INSTALLATION QUALIFICATION FOR AUTOMATIC MEASURING CUP PLACEMENT

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1.0 PROTOCOL APPROVAL:

Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved .The protocol cannot be used for execution unless approved by the following authorities.

This Installation Qualification protocol of Automatic Measuring Cup Placement Machine has been reviewed and approved by the following persons:

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		

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2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Automatic Measuring Cup Placement and define the installation qualification requirements and acceptance criteria for the Automatic Measuring Cup Placement. Successful completion of these installation qualification requirements will provide assurance that the Automatic Measuring Cup Placement was installed as required in the manufacturing area.

The Qualification of Automatic Measuring Cup Placement performed in view of Dry Syrup in manufacturing facility.

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the Automatic Measuring Cup Placement system received matches the Design specification and also to ensure that it is properly and safely installed.

2.3 SCOPE:

This Protocol is applicable to installation of Automatic Measuring Cup Placement in Dry Syrup in Production Cepha Oral Block of the manufacturing facility.

2.4 RESPONSIBILITY:

In accordance with protocol, following functions shall be responsible for the qualification of system.

Execution Team (Comprising members from Production, Engineering and Quality Assurance) and their responsibilities are following:

- Prepares the qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.

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- The installation checks, operational checks, calibration, SOP identification, identification features, identification of utility supply shall be carried out by engineering persons
- The production operator / supervisor shall carry out the cleaning and operation of machine.

Head – Production/ Engineering:

- Review of protocol, the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

Head – Operation and Quality Assurance:

- Review and approval of protocol, the completed qualification data package, and the final report.

2.5 EXECUTION TEAM:

The satisfactory installation of the Automatic Measuring Cup Placement shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Automatic Measuring Cup Placement is installed satisfactorily. Execution team is responsible for the execution of installation of Automatic Measuring Cup Placement Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

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3.0 ACCEPTANCE CRITERIA:

3.1 The Automatic Measuring Cup Placement shall meet the system description given in design qualification.

3.2 The Automatic Measuring Cup Placement shall meet with the acceptance criteria mentioned under the topic “Identification of major components”

3.3 The safety feature of machine should be in place

4.0 REQUALIFICATION CRITERIA:

The machine shall be requalified if

- There are any major changes in system components which affect the performance of the system
- After major breakdown maintenance is carried out.
- As per revalidation date and schedule

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5.0 INSTALLATION QUALIFICATION PROCEDURE:

5.1	SYSTEM DESCRIPTION:		
1	Equipment Name	:	Automatic Measuring Cup Placement
2	Supplier/Manufacturer	:	Parth Engineers & Consultant
3	Model	:	……
4	Serial no.	:	…….
5	Capacity	:	80-100 BPM
6	Dimension	:	1800 mm (L) X 745 mm (W) X 1525 mm (H)
7	Location	:	Dry Syrup-1

5.1.1 Brief process description:

Automatic Measuring Cup Placement Machine suitable for placement of Measuring Cup on the sealed bottle. The Cup Dispenser Unit is located on the top plate of the machine & it also provides up-down mechanism by screw & Ratchet Spanner the height of the Cup feeder required on the bottle can be adjusted. The container separator assembly is located on the top plate of the machine related to the conveyor. The main purpose of the container separator assembly is to maintain gap between two containers which is required for particular cup feeding procedure. It is located on the top plate of the machine & drive is synchronized with pressing belt & container separator. Pressing belt assembly is fitted on the top plate of the machine & main function of the pressing belt assembly is to hold the bottle till the cup placement operation is completed.

5.1.2 MACHINE DESCRIPTION

Automatic Measuring / Dozing Cup Placement & pressing machine is highly efficient machine with elegant look, consists of conveyor, vibrator, container holding pressing device & pressing belt. All the exposed parts of the unit are in SS, chrome plated or cladded with SS. The machine is precision built on sturdy welded steel frame completely enclose in stainless steel sheet doors are provided to facilitate the servicing of machine.

5.2 INSTRUCTION FOR FILLING THE CHECKLIST:

5.2.1 In case of identification of major component actual observation should be written in specified location.

5.2.2 In case of the compliance of the test actual observation should be written in specified location.

5.2.3 For identification of utilities actual observation should be written in specified location.

5.2.4 Give the detailed information in the summary and conclusion part of the installation Qualification report.

5.2.5 Actual observation of the component should be written in specified location.

5.2.6 Whichever column is blank or not used ‘NA’ shall be used.

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5.3 INSTALLATION CHECKLIST:

Installation checklist is as follows:

