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Parent Document: PROC-0015819

Template Title: Global Template, Analytical Instrument User Requirements Specification

1.0 PURPOSE

The purpose of this User Requirements Specification (URS) is to define the user requirements for Waters e2695 Separations Module (HPLC) configured with Waters 2475 Fluorescence Detector (FLD) and Waters 2414 Refractive Index Detector (RID) (Equipment ID: 512Q2402) used in the Quality Control (QC), Takeda Singapore. This document will provide the foundation for the specification, design, verification, and operation of the system. The requirements in this URS should be satisfied to ensure the system meets its intended purpose and is fit for its intended use.

2.0 SCOPE

This document applies specifically to Waters e2695 Separations Module (HPLC) configured with Waters 2475 Fluorescence Detector (FLD) and Waters 2414 Refractive Index Detector (RID) used in Quality Control (QC), Takeda Singapore. The scope of this URS is limited to what is required of the system without being prescriptive of how the requirements are to be satisfied.

3.0 RESPONSIBILITIES

3.1 Qualification Designee

3.1.1 Generate, review, and approve the URS

3.2 System Owner or Designee

3.2.1 Provide input on requirements related to the intended use of the instrument.

3.2.2 Review and approve the URS.

3.3 Quality

3.3.1 Provide input on relevant validation requirements (e.g., documentation practices, verification methods, etc., relevant to the system).

3.3.2 Review and approve the URS.

4.0 RELATED DOCUMENTS

4.1 G-TAK-000225 Global Standard, Analytical Instrument Lifecycle

4.2 G-TAK-000219 Global SOP, Analytical Instrument Qualification

4.3 STRD-000054 Takeda Global Quality Standard Glossary

4.4 SOP-037827 Operation and Project Administration of Empower 3 Chromatographic Data System

4.5 SOP-028282 Backup and Restore Operation for Validated System

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5.0 KEY TERMS AND DEFINITIONS

- 5.1 **Analytical Instrument** – Any equipment or instrument that is not integral to a manufacturing system and is used in the testing of raw material, stability, release, intermediate process, or product samples or used for quantitative or qualitative analysis that directly or indirectly impacts products at Takeda.
- 5.2 **Process Owner** – The process owner is ultimately responsible for ensuring that the computerized system and its operation is in compliance and fit for intended use in accordance with applicable SOPs. The person or group responsible for developing, reviewing, approving, and executing qualification deliverables. The process owner also may be the system owner.
- 5.3 **System Owner** – The System Owner is responsible for the availability, and support and maintenance, of a system and for the security of the data residing on that system. The system owner is responsible for ensuring that the computerized system is supported and maintained in accordance with applicable SOPs. The person or group responsible for developing, reviewing, approving, and executing qualification deliverables. The system owner also may be the process owner.
- 5.4 **Qualification Designee** – People or groups responsible for developing, reviewing, approving, and executing qualification deliverables.
- 5.5 **QC** – Quality Control
- 5.6 **HPLC** - High-performance liquid chromatography
- 5.7 **FLD** - Fluorescence Detector
- 5.8 **RID** - Refractive Index Detector
- 5.9 **IP** – In-Process
- 5.10 **BDS** – Bulk Drug Substances
- 5.11 Refer to **STRD-000054**, TO STRD-048 Shire Global Quality Standard Glossary, for additional definitions.

6.0 SYSTEM DESCRIPTION

The Waters e2695 Separations Module (HPLC) configured with Waters 2475 Fluorescence Detector (FLD) and Waters 2414 Refractive Index Detector (RID) used in the Quality Control (QC), Takeda Singapore. The purpose is for the analysis for In-Process (IP) and Bulk Drug Substances (BDS) samples. The HPLC system has an integrated solvent and sample management platform. Integration of these platforms and traditional high-performance chromatography (HPLC) components facilitates the critical separations functions as per required by the assays.

The instrument connects to workstation with Empower 3 Software for data acquisition, instrument control, electronic signatures, audit trails, and user account management.

The instrument connects (through Sample Manager) directly to the Instrument LAN port in the LAC/E³² box or to the switch-hub provided.

