OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

VIBRO SIFTER 30”

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

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30”

PROTOCOL CONTENTS

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30”

1.0 PROTOCOL PRE-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)			

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30"

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Vibro Sifter and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of **Vibro Sifter 30"** (Make- **Elicon Pharma**) Installed in the ……..
- 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 perform OQ activity the Vibro Sifter for OQ. Successful completion of this Protocol will verify that Vibro Sifter meet all acceptance criteria and ready for Performance Qualification.

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 Operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operational Qualification Activity. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Production	• Review & Pre Approval of Operational Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of Operational Qualification Protocol cum Report. • Co-ordination, Execution and technical support in Vibro Sifter Installation Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Operational Qualification Protocol cum Report after Execution.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Vibro Sifter 30’’
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 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol Cum Report
- IQ Protocol cum Report
- SOP for Operation & Cleaning of Vibro Sifter
- SOP for Preventive Maintenance of Vibro Sifter

7.1.1 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. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the OQ Protocol cum report.

7.1.2 Acceptance Criteria:

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

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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

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 OQ commencing.

S.NO.	DOCUMENT NAME	DOCUMENT/SOP NO.	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE	VERIFIED BY QA OFFICER/EXE. SIGN/DATE
1.	DQ Protocol Cum Report				
2.	IQ Protocol Cum Report				
3.	SOP for Operation & Cleaning of Vibro Sifter.				
4.	SOP for Preventive Maintenance of Vibro Sifter				

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30"

8.2 Operational and Functional Checks:

Operate the Vibro Sifter as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

S. NO	FUNCTION	OPERATION	ACCEPTANCE CRITERIA	OBSERVATION
1.	**Power supply**	Connect the power supply to the equipment	Display for electrical supply appears on the power control panel and Machine will ready for operation	
2.	**Motor operation**	Switch ON the equipment	Equipment starts operating and generates vibration	
3.	**Movement of Equipment**	Move the equipment in all directions	Smooth & easy movement should be facilitated by castor wheels.	
4.	**Interlocking**	Lock the castor wheels and Move the equipment in all directions	Movement of equipment in all direction should be blocked by castor wheels.	

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

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8.3 Power Failure Verification:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Main Power shut down	Equipment stops in safe and secure condition		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

9.0 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.

10.0 DOCUMENTS TO BE ATTACHED:

- Operation And Maintenance Manual
- Any Other Relevant Documents.

11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practices
CQA	:	Corporate quality assurance
GB	:	General Block
ID.	:	Identification
IQ	:	Installation Qualification
MCB	:	Miniature circuit break
mm	:	Millimeter
No.	:	Number
OQ	:	Operational Qualification
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure
VSF	:	Vibro Sifter
WHO	:	World Health Organization

17.0 PROTOCOL POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

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