S.No.	Statement	Method of Verification	Actual Observation	Checked By Sign/Date
1	Verify purchase order copy and write down P.O. number	Physically		
2	Verify that there is no observable physical damage	Physically		
3	Examine All access ports are cleared of any debris.	Physically		
4	Verify that all components are properly assembled, securely anchored and shock proof.	Physically		
5	Verify that all electrical connections are properly done and safe	Physically		
6	Verify that the equipment is properly earthed	Physically		
7	Verify that utility line is properly connected	Physically		
8	Verify the proper leveling of equipment	Physically		
9	Verify that there is sufficient space provided for operation, cleaning, preventive maintenance	Physically		
10	Equipment/system identification no. Is visible	Physically		

Remark: ----------

Reviewed by (Sign/Date)

INSTALLATION QUALIFICATION FOR AUTOMATIC MEASURING CUP PLACEMENT

5.4 IDENTIFICATION OF MAJOR COMPONENTS:

Describe each critical component and check them and fill the inspection checklist.

System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
Main Motor	Location	Bottom of the machine	Physically		
	Make	Bonfiglioli	Physically		
	Spec.	1.87 A/0.75 KW/230-400 V/ 3 Phase/ 50 Hz/ 1400 RPM	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
Main AC Drive	Make	Allen Bradley	Physically		
	Spec.	1 HP, Single phase, Output: 3 Phase	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
Main Gear Box	Location	Bottom of the Machine	Physically		
	Make	Bonfiglioli	Physically		
	Ratio	30:1	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
Contactor	Make	Schneider	Physically/ Technical Specification		
Selector Switch	Make	Schneider	Physically/ Technical Specification		
Instruments					
Cup Sensor	Make	Panasonic	Physically/ Technical Specification		
	Model	EX14	Physically/ Technical Specification		
Potentiometer	Make	Potel	Physically/ Technical Specification		

Remark: ----------

Reviewed by (Sign/Date)

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5.5 VERIFICATION OF MATERIAL OF CONSTRUCTION:

Name of Components	Material of Construction	Method of Verification	Observation	Verified By Sign/Date
Machine Frame Structure	M.S. Angle powder coated	Physically		
External Cladding	SS 304	By Molybdenum Kit/ Test Certificate		
Guide for Conveyor Belt	SS 304	By Molybdenum Kit/ Test Certificate		
Pressing Belt	Rubber	Test Certificate		

Remark: ----------

Reviewed by (Sign/Date)

5.6 IDENTIFICATION OF SUPPORTING UTILITIES:

S.No.	Utility	Method Of Verification	Observation	Checked By Sign/Date
1.	**Electrical Power Supply:** 3 phase, 230- 400 V, 50Hz supply with neutral and proper earthing	Physically with clamp meter		

Remark: ----------

Reviewed by (Sign/Date

5.7 IDENTIFICATION OF SAFETY FEATURES:

Identify and record the safety/interlocking features (if any) and their function in following tables:

Safety Features Description	Location/Identification	Method Of Verification	Observation	Identified By Sign/Date
Earthing	Equipment connected with earthing strip	Physically		
Cup Sensor	To stop the machine in case of blockage of cup	Physically		

Remark: ----------

Reviewed by (Sign/Date)

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5.8 IDENTIFICATION OF COMPONENT TO BE CALIBRATED

Name of Components	Range	Make	Location	Identified By Sign/Date

Remark: ----------

Reviewed by (Sign/Date)

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5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP):

The following Standard Operating Procedures were identified as important for effective performance of Automatic Measuring Cup Placement operation.

S.No.	SOP Title	Verified By Sign/ Date

Remark: ----------

Reviewed by (Sign/Date)

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5.10 VERIFICATION OF DRAWING AND DOCUMENTS:

Following documents are reviewed and attached as listed below:

S.No.	Drawing And Document Detail	Verified By Sign/Date

Remark: ----------

Reviewed by (Sign/Date)

5.11 ABBREVIATIONS

Following Abbreviations are used in the installation qualification protocol of Automatic Measuring Cup Placement.

MOC: Material of construction

Spec.: Specification

V: Voltage

Hz: Hertz

A: Ampere

SS: Stainless Steel

RPM: Rotation per minute

HP: Horse Power

NA: Not Applicable

5.12 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S)

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.

Description of deficiency:

Corrective action(s) taken:

Deviation accepted by
(Sign/Date)

Deviation Approved by:
(Sign/Date)

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5.13 Annexure (S)

Annexure No.	Details Of Annexure

Remarks (if any)**:**

Done By & Date: **Verified By & Date:**

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6.0 INSTALLATION QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

Prepared By
Sign/Date

Checked By
Sign/Date

6.3 FINAL REPORT APPROVAL

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. All amendments and discrepancies are documented, approved and attached to this protocol, If applicable. Signature in the block below indicates that all items in this qualification report of Automatic Measuring Cup Placement have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved. After the successful installation qualification of the Automatic Measuring Cup Placement the equipment can be taken for operational qualification.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		