PERFORMANCE QUALIFICATION

PROTOCOL

FOR

VIBRO SIFTER 30”

EQUIPMENT ID. No.	
LOCATION	
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PERFORMANCE QUALIFICATION PROTOCOL FOR VIBRO SIFTER 30”

PROTOCOL CONTENTS

PERFORMANCE QUALIFICATION PROTOCOL FOR VIBRO SIFTER 30”

1.0 PROTOCOL – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all the test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the **Vibro Sifter 30” (Make-Elicon Pharma)** Installed in …….
- The Vibro Sifter is a standalone unit with plug in type electrical connections for operation and is on castor wheel. Hence, may be moved as per requirement to other area of operation which shall not change the performance of equipment.
- This Protocol will define the methods and documentation used to qualify the Vi*b*ro Sifter for PQ.

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4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and Compilation of the Performance Qualification. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review & Pre Approval of Performance Qualification Protocol. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Review & Pre Approval of Performance Qualification protocol for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & Preventive maintenance as per schedule.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Vibro Sifter
Equipment	
Manufacturer’s Name	Elicon Pharma
Model	cGMP Model
Supplier’s Name	Elicon Pharma
Location of Installation	

6.0 SYSTEM DESCRIPTION:

Vibro sifter is an efficient & compact unit self contained & mounted on castor wheels. Vibro sifter have circular unitary vibrating screen used for gradation of material & its proven records over the rotary or longitudinal movement used in the conventional type of sieving machine, both in term of output & uniform grading of materials. Specially designed motor with eccentric weights imparts vibratory motion to the hopper, which have a screen in between them. Material finer than the screen mesh pass through the screen & are collected in the bottom hopper. Coarse material is retained on top of the screen. The amplitude of vibration can be varied from minimum to maximum by adjusting the eccentric weights to suit the process requirement in base minimum time. The machine is generally as per enclosed specs & consists of:

1. **Motor:** It is fitted with top & bottom eccentric weights designed as per required centrifugal force. This whole assembly is covered by SS plate. The motor is flanged mounted & is fixed on the mounting plate by hex. Bolts. The top weights are fixed on the output shaft over the mounting plate.
2. **Spring:** the eight number chrome plated spring are fixed on the base flange at equi-distance. These springs are provided with the ends of the springs. The springs are then screwed on at both the bolts at one end to the base & on the mounting plate at the top. These rugged springs amplify the vibration & restrict them from being transmitted to the floor.
3. **Hopper:** It is a cylindrical, flanged body with an inverted cone at the bottom. This is placed over the mounting plate. The bottom flange is used for clamping to the base plate with a rubber gasket in between the hopper & plate. Hopper is provided with an outlet, tangential to the periphery for discharge of sieved material. The top flange is to provide for holding the charging/ intermediated hopper with a sieve in between them. It is fabricated from stainless steel sheet and works for loading the materials for sifting.

4. **Screen:** based on the product size required a suitable screen is clamped in between the two hopper. Finer mesh sieves can be or with back up cross support to ensure longevity of sieve. This is recommended for sieves finer than 150 meshes.
5. **Discharge port:** To collect the processed materials.
6. **Conical shape top lid:** It is provided with charging port. Screen is fitted in between the hopper & top lid.

7.0 REASON FOR QUALIFICATION:

- New Equipment in …….
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

…….

9.0 FREQUENCY OF QUALIFICATION:

- Once in every two years time period.
- After any major breakdown or after major modification.

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10.0 PRE – QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- SOP for Operation & Cleaning of Vibro Sifter.
- SOP for Preventive Maintenance of Vibro Sifter.

11.0 TESTS AND CHECKS:

11.1 Verification of Documents:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of Vibro Sifter.
- SOP for Preventive Maintenance Vibro Sifter.

Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved.
- Supporting documents would form a part of the PQ report.

Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.

11.2 Evaluation of Performance Using Placebo Formulation:

Objective:

- To verify the performance of equipment in the range of operational parameters established in Operational Qualification Activity.
- To establish the performance based range of operating parameters for performance qualification activity using drug product.

11.2.1 Checks:

- Sifting Efficiency.

11.2.2 Method:

- Install sieve of specified mesh size as Per BMR.
- Load weighed quantity the materials to the hopper of Sifter (approximately 80% of total volume of top lid).
- Perform sifting.
- Record the sifting operation time.
- Perform visual checks for integrity of sieve.
- Record the observations in the report.

11.2.3 Acceptance Criteria:

- Integrity of sieve should be intact before and after the operation.
- Required process time should be relevant to the standard.

11.3 Evaluation of Performance Using Drug Products:

Objective:

- To verify the performance of equipment in the range of operational parameters established in Operational Qualification Activity.
- To establish documented evidence that the Vibro Sifter is performing consistently and the result of all test parameters meet the pre – defined acceptance criteria of sifted products.

11.3.1 Checks:

- Sifting Efficiency

11.3.2 Method:

- Install sieve of specified mesh size as BMR.
- Load weighed quantity the materials to the hopper of Sifter (approximately 80% of total volume of top lid).
- Perform sifting.
- Record the sifting operation time.
- Perform visual checks for integrity of sieve.
- Record the observations in the report.

11.3.3 Acceptance Criteria:

- Integrity of sieve should be intact before and after the operation.
- Required process time should be relevant to the standard.

12.0 CHECKLIST OF ALL TESTS AND CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

- Verification of DQ, IQ & OQ & other documents.
- Verification of performance using placebo formulation.
- Verification of performance using Drug product.

13.0 REFERENCES:

The Principle Reference is the following:

- Validation Master Plan
- 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.

14.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Operation and Maintenance Manual.

15.0 NON COMPLIANCE:

- All the Non-compliances of procedure, specifications, sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

18.0 ABBREVIATIONS:

BMR	:	Batch Manufacturing Record
cGMP	:	Current Good Manufacturing Practices
CQA	:	Corporate Quality Assurance
DQ	:	Design Qualification
GB	:	General Block
IQ	:	Installation Qualification
mm	:	Millimetre
No.	:	Number
OQ	:	Operational Qualification
PPQ	:	Performance Qualification Protocol
SOP	:	Standard Operating Procedure
VSF	:	Vibro Sifter
WHO	:	World Health Organization