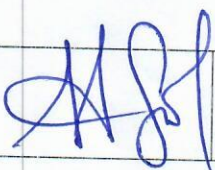


PT. Mersifarma TM				
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User Requirement Specification For Automatic Folding Machine

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			
Angga Nugraha	Production Supervisor Unit 4		05/08 ²⁰
Budianto Chandra	Production Manager Unit 4		07/08 ²⁰
Hermawan	Engineering Manager		14/08 ²⁰
Sumardi	QA Manager		18/08 ²⁰
The Project Group is signing to confirm that the content reflects their requirements			
Adhi Susanto	Plant Director		28/08 ²⁰

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1 Introduction

This document specifies the User Requirements for the determination of Automatic Folding Machine in 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 within automatic folding machine 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 Automatic Folding Machine that used within the PT Mersifarma TM. The machine shall be used for automatic folding of pharmaceutical leaflets (folding insert for secondary packaging operations), continuous operation in pharmaceutical packaging areas, compliance with GMP/CPOB requirements, integration with existing packaging processes when applicable.

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

Automatic Folding Machine that used within the PT Mersifarma TM automatic folding of pharmaceutical leaflets.

2.2 Machine

The scope of systems / equipment provided by Supplier included:

- M

2.3 Service

The scope of services delivered by the Supplier included:

- Machine design and construction,
- FAT

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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, and required utilities such as compressed air and power supply requirements.

Req. No.	Parameter	Requirement	M/D/NA
3.2.1	To be installed on the existing production area.	Temperature between 20-28°C;	M
3.2.2	Voltage	AC220V/1P/50Hz / AC380/3P/50Hz	M
3.2.3	Power	50W	D
3.2.4	Machine's water and dust resistance	IP 55	D
3.2.5	Compressed Air	6-8 Bar	D
3.2.6	Noise Level	≤ 75 dB	D

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 stop buttons shall be installed	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 Capacity

This section defines any requirements for capacity of the machine.

Req. No.	Requirement	M/D/NA
3.4.1	Folding speed minimum 20.000 leaflets/hour	D
3.4.2	Speed shall be adjustable	M
3.4.3	Machine shall maintain folding accuracy at maximum speed	D
3.4.4	Machine shall have production counter	M

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3.5 Product Requirements

This section defines any requirements for leaflet size and various fold type

Req. No.	Parameter	Requirement	M/D/NA
3.5.1	Minimum Sheet Size	50 x 80 mm	M
3.5.2	Maximum Sheet Size	300 x 600 mm	M
3.5.3	Paper Weight / Thickness	30 – 125 gsm	D
3.5.4	Fold Accuracy	± 1 mm	D
3.5.4	Fold Type	Can fold with various types of folds (Parallel, Letter, Z-Fold, Double Parallel, Gate Fold)	M
		Can fold single fold – four fold (or more)	M

3.6 Mechanical Requirements

This section defines any mechanical requirements

Req. No.	Requirement	M/D/NA
3.6.1	Product contact parts shall be SS304 minimum	D
3.6.2	Machine frame shall be corrosion resistant	D
3.6.3	Surfaces shall be smooth and cleanable	D
3.6.4	No sharp edges permitted	D
3.6.5	Machine shall be equipped with adjustable folding plates	M
3.6.6	Machine shall have jam detection	M
3.6.7	Machine shall have automatic stop during jam	M
3.6.8	Machine shall minimize paper dust generation	M

3.7 Control System Requirements

This section defines any requirements for how the system and machine can operate

Req. No.	Requirement	M/D/NA
3.7.1	PLC-based control system	D
3.7.2	Colour HMI touchscreen minimum 10 inch	D
3.7.3	Password-protected access levels (operator, supervisor and administrator access levels)	D
3.7.4	Alarm history shall be available	M
3.7.5	Production data shall be displayed	M
3.7.6	Machine status shall be visible on HMI	M
3.7.7	Recipe management shall be available	D