TABLE CONTENT

1.0 PRE- APPROVAL

Signing of this Operational Qualification Protocol indicates agreement with the Validation Master Plan approach of the equipment. Further if any changes in this protocol are required, protocol will be revised and duly approved.

PREPARED BY:

Organization	Name	Signature	Date
Production			

CHECKED BY:

Organization	Name	Signature	Date
Engineering			
Production			
Quality assurance			

APPROVED BY:

Organization	Name	Designation	Signature	Date
Head Engineering				
Head Manufacturing				

2.0 OBJECTIVE:

The objectives of this Operational Qualification (OQ) are as follows:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set acceptance criteria and complies with relevant cGMP requirements.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

Following execution of the protocol a summary report will be written and approved. All results, conclusions, exceptions and variances will be addressed and final disposition of the equipment will be stated. Successful completion of this protocol and approval of the summary report will verify that the RCVD meets all the acceptance criteria and is ready for PQ.

3.0 SCOPE:

This protocol covers all aspects of Operational Qualification for the Rotocone Vacuum Dryer Machine Tablets, Capsules Dry Syrup and Dry Powder Injection Facility. Scope incorporates qualification of Rotocone Vacuum Dryer components. This protocol will define the methods and documentation used to qualify the Rotocone Vacuum Dryer. Successful completion of this protocol will verify that the Rotocone Vacuum Dryer meets all acceptance criteria and is ready for Performance Qualification.

4.0 RESPONSIBILITIES:

In accordance with protocol, following functions shall be responsible for the qualification of equipment regardless of whether such work is performed by own staff or contract / consulting staff. When the work is carried by contract/ consulting staff, all the work is to be performed under the oversight of Site.

Department	Responsibilities
Production	Prepare, check and approve the Operational Qualification Protocol.
	Distributes the finalized protocol for check, approve and authorization signatures.
	Execution of Operational Qualification Protocol.
	Complied qualification data package, and final report.
Engineering	Check, approve and execution of Operational qualification protocol.
Quality Assurance	Check the protocol for operation of equipments.
	Final authorization of protocol.

5.0 SYSTEM DESCRIPTION

The Rotocone Vacuum Dryer Machine and its associated equipments are designed to process pharmaceutical products in accordance with cGMP principles. The purpose of Rotocone Vacuum Dryer Machine is to drying and blending of powder. In this equipment drying takes place at even low temperature and under vacuum.that is why it is used economically and effectively for drying pharmaceutical products temperature sensitive or easily oxidable materials.when the solvent is present in the material/its easy recovery is possible.Drying takes place when the blender heated from outside jacket and vacuum is applied inside.

5.1 Rotocone Vacuum Dryer

The basic Rotocone Vacuum Dryer consists of the following sub-assemblies and cleaning of the capsules bushes.

5.2 Electrical Control Assembly

The electrical control panel is mounted inside the structure of the machine. The mains ON/OFF switch are on the cover of the machine. The Drive ON/OFF, Control ON, Speed regulator and the Emergency OFF switches are mounted on the pendant of the machine. Inching facility is provided for easy checking of various settings on the machine. The display screen of the PLC has various selector keys for performing various operations. The control cabinet inside the structure houses the AC drive, the PLC, MCBs, contractors, overload relays.

5.3 PLC Description

The main function of a PLC is to translate the instructions into the digital codes needed to operate the device or machine. The main function of this PLC system is to collect data from field instrumentation and display the information on the operator station. The instruments are connected to the system equipment. The collected data will be utilized by the PLC for process control. The user interface, based in an industrial type MMI, will assist the operator to supervise and control the process. Based on the displayed information the operator, by means of the user interface, can provide commands to the PLC. The PLC then executes the operator instructions.
The structure consists of a main SS frame of tubular construction on which the polishing chamber is mounted. The main frame is fixed to a bracket that is supported on a five-wheel stand.

