Requirement
Feeder Motor	Make : Rotomotive Type : Squarrel cage Induction Motor RPM : 1380 Sr. No.: M02177400	Design Requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Feeder gear Box	Make : Rotomotive Model: Box 040 PAM : 71B14 Sr. No.: G02170822	Design Requirement
VFD	Make : Delta Model: VFD004L21A Kw/Hp: 0.18/0.5 Sr. No.: 004L21A6W16400548 004L21A6W16400514 Qty : 02 Nos.	Design Requirement
Contactora	Make : Telemacaneque Model : LC1D093	Design Requirement
Vibrator Card	Make : Harikrushna Model : HMPL/VC-230	Design Requirement
Relay	Make : Pla Type : MPC-2C, 240A-5	Design Requirement
MCB	Make : Schneider Model : HPL Rating : C10A	Design Requirement
Timer	Make : Emtech Model : EPT2400 Type : Dual Timer	Design Requirement
SMPS	Make : Del Model : ME-50W	Design Requirement
No cup Sensor	Make : Leuze Electronics Model : D-7327 & LV461.1/P2 Sr. No. : 50118398	Design Requirement
Emergency Switch	Make : Schneider Model : ZBE-102N	Design Requirement



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CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Push Button	Make : Schneider Model : Green, Yellow, Red	Design Requirement
Selector Switch	Make : Schneider Qty : 04 Nos.	Design Requirement
Indication Light	Make : Jigo Model : AD18-22D/S Qty : 01 Nos.	Design Requirement
Variable Pot	Make : Pankaj Model : RW-3	Design Requirement
FRL	Make : Genetics	Design Requirement
Coil & Valve Set	Make : Genetics	Design Requirement
Cup Pressing Cylinder	Make : Genetics Model : A810200250 Max. Pr.: 10 Bar	Design Requirement



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8.4 MATERIAL OF CONSTRUCTION:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
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

8.5 SAFETY:

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

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

8.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Measuring Cup Placement Machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Reference: (1) Specifications and Requirements as specified in P.O. and URS.
 (2) Operating and service manual for Measuring Cup Placement Machine.

9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Any other relevant documents.

10.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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11.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATIONS:

cGEP	:	Current Good Engineering Practice
cGMP	:	Current Good Manufacturing Practice
CI.	:	Cast Iron
FRL	:	Filter Regulator Lubrication
HP	:	Horse Power
Hr	:	Hour
Kg	:	Kilogram
MCB	:	Miniature circuit breaker
mm	:	Millimeter
MMI	:	Man Machine Interface
MOC	:	Material of Construction
MS	:	Mild Steel
P & ID	:	Piping and Instrumentation Diagram
PO	:	Purchase Order
SLM	:	Measuring Cup Placement Machine
SS	:	Stainless steel
URS	:	User requirement specification



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14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			