USER REQUIREMENT SPECIFICATION

EQUIPMENT NAME	AUTOMATED FRIABILATOR
USER DEPARTMENT	EXHIBIT BATCH AREA

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(A) PROCESS/PRODUCT REQUIREMENTS

1.0 Name/Description of the equipment

Automated Tablet Friabilator with 2 drums.

2.0 Purpose of the equipment

To determine percentage friability loss of tablets

3.0 Number Of equipments Required

Two

4.0 Tentative Process schematic flow diagram

NA

5.0 Product Dosage type for which to be used

Tablet

6.0 Suggested capacity and model with suppliers name

Model which is designed to comply friability test apparatus specifications of tablets according to pharmacopoeias like IP, BP, USP-NF, Ph.Eur. etc.
Suggested Model: EF-1W

7.0 Suggested Supplier

Electrolab, INDIA.

8.0 Requirements for any power failure backup's

It is attached with UPS all the time.

9.0 Any other specific requirements

Tilting facility according to the requirement of USP-NF

(B) OPERATIONAL REQUIREMENTS

(1) Production stage

Compression

(2) Material inputs into the equipment

Core tablets during compression

(3) Desired out come from the equipment

Equipment must comply the operational parameters as designed in Pharmacopoeias.
Speed of the drum must be 25 RPM accurately.

(4) Charge size / lot size

According to the test of compendia.

(5) Method for loading material into the equipment

Manually

(6) Method for unloading material from the equipment

After completion of the set resolution/time tablets will be discharged into their individual trays.

(7) Expected running time per day

Total 3 shifts in a day running continuously/intermittently according to the need of the product.

(8) Method of cleaning

Manually with lint free cloth (If Require) with Tissue paper.

(9) Recommended solvent for cleaning with its chemical nature

Purified water

(10) Utilities required

UPS-230V AC, 50Hz, 1Ø Power

(11) Instrumentation

According to the design of Instrument

(12) Process control requirements

RPM of the friabilator must be accurate and validated as per the compendial requirement.

(13) Change over parts requirements

NA

(14) Available size of the room for installation

According to the Layout of Exhibit Batch Area
(Compression Area Room No.:FN58)
Size: 3.8M×5.6M

(15) Online attachments with other equipments

Online attached with analytical balance and printer to get printout of % friability loss.

(16) Any other specific requirements

Model should be compact
Adjustable height & angle
Instrument should operate on either Time set or revolution set mode.
LED Display.

(C) GMP REQUIREMENTS

(1) Material of construction specifications

Material used according to compendial requirements.

(2) Working area environment requirement

Instrument will be kept in class 'D' area.

(3) GMP requirements

Easy to clean

(D) DOCUMENTATION REQUIREMENTS:

(1) Specify the drawings/certificates/manual required

GA Drawing
Operating Manual & maintenance Manual
List of Standard Recommended spares
Electrical control circuit diagram
Test certificate for bought out item
Certificates for motor and starter
DQ, IQ& OQ Certificate.

(2) Any other specific requirements

NA

(E) SAFETY REQUIREMENTS:

(1) Information related to safety

NA

(2) Process Control Alarms

Buzzer to inform end of process.
Indicator stating time elapsed and number of revolution passed

(3) Safety Interlocks

NA.

(4) Password protection (In case of PLC systems)

NA.

(5) Any other specific requirement

NA.

(F) ABBREVIATION:

Abbreviation	Full Form
EBA	Exhibit Batch Area
URS	User Requirement Specification
NA	Not Applicable
IP	Indian Pharmacopoeia
BP	British Pharmacopoeia
USP-NF	United State Pharmacopoeia-National Formulary
Ph.Eur.	European Pharmacopoeia
UPS	Uninterrupted Power Supply
RPM	Revolution Per Minute
IPA	Iso Propyl Alcohol
V	Volt
AC	Alternate Current
Hz	Hertz
Ø	Phase
M	Meter
LED	Liquid Electronics Diode
GA	General Arrangement
DQ	Design Qualification
IQ	Installation Qualification
OQ	Operational Qualification
SS	Stainless Steel
MOC	Material of Construction
PLC	Programmable Logic Control
STA	Senior Technical Assistant

(G) DISCUSSION/REVIEW/COMMENTS:

(H) USER REQUIREMENT SPECIFICATION APPROVAL:

PREPARED BY

Name & Designation	Sign & Date

CHECKED BY

Name & Designation	Sign & Date

APPROVED BY

Name & Designation	Sign & Date