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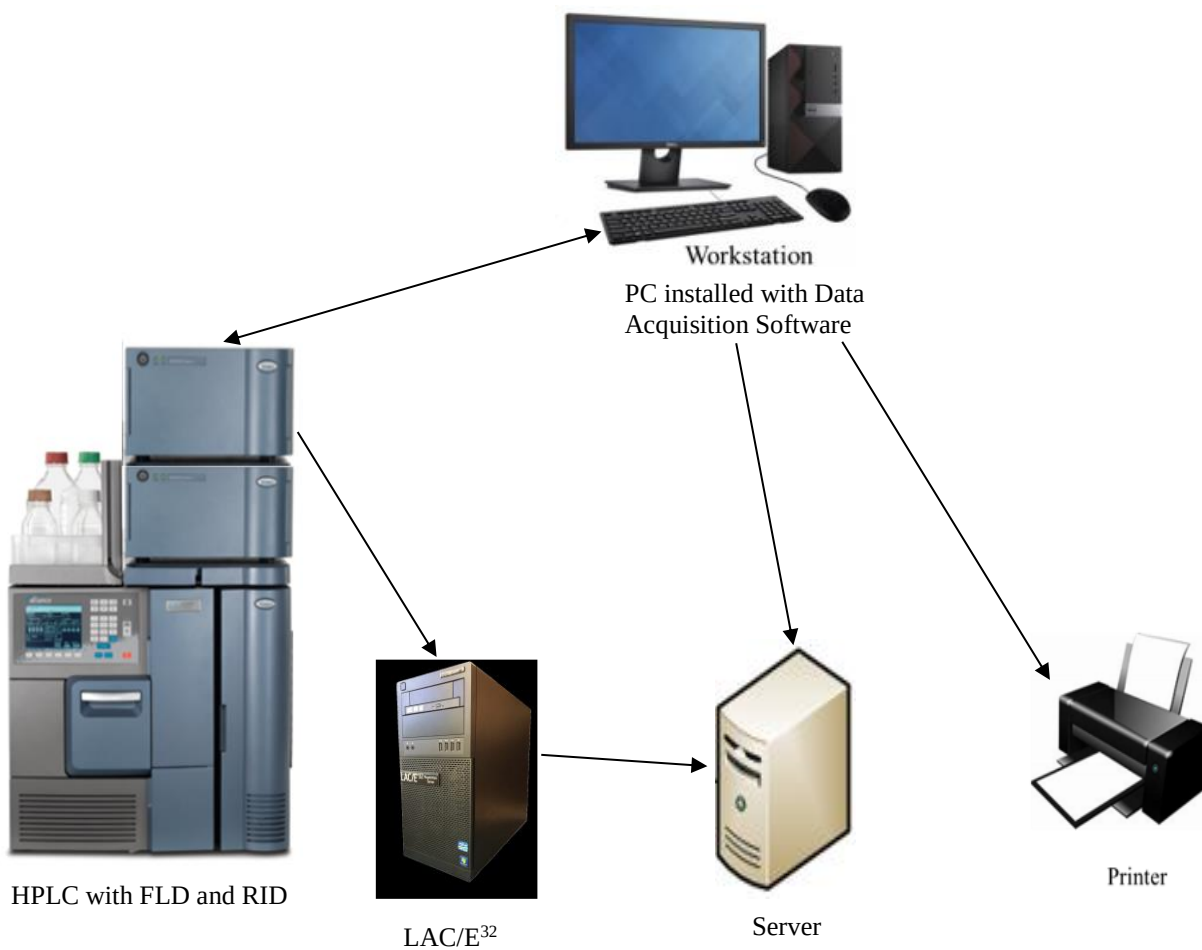
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The system utilizes electronic records along with paper printouts and is connected to the network for data storage and backup.

Figure 1: System Architecture Diagram



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7.0 USER REQUIREMENTS

7.1 Operation and Business Process Requirements

URS Number	URS Description
URS-OPR-001	Operational system checks must exist to enforce sequencing of steps and events.
URS-OPR-002	The system must be able to create and store electronic records.
URS-OPR-003	The system must produce records that uniquely identify the individual that created the record along with the date and time the record was created.
URS-OPR-004	The system must support electronic signatures.
URS-OPR-005	System specific instruction manuals must be delivered by the supplier in the form of a hardcopy or softcopy or both.
URS-OPR-006	Waters e2695 Separations Module (HPLC) shall be compatible with Waters 2475 Fluorescence Detector (FLD) and Waters 2414 Refractive Index (RID) Detector. These Modules will be connected to workstation with Empower 3 Software.
URS-OPR-007	The system must have provision to select the sample name and type from a dropdown list of standard and should be entered for the sample name.
URS-OPR-008	System must have ability to perform diagnostic checks to ensure that it is functioning correctly upon initialization.
URS-OPR-009	There must be a system check in place before operation to determine if the instrument is operating properly.
URS-OPR-010	The system must have the ability to run a single determination or a series of samples.
URS-OPR-011	The system must be able to generate, display, and record error, warning, or abort messages when unexpected conditions are encountered.
URS-OPR-012	The systems must analyze, and report result when only one of the detectors is used.

