PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM TRANSFERRING SYSTEM FOR FBD 500 kg	PROTOCOL No.:

1.0 PROTOCOL APPROVAL:

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VACUUM TRANSFERRING SYSTEM FOR FBD 500 kg	PROTOCOL No.:

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 signatories.

This Installation Qualification protocol of VACUUM TRANSFERING SYSTEM has been reviewed and approved by the following signatories:

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 executing this protocol is to collect sufficient data pertaining to the VACUUM TRANSFERING SYSTEM and define the qualification requirements and acceptance criteria for the unit. Successful completion of these qualification requirements will provide assurance that the VACUUM TRANSFERING SYSTEM was installed as required in Granulation I.

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the VACUUM TRANSFERING SYSTEM received matches the Design specification and also to ensure that it is properly and safely installed.

2.3 SCOPE:

The installation qualification protocol shall be followed for VACUUM TRANSFERING SYSTEM. This protocol defines the methods and documentation that shall be used to evaluate the system installation in accordance with the specifications and intended use. Successful implementation of this protocol shall verify that the systems installed meet the requirements specified.

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 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 VACUUM TRANSFERING SYSTEM shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the VACUUM TRANSFERING SYSTEM is installed satisfactorily.

Execution team is responsible for the execution of installation qualification of VACUUM TRANSFERING SYSTEM and Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCEPTANCE CRITERIA:

3.1 The VACUUM TRANSFERING SYSTEM shall meet the system description given in design specification.

3.2 The VACUUM TRANSFERING SYSTEM 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.

4.0 REVALIDATION CRITERIA:

The machine has to be revalidated if

- There are any major changes, which affect the performance of the equipment.
- After major breakdown, maintenance is carried out.
- As per revalidation date and schedule.

5.0 INSTALLATION 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

Process Equipment Description

The proposed system is a TRANSFERING SYSTEM in the lean phased Vacuum conveying mode, which achieves material transfer by introducing the material into the moving stream of air at desired rate. Conveying is achieved automatically and continues till the material reaches its final destination.

The major components of the VACUUM TRANSFERING SYSTEM are:

- 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 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.

5.3 INSTALLATION CHECKLIST:

Installation checklist is as follows:

S.No.	Statement	Method of verification	Actual observation	Checked By Sign/Date
1.	Verify the purchase order copy and PO no. Shall be written in observation column	Physically		
2.	Verify that the "As Built" drawing is complete and represents the design concept.	Physically		
3.	Verify that major components are securely anchored and shock proof.	Physically		
4.	Verify that there is sufficient room provided for servicing.	Physically		
5.	Verify that all piping and electrical connections are done according to the drawings.	Physically		
6.	All access ports are examined and cleared of any debris.	Physically		
7.	Safe electrical connections.	Physically		

8.	Sufficient room provided for maintenance.	Physically		
9.	Equipment identification name plate should be visible.	Physically		
10.	Units installed on foundation are secure in place as per manufacturer's recommendations.	Physically		
11.	Verify that there is no observable physical damage of following components			
11.1	Vacuum Pump	Physically		
11.2	Pneumatic Vacuum Transfer System	Physically		
11.3	Pneumatic Vacuum Supporting Device	Physically		
11.4	Silencers	Physically		
11.5	Non Return Valve	Physically		
11.6	Suction Air Filter	Physically		
11.7	Safety Valve	Physically		
11.8	Measuring and Monitoring Device	Physically		
11.9	Electrical Actuated Solenoid Valve	Physically		
11.10	Control Panel	Physically		

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

Reviewed by (Sign/Date)

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
Shell	Make	Bectochem	Physically/ Technical Specification		
	Size	2 MM Thk	Physically/ Technical Specification		
Bottom Cone	Make	Bectochem	Physically/ Technical Specification		
	Size	2 MM Thk	Physically/ Technical Specification		
Top Flange	Make	Bectochem	Physically/ Technical Specification		
	Size	12 MM Thk	Physically/ Technical Specification		
Top Dish	Make	Bectochem	Physically/ Technical Specification		
	Size	2 MM Thk	Physically/ Technical Specification		
Eye bolt	Make	Bectochem	Physically/ Technical Specification		
	Size	M12	Physically/ Technical Specification		
Sq. Gasket	Make	Acrosil	Physically/ Technical Specification		
	Specification	Food grade Silicone 8 Width×8 Thk	Physically/ Technical Specification		
Manually operated Butterfly Valve at discharge	Make	Valfit Engg	Physically/ Technical Specification		
	Specification	4” ID with Handle one side neck	Physically/ Technical Specification		

