INSTALLATION QUALIFICATION

PROTOCOL CUM REPORT

FOR

VIBRO SIFTER 30”

EQUIPMENT ID. No.	
LOCATION	GRANULATION AREA
DATE OF QUALIFICATION	07/01/25
SUPERSEDE PROTOCOL CUM REPORT No.	NIL

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30"

PRTOCOL CUM REPORT CONTENTS

QUALITY ASSURANCE
CONTROLLED COPY
Sign. .....
Date. 01/01/25

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30"

QUALITY ASSURANCE
MASTER COPY
Sign. .....
Date. 01/01/25

1.0 PRTOCOL CUM REPORT PRE-APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)	QA Executive		01/01/25

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)	Head Production		01/01/25
HEAD (ENGINEERING)	Head Engineering		01/01/25

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)	Head Quality Assurance		01/01/25

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30”

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Vibro Sifter for ……
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of **Vibro Sifter 30’’ (Make – Elicon Pharma)** to be 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 document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Vibro sifter.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30"

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	• Initiation, Review, Approval and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity. • Post Approval of Installation Qualification Protocol cum Report after Execution.
Production	• Review & Pre Approval of Installation Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Installation Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of Installation 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 Installation Qualification Protocol cum Report after Execution.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30"

5.0 EQUIPMENT DETAILS:

Equipment Name	Vibro Sifter 30''
Equipment ID	-
Manufacturer's Name	Elicon Pharma
Model	cGMP Model
Supplier's Name	Elicon Pharma
Location of Installation	Granulation

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:

- Executed and approved design qualification document
- Piping and instrumentation diagram (P& ID)
- Electrical circuits diagram
- Technical specification of equipment
- Certificate of material of construction of components.

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 IQ Protocol cum report.

7.1.2 Acceptance Criteria:

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

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30"

8.0 CRITICAL VARIABLES TO BE MET:

8.1 General Checks and Location Suitability:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Leveling	Should be properly balanced and leveled	Vibro Sifter is found properly balanced & leveled.	
Edges of parts	Metal parts should be properly grind without any sharp edges	All the edges of parts are properly grinded without any sharp edges.	
Welding of Joints	Welding of joints should be without any welding burrs	All welding joints are smooth without any welding burrs.	
Place of Installation	Granulation Area- 08	Vibro Sifter is installed in Granulation area.	
Room Condition	General working condition	Vibro Sifter is installed in classified area under controlled temperature & RH.	
Illumination in area	NLT 300 Lux.	Illumination found 348 lux.	
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance	Space round the Vibro Sifter found sufficient to perform Operation, Cleaning, Sanitation & Maintenance activity.	

Checked By (Production) Sign/Date: 01/01/25

Verified By (Quality Assurance) Sign/Date: 01/01/25

Inference:

All General checks (Leveling, Edges of parts, Welding of Joints, Place of Installation, Room Condition, Illumination in area & Work space around the equipment) have been verified and found within the acceptance criteria.

Reviewed By (Manager QA) Sign/Date: 01/01/25

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30"

8.2 Equipment Verification:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA		OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Equipment	Vibro Sifter		Equipment named Vibro Sifter found installed in Granulation area.	
Model	cGMP Model		Vibro Sifter is of cGMP model.	
Capacity	30 Inch		Capacity of Vibro Sifter is measured in inches, observed 30 inches.	
ELECTRICAL INSTALLATION:				
Electricity	Voltage	415 V	Voltage: 415 V Phases: 3 Phase Frequency: 50 Hz	
	Phases	3 Phase		
	Frequency	50 Hz		
Electrical connections have been provided and secured.	Should be provided & secured		Electrical connection is provided and found	
All components in the panel are properly secured	Should be properly secured		Components found properly secured in panel	
All terminals are tightened	Should be tightened		All terminals found tightened	
Earthing connection to control panel & equipment	Earthing connection to control panel & equipment should be provided.		Earthing found in place for Control panel & equipment.	

