

PT. Mersifarma TM				
Judul Dokumen Document Title	Spesifikasi Kebutuhan Pengguna untuk Mesin Labelling Ampul User Requirement Specification for Ampoule Labelling Machine			
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User Requirement Specification For Ampoule Labelling Machine

Pengesahan Approvals

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Sejarah Revisi

Revision History



Document Info:			
Spesifikasi Kebutuhan Pengguna Mesin Labelling Ampul			
<i>User Requirement Specification for Ampoule Labelling Machine</i>			
Revision	Issue Description	By	Date
00	New issue	Muhammad Aradhana	01 OCT 2026

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1 Latar Belakang

Introduction

Dokumen mendeskripsikan Spesifikasi Kebutuhan Pengguna untuk Mesin Labelling Ampul pada PT Mersifarma TM Sukabumi. URS berdasarkan pada kebutuhan yang ada di produksi Unit 1 Steril.

This document specifies the User Requirements for the determination of Ampoule Labelling Machine in PT Mersifarma TM Sukabumi Site. The URS is based on existing needs in the production unit 1 sterile.

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1.1 Tujuan

Purpose

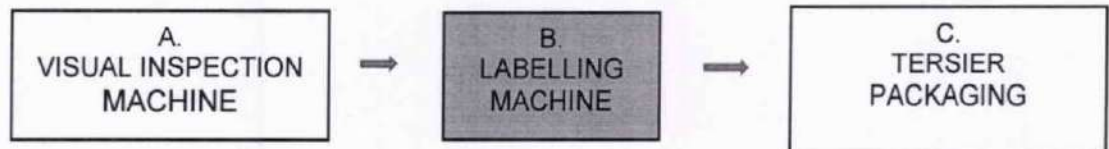
Tujuan dari dokumen ini ialah mendefinisikan persyaratan antara fungsional dan non-fungsional agar sesuai dengan sistem serta memastikan sesuai digunakan untuk labelling produk ampul. Dokumen ini merupakan dasar untuk sistem kualifikasi yang di mana akan dilakukan pengecekan desain dan beberapa pengujian.

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 labelling ampoule product. This document forms the foundation of the system qualification on which the design and testing activities are based.

1.2 Ruang Lingkup/Scope

Dokumen Spesifikasi Kebutuhan Pengguna ini berlaku untuk mesin labelling ampul yang digunakan pada PT Mersifarma untuk pengemasan produk ampul unit 1 steril.

This user requirement document applies to ampul labelling machine that used within the PT Mersifarma TM for packaging product Ampoule unit 1 sterile..



1.3 Definisi dan Singkatan

Definitions and abbreviations

List di bawah termasuk definisi dari kata-kata teknikan dan fungsional yang spesifik yang digunakan dalam dokumen ini

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

Term	Definition
Harus /Wajib/ M Must / Mandatory / M	Persyaratan adalah wajib dan harus dipenuhi yang mana non-negotiable untuk memenuhi GMP atau persyaratan kritikal perusahaan <i>The requirement is mandatory and compliance with it is non-negotiable.</i> <i>Essential to meet GMP or business critical requirements.</i>
Sebaiknya /Diinginkan / D	Persyaratan Opsional <i>Optional requirement.</i>

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<i>Should /Desirable /D</i>	Persyaratan yang tidak wajib, tapi setiap perbedaan dari yang ditentukan harus mendapat persetujuan tertulis terlebih dahulu dari Mersifarma <i>The requirement is not mandatory, but any departure from compliance with it is subject to Mersifarma's prior written approval.</i>
Tidak dapat diaplikasikan <i>/NA</i> <i>Not Applicable /NA</i>	Section ini tidak dapat diaplikasikan <i>Where a section is not applicable</i>
URS	User Requirements Specification

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2. Deskripsi Umum

General Description

2.1 Scope Pembahasan

Delivery Scope

Ruang lingkupnya meliputi penyediaan mesin labelling ampul beserta aksesoris, instalasi, dan *comissioning*.

The scope includes the supply of a Ampoule labelling machine along with necessary accessories, installation, and commissioning.

