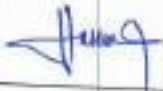


PT. Mersifarma TM				
Document Title	User Requirement Specification for Mixing Tank Double Jacket 1000L			
Filename/Document Identifier	Ver.	Ver. Date	Type	Page No
2PROG/URS/062.00	00		URS	1 of 13

Mixing Tank Double Jacket 1000 L
User Requirement Specification For Mixing Tank Double Jacket 1000 L

**Pengesahan
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 Staff		22/25/10
Production, Engineering and QA is signing to confirm that the content reflects their requirements			
Indra Sinuhaji	Sterile Production Manager		22/25/10
Yohanes Reyaan	Sterile Production Manager		22/25/10
Firman Ardi B.	Ass. Manager Utility		27/25/10
Hendrawan	Ass. Engineering Manager		27/25/10
Hermawan W.	Engineering Manager		27/25/10
Dicky. M. Tasdik	Project Engineering Manager		27/25/10
Sumardi	QA Manager		29/25/10
Management is signing to confirm that the content reflects their requirements			
Fina Alfiani	Deputy Director of QO		03/25/11
Adhi Susanto	Plant Director		05/25/11

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PR00/URS/052.00	00		URS	2 of 13

TABLE OF CONTENTS

1	Latar Belakang.....	5
	<i>Introduction.....</i>	<i>5</i>
2	Deskripsi Umum.....	6
	<i>General Description.....</i>	<i>6</i>
2.1	Lingkup Pembahasan.....	6
	<i>Delivery Scope.....</i>	<i>6</i>
2.2	Mesin.....	6
	<i>Machine.....</i>	<i>6</i>
2.3	Servis.....	7
	<i>Service.....</i>	<i>7</i>
3	Persyaratan Umum.....	7
	<i>General Requirements.....</i>	<i>7</i>
3.1	Persyaratan Fungsional Mesin.....	7
	<i>Machine Functionality Requirement.....</i>	<i>7</i>
3.2	Fungsional Umum.....	9
	<i>General Functionality.....</i>	<i>9</i>
3.3	Kondisi Pengoperasian.....	9
	<i>Operating Environment.....</i>	<i>9</i>
3.4	Keselamatan dan Keamanan.....	9
	<i>Environmental Health and Safety.....</i>	<i>9</i>
3.5	Interface.....	10
	<i>Interfaces.....</i>	<i>10</i>
3.6	Kondisi Komputerisasi.....	10
	<i>Computing Environment.....</i>	<i>10</i>
3.7	Akuisisi Data, Pengolahan, dan Pelaporan.....	10
	<i>Data Acquisition, Processing, and Reporting.....</i>	<i>10</i>
3.8	Sistem Pengamanan.....	11
	<i>System Security.....</i>	<i>11</i>
3.9	Integritas Data.....	11
	<i>Data Integrity.....</i>	<i>11</i>
3.10	Additional Requirement.....	11
	<i>Additional Requirement.....</i>	<i>11</i>

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PRDO/URS/062.00	00		URS	3 of 13

DAFTAR PUSTAKA
TABLE OF CONTENTS

4	Persyaratan Lainnya	12
4	<i>Other Requirements</i>	12
5	Pelatihan	13
5	<i>Training</i>	13
6	Referensi	13

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PR00/URS/062.00	00		URS	4 of 13

Sejarah Revisi

Revision History

Document Info:			
Spesifikasi Kebutuhan Pengguna Mixing Tank Double Jacket 1000 L			
<i>User Requirement Specification for Mixing Tank Double Jacket 1000 L</i>			
Revision	Issue Description	By	Date
00	New issue	Syahrii Purnama Sidik	25 Ags 2025

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PROG/URS/062.00	00		URS	5 of 13

1 Latar Belakang

Introduction

Dokumen mendeskripsikan Spesifikasi Kebutuhan Pengguna untuk Mixing Tank Double Jacket 1000 L pada PT Mersifarma TM Sukabumi. URS berdasarkan pada kebutuhan yang ada di produksi steril unit 6A.

This document specifies the User Requirements for the determination of Mixing Tank Double Jacket 1000 L in PT Mersifarma TM Sukabumi Site. The URS is based on existing needs in the sterile production unit 6A.

