Instrument Name	Computer System
System ID.	.....
System Used For	High Pressure Liquid Chromatography
Make	Waters
HPLC ID.	.....
Application Software Type	Chromatographic ☑ Non Chromatographic ☐
Application Software	Empower
Software Version	3.0
Make	Waters
System Type	New System ☐ Existing system ☑
Location	Instrument Room – I

1.0 CONTENTS:

3.0 OBJECTIVE:

This document is prepared to provide user requirement specification for the system from a user, functional, and technical perspective. It includes the business, system, data, performance, configuration, environmental/operational, security and audit trail capabilities that the system shall provide to meet the business needs of the users in the QC Lab at Site.

4.0 SCOPE:

This Document is limited to Computer System and installed Application Software for HPLC in QC Lab at Site.

This Document is Applicable to Workstation and Applicable Software which covers the following requirements.

- Configuration Requirements
- Technical Requirements
- Operational / Functional Requirements
- Data Requirements
- Lifecycle Requirements

5.0 RESPONSIBILITIES:

The validation group comprising of the representative from each of the following departments shall be responsible for overall compliance with the validation plan.

Role	Responsibility
Validation Agency	➢ To prepare user requirement specification.
System owner, IT (Site)	➢ To provide necessary documents / support required for user requirement specification. ➢ To help in preparation for user requirement specification. ➢ To review user requirement specification.
QA (Site)	➢ To provide necessary support required for user requirement specification. ➢ To review user requirement specification.
QA Head (Site)	➢ To approve user requirement specification.

6.0 REFERENCES:

Document	Description
CFR Title 21, Part 11	Code of Federal Regulations : Electronic Records; Electronic Signatures.
EU GMP Annexure 11	Good Manufacturing Practice; Medical Products for Human and Veterinary use,Annex 11; Computerized Systems; Volume 4
GAMP5	A Risk – Based Approach to Compliant GxP Computerized Systems(Good Automated Manufacturing Practices Version 5.0)

7.0 SYSTEM OVERVIEW:

The System used for HPLC (High Pressure Liquid Chromatography) consists of Computer System Workstation with operating system and Installed Application Software this includes the following:

- Installed Hardware and Operating System Software Configuration.
- Application Software Installation and Configuration.
- Administration and User Access Controls and Configuration for Workstation and Application Software.
- Operational And Functional Requirements of Workstation and Application Software.
- Interface Between Third Party Software and Hardware.

8.0 CONFIGURATION:

7.1 System security

Req. No.	Requirement Description
7.1.1	The System/ Software should provide the facility to creation of new user account.
7.1.2	The Software should not allow to create duplicate user account.
7.1.3	The Software should provide the facility to Modification in user account.
7.1.4	The System/ Software should not allow user to login without correct combination of User Name/ ID and Password.
7.1.5	The System/ Software must mask password entry.
7.1.6	The System/ Software should allow administrator to reset user account.
7.1.7	The System/ Software should provide the facility to Disable/ Remove user accounts.
7.1.8	The System/ Software should be locked after pre-defined time.
7.1.9	The Software should configured to define the password age.
7.1.10	The Software should configured to define minimum password length
7.1.11	The Software should configured to define complexity requirement.
7.1.12	The Software should configured to define auto lockout duration
7.1.13	The Software should configured to define invalid login attempts
7.1.14	The Software should configured to change own password.

7.2 User Role / Authorization Control Requirements:

7.2.1 Application Software:

Req. No.	Requirement Description
7.2.1.1	The Application software must support at least the following user roles but not limited to: 1. Analyst 2. Reviewer 3. Administrator
7.2.1.2	Access to the system function shall be control based on user roles and privileges. Privileges should be verified with respect to SOP.

8.0 TECHNICAL REQUIREMENTS:

8.1 HARDWARE REQUIREMENTS:

8.1.1 Workstation Specification:

Req. No.	Description	Minimum Requirement
8.1.1.1	Make	Any Reputed
8.1.1.2	Model	As specified
8.1.1.3	Processor	As specified
8.1.1.4	RAM	As specified
8.1.1.5	Capacity of HDD	As specified
8.1.1.6	Operating System	As specified
8.1.1.7	License of OS	Should be Available

8.2 Software Requirements:

Req. No.	Description	Software Specification
Application Software		
8.2.1	Software Name	Empower
8.2.2	Version	Version 3.0
8.2.3	License	Should be Available

8.3 Environmental Condition:

The Environmental Condition for Workstation should be in specified range as follows:

Req. No.	Description	Specified Requirement
8.3.1	Operating temperature (˚C)	Below 30℃
8.3.2	Operating Relative humidity (%)	Below 60%

8.4 Electrical Supplies:

The electrical supply requirements for the configuration hardware system should be within specified as follows:

Req. No.	Description	UPS Specification
8.4.1	UPS	UPS should be available
8.4.2	Power Supply	110-240 VAC or as per system recommendation

8.5 Communication/Power Failure And Recovery:

Req. No.	Requirement Description
8.5.1	Communication failure indication should be displayed in the software.
8.5.2	After reestablishing the communication, the set parameters / process activity should remain unchanged. OR No any error message shall display.
8.5.3	In case of power failure, system should be normally start after power resume
8.5.4	In case of power failure; Method Parameters / sequence should not be affected.

