USER REQUIREMENT SPECIFICATION

Name of Item: Automated Friabilator	**Protocol No.**:.....
Functional Area: Quality Control	**Page No.**: 1 of 7

Name of Equipment: Automated Friabilator

Document Reference Number: …….

Effective Date: ……..

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 Contents:

3.0 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 of the Client.

The Friability test apparatus shall be located wet lab area of Quality Control.

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.

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

4.0 OVERVIEW DEFINITION:

4.1 The friability apparatus shall have the following features:

4.1.1. The Friability test apparatus is designed to meet USP, IP, BP & Eur offers a counter and timer mode of operation.

4.1.2. The unique design allows filling and auto discharging of test samples Without opening or removing the drums from its axis.

4.1.3. 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.

4.1.4. 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.

4.1.5. The instrument shall be provided with printer output for documenting test results as per GMP/GLP standards.

4.1.6. 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.

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

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

4.1.9. 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.

4.1.10. The test can be performed in two modes –
(1) Time mode
(2) Revolution Count Mode

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

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

4.1.13The values once programmed are retained in the memory of the instrument. The microcontroller, self validates the speed and revolution count.

4.2 The friability apparatus shall be used primarily for:

For the determination Friability testing of Tablet

4.3 Technical Specifications:

4.4.1	Speed	: 25 RPM
4.4.2	Display	: LCD screen
4.4.3	Count range	: 1 to 99999 revolutions
4.4.4	No of Drum	: Two

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 system 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 apparatus should have power failure detection facility system get off automatically. If the power fails during the test, Fresh test need to be started.

5.4 ALARMS AND WARNINGS:

The friabilator shall have alarm after the completion of the test.

6.0 SALIENT FEATURES:

6.1 COMPATIBILITY AND SUPPORT:

ELECTRIC CONTROL:

Friability test apparatus should consist of electrical on / off switch for operation and front screen keys for the programming.

UTILITIES:

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

6.2 MATERIAL OF CONSTRUCTION:

Drum **:** Glass acrylic
Body of Instruments : SS 304

6.3 Instruments & controls : Programmable 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 friability test apparatus with all options, equipment, and the documentation listed below shall be delivered to the Client Site.

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 Instrument listing

9.9 Material of construction