Checked By (Production) Sign/Date: 01/01/25

Verified By (Quality Assurance) Sign/Date: 01/01/25

Inference:

Equipment verified for its location of installation, model, capacity, electrical connections verification like voltage, phase, frequency & safety, all critical variables found as per the acceptance criteria.

Reviewed By (Manager QA) Sign/Date: 01/01/25

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30"

S.No.	SPECIFICATION	OBSERVATION	OBSERVED BY SIGN/DATE
1.	The machine should be positioned as per the room layout drawing	Equipment positioning layout is in place & Vibro Sifter found positioned at the specific location.	
2.	The machine should be leveled	Vibro Sifter found leveled.	
3.	The machine should be cleaned	Vibro Sifter found cleaned.	
4.	Utility should be properly connected	Utility (Electrical/ Earthing) found properly connected.	
5.	Visually check the M/C for damage due to transportation. Etc	Before Installation, the Vibro Sifter was found intact without any damage.	

Checked By (Production)
Sign/Date: 01/01/25

Verified By (Quality Assurance)
Sign/Date: 01/01/25

Inference:

Vibro Sifter found verified for its positioning as per the room drawing, observed leveled with the ground, cleaning process is in place, utility found properly connected and observed no damage to the Vibro Sifter during transportation.

Reviewed By (Manager QA)
Sign/Date: 01/01/25

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30"

8.3 Installation Checks:

S.No.	SPECIFICATION	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	Check the proper Mechanical installation of Vibro Sifter.	Vibro Sifter found properly Installed.	
2.	Check the proper electrical installation of Vibro Sifter.	Electrical connections found properly installed.	
3.	Check the parts are working properly	All parts found in proper working condition.	
4.	Check the equipment is free from any defects	No defects found.	
5.	Check the finishing of product contact parts	Product contact parts are smooth & impervious.	
6.	Check that all parts are getting lubricated	All parts found lubricated.	

Checked By (Production)
Sign/Date: 01/01/25

Verified By (Quality Assurance)
Sign/Date: 01/01/25

Inference:

Vibro Sifter found properly installed with electrical installations, verified for the working of components & change parts. The equipment found free from defects, its contact parts are smooth in finishing, all parts are well lubricated.

Reviewed By (Manager QA)
Sign/Date: 01/01/25

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30"

8.4 MOC Verification List:

COMPONENT	MOC	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Top Lid	AISI 316	Verified by Molybdenum kit & MOC certificate, found of AISI316.	Pharmadevils
Top Deck	AISI 316	Verified by Molybdenum kit & MOC certificate, found of AISI316.	Pharmadevils
Bottom Deck	AISI 316	Verified by Molybdenum kit & MOC certificate, found of AISI316.	Pharmadevils
Mesh	AISI 316	Verified by Molybdenum kit & MOC certificate, found of AISI316.	Pharmadevils
Base	AISI 316	Verified by Molybdenum kit & MOC certificate, found of AISI316.	Pharmadevils
'C' - Clamp	AISI 316	Verified by Molybdenum kit & MOC certificate, found of AISI316.	Pharmadevils
Gasket	White Food Grade	Gasket verified physically & found of Silicone.	Pharmadevils
Spring	AISI 304	Verified by Molybdenum kit & MOC certificate, found of AISI304.	Pharmadevils
Motor Mounting Plate	MS	Motor mounting plate made of MS.	Pharmadevils
Motor	STD	Motor found of standard size.	Pharmadevils
Castor Wheel	Polyurethane	Castor wheels found of Polyurethane.	Pharmadevils

Checked By (Production) Pharmadevils 01/01/25
Sign/Date: .....

Verified By (Quality Assurance) Pharmadevils 01/01/25
Sign/Date: .....

Inference:
Material of Construction of all contact & non-contact change parts verified by using Molybdenum Kit, Red color shows for SS316 & Green color shows for SS304.

Reviewed By (Manager QA) Pharmadevils 01/01/25
Sign/Date: .....

