TABLE CONTENT

1.0 PRE -APPROVAL

Signing of this Installation 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
Engineering			

CHECKED BY:

Organization	Name	Signature	Date
Engineering			
Production			
Quality Assurance			

APPROVED BY:

Organization	Name	Signature	Date
Head Engineering			
Head Manufacturing			

2.0 OBJECTIVES

The objectives of this Installation Qualification (IQ) are as follows:

- To verify that the Rotocone Vacuum Dryer in Tablets, Capsules Dry Syrup and Dry powder injection Facility has been installed in accordance with the set acceptance criteria and meets GMP requirements.
- To verify that there is sufficient and accurate information to operate and maintain the machine reliably and reproducibly.
- To verify that the requirements specified at the time of purchase are met in the delivered and installed item. Purchase Order and Equipment Specifications have been used to prepare this Protocol. Confirmation of the installed system to pre-determined specifications will verify that user requirements have been met.

3.0 SCOPE

The Rotcone Vacuum Dryer 1500 Ltrs is located at site. 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 voidable 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.

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..

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

5.1.1 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. 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.

5.1.2 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. .

6.0 DOCUMENTATION REQUIREMENTS

The IQ File should include:

- This IQ Protocol
- All printouts and handouts generated during qualification procedure
- A Signature Sheet where all people, performing the qualification checks, are listed
- Any change control actions that may have occurred during the qualification activities.
- Any deviations, exceptions or investigation reports generated during the qualification activities.

7.0 DATA COLLECTION

All individuals executing this Protocol shall complete the attached *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.
When appropriate, Drawings shall be marked up as following:

- System checked and conforms to the Drawing: ***YELLOW*** highlighter
- System checked and does not conform to the Drawing: ***RED*** highlighter and notes in ***RED*** pen.
- Personnel who mark up the drawing shall initial and date it.

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 checks, collect all relevant printouts and certificates and retain for inclusion in the IQ File. If more Data Sheets or Deviation Sheets are required, they are to be attached to this Protocol as *Annexures* and to be listed in *Section 14. List of Annexures*.

8.0 CHANGE CONTROL

Any changes or modifications to the system shall be performed in accordance with the site.

Change Control Forms raised during the execution of this IQ will be filed with the protocol. An assessment will be made to check whether any re-validation is required by site before the change request is closed out.

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 IQ commencing. Open action items resulting from these tests shall be listed in the Comments section.

Test	Test Date	Documentation [Title, Rev.]	Documentation Location	Complete [Y/N]	Initial / Date
FAT					
Commissioning / SAT					

Comments:

Reviewed by		Date	

10.0 TESTS AND CHECKS

The following tests and checks are to be completed for IQ of Rotocone Vacuum Dryer System. After completion of this section, fill the *Checklist* in *Section 11*.

10.1 Drawing Verification (Ref :)

10.1.1 Objective

To verify that relevant drawings of the equipment are available and current.

10.1.2 Method

Examine whether the specified drawings of equipment are available and current. Ensure Title, Revision No., Originator and Document Location are recorded in *Section 10.1.4 Data*. Record any deviation / non-conformance as described in *Section 12. Deviation Sheet.*

10.1.3 Acceptance Criteria

Drawings must be of the latest version approved and filed correctly.

10.1.4 Data

Reference Engineering Drawings	Drawings Rev. No. & Issue Date	Document Location	Acceptable [Y/N]	Initial / Date

Comments:

Reviewed by		Date	

10.2 Documentation Verification (Ref:)

10.2.1 Objective

To verify that sufficient documentation exists to operate and maintain the system reliably and reproducibly.

10.2.2 Method

Verify that Rotocone Vacuum Dryer Machine Turnover Package contains the following documents where deemed appropriate. Identify the sub-folder index of each available document. Examine whether the available documents are as listed in *Section 10.2.4 Data*. Fill detailed information of the Obligatory documents, such as title, revision number, and location in *Section 10.2.4.1 Document Details*.
Report any deviations / non- conformances as described in *Section 12 Deviation Sheet*.

10.2.3 Acceptance Criteria

All obligatory documents must be available in a current status. Where relevant, documents must be approved.

10.2.4 Data

When a specified document is located within another document, cross-refer to the main document at the Comment Column.

Document	Available [Y/N]	Comment	Initial / Date
General Documentation			
Purchase Orders			
Vendor Offer			
URS:			
Design Qualification			
Engineering Drawings List			
Enhanced Commissioning Documentation			
Operation Manuals			
Certificates of Conformity			
Equipment Logbook			
Spare Parts List			
Mechanical Documentation			
Mechanical Parts List			
Description of mechanical parts			
Maintenance Manuals			
Material Specifications			
Equipment schedule			
Termination and Utilities schedule			
Product contact material certificate			
Electrical Documentation			
Electrical Parts List			
Electrical Diagrams			
Electrical Installation test specification			
Instrument List			
Instrument calibration certificates			

