INSTALLATION QUALIFICATION FOR ELECTROMAGNETIC SIEVE SHAKER

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

INSTALLATION QUALIFICATION FOR ELECTROMAGNETIC SIEVE SHAKER

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1.0 Pre-Approval:

Signing of this Approval page of Installation Qualification Protocol No. ..... indicates agreement with the Installation Qualification approach described in this document. Should Modifications to the Installation Qualification become necessary; an addendum will be prepared and approved.

Compiled By	Signature	Date
Manager - Engineering		

Checked By	Signature	Date
Manager - Production		
Manager - Quality Assurance		

Approved By	Signature	Date
Manager - Quality Control		
General Manager - Projects		

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2.0 Overview:

2.1 Purpose:

The purpose of this protocol is to provide an outline for the Installation Qualification of the Instrument for static attributes to verify that:

- Each installed sub component complies with the Instrument data sheets / specifications, agreed upon with the manufacturer.
- All supporting utilities are connected.
- The Instrument is installed as per the laid down specifications.
- No unauthorized or unrecorded modifications have taken place.
- Required testing reports are available.

2.2 Scope:

This protocol covers the installation qualification of the Electromagnetic Sieve Shaker.

2.3 Responsibility:

The validation group comprising of a representative from each of the following departments shall be responsible for the overall compliance with this protocol:

- Engineering Department
- Production Department
- Quality Assurance Department

The Engineering and Production Departments shall be responsible for checking proper installation and recording installation data as per the procedures outlined in this protocol.

The Quality Assurance Department shall be responsible for the final review of the qualification documents and its compliance to meet the acceptance criteria of the Installation Qualification protocol.

The Protocol shall be approved by the Engineering, Quality Assurance and Plant Head.

2.4 Requalification:

Installation Qualification to be requalified on:

- Replacement of major component of the Instrument with a new component.
- Any major modification in the existing Instrument.
- Shifting of the Instrument from one location to another.

2.5 System Description:

Sieving is one of the oldest methods of classifying powders by particle size distribution.
In Pharmaceutical terms, sieving is usually the method of choice for the classification of the coarser grades of single powders. It is a particularly attractive method where in the powders are classified only on the basis of particle size and in most cases the analysis can be carried out in the dry state.

A sieve separates a specific sample material in two fractions – one is retained by the sieving media, which is the rejected or oversized material and the other, which passed through the openings. This particle size sieving for sample preparation is not exact science for sampling as they are bound to give errors. The effectiveness of the sieving depends on the sample load feed, the type of the movement imposed on the sample, the heterogeneity either in the composition or in the non random particle size distribution, which usually occurs as result of gravitational forces and the precise time especially for short sieving time .

To eliminate the errors electromagnetic sieve shakers have been introduced and are recommended by USP (maintaining amplitude between 1 and 2 mm). An advantage of electromagnetic design is that, for a given period of time, constant force will be applied to the particles, independent of the number of sieves. This allows for precise reproducibility.

ELECTROPHARMA – introduces ELECTROMAGNETIC SIEVE SHAKER, MICROCONTROLLER BASED, which have been developed applying the latest technological advances of Power Control.

The unit has been designed for user-friendly operation and supports a menu driven 16 X 2 characters LCD Display. The unit is robustly built and can be used in laboratories or on site. It is compact and portable.

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The Instrument is powered by an electromagnetic drive which has no rotating parts to wear making it maintenance free and extremely quiet in operation. The movement is tri-dimensional combining a vertical movement of variable amplitude and rotation causing the material to be shifted over the sieve in a unique way producing faster, more efficient sieving.

The sieve shaker's microcontroller is used to set both the process time from 1 min to 99 min and the amplitude from 0.5 to 2.5. The unit has 2 modes of operation – Continuous and Intermittent. Intermittent vibration improves performance and helps to clear blocked apertures. The ELECTROPHARMA Sieve Shaker offers total flexibility enabling optimum settings to be established for virtually any material under test.

The instrument has a capacity of maximum 5 kg and 8 sieves. The special clamping device ensures that the sieves are held firmly and allows them to be quickly removed and replaced. Non – metallic springs and anti – vibration mountings are fitted to isolate vibrations from work surfaces and reduce noise levels.

Also the most important part for particle size analysis is the sieves. The sieves lie at the heart of the technique. Great care must be taken to ensure that the sieves are of correct design and manufactured under controlled condition as described in ISO 3310 part 1, 2, 3.

The ELECTROPHARMA sieves are specially designed and manufactured as per the ISO 3310.1 standards. The body is made of S.S. 316 and the mesh is designed without crevasses and without lead.

Each sieve is thoroughly checked and validated in house. Certificate of compliance along with Laser marking of serial no and specification are given to the user.