2.2 Mesin

Machine

Cakupan dari sistem/ peralatan yang disediakan oleh supplier termasuk:

The scope of systems / equipment provided by Supplier include:

- Able to use for ampoule 1 mL – 30 mL
- Labelling speed up to 20 – 200 pcs/min
- Machine Dimension : 1900 (L) × 700 (W) × 1600 (H) mm
- Height of conveyor belt above ground 780 mm
- Labeling object length 150 mm
- Conveyor belt width 25 - 95 mm
- Label Height 40 - 60 mm
- Label length 20 - 80 mm
- Labeling Accuracy ±1 mm
- Accommodate to change in between desired parts (tool-less change part)
- PLC with HMI (Human Machine Interface)
- Equipped with a sensor checker to verify label presence.
- Wrap-around labelling mechanism ensuring no bubbles, folds, or wrinkles.
- Automatic reject system for defective units (e.g., missing label, misaligned label) with verification sensor
- Equipped with machine alarm system.
- Machine construction material of Stainless Steel (SS) 304
- Equipped with tower lamp (signal light indicator)
- Inner diameter of paper roll 76 mm
- Outer Diameter of Paper Roll Less than 360 mm

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- FS/DS (Functional Specification / Design Specification) Machine document provided

Service

Cakupan dari servis yang disediakan oleh supplier termasuk:

The scope of services delivered by the Supplier include:

- Machine design and construction
- FAT
- Installation
- Acceptance testing, commissioning, IQ/OQ execution at site
- Training for staff and operators,
- System operations support and spare parts
- Protocol Documentation, FS – DS and IQ OQ (English Version)

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3. Persyaratan Umum

General Requirements

3.1 Persyaratan Fungsionalitas Mesin			
<i>Machine Functionality Requirements</i>			
Bagian ini mendefinisikan persyaratan dan kriteria penerimaan dari user dari sudut performa mesin			
<i>This section defines the user requirements and acceptance criteria from machine performance perspective</i>			
Req. No.	Parameter Parameters	Persyaratan Requirement	M/D/NA
3.1.1	Able to use for ampoule 1 mL – 30 mL	The labelling machine must be capable of processing ampoules ranging from 1 mL to 30 mL in compliance with CPOB/GMP standards.	M
3.1.2	Labelling speed up to 20 – 200 pcs/min	The machine must operate stably at a production speed of 20 - 200 ampoules/minute (per supplier's technical specification, Model LW300) without compromising product quality and label alignment.	M
3.1.3	Accommodate to change in between desired parts (tool-less change part)	The machine must be capable of accommodating change parts for different ampoule sizes smoothly, with minimal downtime and clear indexing. Change parts must be tool-less (quick-change design) to minimize changeover time.	M
3.1.4	Wrap-around labelling mechanism	The machine must apply labels using a wrap-around mechanism to ensure labels adhere perfectly without bubbles, wrinkles, or skewing.	M
3.1.5	Label Presence Sensor	The machine must be equipped with a checking/photoelectric sensor to detect and verify the physical presence of the label on the ampoule.	M
3.1.6	Have an auto reject system for non label ampoule	The machine shall be equiped with an automatic reject system to detect ampoule without label during operation. When an unlabeled ampoule is detected, the machine shall automatically sound an alarm. The reject system accuracy must achieve a maximum reject error rate of 0.01%	M

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3.1.7	Label Roll / Splicing Management	Equipped with a "Label Low" sensor and alarm indicator to notify operators before the label roll runs out, minimizing machine stoppage.	D
3.1.8	Inline coding system for label	Can connected or equipped with the label coding system for batch number, manufacturing date, expired date and maximum retail price	D

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3.2 Fungsi Umum

General Functionality

Pada bagian ini mendefinisikan persyaratan umum operasional dari user (seperti penyimpanan dan recall parameter dari mesin). Persyaratan dibawah disertai referensi apabila memungkinkan.

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.	Persyaratan Requirement	M/D/NA
3.2.1	The system allows calibration and preventive maintenance features	M
3.2.2.	Easy to maintains and operate	M

3.3 Kondisi Pengoperasian

Operating Environment

Pada bagian ini mendefinisikan persyaratan khusus untuk kondisi fisik lingkungan di mana mesin beroperasi seperti temperature, getaran, kelembapan, layout ruang dan kebutuhan utility lain seperti kompresor dan persyaratan power supply.

