

PT. Mersifarma TM				
Judul Dokumen <i>Document Title</i>		Spesifikasi Kebutuhan Pengguna untuk Pompa Transfer <i>User Requirement Specification for Transfer Pump</i>		
Nama File /Identitas Document <i>File Name /Document Identifier</i>		Rev. <i>Ver.</i>	Tanggal Rev. <i>Ver. Date</i>	Tipe <i>Type</i>
2PR00/URS/0080.00		01	07 MAY 2026	URS
				Halaman <i>Page No</i>
				1 of 11

**Spesifikasi Kebutuhan Pengguna
Untuk Pompa Transfer**
*User Requirement Specification
For Transfer Pump*

Pengesahan
Approvals



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Penyusun menandatangani untuk memastikan bahwa dokumen ini telah disiapkan sesuai dengan standard kebutuhan PT. Mersifarma TM <i>The Lead Author is signing to confirm that this document has been prepared in accordance with PT Mersifarma TM standards</i>			
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Nama File /Identitas Document <i>File Name /Document Identifier</i>	Rev. <i>Ver.</i>	Tanggal Rev. <i>Ver. Date</i>	Tipe <i>Type</i>	Halaman <i>Page No</i>
2PR00/URS/0080.00	01	07 MAY 2026	URS	2 of 13

DAFTAR PUSTAKA TABLE OF CONTENTS



1	Latar Belakang	
	<i>Introduction</i>	
2	Deskripsi Umum	
	<i>General Description</i>	
2.1	Lingkup Pembahasan	
	<i>Delivery Scope</i>	
2.2	Mesin	
	<i>Machine</i>	
2.3	Servis	
	<i>Service</i>	
3	Persyaratan Umum	
	<i>General Requirements</i>	
3.1	Persyaratan Fungsional Mesin	
	<i>Machine Functionality Requirement</i>	
3.2	Fungsional Umum	
	<i>General Functionality</i>	
3.3	Kondisi Pengoperasian	
	<i>Operating Environment</i>	
3.4	Keselamatan dan Keamanan	
	<i>Environmental Health and Safety</i>	
3.5	Interface	
	<i>Interfaces</i>	
3.6	Kondisi Komputerisasi	
	<i>Computing Environment</i>	
3.7	Akuisisi Data, Pengolahan, dan Pelaporan	
	<i>Data Acquisition, Processing, and Reporting</i>	
3.8	Sistem Pengamanan	
	<i>System Security</i>	
3.9	Integritas Data	
	<i>Data Integrity</i>	
3.10	Additional Requirement	
	<i>Additional Requirement</i>	

Nama File /Identitas Document File Name /Document Identifier	Rev. Ver.	Tanggal Rev. Ver. Date	Tipe Type	Halaman Page No
2PR00/URS/0080.00	01	07 MAY 2026	URS	3 of 13

DAFTAR PUSTAKA
TABLE OF CONTENTS



4	Persyaratan Lainnya
4	<i>Other Requirements</i>
5	Pelatihan
5	<i>Training</i>
6	Referensi
6	<i>References</i>

Nama File /Identitas Document <i>File Name /Document Identifier</i>	Rev. <i>Ver.</i>	Tanggal Rev. <i>Ver. Date</i>	Tipe <i>Type</i>	Halaman <i>Page No</i>
2PR00/URS/0080.00	01	07 MAY 2026	URS	4 of 13

Sejarah Revisi

Revision History

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Spesifikasi Kebutuhan Pengguna Pompa Transfer <i>User Requirement Specification for Transfer Pump</i>				
Revisi <i>Revision</i>	Deskripsi Isu <i>Issue Description</i>	Oleh <i>By</i>	Tanggal <i>Date</i>	
01	URS Baru	Ilga Priskilla Romauli P.		

Nama File /Identitas Document <i>File Name /Document Identifier</i>	Rev. <i>Ver.</i>	Tanggal Rev. <i>Ver. Date</i>	Tipe <i>Type</i>	Halaman <i>Page No</i>
2PR00/URS/0080.00	01	07 MAY 2026	URS	5 of 13

1 **Latar Belakang**

Introduction

Dokumen mendeskripsikan Spesifikasi Kebutuhan Pengguna untuk Pompa Transfer pada PT Mersifarma TM Sukabumi. URS berdasarkan pada kebutuhan peralatan untuk proses produksi.

This document specifies the User Requirements Specification for Transfer Pump in PT Mersifarma TM Sukabumi Site. The URS is based on equipment requirements for the production process.

