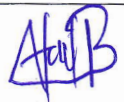
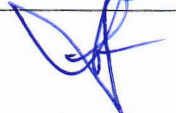
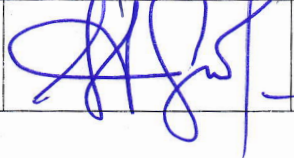


| PT. Mersifarma TM                   |                                                           |                  |             |                |
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| <b>Document Title</b>               | User Requirement Specification for Vial Labelling Machine |                  |             |                |
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## Vial Labelling Machine User Requirement Specification For Vial Labelling Machine

### Pengesahan 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 |                               |                                                                                       |          |
| Rafli Naufal Hilmi                                                                                                       | Sterile Production Supervisor |    | 09/01/26 |
| Production, Engineering and QA is signing to confirm that the content reflects their requirements                        |                               |                                                                                       |          |
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| Management is signing to confirm that the content reflects their requirements                                            |                               |                                                                                       |          |
| Fina Alfiani                                                                                                             | Deputy Director of QO         |  | 10/02/26 |
| Adhi Susanto                                                                                                             | Plant Director                |   | 10/02/26 |

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Revision History

| Document Info:                                            |                   |                    |          |
|-----------------------------------------------------------|-------------------|--------------------|----------|
| User Requirement Specification for Vial Labelling Machine |                   |                    |          |
| Revision                                                  | Issue Description | By                 | Date     |
| 00                                                        | New issue         | Rafli Naufal Hilmi | Jan 2026 |

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## 1 **Introduction**

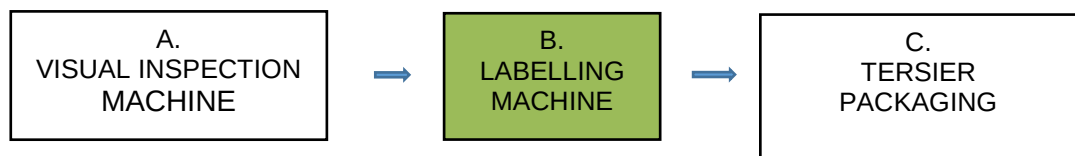
This document specifies the User Requirements for the determination of Vial Labelling Machine in PT Mersifarma TM Sukabumi Site. The URS is based on existing needs in the sterile production unit 6A.

### 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 labelling vial product. 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 vial labelling machine that used within the PT Mersifarma TM for labelling product vial unit 6A.



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

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## 2. General Description

### 2.1 Delivery Scope

Vial Labelling Machine that used

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

### 2.2 Machine

The scope of systems / equipment provided by Supplier include:

- Able to use for vial 1 mL – 30 mL
- Labelling speed up to 250 vial /minutes
- Accommodate to change in between desired parts
- Digital interface / PLC
- The machine shall be equipped with an in-line printing system

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
- Documentation

## 3. General Requirements

### 3.1 Machine Functionality Requirements

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

| Req. No. | Parameters                                       | Requirement                                                                                                                                     | M/D/NA |
|----------|--------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| 3.1.1    | Able to use for vial 1 mL – 30 mL                | The machine must be capable for processing vial 1- mL – 30 mL vial in compliance GMP                                                            | M      |
| 3.1.2    | Labelling speed up to 250 Vial / minutes         | The labelling machine have to operate at production speed up to 250 Vial / minutes without compromising product quality                         | M      |
| 3.1.3    | To be installed on the existing production area. | The labelling machine have compact design able to installation with maximum width 1 Meters, maximum length 4 Meters and maximum height 1 Meters | M      |

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### **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                                                                                                                                                                                                                                          | M      |
| 3.2.2.   | Easy to maintains, and Operate                                                                                                                                                                                                                                                                             | M      |
| 3.2.3    | The PLC of the labelling machine is designed with main screen, parameter process, recipe management, data logging, alarm diagnostic function, maintenance functions                                                                                                                                        | M      |
| 3.2.4    | The machine shall be equipped with an in-line printing system capable of printing variable information directly on the label during the labelling process. The in-line printer shall be able to print critical data such as batch number, expired date, manufacturing date, and maximum retail price (MRP) | M      |
| 3.2.5    | The machine have to design to accommodate change in between desired parts, to support different size vial as required without any setting parameters (SMED System)                                                                                                                                         | M      |
| 3.2.6    | If a label splice or joint is detected on the label roll, the labeling machine shall automatically stop to prevent the use of nonconforming labels and to ensure product quality, process reliability, and compliance with GMP requirements.                                                               | M      |

### **3.3 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 |
|----------|--------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| 3.3.1    | To be installed on the existing production area. | The machine shall be suitable for installation at temperature 10°C - 40°C with relative humidity 20 – 80%. The machine shall remain functional and physically intact under condition when the HVAC syetem either operating or shut down. | M      |

