USER REQUIREMENT SPECIFICATION

Name of Item: Dissolution Test Apparatus	**Protocol No**.:.....
Functional Area: Quality Control	**Page No.:** 1 of 8

Name of Equipment: Dissolution test Apparatus

Document Reference Number: ……

Effective Date: ……..

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Name of Item: Dissolution Test Apparatus	**Protocol No**.:.....
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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**

2.0 Table of Contents:

3.0 INTRODUCTION:

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

Dissolution tester gives the amount of active substance in a pharmaceutical dosage form dissolved in a defined medium within a defined period of time.

The dissolution test apparatus shall be interfaced with following components.

1. Basic Unit
2. Temperature Controller
3. S.S. Paddle Rod as per USP
4. S.S. Basket Rod as per USP
5. S.S. USP Basket without Clip Assembly.
6. Merlon Jars
7. External Probes
8. Top plate Assembly
9. Bath

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 Dissolution test apparatus shall have the following features:

4.1.1. The All components coming in the contact with the dissolution media must be chemically inert.

4.1.2. The dissolution test apparatus fulfills the requirements laid down in USP, IP ,BP, EUR Pharmacopoeia

4.1.3. The Apparatus should have 8 stirring station and is equipped with the stirrer, the user can use one test vessel for the replenish media; one can be used to test a placebo or an empty capsule shell simultaneously with the 6 samples under the same test conditions.

4.1.4. The paddle and the basket shaft are provided with the Snap _ Fit mechanism

4.1.5. The stirrer unit can be move UP/Down using the lift Keys provided on the front panel.

4.1.6. On lowering the instrument, the precise height positioning of the stirrers is achieved automatically without additional equipment and device.

4.1.7. The test vessels are provided on the periphery for the ease of the sampling.

4.1.8. The molded bath is used to prevent any leakage at the joints and avoids any deposition in the corner of the bath.

4.1.9. Adjustable legs are provided at the base of the instrument for the leveling of the instrument.

4.1.10. The dissolution apparatus shall be provided with vibration free motors with control system. The system shall be programmed as per required parameters for dissolution test.

4.1.11. The dissolution apparatus shall have facility to indicate audio alarm after completion of the test.

4.1.12. The dissolution test apparatus shall have digital display of RMP, time and temperature.

4.1.13. 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.

4.1.14. Apparatus should works in two different modes – Timer Mode and Manual Mode.

4.1.15. An acrylic water bath is provided to give uniform temperature through out the system. The temperature can be set from 20.0°C to 39.9°C and is controlled with accuracy of ± 0.5°C.

4.1.16. The dissolution test apparatus shall have provision to store 16 sampling intervals in a single protocol and total 20 protocols.

4.2 Technical Specifications:

Detailed Instrument Specifications for instrument are as follows:

ITEM	SPECIFICATIONS
Revolution setting	25 to 200 rpm
Temperature Setting	30.0 to 40.0 ºC
Sampling interval setting	23 hrs ,59 minutes

ITEM	SPECIFICATIONS
Control system	manual
Water bath	circulating water bath
Temperature accuracy	± 0.5 ºC
Wobble check	± 0.5 mm for paddle & ± 1.0 mm for basket
Timer accuracy	± 2.0%

4.3 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 %

4.4 Base Utilities Available:

Electrical **:** Single Phase, 230V ± 10 % 50 HZ
Control system requirements : Semi Automatic

5.0 OPERATIONAL REQUIREMENTS:

5.1 OPERATION:

The dissolution 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 upon loss of electricity, and will not require operator intervention to re-start. It will start considering elapsed power failure time.

5.3 SAFETY FEATURE:

The dissolution test apparatus shall have alarm after when it stopped by any reason.

5.4 ALARMS AND WARNINGS:

The Dissolution test apparatus shall have alarm after the completion of the test.

6.0 SALIENT FEATURES:

6.1 COMPATIBILITY AND SUPPORT:

6.1.1. ELECTRIC CONTROL:

Dissolution Test apparatus should consist of electrical on / off switch for operation and front screen for the programming and setting the instruments as per the requirements.

6.1.2. UTILITIES:

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

6.2 MATERIAL OF CONSTRUCTION:

Dissolution test apparatus : SS 304

Water bath : Acrylic

Beaker : Marlon Jar

6.3 Instruments & Control: Programmable Operating 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 Dissolution 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 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