USER REQUIREMENTS SPECIFICATIONS

FOR

ELECTROMAGNETIC SIEVE SHAKER

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION FOR ELECTROMAGNETIC SIEVE SHAKER

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**
Officer-Quality Assurance		
Officer-Production		
Officer-Engineering		
Checked By	**Signature**	**Date**
Manager- Production		
Manager - Engineering		
Approved By	**Signature**	**Date**
Head Quality		
General Manager – Projects		
Plant head		

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1.0 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.

The Electromagnetic sieve shaker shall be located at IPQC room of manufacturing area. 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 Electromagnetic sieve shaker shall be interfaced with following components.

1. Basic Unit
2. Stack to clamp
3. Vertical bars to hold the top clamp
4. Main Cord

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

The unit shall be feasible to be installed in the current building facility.

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2.0 OVERVIEW DEFINITION:

The Electromagnetic Sieve Shaker shall have the following features:

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

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

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

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

2.5 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.

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

2.7 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.

2.8 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.

2.9 Intermittent vibration improves performance and helps to clear blocked apertures

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

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2.11 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.

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

2.13 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.

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

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

2.16 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.

2.17 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

c) The Electromagnetic Sieve Shaker shall be used primarily for :

Particle Size Analysis

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d) Technical Specifications: 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

e) Cleaning Requirements: Manual cleaning with Lint free wipe.

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

Indoor Temperature: NMT 24 °C

Relative Humidity: NMT 55 %

g) Base Utilities Available:

Electrical: Single Phase, 230V ± 10% 50 Hz

h) Control system requirements: Manual.

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3.0 OPERATIONAL REQUIREMENTS:

3.1 OPERATION:

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

3.2 POWER FAILURE/RECOVERY:

In the event of a power failure, the system shall protect product against damage. The system will stop automatically upon loss of electricity, air, or other major utility and will require operator intervention to re-start.

3.3 SAFETY FEATURE :

The apparatus should have power failure detection facility. If the power fails during the test, the remaining test is completed when the power supply is resumed.

4.0 SALIENT FEATURES:

4.1 COMPATIBILITY AND SUPPORT:

4.1.1 Utilities

The Supplier shall specify utility data. The User shall ensure that the utilities are available and that the utility supply lines and piping are terminated with fittings or connections.

4.2 MATERIAL OF CONSTRUCTION:

NA

4.3 INSTRUMENTS AND CONTROLS:

Control Panel: The control panel should be provided with main switch on/off push buttons with indication lamps.

5. MAINTENANCE:

System shall be maintained on a schedule as indicated by the supplier. Supplier is to provide (at minimum) the following maintenance instructions:

- All sub-systems provided (Maintenance and operation manuals of vendor equipment)
- A comprehensive lubrication list and recommended lubrication schedule

- A comprehensive recommended maintenance (regular recommended inspection intervals, wear points, recommended spare parts list)
- Supplier shall supply 2 Copies of Operation, Installation, and Maintenance manual

6. FAT:

The manufacture should allow factory acceptance test (FAT) to be performed on completion of the manufactures of the machine .The observation indicated during FAT should be complied in agreement before shipment of the machine

7. DELIVERY:

The Disintegration test apparatus with all options, equipment, and the documentation listed below, shall be delivered.

Delivered should be confirmation of the purchase order.

8. DOCUMENTATION:

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

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.

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

- Installation Qualification
- Operational Qualification
- Operator, Maintenance and Service Manuals
- Process and Instrumentation Diagram (P&ID)
- Instrument Listing
- Control Schematics
- Control Panel Assembly Drawings
- Machine Assembly Drawings
- Bill of Materials
- Spare Parts List along with quotation
- PLC Program Printout
- Test certificates
- Material of construction