10.2.4.1 Document Details

Document Title / No./ Originator (Company)	Revision No. / Issue Date	Document Location	Acceptable [Y / N]	Initial / Date
Purchase Orders				
URS Doc. No.:				
Design Descriptions Doc. No				
Engineering Drawings List				
Enhanced Commissioning Documentation				
Operation Manuals				
Certificates of Conformity				
Mechanical Parts List				
Description of mechanical parts				
Maintenance Manuals				
Material Specifications				
Product contact material certificate				
Electrical Parts List				
Electrical Diagrams				
Description of electrical parts				
Electrical Installation test specification				
Instrument calibration certificates				

Comments:

Reviewed by		Date	

Physical Verification of Area & Installation: (Ref.:)

S.No.	Title	Observation	Initial / Date
1.	Verify that there is sufficient space for easy movement of man and material after installation		
2.	Verify that foundation arrangement has been made for proper fixing of equipment		
3.	Other provisions: (if any)		
	Equipment lifting and positioning arrangement		
4.	Verify that provisions for required utilities are provided.		
	Electricity		
	Vacuum		
	Air		
	Nitrogen		
5.	A process instruments diagram (P & ID).	All instruments and components shall be installed as per approved P & ID.	
6.	Spirit Level of the Machine	Bubble should be inside the circle	
7.	Guarding over moving parts	No damages as well as properly interlock.	

10.3 Equipment Verification (Ref :)

10.3.1 Objective

To verify that the equipment components are as specified.

10.3.2 Method

Visually examine all equipment components as listed in the tables below. Confirm that all specified requirements listed in SPECIFIED column [*Section 10.3.4. Data*] have been met. Record any deviations/non-conformances as described in *Section 12. Deviation Sheet*.

10.3.3 Acceptance Criteria

Equipment must be in conformance to specifications as listed in the SPECIFIED column in *Section 10.3.4 Data.*

10.3.4 **Data**

S.No.	Name of component	Specified	Observation	Checked by Sign/ date
1	**Shell**			
	Make	BCEPL		
	specification	8 thk		
2	**Top and bottom cone**			
	Make	BCEPL		
	specification	8 thk		
3	**Jacket shell**			
	Make	BCEPL		
	specification	6 thk		
4	**Jacket cone**			
	Make	BCEPL		
	specification	6mm thk		

5.	**Insulation cladding**			
	Make	BCEPL		
	specification	14 SWG		
6	**Stiffener**			
	Make	BCEPL		
	specification	5mm thick		
7	**Drive shaft(Hollow)**			
	Make	BCEPL		
	specification	Φ 135mm		
8	**Non drive shaft(hollow**			
	Make	BCEPL		
	specification	Φ 135mm		
9	**Plummer block**			
	Make	Skf		
	specification	SN 530		
10	**Electric Motor**			
	Make	HMM		
	specification	7.5hp,1440rpm,NELP,Foot mounted		
11	**Gear Box**			
	Make	Elecone		
	specification	5” SNU-U, Ratio-60:1 Shaft Handing-SNU-UR		
12	**Filter**			
	Make	BCEPL		
	specification	05 micron		

S.No.	Name of component	Specified	Observation	Checked by Sign/ date
13	**Baffle**			
	Make	BCEPL		
	specification	40 NB Sch 40		
14	**Cyclone Separator**			
	Make	BCEPL		
	specification	5mm thick		
15	**Mechanical seal for steam shaft**			
	Make	Hi Fab		
	specification	Single dry seal for Φ 60 mm shafts. Carbon vs T carbide, ss 304		
16	**Mechanical seal for vacuum shaft**			
	Make	Hi Fab		
	specification	Single dry seal for Φ 60 mm shafts. Carbon vs T carbide, ss 304		

Comments:

Reviewed by		Date	

10.4 Instrumentation Verification (Ref :)

10.4.1 Objective

To verify the lists of instruments included in the system are as specified. (See *Section 10.5* for *Calibration Verification*)

10.4.2 Method

Visually check whether instruments are installed according to the engineering drawings and system specification. Confirm that all specified requirements have been met. List Tag number, serial number and location for each instrument. Record any deviations / non-conformances as described in *Section 12. Deviation Sheet*.

10.4.3 Acceptance Criteria

All instruments listed must be tagged and in conformance to the specifications listed in the SPECIFIED column in *Section 10.3.4. Data*.

10.5 Calibration Verification (Ref:)

10.5.1 Objective

To verify that critical instruments have been calibrated as specified.

10.5.2 Method

Verify that all critical instruments have been calibrated on site in accordance with the applicable vendor procedure and that current calibration certificates are available. Indicate the calibration certificate location, if a copy of the certificate is not attached. Record any deviation / non-conformance as described in *Section 12. Deviation Sheet*.

10.5.3 Acceptance Criteria

Critical instruments must be labeled and within the validation calibration period during qualification.

