USER REQUIREMENTS SPECIFICATIONS

FOR

AUTOMATED FRIABILATOR EF-2 (USP)

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION (URS) OF AUTOMATED FRIABILATOR EF-2 (USP)

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**
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1.0 INTRODUCTION:

This document is generated for the purpose of specifying the user requirements for the Friability test apparatus.

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 Friability test apparatus shall be located at instrument lab of Quality Control area.

Checking the Friability is a very essential step during tablets compression. Friabilator gives

us the idea about the product's performance during transportation, Packing & Coating.

The Friability test apparatus shall be interfaced with following components.

1. Basic Unit
2. USP Drum Friability
3. Abrasion Drum (Optional)
4. Tablet Collection Tray
5. Drum Fixing Knob
6. Mains cord

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

2.0 OVERVIEW DEFINITION:

The Friabilator tester shall have the following features:

2.1 Friability test apparatus is designed to meet USP, IP, BP & Eur2 offers a counter and timer

mode of operation.

2.2 The unique design allows filling and auto discharging of test samples without opening or

removing the drums from its axis.

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2.3 The unit should have ELECTROLAB AD Drums as well as “Abrasion” Drums. It has a unique front-loading system, which allows up to two drums to be loaded simultaneously on the instrument.

2.4 The drums are designed to positively engage with the drive to prevent any slippage. Single or double drums can be held in position by a snap lock knob.

2.5 At the end of the test the test samples are automatically discharged into their individual trays. After discharging the samples, the drum positions itself automatically for loading new samples.

2.6 The drums are rotated by a maintenance free stepper motor drive with a constant speed of 25 RPM.

2.7 The specially designed drive provides a gentle starting and stopping of the drum.

2.8 A 10° tilt of the drum with the bench top as per USP is provided to prevent any irregular tumbling of the test samples causing reproducibility problem due to shape and the size of the tablets. The 10° tilt no longer binds the tablets when lying next to each other which prevent them from falling freely.

2.9 The test can be performed in two modes –

(1) Time mode

(2) Revolution Count Mode

2.10 Time mode: In this mode, the test duration is programmable. User can program the test duration .

2.11 Revolution Count Mode: In this mode, the number of rotations can be programmed from 1 to 99999 counts.

2.12 The values once programmed are retained in the memory of the instrument. The

microcontroller, self validates the speed and revolution count.

c) The Friability test apparatus shall be used primarily for:

Friability testing of Tablet

d) Technical Specifications: Detailed Instrument Specifications for instrument are as follows:

ITEM	SPECIFICATIONS
Motor	DC Stepper Motor of 3.5 KgCm Torque, 6 Volts
Speed	25 RPM Fixed
Speed Accuracy	± 1 RPM
Count Range	1 to 99999 revolutions
No. of Drums	Two
Type of the Drum	* ELECTROLAB AD Drum and Abrasion Drum (Optional)
Power Supply	220 / 230 V AC, 50 / 60 Hz, 20 VA 100 / 110 V AC, 50 / 60 Hz, 20 VA
Fuse Rating	T 160 mAmp (For I/P Supply as 220/230 VAC, 50/60 Hz) T 160 mAmp (For I/P Supply as 100/110 VAC, 50/60 Hz)
Size	L = 350 mm, W = 310 mm, H = 430 mm (Approx)
Weight	12 Kg (Approx.)

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

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h) Control system requirements : Manual.

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:

The system will stop automatically upon loss of electricity, 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 fresh test need to be start.

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 .

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: NA

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
- Performance 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