



Installation Qualification for Automatic Rotary Vacuummetric Dry Syrup Filling with ROPP Capping Machine

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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 rotary vacuummetric dry syrup filling with ROPP capping 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 rotary Vacuummetric dry syrup filling with ROPP capping machine and define the installation qualification requirements and acceptance criteria for the Automatic rotary Vacuummetric dry syrup filling with ROPP capping machine. Successful completion of these installation qualification requirements will provide assurance that the Automatic rotary Vacuummetric dry syrup filling with ROPP capping machine was installed as required in the manufacturing area.

The Qualification of Automatic rotary Vacuummetric dry syrup filling with ROPP capping machine performed in view of Dry Syrup facility.

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the Automatic rotary Vacuummetric dry syrup filling with ROPP capping machine 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 rotary Vacuummetric dry syrup filling with ROPP capping machine in Dry Syrup in Production Cepha Oral Block of the manufacturing facility & the subsequent documentation.

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.



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- Review of protocol, the completed qualification data package, and the final report.
- 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 rotary Vacuummetric dry syrup filling with ROPP capping machine shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Automatic rotary Vacuummetric dry syrup filling with ROPP capping machine is installed satisfactorily.

Execution team is responsible for the execution of installation of Automatic rotary Vacuummetric dry syrup filling with ROPP capping machine Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE



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3.0 ACCEPTANCE CRITERIA:

- 3.1 The Automatic rotary Vacuummetric dry syrup filling with ROPP capping machine shall meet the system description given in design qualification.
- 3.2 The Automatic rotary Vacuummetric dry syrup filling with ROPP capping machine shall meet with the acceptance criteria mentioned under the topic “Identification of major components”
- 3.3 All material of constructions of the contact parts to be checked as per the specifications.
- 3.4 The Automatic rotary Vacuummetric dry syrup filling with ROPP capping machine shall be operated by PLC.

4.0 REQUALIFICATION CRITERIA:

The machine shall be re-qualified 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

5.0 INSTALLATION QUALIFICATION PROCEDURE:

5.1 SYSTEM DESCRIPTION:			
1	Equipment Name	:	Automatic rotary Vacuummetric Dry Syrup Filling with ROPP capping machine
2	Supplier/Manufacturer	:
3	Model	:
4	Serial no.	:
5	Capacity	:	80-100 bottles per minute
6	Dimension	:	2700 mm (L) X 1200 mm (W) X 2011 mm (H)
7	Location	:	Dry Syrup



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5.1.1 Brief process description:

Automatic rotary Vacuummetric dry syrup filling with ROPP capping machine (Monobloc) Head: 16X8, is versatile, self-supported on stainless steel leg with height adjustable adjustment system. The machine is precision built on sturdy welded MS frame completely enclosed in stainless steel sheet & doors are provided to facilitate the servicing of machine, work on volumetric principle with rotary motion. The unit is made compact, versatile & enclosed in stainless steel elegantly matt finish body.

The main drive of the machine & conveyor controlled by A.C. Motor with separate variable ACVFD.

5.1.2 MACHINE DESCRIPTION

The Automatic rotary Vacuummetric dry syrup filling with ROPP capping machine (Monobloc) Head: 16X8 works on the principle to fill the powder in the bottle with the basic concept of Vacuummetric fill process & ROPP capping of the filled bottle.

The bottle fed through infeed turn table via conveyor belt when comes under the funnel plate, it is lifted by lifter assembly & get inserted into funnel tight fit for powder filling. The powder wheel with piston sets delivered the precise volume of powder with the release of vacuum when time dose of compressed air, sterilized low pressure air/nitrogen gas flushes out the powder from the powder wheel into the funnel when the port just reaches in vertical position. In case, the powder does not come out from the funnel smoothly, the funnel vibrating system is started. Then the bottle is filled, then moves to another star plate for ROPP capping operation. During the movement into the star plate bottle picks up a cap from the chute end & in rotary motion comes under the capping head where the cap is capped on the bottle mouth perfectly & neatly.



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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)



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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.	3.7 A/1.5 KW/415 V/ 3 Phase/ 50 Hz/ 1410 RPM	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
Drive Shaft Housing	Location	Centre of the main body	Physically		
Filling Head	Location	Machine Top Plate on L.H side	Physically		
ROPP capping Head	Location	Machine Top Plate on R.H side	Physically		
Main ACVFD for Main Motor	Make	Allen Bradley	Physically		
	Spec.	2 HP, 430 V, 3 phase, Output: 3 Phase	Physically/ Test Certificate/ Technical Specification		
	Sr. No.	To be recorded	Physically		
Conveyor Motor-1	Make	Bonfiglioli	Physically		
	Spec.	0.18 kw, 1320 RPM, 200/415 V, 50 Hz, 1.23 A	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
ACVFD for Conveyor-1	Make	Allen Bradley	Physically		
	Spec.	0.5 HP, 220 V, Single phase, Output: 3 Phase	Physically/ Test Certificate		



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	Sr. No.	To be recorded	Physically		
Conveyor Motor-2	Make	Bonfiglioli	Physically		
	Spec.	0.18 kw, 1320 RPM, 200/415 V, 50 Hz, 1.23 A	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
ACVFD for Conveyor-2	Make	Allen Bradley	Physically		
	Spec.	0.5 HP, 220 V, 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	46:1	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
Conveyor Gear Box-1	Make	Bonfiglioli	Physically		
	Ratio	20:1	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
Conveyor Gear Box-2	Make	Bonfiglioli	Physically		
	Ratio	28:1	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		



