USER REQUIREMENT SPECIFICATION	
Name of Item: Analytical Balance	**Protocol No.:**.....
Functional Area: Quality Control	**Page No.:** 1 of 7

Name of Instrument: Analytical Balance

Document Reference Number: …….

Effective Date:

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 an analytical balance. The URS is provided to aid the user through the important components, variables and options necessary to procure a functional analytical 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 analytical 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 of the Client.

The analytical balance shall be located in quality control.

The document encompasses the normal range of analytical 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 analytical balance shall have the following features:

4.1.1. The analytical 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 analytical 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 Analytical Balance shall be provided with all accessories to utilize Analytical 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 analytical balance should have the basic weighing functions with GLP compliant printout.

4.1.5. The Analytical 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. Analytical Balance shall require negligible maintenance.

4.1.6. The Analytical Balance shall be provided with detachable printer facility, built-in controller and programmable software. The Analytical Balance shall have facility to set / change year, date, time as per the set requirements.

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 Analytical Balance shall have facility to adjust , and check/verification externally the following parameters -

a)Instrument Level.
b) Load cell lock.
c) Built in calibration.
d) Built in self check.
e) External calibration.
f) Tarring, Standby option.

4.1.9. The Analytical 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 Analytical Balance shall be provided with vibration free smooth glass doors, with grip for operating the same.

4.1.13. The Analytical Balance shall be provided with vibration free mechanism.

4.1.14. The Analytical 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 analytical balance shall be used primarily for:

For the weighing of all type of analysis

4.3 Technical Specifications:

4.4.1 Weighing capacity **:** 0.1 mg to 220 mg.

4.4.2 Readability **:** 0.1 mg.

4.4.3 Repeatability **:** 0.1 mg.

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 : AC adapter,230 V.

5.0 OPERATIONAL REQUIREMENTS:

5.1 OPERATION:

The analytical 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 starts 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 analytical balance shall not have necessarily emergency alarming facility.

6.0 SALIENT FEATURES:

6.1 COMPATIBILITY AND SUPPORT

ELECTRIC CONTROL:

The analytical 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

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 analytical balance 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