OPERATIONAL 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 Operation Qualification protocol of Automatic Rotary Vacuumatric 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 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 Rotary Vacuumatric Dry Syrup Filling with ROPP Capping Machine performed in view of Dry Syrup of production Cephalosporin oral manufacturing facility.

2.2 PURPOSE:

The purpose of this protocol is to establish the documentary evidence to ensure that the installed Automatic Rotary Vacuumatric Dry Syrup Filling with ROPP Capping Machine shall operate reproducibly and consistently within its full dynamic range of operation according to manufacturer's specification.

2.3 SCOPE:

The Scope of this protocol is limited to the operational Qualification of Automatic Rotary Vacuumatric Dry Syrup Filling with ROPP Capping Machine, installed in Dry Syrup of Production Cepha Oral 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.

- 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 Rotary Vacuumatric 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 Vacuumatric Dry Syrup Filling with ROPP Capping Machine is operational and is satisfactorily working.

Execution team is responsible for the execution of operation of Automatic Rotary Vacuumatric Dry Syrup Filling with ROPP Capping Machine. 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

3.5 The RPM of motor should be in the range of ± 5%.

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

5.0 OPERATIONAL QUALIFICATION PROCEDURE:

5.1 SYSTEM DESCRIPTION:

1.	Equipment Name	:	Automatic Rotary Vacuumatric dry syrup filling with ROPP capping machine
2.	Supplier/Manufacturer	:	Parth Engineers & Consultant
3.	Model	:	PRPM-120
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 MACHINE DESCRIPTION:

The Automatic rotary vacuumatric dry syrup filling with ROPP capping machine (Monobloc) Head: 16X8 works on the vacuumatric principle with powder wheel for filling pre-set powder volume in the bottle & subsequently pressing cap on the bottle.

- The drive unit is fitted with foot mounted motor (2 HP/ 415 V/50 Hz/ 3 Phase) on reduction gear box.
- Separate ACVFD is fitted with machine for speed control of conveyor.
- This worm gear reduction is the major speed- reducing unit.
- The drive assembly with gearbox & motor is mounted on the structure.
- The funnel plate is having 16 Nos. of funnels & powder wheel is mounted on the centre pipe.
- Powder wheel consist of a piston set & vacuum plate with back spring pressure does not leave any clearance.
- Precise volume of powder is sucked into the powder wheel during the vacuum according to the piston length.
- Vibrating mechanism is provided for vibrating funnel to fill the powder into the bottle, if so required.
- Caps loaded in the vibrator bowl are transferred to the chute & at the end of chute it being picked up by the bottle itself & move further in rotary motion under capping head where cap is capped on bottle mouth.

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.

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5.3 TEST INSTRUMENT DETAILS

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 Rotary Vacuumatric Dry Syrup Filling with ROPP Capping Machine.

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

Checked by Date:

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

Reviewed by (Sign/Date)

OPERATIONAL QUALIFICATION FOR AUTOMATIC ROTARY VACUUMMETRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

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 Rotary Vacuumatric Dry Syrup with Filling ROPP Capping Machine.

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)

OPERATIONAL QUALIFICATION FOR AUTOMATIC ROTARY VACUUMMETRIC DRY SYRUP FILLING WITH ROPP CAPPING MACHINE

5.5 VERIFICATION OF FUNCTIONAL CHECKS:

Procedure	Acceptance Criteria	Observation	Checked By Sign/Date
Verification of Operational Functionality Checks:			
Main Power ON/OFF switch	To supply power to the unit with Green indication 'ON'		
Touch the Auto display button in the HMI screen	Auto mode shall get selected		
Touch the Manual display button in the HMI screen	Manual mode shall get selected		
Touch the Start display button in the HMI screen	Machine shall get start with yellow indication on the screen		
Touch the Stop display button in the HMI screen	Machine shall get stop with red indication on the screen		
Stop the machine by pressing Emergency Stop button	The machine shall get stop		
Press Main Switch for vacuum pump	Pump shall get start with green indication 'ON'		
Rotate Potentiometer in both direction	Vibrator speed will get varied for the cap feeder		
Deduster- For starting press the green button	Unit shall get start		
Deduster- For stopping press the red button	Unit shall get stop		
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
Photo Electric Sensor	Start the machine without the bottle in front of sensor	The machine should not start		
	In operation, remove the bottle from the machine	The machine shall be in operation but no filling shall be observed		
No Bottle No Cap	In operation, remove the bottle from the machine	The machine shall be in operation but no cap placement shall be observed		
No Cap No Chute	Block the cap from the feeder	Machine shall be stopped & NO Cap message shall be displayed		
Air Pressure Switch	Close the compressed air supply while the machine in operation	Machine will get stopped & LOW AIR message will be displayed		
Emergency Stop Button	In operation of machine, press the emergency stop button	Machine shall stop & EMERGENCY STOP OPERATE shall be displayed		
Vacuum Pressure Switch	In operation of machine, block the vacuum line	Machine shall stop & VACUUM LEVEL LOW shall be displayed		
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)

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5.7 VERIFICATION 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 bar	Physically		

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

Reviewed by (Sign/Date)

5.8 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

The following Standard Operating Procedures were verified as important for effective performance of Automatic Rotary Vacuumatric Dry Syrup Filling ROPP Capping Machine operation.

S.No.	SOP TITLE	SOP NUMBER	VERIFIED BY	DATE

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

Reviewed by (Sign/Date)

5.9 TRAINING RECORD OF PERSONNEL (S):

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

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

Reviewed by (Sign/Date)

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 Rotary Vacuumatric Dry Syrup Filling with ROPP Capping Machine 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 Rotary Vacuumatric Dry Syrup Filling with ROPP Capping Machine, 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		