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30"

8.5 EQUIPMENT VERIFICATION

S.No.	NAME OF COMPONENTS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	**Model**	cGMP.	Vibro Sifter is of cGMP model.	
2.	**All contact parts**	AISI 316	All contact parts of AISI 316.	
3.	**All non-contact Parts**	AISI 304	All contact parts of AISI 304.	
4.	**Capacity**	Std.	Capacity is of Standard.	
5.	**Dimension (in mm)**	1300 (W) x 800 (D) x 1250 (H)	Dimension measured and observed 1300 (W) X 800 (D) X 1250 (H)	
6.	**Charging height**	Approx.: 1350 mm	Approx.: 1350 mm	
7.	**Discharging height**	Approx.: 780 mm	Approx.: 780 mm	
8.	**Electric motor**	Make : VIKRANT Type : vibratory H.P : 0.5 HP RPM : 1440 Volt : 415± 10 V Amp : 1.2	Make : Vikrant Type : Vibratory HP : 0.5 HP RPM : 1440 Volt : 415± 10 V Amp : 1.2	
9.	**Screen Diameter**	750 mm	750 mm	

Checked By (Production)
Sign/Date: 01/01/25

Verified By (Quality Assurance) 01/01/25
Sign/Date: .....

Inference:

Physical Verification done for dimensions of Vibro Sifter & its capacity; all dimensions were found within the acceptance criteria.

Reviewed By (Manager QA) 01/01/25
Sign/Date: .....

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30"

8.6 Safety:

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN/DATE
Well embedded equipment	For proper sifting	Vibro Sifter found well embedded for proper sifting.	
Electrical wiring and Earthing	Electrical wiring should be as per approved drawings. Double external earthing to control machine (panel and motors).	Electrical wiring found as per the approved drawings. Double earthing provided to control machine.	
Guards	Guards for all moving parts	Guards provided for all moving parts.	
	Should be provided for Motor safety	Guards provided for motor safety.	
Start On/Off switch: To stop the process immediately	Should be provided for equipment and operator safety	Start ON/OFF switch provided for equipment & operator safety.	

Checked By (Production) 01/01/25
Sign/Date: .....

Verified By (Quality Assurance) 01/01/25
Sign/Date: .....

Inference:

Verification done for Safety related features like proper fitting of Vibro Sifter, its electrical wirings, Guards for moving parts & Switch for ON & OFF during Emergency.

Reviewed By (Manager QA) 01/01/25
Sign/Date: .....

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30"

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:

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

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

All Installations checks verified and observed as per approved Design Specification, no Deviation observed from the pre-defined acceptance criteria.

12.0 CHANGE CONTROL, IF ANY:

No any Change Control initiated during the Installation Verification; all checks were found as per the Design Specification.

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

Reviewed all Installation Checks (Leveling of Sifter / grinding of sharp edges / Welding joints / Illumination in area of Installation / working space / Equipment make & model / its components / Electrical fittings / MOC of Components / Dimensions & Safety features), all checks verified were found within the acceptance criteria, hence no any follow up action required.

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30"

14.0 CONCLUSION:

On the basis of above review, it can be concluded that all the Installation Checks were verified and observed as per the Design Specification provided to vendor and physically verified during FAT done by the site.

15.0 RECOMMENDATION:

On the basis of the above conclusion, the Installed Vibro Sifter shall be forwarded for Operational Qualification to find out the mechanical working of the Vibro Sifter.

16.0 ABBREVIATIONS:

Amp.	:	Ampere
cGEP	:	Current Good Engineering Practices
cGMP	:	Current Good Manufacturing Practices
CQA	:	Corporate Quality Assurance
GB	:	General Block
HP	:	Horse power
ID.	:	Identification
IQ	:	Installation Qualification
Kg	:	Kilo gram
KW	:	Kilo watt
MCB	:	Miniature Circuit Break
mm	:	Mili meter
MOC	:	Material of construction
NLT	:	Not less than
No.	:	Number
QA	:	Quality Assurance
SS	:	Stainless Steel
VSF	:	Vibro Sifter
WHO	:	World Health Organization

INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30"

17.0 PROTOCOL CUM REPORT POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)	QA Executive		02/01/25

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)	Head Production		03/01/25
HEAD (ENGINEERING)	Head Engineering		04/01/25

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)	Head Quality Assurance		06/01/25