



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Tap Density Tester

Protocol No.:.....

Functional Area: Quality Control

Page No.: 1 of 7

Name of Equipment: Tap density 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 tap density tester.

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.

The Tap density tester shall be located at wet lab area of quality control area.

Tap density tester is used to find out the tap density of raw material and granules.

An advantage of tap density tester is to calculate the filled weight capacity of capsules.

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 tap density tester shall have the following features:

- 4.1.1. The unit has been designed for user-friendly operation and supports a menu.
- 4.1.2. The tap density tester shall have designed to meet the specification of USP,BP, IP and EUR.
- 4.1.3. The unit has been designed for user-friendly operation and supports a menu driven 24 x 2 characters LCD Display.
- 4.1.4. The tap density tester shall be provided with two holders for measuring cylinders. One for 100 ml capacity and second is for 250 ml capacity.
- 4.1.5. The instrument shall be provided with printer output for documenting test results as per GMP/GLP standards.
- 4.1.6. The instrument shall be provided with simultaneous rotating and tapping motion to assure an evenly packed surface.
- 4.1.7. The instrument shall be provided with online validation of strokes / min.

4.2 The Tap density tester shall be used primarily for:

For the determination tapped density of raw material and granules.

4.3 Technical Specifications:

4.3.1 Stroke height : 14 mm and 3 mm

4.3.2 Stroke / minute : 300 and 250



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4.3.3 Display : 24 x 2 characters back lighted LCD.

4.3.4 No. of Tap : 1 – 9999

4.3.5 Measuring Cylinder : 250 ml – readable to 2 ml and 100 ml-
readable to 1ml

4.4 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 %

4.5 Base Utilities Available:

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

5.0 OPERATIONAL REQUIREMENTS

5.1 OPERATION:

The tap density apparatus shall operate with a minimum of operator involvement. Operation shall be safe both from an operator and environmental standpoint.

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 system shall be stop safely in emergency.

5.4 ALARMS AND WARNINGS:

The tap density apparatus shall have alarm after the completion of the test.

6.0 SALIENT FEATURES

6.1 COMPATIBILITY AND SUPPORT

ELECTRIC CONTROL:

Tap density tester should consist of electrical on / off switch for operation.

UTILITIES:

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



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available.

6.2 MATERIAL OF CONSTRUCTION:

Measuring cylinder : Glass (Duron)

Body of Instruments : SS 304

6.3 Instruments and control : Semi automatic

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, DQ.

8.0 DELIVERY:

The tap density tester with all options, equipment, and the documentation listed below, shall be delivered to 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



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9.7 Maintenance and service manuals

9.8 Instrument listing

9.9 Material of construction