PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM TRANSFER SYSTEM	PROTOCOL No.:

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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 Vacuum Transferring System has been reviewed a 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		

2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and To perform the Operational Qualification of Vacuum Transferring System and define the qualification requirements and acceptance criteria for the unit. Successful completion of these qualification requirements will provide assurance that the Vacuum Transferring System was use as required in Granulation.

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the installed Vacuum Transferring System will operate reproducibly and consistently within its full dynamic range of operation according to manufacturer's specifications.

2.3 SCOPE:

The Scope of this protocol is limited to the Operational Qualification of Vacuum Transferring System Granulation area of the 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.

2.5 EXECUTION TEAM:

The satisfactory operation of the Vacuum Transferring System shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Vacuum Transferring System is operational and is satisfactorily working.

Execution team is responsible for the execution of Operational of Vacuum Transferring System. Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCEPTANCE CRITERIA:

3.1 The equipment shall be operational as per its specified operating instructions.

3.2 All SOP's for the equipment to be verified and checked.

3.3 Training is important to all the concerned personnel.

3.4 All the functionality of equipment components to be checked for its full range.

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

4.0 REVALIDATION CRITERIA:

The Vacuum Transferring System has to be revalidated if

- During relocation of equipment.
- There are any major changes, which affect the performance of equipment.
- During preventive maintenance or break down maintenance if any major components is replaced which affects the performance of equipment?
- As per revalidation date and schedule.

5.0 OPERATIONAL QUALIFICATION PROCEDURE

5.1 EQUIPMENT DESCRIPTION:

Equipment Name	:	VACUUM TRANSFERING SYSTEM
Supplier / Manufacturer	:	Bectochem Loedige Process Technology Pvt.Ltd.
Model	:	GMP
Serial No.	:	….
Dimension	:	Air Pulsing Mainfold to Actuated Solenoid Valve distance 432 mm
Capacity	:	10 HP
Location	:	Granulation

VACUUM TRANSFERING SYSTEM comprises of following components.

- Vacuum Pump
- Pneumatic Vacuum Transfer System
- Pneumatic Vacuum Supporting Device
- PU Cloth
- Silencers
- Non Return Valve
- Suction Air Filter
- Safety Valve
- Measuring and Monitoring Device
- Electrical Actuated Solenoid Valve
- Control Panel

5.2 INSTRUCTION FOR FILLING THE CHECKLIST

5.2.1 Write the actual observation in observation column

5.2.2 Give the detailed information in the summary and conclusion part of the operational Qualification report.

5.2.3 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 a traceability to the national standard which is to be used for the verification of the operation of the Vacuum Transferring System.

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

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

Reviewed by (Sign/Date)

5.4 VERIFICATION OF FUNCTIONAL CHECKS

`Name of system component	Specified function	Observation	Verified by (sign/date)
Main Power supply			
Connect the main power supply to the control cum operating panel of the machine	Check that there is no power supply to the machine when M.C.B. is off		
Switch "ON" the Vacuum Transferring System	Check the main motor of Vacuum Transferring System rotates in clockwise direction.		
Operating panel (Wiring Tug test)			

`Name of system component	Specified function	Observation	Verified by (sign/date)
Lightly pull all the wires connected to the electrical switchgears one by one.	To Confirm that the wires are connected to the electrical switchgears tightly.		
Equipment Control Functions and Interlock Verification			
Run the Vacuum Transferring System.	The controls and interlocks should function.		
Emergency push button	When it pressed, machine should stop.		

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

Reviewed by (Sign/Date)

5.5 VERIFICATION OF SAFETY FEATURES:

SAFETY FEATURES DESCRIPTION	FUNCTION	OBSERVATION	VERIFIED BY(SIGN/ DATE)
1. Earthing	To avoid electrical shocks due to leakage current.		
2. Emergency push button	It is provided to stop the machine in case of emergency		

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

Reviewed by (Sign/Date)

5.6 VERIFICATION OF SUPPORTING UTILITIES:

Utility	Method of verification	Observation	Checked by Sign/ Date
Electricity: 3 phase, 415V AC, 50Hz supply with neutral and proper earthing	Physically		

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

Reviewed by (Sign/Date)

5.7 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP):

The following Standard Operating Procedures were verified as important for effective performance of Vacuum Transferring System operation.

S.No.	SOP TITLE	SOP NUMBER	VERIFIED BY SING/DATE

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

Reviewed by (Sign/Date)

5.8 VERIFICATION OF CALIBRATED COMPONENT (S):

Verify that the drafted calibration procedures for different identified components in the Vacuum Transferring System are adequate and appropriate covering the operating range(s). e.g. Pressure gauge, counter etc (As applicable).

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)

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 LIST OF ANNEXURES:

Annexure No.	Document Title

Remarks (if any)**:** ----------

Done By & Date: **Verified By & Date:**

5.11 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S):

Following deficiency was identified and corrective actions taken in consultation with the validation team.

Description of deficiency:

Corrective action(s) taken:

Deviation accepted by
(Sign/Date)

Deviation Approved by
(Sign/Date)

6.0 OPERATIONAL QUALIFICATION FINAL REPORT:

All the OQ data sheets and discrepancy report shall be reviewed by validation team to prepare summary report. The summary of OQ shall be used to draw conclusion for approval of Operation qualification report.

6.1 SUMMARY:

6.2 CONCLUSION:

Prepared By
Sign/Date

Checked By
Sign/ Date

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. Signature in the block below indicate that all items in this qualification report of Vacuum Transferring System have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

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