

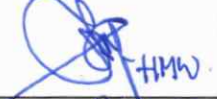
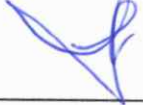
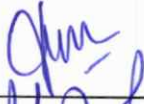
PT. Mersifarma TM				
Document Title	<i>User Requirement Specification for Leak Check Machine for Large Volume Parenteral (LVP) Softbag</i>			
Filename/Document Identifier	Ver.	Ver. Date	Type	Page No
2PR00/URS/078.00	00	30 APR 2026	URS	1 of 8

UNCONTROLLED COPY

Leak Check Machine
User Requirement Specification For Leak Check Machine for Large Volume Parenteral (LVP) Softbag

PT. MERSIFARMA

Approvals

Name	Job Title or Role	Signature	Date (dd-mm-yyyy)
The Lead Author is signing to confirm that this document has been prepared in accordance with PT Mersifarma TM standards			
Syahril Purnama Sidik	Sterile Production Supervisor		15/26/09
Production, Engineering, QC and QA is signing to confirm that the content reflects their requirements			
Yohanes Reyaan	Sterile Production Manager		15/04
Firman Ardi B.	Utility Assistant Manager		17/26/09
Hendrawan	Engineering Assistant Manager		17/26/09
Hermawan W.	Engineering Manager		17/04 26.
Robertus Iuki P.	QC Manager		20/26/09
Sumardi	QA Manager		20/26/09
Management is signing to confirm that the content reflects their requirements			
Fina Alfiani	Deputy Director of QO		22/04/26
Adhi Susanto	Plant Director		30/04/26

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PR00/URS/078.00	00	30 APR 2026	URS	2 of 8

TABLE OF CONTENTS

UNCONTROLLED COPY

1	Introduction	1
2	General Description	5
2.1	<i>Delivery Scope.....</i>	5
2.2	<i>Machine</i>	5
2.3	<i>Service.....</i>	5
3	General Requirements	6
3.1	<i>Machine Functionality Requirement.....</i>	6
3.2	<i>General Functionality</i>	6
3.3	<i>Operating Environment.....</i>	6
3.4	<i>Environmental Health and Safety.....</i>	6
3.5	<i>Interfaces</i>	6
3.6	<i>Computing Environment</i>	7
3.7	<i>Data Acquisition, Processing, and Reporting.....</i>	7
3.8	<i>System Security.....</i>	7
3.9	<i>Data Integrity.....</i>	8
3.10	<i>Additional Requirement.....</i>	8
4	Other Requirements	8
5	Training	9
6	Referensi	9

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PR00/URS/078.00	00	30 APR 2026	URS	3 of 8

Revision History

Document Info:			
User Requirement Specification For Leak Check Machine for Large Volume Parenteral (LVP) Softbag			
Revision	Issue Description	By	Date
00	New issue	Syahril Purnama Sidik	30 APR 2026

UNCONTROLLED COPY

PT. MERSIFARMA

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PR00/URS/078.00	00	30 APR 2026	URS	4 of 8

1 Introduction

1.1 **Purpose**

This URS defines the minimum technical, quality, safety, performance, and regulatory requirements for procurement, installation, qualification, and operation of one (1) Pressure Leak Check Machine for Large Volume Parenteral (LVP) Softbag products in sterile manufacturing area.

The system shall ensure reliable detection of leakage defects on IV softbags prior to secondary packaging.

UNCONTROLLED COPY

PT. MERSIFARMA

1.2 **Scope**

This URS covers design, fabrication, testing, delivery, installation, qualification support, and training for Pressure Leak Check Machine to be installed in sterile production area for LVP Softbag (Unit 8B – PT Mersifarma TM).

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

2. General Description

2.1 **Scope of Supply (Delivery Scope)**

Supplier shall provide a complete Pressure Leak Check Machine for LVP Softbag including but not limited to:

- Compression conveyor system (top & bottom)
- Pressure application system
- Digital pressure control
- Adjustable guide rail
- Control panel with digital display
- Emergency stop system
- Stainless steel structure
- Operation & Maintenance Manual
- Electrical drawing & mechanical drawing
- FAT & SAT support
- IQ & OQ documentation support

The machine shall be delivered fully assembled and ready for qualification.

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PR00/URS/078.00	00	30 APR 2026	URS	5 of 8

2.2 Machine

The Leak Check Machine unit shall meet the following minimum requirements:

- Type : Pressure Leak Check Machine (for IV Softbag)
- Application : Leak detection for LVP Softbag (100–1000 mL)
- Testing Method : Pressure compression method
- Installation Area : Secondary packaging / controlled area

2.3 Service

The the supplier shall provide following services:

- FAT at vendor site
- SAT at PT Mersifarma TM
- Installation supervision
- IQ/OQ protocol support
- Operator & maintenance training
- Minimum 12 months warranty

