

PT. Mersifarma TM				
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User Requirement Specification For Analytical Balance Shimadzu TX 323L

Approvals

Name	Job Title or Role	Signature	Date
The Lead Author is signing to confirm that this document has been prepared in accordance with PT Mersifarma TM standards			
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1 Introduction

This document specifies the User Requirements for the determination of Analytical Balance Shimadzu TX 323L PT Mersifarma TM Sukabumi Site.

The approval of this document by:

- QA Qualification Supervisor indicates that the document is ready for general approval.
- The owner indicates that the document describes appropriate/relevant user requirements and the user understands that it may not be practical to develop/implement all requirements.
- Quality Assurance indicates that QA has read the document and has discussed with the author and/or project leader areas that may be quality critical.

1.1 Purpose

The purpose of this document is to define both functional and non-functional requirements to be met by the system to ensure that it is fit for use for Analytical Balance Shimadzu TX 323L in production unit. This document forms the foundation of the system qualification on which the design and testing activities are based.

1.2 Scope

This user requirement document applies to Analytical Balance Shimadzu TX 323L that used within the PT Mersifarma TM to weigh folding box with direct connectivity to the QAD system for data recording and traceability. It is decided to purchase Analytical Balance Shimadzu TX 323L, since the purpose of this tools to weigh folding box as stated in the monograph.

1.3 Definitions and abbreviations

The list given below includes definitions of specific technical and functional terms which may be used in this document.

Term	Definition
Must / Mandatory / M	The requirement is mandatory and compliance with it is non-negotiable. Essential to meet GMP or business critical requirements.
Should / Desirable / D	Optional requirement. The requirement is not mandatory, but any departure from compliance with it is subject to Mersifarma's prior written approval.
Not Applicable / NA	Where a section is not applicable
URS	User Requirements Specification

2. General Description

2.1 Delivery Scope

Analytical Balance Shimadzu TX 323L within the PT Mersifarma TM weigh folding box with direct connectivity to the QAD system for data recording and traceability. The analytical balance that connect to a computer and/or QAD system is needed for automatic data capture, electronic record management, and traceability of weighing result.

2.2 Machine

The scope of systems / equipment provided by Supplier included:

- Capacity minimum 320 gram with readability 0.001 g (1 mg)
- Repeatability ± 0.001 g or better
- Linearity ± 0.002 g or better

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- Pan size approximately Ø110 mm
- Digital LCD Display with backlight
- RS-232 interface for computer connectivity
- Capable to transmitting weighing result directly to PC.
- The analytical balance shall be equipped with the following accessories glass door type windbreak (draft shield), AC adapter, RS-232C communication interface/cable, user manual, calibration certificate.
- The balance shall display weighing results in multiple units, including gram (g) and milligram (mg).

2.3 Service

The scope of services delivered by the Supplier included:

- Machine design and construction
- Commissioning, IQ/OQ execution at site
- Installation
- Training for staff and operators
- System operations support and spare parts
- Documentation

3. General Requirements

3.1 Machine Functionality Requirements

This section defines the user requirements and acceptance criteria from machine performance perspective

Req. No.	Machine Features	Description	Limit	M/D/N A
1	Capacity	Maximum weight that the balance can measure accurately while maintaining its specified performance accuracy	The analytical balance shall have a maximum weighing capacity of 320 g.	M
2	Readability	Smallest change in weight that an analytical balance can display	The balance shall have a readability of 0.001 g (mg) or better	M
3	Repeatability	The ability of an analytical balance to produce the same weighing result when the same sample is weighed repeatedly under the same conditions	The balance shall have a repeatability of $\leq \pm 0.001$ g (mg)	M
4	Linearity	The ability of the balance to provide accurate measurements throughout its entire weighing range	The balance shall have a linearity of ± 0.002 g or better	M
5	Weighing Units	Measurement units available on the analytical balance for displaying weight values	gram (g) and milligram (mg)	M

