TRACEABILITY MATRIX OF COMPUTER SYSTEM

Name of Item: Computer System	**Protocol No**.:.........................
Functional Area: IT	**Page No.:** 1 of 5

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

TRACEABILITY MATRIX OF COMPUTER SYSTEM

Name of Item: Computer System	**Protocol No**.:........................
Functional Area: IT	**Page No.:** 2 of 5

1.0 DOCUMENT PRE-APPROVAL:

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.				

TRACEABILITY MATRIX OF COMPUTER SYSTEM	
Name of Item: Computer System	**Protocol No**.:.........................
Functional Area: IT	**Page No.:** 3 of 5

QUALITY ASSURANCE			

2.0   TABLE OF CONTENTS:

TRACEABILITY MATRIX OF COMPUTER SYSTEM

Name of Item: Computer System	**Protocol No**.:........................
Functional Area: IT	**Page No.:** 4 of 5

3.0   OBJECTIVE:
The Objective of Traceability Matrix is to Document and assure that all User System and Software requirements are mapped and verified.

4.0   SCOPE:

This Traceability Matrix is prepared to provide documented traceability evidence of User/ System Requirements Specification and qualification protocol cum report.

This document is applicable to Computer system and Software as per there operations in Quality Control.

5.0   REFERENCE:
The Publications listed below are referred while preparing the Traceability Matrix.

Document	**Description**
	User Requirement Specification
	Installation Qualification Protocol Cum Report
	Operational And Performance Qualification Protocol Cum Report

6.0   SYSTEM DESCTIPTION:

HPLC is an abbreviation for High Performance Liquid Chromatography. "Chromatography" is a technique for separation, "chromatogram" is the result of chromatography, and "chromatograph" is the instrument used to conduct.

7.0   RESPONSIBILITIES:

TRACEABILITY MATRIX OF COMPUTER SYSTEM

Name of Item: Computer System	Protocol No.:........................
Functional Area: IT	Page No.: 5 of 5

Department	Responsibility
Engineering and IT	Review of Traceability Matrix document.
Quality Assurance	Review and approval of Traceability Matrix document.
Consultant	Prepare Traceability Matrix Document

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TRACEABILITY MATRIX OF COMPUTER SYSTEM	
Name of Item: Computer System	**Protocol No**.:........................
Functional Area: IT	**Page No.:** 6 of 15

8.0 TRACEABILITY MATRIX:

The Traceability document provides traceability between the User/ System Requirements Specification to the qualification Protocols to ensure that all the specification listed in the System/ User Requirements Specification have been adequately tested. Whenever certain requirements are not tested explicitly. Justification for the same are provide in the comments column of the traceability matrix.

S. No.	URS ID	DESCIRPTION	Related IQ Test	Related OPQ Test	Comments/ Remarks
	7.0	**CONFIGURATION**			
	7.1	**System Security**			
1.	7.1.1	Maximum password age	NA	Test No. 13.1& 13.2	Found Satisfactory.
2.	7.1.2	Minimum password length	NA	Test No. 13.1& 13.2	Found Satisfactory.
3.	7.1.3	Password must meet the complexity requirement	NA	Test No. 13.1& 13.2	Found Satisfactory.
4.	7.1.4	Auto lockout duration	NA	Test No. 13.1& 13.2	Found Satisfactory.
5.	7.1.5	Account should be lockout after define invalid login attempts	NA	Test No. 13.1& 13.2	Found Satisfactory.
6.	7.1.6	Reset password	NA	Test No. 13.1& 13.2	Found Satisfactory.
7.	7.1.7	Own password change	NA	Test No. 13.1& 13.2	Found Satisfactory.