6.0 DOCUMENTATION REQUIREMENTS

The OQ File should include:

- This OQ Protocol.
- All printouts and handouts generated during the qualification procedure.
- Any laboratory test results or their referenced location.
- A Signature Sheet where all people, performing the qualification tests, are listed.
- Any change control actions that may have occurred during the qualification activities.
- Any variances, exceptions or investigation reports generated during the qualification activities.

7.0 DATA COLLECTION

All individuals executing this Protocol shall complete the *Signature Sheet*. All personnel shall have suitable documented training or experience.

All approvals shall be made in *BLACK* ink.
All data entry shall be made in *BLACK* ink.

All corrections to this Protocol, which are not retyped, are to be made in *BLACK* ink. All written corrections to this Protocol or to data entered in this Protocol should be made by using a single line to delete the error. The person who makes the correction shall initial and date it and add comment to explain reason for correction.

After performing the qualification tests, collect all relevant printouts and certificates and retain for inclusion in the OQ File. If more Data Sheets or Variance Sheets are required, they are to be attached to this Protocol as *Annexure* and to be listed in *Section 13. List of Annexure*.

8.0 CHANGE CONTROL

Any changes or modifications to the system shall be performed in accordance with the Site Project Change Control Procedure.

Change Control Forms raised during the execution of this OQ will be filed along with the protocol. An assessment will be made for each change to determine whether or not any re-validation is required.

9.0 PRE-QUALIFICATION REQUIREMENTS

The results of any tests should meet the limits and acceptance criteria specified in the test documents. Any deviations or issues should be rectified and documented prior to OQ commencing. Open action items resulting from these tests shall be listed in the Comments section.

9.1 System Pre-requisites

S.No.	Description of Pre-requisite	Completed Yes or No	Verified By	Date
1	Verify that the IQ of the Rotocone Vacuum Dryer has been executed and approved. IQ Protocol Document No:	Yes/No*		
2	Verify that Site Acceptance Tests (SAT) of the Rotocone Vacuum Dryer has been executed and approved.	Yes/No*		
3	Verify that the safety walk through has been completed and that the system is safe to use.	Yes/No*		
Verify that authorised drafts of the following procedures (SOP / PMI) relevant to operation of the Rotocone Vacuum Dryer are available.				
4	SOP of Roto Cone vacuum dryer machine.	Yes/No*		
5	SOP of Roto Cone vacuum dryer Maintenance.	Yes/No*		
6	SOP of Roto Cone vacuum dryer Cleaning /Washing	Yes/No*		
7	Verify that all critical instruments associated with the system will be in a calibrated state during OQ execution.	Yes/No*		

Note: - * -Circle one, which is appropriate.

9.2 Test Equipment Calibration

Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All equipment / instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment Name	Equipment Owner	Equipment Number	Due Date	Signature	Date

Reviewed by		Date	

10.0 TESTS AND CHECKS

10.1 SOP Verification

10.1.1 Purpose

To verify the accuracy of Standard Operating Procedures applicable to the Rotacone Vacuum Dryer.

10.1.2 Method

Obtain a controlled copy of each SOP referenced within section 10.1.4. During the course of OQ testing, perform each operation according to the instruction indicated within the appropriate SOP. Mark with a highlighter pen each instruction or statement within the SOP which is verified and in accordance with the actual practice. Write any differences from actual practice in red ink on the copy of the SOP. On completion, write "Operational Qualification - SOP Verification" on the marked-up copy of the SOP, sign & date it and attach as an appendix to the OQ protocol together with any other raw data such as printouts.
Ensure all SOP's identified in Section 10.1.4 are evaluated and checked.

10.1.3 Acceptance Criteria

At the completion of OQ testing, all standard operating procedures referenced within section 9.1.4 will be annotated to correctly reflect the applicable method instruction(s) required to obtain intended operation or function result.

10.1.4 Results

Enter the SOPs into the table below and verify that they have been evaluated and checked. Incorporate the marked up SOPs as an appendix to the OQ report together with any other raw data such as printouts.

SOP Number	SOP Description	SOP accurate after check [Y/N]	Initial / Date
	Rotocone Vacuum Dryer Operation and cleaning.		

