



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## USER REQUIREMENT SPECIFICATION

**NAME OF ITEM:** WEIGHING BALANCE

**PROTOCOL No.....**

**FUNCTIONAL AREA:** PRODUCTION

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# USER REQUIREMENT SPECIFICATIONS

## WEIGHING BALANCE

**Document Reference:** Nil

**Issue Date:** Nil



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### 1.0 Approval:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution.

Functional area	Name	Designation	Signature	Date
<b>PREPARED BY</b>				
User Department				
<b>REVIEWED BY</b>				
User Dept. Head				
Engineering Dept. Head				
Environment, health and safety				
Quality Control (if applicable)				
Quality Assurance				
<b>APPROVED BY</b>				
QA Head				
Plant Head				



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- 2.0 OBJECTIVE:** The objective of this document is to provide the requirement and appropriate design to support the prospective supplier to identify company needs, price quote for the subject equipment and performance requirements for procurement of equipment including major ancillary component or fabrication of the area so as to meet the in-house requirements as well as compliance with cGMP.

The supplier shall abide by the information and conditions set forth by this document as well as the standard purchasing terms and conditions of company.

- 3.0 Scope:** This user requirement specification (URS) is applicable for the procurement of weighing balance.

- 4.0 Reason for URS:** To procure weighing balance for installation in Block-1 for weighing of materials.

**The reason for preparing this document is:**

Please tick any one (or multiple) option(s) from the following (☑):

- Refurbished premises/equipment
- Purchase of Utility Systems
- Purchase of Process Equipment
- Purchase of Laboratory Equipment
- Bespoke or user configured computer systems
- In-Use Systems that don't have a URS
- Others (Specify)



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**5.0 Responsibility:** Personnel involved in qualification activity.

Department	Name	Activity
User		To provide the User Requirement Specification (URS)
Engineering		To provide requirements with respect to utilities, components, based on the location of use and desired equipment parameters
Health Safety and Environment		To provide the safety requirements of equipment and facility
Quality Assurance		To be a part of qualification team
QA Head		To review and approve the requirement and Qualification document
Plant Head		To review and approve the requirement and Qualification document



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**6.0 Equipment Description:** The weighing balance is designed in accordance with cGMP principles and is used for weighing of materials. Weighing balances incorporate different types of weighing system, they differ from one another in the scope of their functions, readability, weighing capacity, response time and verification scale interval.

**7.0 Information of Input Material:** NA

**8.0 Information of Output Material:** NA

**9.0 Environment:** This section gives a brief summary of the layout and physical condition of the proposed site of the equipment. This includes (but not limited to), the data sheet of the room where proposed equipment is to be placed with proposed placement drawing showing room dimensions, door/window locations and dimensions, HVAC supply/return grill locations, utility point locations, etc.

S.No.	Parameter	Specifications/Dimension
9.1	Available area	<ul style="list-style-type: none"><li>➤ Area (L x B x H)</li><li>➤ Area grade/class: ISO 8</li><li>➤ As Built Area Layout attached as attachment No. _____.</li><li>➤ Should be able to accommodate in dispensing area.</li><li>➤ Should be installed at the suitable area for ease in cleaning.</li></ul>
9.2	Maximum Expected size of equipment (approx.)	<ul style="list-style-type: none"><li>➤ Suitable for installation in the area shall be provided</li></ul>

**10.0 Equipment Design and Principle of Working:** NA.

**11.0 Process Description:** This section mentions in brief the details of the process to be handled by the equipment.

- a) Ensure the cleanliness of the balance.
- b) Ensure calibration or verification of the balance has been done.
- c) Keep the material to be weighed on the balance platform and note down the displayed value.
- d) Take out the material from the balance.
- e) Ensure the zero reading of the balance before taking next weighing on it.

**12.0 Functional Requirements of Equipment:**

**12.1 Functionality of the Equipment:** The desired functional requirements and how it operates are



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listed under this section.

S.No.	Parameter	Specifications
12.1.1	Use/Purpose	➤ For weighing of materials.
12.1.2	Capacity/Working Capacity	➤ Maximum 100 Kg
12.1.3	Model	➤ cGMP Model

**12.2 Instrumentation Requirements:** This section mentions in brief the minimum requirement for measuring instrumentation for controlling and monitoring of process parameters etc.

S.No.	Parameter	Specifications
NA		

**12.3 Data Collection and Reporting:** NA

**12.4 Recipe Provision/Data saving/Data Back-up/Data Security:** This section specifies the requirements (as applicable) for, data security facilities, etc.

S.No.	Parameter	Specifications
NA		

**13.0 Performance Features:** The parameters that are planned to be evaluated during performance qualification and process validation activities are mentioned.

S.No.	Parameter	Specifications
13.1	Performance of the machine according to operation.	The machine is intended to be operated regularly: 24 hours, 7 days per week with cleaning in between batch/ product changeover.
13.2	Cleaning Requirements	Easy accessible for cleaning.

