USER REQUIREMENT SPECIFICATION	
NAME OF ITEM: Disintegration Tester	**PROTOCOL No.:**.....
FUNCTIONAL AREA: Production	**PAGE No.:** 1 of 7

USER REQUIREMENT SPECIFICATION

(SECTION: FORMULATION)

EQUIPMENT NAME	DISINTEGRATION TESTER
USER DEPARTMENT	EXHIBIT BATCH AREA

USER REQUIREMENT SPECIFICATION

NAME OF ITEM: Disintegration Tester	**PROTOCOL No.:**.....
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(A) PROCESS/PRODUCT REQUIREMENTS

1.0 Name/Description of the equipment
Tablet Disintegration Tester of compendia l specification

2.0 Purpose of the equipment
To determine disintegration of tablet & capsule.

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 Disintegration test apparatus specification of IP, BP, USP-NF, and Ph.Eur.
Model: ED-2L

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
All parameters including strokes, timer and temperature probe must be validated.
Uniform temperature in both the beaker. External temperature probe required.

(B) OPERATIONAL REQUIREMENTS

(1) Production stage
Compression & coating

(2) Material inputs into the equipment
Core tablets & coated tablets

(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
NA

(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-230V AC, 50Hz, 1Ø Power

(11) Instrumentation
According to design of Instrument

(12) Process control requirements
Temperature of the DT apparatus must be accurate as per the compendial requirement. It strokes 30 times per minute to the height of 55mm. Resolution of temperature 0.1ºC & minimum accuracy of temperature of ±0.3ºC

(13) Change over parts requirements
Vendor should specify.

(14) Available size of the room for installation
According to the Layout of Exhibit Batch Area One Apparatus required in (Compression Area Room No.: FN 58) **Size: 3.8M×5.6M** Other Apparatus required in (Coating Area Room No. FN 59), **Size: 3.1M×3.3M**

(15) Online attachments with other equipments
NA

(16) Any other specific requirements
Model should be compact Programmable timer with alarm& temperature controller External probe for beaker temperature validation. Illuminated Bath for better visibility.

(C) GMP REQUIREMENTS

(1) Material of construction specifications
Material used according to Compendial requirements.

(2) Working area environment requirement
Instruments 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 & motor.
- Calibration Certificates for timer, temperature probe, beaker & temperature controller.
- DQ, IQ &OQ certificates.

(2) Any other specific requirements
None

(E) SAFETY REQUIREMENTS:

(1) Information related to safety
NA

(2) Process Control Alarms

Indicator showing:
Time elapsed
Bath & Beaker temperature.
Set temperature
Set Time

(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 States Pharmacopoeia-National Formulary
Ph.Eur.	European Pharmacopoeia
V	Volt
AC	Alternate Current
Hz	Hertz
Ø	Single Phase
DT	Disintegration
mm	millimetre
ºC	Celsius
DQ	Design Qualification
IQ	Installation Qualification
OQ	Operational Qualification
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