 PHARMA DEVILS	INSTALLATION QUALIFICATION PROTCOL CUM REPORT FOR VIBRO SIFTER	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 signatories.

This Installation Qualification protocol of Vibro sifter 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 Vibro sifter and define the qualification requirements and acceptance criteria for the unit. Successful completion of these qualification requirements will provide assurance that the Vibro sifter was installed as required in granulation area.

The Qualification of Vibro sifter performed in view of Sifting area of manufacturing facility.

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the Vibro sifter 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 installation qualification of Vibro sifter. 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 vibro sifter shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the vibro sifter is installed satisfactorily.

Execution team is responsible for the execution of installation qualification of vibro sifter. Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCEPTANCE CRITERIA:

3.1 The vibro sifter shall meet the system description given in design specification.

3.2 The vibro sifter 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.

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5.0 INSTALLATION QUALIFICATION PROCEDURE

5.1 EQUIPMENT DESCRIPTION:

Equipment Name	:	Vibro Sifter 30 “
Supplier / Manufacturer	:	Avon Pharma Machines Pvt. Ltd.
Model	:	GMP
Sr. No.	:	
Dimension(mm)	:	Charging Height- 1450 Discharge Height- 820
Location	:	Sifting I

Process Equipment Description

The purpose of the Vibro sifter is to separate the powder into different fractions depending upon their particle size distribution and the number of screens used.

Vibro Sifter is an efficient and compact unit, self contained and mounted on castor wheels. Its specially designed motor with eccentric weights mounted on the output shaft of the motor imparts gyro vibratory motion to the deck assembly, where the screen is sandwiched between the two halves. Material finer than the screen mesh passes through the screen and is collected in the bottom deck. The graded material is fed to the next screen in case of multiple decks, and finally discharges through the port at the deck. Coarse material is retained on the top of the screen.

The amplitude of the vibrations can be varied from minimum to maximum by adjusting the eccentric weight mounted on the shaft of the motor to suit the process requirements, in least time.

Vibro Sifter comprises of following components:

1. Charging Nozzle
2. Top lid.
3. Clamp (“C” Clamp)
4. Gasket
5. Top Deck
6. Mesh
7. Bottom Deck
8. Discharge chute
9. Motor Mounting Plate
10. Spring locating bush
11. Spring
12. Motor
13. Eccentric top weight
14. Auxillary top weight
15. Eccentric bottom weight
16. Auxillary bottom weight
17. Spring cover
18. Castor wheel

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.

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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 nameplate 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	Charging Nozzle	Physically		
11.2	LID	Physically		
11.3	Clamp	Physically		
11.4	Gasket	Physically		
11.5	Top deck	Physically		
11.6	Bottom deck	Physically		

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S.No.	Statement	Method of Verification	Actual observation	Checked By Sign/Date
11.7	Discharge nozzle	Physically		
11.8	Base Stand	Physically		
11.9	Motor mounting plate	Physically		
11.10	Spring	Physically		
11.11	Motor	Physically		
11.12	Sieve	Physically		
11.13	Castor Wheel	Physically		
11.14	Starter	Physically		

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

Reviewed by (Sign/Date)

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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
Charging Nozzle	Position	On top of lid	Physically		
	Quantity	One	Physically		
	Size	To be recorded.	Measuring tape		
LID	Position	On top deck	Physically		
	Quantity	One	Physically		
	Size	To be recorded.	Measuring tape		
Clamp	Quantity	Three	Physically		
	Size	To be recorded.	Measuring tape		
Gasket	Quantity	Three	Physically		
	Make	Acrosil	Physically		
Top deck	Position	Between lid and bottom deck	Physically		
	Quantity	One	Physically		
	Size	To be recorded.	Measuring tape		
Bottom deck	Position	Above motor mounting plate	Physically		
	Quantity	One	Physically		
	Size	To be recorded.	Measuring tape		
Discharge chute	Position	On bottom deck	Physically		
	Quantity	One	Physically		
	Size	To be recorded.	Measuring tape		
	Quantity	One	Physically		

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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
	Size	To be recorded.	Measuring tape		
Base Stand	Position	Holding vibrating assembly on castor wheel	Physically		
	Quantity	One	Physically		
Motor mounting plate	Position	On spring assembly	Physically		
	Quantity	One	Physically		
Spring	Position	Fixed on top base flange	Physically		
	Quantity	12	Physically		
Spring locating bush	Quantity	24	Physically		
Motor	Position	On base frame	Physically		
	Quantity	One	Physically		
	Make	Good Earth	Physically		
	Model	HP-1.5	Physically		
	Rated RPM	RPM-1400	Physically		
	Serial No.	11627	Physically		
Sieve	Position	On bottom deck	Physically		
	Quantity	One	Physically		
	Make	Filter woven India	Physically		
	Mesh size.	40	Physically		
Castor Wheel	Quantity	Four	Physically		
	Make	Swiss Engg.	Physically		

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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
	Size	4” x 2”	Physically		
Starter	Make	FCG	Physically/ Technical Specification		
Bolt	Quantity	16 No	Physically		

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
Charging Nozzle	SS316L	Molybdenum Kit/Test Certificate		
LID	SS316L	Molybdenum Kit/Test Certificate		
Clamp	SS304	Molybdenum Kit/Test Certificate		
Top deck	SS316L	Molybdenum Kit/Test Certificate		
Bottom deck	SS316L	Molybdenum Kit/Test Certificate		
Discharge nozzle	SS316L	Molybdenum Kit/Test Certificate		
Base Stand	SS304	Molybdenum Kit/Test Certificate		
Gasket	Silicon Food Grade	Test Certificate		
Sieve	SS316L	Molybdenum Kit/Test Certificate		

* Test certificate to be verified and attached to protocol.

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

Reviewed by (Sign/Date)

5.6 IDENTIFICATION OF SUPPORTING UTILITIES:

Utility	Method of verification	Observation	Checked by Sign/ Date
Electricity: 3 phase, 415V±5%, 50Hz ± 2%, supply with neutral and proper earthing.	Physically and with clamp meter		

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 current.	Physically		
Gasket	To prevent dusting while vibration	Physically		
Castor wheel with locking arrangement	The castors are provided with a locking arrangement to position the unit in one place.	Physically		
Emergency stop button	To stop machine immediately in case of emergency.	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 Vibro sifter.

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 Vibro sifter 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		