1.1 Tujuan

Purpose

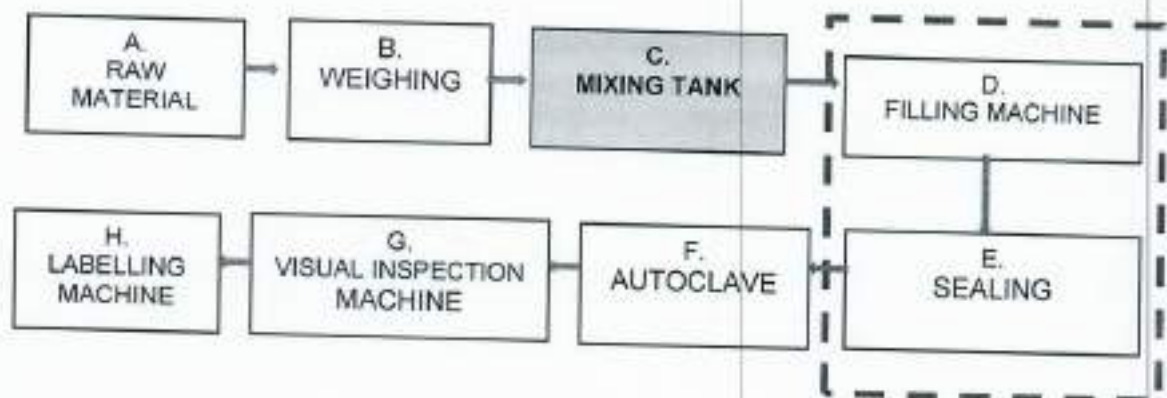
Tujuan dari dokumen ini ialah mendefinisikan persyaratan antara fungsional dan non-fungsional agar sesuai dengan system serta memastikan sesuai digunakan untuk transfer produk steril. Dokumen ini merupakan dasar untuk sistem kualifikasi yang dimana akan dilakukan pengecekan desain dan beberapa pengujian.

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 within transfer sterile 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 mixing tank yang digunakan pada PT Mersifarma untuk pencampuran produk injeksi steril unit 6A.

This user requirement document applies to mixing tank that used within the PT Mersifarma TM for mixing product sterile injectable unit 6A.



1.3 Definisi dan Singkatan

Definitions and abbreviations

List dibawah 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.

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PR00/URS/062.00	00		URS	6 of 13

Term	Definition
Harus /Wajib/M <i>Must /</i> <i>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. Essential to meet GMP or business critical requirements.</i>
Sebaiknya /Diinginkan /D <i>Should</i> <i>/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</i> /NA	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

Ruang lingkupnya meliputi penyediaan mixing tank beserta aksesoris, instalasi, dan comisioning.

The scope includes the supply of a mixing tank 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:

- Mixing Tank 1000 L with double jacket system
- Agitator System the Under Machine
- Control Panel
- Liquid Measurement Device
- Wheels for mobility
- Nitrogen Port
- Digital timer
- Lights
- Accessories for integration
- Spray Bowl
- Vacuum System

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PROJ/URS/062.00	00		URS	7 of 13

2.3 Servis

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
- Documentation

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/N A
3.1.1	Capacity	The tank shall have a capacity of 1000 Liters.	1000 Liters + 20%	M
3.1.2	Capacity Proses	The tank capacity should be large enough to handle the maximum batch size while leaving adequate headspace to avoid spilling during the mixing. The design must also support R&D/Trial run at minimum volumes (e.g., 10% to 20 %) while maintaining effective agitation.	Capacity minimum for mixing 10%	M
3.1.3	High Pressure tank	Maximum Allowable Working Pressure, Pressure gauge (+)	Max Operational Pressure :3 Bar Test Pressure : 5 Bar Safety Valve : 3,5 bar	M
3.1.4	Vacuum pressure tank	Maximum Allowable Working Pressure, Pressure gauge (-)	Vacuum Pressure Max -2,35 mbar	M
3.1.5	Safety Valve	The tank should provide safety valve	Equipped with a pressure-relief safety valve to prevent overpressure.	M
3.1.6	Material	The tank shall be made of SS316L stainless steel.	SS316L	M
3.1.7	Insulation Double Jacket	Mixing tanks are used to heat liquids and cool liquids, so a good insulator is needed so that the process does not affect the temperature and humidity of the room. Insulation that does not absorb liquids, does not mold. And does not shed fibers is the best choice	Surface temp NMT 50°C	M

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PR00/URS/062.00	00		URS	8 of 13