Pengesahan pada dokumen ini oleh :

The approval of this document by:

- *Faizal Ardhi sebagai Manager Unit 1 & 3*
Faizal Ardhi as Production Manager of Unit 1 & 3
- *Hermawan Widya sebagai Manager Engineering*
Hermawan Widya as Engineering Manager
- *Sumardi sebagai Manager QA*
Sumardi as QA Manager
- *Fina Alfiani sebagai Head of Quality Operation*
Fina Alfiani as Head of Quality Operation
- *Adhi Susanto sebagai Plant Director*
Adhi Susanto as Plant Director

1.1 **Tujuan**

Purpose

Tujuan dari dokumen ini ialah mendefinisikan persyaratan antara fungsional dan non-fungsional agar sesuai dengan system serta memastikan sesuai digunakan untuk proses transfer cairan dari mesin *mixing tank* ke *holding tank* atau *mixing/holding tank* ke wadah penampung mesin *filling*. Dokumen ini merupakan dasar untuk sistem kualifikasi yang dimana 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 in the process of transferring liquid from the mixing tank to holding tank or mixing/holding tank to filling machine container. This document forms the foundation of the system qualification on which the design and testing activities are based.

1.2 **Lingkup**

Scope

Dokumen Spesifikasi Kebutuhan Pengguna ini berlaku untuk Pompa Transfer yang digunakan pada PT Mersifarma untuk transfer cairan.

This user requirement document applies for Transfer Pump that used within the PT Mersifarma TM for transferring liquid.

1.3 **Definisi dan Singkatan**

Definitions and abbreviations

List dibawah termasuk definisi dari kata kata teknis dan fungsional yang spesifik yang digunakan dalam dokumen ini

Nama File /Identitas Document File Name /Document Identifier	Rev. Ver.	Tanggal Rev. Ver. Date	Tipe Type	Halaman Page No
2PR00/URS/0080.00	01	07 MAY 2026	URS	6 of 13

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

<i>Term</i>	<i>Definition</i>
Harus /Wajib/ M <i>Must / Mandatory/M</i>	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>

<i>Term</i>	<i>Definition</i>
Sebaiknya /Diinginkan / D <i>Should /Desirable /D</i>	Persyaratan Opsional <i>Optional requirement.</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 / NA <i>Not Applicable /NA</i>	Section ini tidak dapat diaplikasikan <i>Where a section is not applicable</i>
URS	<i>User Requirements Specification</i>

2. Deskripsi Umum

General Description

2.1 Scope Pembahasan

Delivery Scope

Pompa Transfer yang digunakan pada PT Mersifarma TM cairan dari mesin *mixing tank* ke *holding tank* atau *mixing/holding tank* ke wadah penampung mesin *filling*.

Transfer Pump that used within the PT Mersifarma TM for transferring liquid from the mixing tank to holding tank or mixing/holding tank to filling machine container.

2.2 Mesin

Machine

Cakupan dari sistem/ peralatan yang disediakan oleh supplier termasuk :

The scope of systems / equipment provided by Supplier include :

- *Machine*
- *Material Certificate*
- *IQ, OQ, and PQ Certificate*

2.3 Servis

Service

Cakupan dari servis yang disediakan oleh supplier termasuk :

Nama File /Identitas Document File Name /Document Identifier	Rev. Ver.	Tanggal Rev. Ver. Date	Tipe Type	Halaman Page No
2PR00/URS/0080.00	01	07 MAY 2028	URS	7 of 13

The scope of services delivered by the Supplier include :

- Guarantee for mechanical and electrical system

3. Persyaratan Umum

General Requirements

3.1 Persyaratan Fungsionalitas Mesin

Machine Functionality Requirements

Bagian ini mendefinisikan persyaratan dan kriteria penerimaan dari user dari sudut performa mesin

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

Req. No.	Parameter Parameters	Deskripsi Description	Persyaratan Requirement	M/D/NA
3.1.1	Design and Material	Type of the machine	Lobe Pump or Gear Pump	M
		Material of the machine	Contact Product : SS316L Non Contact Product : SS304 Roughness Average : $\leq 0.5 \mu\text{m}$	M
3.1.2	Gasket and Seal Material	Product contact sealing material	Product contact gasket/O-ring/seal material shall be FDA compliant and suitable for pharmaceutical application such as EPDM, PTFE, or silicone. Supplier shall provide material certificate/FDA compliance certificate	M
3.1.3	Capacity	Transfer Capacity	2000 L/hour	M
3.1.4	Flow Rate Control	Transfer flow adjustment	System shall provide adjustable flow rate control in L/hour or L/min during operation	M
3.1.5	Motor Control	Pump speed adjustment	Pump motor shall be equipped with VSD/Inverter for adjustable speed and flow control during operation	M

Nama File /Identitas Document File Name /Document Identifier	Rev. Ver.	Tanggal Rev. Ver. Date	Type Type	Halaman Page No
2PR00/URS/0080.00	01	07 MAY 2026	URS	8 of 13

