



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Disintegration Tester

Protocol No.:.....

Functional Area: Quality Control

Page No.: 1 of 8

Name of Equipment: Disintegration Tester

Document Reference Number:.....

Effective Date:.....



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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



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3.0 INTRODUCTION:

This document is generated for the purpose of specifying the user requirements for the Disintegration 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 disintegration test apparatus shall be located at wet lab area of Quality control area.

Disintegration tester gives the time required for a tablet / capsule to disintegrate into the granules.

The disintegration test apparatus shall be interfaced with following components.

1. Basic Unit with bottom illumination Basket Assembly
2. Guided Discs
3. External Probe
4. Top Plate Assembly
5. Bath with Heater
6. Mains cord

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

The unit shall be feasible to be installed in the current building facility.

4.0 OVERVIEW DEFINITION:

4.1 The Disintegration test apparatus shall have the following features:

- 4.1.1. The Disintegration test apparatus is used for testing the Disintegration time of the tablets, capsules & empty capsules. Instrument is designed to meet the specifications of USP, BP, EUR and IP
- 4.1.2. The base of the instrument is illuminated for viewing of the disintegration process of the tablets.
- 4.1.3. The built – in RTD sensor monitors the bath temperature and the external probe monitors beaker temperature. A user – friendly designed splash proof panel is provided with membrane keys for settings



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- 4.1.4. The Instrument design allows easy installation of the unit. A special cam drive ensures jerk – free movement.
- 4.1.5. The instrument would stroke for 30 strokes (between 29 to 32 strokes per minutes) / minute and with the stroke height of 55 mm.
- 4.1.6. The Disintegration test apparatus should have easy loading of the baskets with swivel free movement through a simple yet unique Snap – Click loading mechanism for attaching and removal of baskets.
- 4.1.7. The instrument shall be provided with simultaneous rotating and tapping motion to assure an evenly packed surface.
- 4.1.8. Apparatus should works in two different modes – Timer Mode and Manual Mode.
- **Timer Mode:** In this mode, the baskets stroke for the programmed time and park itself on the top position at the end of the test giving an alarm. The programmable Timer can be set from – Seconds to Minutes and Minutes to Hours. This ensures that a short and a long duration test can be conducted on the same unit.
 - **Manual Mode:** In this mode, the display shows ‘ - - - -’. No time is displayed in this mode. The elapsed time can be viewed by pressing the Timer key. The display will display the elapsed Time for about 5 sec. When the test is over & the instrument is stopped, the total disintegration Time can be seen by pressing the Timer key
- 4.1.9. An acrylic water bath is provided to give uniform temperature in the beaker. The temperature can be set from 20.0°C to 39.9°C and is controlled with accuracy of $\pm 0.5^\circ\text{C}$.

4.2 Technical Specifications:

Detailed Instrument Specifications for instrument are as follows:

ITEM	SPECIFICATIONS
No. of Stroke	29 to 32 Strokes / minute
Stroke Height	55 mm \pm 2 mm
Motor	230 V AC Synchronous Motor 3.5 KG cm
No. Of Baskets	2 Nos. (Each carrying 6-test positions)
Water batch	6 mm thick Transparent Acrylic
Heater	400 – Watts, S.S. 304
Temperature Range	20.0°C to 39.9°C



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ITEM	SPECIFICATIONS
Temperature Resolution	0.1°C
Temperature Control Accuracy	± 0.5°C
Timer	Range 1:1 Sec to 99 Min & 59 Sec Range 2:1 Min to 9 Hrs & 59 Min
Dimensions	350 mm x 390 mm x 510 mm (Approx.)
Weight	18 Kg (Approx.)
Control system requirements	Semi Automatic

4.3 The machine is to be used at the following environmental conditions:

4.3.1 Room Temperature : 24± 2 °C

4.3.2 Relative Humidity : NMT 55 %

4.4 Base Utilities Available:

Electrical : Single Phase, 230V ± 10 % 50 HZ

Control system requirements : Semi Automatic

5.0 OPERATIONAL REQUIREMENTS:

5.1 OPERATION:

The Disintegration Tester shall operate with a minimum of operator involvement. Operation shall be safe both from an operator and environmental stand point.

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 Disintegration test apparatus shall have alarm after completion of test.

5.4 ALARMS AND WARNINGS:

The Disintegration Tester apparatus shall have alarm after the completion of the test.



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6.0 SALIENT FEATURES:

6.1 COMPATIBILITY AND SUPPORT:

ELECTRIC CONTROL:

Disintegration Tester apparatus should consist of electrical on / off switch for operation.

UTILITIES:

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

6.2 MATERIAL OF CONSTRUCTION:

Disintegration test apparatus body : SS 304

Water bath : Acrylic

Beaker : Glass

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 Disintegration Tester 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



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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