This section defines any special requirements for tshe 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.	Persyaratan Requirement	M/D/NA
3.3.1	To be installed on the existing production area : L 2447mm x W 1502 mm	M
3.3.2	Machine's shard and dust resistance	M
3.3.3	System is compatible with typical power requirements 220V 50/60HZ 1.5KW	M
3.3.5	To be operated at 25 - 27°C room temperature	M
3.3.6	To be operated by operator from the left side of machine	M

3.4 Kesehatan dan Keselamatan

Environmental Health and Safety

Pada bagian ini mendefinisikan persyaratan terkait keselamatan operasional dan ekspektasi dampak terhadap kesehatan.

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

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

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3.5 Interfaces

Interfaces

Pada bagian ini mendefinisikan persyaratan terkait bagaimana tampilan interface dari system seperti internet, LIMS dan CDS

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.	Persyaratan Requirement	M/D/NA
3.5.1	PLC with HMI (Human Machine Interface) for system operation and monitoring with english language.	M
3.5.2	Real-time data display	M

3.6 Kondisi Komputerisasi

Computing Environment

Pada bagian ini mendefinisikan kebutuhan persyaratan PC untuk memastikan system operasi, kapasitas, kecepatan processor, memori dan kompatibilitas dengan standart perusahaan termasuk persyaratan untuk kapabilitas untuk tersambung ke network.

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.	Persyaratan Requirement	M/D/NA
3.6.1	The system is compatible with minimum currently Windows 11 operating system	NA

3.7 Data Akuisisi, Pengolahan dan Pelaporan

Data Acquisition, Processing, and Reporting

Pada bagian ini mendefinisikan persyaratan terkait bagaimana data elektronik direkam, diproses, output, diedit, dan disetujui. Termasuk persyaratan terkait pengendalian sharing file atau database untuk penyimpanan data

This section defines any requirements related to how electronic data is to be captured, processed, output, formatted and approved. Any requirements related to use of controlled file shares or compliant databases for storing data are included.

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Req. No.	Persyaratan Requirement	M/D/N A
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.	M
3.7.2	The system must have a precise counting capability for incoming ampoules, successfully labelled ampoules, and rejected ampoules to provide accurate batch reconciliation data.	M
3.7.3	The software can record, store, and generate a summary report for the labelling batch, including yield percentage and specific reject categories.	M

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3.8 Sistem Pengamanan

Security System

Pada bagian ini mendefinisikan level pengamanan yang dibutuhkan oleh system dan dapat diaplikasikan, seperti pengaman fisik, pengaman terkait kesehatan dan keselamatan fisik, pengaman parameter mesin, access control, access level, indentitas user dan otoritas proses, sinkronisasi password, dan kegagalan logging access.

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.	Persyaratan Requirement	M/D/N A
3.8.1	Provided emergency button and stop system	M
3.8.2	Provided hazard warning labels on dangerous machine area	M
3.8.3	Provide alarm system	M

3.9 Integritas Data

Data Integrity

Pada bagian ini semua detail persyaratan bagaimana data electronic diatur, disimpan, diakses, dibackup, direcoveri, dimigrasi, diamankan, audit trail dan archive

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.	Persyaratan Requirement	M/D/N A
3.9.1	The capability to share electronic records on a routine basis should be available wherever electronic records are stored.	D

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3.10 Persyaratan Tambahan

Additional Requirement

Pada bagian ini mendefinisikan aksesoris yang dibutuhkan dan secara periodic dibutuhkan untuk kesesuaian sistem (seperti special setup atau alat kalibrasi)

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.	Persyaratan Requirement	M/D/N A
NA	NA	NA

4. Persyaratan Lain-lain

Other Requirements

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4.1 Persyaratan Supplier

Supplier Requirements

Pada bagian ini mendefinisikan persyaratan yang dibuat supplier yang dibutuhkan untuk mengenalkan system.

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

Req. No.	Persyaratan Requirement	M/D/N A
4.1.1	Certificate of conformity for each component	M
4.1.2	Training to service engineers and operators 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 & 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	D
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 Preventive 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
4.1.10	One year consumable parts provided	M

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4.2 Dokumen Validasi

Validation Documentation

Pada bagian ini mendefinisikan terkait dokumentasi yang dilakukan untuk memastikan bahwa system telah tervalidasi sesuai dengan prosedur

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

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

5. Pelatihan

Training

5.1 Pelatihan

Training

Req. No.	Persyaratan Requirement	M/D/N A
5.1.1	Production, QA, and Engineering teams require comprehensive training covering the operation, change parts setup, and basic troubleshooting of the ampoule labelling machine .	M

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Line Secondary Packaging

