

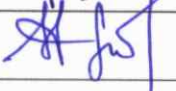
PT. Mersifarma TM				
Judul Dokumen <i>Document Title</i>	Spesifikasi Kebutuhan Pengguna untuk Hardness Tester <i>User Requirement Specification for Hardness Tester</i>			
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**Spesifikasi Kebutuhan Pengguna
Untuk Hardness Tester**
*User Requirement Specification
For Hardness Tester*

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PT. MERSIFARMA

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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1 Latar Belakang

Introduction

Dokumen mendeskripsikan Spesifikasi Kebutuhan Pengguna untuk Hardness Tester pada PT Mersifarma TM Sukabumi. URS ini didasarkan pada kebutuhan pengguna terhadap alat uji kekerasan tablet yang akan digunakan untuk pengujian kekerasan tablet selama kegiatan *in process control*

The document specifies the User Requirements Specification for Hardness Tester in PT Mersifarma TM Sukabumi Site. This URS is established based on the user requirements for a tablet hardness tester to be used for tablet hardness testing during In-Process Control (IPC) activities.

Pengesahan pada dokumen in oleh :

The approval of this document by:

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Adhi Susanto as Plant Director

1.1 Tujuan

Purpose

Tujuan dari dokumen ini ialah mendefinisikan persyaratan fungsional dan non-fungsional agar sesuai dengan system serta memastikan peralatan yang digunakan sesuai untuk pengukuran parameter kekerasan tablet di ruang inspeksi IPC. 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 and to ensure that it is fit for measuring tablet's hardness parameter in IPC inspection room. 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 Hardness Tester yang digunakan pada PT Mersifarma untuk parameter pengukuran kekerasan tablet

This user requirement document applies to Hardness Tester that used within the PT Mersifarma TM for for measuring tablet's hardness parameter

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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

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 internal perusahaan <i>The requirement is mandatory and must be complied with. These non – negotiable requirements shall be fulfilled to ensure compliance with GMP & company internal requirements</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. However, any deviation 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>
GMP	<i>Good Manufacturing Practice</i>

2. Deskripsi Umum

General Description

2.1 Lingkup Pembahasan

Delivery Scope

URS ini berlaku untuk proses pengadaan instalasi, kualifikasi, pengoperasian, kalibrasi dan pemeliharaan Hardness Tester yang digunakan untuk pengujian kekerasan tablet.

This URS applies to the procurement, installation, qualification, operation, calibration, and maintenance processes for the Hardness Tester used for tablet hardness testing.

2.2 Mesin

Machine

Cakupan dari sistem/ peralatan yang disediakan oleh suplier termasuk :

The scope of systems / equipment provided by Supplier include :

- *Equipment*
- *Certificate of compliance to USP and EP*
- *IQ and OQ Document*

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2.3 Servis

Service

Cakupan dari servis yang disediakan oleh supplier termasuk :

The scope of services delivered by the Supplier include :

- Installation
- Gurantee for two (2) year after installation

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	Measurement Range	Responsible to provide a hardness measurement range suitable for intended product	1 – 25 kgf	M
3.1.2	Measurement Units	The equipment shall display hardness results in selectable units	Kgf or N	M
3.1.3	Accuracy	Ability to produce true, repeatable, and traceable measurements	± 0.5% of the maximun value	M
3.1.4	Calibration Function	Ensures measurement traceability and compliance with GMP requirements	The equipment shall support routine calibration and verification activities.	M
3.1.5	Data Export	Digital result information transfer	The equipment shall allow data export to external devices such as printers	M

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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 have calibration features	M
3.2.2	Easy to maintenance, operate, overhaul and cleaning	M
3.2.3	Qualification can be carried out	M
3.2.4	Instrument able to store and recall measurement or calibration data	D
3.2.5	Instrument have off display indicators of turned on, running measurement, calibration progress and data transfer	D

3.3 Kondisi Pengoperasian

Operating Environment

Pada bagian ini mendefinisikan persyaratan khusus untuk kondisi fisik lingkungan dimana Hardness Tester akan beroperasi seperti suhu, getaran, kelembapan, layout ruang dan kebutuhan utility lain seperti kompresor dan persyaratan power supply.

This section defines any special requirements for the physical environment where the equipment will 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 testing hardness of the tablet	M
3.3.3	Electricity	240 ± 10% V ; 50 – 60 Hz ; Max power 40W	M
3.3.4	Dust resistance	The machine is not easily damaged by dust	M

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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	<i>The instrument shall be designed to ensure safe operation during routine use</i>	M
3.4.2	<i>The instrument shall remain mechanically stable during operation and shall not tip or move under normal operating conditions.</i>	M

3.5 Interfaces

Interfaces

Pada bagian ini mendefinisikan persyaratan terkait bagaimana tampilan interface dari sistem 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	NA	NA

3.6 Kondisi Komputerisasi

Computing Environment

Pada bagian ini mendefinisikan kebutuhan persyaratan PC untuk memastikan sistem operasi, kapasitas, kecepatan processor, memori dan kompatibilitas dengan standard 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

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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 sistem 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	NA	NA

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	NA	NA

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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	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 conformity for each component	M
4.1.2	Spare part list	M
4.1.3	Test equipment calibration certificates	M
4.1.4	Component specification	M

4.2 Dokumen Validasi

Validation Documentation

Pada bagian ini mendefinisikan terkait dokumentasi yang dilakukan untuk memastikan bahwa sistem 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	Manual book	M
4.2.2	IQ & OQ Documentation	M
4.2.3	Maintenance book	M
4.2.4	SAT Report	M
4.2.5	Calibration Certificate	M

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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

- CPOB 2024
- 21CFR Part 11 – Electronic Records and Electronic Signatures, FDA Federal Register, March 20th 1997