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|       |                                                                   |                                                                             |   |
|-------|-------------------------------------------------------------------|-----------------------------------------------------------------------------|---|
| 3.3.2 | System is compatible with typical power requairments in Indonesia | 220 V AC, 50 Hz, single phase / 380 V AC, three phase                       | M |
| 3.3.3 | Material of The Machine                                           | The machine is corrosion resistant and constructed from stainless steel 304 | 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    | Provide hazard warning labels on dangerous machine area                                                                                 | 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      |
| 3.4.6    | Surface machine temperature doesn't more than 60°C                                                                                      | M      |
| 3.4.7    | The machine shall be designed with zero acces to moving parts, and all machine shall be free from sharp edges                           | M      |
| 3.4.8    | The maximum noise level of the vial labelling machine doesn't more than 75 dB measured at a distance of 1 meter during normal operation | 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 | NA     |
| 3.5.2    | Real-time data display  | NA     |
| 3.5.3    | Digital Interface /PLC  | NA     |

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### **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.

| <b>Req. No.</b> | <b>Requirement</b>                                                       | <b>M/D/NA</b> |
|-----------------|--------------------------------------------------------------------------|---------------|
| 3.6.1           | The system is compatible with minimum currently Windows operating system | NA            |

### **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. Any requirements related to use of controlled file shares or compliant databases for storing data are included.

| <b>Req. No.</b> | <b>Requirement</b>                                                                                                                                                                                                                                                                                                                                                                                                         | <b>M/D/NA</b> |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| 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 have counting capability of produce labelling in order serve data for users                                                                                                                                                                                                                                                                                                                                     | M             |
| 3.7.3           | The software can record and make a count summary for labelling produced                                                                                                                                                                                                                                                                                                                                                    | M             |

### **3.8 Security System**

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

| <b>Req. No.</b> | <b>Requirement</b>                                                                                                                                            | <b>M/D/NA</b> |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| 3.8.1           | Logical security measures for access control should be defined and maintained.                                                                                | M             |
| 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. | M             |

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|       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |          |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| 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.                                                                                                                                                                                                                                                                                                                                                                                                                           | <i>M</i> |
| 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:<br>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.<br>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.                                                                                                                                                                                                                                          | <i>M</i> |
| 3.8.5 | Users entering new passwords should be instructed to enter confidential passwords that have not been previously used by the user.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <i>M</i> |
| 3.8.6 | The labeling machine shall be equipped with a user level-based access control system to ensure process security, GMP compliance, and data integrity, operators are only permitted to run the machine using parameters and settings predefined by the technician without authorization to modify any process or system configurations. Supervisors are authorized to adjust process parameters and control operational settings technician are granted technical access for maintenance, calibration, troubleshooting, and repair activities; while Quality Assurance (QA) has view-only access to production data and electronic records, including the audit trail, for the purpose of reviewing user activities and verifying compliance with data integrity requirements | <i>M</i> |

| <b>3.9 Data Integrity</b>                                                                                                                                               |                                                                                                                           |               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|---------------|
| This section details any requirements for how electronic data are to be managed, stored, accessed, backed up, recovered, migrated, secured, audit trailed and archived. |                                                                                                                           |               |
| <b>Req. No.</b>                                                                                                                                                         | <b>Requirement</b>                                                                                                        | <b>M/D/NA</b> |
| 3.9.1                                                                                                                                                                   | The capability to share electronic records on a routine basis should be available wherever electronic records are stored. | <i>D</i>      |
| 3.9.2                                                                                                                                                                   | Data can be printed directly or saved within the system and the result can be transferred using a flash disk              | <i>D</i>      |

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|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| 3.9.3 | The labelling machine system shall ensure data integrity in accordance with ALCOA+ principles by implementing secure user access with user login and role-based authorization, and by automatically recording all critical activities and parameter changes in a secure and- non editable audit trail. All process, batch, inspection, and reject data shall be recorded in real time, securely stored and available for review and regulatory inspection | <i>D</i> |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|

### **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).

| <b>Req. No.</b> | <b>Requirement</b> | <b>M/D/NA</b> |
|-----------------|--------------------|---------------|
| NA              | NA                 | NA            |

