



OPERATIONAL 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.

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 the operational qualification is to prove that each operation proceeds as per design specification and the tolerances prescribed there in the document are the same at utmost transparency.

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

2.2 PURPOSE:

The purpose of this protocol is to establish the documentary evidence to ensure that the installed Automatic Measuring Cup Placement shall operate reproducibly and consistently within its full dynamic range of operation according to manufacturer's specification.

2.3 SCOPE:

This protocol shall define the test procedures, documentation, references and acceptance criteria to establish that the Automatic Measuring Cup Placement operates and performs as intended in accordance with the design qualification.

The Scope of this protocol is limited to the operational Qualification of Automatic Measuring Cup Placement installed in Dry Syrup in Production Cepha Oral Block of manufacturing,

Once the operational qualification of Automatic Measuring Cup Placement has been completed successfully, the equipment shall be preceded for the performance qualification procedure.

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.



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- 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.
- The operational checks, calibration, SOP verification, verification of safety features, verification of utility supply shall be carried out by engineering persons and production person.
- 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.



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2.5 EXECUTION TEAM:

The satisfactory operation 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 operational and is satisfactorily working.

Execution team is responsible for the execution of operation of Automatic Measuring Cup Placement. All executors involved with this protocol shall sign within the prescribed format given below.

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE



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3.0 ACCEPTANCE CRITERIA:

- 3.1 The equipment shall be operational as per its specified operating instructions
- 3.2 All SOPs for the equipment to be verified and checked.
- 3.3 Training shall be given to all the concerned personnel.
- 3.4 All the functionality of equipment components to be checked.

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 OPERATIONAL 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

5.1.1 MACHINE DESCRIPTION:

Automatic Measuring Cup Placement Machine is used to put cup on filled bottles & transfer it for further operation to subsequent machine.

- The drive unit is fitted with flange mounted motor (0.75 kw/ 1.87 A/ 280-400 V/ 50 Hz/ 1400 RPM) on reduction gear box.
- This reduction gear box is having closed helical gear drive with oil bath.
- Separate AC frequency drive is fitted with machine for speed control of conveyor.
- This helical reduction is the major speed- reducing unit.
- The drive assembly with gearbox & motor is mounted on structure.



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5.2 INSTRUCTION FOR FILLING THE CHECKLIST

- 5.2.1 Write down the actual observation in observation column as per design specification
- 5.2.2 Observation functional parameter should be write actual function in specified column.
- 5.2.3 Give the detailed information in the summary and conclusion part of the Operational Qualification report.
- 5.2.4 Whichever column is blank or not used 'NA' shall be used.

5.3 TEST INSTRUMENT DETAILS

This test is intended to describe the equipments / instruments and its complete details to have traceability to the national standard which is to be used for the verification of the operation of the Automatic Measuring Cup Placement.

S.No.	Name of Instrument	Inst. ID. Number	Calibration done on	Calibration Due date	Certificate Number

Checked by Date:

Remark: -----

Reviewed by (Sign/Date)



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5.4 Verification of Calibrated component:

This test is intended to describe the equipments/instruments and its complete details to have a traceability to the national standard, which is to be used for the verification of the operation of the Automatic Measuring Cup Placement.

S.No.	Name of Instrument	Inst. ID. Number	Calibration done on	Calibration valid up to	Certificate number

Checked by Date:

Remark: -----

Reviewed by (Sign/Date)



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5.5 VERIFICATION OF FUNCTIONAL CHECKS:

5.5.1 VERIFICATION OF KEY FUNCTIONALITY:

NAME OF EQUIPMENT COMPONENT	SPECIFIED FUNCTION	OBSERVATION	Checked By Sign/Date
Conveyor assembly	To carry the filled & sealed bottle for placing of measuring cup.		
Hopper assembly	To carry the measuring cup for feed up to the bottle through chute.		
Drive assembly	Main gear motor to drive the feeder conveyor.		
Output capacity	80-100 bottle / Min.		
Machine Speed	Min. -----bottle/ Min. Max.-----bottle/Min.		

Remark: -----

Reviewed by (Sign/Date)



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5.5.2 Verification of Functionality of Control Panel:

Procedure	Acceptance Criteria	Observation	Checked By Sign/Date
Machine START/ STOP Green Actuator on Control panel	To start & stop Conveyor Green indication On/ Off		
Check the speed variation by Potentiometer	Speed of machine will get varied		
Run Test:			
Run the machine in empty	There should not be any abnormal sound		
Power Failure & Restoration Test:			
Start the machine as per manufacturer's instruction. Trip the main incoming power supply. Wait for sometime & switch ON the machine.	The machine should not start until & unless it is started manually.		

Remark: -----

Reviewed by (Sign/Date)



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5.6 VERIFICATION OF SAFETY FEATURES:

Safety Features Description	Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
Cup sensor	In operation, block the cup in the chute	Machine shall get stopped		
Earthing	Run machine and check with multimeter / clamp meter at the body cover of the machine.	No current should be sensed over whole body		

Remark: -----

Reviewed by (Sign/Date)

5.7 VERIFICATION 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)



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5.8 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

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

S.No.	SOP TITLE	SOP NUMBER	VERIFIED BY	DATE

Remark: -----

Reviewed by (Sign/Date)



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5.9 TRAINING RECORD OF PERSONNEL (S):

S.No.	Name of Personnel	Designation	Sign & Date	Trained By	Remark

Remark: -----

Reviewed by (Sign/Date)



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5.10 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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5.11 Annexure (S)

Annexure No.	Details Of Annexure

Remarks (if any):

Done By & Date:

Verified By & Date:



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6.0 OPERATIONAL QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

**Prepared By
Sign/ Date**

**Checked By
Sign/ Date**



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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. Verified that 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 (If applicable) have been satisfactorily resolved. After the successful operational qualification of the Automatic Measuring Cup Placement the equipment can be taken for performance qualification.

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