The Strong, Reliable, maintenance free and extremely quite operation of instrument and validation and correct design of sieves makes sieving process easy, assuring a maximum repetitiveness of the tests for high density products and for dry and wet sieving analysis

3.0 Instrument Specification:

Detailed Instrument Specifications for Instrument are as follows:

ITEM	SPECIFICATIONS
Dry Sieving	Standard
Wet Sieving	Operational Kit
Mode of Operation	Continuous and Intermittent
Intermittent Operation	At intervals up to 0.5 seconds
Capacity	Up to 8 sieves of 50 mm height Up to 16 sieves of 25 mm height
Shake Time	Programmable from 1 min to 99 min
Amplitude level	Programmable from 5 to 20
Display	16 x 2 character alphanumeric LCD
Noise Level	Less than 61 dB without sieves at maximum amplitude Less than 71 dB with sieves and material at maximum amplitude
Power	220 / 230 VAC, 50 Hz, 600 VA 100 / 110 VAC, 60 Hz, 600 VA
Primary Fuse	T 2.5 Amp (for Input Supply as 220 / 230 VAC, 50 Hz) T 5 Amp (for Input Supply as 100 / 110 VAC, 60 Hz)
Dimension (mm)	L 339 x W 312 x H 270
Net Weight	50 kg without sieves (Approx.)

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4.0 Instrument Identification:

The subjected Instrument is identified as	**:**	Sieve Shaker
Serial No.	**:**	_____
In-house Tag No.	**:**	_____
Name of the Supplier	**:**	_____

5.0 Instrument Location:

Facility	:	Oral Formulation Facility
Area	:	Production
Room / Lab. Identification	:	In Process Quality Control.

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6.0 Installation Qualification Procedure:

6.1 Inspection Checklist

Instructions:

6.1.1 Carry out the physical verification of the instrument/ environment. Record the observations in the Data Sheet of section 6.2.1.

6.1.2 Identify the critical components of Instrument and verify that the components are complying as per desired specifications. Record the observations in the Data Sheet of section 6.2.2.

6.1.3 Identify the utility supplies required for Instrument operation. Verify that utilities are as per the specification mentioned in the Check Point 6.2.3. Record the observation in the Data Sheet of section 6.2.3

6.1.4 Identify the critical instruments supplied with the Instrument or installed on the utility supply line. Verify that instruments are as per the desired specifications. Review the calibration status of the instruments. Record the availability of the calibration record provided by the supplier. Record the observation in Data Sheet of section 6.2.4.

6.1.5 Check the installation of Instrument :

- To verify the location of installation as per the Instrument layout attached as **Attachment - 'A'**.
- Record the installation location and verification of assembly in Test Data section 6.2.5.1.
- To check the leveling and alignment as per the procedure given in the section 6.2.5.2. Record the observation in the Data Sheet of section 6.2.5.3.

6.1.6 List the available drawing and record the Ref. No. for their location / availability in the format under section 6.2.6.

6.1.7 Identify the SOPs and assign SOP Numbers, record the SOP Title and Number in Section No. 6.2.7.

6.1.8 Record the deficiency (if any) in section number 6.2.8 and report the details of action taken.

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Note:

1. *Record all the observations against the respective specifications, mentioned in the specific checkpoints, under section 6.2 (The specifications are extracted from the Purchase order / Manual / Manufacturer's Recommendations).*
2. *Wherever specifications are not mentioned, record the observations as per the statement of the data sheet.*
3. *Incase of non-compliance, give the explanation / justification in the deviation format under section 6.2.8.*
4. *When more than one unit of the same type exists, replicate the corresponding data sheet to match and uniquely identify each page.*
5. *Incase of multiple options; clearly identify the one, which has been supplied.*
6. *The calibration certificates of the instruments shall be traceable to National/International standards.*
7. *Define all technical terms and abbreviations in the appendix under section 10.0.*

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6.2 Installation Qualification:

6.2.1 Physical verification of the Instrument / Environment

Objective: To verify that any physical damage of the Instrument and Environmental condition for the operation of the Instrument.

S.No.	Test Particulars	Specifications	Observations	Acceptance Yes/No
Physical Verification				
1.	Check the Instrument for any damages.	There should not be any damages.		
Environmental Conditions				
1.	Room Temperature	5°C to 40°C		
2.	Relative Humidity	10% to 85%		
3.	Away from the direct Sunlight	-		
4.	Free from Vibrations	-		
5.	No corrosive Gases	-		
6.	Free from excess dust and moisture	-		

Checked by (Engineering) _____ **Name** _____ **Sign.** _____ **Date**

Verified by (Quality Assurance) _____ **Name** _____ **Sign.** _____ **Date**

6.2.2 Major Component Verification:

Objective: To verify that major components as identified below are complying as per the desired specifications.

S.No.	Name	Qty. Supplied	Observation	Acceptance Yes / No
1.	Basic Unit	1 No.		
2.	Stack to clamp	2 No.		
3..	Vertical bars to hold the top clamp	2 No.		
4..	Main Cord	1 No.		
5..	Operation Manual	1 No.		