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.2 Input / Output (I/O) Test

10.2.1 Objective

To verify that PLC Inputs and Outputs (I/Os) are connected to the correct field device.

10.2.2 Method

Input/output checks have been carried out as part the site acceptance/commissioning process, as such, results are documented in Site Acceptance Test (SAT) document. Ensure that all tasks have been completed and signed off as correct.
Check the machine operation either by sequence of operation by forcing the signal and record the result.

10.2.3Acceptance Criteria

SAT must show that all field devices operate and communicate correctly with the control system in agreement with the electrical schematics. Therefore, verify that all testing was witnessed, completed and signed off as correct.
Where Digital I/Os have been re-tested, verify that all field devices operate and communicate in accordance with the control system and in agreement with associated electrical schematics.

10.2.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Verify Digital Input/Output Tests have been Completed as specified in SAT document	Tests have been witnessed, completed and signed off as correct.			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.3 System Security Test

10.3.1 Objective

To verify that access to system programs and data are protected in an adequate manner.

10.3.2 Method

Follow instructions in the Test Method column in section 10.3.4 to test security of the system. Record all observations in the actual results column in section 10.3.4 and attach any raw data printouts as an appendix to this protocol.

10.3.3 Acceptance Criteria

Access to control system and software is to authorised personnel only. Specific acceptance criteria for each test are provided in section 10.3.4.

10.3.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Enter test methods for testing in-built security access to the control system (for operator, supervisor and maintenance)	One level password for Maintenance, Manual and Auto.			
Attempt to access PLC.	Physical restriction by lock to an unauthorised user is in place.			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.4 System Start-Up and Shutdown Test

10.4.1 Objective

To verify that the system components will power-up and start as defined by the design documentation.

10.4.2 Method

Follow instructions in the Test Method column of section 10.4.4 to test the start-up and shutdown of each system component. Obtain approval from the Production, Electrical and Mechanical Departments (where applicable) prior to this test and attach the approval slip as an appendix to this protocol. Record all observations in section 10.4.4 and attach any raw data printouts as an appendix to this protocol.

10.4.3 Acceptance Criteria

All Start-up and Shutdown functions operate correctly as specified in the following document:

- System Operating and Maintenance Manual Rotocone Vacuum Dryer:

Specific acceptance criteria for each test are provided in the tables in section 10.4.4.

10.4.4 Results

10.4.4.1 Shutdown Procedure

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
While the system is operating, cease operation by assigning the following mode on the Man Machine Interface (MMI):				
Stop vacuum.	Reading drops to zero in vacuum gauge located outside structure of Rotocone Vacuum Dryer machine			
Stop Compressed air supply to the equipment	Reading drops to zero in pressure gauge mounted on FRL unit inside structure of Rotocone Vacuum Dryer machine.			
Switch “OFF” the mains	No Power distributed to electrical components. System returns to safe mode.			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.4.4.2 Power-Up and Start Test

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
The system is operating, by assigning the following mode on the Man Machine Interface (MMI)				
Observe Rotocone Vacuum Dryer machine physically	Visual Inspection of Rotocone Vacuum Dryer			
Switch "ON" the mains	Power is distributed to electrical components in control Panel. System returns to operation mode			
Compressed air supply to the equipment.	Reading appears in pressure gauge mounted on FRL unit inside structure of Rotocone Vacuum Dryer			
Check the system for required vacuum.	Reading appears in vacuum gauge located inside structure of automatic Rotocone Vacuum Dryer			
Operate different system component in sequence	All the system component starts functioning as per the sequence mentioned in point no. 4 (system description)			

Equipment Operated By		Date	

Comments:

Reviewed by		Date	

10.5 Operator Data Entry Test

10.5.1 Objective

To verify system response following Operator Data Entry and to ensure that the system will only accept approved inputs and that all other inputs are rejected in a controlled manner.

10.5.2 Method

Follow the instruction within the test method column of section 10.5.4 to test the data entry of the system. Record all observations in the actual results in section 10.5.4 and attach any raw data printouts as an appendix to this protocol.

Ensure that upon test conclusion, all parameter set points are returned to normal operating status.