9.0 OPERATIONAL/FUNCTIONAL REQUIREMENTS

9.1 Operational Requirements:

Req. No.	Requirement Description
9.1.1	• The software should be controlled by username and password.
9.1.2	• The software should allow user to fill the required details to start the sample. • The Software should allow user to view analysis result on the display. • The Software should allow user to view report of generated data. • The Software should allow user to print the report in predefined format. • The software should generate data/report in unalterable way.

9.2 Functional Requirements:

Req. No.	Requirement Description
9.2.1	• Software should allow authorized personnel to access the existing records.
9.2.2	• E-records should not be deleted by users.
9.2.3	• Report templates should not be editable by unauthorized users.
9.2.4	• The Software shall not allow to manipulate/ change any parameter in existing Batch/ Project.

9.3 Report Output Requirements:

Req. No.	Requirement Description
9.3.1	• Printed report from software should be match with displayed in application software.

9.3.2	• Report must have the following parameters but not limited to:
	  • Test Info
	  • Sample Info
	  • Results Data

9.3.3	• The software should generate data/report in unalterable way.
9.3.4	• Report should be printable in pre-defined format.
9.3.5	• The software shall be capable to producing accurate and complete copies of electronic records in both human readable and electronic form for inspection, review and copy.

10.0 DATA REQUIREMENTS:

10.1 Audit Trail Requirements:

10.1.1 Application Software:

Audit trail shall be generated as per requirements outlined below:

Req. No.	Requirement Description
10.1.1.1	The system audit trail must track the creation, modification, and deletion of records, Including the time, date, person, and reason for the change. E.g. • User login/ logout. • Change in parameters. • Incorrect login attempts • Change in user authorization of application software
10.1.1.2	The audit trail must be viewable, and can be exported in protected non-editable format.
10.1.1.3	The audit trail must be protected from intentional or accidental modification.
10.1.1.4	It must not be possible to modify or delete audit reports / audit trails.
10.1.1.5	Generated Audit Trail should be printable. Print should be in human readable format.

10.2 Data Backup Requirements:

Req. No.	Requirement Description
10.2.1	All GxP Critical data should be backup as per procedure.
10.2.2	Data Backup mechanism should be available.
10.2.3	Backup schedule should be available

10.3 Data Restoration Requirements:

Req. No.	Requirement Description
10.3.1	Data restoration policy should be define as per the procedure.
10.3.2	Data restoration mechanism should be available.

10.4 Data Migration Requirements:

NA

11.0 CONSTRAINTS:

11.1 Compatibility:

The URS document primarily covers the requirements of Workstation/ Software and related services (e.g. OS, Equipment, Instrument, Power requirements etc.) While the compatibility may not be a major constraint, the following points should be addressed during design and installation:

- Operating system and application software.
- Third party interfaces
- Compatibility of Application Software with Devices which captures Data (e.g. Instruments, Equipment, Data Entry terminals)

11.2 Availability:

The System data flow requirements high availability of the system due to its critical nature following points should be addressed during design and installation:

- Workstation hardware
- Network
- Reference documentation
- Service provider support
- Trained Man power for operation and maintenance.
- Application backup with configuration
- Data backup

11.3 Reliability:

The system is being installed should be treated as highly critical due to its novelty and complexity. following points should be addressed during design and installation:

- Design review by Subject Matter Experts for end to end data flow
- Supplier Qualification
- Training records of development engineers
- Comprehensive risk assessment

12.0 LIFE CYCLE REQUIREMENTS:

12.1 Documentation Requirements:

Req. No.	Description
12.1.1	Software Manual
12.1.2	Vendor documents
12.1.3	Application Software License Copy/ Media
12.1.4	Training Records

12.2 Standard Operating Procedures:

Req. No.	Description
12.2.1	SOP for Computer System Operation
12.2.2	SOP for Change Control
12.2.3	SOP for Access Control
12.2.4	SOP for User Creation/Deletion/ Role and Authorization.
12.2.5	SOP for Preventive Maintenance
12.2.6	SOP for Data Backup and Restoration
12.2.7	SOP for Disaster recovery Plan and Policy
12.2.8	SOP for Group Desktop and Security Policy
12.2.9	SOP For Training and Evaluation

13.0 ABBREVIATIONS:

Abbreviation	Full form
AAT	Validation Agency
CSV	Computerized System Validation
QM	Quality Management
QC	Quality Control
QA	Quality Assurance
GxP	Generic acronym for pharmaceutical regulations, Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) & Good Clinical Practice (GCP)
URS	User Requirement Specification
GAMP	Good Automated Manufacturing Practices
GMP	Good Manufacturing Practices
mA	Milli Ampere
EU	European Union
IT	Information Technology
LAN	Local Area Network
NA / N/A	Not Applicable
No.	Number
QA	Quality Assurance
Ref.	Reference
QC	Quality Control
Req.	Requirement

Abbreviation	Full form
SOP	Standard Operating Procedure
Sr.	Serial
UPS	Uninterrupted Power Supply
USFDA	United States Food and Drug Administration
Y/N	Yes/ No
GB	Gigabytes
GHz	Giga Hertz
CAT	Category
VAC	Voltage - Alternating Current
RH	Relative humidity

14.0 APPROVAL PAGE

Department	Name	Designation	Signature	Date
Prepared by: M/s.				
ENGINEERING				
Reviewed by: M/s.				
QUALITY ASSURANCE				
Reviewed by: M/s.				
ENGINEERING				
Reviewed by: M/s.				
IT DEPARTMENT				
Reviewed by: M/s.				
QUALITY CONTROL				
Approved by: M/s.				
QUALITY ASSURANCE				