OPERATIONAL QUALIFICATION FOR ELECTROMAGNETIC SIEVE SHAKER

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

OPERATIONAL QUALIFICATION FOR ELECTROMAGNETIC SIEVE SHAKER

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1.0 Pre-Approval:

Signing of this Approval page of Operational 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
Officer – Quality Assurance		

Checked By	Signature	Date
Manager - Production		
Manager - Quality Assurance		

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

2.0 Overview:

2.1 Purpose:

The purpose of this protocol is:

To verify the operational attributes of Electromagnetic Sieve Shaker Model EMS - 8

- Critical to serve the intended purpose.
- To establish the suitability of the draft SOP prepared for the operation of System.
- To document the observations for future reference.

2.2 Scope:

This protocol covers the operational qualification of Electromagnetic Sieve Shaker.

2.3 Responsibility:

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

- Production Department
- Quality Assurance Department
- Engineering Department

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

Engineering shall collect all the test data and shall compile the results to make the reports of qualification studies.

The Reports shall be checked by Engineering and Quality Assurance.

The post approval of the qualification shall be done by Engineering, Quality Assurance and plant Head.

2.4 Requalification:

Operational Qualification to be repeated incase of

- Replacement of any major component.
- Major modification in the existing Instrument.
- During monitoring if Instrument is found to be malfunctioning.
- 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.

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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.

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.

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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

2.6 Instrument Identification:

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

3.0 Operational Qualification Procedure

1) Existing SOP No. ..... shall be changed to ..... for operation before the Qualification testing.

2) Prior to the Qualification test, the Personnel shall be trained on the operational features of the Instrument. This training shall be recorded in Section 3.1.

3) The trained personnel shall carry out the Operational Qualification, following the Procedures mentioned under Section 3.2.1 for Key Functionality and Safety Features. Record the observations of Qualification Test in Test Data Sheet of Section 3.2.1. Checkpoints designed for the purpose of OQ are also aimed at verification of this draft SOP.

4) Operate the Instrument as per the draft SOP. Record the change if any and confirm the SOP. Report the confirmation of SOP in the Section 3.3.

5) Report the deficiency from the specified function, if any in the section 3.4

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3.1 Training **Date: _____**

Title: Operation of Electromagnetic Sieve Shaker

Name of the Trainer(s): _____

S.No.	Name of the Trainee	Employee Number	Signature
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

Signature of Trainer(s) : _____

Date : _____

3.2 Key Functionality & Safety Features

A. Purpose:

The purpose of this procedure is to demonstrate that the control panel and other manual operations (if any) of Electromagnetic Sieve Shaker Model
EMS - 8; as specified by the manufacturer.

B. Testing:

1. Check all the displays on the panel are identified.
2. Turn on the power from the electrical panel.
3. Set the control(s) on the panel.
4. Verify functionality of each component on the panel against its Specified functions as per the SOP and Instrument Operation Manual.
5. Observe and record the responses in the Test Data Sheet, under section 3.2.1.

3.2.1 TEST DATA SHEET (Confirmation of Services Connection)

S.No.	Test Particulars	Observations	Checked By
1.	Switch 'ON' the Instrument (The Instrument will initialize itself).		
2.	Set the Parameters from the front panel and confirm the following Operations		
3.	After the Start up screen, the display will show the screen for the time and Power Setting. Set the desired mode of operation in either continuous or intermittent .The time can be set from 1 min to 99 min and the power level can be varied from 5 to 20		

Verified By:

Name: _____ Signature: _____ Date: _____

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S.No	Test Particulars	Observations	Checked By
4.	Set the desired power level / TIME fro the test by the INCREMENT / DECREMENT key provided on the front panel for the POWER & TIME respectively		
5.	Press the START key from the front panel to start the Test. The display would now show the elapsed Time and the set value of the power. The mode of operation and the power level can be changed online during the test.		

Verified By:

Name : _____ Signature : _____ Date : _____

3.3 SOP Verification:

Draft SOP No. :

Title :

Operate the Instrument as per the draft SOP and record the details given below:

Operated By : ……

Checked By : ……...

The operating personnel understand and follow the SOP description (Yes/No) :

Changes required in draft SOP (If any) : _____

_____NO_____

_____

SOP to be revised (Yes/No) :

If yes, Review No. _____

Remarks: SOP Confirmed / Not Confirmed

Verified By:

Name: _____ Signature: _____ Date: _____

3.4 Deficiency (if any) and Corrective Actions 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: _____

4.0 Acceptance Criteria:

Operational Qualification shall be considered acceptable when all the conditions specified in various data sheets under section 3.0 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.

5.0 Summary:

Checks	Observations Yes / No	Remarks (if any)
Whether the acceptance criteria of the protocol and specific check points as mentioned below are met: • Training • Key Functionality • Safety Features • SOP verification • Deficiency (if any) and Corrective Action Report • Acceptance criteria		

5.1 Conclusion:

The *Electromagnetic Sieve Shaker Model EMS – 8* bearing Instrument No..... **is / is not** qualifying the Operational Qualification tests as per Protocol No..... The Instrument **can / cannot** be tested for its Performance Qualification as per Protocol No.....

5.2 Post-Approval:

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

6.0 Appendix:

6.1 Abbreviations and Definitions:

OQ	- Operation Qualification
mm	- Millimeter
Min	- Minutes
S. No.	- Serial Number
Sr.	- Senior
°C	- Degree Centigrade
USP	- United States Pharmacopoeia
SOP	- Standard Operating Procedure

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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.
Operational qualification	The documented verification that all aspects of a facility, utility, or instrument that can affect product quality operate as intended throughout all anticipated ranges.
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