Checked by (Engineering)	**Name**	**Sign.**	**Date**
Verified by (Quality Assurance)	**Name**	**Sign.**	**Date**

6.2.3 Verification of Utility Supply:

Objective: To verify that necessary utility supplies required for Instrument operation are as per the desired specification and connected properly.

S.No.	Utility	Specifications	Observations	Connected and Identified (Yes / No)
1.	Power	Single Phase, 230V ± 10% 50 Hz		

Note: *Power Supply to be checked with a Multimeter.*

Checked by (Engineering)	**Name**	**Sign.**	**Date**
Verified by (Quality Assurance)	**Name**	**Sign.**	**Date**

6.2.4 Verification for Installation:

6.2.4.1 Location and Assembly:

S.No.	Test Particulars	Specifications	Observations	Acceptance Yes/No
1.	Check that Instrument is installed in the in process quality control.	----		

Checked by (Engineering)	**Name**	**Sign.**	**Date**
Verified by (Quality Assurance)	**Name**	**Sign.**	**Date**

6.2.4.2 Method for checking the Leveling of the Instrument:

- Using Spirit Level Indicator

- Place the spirit level indicator at different points on the machine frame.

Acceptance Criteria:

The air bubble of the spirit level indicator shall be observed in the center.

- Using Water Level Indicator

- Place transparent tube filled with water of suitable length at various corners. Compare the levels of water and align the Instrument

6.2.4.3 Leveling and Alignment:

S.No.	Item Description	Leveling / Alignment OK / Not OK	How Verified *
1.	Platform leveling		

* Refer to the method mentioned under section 6.2.4.2

Checked by (Engineering)	**Name**	**Sign.**	**Date**
Verified by (Quality Assurance)	**Name**	**Sign.**	**Date**

6.2.5 Standard Operating Procedures (SOPs) Identification:

SOP Number	Title

Checked by (Engineering)	**Name**	**Sign.**	**Date**
Verified by (Quality Assurance)	**Name**	**Sign.**	**Date**

6.2.5 Deficiency (if any) and Corrective Action Report:

If there is no deficiency, then write NA.

Description of deficiency and date observed:

_____
_____
_____
_____

Person, responsible for corrective action and date assigned:

_____
_____
_____
_____

Corrective actions taken and date conducted:

_____
_____
_____
_____
_____
_____

Conducted By : _____ Approved By : _____

Date : _____ Date : _____

Comments (if any):

_____

_____

Verified By:

Name: _____ Signature: _____ Date: _____

7.0 Acceptance Criteria:

Installation Qualification shall be considered acceptable when all the conditions specified in various forms under section 6.0 have been met.

Any deviation from the acceptance criteria of the specific check point shall be reported and decision should be taken for the rejection, replacement or rectification of the Instrument / component.

8.0 Remarks (if any) :

_____

_____

_____

_____

_____

9.0 Summary:

Checks	Observations (Yes / No)	Remarks
Whether acceptance criteria of the protocol and Specific check points as mentioned below are met : • Physical verification of the instrument. • Major Component Verification • Verification of Utility Supply • Identification of Instruments and their Calibration Review • Verification for Installation • Standard Operating Procedures (SOP's) • Deficiency (if any) and corrective Action Report • Acceptance criteria		

9.1 Conclusion:

The *Electromagnetic Sieve Shaker Model – EMS-8* bearing Instrument No. ....., **is / is not** qualifying the installation qualification test as per the Protocol No..... *Electromagnetic Sieve Shaker* ..... **can / cannot** be tested for its operational qualification as per Protocol No. .....

9.2 Post-Approval Signatures

Name	Signature	Date
Manager - Engineering		
Manager – Quality Control		
General Manager - Projects		

10.0 Appendix:

10.1 Abbreviations and Definitions

IQ	-	Installation Qualification
Min	-	Minutes
V	-	Volt
Hz	-	Hertz
cm	-	Centimeter
N.A.	-	Not Applicable
S. No.	-	Serial number
Sr.	-	Senior
mV	-	milli Volt
°C	-	Degree Centigrade
AC	-	Alternate Current
gm	-	Gram
RH	-	Relative Humidity
UPS	-	Uninterrupted Power Supply
Kg	-	Kilogram
Hr.	-	Hour
Sec	-	Seconds
No.	-	Number
mAmp	-	Milli Amperes
USP	-	United States Pharmacopoeia

PHARMA DEVILS

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Acceptance criteria	:	The product, Instrument., and / or process specifications and limits, such as acceptable quality level and unacceptable quality level, that are necessary for making a decision to accept or reject.
Installation qualification	:	The documented verification that all aspects of a facility, utility or instrument that can affect product quality adhere to approved specifications (e.g., construction, materials) and are correctly installed?
Validation	:	Establishing documented evidence that a system does what it purports to do.
Revalidation	:	Repetition of the validation process or a specific portion of it

10.2 List of Documents:

1. Instrument manuals
2. Calibration Certificates