USER REQUIREMENT SPECIFICATION

Name of Item: Electromagnetic Sieve Shaker	**Protocol No**.:.....
Functional Area: Quality Control	**Page No**.: 1 of 8

Name of Equipment: Electromagnetic Sieve Shaker

Document Reference Number: ……

Effective Date: …….

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Name of Item: Electromagnetic Sieve Shaker	**Protocol No**.:.....
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1.0 Approval:

Signing of this approval page of URS indicates agreement in this document. Should Modifications to the user Requirements Specification approach become necessary, an addendum will be prepared and approved.

Prepared by	**Signature**	**Date**
Checked By	**Signature**	**Date**
Reviewed By	**Signature**	**Date**
Approved By	**Signature**	**Date**

2.0 Table of Content:

3.0 INTRODUCTION:

This document is generated for the purpose of specifying the user requirements for the electromagnetic sieve shaker.

The URS shall be recognized as the integral part of the procurement agreement with the selected equipment vendor. The equipment supplier or vendor shall abide by the information and condition set forth by this document as well as purchasing and delivery terms and conditions of the Client.

The Electromagnetic sieve shaker shall be located at wet lab area of quality control.

Sieving is one of the oldest methods of classifying powders by particle size distribution. 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.

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.

The utilities and space involved needs to be discussed prior to the purchase of the equipment.

4.0 OVERVIEW DEFINITION:

4.1 The Electromagnetic sieve shaker shall have the following features:

4.1.1. The unit has been designed for user-friendly operation and supports a menu driven 16 X 2 characters LCD Display.

4.1.2. The electromagnetic sieve shaker apparatus shall have designed to meet the specification of USP,BP,IP and EUR.

4.1.3. The unit is robustly built and can be used in laboratories or on site. It is compact and portable.

4.1.4. The tap density tester shall be provided with two holders for measuring cylinders. One for 100 ml capacity and second is for 250 ml capacity

4.1.5. The instrument is powered by an electromagnetic drive, which has no rotating parts to wear making it maintenance free and extremely quiet in operation.

4.1.6. To eliminate the errors electromagnetic sieve shakers have been introduced and are recommended by USP (maintaining amplitude between 1 and 2 mm).

4.1.7. 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.

4.1.8. The instrument is powered by an electromagnetic drive which has no rotating parts to wear making it maintenance free and extremely quiet in operation.

4.1.9. 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.

4.1.10. 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.

4.1.11. Intermittent vibration improves performance and helps to clear blocked apertures.

4.1.12. The ELECTROPHARMA Sieve Shaker offers total flexibility enabling optimum settings to be established for virtually any material under test.

4.1.13. 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.

4.1.14. Non – metallic springs and anti – vibration mountings are fitted to isolate vibrations from work surfaces and reduce noise levels.

4.1.15. 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 controller condition as a described in ISO 3310 part 1,2,3.

4.1.16. The ELECTROPHARMA sieves are specially designed and manufactured as per the ISO 3310.1 standards.

4.1.17. The body is made of S.S. 316 and the mesh is designed without crevasses and without lead.

4.1.18. 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.

4.1.19. 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.

4.2 The Electromagnetic Sieve Shaker shall be used primarily for:

For the determination of particle size of granules and raw material

4.3 Technical Specifications:

4.3.1	**Mode of Operation**	**:**	Continuous and intermittent
4.3.2	**Intermittent Operation**	**:**	At intervals up to 0.5 seconds
4.3.3	**Capacity**	**:**	Up to 8 sieves of 50 mm height Up to 16 sieves of 25 mm height
4.3.4	**Shake Time**	**:**	Programmable from 1 min to 99 min
4.3.5	**Amplitude level**	**:**	Programmable from 5 to 20
4.3.6	**Display**	**:**	16 x 2 character alphanumeric LCD
4.3.7	**Dimension (mm)**	**:**	L 339 x W 312 x H 270

4.4 The machine is to be used at the following environmental conditions:

4.4.1	Room Temperature	**:**	24± 2 °C
4.4.2	Relative Humidity	**:**	NMT 55 %

4.5 Base Utilities Available:

Electrical	**:**	**Single Phase, 230V** ± 10 % 50 HZ

5.0 OPERATIONAL REQUIREMENTS

5.1 OPERATION:

The tap density apparatus shall operate with a minimum of operator involvement. Operation shall be safe both from an operator and environmental standpoint.

5.2 POWER FAILURE/RECOVERY:

In the event of a power failure, the system will stop automatically and will require operator intervention to re-start.

5.3 SAFETY FEATURE:

The system shall be stop safely in emergency.

5.4 ALARMS AND WARNINGS:

The sieve shaker apparatus shall have alarm after the completion of the test.

6.0 SALIENT FEATURES

6.1 COMPATIBILITY AND SUPPORT

ELECTRIC CONTROL:

Electromagnetic sieve shaker apparatus should consist of electrical on / off switch for operation.

UTILITIES:

The Supplier shall specify utility requirement. The User shall ensure that the utilities are available.

6.2 MATERIAL OF CONSTRUCTION:

Body of Instruments **:** SS 304.
Instruments and controls **:** Programmable Operating screen

7.0 MAINTENANCE

Do's and Don'ts to be provided

7.1 Preventive maintenance system and checks to be provided (Maintenance and operation manuals of vendor equipment)

7.2 A comprehensive lubrication list and recommended lubrication schedule

7.3 A comprehensive recommended maintenance (regular recommended inspection intervals, wear points, recommended spare parts list)

7.4 Supplier shall supply 2 Copies of Operation, Installation, and Maintenance manuals and design qualification.

8.0 DELIVERY

The electromagnetic sieve shaker with all options, equipment, and the documentation listed below, shall be delivered to the client.

Delivered should be confirmation of the purchase order.

9.0 DOCUMENTATION

9.1 The Supplier shall provide the documentation for preliminary review. The Supplier shall provide documentation reflecting "as-built" condition with final delivery.

9.2 All final documents shall be shipped with transmittals that identify them as contractually required documents. All final documents and drawings shall reflect "As-Built" condition.

9.3 All documents shall be in English language and supplied with hard copies and supplied in the format identified for each document:

9.4 Design qualification

9.5 Installation Qualification

9.6 Operational Qualification

9.7 Maintenance and service manuals

9.8 Material of construction