10.5.3 Acceptance Criteria

Operator inputs with limits / formats associated with them will accept values as stated in column "System accepts Input as Valid". Entered value or format stated in column "System rejects Input as invalid" will be rejected by the system.

10.5.4 Results

System Variable	Limits		Value Smaller than Min	Value Greater than Max	Expected Result Met? [Yes/No]	Initial / Date
	Min	Max				
Expected Result	**System accepts Input as Valid**		**System rejects Input as Invalid**			
Speed						
Temperature						

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.6 System Functionality Tests

10.6.1 Objective

To verify Rotocone Vacuum Dryer components functionality.

10.6.2 Method

Prior to this test, power up and start-up each component as described in Section 10.6.4: *Power up and Start Test.* Operate each item as described in Section 10.6.4 to test the functionality of the system. Record all observations in the Actual Results column in Section 10.6.4.

10.6.3 Acceptance Criteria

All aspects of control for individual components integrated within the Rotocone Vacuum Dryer shall function as specified in the expected results column in Section 10.6.4.

10.6.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Switching on the Power and Utilities to the System				
Switch on the power & utilities to Rotocone Vacuum Dryer	System will start			
Monitor and Log the readings.	Log the following readings: 1. Voltage. 415 ± 10 % Volts 2. Compressed air pressure – 2 bar.			
Observe RCVD machine physically	Visual Inspection of Rotocone Vacuum Dryer			
Switch “ON” the mains	Power is distributed to electrical components in control Panel. System returns to operation mode			
Compressed air supply to the equipment.	Reading appears in pressure gauge mounted outside of RCVD			
Check the system for required vacuum.	Reading appears in vacuum gauge located outside structure of RCVD			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.7 System Alarm and Interlocks Test

10.7.1 Objective

To verify that operation of system alarms and interlocks are functioning correctly.

10.7.2 Method

Rotocone Vacuum Dryer Alarm Tests have been carried out as part the site acceptance/commissioning process, as such, results are documented in Site Acceptance Test (SAT) document Ensure that all tasks have been completed and signed off as correct. State this in the section below and refer to the relevant supporting documentation in the Actual results column.

With a copy of the SAT document and relevant sections of the Software Design Specification for the RCVD, re-test 10% of all alarms in accordance with the method described in the SAT. List down the names of individual alarms and interlocks re-tested on a check sheet. Verify on the check sheet that the alarm/ interlock has passed or failed.

If there are no failures when testing 10% of the alarms, then alarms testing are complete. Record results in section 10.7.4. Should there be a failure of one or more alarm proceed to re-test 50% of all alarms in the manner described above. If no failures are found while checking 50% of the alarms, then alarms testing are complete. Record results in section 10.7.4. If there are one or more failures while testing 50% of the Alarms, proceed to test 100% of the Alarms in the manner described above.

Note: Only test the alarms / interlocks that will not result in any physical/ structural damage to the system as a result.

Ensure that all instruments or equipment used to conduct this test are calibrated. Attach copies of calibration certificates as an annexure to this protocol, and record details as necessary in Section 10.2.

10.7.3 Acceptance Criteria

SAT document must show that the system alarms/ interlocks activate in the correct situation and with the correct effect.
Alarm / Interlock retesting must activate in the correct situation and with the correct effect as described in the SAT document.

System cannot be started when critical alarms are activated.
Record of alarms/interlocks testing check sheet is attached in the annexure.

10.7.4 Results

Item	Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Clear all the alarms. Press the alarm reset key. Press the drive on. Then follow the test method.					
Railing	Ensure that door is not in bypass mode. Open the door one at a time.	On each opening of the railing, the machine should stop.			
Hand wheel IN	Put the Hand wheel IN	The machine should display "HANDWHEEL IN" and machine should not start when the drive is ON.			
Air pressure low	Forcefully lower down the air pressure to less than 6 bar.	The machine should stop.			
Emergency stop	Press the emergency off switch. PLC INPUT X16 will switch off.	When the machine trips, it should display "EMERGENCY STOP BUTTON PRESSED".			
Motor clutch trip	Forcefully keep the motor clutch trip proximity switch in ON condition for one second.	The machine should stop and display "MOTOR CLUTCH TRIP"			
Main motor drive trip	Forcefully switch OFF the power to the A.C. drive.	The machine should stop and display "MAIN MOTOR DRIVE TRIP"			
Thermal overload	Forcefully switch OFF one of the thermal overload one at a time. The thermal overload is for vacuum pump for capsule separation, ADU motor and powder feed motor.	The machine should stop and display "OVERLOAD OF VACUUM PUMP / POWDER MOTOR"			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.8 System Emergency Shutdown Stop