**14.0 Capacity/Speed:** The desired capacity/speed with the UOM is specified in this section.

S.No.	Parameter	Specifications
14.1	Capacity	100 Kg Maximum





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**15.0 Automation and Safety Features:** The minimum required as well as desired automation and safety features (Alarms, Locking, etc.) are listed in this section.

S.No.	Parameter	Specifications
15.1	Electrical connection & System design	➤ All Electrical connections should made through Sockets & shielded cables, no exposure to surroundings.

**16.0 System Boundaries:**

Description of the attached components and accessories to the main machine.

S.No.	Parameter	Specifications
NA		

**17.0 Material of Construction:** Specifications for material of construction of contact parts, non-contact parts of are listed here.

S.No.	Parameter	Specifications
17.1	Balance platform	➤ Should be SS 304 Grade.

**18.0 Surface Finish:** Specifications for surface finish of contact parts, non-contact parts, etc. are listed here.

S.No.	Parameter	Specifications
18.1	No Sharp Edges	➤ Should be free of Sharp Edges.

**19.0 Electrical and Control Equipment Philosophy:** A brief detail of the control requirements and whether the equipment is to be controlled using electrical system/ microprocessor/ PLC/ computers or a combination of these are mentioned in this section.

S.No.	Parameter	Specifications
NA		

**20.0 cGxP Considerations:** The requirements for electronic compliance of the equipment.

S.No.	Parameter	Specifications
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NA

**21.0 Expected Documents and Drawings:** Requirement of documents to be delivered by the suppliers during the procurement life cycle. A suggestive list (but not limited to), is as listed below:

S.No.	Document details	Required (✓ / ✗)
21.1	Design Specifications	<input checked="" type="checkbox"/>
21.2	Functional Specifications	<input type="checkbox"/>
21.3	PLC Alarm/Interlock/Safety/ communication/power failure test procedures	<input type="checkbox"/>
21.4	Piping and Instrumentation Diagram (P&ID)	<input type="checkbox"/>
21.5	Instrument Listing	<input type="checkbox"/>
21.6	Control Schematics	<input type="checkbox"/>
21.7	Control Panel Assembly Drawings	<input type="checkbox"/>
21.8	Machine Assembly Drawings	<input type="checkbox"/>
21.9	Bill of Materials	<input type="checkbox"/>
21.10	Operator, Maintenance and Service Manuals	<input checked="" type="checkbox"/>
21.11	Spare Parts List	<input type="checkbox"/>
21.12	MOC certificates	<input checked="" type="checkbox"/>
21.13	Calibration certificates of instruments	<input type="checkbox"/>
21.14	Test certificates of components/test devices	<input type="checkbox"/>
21.15	Weld certificates (if any)	<input type="checkbox"/>
21.16	'As-built' P&ID	<input type="checkbox"/>
21.17	GA drawing	<input type="checkbox"/>
21.18	Isometric drawing (if any)	<input type="checkbox"/>
21.19	Electrical drawings	<input type="checkbox"/>
21.20	Component Cut Sheets (optional)	<input type="checkbox"/>



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S.No.	Document details	Required (✓ / ✗)
21.21	PLC Program Printouts and Disk File (optional)	<input checked="" type="checkbox"/>
21.22	HMI Configuration Printout and Disk File (optional)	<input checked="" type="checkbox"/>
21.23	Other (Specify)	<input checked="" type="checkbox"/>

✓: Applicable & required    ✗ : Not applicable

### 22.0 Available Utilities:

S.No.	Parameter	Specifications
22.1	Electricity	➤ Single Phase/ 230 Volt $\pm$ 10%, 50 HZ $\pm$ 5%

**23.0 Maintenance Requirements:** Maintenance related requirements like accessibility for easy maintenance, required spares, etc. are listed here.

S.No.	Parameter	Specifications
23.1	Maintenance	➤ Easy accessibility for maintenance

### 24.0 Delivery, Installation and Commissioning Requirements:

**24.1** Should be delivered in disassembled condition and to be assembled at the site by the manufacturer/supplier service engineer.

**24.2** Manufacturer should provide support in case of problems, which may not be able to rectify at the user end.

**24.3** FAT if any required by the customer then, same to be performed jointly by the nominated persons from both the side at the manufacturer's site.

**24.4** The manufacturer should install, qualify and commission the equipment at the user site. and provide the necessary training to the user for operation and cleaning. Training to be provided by the manufacturer for the necessary critical steps involved in the operation, cleaning, maintenance, safety and handling of equipment.

**25.0 Other Specific Requirements:** To provide the necessary servicing at the site at defined intervals. Language requirements in manual should be in English.



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**26.0 Reference Documents:** Nil.

**27.0 Abbreviations:** Full forms of all abbreviations are listed here.

<u>Abbreviation</u>	<u>Full form</u>
cGMP	: Current Good Manufacturing Practice
HZ	: Hertz
ISO	: International Standard Organization
MOC	: Material of Construction
Nos	: Number
L x B x H	: Length x Breadth x Height
Sr. No.	: Serial Number
SS	: Stainless Steel
URS	: User Requirement Specification
mm	: Millimetre

**28.0 Attachments:** This section contains a list of all attachments referenced in the protocol.

S.No.	Attachment Details	Attachment No.