TRACEABILITY MATRIX OF COMPUTER SYSTEM

Name of Item: Computer System	**Protocol No**.:........................
Functional Area: IT	**Page No.:** 7 of 15

Sr. No.	URS ID	DESCIRPTION	Related IQ Test	Related OPQ Test	Comments/ Remarks
8.	7.1.8	The System/ Software should provide the facility to creation of new user account.	NA	Test No. 13.1& 13.2	Found Satisfactory.
9.	7.1.9	The Software should not allow to create duplicate user account.	NA	Test No. 13.1& 13.2	Found Satisfactory.
10.	7.1.10	The Software should provide the facility to Modification in user account.	NA	Test No. 13.1& 13.2	Found Satisfactory.
11.	7.1.11	The System/ Software should not allow user to login without correct combination of User Name/ ID and Password.	NA	Test No. 13.1& 13.2	Found Satisfactory.
12.	7.1.12	The System/ Software must mask password entry.	NA	Test No. 13.1& 13.2	Found Satisfactory.
13.	7.1.13	The System/ Software should allow administrator to reset user account.	NA	Test No. 13.1& 13.2	Found Satisfactory.
14.	7.1.14	The System/ Software should provide the facility to Delete/ Disable/ Remove user accounts.	NA	Test No. 13.1& 13.2	Found Satisfactory.
15.	7.1.15	The System/ Software should be locked after pre-defined time.	NA	Test No. 13.1& 13.2	Found Satisfactory.

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TRACEABILITY MATRIX OF COMPUTER SYSTEM

Name of Item: Computer System	**Protocol No**.:........................
Functional Area: IT	**Page No.:** 8 of 15

Sr. No.	URS ID	DESCIRPTION	Related IQ Test	Related OPQ Test	Comments/ Remarks
	7.2	**User Role/ Authorization Control Requirements**			
	7.2.1	**Application Software**			
16.	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	NA	Test No. 13.1& 13.2	Found Satisfactory.
17.	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.	NA	Test No. 13.1& 13.2	Found Satisfactory.
	8.0	**TECHNICAL REQUIREMENTS**			
	8.1	**Hardware Requirements**			

TRACEABILITY MATRIX OF COMPUTER SYSTEM					

Name of Item: Computer System   **Protocol No**.:........................

Functional Area: IT

18.	8.1.1	Client Station Specifications	Test No. 11.1	NA	Found Satisfactory.

Sr. No.	URS ID	DESCIRPTION	Related IQ Test	Related OPQ Test	Comments/ Remarks
8.2		**Software Requirement**			
19.	8.2.1 – 8.2.3	Client system - Application Software	Test No. 11.1	NA	Found Satisfactory.
8.3		**Environmental Conditions**			
20.	8.3.1	Operating temperature (˚C)	Test No. 11.1	NA	Found Satisfactory.
21.	8.3.2	Operating Relative humidity (%)	Test No. 11.1	NA	Found Satisfactory.
8.4		**Electrical Supplies**			
22.	8.4.1- 8.4.2	Workstation System	Test No. 11.1	NA	Found Satisfactory.

TRACEABILITY MATRIX OF COMPUTER SYSTEM

Name of Item: Computer System	**Protocol No**.:........................
Functional Area: IT	**Page No.:** 10 of 15

Sr. No.	URS ID	DESCIRPTION	Related IQ Test	Related OPQ Test	Comments/ Remarks
8.5		**Communication/ Power Failure and Recovery**			
23.	8.5.1	Communication failure indication should be displayed in the software.	NA	Test No. 13.1& 13.2	Found Satisfactory.
24.	8.5.2	After reestablishing the communication, the set parameters/ process activity should remain unchanged. OR No any error message shall display.	NA	Test No. 13.1& 13.2	Found Satisfactory.
25.	8.5.3	In case of power failure, system should be normally start after power resume	NA	Test No. 13.1& 13.2	Found Satisfactory.
26.	8.5.4	In case of power failure; Method Parameters / sequence should not be affected.	NA	Test No. 13.1& 13.2	Found Satisfactory.
9.0		**OPERATIONAL / FUNCTIONAL REQUIREMENTS**			
9.1		**Operational Requirements**			
27.	9.1.1	• The software should be controlled by username and password.	NA	Test No. 13.1& 13.2	Found Satisfactory.
28.	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.	NA	Test No. 13.1& 13.2	Found Satisfactory.

TRACEABILITY MATRIX OF COMPUTER SYSTEM	
Name of Item: Computer System	**Protocol No**.:........................
Functional Area: IT	**Page No.:** 11 of 15

		• The Software should allow user to print the report in predefined format. • The software should generate data/report in unalterable way.			

