

| PT. Mersifarma TM            |                                                                    |           |      |         |
|------------------------------|--------------------------------------------------------------------|-----------|------|---------|
| Document Title               | User Requirement Specification for Holding Tank Double Jacket 100L |           |      |         |
| Filename/Document Identifier | Ver.                                                               | Ver. Date | Type | Page No |
| 2PROG/URS/086.00             | 00                                                                 |           | URS  | 1 of 13 |

## Holding Tank Double Jacket 100 L

### User Requirement Specification For Holding Tank Double Jacket 100 L

#### Pengesahan Approvals

| Name                                                                                                                     | Job Title or Role           | Signature                                                                             | Date<br>(dd-mm-yyyy) |
|--------------------------------------------------------------------------------------------------------------------------|-----------------------------|---------------------------------------------------------------------------------------|----------------------|
| The Lead Author is signing to confirm that this document has been prepared in accordance with PT Mersifarma TM standards |                             |                                                                                       |                      |
| Syahrii Purnama Sidik                                                                                                    | Sterile Production Staff    |     | 17/25/12             |
| Production, Engineering and QA is signing to confirm that the content reflects their requirements                        |                             |                                                                                       |                      |
| Indra Sinuhaji                                                                                                           | Sterile Production Manager  |     | 17/12/25             |
| Yohanes Reyaan                                                                                                           | Sterile Production Manager  |  | 4/12/25              |
| Firman Ardi B.                                                                                                           | Ass. Manager Utility        |   | 22/21/12             |
| Hendrawan                                                                                                                | Ass. Engineering Manager    |   | 22/25/12             |
| Hermawan W.                                                                                                              | Engineering Manager         |   | 22/12/25             |
| Dicky. M. Tasdik                                                                                                         | Project Engineering Manager |   | 22/12/25             |
| Sumardi                                                                                                                  | QA Manager                  |   | 24/12/25             |
| Management is signing to confirm that the content reflects their requirements                                            |                             |                                                                                       |                      |
| Fina Alfiani                                                                                                             | Deputy Director of QO       |   | 06/01/26             |
| Adhi Susanto                                                                                                             | Plant Director              |   | 06/01/26             |

| Filename/Document Identifier | Ver | Ver Date | Type | Page No |
|------------------------------|-----|----------|------|---------|
| 2PROD/URS/066.00             | 00  |          | URS  | 2 of 13 |

## TABLE OF CONTENTS

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

| Filename/Document Identifier | Ver | Ver Date | Type | Page No |
|------------------------------|-----|----------|------|---------|
| 2PROCURS/066.00              | 00  |          | URS  | 3 of 13 |

**DAFTAR PUSTAKA**  
*TABLE OF CONTENTS*

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



| Term                                                         | Definition                                                                                                                                                                                                                                                                                                                                    |
|--------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Harus /Wajib/M<br>Must /<br>Mandatory /M                     | Persyaratan adalah wajib dan harus dipenuhi yang mana non-negotiable untuk memenuhi GMP atau persyaratan kritikal<br><i>The requirement is mandatory and compliance with it is non-negotiable. Essential to meet GMP or business critical requirements.</i>                                                                                   |
| Sebaiknya<br>/Dinginkan /D<br>Should<br>/Desirable /D        | Persyaratan Opsional<br><i>Optional requirement.</i><br>Persyaratan yang tidak wajib, tapi setiap perbedaan dari yang ditentukan harus mendapat persetujuan tertulis terlebih dahulu dari Mersifarma<br><i>The requirement is not mandatory, but any departure from compliance with it is subject to Mersifarma's prior written approval.</i> |
| Tidak dapat<br>diaplikasikan<br>/NA<br>Not Applicable<br>/NA | Section ini tidak dapat diaplikasikan<br><i>Where a section is not applicable</i>                                                                                                                                                                                                                                                             |
| URS                                                          | User Requirements Specification                                                                                                                                                                                                                                                                                                               |

## 2. Deskripsi Umum

### General Description

#### 2.1 Scope Pembahasan

##### *Delivery Scope*

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

*The scope includes the supply of a holding 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:*

- Holding Tank 100 L with double jacket system
- Control Panel
- Wheels for mobility
- Nitrogen Port
- Lights
- Accessories for integration
- Vacuum System
- Liquid Measurement Device

| Filename/Document Identifier | Ver | Ver Date | Type | Page No |
|------------------------------|-----|----------|------|---------|
| 2PR00/URS/088.03             | 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 / SAT
- 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 100 Liters.                                                                                                                                                                                                                               | 100 Liters +                                                                                                                                               | M       |
| 3.1.2    | High Pressure tank       | Maximum And Minimum Allowable Working Pressure, Pressure Gauge (+)                                                                                                                                                                                                          | Max Operational Pressure : 3 Bar<br>Test Pressure : 5 Bar<br>Safety Valve : 3,5 bar<br>The standard is to maintain a minimum positive pressure of 0.2 Bar. | M       |
| 3.1.3    | Vacuum pressure tank     | Maximum Allowable Working Pressure, Pressure gauge (-)                                                                                                                                                                                                                      | Vacuum Pressure Max -2,35 mbar                                                                                                                             | M       |
| 3.1.4    | Safety Valve             | The tank should provide safety valve                                                                                                                                                                                                                                        | Equipped with a pressure-relief safety valve to prevent overpressure.                                                                                      | M       |
| 3.1.5    | Material                 | The tank shall be made of SS316L stainless steel.                                                                                                                                                                                                                           | SS316L                                                                                                                                                     | M       |
| 3.1.6    | Insulation Double Jacket | Holding 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.<br>Insulation that does not absorb liquids, does not mold. And does not shed fibers is the best choice | Surface temp NMT 50°C                                                                                                                                      | M       |
| 3.1.7    | Temperatures Control     | The tank shall have a temperature control system with a double jacket.                                                                                                                                                                                                      | 0 - 200°C                                                                                                                                                  | M       |



