DESIGN QUALIFICATION

PROTOCOL CUM REPORT

FOR

VIBRO SIFTER 30”

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER

PRTOCOL CONTENTS

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR VIBRO SIFTER

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)			

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2.0 OBJECTIVE:

- To prepare the Design Qualification document for Vibro Sifter on basis of URS and information given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of **Vibro Sifter 30" (Make: Elicon Pharma)** for …….
- 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.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & IDs provided by Vendor shall be verified during Design Qualification.

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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 and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity. • Review of Design Qualification Protocol cum Report after Execution.
Production	• Review of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Design Qualification Protocol cum Report after Execution.
Engineering	• Review of Design Qualification Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e. ➢ GA Drawing ➢ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/brochures. ➢ Details of utilities Required. ➢ Identification of components for calibration ➢ Material of construction of Product Contact Parts ➢ Brief Process Description ➢ Safety Features and Alarms • Review of Design Qualification Protocol cum Report after Execution.

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5.0 PROJECT REQUIREMENTS:

To confirm that safe delivery of the equipment from the supplier site. To ensure that no un-authorized or unrecorded design modification shall take place.

If at any point in time, any change is desired in the mutually agreed design, change control procedure shall be followed and documented.

6.0 BRIEF EQUIPMENT 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 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared by ……. The manufacturer of equipment ensures complies with User Requirement Specification.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS/PRODUCT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application: The Vibro Sifter shall be able for sifting of raw material, APIs, Excipients during the manufacturing process.	The Vibro Sifter should be able for sifting of raw material, APIs, Excipients during the manufacturing process.	Process Requirement
Working: Working of Vibro Sifter	Vibro Sifter should capable of sifting the various drugs, raw material, excipients with desired uniformity as per product requirement.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Electrical Supply	The electrical system of the equipment shall be housed as per the cGMP and cGEP standards, with adequate safety.	cGMP Requirement
Room Condition	Temperature and RH requirement as per requirement of product	Process Requirement

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8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.NO.	NAME OF THE COMPONENT	TECHNICAL SPECIFICATION
1.	**Model**	cGMP
2.	**All contact parts**	SS316
3.	**All non-contact parts**	SS304
4.	**Capacity**	Std.
5.	**Dimension**	1300 (W) x 800 (D) x 1250 (H) in mm
6.	**Charging height**	**Approx.**: 1350 mm,
7.	**Discharging height**	**Approx.**: 780 mm, As per your specifications and purchase order.
8.	**Electric motor**	**Make** : Vikrant **Type** : Vibratory **H.P** : 0.5 HP **RPM** : 1440 **Volt** : 415± 10V **Amp** : 1.2
9.	**Screen Diameter**	750 mm

8.4 MATERIAL OF CONSTRUCTION:

MACHINE PARTS	ACCEPTANCE CRITERIA	REFERENCE
Top Lid	AISI 316 L	GMP Requirement
Top Deck	AISI 316 L	GMP Requirement
Bottom Deck	AISI 316 L	GMP Requirement
Mesh	AISI 316 L	GMP Requirement
Base	AISI 304	GMP Requirement
'C' - Clamp	AISI 304	GMP Requirement
Gasket	White Food Grade	GMP Requirement
Spring	AISI 304	Design Requirement
Motor Mounting Plate	MS	Design Requirement
Motor	STD	Design Requirement
Castor Wheel	Polyurethane (PU)	GMP Requirement

8.5 SAFETY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips	Safety Requirement
Mechanical Guard	Mechanical guard for all rotating parts.	Safety Requirement
Joints	Welding of joints without any welding burrs	Safety Requirement
Metal Parts	All the metal parts should be Properly grind without any sharp edges.	Safety Requirement
Leveling And Balancing	Equipment should be properly balanced & leveled	Safety Requirement
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Single external Earthing to control machine (panel and motors) and operator should be provided	Safety Requirement
Noise Level	Below 80 db	GMP & Safety Requirement
Emergency Switch	Provided easy access position	GMP & Safety Requirement

8.6 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for supplying the Vibro Sifter	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowhow, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Reference: (1) User Requirement Specifications (URS).

(2) Design & Functional Specifications provided by Vendor.

Verified
(Quality Assurance)
Sign/Date: ……

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9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Any other relevant documents.

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

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11.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATIONS:

AISI	:	American Iron Steel Institute
cGMP	:	Current Good Manufacturing Practice
DQ	:	Design Qualification
GA	:	General Arrangement
GB	:	General Block
mm	:	Millimeter
MOC	:	Material of Construction
P & ID	:	Piping and Instrumentation Diagram
QA	:	Quality Assurance
SS	:	Stainless Steel
STD	:	Standard
URS	:	User requirement specification.
VSF	:	Vibro Sifter

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14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			