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URS Number	URS Description
URS-OPR-013	General requirements: Waters e2695 Separations Module: Operating flow rate range: 0.050 - 5.000 mL/min Solvent Composition range: 0 - 100 % Injection volume range: 0.1 to 100 µL Waters 2475 Fluorescence Detector: Wavelength range: Excitation 200 - 890 nm Wavelength range: Emission 210 - 900nm Bandwidth: 20 nm Measurement range: 0.001 - 100000.0 EU Waters 2414 Refractive Index Detector: RI range: 1.00 to 1.75 RIU Measurement range: 5.0×10^{-4} RIU - 7.0×10^{-9} RIU

7.2 Data Requirements

URS Number	URS Description
URS-DAT-001	System must have data checks to determine invalid and altered records.
URS-DAT-002	When exchanging data electronically with other systems, the system must include appropriate built-in checks for the correct and secure entry and processing of data.
URS-DAT-003	Regular back-ups of all relevant data should be done. Integrity and accuracy of backup data and the ability to restore the data must be checked during validation and monitored periodically.
URS-DAT-004	The system shall be able to generate result report.
URS-DAT-005	Data shall be stored in a suitable location e.g. local hard disk or validated server which can be periodically backup for disaster recovery purpose.
URS-DAT-006	The system shall encompass data security, access control, data integrity and audit trail features
URS-DAT-007	Access to the backup location restricted via procedure, physical security and logical security.
URS-DAT-008	The system shall have audit trail function for all changes that will impact the results (e.g. instrument method changes, processing method changes, result changes), administrator and user activities including parameter changes and error messages

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URS Number	URS Description
URS-DAT-009	The audit trail shall minimally have the following: - Be date-time stamped - Assigned to specific user - Describe activity type (for parameter changes, the audit trail entry shall reflect both the old and new values) - Audit trail is secure (unable to change even by an administrator level access) - The audit trail shall be generated by the software
URS-DAT-010	The software shall have the capability to access, print and archive audit trails and raw data.
URS-DAT-011	The software shall have the function to print reports if required.
URS-DAT-012	The software shall have reporting capabilities for calibration and measurements
URS-DAT-013	The software shall be able to be cloned and backed up for disaster recovery purpose
URS-DAT-014	Data archival and backup system shall be available for backup and archival

7.3 Technical Requirements

URS Number	URS Description
URS-TEC-001	The computerized system time must be routinely synchronized to ensure accuracy.
URS-TEC-002	The system must only allow valid devices (e.g. terminals, instrumentation, etc.) to input data or perform operational instruction.
URS-TEC-003	The system includes USB (2.0 or above) port for PC connection
URS-TEC-004	The system minimum hardware requirements for the PC with monitor: - USB device port (1), USB Host ports (3), Modbus TCP/IP - CD-ROM drive - RAM: 2 GB (Minimum) - CPU Speed: 1 GHz (Minimum) - Available Hard Disk Space: 5 GB (Minimum) - Screen Resolution: 1024 x 768 (Minimum) - Microsoft Windows 7 or higher Operating System 64 bit.
URS-TEC-005	The System must be connected with the respective analysis software that runs on Windows 7 or higher Operating System 64 bit.
URS-TEC-006	Instrument settings should be fully automated, and computer controlled.

