



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATION

Name of Item: Karl Fischer Titrator

Protocol No.:.....

Functional Area: Quality Control

Page No.: 1 of 7

Name of Instrument: Top Pan Balance

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 a top pan balance. The URS is provided to aid the user through the important components, variables and options necessary to procure a functional top pan balance that meets the user requirement in the most cost effective method.

The URS is thus provided to the supplier to provide a price quote for the top pan balance, including design and manufacture of the equipment.

The URS will be recognized as the integral part of the procurement agreement with the selected instrument vendor. The instrument supplier or vendor will abide by the information and condition set forth by this document as well as purchasing and delivery terms and condition.

The top pan balance shall be located in quality control.

The document encompasses the normal range of top pan balance operation. Obviously technology improvements and new applications may require deviations from these specifications. These specifications are to be utilized as a guide for the user to answer the majority of the questions involved in specifying and using the equipment. Amended may be use to round out the requirements.

4.0 OVERVIEW DEFINITION:

4.1 The top pan balance shall have the following features:

- 4.1.1. The top pan balance shall have updated touch screen key panel for operating control panel. Various screens shall be as follows.
 - I. Set screen parameters
 - II. Operate screen parameter
- 4.1.2. The top pan balance should be capable of handling of different size and type of samples, at minimum / maximum capacity of the balance selected.
- 4.1.3. The Top pan balance shall be provided with all accessories to utilize Top pan balance. Which shall facilitate any weighing of powder, products and liquids (Which are non corrosive, non hazardous and safe for weighing) within specific size and requirement as per pharmacopoeia.
- 4.1.4. The top pan balance should have the basic weighing functions with GLP compliant printout.
- 4.1.5. The Top pan balance shall be provided with power fuse and safety features to avoid failure and personal safety, which shall have feature of wear free drive and self-initialization / self-check. No complicated operations or chains shall be used for drive mechanism. Top pan balance shall require negligible maintenance.
- 4.1.6. The Top pan balance shall be provided with detachable printer facility, built-in controller and programmable software. The Top pan balance shall have facility to set / change year, date, time as per the set requirements.



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- 4.1.7. The drums are rotated by a maintenance free stepper motor drive with a constant speed of 25 RPM.
- 4.1.8. The Top pan balance shall have facility to adjust , and check verification externally the following parameters -
 - a) Instrument Level.
 - b) Built in calibration.
 - c) Built in self check.
 - d) External calibration.
 - e) Tarring, Standby option.
- 4.1.9. The Top pan balance shall have Analytical drift shield, weighing pan, of good quality materials.
- 4.1.10. The test can be performed in two modes –
 - (1) Time mode
 - (2) Revolution Count Mode
- 4.1.11. Time mode: In this mode, the test duration is programmable. User can program the test duration.
- 4.1.12. The Top pan balance shall be provided with vibration free smooth glass doors, with grip for operating the same.
- 4.1.13. The Top pan balance shall be provided with vibration free mechanism.
- 4.1.14. The Top pan balance shall be provided with following interlocks in case of overload failure.
- 4.1.15. Printer port facility.
- 4.1.16. Printout should have date , time of start , Software Version No., Serial No., Make and Model of same balance, ID, Serial No. of weighing, Unit of measurement, Static data like No. of total weighing, mean, Standard deviation, Relative Standard deviation, minimum, maximum of total weighing.
- 4.1.17. Battery backup for software and hardware.

4.2 The top pan balance shall be used primarily for:

For the weighing of all type of analysis

4.3 Technical Specifications:

- 4.4.1 Weighing capacity :** 10 mg to 220 mg.
- 4.4.2 Readability :** 10 mg.
- 4.4.3 Repeatability :** 10 mg.

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

- 4.4.1 Room Temperature :** 24± 2 °C



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4.4.2 Relative Humidity: NMT 55 %

4.5 Base Utilities Available:

Electrical : AC adapter, 230 V.

5.0 OPERATIONAL REQUIREMENTS:

5.1 OPERATION:

The top pan balance shall have touch screen operating system.

5.2 POWER FAILURE/RECOVERY:

In the event of a power failure, the balance shall shut off automatically. The balance will start after pressing the start key and balance display ready over screen after calibrating automatically.

SAFETY FEATURE:

The apparatus should have power failure detection facility system get off automatically. If the power fails during the test, Fresh test need to be start.

5.3 ALARMS AND WARNINGS:

The semi micro top pan balance shall not have necessarily emergency alarming facility.

6.0 SALIENT FEATURES:

6.1 COMPATIBILITY AND SUPPORT

ELECTRIC CONTROL:

The top pan balance shall 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:

Body of Instruments : SS 304.

Pan platform : SS 304 Mirror Polish

Weighing Pan : Aluminium with mirror polish



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6.3 Instruments & controls : Touch screen controller

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., design qualifications.

8.0 DELIVERY

The top pan balance with all options, equipment, and the documentation listed below, shall be delivered.

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