# INSTALLATION QUALIFICATION

# PROTOCOL CUM REPORT

# FOR

# VIBRO SIFTER 30”

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

# INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30”

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# INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER 30”

## 1.0 PRTOCOL 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) | | | |

# 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.

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

- 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 | | |
| **Edges of parts** | Metal parts should be properly grind without any sharp edges | | |
| **Welding of Joints** | Welding of joints should be without any welding burrs | | |
| **Place of Installation** | Granulation Area- 08 | | |
| **Room Condition** | General working condition | | |
| **Illumination in area** | NLT 300 Lux. | | |
| **Working space around the equipment** | Should be sufficient for easy operation, cleaning, sanitation and maintenance | | |

**Checked By**
**(Production)**
**Sign/Date:** ……

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

**Inference:**

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

# 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 | | | |
| **Model** | cGMP Model | | | |
| **Capacity** | 30 Inch | | | |
| **ELECTRICAL INSTALLATION:** | | | | |
| **Electricity** | Voltage | 415 V | | |
| | Phases | 3 Phase | | |
| | Frequency | 50 Hz | | |
| **Electrical connections have been provided and secured.** | Should be provided & secured | | | |
| **All components in the panel are properly secured** | Should be properly secured | | | |
| **All terminals are tightened** | Should be tightened | | | |
| **Earthing connection to control panel & equipment** | Earthing connection to control panel & equipment should be provided. | | | |

| S. NO. | SPECIFICATION | OBSERVATION | OBSERVED BY SIGN/DATE |
|---|---|---|---|
| **1.** | The machine should positioned as per the room layout drawing | | |
| **2.** | The machine should leveled | | |
| **3.** | The machine should cleaned | | |
| **4.** | Utility should properly connected | | |
| **5.** | Visually check the M/C for damage due to transportation. Etc | | |

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**(Quality Assurance)**
**Sign/Date:** ……

**Inference:**

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**(Manager QA)**
**Sign/Date:** ……

# 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. | | |
| 2. | Check the proper electrical installation of Vibro Sifter. | | |
| 3. | Check the parts are working properly | | |
| 4. | Check the equipment is free from any defects | | |
| 5. | Check the finishing of product contact parts | | |
| 6. | Check that all parts are getting lubricated | | |

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**(Quality Assurance)**
**Sign/Date:** ……

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**(Manager QA)**
**Sign/Date:** ……

**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 | | |
| **Top Deck** | AISI 316 | | |
| **Bottom Deck** | AISI 316 | | |
| **Mesh** | AISI 316 | | |
| **Base** | AISI 316 | | |
| **‘C’ - Clamp** | AISI 316 | | |
| **Gasket** | White Food Grade | | |
| **Spring** | AISI 304 | | |
| **Motor Mounting Plate** | MS | | |
| **Motor** | STD | | |
| **Castor Wheel** | Polyurethane | | |

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**Sign/Date:** ……

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**(Quality Assurance)**
**Sign/Date:** ……

**Inference:**

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**(Manager QA)**
**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. | | |
| 2. | **All contact parts** | AISI 316 | | |
| 3. | **All non-contact Parts** | AISI 304 | | |
| 4. | **Capacity** | Std. | | |
| 5. | **Dimension (in mm)** | 1300 (W) x 800 (D) x 1250 (H) | | |
| 6. | **Charging height** | Approx.: 1350 mm, | | |
| 7. | **Discharging height** | Approx.: 780 mm, | | |
| 8. | **Electric motor** | Make : VIKRANT<br>Type : vibratory<br>H.P : 0.5 H.P<br>RPM : 1440<br>Volt : 415± 10 V<br>Amp : 1.2 | | |
| 9. | **Screen Diameter** | 750 mm | | |

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**(Manager QA)**
**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 | | |
| **Electrical wiring and Earthing** | Electrical wiring should be as per approved drawings. Double external earthing to control machine (panel and motors). | | |
| **Guards** | Guards for all moving parts | | |
| | Should be provided For Motor safety | | |
| **Start On/Off switch: To stop the process immediately** | Should be provided For equipment and operator safety | | |

**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:

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

## 11.0 DEVIATION FROM PRE-DEFINED 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:

| | | |
|---|---|---|
| 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 |

## 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) | | | |

**APPROVED BY:**

| DESIGNATION | NAME | SIGNATURE | DATE |
|---|---|---|---|
| HEAD (QUALITY ASSURANCE) | | | |