## **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.*

| <b>Req. No.</b> | <b>Requirement</b>                                                                                                                                                                                                                                                                                                                                                                       | <b>M/D/NA</b> |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| 4.1.1           | Certificate of conformity for each component                                                                                                                                                                                                                                                                                                                                             | <i>M</i>      |
| 4.1.2           | Training to service engineers and operators provided                                                                                                                                                                                                                                                                                                                                     | <i>M</i>      |
| 4.1.3           | Test equipment calibration certificates                                                                                                                                                                                                                                                                                                                                                  | <i>M</i>      |
| 4.1.4           | Qualification folder                                                                                                                                                                                                                                                                                                                                                                     | <i>M</i>      |
| 4.1.5           | Checklist identifying model and serial numbers of components installed                                                                                                                                                                                                                                                                                                                   | <i>M</i>      |
| 4.1.6           | Component specification                                                                                                                                                                                                                                                                                                                                                                  | <i>M</i>      |
| 4.1.7           | Supplier must deliver as minimum: <ul style="list-style-type: none"> <li>• Operating &amp; Maintenance Manuals (English)</li> <li>• Comprehensive recommended spares list for 2 years operation, including anticipated usage and details for consumable parts</li> <li>• Software on CD-ROM. The software must be labelled with part number, serial number and version number</li> </ul> | <i>D</i>      |
| 4.1.8           | The Supplier must carry out SAT/IQ/OQ on Site.                                                                                                                                                                                                                                                                                                                                           | <i>M</i>      |

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| 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.<br>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. | <i>D</i> |
| 4.1.10 | One year consumable parts provided                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <i>M</i> |
| 4.1.11 | The supplier shall provide a complete list of consumable parts with part number and recommended replacement intervals for routine operation and maintenance                                                                                                                                                                                                                                                                                                                                                                      | <i>M</i> |

#### **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.

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

### **5. Training**

#### **5.1 Training**

| <b>Req. No.</b> | <b>Requirement</b>                                                               | <b>M/D/NA</b> |
|-----------------|----------------------------------------------------------------------------------|---------------|
| 5.1.1           | Production, QA, and Engineering team required training of vial labelling machine | <i>M</i>      |

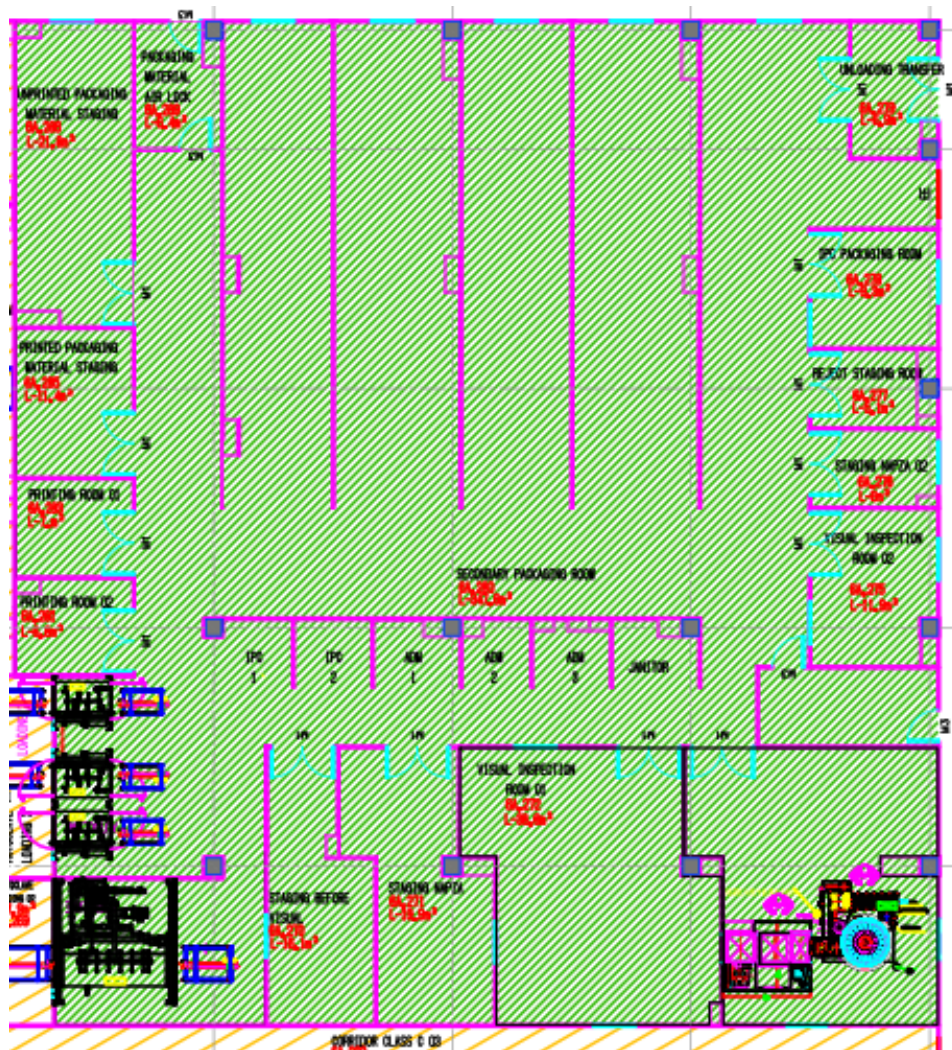
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## 6. Reference

- *21CFR Part 11 – Electronic Records and Electronic Signatures, FDA Federal Register, 20<sup>th</sup> March 1997*

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