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7.4 Interface Requirements

URS Number	URS Description
URS-INT-001	The system must be connected to PC workstation with Empower 3 Software.
URS-INT-002	The associated PC should be connected to an Ethernet network to allow the system to be networked to the Takeda domain.
URS-INT-003	The system must be connected to LAC/E ³² .
URS-INT-004	The system must be connected to a network printer.
URS-INT-005	User access shall be based on at least two distinct identification components such as an identification code and password.
URS-INT-006	The Software shall have a minimum of two levels of access.
URS-INT-007	An access level for administrator shall be available with access to the software administrative functions (e.g. create users, reset password etc.)
URS-INT-008	There shall be a user access level for performing user activities/tasks such as measurements and report generation.
URS-INT-009	Every user shall be assigned a unique user ID and password combination.
URS-INT-010	The software shall allow alphanumeric passwords.
URS-INT-011	All passwords shall have a minimum of 8 alphanumeric characters
URS-INT-012	Password can be set to expiry.

7.5 Environment Requirements

URS Number	URS Description
URS-ENV-001	The system location must meet the temperature requirement of 4°C to 40°C and relative humidity requirement of 20% to 80%.
URS-ENV-002	The system must be able to operate on the standard electrical supply found in Singapore. The voltage and frequency shall be: Single phase 220VAC – 240VAC, 50 – 60 Hz.
URS-ENV-003	The system must operate in a visually clean laboratory and free of physical blemishes or surface damage(s).
URS-ENV-004	The bench space for the system must be rigid with minimal vibration.
URS-ENV-005	The system and surrounding environment must be free liquids, out of direct sunlight and not directly under ventilation outlets.
URS-ENV-006	System must be plugged into an uninterruptible power supply (UPS) backup power system.

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7.6 Performance Requirements

URS Number	URS Description		
URS-PER-001	The system should have ability to perform user performance specifications as below: e2695 Separations Module:		
	Number	Test Parameter	Acceptance Criteria
	i.	Sample heater/ cooler temperature accuracy test at 4°C	± 4.0°C of Set Point Temperature
	ii.	Column heater or Column heater/ cooler temperature accuracy test at 25°C, 30°C and 40°C	± 2.0°C of Set Point Temperature
	e2695 Alliance with 2475 Fluorescence Detector:		
	Number	Test Parameter	Acceptance Criteria
	iii.	Flow rate Accuracy at 0.5, 2.0 and 5 mL/min	0.494 – 0.506 mL/min 1.98 – 2.02 mL/min 4.94 - 5.06 mL/min
	iv.	Raman signal to Noise	> 1000
	v.	System readiness check RT %RSD	≤ 1.0 %
	vi.	System readiness check Area %RSD	≤ 1.0 %
	vii.	System readiness check Height %RSD	≤ 1.5 %
	viii.	System Precision (with 250 µL syringe) RT %RSD	≤ 1.0 %
	ix.	System Precision (with 250 µL syringe) Area %RSD	≤ 1.0 %
	x.	System Precision (with 250 µL syringe) Height %RSD	≤ 1.5 %
	xi.	Injector Linearity and Accuracy	R ² ≥ 0.9990 Accuracy ≤ 1.0 µL
	xii.	Injector Carryover	≤ 0.1 %
	xiii.	Compositional Accuracy	RT %RSD ≤ 3.0
	xiv.	Gain Linearity (Area and Height)	%RSD ≤ 4.0
	xv.	Emission Wavelength Accuracy	700 ± 6 nm
	xvi.	Excitation Wavelength Accuracy	350 ± 6 nm
	xvii.	Detector Linearity (Area and Height)	R ² ≥ 0.990 Sensitivity %RSD ≤ 5.0
	xviii.	Detector Noise and Drift	Noise ≤ 5 EU Drift ≤ 10 EU/Hr

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URS Number	URS Description		
URS-PER-002	The system should have ability to perform vendor performance specifications as below: e2695 Alliance with 2414 Refractive Index (RI) Detector		
	Number	Requirement	Specification
	i.	Flow rate Accuracy at 5 mL/min	4.94 - 5.06 mL/min
	ii.	System readiness check RT %RSD	≤ 1.0 %
	iii.	System readiness check Area %RSD	≤ 1.0 %
	iv.	System readiness check Height %RSD	≤ 1.5 %
	v.	System readiness check Diluent RT range	0.705 - 0.855 min
	vi.	System Precision (with 250 µL syringe) RT %RSD	≤ 1.0 %
	vii.	System Precision (with 250 µL syringe) Area %RSD	≤ 1.0 %
	viii.	System Precision (with 250 µL syringe) Height %RSD	≤ 1.5 %
	ix.	Injector Linearity and Accuracy	R ² ≥ 0.9990 Accuracy ≤ 1.0 µL
	x.	Injector Carryover	≤ 1.00 %
	xi.	Flow rate Linearity and Accuracy	R ² ≥ 0.90 Accuracy ≤ 100 µL/min
	xii.	Detector Linearity & Sensitivity (Height)	R ² ≥ 0.990 Sensitivity % RSD ≤ 1.5 %
	xiii.	Detector Noise and Drift	Noise ≤ 20 nRIU Drift ≤ 10 µRIU/Hr
	xiv.	Signal to Noise	> 500