Sr. No.	URS ID	DESCIRPTION	Related IQ Test	Related OPQ Test	Comments/ Remarks
9.2		**Functional Requirements**			
29.	9.2.1	• Software should allow authorized personnel to access the existing records.	NA	Test No. 13.1& 13.2	Found Satisfactory.
30.	9.2.2	• E-records should not be deleted by users.	NA	Test No. 13.1& 13.2	Found Satisfactory.
31.	9.2.3	• Report templates should not be editable by unauthorized users.	NA	Test No. 13.1& 13.2	Found Satisfactory.
32.	9.2.4	• The Software shall not allow to manipulate/ change any parameter in existing Batch/ Project.	NA	Test No. 13.1& 13.2	Found Satisfactory.
9.3		**Report Output Requirements**			
33.	9.3.1	• Printed report from software should be match with displayed in application software.	NA	Test No. 13.1& 13.2	Found Satisfactory.
34.	9.3.2	• Report must have the following parameters but not limited to: • Test Info • Sample Info	NA	Test No. 13.1& 13.2	Found Satisfactory.

TRACEABILITY MATRIX OF COMPUTER SYSTEM

Name of Item: Computer System			**Protocol No**.:.........................	
Functional Area: IT			**Page No.:** 12 of 15	

		• Results Data		

TRACEABILITY MATRIX OF COMPUTER SYSTEM

Name of Item: Computer System	**Protocol No**.:........................
Functional Area: IT	**Page No.:** 13 of 15

		TRACEABILITY MATRIX OF COMPUTER SYSTEM			
Name of Item: Computer System				**Protocol No**.:........................	
Functional Area: IT				**Page No.:** 14 of 15	

28.	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.	NA	Test No. 13.1& 13.2	Found Satisfactory.
35.	9.3.3	• The software should generate data/report in unalterable way.	NA	Test No. 13.1& 13.2	Found Satisfactory.
36.	9.3.4	• Report should be printable in pre-defined format.	NA	Test No. 13.1& 13.2	Found Satisfactory.

TRACEABILITY MATRIX OF COMPUTER SYSTEM					

Name of Item: Computer System	**Protocol No.**:.........................
Functional Area: IT	**Page No.:** 15 of 15

37.	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.	NA	Test No. 13.1& 13.2	Found Satisfactory.

Sr. No.	URS ID	DESCIRPTION	Related IQ Test	Related OPQ Test	Comments/ Remarks
10.0		**DATA REQUIREMENTS**			
10.1		**Audit Trail Requirements** **10.1.1 - Application Software**			
38.	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	NA	Test No. 13.1& 13.2	Found Satisfactory.
39.	10.1.1.2	The audit trail must be viewable, and can be exported in protected non-editable format.	NA	Test No. 13.1& 13.2	Found Satisfactory.
40.	10.1.1.3	The audit trail must be protected from intentional or accidental modification.	NA	Test No. 13.1& 13.2	Found Satisfactory.

TRACEABILITY MATRIX OF COMPUTER SYSTEM

Name of Item: Computer System	Protocol No.:........................
Functional Area: IT	Page No.: 16 of 15

41.	10.1.1.4	It must not be possible to modify or delete audit reports / audit trails.	NA	Test No. 13.1& 13.2	Found Satisfactory.
42.	10.1.1.5	Generated Audit Trail should be printable. Print should be in human readable format.			

Sr. No.	URS ID	DESCIRPTION	Related IQ Test	Related OPQ Test	Comments/ Remarks
10.2		**Data Backup Requirements**			
43.	10.2.1	All GxP Critical data should be backup as per procedure.	NA	Test No. 13.1& 13.2	Found Satisfactory.
44.	10.2.2	Data Backup mechanism should be available.	NA	Test No. 13.1& 13.2	Found Satisfactory.
45.	10.2.3	Backup schedule should be available	NA	Test No. 13.1& 13.2	Found Satisfactory.
10.3		**Data Restoration Requirements**			
46.	10.3.1	Data restoration mechanism shall be in place.	NA	Test No. 13.1& 13.2	Found Satisfactory.
47.	10.3.2	Data restoration policy should be available.	NA	Test No. 13.1& 13.2	Found Satisfactory.