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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
Pad Plate for Leg	Make	Bectochem	Physically/ Technical Specification		
	Size	75X75X14 SWG	Physically/ Technical Specification		
Pipe for Leg	Make	Bectochem.	Physically/ Technical Specification		
	Size	50×50 mm	Physically/ Technical Specification		
Cartridge Filter	Make	TFI	Physically/ Technical Specification		
	Size	5 MICRON (Washable)	Physically/ Technical Specification		
Pulsing Receiver	Make	Bectochem	Physically/ Technical Specification		
	Size	1.6 Thk	Physically/ Technical Specification		
Solenoid Valve	Make	Avcon	Physically/ Technical Specification		
	Size	1” BSP	Physically/ Technical Specification		
Air Pulsing manifold	Make	Bectochem	Physically/ Technical Specification		
Actuator	Make	Rotex	Physically/ Technical Specification		
	Specification	ECF63	Physically/ Technical Specification		
Pneumatic Actuated Ball valve	Make	Seeco	Physically/ Technical Specification		
	Specification	3” TC End	Physically/ Technical Specification		

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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
Serrated Nozzle with TC	Make	Bectochem	Physically/ Technical Specification		
	Specification	2½" × 14SWG	Physically/ Technical Specification		
Actuator	Make	Rotex	Physically/ Technical Specification		
	Specification	ECF50	Physically/ Technical Specification		
Pneumatic Actuated Butterfly valve at powder Inlet	Make	Valfit Engg	Physically/ Technical Specification		
	Specification	2½" ID	Physically/ Technical Specification		
Pipe with TC	Make	Bectochem	Physically/ Technical Specification		
	Specification	2½" × 14SWG	Physically/ Technical Specification		
Motor for vacuum pump	Make	HMM	Physically/ Technical Specification		
	Specification	HP-10,RPM-1450, V-415, HZ-50,FR.-132M	Physically/ Technical Specification		
	Sr. No.	To be recorded	Physically		
Vacuum pump	Make	Comp-Vac Technology PVT. LTD	Physically/ Technical Specification		
	Specification	SGR-116,CMH-400	Physically/ Technical Specification		
Operating Panel	Make	Flame & Explosion Proof Mfg. Co.	Physically/ Technical Specification		
	Specification	FLP + EX-150	Physically/ Technical Specification		

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

Reviewed by (Sign/Date)

5.5 VERIFICATION OF MATERIAL OF CONSTRUCTION:

Should be verified by test certificates of respective material apart from that SS material should be verified by molybdenum kit in absence of test certificate.

Name of Components	Material of Construction	Method of Verification	Observation	Checked By Sign/Date
Shell	SS 304	Molybdenum kit/ Test Certificate		
Bottom Cone	SS 304	Molybdenum kit/ Test Certificate		
Top Flange	SS 304	Molybdenum kit/ Test Certificate		
Top Dish	SS 304	Molybdenum kit/ Test Certificate		
Eye bolt	SS 304	Molybdenum kit/ Test Certificate		
Lug Pipe	SS 304	Molybdenum kit/ Test Certificate		
Pad Plate for Leg	SS 304	Molybdenum kit/ Test Certificate		
Pipe for Leg	SS 304	Test Certificate		
Pulsing Receiver	SS 304	Molybdenum kit/ Test Certificate		
Solenoid Valve	SS 304	Molybdenum kit/ Test Certificate		
Air Pulsing manifold	SS 304	Molybdenum kit/ Test Certificate		
Pneumatic Actuated Ball valve	SS304	Molybdenum kit/ Test Certificate		
Serrated Nozzle with TC	SS316	Molybdenum kit/		

		Test Certificate		
Pneumatic Actuated Butterfly valve at powder Inlet	SS316	Molybdenum kit/ Test Certificate		
Pipe with TC	SS316	Molybdenum kit/ Test Certificate		
Handle	SS304	Molybdenum kit/ Test Certificate		
Gasket	Food Grade Silicone	Test Certificate		

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

Reviewed by (Sign/Date)

5.6 IDENTIFICATION 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 IDENTIFICATION OF SAFETY FEATURES:

Identify and record the safety features (if any) and their function in following tables:

Safety Features Description	Function	Method of Verification	Observation	Checked By Sign/ Date
Earthing	To avoid electrical shocks due to leakage of current.	Physically		
Gasket	To prevent dusting while operation	Physically		
Motor housing	To guard moving part	Physically		

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

Reviewed by (Sign/Date)

5.8 IDENTIFICATION OF COMPONENT TO BE CALIBRATED

Name of Components	Range	Make	ID	Location	Identified By Sign/Date

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

Reviewed by (Sign/Date)

5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP):

The following Standard Operating Procedures were identified as important for effective performance of VACUUM TRANSFERING SYSTEM.

S.No.	SOP TITLE	IDENTIFIED BY	DATE

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

Reviewed by (Sign/Date)

5.10 VERIFICATION OF DRAWING AND DOCUMENTS:

Following documents are reviewed and attached as listed below:

S.No.	DRAWING AND DOCUMENT DETAIL	CHECKED BY (SIGN)	DATE

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

Reviewed by (Sign/Date)

5.11 LIST OF ANNEXURES:

Annexure No.	Document Title

Remarks (if any)**:**

_____

_____

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

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)

6.0 INSTALLATION QUALIFICATION FINAL 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. If applicable signature in the block below indicates that all items in this qualification report of VACUUM TRANSFERING 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		