PERFORMANCE REQUALIFICATION REPORT

OF

VIBRO SIFTER 30”

(EQUIPMENT ID No.: ……..)

PERFORMANCE QUALIFICATION REPORT FOR VIBRO SIFTER 30”

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

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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

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2.0 OBJECTIVE:

The objective of this report is to provide the Qualification data for Vibro Sifter.

- To qualify the performance of the equipment.
- To ensure performance of Vibro Sifter in Granulation section of Production department is in accordance to its intended purpose.
- To ensure that when operated within the established parameters, it performs effectively & reproducibly to the required quality standards in actual working condition.

3.0 SCOPE:

This document is applicable for qualifying the Performance Qualification report & data of the Vibro Sifter installed in Granulation Section.

- Machine Name : Vibro Sifter
- Model No. : GMP Model
- Manufacturer : ……
- Equipment ID : ……..
- Location : Granulation Area

4.0 BRIEF DESCRIPTION OF EQUIPMENT:

4.1 Working principle:

The basic working principle of this machine works on the gravity principal of the material and vibration through main motor. Main motor 1440 RPM transferred the material through unbalanced weight and springs to the main bowl and screen / filter. Due to plain and smooth surface of the screen conveying route granules can be easily moved to the discharge track with heavy vibration and gravity.

Due to the unbalance weight the amplitude of vibration can increased or decreased by loosing the Allen cap screw of unbalance counter located on the motor shaft at suit various type speed of vibration.

4.2 Equipment Capacity:

The output capacity of the equipment depends on the material gravity, flow property of the material, mesh size and filter size used during the operation of the machine.

4.3 Major components:

- Electric motor

- Discharge pipe
- Hopper or inlet bowl
- Starter
- Clamps

5.0 QUALIFICATION OBSERAVATION AND RESULTS:

5.1 Installation review:

Check Points	Acceptance Criteria	Observation	Result (Pass/Fail)
Equipment identification name plate/Equipment code is available.	Equipment code should be available.	Equipment Identification name plate is available.	Pass
There is no physical damage.	No physical damage observed	No any physical damage observed.	Pass
Required electric connections are tight and grounded.	Required electric connections should be tight and grounded.	Electric connections found tight & grounded.	Pass
Earthing connections are done properly.	Earthing connections should be done properly.	Earthing connections are done properly.	Pass
Sufficient spaces are provided around the equipment for safe working.	Sufficient spaces should be available around the equipment for safe working.	Sufficient surrounding space is available for safe working & maintenance.	Pass
Major component are securely assembled.	All component should be securely assembled.	All major components are securely assembled.	Pass
Utilities are connected properly as per manufacturer recommendation.	Utilities should be connected properly as per manufacturer recommendation.	Utility connections are provided as per the approved Design Specification.	Pass
Product contact parts are smooth and have no rough surface/edge where material can be accumulated.	Product contact parts should be smooth and have no rough surface/edge where material can be accumulated.	Product contact parts are smooth with no rough surfaces where the material can be accumulated.	Pass
Product contact areas free of trap points such as threads, keyways, sleeves etc.	All the Product contact areas free of trap points such as threads, keyways, sleeves etc.	Product contact areas are free of trap points to avoid storage of any previous product.	Pass
Welds are of appropriate quality, free from	Welds should be of appropriate quality, free	Welding joints are free from any crevices and burrs. No any	Pass

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Check Points	Acceptance Criteria	Observation	Result (Pass/Fail)
imperfections - orbitally welded where possible. Verify the Equipment history with respect to any major maintenance/ components’ replacement, calibration failure or any other incidents occurred.	from imperfections - orbitally welded where possible. There should not any major maintenance/ components replacement, calibration failure or any other incidents occurred.	major maintenance or incidents occurred.	

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

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

Inference:

Reviewed all installation checks like Equipment Identification, physical damage verification, electric connections, earthing, surrounding space for proper operation and maintenance, utility connections, contact parts finishing, welding joint perfection, all observations found within the acceptance criteria.