3.1.8	Water Volume	This system a defined water volume.	Load cell sensor with 0,5% accuracy	M
3.1.9	Temperatures Control	The tank shall have a temperature control system with a double jacket.	0 - 200°C	M
3.1.10	Speed Control	Agitator speed shall be variable and adjustable via control panel/HMI, equipped with RPM display and safety speed protection system.	0 - 1000 RPM	M
3.1.11	Time Control	Settable via HMI with auto-stop function after the preset time.	0 - 24 Hours	M
3.1.12	There are two nitrogen ports on the top surface of the tank.	There is a nitrogen port to protect the liquid surface from being oxidized by dissolved oxygen	Materials SUS 316L ferrule triclamp with neeple hose connector type after filter	M
		A stainless-steel nitrogen pipe is provided to protect the product liquid in the tank from oxidation by dissolved oxygen.	Material SUS316L pipe with triclamp ferrule	M
3.1.13	Sight glass in the top in the tank to see the product liquid.	LED light provided for visibility and operation monitoring.	Enough lamination to inspect insight the tank during operation	M
3.1.14	CIP/SIP	Clean-in-Place and Sterilize-in-Place (CIP/SIP) system. Port PSG.	Spray ball	M
3.1.15	Surface Finish	Electropolished smooth surface (low Ra) minimizes areas where bacteria, viruses, or fungi can adhere and grow. This facilitates the Clean-in-Place (CIP) cleaning and sterilization processes	-Ra 0,2µm- 0,4 µm	M
3.1.16	Motor Vacuum	Oil-free diaphragm vacuum pump: does not use oil or other liquids, eliminating the risk of product contamination and ensuring compliance with GMP standards	Ensure a flow rate of 1 m³/h (or equivalent CFM) sufficient for the tank volume and filter system.	M
3.1.17	Dissolved Oxygen	measuring the solubility of oxygen in a solution so that the product solution is stable	Dissolved oxygen values can measure up to ppb levels	D
3.1.18	Agitator	The mixing tank shall be equipped with a magnetic stirrer agitator system to ensure homogeneous mixing under sterile conditions. The agitator shall be designed to minimize particle generation and be compatible with CIP/SIP.	Type: Magnetic Stirrer • Suitable for aseptic operation • No mechanical shaft penetration • Low maintenance • Variable speed control • Compatible with CIP/SIP	M
3.1.19	Double Jacket Heating and Cooling	The tank shall be equipped with a dimple jacket for heating and cooling process with controlled flow direction to ensure uniform temperature distribution.	• Hot cycle flow: from top to bottom • Cooling cycle flow: from bottom to top • Jacket designed for efficient heat transfer and safety pressure rating	M

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PR00/URS/062.00	00		URS	9 of 13

3.1.20	Ergonomic Sampling Point	The tank shall have an ergonomic sampling point for safe and easy sample collection.	• Located at operator-friendly height • One-hand operation • SS316L, CIP/SIP compatible • Tri-clamp connection • Zero dead-leg design	M
3.1.21	Temperature Control Valve For Jacketing	The system shall include a 5-way control valve to regulate the media flow for heating, cooling, air purging, returning, and draining processes in the jacket.	The system shall include a 5-way control valve to regulate media flow for jacket processes (heating, cooling, air purging, returning, and draining) Material: SS316L Type: Actuated (pneumatic/electric) Function: Automatic switching based on PID temperature control	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	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 dimana 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 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	To be installed on the existing production area.	Temperature between 20 to 55°C; 20 to 80% RH,	M
3.3.2	Machine's water and dust resistance	IP 55	M
3.3.3	System is compatible with typical power requirements	220 V AC, 50 Hz, single phase / 380 V AC, three phase	M

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PR00/URS/062.00	00		URS	10 of 13

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	Safety valve	
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
3.4.6	3 level access	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
3.5.1	User-friendly interface	
3.5.2	Real-time data display	M
		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 operating system	NA

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PR00/URS/062.00	00		URS	11 of 13

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	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

3.8 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, identitas 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	Logical security measures for access control should be defined and maintained	D

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/NA
3.9.1	Stand-alone electronic records shall have routin backup capability.	D
3.9.2	Networked and stand-alone applications dealing with large volumes of electronic records should have daily backups as appropriate.	NA
3.9.3	Data can be printed directly or saved on a flash disk.	D

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PR00/URS/062.00	00		URS	12 of 13

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/NA
3.10.1	Alarm or auto stop if there is something not working properly etc.	M
3.10.2	Scalability to accommodate future production needs	NA
3.10.3	Equipped with ladder and safety for the operator	M

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 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 Preventative 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

Filename/Document Identifier	Ver	Ver Date	Type	Page No
2PR00/URS/062.00	00		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	Protocol Acceptance/Approval sign off by customer	M
4.2.2	Installation Book	M
4.2.3	IQ and OQ Documentation	M
4.2.4	Maintained book	M
4.2.5	Electrical and Machine Drawing	M
4.2.6	Sensor list	M
4.2.7	Calibration Certificate	M
4.2.8	Machine Diagram (P&ID)	M
4.2.9	Machine Work Process	M
4.2.10	Troubleshoot Document	M
4.2.11	Critical Component List	M
4.2.12	SAT Report	M
4.2.13	FAT Report	M
4.2.14	Trial Report	M
4.2.15	Validation Computerized	M

5. Pelatihan

Training

5.1 Pelatihan

Training

Req. No.	Persyaratan Requirement	M/D/NA
5.1.1	Production, QA, and Engineering team required training of Mixing Tank	M

6. Referensi

References

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