		TRACEABILITY MATRIX OF COMPUTER SYSTEM			

Name of Item: Computer System | **Protocol No.**:........................

Functional Area: IT | **Page No.:** 17 of 15

Sr. No.	URS ID	DESCIRPTION	Related IQ Test	Related OPQ Test	Comments/ Remarks
12.0		**LIFECYCLE REQUIREMENTS**			
12.1		**Documentation Requirements**			
48.	12.1.1	System / Software Manual	Test No. 11.1	NA	Found Satisfactory.
49.	12.1.2	Vendor documents	Test No. 11.1	NA	Found Satisfactory.
50.	12.1.3	Application Software License Copy/ Media	Test No. 11.1	NA	Found Satisfactory.
51.	12.1.4	Training Records	NA	Test No. 13.1 &13.2	Found Satisfactory.

TRACEABILITY MATRIX OF COMPUTER SYSTEM

Name of Item: Computer System	**Protocol No**.:........................
Functional Area: IT	**Page No.:** 18 of 15

Sr. No.	URS ID	DESCIRPTION	Related IQ Test	Related OPQ Test	Comments/ Remarks
12.2		**Standard Operating Procedures**			
52.	12.2.1	SOP for Computer System Operation	NA	Test No. 14.1	Found Satisfactory.
53.	12.2.2	SOP for Change Control	NA	Test No. 14.1	Found Satisfactory.
54.	12.2.3	SOP for Access Control	NA	Test No. 14.1	Found Satisfactory.
55.	12.2.4	SOP for User Creation/Deletion/ Role and Authorization.	NA	Test No. 14.1	Found Satisfactory.
56.	12.2.5	SOP for Preventive Maintenance	NA	Test No. 14.1	Found Satisfactory.

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TRACEABILITY MATRIX OF COMPUTER SYSTEM	
Name of Item: Computer System	**Protocol No**.:.........................
Functional Area: IT	**Page No.:** 19 of 15

57.	12.2.6	SOP for Data Backup and Restoration	NA	Test No. 14.1	Found Satisfactory.
58.	12.2.7	SOP for Disaster recovery Plan and Policy	NA	Test No. 14.1	Found Satisfactory.
59.	12.2.8	SOP for Group Desktop and Security Policy	NA	Test No. 14.1	Found Satisfactory.
60.	12.2.9	SOP For Training and Evaluation	NA	Test No. 14.1	Found Satisfactory.

9.0   CONCLUSION:

As a result, it is concluded that Computer System and Application Software as mentioned in this report, has been passed in accordance with the requirement of validation plan and can be used in operational / production environment by suitable trained and authorized business personnel.

10.0   ABBREVIATIONS:

ABBREVIATION	FULL FORM
VA	Validation Agency
CSV	Computer System Validation
IQ	Installation Qualification
RTM	Requirement Traceability Matrix
OPQ	Operational and Performance Qualification
URS	User Requirement Specification
ID	Identification
CC	Change Control

TRACEABILITY MATRIX OF COMPUTER SYSTEM	
Name of Item: Computer System	**Protocol No**.:........................
Functional Area: IT	**Page No.:** 20 of 15

ABBREVIATION	FULL FORM
CFR	Code of Federal Regulations
GAMP	Good Automated Manufacturing Practices
GDP	Good Documentation Practices
GxP	Generic acronym for pharmaceutical regulations Good Manufacturing Practice (GMP), Good Laboratory Practice(GLP) & Good Clinical Practice (GCP)
QA	Quality Assurance
IT	Information Technologies
No.	Number
cGMP	Current Good Manufacturing Practices
NA	Not Applicable
Sr. No.	Serial Number
Ref.	Reference
TM	Traceability Matrix
SOP	Standard Operating Procedure
VP	Validation Plan
SQL	Structured Query Language
DNS	Domain Name System
ICH	International Council for Harmonization
EU	European Union
CFR	Code of Federal Regulations
N/A or NA	Not Applicable