10.5.4 Data

Instrument	Tag No.	Cal'n Date	Maximum Calibration Interval	Calibration Due Date	Calibration Certificate Available [Y/N; Attached or Location]	Acceptable [Y/N]	Initial / Date
Pressure gauge							
Pressure gauge							
Temperature sensor for product							
Temp. controller							

Comments:

Reviewed by		Date	

10.6 Materials in Product Contact (Ref:)

10.6.1 Objective

To verify that all materials in product contact meet the specified requirements.

10.6.2 Method

Examine there is documented evidence that all materials that come into product contact meet the required specifications for material type and surface finish as applicable. Attach documents/identify the location. Utilities (such as nitrogen, air, steam, water) that subsequently come into contact with the pharmaceutical products shall be deemed as "product". Report any deviation / non-conformances as described in *Section 12. Deviation Sheet*.

10.6.3 Acceptance Criteria

All materials in product contact must be in conformance with the specifications listed in the SPECIFIED column in *Section 10.6.4. Data*.
Documented evidence attached/location checked.

10.6.4 Data

System Component	Reference Document [Title, No., Rev. No., Date]	Specified/ Surface Treatment	Actual	Material Certificate Available [Y/N, Location]	Acceptable [Y/N]	Initial / Date
Machine frame structure	Instatallation Qualification Rotocone Vacuum Dryer	SS 304				
External cladding		SS 304				
Shell		SS 316				
Charging/Discharge	Instatallation Qualification Rotocone Vacuum Dryer	SS 316				
Baffle		SS 316				
Mounting		SS 304				
Jacket		SS 304				

Comments:

Reviewed by		Date	

10.7 Services Verification (Ref:)

10.7.1 Objective

To verify that all services required for the operation of the system are available and connected to the system and that these utilities conform to the system requirement.

10.7.2 Method

Visually examine that all services are available and connected in accordance with the applicable engineering drawings and system specifications. Complete the list of services installed in *Section 10.7.4 Data*. Record any deviation / non-conformances as described in *Section 12. Deviation Sheet*.

10.7.3 Acceptance Criteria

All services are available and connected in conformance to specifications listed in the SPECIFIED column in *Section 10.7.4 Data*.

10.7.4 Data

Services	Specified	Actual	Acceptable [Y/N]	Initial / Date
Electricity	Power supply- ▪ HP: 7.5 H.P. • Power Supply:415 V AC, 3 Phase, 50 Hz	• Voltage • Phases: • Frequency:		
Vacuum				
Comp air for purging				
Steam				

Comments:

Reviewed by		Date	

10.8 Lubricants List (Ref:)

10.8.1 Objective

To verify all Lubricants used in the system are as specified

10.8.2 Method

Examine whether all lubricants used in the system are as listed in the SPECIFIED column in *Section 10.8.4. Data*. Classify whether each lubricant may be in product contact or not. Record the quantity and location of the lubricants inventory. Confirm that all specified requirements have been met. Record any deviations / non-conformances as described in *Section 12. Deviation Sheet*.

10.8.3 Acceptance Criteria

Lubricants used must be in conformance with the specifications listed in the SPECIFIED column.

10.8.4 Data

Lubricant	Product Contact [Y/N]	Specified	Actual	Quantity & Location of Inventory	Acceptable [Y / N]	Initial / Date

Comments:

Reviewed by		Date	

10.9 Visual Inspection (Ref:)

10.9.1 Objective

To verify that the Rotocone Vacuum Dryer is ready for operation.

10.9.2 Method

Visually examine that the installation of Rotone Vacuum Dryer is completed and that all instrument / component packaging is removed. Visually examine the cleanliness of the Rotone Vacuum Dryer Machine and verify that all connections to instrument/components (electrical wire, pipes, clamps, etc) are firmly affixed. Confirm that the Rotocone Vacuum Dryer Machine is ready for operation.

10.9.3 Acceptance Criteria

The specifications listed in the SPECIFIED column are met.

10.9.4. Data

S.No.	Specified	Acceptable [Y/N]	Initial / Date
1.	Installation of Rotocone Vacuum Dryer is completed.		
2.	Rotocone Vacuum Dryer Machine is clean.		
3.	All instrument/component packaging is removed.		
4.	All instrument/ component, piping, clamps, wire etc firmly affixed.		
5.	All accessories are available.		

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 IQ have been executed.

Reference No.	Tests or Checks	Executed [Y/N]	Comment
10.1	Drawing Verification		
10.2	Documentation Verification		
10.3	Equipment Verification		
10.4	Instrumentation Verification		
10.5	Calibration Verification		
10.6	Material Verification		
10.7	Services Verification		
10.8	Lubricant List		
10.9	Visual Inspection		

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:
<u>Corrective Action Implemented:</u>
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 site Tablets, Capsules, Dry Syrup and Dry Powder Injection 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 ANNEXURES

Annexure No.	Document Title

15.0 SUMMARY

16.0 POST APPROVALS

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

PREPARED BY:

Functional area	Name	Signature	Date
Engineering			

CHECKED BY:

Functional area	Name	Signature	Date
Engineering			
Production			
Quality assurance			

APPROVED BY:

Functional area	Name	Signature	Date
Head Engineering			
Head Manufacturing			