7.7 Availability Requirements

URS Number	URS Description
URS-AVA-001	Waters Alliance HPLC operation and maintenance procedure must be available.
URS-AVA-002	Operation and administration procedure for the associated software Empower 3 Chromatographic Data System must be available.
URS-AVA-003	The system must have Backup and restoration procedure.
URS-AVA-004	Disaster Recovery Plan must be available

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URS Number	URS Description
URS-AVA-005	Software manuals and documentation from the vendor must be available.
URS-AVA-006	A unique ID is assigned to the system.

7.8 Health, Safety, and Environment (HSE) Requirements

URS Number	URS Description
URS-HSE-001	The system power socket shall meet the Singapore 3-pin plug requirement.
URS-HSE-002	Risk Assessment for the Operation and Maintenance of Waters Alliance HPLC System must be available.

7.9 Security Requirements

URS Number	URS Description
URS-SEC-001	System must have authority checks to limit access to specific functions to authorized individuals, e.g., altering or signing electronic records.
URS-SEC-002	The system must provide the ability to disable user accounts. If the system does not have the capability, procedural controls must be in place.
URS-SEC-003	The system must prevent the deletion of user accounts. If the system does not have the capability, procedural controls must be in place.
URS-SEC-004	Creation, change, and cancellation of access authorizations should be recorded.
URS-SEC-005	The system must have physical and/or logical security measures in place, limiting system access to authorized individuals. If the system does not have the capability, procedural controls must be in place.
URS-SEC-006	The system must be capable of maintaining the uniqueness of each combined identification code and password, such that no two individuals can have the same combination of identification code and password.
URS-SEC-007	The system must be able to create at least two user's groups in the application software and assign specific privileges to each one of them: • Routine Users: These users can perform a test or load sample into device but should not have the opportunity to change the configurations/ parameters. • Administrators: A change to critical configurations and parameters, which must not be constantly adjusted, should be possible by this user level.
URS-SEC-008	The system must comply to PROC-0001029 — Global SOP, Identity, Access and Password Management. • Password Requirement • Period of inactivity as specified • Number of failed login attempts

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URS Number	URS Description
URS-SEC-009	Password(s) for access to electronic data and/or for executing an electronic signature must be encrypted.
URS-SEC-010	User passwords must not be retrievable by the system administrator and system administrators must not have unencrypted access to the user password.
URS-SEC-011	The system must require the user to change a new or reset password at initial login to preserve the secrecy of the user id and password combination.
URS-SEC-012	Users must not be able to change the clock time identified for the computerized systems and the associated audit trail(s).
URS-SEC-013	System date and time should be synchronized with the site network. If the system does not have the facility, procedural controls must be in place.

7.10 Regulatory Requirements

7.10.1 Electronic Records

URS Number	URS Description
URS-ER-001	The system must have the ability to discern invalid or altered records, and should include accuracy checks on manually entered, critical data.
URS-ER-002	For records supporting batch release it should be possible to generate printouts indicating if any of the data has been changed since the original entry.
URS-ER-003	When a computerized system is used for recording certification and batch release, the system should allow only Qualified Persons to certify the release of the batches and it should clearly identify and record the person releasing or certifying the batches. This should be performed using an electronic signature.
URS-ER-004	The system must be capable of producing and printing accurate and complete copies of records in electronic and human readable format, suitable for inspection, review and copying.
URS-ER-005	Records must be stored in such a way as to enable their accurate and ready retrieval throughout the specified retention period. Stored data should be periodically checked for accessibility and readability.
URS-ER-006	The system must have a secure, computer-generated time stamped audit trail to independently record date, time, and operator identification of actions that create, modify or delete electronic records.
URS-ER-007	When a record changes, the audit trail must preserve previously recorded information
URS-ER-008	Audit trails must be retained for at least as long as the corresponding record retention period.

