



PHARMA DEVILS

IT DEPARTMENT

OPERATIONAL & PERFORMANCE QUALIFICATION FOR COMPUTER SYSTEM

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Instrument Name	Computer System
System ID.
System Used For	High Pressure Liquid Chromatography
Make	Waters
HPLC ID.
Application Software Type	Chromatographic <input checked="" type="checkbox"/> Non Chromatographic <input type="checkbox"/>
Application Software	Empower
Software Version	3.0
Make	Waters
System Type	New System <input type="checkbox"/> Existing system <input checked="" type="checkbox"/>
Location	Instrument Room



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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.				
QUALITY ASSURANCE				



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3.0 PURPOSE:

This document covers the Operational and Performance Qualification for the Computer System and Software for HPLC installed. The purpose of this document is to properly document and evidence that the Instrument installation has been done in accordance with the given specifications and is operating as desired.

4.0 SCOPE:

Scope of this document is to record and report the execution of OQ an PQ (Collectively OPQ) of the computer system and Software as per there operations in Quality Control, Production and Documentation.

5.0 DESCRIPTION:

The Operational and Performance Qualification (OPQ) execution; verifies that the Instrument, and its ancillary systems or Sub-Systems and Installed Application Software have been operating and Performing in accordance with the Requirements and specifications. It further details a list of all the cGMP requirements that are applicable to this particular Operational and Performance qualification. These requirements must be all satisfied before the OPQ can be completed
The Operational and Performance qualification (OPQ) is a collection of test cases used to verify the proper functioning status of a system. OPQ is majorly performed in case of:

- a. New Installation (When there is fresh installation of Hardware/Software or both)
- b. Existing system (When Hardware/ Software is already Installed and running properly)
- c. Change in Location of the system (When Hardware is shifted from initially installed location to new location according to approved change control procedure.

This Document covers the reports of OPQ for Existing System.

6.0 REFERENCES:

- a. Good Automated Manufacturing Practices (GAMP)-5 Guidelines (This guideline is the latest, upto date thinking in the approach to validation of GxP computerized system.
- b. EU GMP Annexure-11(Annex. -11 is part of European GMP Guidelines and defines the terms of references for computerized systems used by the organizations in the pharmaceutical industry.



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- c. 21 CFR Part 11 (Title 21 CFR Part 11 is the part of Title 21 of the Code of Federal Regulations that establishes the United States Food and Drug Administration (FDA) regulations on electronic records and electronic signatures (ERSE).
- d. Who Guidelines on Validation- Appendix 5 Validation of Computerized Systems.

7.0 RESPONSIBILITIES:

Department	Responsibility
Engineering and IT	Review of OPQ Document. Verification of OPQ test. Provide support required during operational qualification.
Quality Assurance	Review and approval of OPQ document. Verification of OPQ tests.
Consultant	Prepare OPQ Document and Performing OQ tests as per OPQ Document.

8.0 DEFINITIONS:

Term	Definition
Actual Result	What a system does when a particular action is performed
Deliverable	A tangible or intangible object produced as a result of project execution, as part of an obligation. In validation projects, deliverables are usually documents.
Deviation	When a system does not act as expected
End-User	A person who uses the validated system
Expected Result	What a system should do when a particular action is performed
Installation Qualification	Establishing confidence that process Instrument and ancillary systems are compliant with appropriate codes and approved design intentions, and that manufacturer recommendations are suitably considered. In practice, the installation qualification is the executed test protocol documenting that a system has the necessary prerequisite conditions to function as expected.
Operational Qualification	Establishing confidence that process Instrument and sub- systems are capable of consistently operating within stated limits and tolerances. In practice, the operational qualification is the executed test protocol documenting that a system meets the defined functional requirements, or that the system does what it's supposed to do.
Performance Qualification	Establishing confidence that the process Instrument and sub- systems are capable of consistently performing well within the specific requirements. In practice performance qualification is the executed test protocol documenting that system meets the defined performance requirements, or that the system perform as it supposed to do.