10.8.1 Objective

To verify that the emergency stop function activation shuts down the system in an appropriate manner.

10.8.2 Method

Ensure system is running under normal operating procedures. Press the emergency stop button and follow instructions in the Test Method column in section 10.8.4. Record all observations in the Actual Result column in section 10.8.4 and attach any raw data printouts as an appendix to this protocol.

10.8.3 Acceptance Criteria

Component comprising the system shut down in a safe and controlled manner when the emergency stop button is pressed. All pumps and motors will trip. An alarm condition is registered with audible alarm.

10.8.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial /Date
Press Emergency Stop Button while the system is running in normal operating mode	The system shuts down in a safe and controlled manner. Indication for emergency shutdown appears in MMI.			
Release emergency stop button when system is in stop mode	System will start in normal mode.			

Equipment Operated by		Date	
Comments:			

Reviewed by		Date	

10.9 System Power Failure and Recovery Test

10.9.1 Objective

To ensure that system integrity is maintained in the event of power loss, that the system operates in accordance with specified acceptance criteria during failure and that the system can be recovered back to a satisfactory operational state without the loss of data

10.9.2 Method

Perform a simulated power loss while the systems operating normally without any faults. Verify the capability of the system to safely recover and resume normal operation. Verify that the system is able to retain the original program without data corruption. Also, verify that the system can prevent loss or corruption of stored data.
Follow instructions in the Test Method column in Section 10.9.4. Record all observations in the Actual Results column in section 10.9.4 and attach any raw data printouts as an annexure to this protocol.

10.9.3 Acceptance Criteria

Upon loss of power the system shuts down safely without causing damage to equipment components and can automatically restart following a power failure event without the need for application of additional resetting procedures.
The system is able to retain the original program upon a loss of power.
The system is able to prevent the loss or corruption of stored data during a power failure.

10.9.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Pressure Gauge	Reading drops to zero			
Vacuum Gauge	Reading drops to zero			

10.9.4.1 Parameter settings after power failure and recovery

System Variable	Prior to Power Failure	Following power restoration	Initial / Date
Pressure Gauge			
Vacuum Gauge			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.10 Filter Integrity Test

10.10.1 Objective

To verify that installed filters have been integrity tested, and that certification remains valid within the period set forth for operational use.

10.10.2 Method

Review filter integrity test documentation for filters listed in section 10.10.4. Verify that the method used for testing was in accordance with the site procedure, that test results conform to specifications contained therein, and that certification encompasses the period intended for operational use of the system.

Attach copies of integrity test printouts / reports for each filter and record results in Section 10.10.4.

10.10.3 Acceptance Criteria

Test methods comply with the site procedure for 'Integrity Testing of Filters'.

All filters have been issued with the site approved integrity test certificate that is valid for the period of operational use.

10.10.4 Results

Filter Installation location/description and Filter Tag No.	Acceptable [Y/N]	Initial / Date

Comments:

Reviewed by		Date	

10.11 Operator Interface and Screen Graphics Testing

10.11.1 Objective

To verify the operation of all push buttons, touch buttons, switches and screen graphics associated with the Rotocone Vacuum Dryer

10.11.2 Method

Verify that all push buttons, touch buttons and switches and screen graphics operate as defined in the tables. Document the results of the test in the table below. Record the results in section 10.11.4 of this protocol.
Verify and mark-up a copy of the following operator screens and attach the copy to the protocol

10.11.3 Acceptance Criteria

The push buttons touch buttons and switches operate as defined in the tables. The screen graphics appear as defined in the table. The actual results meet the expected results as defined in the test table(s) provided.