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6	Balance pan	The balance pan size shall be suitable for weighing folding boxes	Equipped with a stainless-steel weighing pan The weighing pan diameter is approximately Ø110 mm	M
7	Display	Visual interface used to show weighing results	Backlight LCD display	M
8	Connection to a computer system	The analytical balance able to communicate and transfer weighing data directly to a computer for data recording, traceability, and further processing	The balance shall have R2-232 or equivalent communication interface for connection to a computer system	M
9	Draft shield	Protective enclosure surrounding the weighing pan of an analytical balance that minimizes the effects of air currents and environmental disturbances on weighing results.	The balance shall include a draft shield	M
10	Level gauge	Built-in indicator (bubble level) used to verify that the balance is properly levelled before use.	The level of the electronic balance can be adjusted	M
11	Calibration	Capability of an analytical balance to be calibrated either automatically using an internal calibration weight or manually using an external certified calibration weight	The balance shall provide internal or external calibration functionality	M
12	Accessories	-	AC adapter/power supply	M

3.2 General Functionality

This section defines general operational user requirements (e.g. ability to store and recall machine parameters).

These requirements are provided below with references as applicable.

Req. No.	Requirement	M/D/NA
3.2.1	The system allows calibration and preventive maintenance features	D
3.2.2	Easy to maintenance, and operate	D

3.3 Operating Condition and Environment

This section defines any special requirements for the physical environment in which the equipment is to operate such as temperature, vibration, humidity, physical layout and required utilities such as compressed air and power supply requirements.

Req. No.	Requirement	Description	M/D/NA
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3.3.1	To be installed on the existing production area.		M
3.3.2	System is compatible with typical power requirement		M
3.3.3	Machines water and dust resistance		M
3.3.4	Operation condition	Working temperature: up to 27°C Working humidity: up to 70%	M

3.4 Environmental Health and Safety

This section defines any requirements that relate to operational safety and environmental expectations.

Req. No.	Requirement	M/D/NA
3.4.1	Emergency button	M
3.4.2	System complies with current IEC regulations for electrical safety	M
3.4.3	The system must meet all current Environmental Health and Safety requirements	M

3.5 Interfaces

This section defines any requirements for how the system is to be interfaced with other equipment or systems such as networks, LIMS and CDS.

Req. No.	Requirement	M/D/NA
3.5.1	User-friendly interface, preferably in English	D

3.6 Computing Environment

This section defines any PC requirements to ensure appropriateness of operating system, capacity, processor speed, memory and compatibility with company standard including any requirements for networking capability.

Req. No.	Requirement	M/D/NA
3.6.1	-	

3.7 Data Acquisition, Processing and Reporting

This section defines any requirements related to how electronic data is to be captured, processed, output, formatted and approved and defines any specific data media requirements where appropriate where these can vary for a specific each product. Any requirements related to use of controlled file shares or compliant databases for storing data are included.

Req. No.	Requirement	M/D/NA
3.7.1	-	

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3.8 System Security

This section details the level of security required of the system, where applicable, e.g. physical security, health and safety related physical security, machine parameters security, access control, access levels, user identification and authorisation processes, password synchronisation, and logging access failures.

Req. No.	Requirement	M/D/NA
3.8.1	-	M
3.8.2		
3.8.3		

3.9 Data Integrity

This section details any requirements for how electronic data are to be managed, stored, accessed, backed up, recovered, migrated, secured, audit trailed and archived.

Req. No.	Requirement	M/D/NA
3.9.1	-	

3.10 Additional Requirement

This section defines any required accessory that may be periodically needed so that their use may be qualified with the rest of the system (e.g. special setup or calibration tools).

Req. No.	Requirement	M/D/NA
3.10.1	-	

4. Other Requirements

4.1 Supplier Requirements

This section defines any requirements made of the Supplier that are necessary only for the introduction of the system.

Req. No.	Requirement	M/D/NA
4.1.1	Certificate of conformity for each component	M
4.1.2	Training to service engineer is provided	M
4.1.3	Test equipment calibration certificates	M
4.1.4	Qualification folder	M
4.1.5	Checklist identifying model and serial numbers of components installed	M
4.1.6	Component specification	M
4.1.7	The supplier shall provide, as minimum, the following: • Operation and cleaning manuals (English) • Maintenance manuals (English) • Comprehensive recommended spares list for 2 years operation, including anticipated usage and details for consumable parts	M
4.1.8	The supplier must carry out SAT, IQ and OQ.	M