| Filename/Document Identifier | Ver | Ver Date | Type | Page No |
|------------------------------|-----|----------|------|---------|
| 2PR00/URS/096.00             | 00  |          | URS  | 8 of 13 |

|        |                                                               |                                                                                                                                                                                               |                                                                                                                                                                                                                                         |   |
|--------|---------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| 3.1.8  | Temperature Sensor                                            | Sensors to monitor the temperature of the product in the tank and the temperature during the sterilization process (SIP).                                                                     | <ul style="list-style-type: none"> <li>- Tipe: RTD Pt100, 3-wire.</li> <li>- Accuracy: <math>\pm 0.1^{\circ}\text{C}</math> or better.</li> <li>- Range: <math>0^{\circ}\text{C}</math> to <math>200^{\circ}\text{C}</math>.</li> </ul> | M |
| 3.1.9  | Water Volume                                                  | This system a defined water volume                                                                                                                                                            | Load cell sensor with 0.5% accuracy                                                                                                                                                                                                     | M |
| 3.1.10 | 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 |
| 3.1.11 | 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 |
| 3.1.12 | CIP/SIP                                                       | Clean-in-Place and Sterilize-in-Place (CIP/SIP) system, Port PSG.                                                                                                                             | Spray ball                                                                                                                                                                                                                              | M |
| 3.1.13 | 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 $0.2\mu\text{m}$ - $0.4\mu\text{m}$                                                                                                                                                                                                 | M |
| 3.1.14 | 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 $1\text{ m}^3/\text{h}$ (or equivalent CFM) sufficient for the tank volume and filter system.                                                                                                                     | M |
| 3.1.15 | 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 |
| 3.1.16 | Double Jacket Heating and Cooling                             | The tank shall be equipped with a diple jacket for heating and cooling process with controlled flow direction to ensure uniform temperature distribution.                                     | <ul style="list-style-type: none"> <li>• Hot cycle flow: from top to bottom</li> <li>• Cooling cycle flow: from bottom to top</li> <li>• Jacket designed for efficient heat transfer and safety pressure rating</li> </ul>              | M |
| 3.1.17 | Ergonomic Sampling Point                                      | The tank shall have an ergonomic sampling point for safe and easy sample collection.                                                                                                          | <ul style="list-style-type: none"> <li>• Located at operator-friendly height</li> <li>• One-hand operation</li> <li>• SS316L, CIP/SIP compatible</li> <li>• Tri-clamp connection</li> <li>• Zero dead-leg design</li> </ul>             | M |

| Filename/Document Identifier |  | Ver | Ver Date | Type | Page No |
|------------------------------|--|-----|----------|------|---------|
| 2PR00/URS/086.00             |  | 00  |          | URS  | 9 of 13 |

|        |                                                   |                                                                                                                                                       |                                                                                                                                                                                                                              |   |
|--------|---------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| 3.1.18 | Temperature Control Valve & Display For Jacketing | The system control valve to regulate the media flow for heating, cooling. Unit to display temperature in real-time and send signal to control system. | The control valve to regulate media flow for jacket processes (heating, cooling)<br>Function: Automatic switching based on temperature control<br>- Output: 4-20 digital<br>- Display: Digital LED/LCD on the control panel. | 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/088.00             | 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                                                                  | M      |
| 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      | M      |
| 3.5.2    | Real-time data display (HMI) | M      |

### 3.6 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      |



| Filename/Document Identifier | Ver | Ver Date | Type | Page No  |
|------------------------------|-----|----------|------|----------|
| 2PRO0/URS/066.00             | 00  |          | URS  | 11 of 13 |

### 3.7 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    | 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      |

### 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      |
| 3.10.4   | Wheels - Strong wheels support the load and are easy to clean / sterilize | M      |

| Filename/Document Identifier | Ver | Ver Date | Type | Page No  |
|------------------------------|-----|----------|------|----------|
| 2PR00/URS/066.00             | 00  |          | URS  | 12 of 13 |

#### 4. Persyaratan Lain-lain

##### *Other Requirements*

#### **4.1 Persyaratan Supplier**

##### Supplier Requirements

Pada bagian ini mendefinisikan persyaratan yang dibuat supplier yang dibutuhkan untuk mengenalkan system.  
*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: <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>                                                                                                                                         | 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.<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. | M      |
| 4.1.10   | One year consumable parts provided                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | M      |

#### **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      |



| Filename/Document Identifier | Ver | Ver Date | Type | Page No  |
|------------------------------|-----|----------|------|----------|
| 2PR00URS/066.00              | 00  |          | URS  | 13 of 13 |

|        |                                |  |   |
|--------|--------------------------------|--|---|
| 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   |                                                                        |  |        |
|-----------------|------------------------------------------------------------------------|--|--------|
| <i>Training</i> |                                                                        |  |        |
| Req. No.        | Persyaratan Requirement                                                |  | M/D/NA |
| 5.1.1           | Production, QA, and Engineering team required training of Holding Tank |  | M      |

## 6. Referensi

### *References*

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