USER REQUIREMENT SPECIFICATION

HARDNESS TESTER

EQUIPMENT NAME	COMBINATION TESTER
USER DEPARTMENT	EXHIBIT BATCH AREA

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(A) PROCESS/PRODUCT REQUIREMENTS

1.0 Name/Description of the equipment
Tablet Combination tester

2.0 Purpose of the equipment
Automatic measurement of weight thickness, length/Diameter & hardness of a tablets.

3.0 Number Of equipments Required
1 No.

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
Any latest model which is designed to give reproducible results with high accuracy.

Suggested Supplier
ERWEKA Gmbh,GERMANY
Dr. SCHLEUNIGER(PHARMATRON)

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 USP

(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.

(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 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

(11) Instrumentation
According to design of Instrument

(12) Process control requirements
RPM of the Hardness Tester must be accurate as per the compendia requirement.

(13) Change over parts requirements
None**.**

(14) Available size of the room for installation
According to the Layout of Exhibit Batch Area
(Compression Area Room No.: FN58)
Size: 3.8 m×5.6 m

(15) Online attachments with other equipments
Calculation of result like % friability, weight loss with printer output.
With Analytical Balance

(16) Any other specific requirements
Model should be compact
Adjustable height & angle of shaft (1 – 3 ft.).

(C) GMP REQUIREMENTS

(1) Material of construction specifications
Vendor to Specify

(2) Working area environment requirement
Instrument will be kept in Class 'D' area.

(3) GMP requirements
NA

(4) Filter requirement on utility lines or for vent purpose
NA.

(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

(2) Any other specific requirements
None

(E) SAFETY REQUIREMENTS:

(1) Information related to safety
Vendor should mention

(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
RPM	Revolution Per Minute
DG	Diesel Generator
Ltrs.	Litre
NA	Not Applicable
IPA	Iso Propyl Alcohol
M	Meter
SS	Stainless Steel
MOC	Material of Construction
PLC	Programmable Logic Control
FnD	Formulation & Development

(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