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Vibrator Motor	Make	Crompton	Physically		
	Spec.	0.37 kw, 2815 RPM, 415 V, 50 Hz, 0.85 A	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
AC Drive for Vibrator Motor	Make	Allen Bradley	Physically		
	Spec.	0.5 HP, 220 V, Single phase, Output: 3 Phase	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
Vacuum Pump	Make	Indovac Pump	Physically		
	Model	IVS-1000	Physically		
	Capacity	1000 lpm	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
Vacuum Pump Motor	Make	Crompton Greaves	Physically		
	Spec.	1632J, 1430 RPM, 3 HP, 4.61 A	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
Solenoid Valve	Make	Festo	Physically		
	Range	1.5 to 8 bar	Physically/ Technical Specification		
HMI	Make	Delta	Physically		
	Model	DOPBO5S111	Physically/ Technical Specification		
	Sr. No.	To be recorded	Physically		



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PLC	Make	Delta	Physically/ Technical Specification		
	Model	DVP12SA211T	Physically/ Technical Specification		
	Sr. No.	To be recorded	Physically		
PLC Module	Make	Delta	Physically/ Technical Specification		
	Model	DVP16SP11R	Physically/ Technical Specification		
	Sr. No.	To be recorded	Physically		
Deduster Motor	Make	Remi	Physically		
	Spec.	1.1 kw, 2870 RPM, 415 V, 50 Hz, 2.25 A	Physically/ Test Certificate		
	Sr. No.	To be recorded	Physically		
Vacuum Filter with Housing	Make	Kanisha Product Technology	Technical Specification/ Test Certificate		
	Filter make	Grace Filter	Technical Specification/ Test Certificate		
	Micron Rating	0.45μ	Test Certificate		
	MOC	Polypropylene	Test Certificate		
Air Filter with Housing	Make	Kanisha Product Technology	Technical Specification/ Test Certificate		



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	Filter make	Grace Filter	Technical Specification/ Test Certificate		
	Micron Rating	0.2μ	Test Certificate		
	MOC	P.T.F.E.	Test Certificate		
De-duster air bags	Make	Parth	Technical Specification/ Test Certificate		
	MOC	PC Satin	Test Certificate		

INSTRUMENTS

No Bottle Sensor	Make	Panasonic	Physically/ Technical Specification		
	Model	EX 14	Physically/ Technical Specification		
Dosing Sensors	Make	Banner	Physically/ Technical Specification		
	Model	QS18VP6FF100	Physically/ Technical Specification		
Purging Sensors	Make	Banner	Physically/ Technical Specification		
	Model	QS18VP6FF100	Physically/ Technical Specification		
Spindle Jam Sensor	Make	Panasonic	Physically/ Technical Specification		
	Model	EX 14	Physically/ Technical Specification		
No Bottle No Cap Sensor	Make	Panasonic	Physically/ Technical Specification		



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	Model	EX 14	Physically/ Technical Specification		
Powder Level Sensor	Make	PEPPERL + FUCHS	Physically/ Technical Specification		
	Model	CCN15-30GS60- E2	Physically/ Technical Specification		
GEP Sensor	Make	Panasonic	Physically/ Technical Specification		
	Model	K44	Physically/ Technical Specification		
No Cap Sensor	Make	Panasonic	Physically/ Technical Specification		
	Model	EX 14	Physically/ Technical Specification		
Pressure Gauge	Make	Shreeji	Physically		
	Range	To be recorded	Physically		
Air Pressure Switch	Make	Danfoss	Physically		
	Range	To be recorded	Physically		
Vacuum Pressure Switch	Make	Indfoss	Physically		
	Range	To be recorded	Physically		
Potentiometer	Make	Pankai	Physically		
Vacuum gauge	Make	Shreeji	Physically		
	Range	To be recorded	Physically		
Air gauge	Make	Shreeji	Physically		
	Range	To be recorded	Physically		

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
CONTACT PARTS				
Hopper	SS 316	By Molybdenum Kit/ Test Certificate		
Powder Wheel	SS 316	By Molybdenum Kit/ Test Certificate		
Piston Set	SS 316	By Molybdenum Kit/ Test Certificate		
Piston Nut Ring	Silicone flat Ring	Test Certificate		
Piston 'O' Ring	Neoprene 'O' Ring	Test Certificate		
Funnel	ASTM:A-351 GR CF8M	Test Certificate		
Bowl & Chute for cap	SS 304	By Molybdenum Kit/ Test Certificate		
Doctor Blade	SS 316L	By Molybdenum Kit/ Test Certificate		
NON CONTACT PARTS				
Machine Frame Structure	M.S. Angle powder coated	Physically		
Door Set	SS 304	By Molybdenum Kit/ Test Certificate		
Conveyor Belt	Polyacetal	Test Certificate		
Feed Worm	Nylon	Test Certificate		
Star plates	Nylon	Test Certificate		

Remark: -----

Reviewed by (Sign/Date)



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5.6 IDENTIFICATION OF SUPPORTING UTILITIES:

S.No.	Utility	Method of Verification	Observation	Checked By Sign/Date
1.	Electrical Power Supply: 3 phase, 415V +/- 5%, 50Hz supply with neutral and proper earthing	Physically with clamp meter		
2.	Compressed Air 6 kg/cm ²	Physically		

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		
Photo Electric Sensor	To sense the presence of bottle in front of it	Physically		
Emergency Stop Button	To stop the machine in case of emergency	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 rotary Vacuummetric dry syrup filling with ROPP capping machine 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)



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5.11 ABBREVIATIONS

Following Abbreviations are used in the installation qualification protocol of Automatic rotary Vacuummetric Dry Syrup Filling with ROPP capping machine

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

ACVFD: Alternate Current Variable Frequency Drive

ROPP :Roll On Pilfer Proof



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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

Remark (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**



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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. 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 rotary Vacuummetric dry syrup filling with ROPP capping machine 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 rotary Vacuummetric dry syrup filling with ROPP capping machine 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		