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Term	Definition
Protocol	A collection of Test Cases, used to document the testing of a system.
Qualification	A testing protocol which designates that a system meets a particular collection of requirements. An Installation Qualification ensures that a system has been properly installed. An Operational Qualification demonstrates that a system functions as expected in a controlled environment. A Performance Qualification verifies that a system works under real-life conditions.
Quality Assurance	Members of the organization who are tasked with ensuring the quality of materials produced at that organization. GxP organizations are required to have robust and independent Quality Assurance operations. Depending on the organization, this group may be titled Quality Control or Quality Organization; other organizations have multiple groups dedicated to quality with their own distinct missions.
Requirement	Something a system must be able to do
Retrospective Validation	Validation of an existing system. Retrospective validations are usually performed in response to a new need for a system to be compliant or an identified gap in GxP compliance.
Specification	A document outlining the requirements for a system. Specifications are usually subdivided into User Requirements Specifications, Functional Requirements, and Design Specifications.
System	Object or process undergoing validation. In these pages, system is intended to be a generic term, meaning computer system, Instrument, method or process to be validated.
System Owner	The individual who is ultimately responsible for a system.
Test Case	A documented procedure, used to test that a system meets a particular requirement or collection of requirements.
Test Plan	A general testing methodology established to ensure that a system meets requirements. A Test Plan can also refer to the collection of protocols or qualifications used to test and document that a system meets requirements.
Test Step	An individual line of a Test Case. Each Test Step should include instructions, an expected result, and an actual result.
Traceability	The ability to ensure that requirements outlined in the specifications have been tested. This is usually recorded in a Requirements Traceability Matrix.



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Term	Definition
Validation	A documented process, testing a system to demonstrate and ensure its accuracy, reliability, and consistent intended performance.
Validation Package	A collection of documents produced during a validation project.

9.0 EXECUTION INSTRUCTIONS:

Completion of OPQ will governed by the following procedures:

- 9.1 Prior to starting any test case, the individual(s) involved must be trained on the particular test case(s) and any other procedure required in executing the test case(s).
- 9.2 Within the exception of the protocol approvers, each person who performs or reviews any section of the tests within this document must complete/verify all information required.
- 9.3 All tests that are require the person executing the protocol make comparison, Calculation or a Judgment of satisfactory completion, will Include “Pass” or “Fail” column. This section will require the person executing the protocol to enter a disposition of each test or test step ass appropriate.
- 9.4 If during the execution of the protocol Deviation occur it shall be documented and appropriate corrective action shall be taken as per the predefined procedure for handling of Deviations.
- 9.5 Any comments regarding test Case(s) shall be recorded on the test sheet under the comments section. If there is no comment, the comments shall be marked as NA for “Not Applicable”.
- 9.6 The “Reviewed by” signature line will be signed by an independent Reviewer who has read and agrees the respective test case execution and conclusion.
- 9.7 All protocol entries will be completed using indelible Blue or Black Ink Pen.
- 9.8 General acceptance criteria:

If all the test case meet the acceptance criteria, the test case is successful and it passes. If a test case does not meet expected results, a deviation document will be created, an investigation will be conducted to determine cause of failure, and after the proper deviation form and corrective action(s) are completed, the test may be repeated if required. The Re-Test data must also be included as an attachment to the referenced Deviation form. If the corrective actions and re-tests fail then the protocol approvers may consider and Qualification effort as failed and will determine other actions necessary to address the impact of the failure; e.g., immediate halt on the use of the Instrument, additional characterization and re-design, further investigation of root cause(s) etc. For closure of the protocol, all the test cases must be successfully completed and all deviations must be addressed and resolved. Once these steps have been accomplished, the OPQ will be considered completed and closed.