10.11.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Control panel:				
Alarm sounder reset: Generate an alarm and press the Alarm sounder reset	The Audible alarm silences, but raised alarm is still active.			
Reset alarm button: Generate an alarm and press the Reset alarm button when the alarm condition has been lifted.	The alarm is reset and the alarm disappears from the alarm status 'active alarms' screen.			
Display or print each of the screens containing critical data, from the system MMI. Verify the screens against those specified. Append printouts to this protocol.	The screens printed or displayed from the system, accurately represent the screens specified by the vendor documentation			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.12 Valve Operational Test

10.12.1 Objective

To ensure that valves located at throughout the Rotocone Vacuum Dryer operate correctly and can be accessed safely.

10.12.2 Method

Locate each valve listed in Section 10.12.4. Perform the test by manually opening and closing the valve. Verify that all valves can be accessed safely and that each valve can be fully opened and closed. Record results following testing in section 10.12.4.

10.12.3 Acceptance Criteria

Each valve can be accessed safely.
Each valve can be operated at full open and full closed positions.

10.12.4 Results

Valve Check	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Verify that each valve can be assessed safely. Verify that each valve operates and seals correctly.	Valve can be accessed safely. Valves operate and seal correctly.			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.13 Confirmation of Critical Parameter and Full Function Testing

10.13.1 Objective

To confirm that the critical parameter and full function of the Rotocone Vacuum Dryer are as defined below:-

- Non-Metallic parts such as Gaskets, and other coming in contact with the product is of food grade quality.
- The lubricants used are food grade and they do not come into contact with product or product contact parts.

10.13.2 Method

Follow the test methods described in section 10.13.4 for various parameters under test.
Record the observation in 10.13.4 actual results column.
Attach supporting documents, as applicable, in the appendix.

10.13.3 Acceptance Criteria

The critical operational parameters and full function testing has been identified and completed satisfactorily.

10.13.4 Results

Test Method	Expected Result	Actual Result	Acceptable [Y/N]	Initial / Date
Product contact Parts				
Gaskets to be of Food Grade – Verification of Test Certificates	Material to Confirm Food Grade quality			
Lubricants are Food Grade & does not come in contact with the Product				
Visual Inspection & test certificates from Vendor	Lubricants are Food Grade & does not come in contact with the Product			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.14 Loss of Utilities

10.14.1 Objective

To verify the loss of utilities supplies will not affect or damage the Rotocone Vacuum Dryer and that the subsequent return of any

failed utility does not pose a threat to the system, the system's operator and the product quality.

10.14.2 Method

- **Compressed Air Supply to the Rotocone Vacuum Dryer**
  Run the Rotocone Vacuum Dryer in normal operation.
  Isolate the supply of compressed air to the Rotocone Vacuum Dryer. Record the system's reactions and any alarms generated in the result table below.
  Reinstate the supply of compressed air and record the systems reactions in the result table 10.14.4 as the system returns to normal operation.

10.14.3 Acceptance Criteria

The Rotocone Vacuum Dryer shall raise an alarm and revert to the scenarios listed in the results section below on the isolation of:

- Compressed air

10.14.4 Results

Test method	Expected Result	Actual Result	Acceptable [Y/N]	Initial/Date
Turn off compressed air supply to the Rotocone Vacuum Dryer by closing valve Record the system's reactions in the "actual result" column.	Air pressure low			
	All actuated valves fail-safe			
	System shuts down			
Restore compressed air supply to the Rotocone Vacuum Dryer by opening valve Record the system's reactions as the system returns to normal operation.	System reverts to normal status			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

10.15 Automation Interface Tests

10.15.1 Objective

To verify that the interface between the control system and other automation is as defined.

10.15.2 Method

Follow the instructions in the Test Method column in the table to test the interface between the control system and other automation.
Record all observations in the Actual Results section of the table.