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

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5.2 Operational Review:

Check points	Acceptance criteria	Observation	Result (Pass/Fail)
Equipment operates as per respective standard operating procedure.	Equipment shall be operate as defined in the standard operating procedure	Vibro Sifter operates as per provided Standard Operating procedure.	Pass
	Operation shall be smooth and there should not be any abnormal sound/ noise.	No any abnormal noise observed during operation.	Pass

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

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

Inference:

Reviewed all Operational parameters & found Vibro Sifter working smoothly without any abnormal noise.

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

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5.3 Performance review:

5.3.1 First Trial:

Product Name	Calcium Carbonate tablets		
Operation time	**Date:** 01/01/25 **From** 13:00 **to** 13:45 **Hrs.**		
Granules Quantity	250 kg		
Total Sifting time	2 minutes		
Check points	**Acceptance criteria**	**Observation**	**Result (Pass/Fail)**
Charge the material in to the Hopper	Material should be freely filter through the filter assembly	Material freely filters through the filter assembly	Pass
	There should not any foreign particles available in the Sifted granules.	No any foreign particle available	Pass
	The entire Calcium Carbonate particle should be retained on the sieve.	Calcium Carbonate particle retained on sieve	Pass

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

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

Inference:

All material passes through the sifter sieve, no any foreign particle observed in sifted material.

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

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5.3.2 Second Trial:

Product Name	Calcium Carbonate tablets		
Operation time	**Date:** 02/01/25 **From** 13:00 **To** 13:30 **Hrs.**		
Material quantity	250 kg		
Total filtration time	2 minutes		
Check points	**Acceptance criteria**	**Observation**	**Result (Pass/Fail)**
Charge the material in to the Hopper	Material should be freely filter through the filter assembly	Material freely filters through the filter assembly	Pass
	There should not any foreign particles available in the Sifted granules.	No any foreign particle available	Pass
	The entire Calcium Carbonate particle should be retained on the sieve.	Calcium Carbonate particle retained on sieve	Pass

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

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

Inference:
All material passes through the sifter sieve, no any foreign particle observed in sifted material.

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

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5.3.3 Third Trial:

Product Name	Calcium Carbonate tablets		
Operation time	**Date:** 03/01/25 **From** 13:00 To 13:30 Hrs.		
Material quantity	250 kg		
Total filtration time	2 minutes		
Check points	**Acceptance criteria**	**Observation**	**Result (Pass/Fail)**
Charge the material in to the Hopper	Material should be freely filter through the filter assembly	Material freely filters through the filter assembly	Pass
	There should not any foreign particles available in the Sifted granules.	No any foreign particle available	Pass
	The entire Calcium Carbonate particle should be retained on the sieve.	Calcium Carbonate particle retained on sieve	Pass

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

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

Inference:

All material passes through the sifter sieve, no any foreign particle observed in sifted material.

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

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6.0 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.

7.0 DOCUMENTS TO BE ATTACHED:

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

8.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

No any Deviation observed from the pre-defined acceptance criteria, Vibro Sifter works as per the operating SOP, all material passes through the specified Sieve without leaving any foreign particle.

9.0 CHANGE CONTROL, IF ANY:

No any Change Control initiated during the Performance Qualification.

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

Reviewed all 03 batches of Calcium Carbonate, the material passes through the sieve without leaving any foreign particle.

11.0 CONCLUSION:

On the basis of above review, it can be concluded that the Vibro Sifter Installation & Operational Qualification has been performed accordingly followed by Performance Qualification. All test results of 03 batches were sifted were found within the acceptance criteria.

12.0 RECOMMENDATION:

On the basis of above conclusion, the Vibro Sifter found qualified & recommended for commercial batches.

13.0 ABBREVIATIONS:

Amp.	:	Ampere
cGEP	:	Current Good Engineering Practices
cGMP	:	Current Good Manufacturing Practices
HP	:	Horse power
Kg	:	Kilo gram
KW	:	Kilo watt
MCB	:	Miniature Circuit Break
mm	:	Mili meter
MOC	:	Material of construction

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14.0 PROTOCOL CUM REPORT POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)	QA Executive	Pharmadevils	04/01/25

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)	Head Production	Pharmadevils	05/01/25
HEAD (ENGINEERING)	Head Engineering	Pharmadevils	06/01/25

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)	Head Quality Assurance	Pharmadevils	07/01/25