USER REQUIREMENT SPECIFICATIONS

FOR

LAB SOLUTIONS SOFTWARE OF HPLC

(VERSION 6.92)

LOCATION	
SUPERSEDES URS No.	**Nil**

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

USER REQUIREMENT SPECIFICATIONS FOR LAB SOLUTIONS SOFTWARE OF HPLC

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1. PREPARATION, REVIEW, APPROVAL AND AUTHORIZATION:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
EXECUTIVE/MANAGER (QUALITY ASSURANCE)			
HEAD (QUALITY CONTROL)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (DEPARTMENT)			

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2. 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.

3. SCOPE:

This document is limited to the Lab Solutions Software (Version 6.92) for HPLC installed in the QC Lab.

This document is applicable to Application Software and Workstation which covers following requirements.

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

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4. RESPONSIBILITIES:

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

Role	Responsibility
System owner, IT (Site)	➢ To prepare user requirement specification. ➢ 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.

5. REFERENCE

Document	Description
CFR Title 21, Part11	Code of Federal Regulations: Electronic Records; Electronic Signatures
EU GMP Annexure11	Good Manufacturing Practice; Medical Products for Human and Veterinary use Annex11;Computerized Systems; Volume4
GAMP5	A Risk–Based Approach to Compliant GxP Computerized Systems (Good Automated Manufacturing Practices Version5.0)

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6. SYSTEMOVERVIEW:

7.1 System Software

Software of the computerized system includes as follows:

- Application software installation and it's configuration.
- Other utilities software installation and configuration.
- Administration and User access control configuration of software system.
- Application software operational and functional requirement.

7.2 System Interface

- Interface between third party Software/ Hardware

8.0 CONFIGURATION:

8.1 System Security

Req. No.	Requirement Description
8.1.1	The System/ Software should provide the facility to creation of new user account.
8.1.2	The Software should not allow to create duplicate user account.
8.1.3	The Software should provide the facility to Modification in user account.
8.1.4	The System/Software should not allow user to login without correct combination of User Name/ID and Password.
8.1.5	The System/Software must mask password entry.
8.1.6	The System/Software should allow administrator to re set user account.
8.1.7	The System/ Software should provide the facility to Disable/Remove user accounts.
8.1.8	The System/Software should be locked after pre-defined time.
8.1.9	The Software should configured to define the password age.
8.1.10	The Software should configured to define minimum password length
8.1.11	The Software should configured to define complexity requirement.
8.1.12	The Software should configured to define auto lock out duration
8.1.13	The Software should configured to define in valid log in attempts
8.1.14	The Software should configured to change own password.

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8.2 User Role/Authorization Control Requirements

8.2.1 Application Software

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

7. TECHNICALREQUIREMENTS:

9.1 Hardware Requirements

9.1.1 Client Station Specifications

Req. No.	Description	Minimum Requirement
9.1.1.1	Make	Any Reputed
9.1.1.2	Model	As specified
9.1.1.3	Processor	As specified
9.1.1.4	RAM	As specified
9.1.1.5	Capacity of HDD	As specified
9.1.1.6	Operating System	As specified
9.1.1.7	License of OS	Should be Available

9.2 Software Requirements

Req. No.	Description	Software Specification
Application Software		
9.2.1	Software Name	Lab Solutions
9.2.2	Version	Version6.92
9.2.3	License	Should be Available

9.3 Environmental Conditions

The environmental condition of workstation should be in the specified range as follows:

Req. No.	Description	Specified Requirement
9.3.1	Operating temperature(˚C)	Below30ºC
9.3.2	Operating Relative humidity (%)	Below60%

9.4 Electrical Supplies

The electrical supply requirements for the configuration hardware system should be in the specified as follows.

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

9.5 Communication/Power Failure and Recovery

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

10.0 OPERATIONAL/FUNCTIONAL REQUIREMENTS:

10.1 Operational Requirements

Req. No.	Requirement Description
10.1.1	• The software should be controlled by user name and password.
10.1.2	• 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.

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10.2 Functional Requirements

Req. No.	Requirement Description
10.2.1	• Software should allow authorized personnel to access the existing records.
10.2.2	• E-record should not be deleted by users.
10.2.3	• Report templates should not be editable by unauthorized users.
Req. No.	**Requirement Description**
10.2.4	• The Software shall not allow to manipulate/change any parameter in existing Batch/Project.

10.3 Report Output Requirements

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

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

10.3.3	• The software should generate data/report in unalterable way.
10.3.4	• Report should be printable in pre-defined format.
10.3.5	• 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.

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8. DATAREQUIREMENTS

11.1 Audit Trail Requirements

11.1.1 Application Software

Audit trail shall be generated as per requirements outlined below.

Req. No.	Requirement Description
11.1.1.1	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
11.1.1.2	The audit trail must be viewable, and can be exported in protected non-editable format.
11.1.1.3	The audit trail must be protected from intentional or accidental modification.
11.1.1.4	It must not be possible to modify or delete audit reports / audit trails.
11.1.1.5	Generated Audit Trail should be printable. Print should be in human readable format.

11.1.2 Data Backup Requirements

Req. No.	Requirement Description
11.2.1	All GxP Critical data should be back up as per procedure.
11.2.2	Data Backup mechanism should be available.
11.2.3	Backup schedule should be available

11.1.3 Data Restoration Requirements

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

9. Data Migration Requirements

NA

10. CONSTRAINTS

13.1 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)

13.2 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 Manpower for operation and maintenance.
- Application backup with configuration
- Data backup

13.3 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

11. LIFECYCLEREQUIREMENTS

14.1 Documentation Requirements

Req. No.	Description
14.1.1	Software Manual
14.1.2	Vendor documents
14.1.3	Application Software License Copy/Media
14.1.4	Training Records

14.2 Standard Operating Procedures

Following Standard Operating Procedures should be available.

Req. No.	Description
14.2.1	Operational and calibration SOP
14.2.2	Operational Change Control
14.2.3	Security Management
14.2.4	User Roles & Authorization
14.2.5	Training Procedure
14.2.6	Data Backup and Restore Procedure

12. ABBREVIATIONS

Abbreviation	Fullform
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	Milliampere
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
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

13. EVISION HISTORY:

Revision No.	Change Control No.	Details of changes	Reason of Changes	Effective Date	Done By