3.1.6	Input & Output	Input and output transfer	One inlet and one outlet port (OD : 35 mm, ID : 25 mm) 1,5 inch ASME BPE ferrule connection with hygienic tri- clamp fitting	M
3.1.7	Filter System	Remove particles or contaminants to ensure cleanliness, safety, and product quality	System shall be equipped with hygienic filter housing and filter element. Filter size and micron rating shall be defined by supplier based on product characteristics and required flow rate to ensure acceptable pressure drop and pump performance (suggested filter rating : 100-500 micron)	M
3.1.8	Shaft Seal Design	Pump Sealing System	Pump shall use hygienic shaft sealing design such as double mechanical seal or seal-less design to prevent leakage and contamination	M
3.1.9	Piping Design	Hygienic piping standard	Product contact piping system shall comply with ASME BPE hygienic design requirements	D
3.1.10	Pump Head / Pressure Monitoring	Monitoring of pump differential pressure to ensure transfer performance from mixing tank to holding tank or holding tank to filling machine	• System shall be equipped with: - Pressure transmitter at suction and discharge line or - Differential pressure transmitter • Operating pressure: 1-4 bar • The system design shall consider fluid characteristics including density (1000-1200 kg/m³) and viscosity (250-550 cps), ensuring adequate pump capacity and pressure to maintain continuous flow	D

Nama File /Identitas Document File Name /Document Identifier	Rev. Ver.	Tanggal Rev. Ver. Date	Tipe Type	Halaman Page No
2PR00/URS/0080.00	01	07 MAY 2026	URS	9 of 13

		Operation Limitation	System shall be designed for maximum operating temperature of 80 °C and maximum allowable pressure of 6 bar	M
3.1.11	Shear Rate	Product handling during transfer	Pump design shall be low shear type to prevent product degradation, foaming, phase separation, or viscosity change during transfer process.	M
3.1.12	Transfer Distance	Transfer distance calculated based on the the distance between mixing to holding tank or holding tank to filling machine	Distance between - Mixing tank to holding tank : 10 m - Holding tank to filling : 9 m	M

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.	Easy to operate	M
3.2.2.	Qualification can be carried out	M
3.2.3.	Easy to overhaul and cleaning (includes filters)	M
3.2.4.	Easy to maintenance	M

Nama File /Identitas Document File Name /Document Identifier	Rev. Ver.	Tanggal Rev. Ver. Date	Tipe Type	Halaman Page No
2PR00/URS/0080.00	01	01 7 MAY 2026	URS	10 of 13

3.3 Kondisi Pengoperasian

Operating Environment

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

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.	Persyaratan Requirement	Deskripsi Description	M/D/NA
3.3.1	Machine can be operated in existing room conditions	Room temperature : 20-27°C RH (Humidity) : Max. 70%	M
3.3.2	Automatically system	Machine can be operated with sensor to transferring liquid automatically	NA
3.3.3	Transferring System	The transfer system must be closed to prevent contamination	M
3.3.4	Electricity	220-380 V AC, 3 phase	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.

Req. No.	Persyaratan Requirement	M/D/NA
3.4.1	The system complies with current IEC (International Electrotechnical Commission) regulations for electrical safety	M
3.4.2	Grounding system to prevent static electricity	M
3.4.3	Emergency stop	M
3.4.4	The system must have protection against overload	M

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
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Nama File /Identitas Document File Name /Document Identifier	Rev. Ver.	Tanggal Rev. Ver. Date	Tipe Type	Halaman Page No
2PR00/URS/0080.00	01	07 MAY 2025	URS	11 of 13

3.5.1.	NA	NA
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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.	NA	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.

Req. No.	Persyaratan Requirement	M/D/NA
3.7.1.	NA	NA

3.8 Sistem Pengamanan

System Security

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/NA
3.8.1.	LOTO (Logout and Tagout System)	D

Nama File /Identitas Document File Name /Document Identifier	Rev. Ver.	Tanggal Rev. Ver. Date	Tipe Type	Halaman Page No.
2PR00/URS/0080.00	01	07 MAY 2020	URS	12 of 13

3.9 Integritas Data

Data Integrity

Pada bagian ini semua detail persyaratan bagaimana data *electronic* diatur, disimpan, diakses, dicadangkan, dpulihkan, 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/NA
3.9.1.	NA	NA

3.10 Persyaratan Tambahan

Additional Requirement

Pada bagian ini mendefinisikan aksesoris yang dibutuhkan dan secara periodik 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/NA
3.10.1	NA	NA

4. Persyaratan Lain-lain

Other Requirements

4.1 Persyaratan Supplier

Supplier Requirements

Pada bagian ini mendefinisikan persyaratan yang dibuat supplier yang dibutuhkan untuk mengenalkan sistem

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/NA
4.1.1.	Certificate of machine material	M
4.1.2.	Wiring diagram	D
4.1.3.	Mechanical drawing	M
4.1.4.	Spare part list	M
4.1.5.	FAT & SAT protocol and report	D

Nama File /Identitas Document File Name /Document Identifier	Rev. Ver.	Tanggal Rev. Ver. Date	Tipe Type	Halaman Page No
2PR00/URS/0080.00	01	07 MAY 2026	URS	13 of 13

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/NA
4.2.1	Drawing of the machine	M
4.2.2	Manual book	M
4.2.3.	IQ, OQ and PQ Certificate	M

5. Pelatihan

Training

5.1 Pelatihan

Training

Req. No.	Persyaratan Requirement	M/D/NA
5.1.1	Training is given at least once before implementation	M

6. Referensi

References

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