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URS Number	URS Description
URS-ER-009	Audit trail information must be available for review and copying. Audit trail must include: • System and/or user identification • Time and date stamp • Identification of electronic data or entry being changed • Previous recorded data (if any) • New or modified data • Reason for any changes
URS-ER-010	Signed electronic records must clearly indicate the printed name of the signer.
URS-ER-011	Signed electronic records must clearly indicate the date and time the signature was executed.
URS-ER-012	Signed electronic records must clearly indicate the meaning associated with the signature (e.g., review, approval, responsibility, authorship).
URS-ER-013	Signature manifestation information (as specified in 21CFR11.50(a)) must be included as part of any human readable form of the record, such as display or printout.
URS-ER-014	The computerized system must be designed to ensure that the execution of critical transactions is recorded contemporaneously by the user and are not combined into a single system transaction with other operations.
URS-ER-015	Electronic data must be secured from accidental or intentional deletion.
URS-ER-016	Access to the electronic data must be ensured throughout the retention period.
URS-ER-017	The system must be capable of restoring all system records, data (including metadata), audit trails, and electronic signatures.
URS-ER-018	For archived electronic records or true copies, the computerized system must permit recovery (reconstruction) and readability of the electronic data, metadata, and its audit trail through the required retention period.

7.10.2 Electronic Signatures

URS Number	URS Description
URS-ES-001	A non-biometric electronic signature must consist of at least two distinct identification components, such as identification code and password.
URS-ES-002	When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by the individual.

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URS Number	URS Description
URS-ES-003	When an individual executes one or more signings not performed during a single, continuous period of controlled system access, each signing shall be executed using all of the electronic signature components.
URS-ES-004	Electronic signatures based on the combination of identification code and password must be unique, such that no two individuals have the same combination of identification code and password.
URS-ES-005	Electronic signatures based on the combination of identification code and password must be periodically checked, recalled or revised, e.g., forced password change after it has been initially set up or reset, forced password change after set number of days, etc.
URS-ES-006	The system must be able to electronically de-authorize lost, stolen, missing, or otherwise potentially compromised identification codes or passwords, and to issue temporary or permanent replacements using suitable, rigorous controls.
URS-ES-007	The system must be able to detect and enable the reporting of, in an immediate and urgent manner, any attempts of unauthorized use of passwords and/or identification codes.
URS-ES-008	Electronic signatures must be linked to their respective electronic records to ensure that the signatures cannot be removed, copied or transferred to falsify an electronic record.
URS-ES-009	Electronic signatures must contain and display the following information with the signing: • Full name of the signer • Date and time when the signature was executed • Meaning associated with the signature
URS-ES-010	The display of the electronic signature information must be included in any human readable form of the record.

7.11 Report Requirements

URS Number	URS Description
URS-RPT-001	Data reports (including metadata) in electronic and paper format must include the following: • Electronic record identifier • Unique user identifier who generated the report • Date and time, it was created • Data and associated metadata to interpret and understand the original data or record • Equipment ID/Serial Number
URS-RPT-002	The system must allow the user to generate and view reports in both electronic form and printouts.

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URS Number	URS Description
URS-RPT-003	System should be capable to provide audit trail report printouts, including following information, but not limited to: • Date and time • Analyst name • Description of the action

8.0 REVISION HISTORY

Rev #.	Summary of Changes
1.0	New document

DOCUMENT APPROVAL ☐ N/A (Approvals obtained electronically)

Completion of the following signature blocks signifies the approver has read, understands, and agrees with the content of this document.

Completed By (Print Name):	Completed By (Signature):	Date:
Process Owner Approval (Print Name):	Process Owner Approval (Signature):	Date:
Quality Approval (Print Name):	Quality Approval (Signature):	Date:

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Document Approvals
Approved Date: 09 Oct 2020

Mandatory Owner Approval Verdict: Approve	Berkinse Kusalavapandy (berkinse.kusalavapandy@shire.com) Document Owner Approval 09-Oct-2020 06:45:30 GMT+0000
Approval Task Verdict: Approve	Kok Hong Law (law.kok.hong@shire.com) Technical Approval 09-Oct-2020 07:12:54 GMT+0000
Quality Approval Verdict: Approve	Vickie Gu (wei.gu@shire.com) Quality Approval 09-Oct-2020 08:33:42 GMT+0000