PERFORMANCE QUALIFICATION

FOR

ELECTROMAGNETIC SIEVE SHAKER

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1.0 Pre-Approval:

Signing of this Approval page of Performance Qualification Protocol No. .....indicates agreement with the Performance Qualification approach described in this document. Should Modifications to the Performance 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		

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2.0 Overview:

2.1 Purpose:

The purpose of this protocol is:

- To verify the performance attributes of the *Electromagnetic Sieve Shaker Model EMS - 8*, critical to serve the intended purpose.
- To document the observations for future reference.
- To provide documented evidence that the *Electromagnetic Sieve Shaker Model EMS - 8*, is operated and performed as per the Standard Operating Procedure.

2.2 Scope:

This protocol covers the performance qualification of Electromagnetic Sieve Shaker.

2.3 Responsibility:

The 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

The Production and In Process Quality Control shall be responsible for Performing as well as the checking of the Performance Qualification along with the Quality Assurance and recording data as per the procedures outlined in this protocol.

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

The Reports shall be checked by Quality Assurance.

Quality Assurance and Plant Head shall finally approve the Qualification report.

2.4 Requalification:

Performance 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.

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3.0 Performance Qualification

3.1 Performance Qualification Procedure

Perform the Qualification as per the following procedure.

3.1.1 Operate the Instrument as per the SOP.

3.1.2 Check the Timer Calibration for both the operation mode ie. Continuous Mode and Intermittent Mode using Digital Stop Watch and record the observations in Section 3.2

3.1.3 Check the Amplitude of the Instrument for both the operation mode ie. Continuous Mode and Intermittent Mode at Power Level (5 to 20) and record the observations in Section 3.2

3.1.4 Report the deficiency from the specified function, if any in the section 3.3

3.3 Performance Qualification Test Data Sheet:

3.3.1 Timer Calibration:

Set the desired time for both the Mode and record the observations:

Stop Watch No. _____

Set Time	Observations (Time observed on Digital Stop Watch) (± 5.0% of the Set Time)		Checked By
	Continuous Mode	Intermittent Mode	
5 minute			
10 minute			
15 minute			
20 minute			

Verified By:

Name: _____ Signature: _____ Date: _____

3.3.2 Amplitude Check:

Set the desired Amplitude for both the Mode and record the observations:

Set Amplitude (Power Level)	Observations on Power Level Display		Checked By
	Continuous Mode	Intermittent Mode	
5	Confirmed / Not Confirmed	Confirmed / Not Confirmed	
10	Confirmed / Not Confirmed	Confirmed / Not Confirmed	
15	Confirmed / Not Confirmed	Confirmed / Not Confirmed	
20	Confirmed / Not Confirmed	Confirmed / Not Confirmed	

Verified By:

Name: _____ Signature: _____ Date: _____

3.4 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: _____

4.0 Acceptance Criteria

Performance 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.

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5.0 Summary:

Checks	Observations Yes / No	Remarks (if any)
Whether the acceptance criteria of the protocol and specific checkpoints are met. • Performance Qualification Procedure. • Performance Qualification test data sheets • Deficiency (if any) and Corrective Action Report		

5.1 Conclusion:

The *Electromagnetic Sieve Shaker Model EMS – 8* bearing Instrument No. .....**is / is not** qualifying the Performance Qualification tests as per the Protocol No. .....

The Instrument **can / cannot** be used for the routine analysis.

5.2 Post-Approval:

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

6.0 Appendix:

6.1 Abbreviations and Definitions:

PQ - Performance Qualification
N.A. - Not Applicable
Sr. - Senior
S. No. - Serial Number
USP - United States Pharmacopoeia

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.

Performance Qualification : The documented verification that all aspects of a facility, utility, or Instrument that can affect product quality perform as intended meeting predetermined acceptance criteria.

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