10.15.3 Acceptance Criteria

The interface between the control system and other automation must be as defined in the expected result column within the table

10.15.4 Results

Test method	Expected Result	Actual Result	Acceptable [Y/N]	Initial/ Date
Disconnect the MMI communication cable.	MMI screen to become blank and message will appear that communication signal is missing.			

Equipment Operated by		Date	

Comments:

Reviewed by		Date	

11.0 CHECKLIST OF ALL TESTS AND CHECKS

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

Reference No.	Tests or Checks	Executed [Y/N]	Comment
10.1	SOP Verification		
10.2	Digital Input & Output Test		

10.3	Rotocone Vacuum Dryer Security Test		
10.4	Rotocone Vacuum Dryer Start-Up and Shutdown Test		
10.5	Operator Data Entry Test		
10.6	Rotocone Vacuum Dryer Functionality Test		
10.7	Rotocone Vacuum Dryer Alarm and Interlocks Test		
10.8	Rotocone Vacuum Dryer Emergency Shutdown Test		
10.9	Rotocone Vacuum Dryer Power Failure and Recovery Test		
10.10	Filter Integrity Test		
10.11	Operator interface and Screen Graphics Testing		
10.12	Valve Operational Test		
10.13	Confirmation of Critical parameter and full function testing		
10.14	Loss of utilities		
10.15	Automation Interface test		

Comments:

Reviewed by		Date	

12.0 DEVIATION SHEET

Report any deviations from the acceptance criteria or exceptions from protocol instructions in the Record Sheet as described in SOP -"Handling of Deviations" Record the total number of exceptions / deviations reported during the qualification activities of this Protocol. Record the Deviation Number and Title in the Table below. Include all Deviation Record Sheets in the IQ File.
TOTAL NO. OF EXCEPTIONS / DEVIATIONS = _____

Exception / Deviation No.	Exception / Deviation Title	Status

Comments:

Reviewed by		Date	

12.1 DEVIATION AND CORRECTIVE ACTION REPORT FORM

This Deviation and Corrective Action Report Form shall be completed for each result that does not meet the expected or as designed condition encountered during the execution of the protocol. Each form shall be numbered sequentially and tracked on the Deviation Sheet within the protocol.

Deviation Report Number:	
PROTOCOL SECTION NO.:	**DATE OF TEST:**.....
Description Of Test Result:	
IMMEDIATE ACTION TAKEN:	
Corrective Action Taken / Planned:	
Deviation Reported By:	
Name: Signature: Date:	
Corrective action must be taken prior to approval of IQ or OQ? :	
HEAD - ENGG. SIGNATURE	**DATE:**
Head-User dept. signature	Date

QA Signature:	Date:
Corrective Action Implemented:	
Corrective Action Implemented By:	
Name: Signature:	Date:
(Attach comments and supporting documentation as necessary)	
Was a re-test or amendment necessary due to the Deviation?	Date of re-test:
Is Deviation Closed (Yes/No):	
QA Signature:	Date:

13.0 REFERENCES

The Principle Reference is the following

- Master Validation Plan for Tablets, Capsules, Dry Syrup and Dry Powder Injection Manufacturing Facility, VMP/00, Revision 00.
- Schedule – M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol 2 – Good Manufacturing Practices and Inspection.

The following references are used to give addition guidance

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition / March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, *Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs*, General. April 1, 1998.

- Code of Federal Regulations (CFR), Title 21, Part 211, *Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals*, April 1, 1998.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission's working party on control of medicines and inspections document, *Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation*, October 1999.
- GAMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.
- SOP "Handling of Deviations".
- SOP "Change Control Procedure".

14.0 LIST OF ANNXEURES

Annexure No.	Document Title

15.0 SUMMARY

16.0 POST APPROVALS

The following approvals signify that the OQ is complete and acceptable and that the system is ready for PQ Execution.

PREPARED BY:

Functional area	Name	Signature	Date
Production			

CHECKED BY:

Functional area	Name	Signature	Date
Engineering			
Production			
Quality assurance			

APPROVED BY:

Functional area	Name	Signature	Date
Head Engineering			
Head Manufacturing			