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10.0 OPERATIONAL AND PERFORMANCE QUALIFICATION:

- a. **Test Purpose:** The purpose of this test is to verify operation and Performance of the computer system and Installed Application Software.
- b. **Test Method:** Record the results in the appropriate row of the test table. Where possible, screen shots and other documented evidence may be included as supporting evidence and attached to the test protocol and marked with the appropriate protocol number.
- c. **Acceptance Criteria:** All the expected results must match the actual results for each test step.

10.1 Test Table:

S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
1.	OPQ pre requisites Verification	All OPQ Pre-Requisites are completed successfully and fully approved.	Computer system with properly implemented Desktop and Security policy for Computer system and Installed Application Software shall be available.		
2.	Users Training Verification	All personnel operating the system and Installed Application Software shall meet training requirements.	Only properly trained and authorized personnel shall be allowed to operate System and Application Software.		



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S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
3.	Process Procedures Compliance Verification	Site procedures must be approved and adequate to allow trained Users and/or personnel to consistently perform the operations in accordance with the specified procedures.	Different procedures for training and operation of system shall be Available, Approved and Implemented.		
4.	Worst case challenge test of Disaster Management	System shall have properly defined and operating as required to handle Worst cases.	Procedures to handle worst case shall be available in place.		

Acceptance criteria:

- The Documents listed in the test result sheet should be available, readable and complete.

Actual result meets acceptance criteria:

- (Yes/No) _____

Tests performed By:

Date

Sign

Consultant

Tests Reviewed By:

Date

Sign



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Comments / Deviations:		

11.0 RECORDED VERIFICATIONS DURING OPERATIONAL AND PERFORMANCE QUALIFICATION:

a. **Test Procedure:** The purpose of this section of report is to record data in the test table of OPQ and is intended to:

- **Computer System Qualification:**
 - ❖ Computer System Bootup Check
 - ❖ Date and Time Check
 - ❖ Hard Disk Check
 - ❖ Print Drive Check
 - ❖ Network Connection Test
 - ❖ Software Version Check
 - ❖ Program alteration Check
- **Software Qualification**
 - ❖ Application Software Configuration
 - ❖ User Authentication and Access Control Check
 - ❖ Password log management
 - ❖ Number of password check
 - ❖ Failed login detection



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- ❖ User lockout function
- ❖ Failed login log check
- ❖ User access right control
- ❖ Password Expiry availability check

- b. Test Method:** Record the results in appropriate row of the test table. Where possible, Screen shots or other documented evidence may recorded as the supporting evidence and attached to this document with appropriate document number and other sequential information.
- c. Acceptance criteria:** Expected results must match the actual results for each test step.



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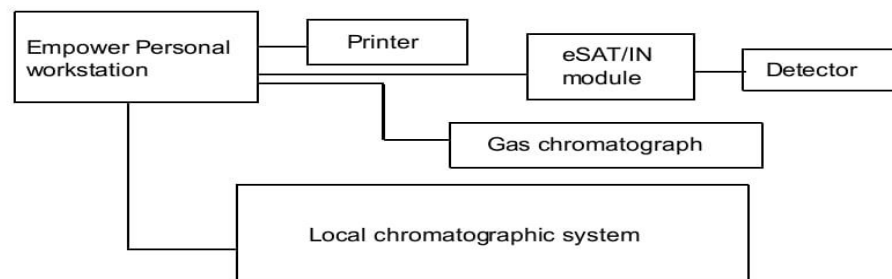
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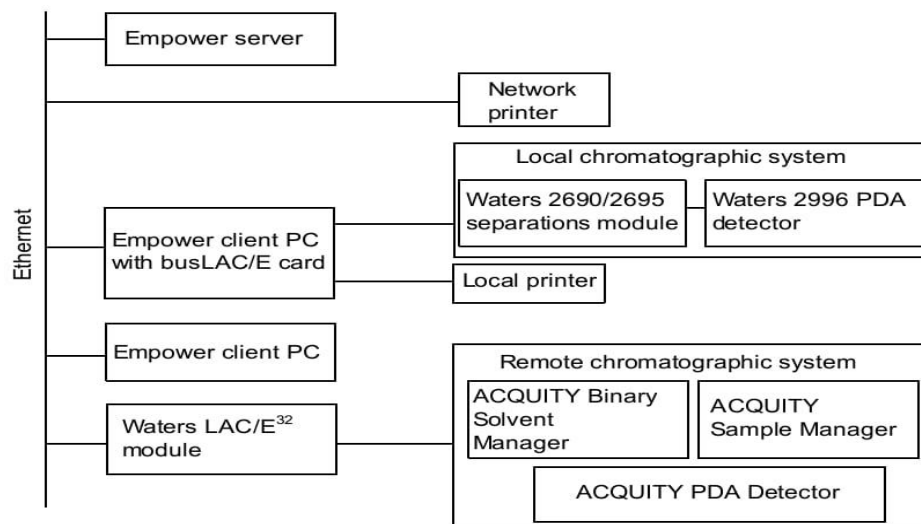
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The following figures show typical Empower Personal workstation and Empower Workgroup system or Enterprise client/server configurations.

