USER REQUIREMENT SPECIFICATION (URS)

FOR

ANALYTICAL BALANCE

Department :

URS no.

Supersede:

USER REQUIREMENT SPECIFICATION

Name of Item: Analytical Balance	**Protocol No.:**.....
Functional Area: Quality Control	**Page No.:** 2 of 7

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Issued to mfg / supplier by purchase department _____

USER REQUIREMENT SPECIFICATION

Name of Item: Analytical Balance	**Protocol No.:**.....
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1. Approval:

ACTIVITY DETAIL	NAME OF PERSON	DESIGNATION	SIGNATURE	DATE
Prepared By				
Reviewed By				
Approved By				

2. Change History:

REVISION NUMBER	REVISION DETAILS	DATE OF REVISION

3. Purpose:

The purpose of the user requirement for Analytical balance is:
To define the instruction for selection of Analytical balance for intended use
To provide a specification to the vendors for their submission of quotation.
To ease the selection process of vendors

4. Scope:

4.1 This document is applicable for Analytical balance intended to use at manufacturing plant.

4.2 The specification and criteria given in this document is to be considered but should not be limited to this.

5. Specifications:

5.1 Description of equipment / system:

The Analytical balance shall have following components.

- Stainless-steel floor pan
- Draft shield disk
- Pan support
- AC adapter
- Leveling bubble
- Leveling foot
- Operating instruction

5.2 Identification number and location:

Equipment Name	**Identification Number**	**Location**
Analytical balance		Instrument room

5.3 Intended use:

Operation of equipment depends upon the production output; the equipment should be designed to work continuously for 3 shifts per day.

5.4 Intended type of material to be handled:

This will include handling of drug products;

- Solid & Liquid pharmaceutical raw materials
- Ophthalmic dosage forms
- Liquid injectable

5.5 Construction:

Not Applicable

5.6 Capacity:

The Analytical balance must be capable for routine laboratory analysis as well as those involved in research and development.

5.7 Electrical construction:

Control panel includes all control equipment and switch cabinet will contain all high voltage equipment, the cabinet will provide the sterilizer with either 440 VAC, 50 Hz, 3Phase. Cabinet enclosure- Protection category will be IP/54, IP/55.

5.8 Control parameters:

Weighing capacity, Readability, linearity, Weighing pan dimensions, Operating temperature, Storage temperature, Humidity etc.

5.9 Acceptable tolerance for control parameters:

Max.weighing capacity	: 220 g.
Readability	: 0.01 mg.
Linearity	: ± 0.02 mg.
Weighing pan Dimensions	: About 100 mm
Operating temp.	: 15ºC to 40ºC
Storage temp.	: - 10ºC to + 40ºC
Humidity	: 80%

5.10 Type of control System:

- The balance meets the highest requirements for accuracy and reliability of weighing results with versatile features.
- Efficient filtering-out of unfavorable ambient conditions.
- Stable-fast response times.
- Easy operation.
- Choice of weight units
- The instrument must be in-built facility for internal and external calibration.
- Selected report format for complying with GLP requirements.
- Error indication helps user to trace the problems.
- Full GLP capability

5.11 Feasible parameters to be set:

Not Applicable

5.12 Parameters to be indicated by control systems:

1. Actual weight taken and instrument ID No.
2. Time and date formatting.

3. Formatting Format for recording data with company's name in header.

5.13 Available utilities:

1. Utilities required for electric connection can be provided.
2. Standard weight for Calibration can be provided.

5.14 Limitations / constraints:

Not Applicable

5.15 Regulatory requirements:

Software employed for having a control on Analytical balance, must be complying with 21 CFR part 11 regulation of USFDA.

5.16 Delivery Address:

……..

6 Safety:

Proper equipment earthing shall be provided.

7 Vendor Scope:

7.1 Spare Parts:

A suggested spare parts listing will be provided that includes:

- Consumable wear parts
- Parts that are easily broken
- Parts that can wear out, and are long lead time availability.
- Electronic components those are not readily available from a local source to the user.
- The Supplier will either stock frequently required spare parts, or provide the manufacturer name and part number for those parts.

7.2 Support:

- Start-up Support
  Start-up support shall consist of full time assistance on the User's site for installation, start-up and commissioning.

- Training
  User training shall consist of equipment training by a qualified trainer. Certificates of training shall be provided for each person completing the training program.

- Post Start-up Support
  Post start-up support shall consist of User site visits for a period of 1 year after the completion of commissioning activities as and when required.

- Technical Support
  Technical support shall be available via telephone for a period of 5 years following the completion of commissioning.

8 Documentation:

S.No.	Document	Mode
1.	User manual	Paper or .pdf
2.	Software guide	Paper or .pdf
3.	Design specification	Paper
4.	Qualification documents	Paper
5.	Spare parts list	Paper

9 References: