User Requirement Specification
For
Tablet Counting and Filling Machine

Approvals

Name	Job Title or Role	Signature	Date
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Revision History:

Document Info:			
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Revision	**Issue Description**	**By**	**Date**
00	New issue		

1 Introduction

This document specifies the User Requirements for the determination of Counting and Filling Machine in PT Mersifarma TM Sukabumi Site. The URS is based on the headings specified in 21 CFR part 11 to use Windows 7.

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 within tablet counting and filling 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 Counting and Filling Machine that used within the PT Mersifarma TM to count and fill tablet productwithin Non Sterile Production. It is decided to purchase Counting and Filling Machine, since the purpose of this machine to count and fill tablets in to bottle 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

Counting and Filling Machine that used within the PT Mersifarma TM for counting and filling tablets product in to bottle.

2.2 Machine

The scope of systems / equipment provided by Supplier included:

- Counting and Filing Capabilities
- Bottle scramble + turn table
- Filling and Counting Station
- Accuracy of Counting and Filling process

- Automatic Bottle weight control and reject
- Desiccant Inserting Station
- Bottle Capping station
- Induction Sealing station

2.3 Service

The scope of services delivered by the Supplierincluded:

- Machine design and construction,
- FAT

2.3.1 Machine Functionality Requirements

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

Req. No.	Parameters	Description	Limit	M/D/ NA
A	Bottle scramble + turn table	Machine can arrange all bottles in the magazine of Machine into right position	Speed of machine is 10-100 bottles /minute Diameter of disk options 900 mm With speed controller	M
		Dimension : L x W x H (mm)	1000 x 1100 x 1200 mm	M
B	Counting and Filling Capabilities	a. Tablet hopper and vibration system b. Machine shall be capable of counting and filling tablets in to bottle. c. Filling count quantity control d. Counting accuracy	a. Volume hopper 20 Liters, bottom vibration system b. Speed of machine is 10-100 bottles /minute with content 10-100 Pcs/bottle c. 1-9999 Pcs/ bottle d. 100 % as required setted number of tablet	M
		Machine should be capable use the bottle with certain dimension	Diameter of bottle : 25 - 75 mm. Height of bottle : 30-150 mm	M
		Dimension : L x W x H (mm)	1100 x 1300 x 1600 mm	M
C	Desiccant Inserting Station	Machine shall have a high accuracy rate to ensure that all bottles filled with predetermined numbers of tablets.	a. Speed of machine is 10-100 bottles /minute b. Machine should be capable to insert 1-10 Pcs/ bottle desiccant into each bottle. c. With speed controller	M
		Dimension: L x W x H (mm)	1100 x 1300 x 1600 mm	M
D	Bottle Capping Station	Speed of machine	10-100 bottles /minute	M
		Diameters of caps	Φ 20-65 mm	M
		Diameters of bottle	Φ25-75 mm	M
		Dimension: L x W x H (mm)	2000 x 1000 x 1800	M

E	Induction Sealing Station	Speed of machine	10-100 bottles /minute	M
		Diameters of caps	Smaller than 65 mm	M
		Height of bottle	30-220 mm	M
		Dimension: L x W x H (mm)	1100 x 780 x 1600	M

- Installation,
- Acceptance testing, commissioning, IQ/OQ execution at site
- Training for staff and operators,
- System operations support and spare parts,
- Documentation

3. General Requirements

3.1 General Functionality

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

Req. No.	Requirement	M/D/NA
3.1.1	The system allows calibration and preventive maintenance features	D
3.1.2	Easy to maintenance, and Operate	D

3.2 Operating 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.

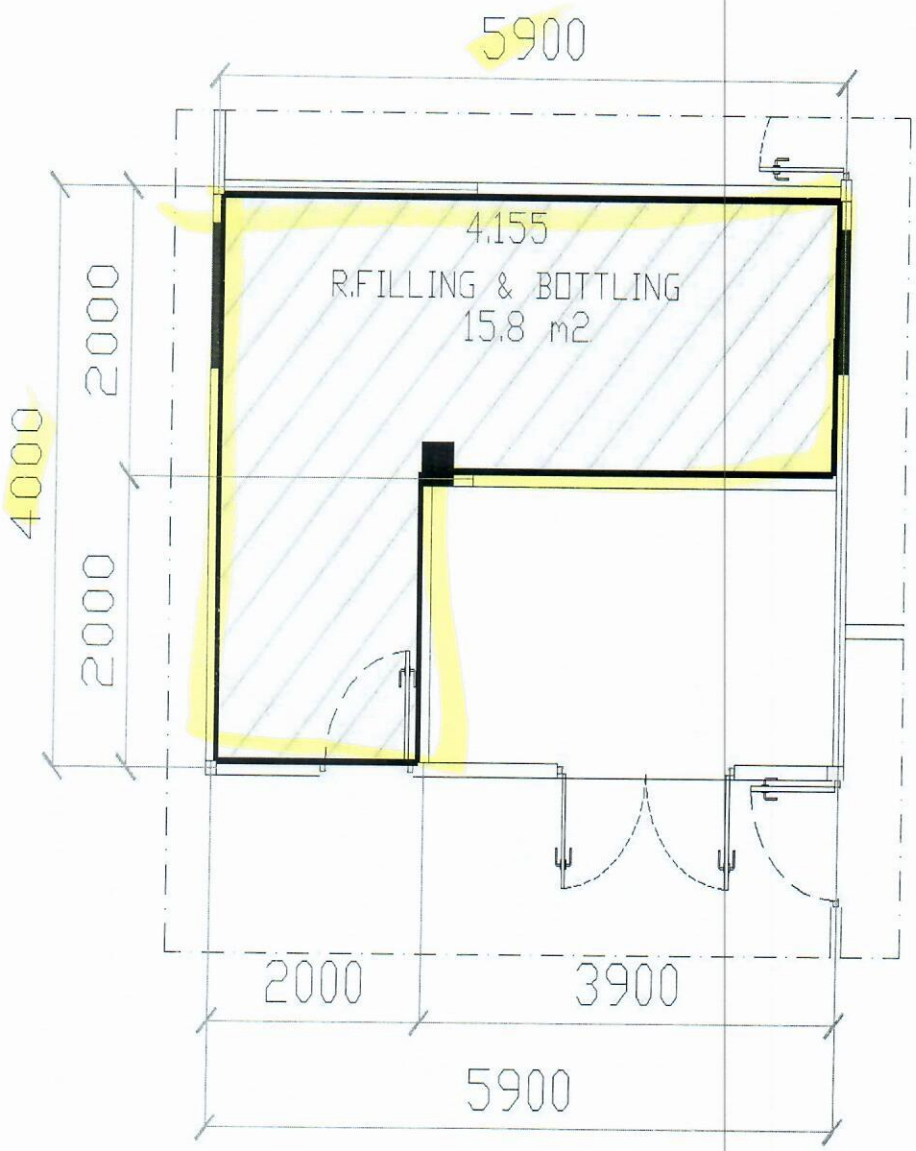
Req. No.	Requirement	Description	M/D/NA
3.2.1	To be installed on the existing production area.	Temperature between 17 to 40°C; 40 to 90% RH. Layout attached Page 7	M
3.2.2	System is compatible with typical power requirements	50 Hz, 220 /380 V AC	M
3.2.3	Machine's water and dust resistance	IP 55	M

3.3 Environmental Health and Safety

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

Req. No.	Requirement	M/D/NA
3.3.1	Emergency button	M
3.3.2	LOTO feature	M
3.3.3	System complies with current IEC regulations for electrical safety	M
3.3.4	The system must meet all current Environmental Health and Safety requirements	M
3.3.5	Interlock safety with positive mode	M
3.3.6	Zero access	M

3.4 Layout


5900
4.155
R.FILLING & BOTTLING
15.8 m2
2000
2000
4000
2000
3900
5900

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	D
3.5.2	Real-time inspection data display	D
3.5.3	Using a USB port to take report data to flash disk	D
3.5.4	Able to interface to printer to generate reports	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	The system is compatible with minimum the Windows 7 operating system	M

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	The system allows runs process parameter to be set up by the parameter setter with certain access level in a workflow pattern for specific product or types of product that creates a simple ways execution process for running to be carried out by the user. Critical parameters are protected and unalterable by the user (e.g. operators can runs process parameter only and cannot access the process parameter edit)	M
3.7.2	The system privileges for the program system are set up in order to control modifications to an electronic record. System privileges are set up for the application and the local PC. These access level privileges control the modification of electronic records and are part of the configuration of the system that is set by the system administrator	D
3.7.3	Update access to electronic records is not permitted	D
3.7.4	Process parameterswhere appropriate are all included in the reports.	D
3.7.5	Every result file is automatically saved	D
3.7.6	The software allows to create and store parameters for each product that running in. Parameters can be created with information such as a summary, time and date stamps, machine settings, and reject/release product disposition.	D
3.7.7	The software should automatically store results to default results folder at time query.	D

3.7.8	The software can record and make a count summary for each type defect parameter after running	D
3.7.9	The software are upgradable	D

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	Logical security measures for access control should be defined and maintained.	D
3.8.2	All users should be positively identified by having a unique user-ID and a personal, secret password before being able to gain access to any computer system.	D
3.8.3	The System should be able to display or report current access control profiles showing all user-IDs and their full access to resources. Procedural controls should be used to define and manage System Administrator (including Super-user) roles. Previous access control profiles should be available through the system or historical reports.	D
3.8.4	Controls to restrict access to only authorized persons should be employed after a number of consecutive unsuccessful attempts to enter a password and/or identification code. For example: a) The involved user-ID should be suspended. The Security Administrator is required to reset the password in order for the User to be able to access the System again. b) Continuous monitoring and alerting functions are employed to detect access failures. The event of access failure needs to be logged to the audit trail.	D
3.8.5	Users entering new passwords should be instructed to enter confidential passwords that have not been previously used by the user.	D
3.8.6	User passwords should be encrypted when entered and stored on the system.	D
3.8.7	A log of all unauthorized access attempts to computer systems should be maintained. The log should include: a) User-ID making access attempt b) Date and time (local) of access attempt c) Resource name (if appropriate) A display or report output should be available for viewing the log of unauthorized access attempts.	D

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	The capability to backup electronic records on a routine basis should be available wherever electronic records are stored.	D

3.9.2	Networked and stand-alone applications dealing with large volumes of electronic records should have daily backups as appropriate.	D

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	Alarm and auto stop for empty station, etc	M
3.10.2	Scalability to accommodate future production needs	D
3.10.3	SMED (Single Minute Exchange Dies)	D

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 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	Supplier must deliver as minimum: • Operating Manuals (English) • Maintenance manuals (English) • Comprehensive recommended spares list for 2 years operation, including anticipated usage and details for consumable parts • Software on CD-ROM. The software must be labelled with part number, serial number and version number	M
4.1.8	The Supplier must carry out SAT/IQ/OQ on Site.	M
4.1.9	One year warranty should be offered including six- monthly service of machine. A support contract must be offered. The minimum requirement is for a six-monthly service of the machine, and repairs following machine breakdowns. A Preventative Maintenance/ Performance Verification (PM/PV) service be offered. Machine performance check should be done during: • Machine Installation • Six-monthly service machine (during one year warranty). • Preventive Maintenance/annual service • Repairs following machine breakdown	M

4.2 Validation Documentation

This section defines any documentation that must be produced to ensure the system has been validated in accordance with site procedures.

Req. No.	Requirement	M/D/NA
4.2.1	Protocol Acceptance/Approval sign off by customer	M
4.2.2	Installation Book	M
4.2.3	IQ and OQ Documentation	M
4.2.4	Maintenance book	M
4.2.5	Electrical and Machine Drawing	M
4.2.6	Sensor list	M
4.2.7	Calibration Certificate	M
4.2.8	Machine Diagram (P&ID)	M
4.2.9	Machine Work Process	M
4.2.10	Troubleshoot Document	M
4.2.11	Critical Component List	M
4.2.12	SAT Report	M
4.2.13	FAT Report	M
4.2.14	Trial Report	M

5. Training

5.1 Training

Req. No.	Requirement	M/D/NA
5.1.1	Production, QA, and Engineering team required training of Counting-Filling-Capping-Induction Sealing Machine	M

6. References

- 21CFR Part 11 – Electronic Records and Electronic Signatures, FDA Federal Register, 20th March 1997