Typical Empower Personal workstation configuration:



Typical Empower Workgroup system or Enterprise client/server configuration:





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SOFTWARE CONFIGURATION FOR EMPOWER SOFTWARE

13.1 TEST DATA TABLE TO RECORD VERIFICATIONS DURING OPERATIONAL AND PERFORMANCE QUALIFICATION:

13.1.1 COMPUTER SYSTEM QUALIFICATION (Work Station software) Operating System

S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
1.	Verification of Startup and Shutdown procedure of computer system.	Start main supply	System shall start and shutdown Normally as per the defined procedure. No adverse alarms/ or messages shall be indicated on the Desktop Screen.		
		Press the power button of Laptop.			
		Logon screen will appear.			
		Enter correct Username and Password			
		Desktop screen will Appear			
		Close all running programs			
		Click Start Icon on the screen and command for shutdown.			
		Ensure all Lights are off.			
		Power off Monitor			
Switch off from the main supply					
2.	Verification of Operating System security.	To login to the computer enter incorrect login ID and password	System Should not allow Login without correct user ID and Password. Error Message shall be displayed.		



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S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
		To login to computer enter Correct login ID and password.	System shall allow login.		
3.	Verification of Operating System Password policy Challenge test.	Login with existing User Account and change the password with less than defined password length.	Error Message shall be displayed on the screen.		
		Login with existing User Account and change the password with More than defined password length. (Without Numbers)	Error Message shall be displayed on the screen.		
		Login with existing User Account and change the password with More than defined password length. (Without special Character)	Error Message shall be displayed on the screen.		
		Login with existing User Account and change the password with More than defined password length. (Without Alphabets)	Error Message shall be displayed on the screen.		
		Try to login with incorrect username and password for more than account lockout threshold.	Error Message shall be displayed on the screen. Access shall be locked.		
		Login with username and password and leave the system on standby for more than Defined Time	User shall signed out automatically after Defined Lockout Time.		



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S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
		Login with existing user account and change the password same as previous password.	Error Message shall be displayed on the screen.		
		Login with existing user account and change the password same as username.	Error Message shall be displayed on the screen.		
4.	Verification of Desktop Policy	SOP for Desktop policy shall be available and implemented	SOP for desktop Policy shall be available and Implemented.		
		Access to USB storage device shall not be available to user.	Access shall not be granted and error message shall be displayed on screen.		
		Task Manager Shall Not be Accessible to user through Ctrl+Alt+Delete key.	Task Manager shall not be available.		
		Task Manager shall not be accessible to user from task bar.	Task Manager shall not be available		



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S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
		User Shall Not be able to open Control panel.	Control Penal Shall not be assessable. To user.		
		Security policies shell not be accessible to User.	Shall not be assessable to user.		
		CMD shall not be accessible to user.	Error Message shall be displayed on screen.		
		Registry Editing shall be disabled to user.	Error Message shall be displayed on screen.		
		Event logs for application shall be enabled.	Event logs for application Shall be available.		
		Event logs for security shall be enabled.	Event logs for Security Shall be available.		



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S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
		Event log for system shall be enabled.	Event logs for System Shall be available.		
		Map network drive shall be disabled.	Map Network Drive feature shall be disabled.		
		There should be no access to Excel, MS Word, or Adobe editor in system attached to analysis Instrument, But Adobe Viewer Can be available for system used for document Purpose.	Limited Access granted for documentation purpose		
5.	Verification of Date and Time check.	Login with user Id and password and try to change set date and time of the computer system.	User shall not change Date and Time in system.		
6.	Verification of Hard disk.	Login with user ID and try to change Or delete Name, disk Space and Partition of system.	Error message shall appear access is denied.		
7.	Verification of Print drive.	Print something using installed print drive and verify that same print is printed by the Instrument.	Printer is not installed.		
8.	Network Connection Test	System shall be connected to LAN of Authorized server.	System shall be connected to LAN if required so.		



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S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
9.	Software version Check	All latest and updated and licensed Software shall be used.	As per requirement latest software shall be available		
10.	Verification of Network connection.	System shall be connected to authorize Network only.	Only Authorized network is allowed.		
11.	Verification Of Desktop Policy.	SOP for desktop policy shall be available and implemented.	SOP shall be available and implemented.		
12.	Verification of Antivirus Installed.	Check status of all the installed software.	Latest, updated and licensed Software shall be used.		
13.	Verification of Access to USB storage device.	Login with user ID and password and insert USB storage device.	Access shall be denied.		
14.	Program alteration test.	Login with user ID and password and try to alter predefined settings in drives and programs of operating system.	Access to drive having OS installed is it shall not be available to user.		
15.	User Authentication and access control check	Local computer policy/Computer configuration /windows settings/Security Settings/Local Policies/User rights assignment.	Only Administrator shall have access to Local computer policy and other information.		



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S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
16.	Password log management Function check	Password policy shall be available to manage system security.	Password Policy shall be implemented.		
17.	Password Complexity Check	Password complexity shall be enabled in System policy.	Password complexity shall be enabled.		
18.	Maximum Password Age	Maximum Age for a password after which it will be expired shall be defined.	Maximum Password age shall be defined.		
19.	Minimum Password Length	Minimum password length shall be defined below which new or change password is not accepted.	Minimum Password age shall be configured.		
20.	Failed login detection Check	Policy for Failed Login detection shall be enabled in system policy.	Policy shall be enabled.		
21.	User lockout function test.	Policy for user Lockout after certain failed login attempts shall be enabled.	Policy shall be enabled		
22.	Account Should Lockout after Defined Invalid login Attempts.	It shall be defined that after how many failed login attempts Account shall be locked out.	Policy shall be enabled		
23.	User access rights check	Access rights for user shall be configured.	Rights shall be configured.		
24.	Password expiry alarm test	Password expiry period shall be defined.	Password expiry policy shall be defined.		



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S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
25.	System policy function check	System User Desktop policy shall be available.	Local system policy shall be enabled.		
26.	The System should provide the facility to create new Users.	Provision to create new user should be available.	System Administrator shall be allowed to create New User as per requirement.		
27.	The system should not allow user to Login without correct combination of User ID. And Password.	Correct Combination of User ID and Password should be required to login.	Login access shall not be granted without Correct combination of User ID and Password.		
28.	The System should allow Administrator to reset user Account	System Administrator should be allowed to reset user account.	Administrator should be allowed to reset user account.		
29.	The system should provide facility to Delete Disable/Remove user Accounts.	Facility to Delete/Disable/Remove user account should be available.	Administrator should have right to Delete/Disable or remove user account.		



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13.1.2 COMPUTER SYSTEM QUALIFICATION (System Application Software):

S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
1.	Name of Software	Empower developed by Waters	Empower developed by Waters	Empower	
2.	Software Version	3.0	3.0	3.0	
SOFTWARE CONFIGURATION					
System Security					
3.	Unique User Account Name	Unique user Account Name should be available for Each User	Each user shall have unique user ID.		
4.	Unique User Password	Unique user Password Should be provided to each user.	Each user should have unique user password.		
5.	Password Expiry	Password Expiry period should be defined for users.	Password expiry duration shall be		



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S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
			implemented as per defined policy		
6.	Limited Entry Attempts	Limited entry attempts should be enforced.	User should be allowed only limited login attempts after which account should lockout itself as per the defined policy/		
7.	Minimum Password length	Minimum Password length for login shall be Implemented.	System should not except change password below defined Password length.		
8.	New User creation	Software should allow should provide the facility to New User Creation.	Facility should be available.		
9.	Duplicate User Account	Software should not allow duplicate user account.	Should not be allowed.		
10.	Modification of User account	Software should have facility to Modify User Account	Facility Should be available		
11.	Login without Correct combination of user ID and Password.	Software should not allow user to Login without Correct Combination of User ID and Password.	Login should not be allowed to without correct Combination of User ID and Password.		
12.	Reset User Account	Software should allow Administrator to Reset User Password.	Should Be allowed.		



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S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
13.	Delete/Disable or Remove User Accounts.	Software should allow Administrator to Delete/ Disable or Remove User Accounts.	Should be allowed		
14.	Software Lockout	Software should lockout after Pre defined Time	Provision should ne available.		
15.	Software Configuration and usage	User Management and for acquiring, processing, reporting, and managing chromatographic information.	User Management and for acquiring, processing, reporting, and managing chromatographic information.		
16.	Software GxP Status	Shall comply with Software Category 4.	Software Category 4		
17.	User Authentication and Access Control Check	User Access Levels are available	Clearly Defined Access levels shall be available.		
18.	Password Log Management	Check Password Policy, Expiry, and complexity.	Well implemented Password policy, Expiry and complexity shall be available.		
19.	Number of Password Check.	System Should Not Accept Last Three Passwords during Password Check.	Policy shall be implemented.		
20.	Failed Login detection	Try to access Software with Wrong User ID and Password.	Error Message shall be generated for failed login.		



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S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
21.	User Lockout Function	In case system is idle for certain period as defined in Policy. System should Lockout automatically and Password shall be required to login into the system Again.	System shall Lockout automatically if Idle.		
22.	Failed Login Log Check	System Shall keep Log for all the Failed Login Attempts.	Log for Failed Login Attempts shall be Available in System.		

USER ROLE / AUTHORIZATION CONTROL

23.	User Management	Application Software must support at least the following user roles but not limited to: <ul style="list-style-type: none"> ➤ Administrator ➤ Reviewer ➤ Analyst 	User roles as per requirement should be available.		
24.	User Access Rights Control.	Well defined assess Rights shall be available. And user is not allowed to assess Rights of admin level.	User is not allowed access rights of other Higher Levels.		

TECHNICAL REQUIREMENTS

Communication/ Power Failure and Recovery



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S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
25.	Communication Failure	<p>Communication failure indication Should be displayed in the screen.</p> <p>After re-establishment of communication, the set parameters/ Process activity .Should remain unchanged or No Any Error Message shall be displayed.</p>	<p>Failure Indication Shall be displayed.</p> <p>No Change should be observed.</p>		
26.	Power Failure	<p>I case of Power failure, the system should start normally after power resume.</p> <p>In case of power failure, Method /Sequence should not be affected.</p>	<p>System Shall starts Normally.</p> <p>Method /Sequence should remain unaffected.</p>		

OPERATIONAL / FUNCTIONAL REQUIREMENTS

Operational Requirements

27.	Software Control	Software should be controlled by User Name and Password.	User Name and Password for user should be available.		
28.	Sample details	The software should allow user to fill sample details.	Should be allowed.		
29.	View Analysis	The software should allow user to view ongoing analysis.	Should be allowed.		
30.	View report of generated Data	The software should allow user to view generated data during analysis.	Should be allowed.		



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S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
31.	Print Report	The software should allow user to print report on pre-defined format.	Should be allowed.		
32.	Alteration of Generated data and report.	The Software should not allow alteration in Data and report generated.	Should not be allowed.		
Functional Requirements					
33.	Access to Existing Record	The Software should allow authorized personnel to access existing records.			
34.	Electronic Records	Provision of electronic records shall be available User should not be allowed to delete E-Records.	E-Records shall be available and user should not be able to delete it.		
35.	Electronic Signature	Provision of electronic Signature shall be available	E-Signature shall be available		
36.	Edit Report Templet	The software should not allow Unauthorized user's to Edit existing Report Templet.	Should not Allow.		
Report Output Requirements					
37.	Printed Report	Printed report from software should Match with displayed in Application Software.	Should Match.		
38.	Report Parameters	The Report must have following parameters but not limited to: ➤ Test Information ➤ Sample Information ➤ Result Data	Should be as per requirement.		



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S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
39.	Report Alteration	The Software should generate Data/Report in unalterable way.	Should not be altered.		
40.	Report Format	The report should be printable in Pre-Defined format.	Should Comply		
41.	Data availability for Inspection	The software should be capable of producing accurate and complete copies of electronic records in both human readable and electronic form for Inspection review and copy.	Should Comply		

DATA REQUIREMENTS

Audit Trail Requirement

42.	Software Audit Trail	System Audit trail must track the creation, modification, and deletion of records Including the Time, Date, User, and reason for the change. E.G., <ul style="list-style-type: none">➤ User logon / Logout➤ Change in parameters	Should Comply		
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S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
		<ul style="list-style-type: none"> ➤ Incorrect Login Attempts ➤ Change in user authorization of application software. 			
43.	Export of Audit Trail	The audit trail must be viewable and can be exported in protected non editable format.	Should Comply		
44.	Modification and Deletion	The audit Trail must be protected from Intentional and accidental Modification. It Must not be possible to modify or delete Audit Reports/ Audit trails.	Should Comply		
45.	Printing Audit Trail	Generated audit trail should be Printable. Prints should be in Human readable format.	Should Comply		
Data Backup Requirement					
46.	Data Backup	All GxP Critical data should be backup as per defined procedure. Data Backup Mechanism should be available.	Should Comply		
47.	Backup Schedule	Schedule for Data Backup should be available.	Should Comply		
Data Restoration					
48.	Mechanism	Data restoration mechanism shall be available.	Shall Be Available		
49.	Policy	Data restoration policy shall be available	Shall Be Available		



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Note: Detailed Validation of Empower 3 software was done by the developer at the time of installation copy of same is attached as annexure herewith.

Acceptance criteria:

- The Documents listed in the test result sheet should be available, readable and complete.

Actual result meets acceptance criteria:

- (Yes/No) _____
-

Tests performed By:	Date	Sign
Tests Reviewed By:	Date	Sign

Comments / Deviations:

14.0 VERIFICATION OF STANDARD OPERATING PROCEDURES AND POLICY:

PURPOSE:

The purpose of this section is to verify the availability of all required Standard Operating procedures (SOPs) for the computer systems.



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PROCEDURE:

- Verify that all the documents required for the computer system are found available.
- Verify availability of SOP for Computer system operation.
- Verify availability of SOP for Change Control.
- Verify availability of SOP for Access Control.
- Verify availability of SOP for User Creation /Deletion/Role and Authorization.
- Verify availability of SOP for Preventive Maintenance.
- Verify availability of SOP for Data Backup and Restoration.
- Verify availability of SOP for Disaster recovery Plan and Policy.
- Verify availability of SOP for Group Desktop and Security Policy.
- Verify SOP For Training and Evaluation.

ACCEPTANCE CRITERIA:

All the required SOPs shall be Available, Reviewed, Approved and Implemented.

14.1 VERIFICATION OF STANDARD OPERATING PROCEDURES AND DATA TABLE:

S.No.	SOP Name	SOP No.	Meet Acceptance Criteria (Yes/No)	Initial & Date
1.	SOP for Computer System Operation			



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2.	SOP for Change Control			
3.	SOP for Access Control			
4.	SOP for User Creation/Deletion/ Role and Authorization.			
5.	SOP for Preventive Maintenance			
6.	SOP for Data Backup and Restoration			
7.	SOP for Disaster recovery Plan and Policy			
8.	SOP for Group Desktop and Security Policy			
9.	SOP For Training and Evaluation			

Acceptance criteria:

- The Documents listed in the test result sheet should be available, readable and complete.



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Actual result meets acceptance criteria:

- (Yes/No) _____

Tests performed By:

Date

Sign

Tests Reviewed By:

Date

Sign

Comments / Deviations:

15.0 DISCREPANCY REPORT:

15.1 Discretion Of Deficiency and its Classification:



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S.No.	Discrepancy/ Deficiency	Category

15.2 Recommended Corrective Action Plan And Person Responsible:



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S.No.	Discrepancy/Deficiency	Responsibility	Category

Initiated By
(Sign and Date)

User Department
(Sign and Date)

I.T.
(Sign and Date)

Quality Assurance
(Sign and Date)



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15.3 Corrective Actions Taken:

Sr. No.	Corrective Action	Sign	Date

Closure Remarks: Allowed/ Not Allowed to Proceed Further

Reviewed and Approved by Projects:

Reviewed and Approved by Quality Assurance:



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16.0 ACCEPTANCE CRITERIA:

Installation and Operational Qualification shall be considered acceptable when actual result/ observed results of all the conditions specified in various data sheets as mentioned prior in this document matches with corresponding expected results.

Any deviation from the acceptance criteria of the specific check point shall be reported and decision should be taken for the rejection, replacement or rectification of the computer system.

17.0 SUMMARY:

All the installation and Operational Qualification tests for computerized system are performed as per written procedures and protocols. The results observed during complete process are recorded and reviewed.

Observed results are found meeting acceptance criteria. During execution no discrepancies were found.

18.0 CONCLUSION:

The computer System Hardware and Operating System are tested and verified as per the guidelines described in this document on the basis of approved protocols and other corresponding references.

The computer system stands **Qualified** as per the tests performed and observed results therein.



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19.0 ABBREVIATIONS:

Acronym	Description
°C	Degree Celsius
21 CFR 11	Code of Federal Regulations, Title 21, Part 11 contains regulations with regards to electronic records and signatures
AC	Alternating Current
ALU	Arithmetic and Logical Unit
AMD	Advanced Micro Devices
API	Application Programming Interface
AuthIP	Authenticated Internet Protocol
AV	Antivirus
BIOS	Basic Input Output System
CD	Compact Disc
CFR	Code of Federal Regulations
CGI	Common Gateway Interface
CGMP	Current Good Manufacturing Practices
CMOS	Complementary Metal-Oxide Semiconductor
CPU	Central Processing Unit
CSV	Computer System Validation



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Acronym	Description
DC	Direct Current
DMI	Direct Media Interface
DVD	Digital Versatile Disc
GAMP	Good Automated Manufacturing Practices
GMP	Good Manufacturing Practices
ID	Identification
IQ	Installation Qualification
NA	Not Applicable
OPQ	Operational and Performance Qualification
OS	Operating System
PC	Personal Computer
RAM	Random Access Memory
PH	Relative Humidity
SOP	Standard Operating Procedure
TCP/IP	Transmitted Control Protocol/ Internet Protocol
UPS	Uninterrupted Power Supply
V	Volts
VAC	Volts Alternating Current
VDC	Volts Direct Current



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21.0 DOCUMENT POST 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.				



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QUALITY CONTROL				
Approved by: M/s.				
QUALITY ASSURANCE				