UNCONTROLLED COPY

PT. MERSIFARMA

3. General Requirements

3.1 Performance Parameter

No.	Parameters	Description	Requirement	M/D/N A
3.1.1	Application	Suitable for IV Softbag and bottle	100–1000 mL LVP bag	M
3.1.2	Testing Method	Leak detection principle	Pressure compression	M
3.1.3	Test Pressure	Adjustable pressure range	0.2 – 0.6 bar	M
3.1.4	Throughput	Production capacity	≥ 50 bags/min	M
3.1.5	Adjustable Setting	Pressure & speed adjustable	Digital setting	M
3.1.6	Reject System	Leak rejection	Easy to detect	D
3.1.6	Detection Sensitivity	Leak detection capability	Detect micro leakage in softbag	M

3.2 Material of Construction

No.	Parameters	Description	Requirement	M/D/N A
3.2.1	Frame Material	External structure	Stainless steel SS304	M
3.2.2	Finish	Surface finish	Stainless steel SS304	M
3.2.3	Contact Area	Conveyor compression surface	Non-damaging material	M
3.2.4	Cleanability	Design	Hygienic design	M

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PR00/URS/078.00	00	30 APR 2026	URS	6 of 8

3.3 Control System

UNCONTROLLED COPY

No.	Parameters	Description	Requirement	M/D/N A
3.3.1	Display HMI	Background classification	Touch screen	M
3.3.2	Speed Control	Conveyor speed control	Adjustable	M
3.3.3	Emergency Stop	Safety feature	Provided	M
3.3.4	Alarm	Over & under pressure alarm	Visual/audible	M
3.3.5	Data Logging	Batch recording	Stored	M
3.3.5	21 CFR Part 11	Compliance	If digital record used	M

3.4 Operating Environment

No.	Parameters	Description	Requirement	M/D/N A
3.4.1	Installation Area	Operation interface	Installed in secondary packaging area	M
3.4.2	Environmental Protection	Machine robustness	Suitable for clean production environment	M

3.5 Safety Guard & Ergonomics

No.	Parameters	Description	Requirement	M/D/N A
3.5.1	Electrical Safety	Protection against electrical hazards	Grounding and overload protection	M
3.5.2	Mechanical Guard	Protection of moving parts	Guarding system installed	M
3.5.3	Emergency Stop	Emergency shutdown system	Easily accessible E-stop	M
3.5.4	Stability	Equipment stability during operation	Anti-vibration & stable base	M
3.5.5	Ergonomic Design	Operator interaction & working height	Comfortable loading/unloading position	M

3.6 Utilities Requirement

No.	Parameters	Description	Requirement	M/D/N A
3.6.1	Electricity	Electrical power supply for machine operation	220V $\pm$ 10%, 50 Hz, Single Phase	M
3.6.2	Power Consumption	Total electrical load	Vendor to specify	D
3.6.3	Utility Connection	Utility interface point	Clearly defined in layout	M

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PR00/URS/078.00	00	30 APR 2026	URS	7 of 8

4. Other Requirements

UNCONTROLLED COPY

4.1 Supplier Requirements

PT. MERSIFARMA

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

No.	Requirement	M/D/NA
4.1.1	Supplier shall design and manufacture the equipment in accordance with GMP principles	M
4.1.2	Supplier shall have proven experience in pharmaceutical packaging equipment	M
4.1.3	Supplier shall provide at least one pharmaceutical reference for similar machine	M
4.1.4	Factory Acceptance Test (FAT) shall be performed and documented	M
4.1.5	FAT protocol and FAT report shall be provided	M
4.1.6	Operation & Maintenance Manual shall be provided in English	M
4.1.7	Electrical drawing and mechanical drawing shall be provided	M
4.1.8	Recommended spare parts list with part number and lead time shall be provided	M
4.1.9	Preventive maintenance schedule shall be provided	M
4.1.10	Calibration certificate for pressure gauge / pressure sensor shall be provided	M
4.1.11	Material certificate for stainless steel parts (minimum SS304) shall be provided	M
4.1.12	Risk assessment document (FMEA or equivalent) shall be provided	M
4.1.13	Supplier shall notify and obtain approval for any design or component changes	M
4.1.14	Minimum warranty period shall be 12 months after SAT or 18 months after shipment (whichever comes first)	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	Design Qualification (DQ) support	M
4.2.2	Installation Qualification (IQ) protocol and report	M
4.2.3	Operational Qualification (OQ) protocol and report	M
4.2.4	FAT report shall be attached to qualification package	M
4.2.5	Calibration certificate for pressure measurement instruments	M
4.2.6	Electrical safety test report	M
4.2.7	Functional testing during OQ shall include pressure setting verification	M
4.2.8	All qualification documents shall be provided in editable format (softcopy)	M

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PR00/URS/078.00	00	30 APR 2026	URS	8 of 8

5. Training

UNCONTROLLED COPY

PT. MERSIFARMA

5.1 Training		
Req. No.	Requirement	M/D/NA
5.1.1	Operator training before routine use	M
5.1.2	Maintenance training for engineering personnel	M
5.1.3	Start-up and shutdown procedures training	M
5.1.4	Pressure setting adjustment training	M
5.1.5	Alarm handling and troubleshooting training	M
5.1.6	Safety and emergency procedures training	M
5.1.7	Training materials provided in English	M
5.1.8	Training records and certificates provided	M

6. References

- 21CFR Part 11 – Electronic Records and Electronic Signatures, FDA Federal Register, 20th March 1997
- CPOB Aneks 1 2025