INSTALLATION QUALIFICATION FOR COMPUTER SYSTEM

Name of Item: Computer System	**Protocol No**.:.....
Functional Area: IT	**Page No.:** 1 of 7

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

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				

TABLE OF CONTENTS

2.0 PURPOSE:

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

3.0 SCOPE:

Scope of this document is to record and report the execution of IQ of the computer systems and Software as per there operations in Quality Control, Production and Documentation.

4.0 DESCRIPTION:

The Installation Qualification (IQ) execution; verifies that the Instrument, and its ancillary systems or Sub-Systems have been installed in accordance with installation drawings and specifications. It further details a list of all the cGMP requirements that are applicable to this particular installation qualification. These requirements must be all satisfied before the IQ can be completed and the qualification process is allowed to progress to the execution of OQ.
The Installation and Operational qualification (IOQ) is a collection of test cases used to verify the proper functioning status of a system. IOQ 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.

NOTE: This Document covers the reports of IQ for Existing System.

5.0 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.

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.

6.0 RESPONSIBILITIES:

Department	Responsibility
Engineering, Information Technology, Quality Control.	Review of IQ Document. Verification of IQ test. Provide support required during operational qualification.
Quality Assurance	Review and approval of IQ document. Verification of IQ tests.
Consultant	Prepare IQ Document and Performing IQ tests as per IQ Document.

7.0 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.
Protocol	A collection of Test Cases, used to document the testing of a system.

Term	Definition
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 sub-divided 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.

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.

8.0 EXECUTION INSTRUCTIONS:

Completion of IOQ will governed by the following procedures:

8.1 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).

8.2 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.

8.3 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.

9.1 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.

9.2 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”.

9.3 The “Reviewed by” signature line will be signed by an independent Reviewer who has read and agrees the respective test case execution and conclusion.

9.4 All protocol entries will be completed using indelible Blue or Black Ink Pen.

9.5 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 IOQ will be considered completed and closed.

9.0 INSTALLATION QUALIFICATION:

a. **Test Purpose:** The purpose of this test is to verify the hardware and software installed in the computer system used for HPLC.

b. **Test Method:** Record results in the appropriate row of the following table. Where possible, screenshots or other documented evidence may be included as supporting evidence and attached to this document with appropriate document number and other sequential information.

c. **Acceptance Criteria:** All the expected results must match the actual results for each test step.

9.1 TEST TABLE:

S.No.	Test Step	Expected Results	Actual results	Pass/Fail	Reference
1.	Pre Requisites verification.	All IQ Pre-Requisite items are completed successfully and fully approved.	System used for HPLC is installed as per URS and Approval for all the Pre-Requisite is successful and fully approved.		Protocols And Validation Plan
2.	Manuals and Technical Documents	All required manuals and technical documentation relating to the computer system	All manuals and Technical Information related to Hardware, Operating system, and installed software found available for the system.		SOP for Operation Of Computer System.
3.	System Instrumentation verification	Each of the identified system instrumentation components has been installed and range / resolution, manufacturer and model no. meet specification.	After running system information Software, all system instrumentation Components found installed within predefined range/ resolution. Manufacturer and model no information. Meets the specification.		Report of System Information Software. Annexure-I

S.No.	Test Step	Expected Results	Actual results	Pass/Fail	Reference
4.	Preventive maintenance, spare and significant Parts List Verification	The Instrument shall be included on the site PM system record and have been maintained as per schedule. Recommended spare parts and significant parts list are included in the PM system record.	Schedule for Preventive Maintenance and record for the same and list of all the recommended spares found available.		
5.	Software/Hardware computer Installation	The Software and Hardware installed meets the design specifications and are under change control.	All the genuine Software and Hardware used in the System are as per Pre –Defined Specifications as per URS. And are under change control.		
6.	Security Verification	User Shall not Access the system configuration. System is properly password protected.	Access to system is properly password protected, User cannot access to configuration of the System, Only Administrator have the rights to do so.		
7.	Loss of Utility Verification	Upon loss and restoration of utility the Instrument will respond as expected. When the utility is restored, the Instrument /system will retain critical parameters or settings and return to a pre-defined safe state or in the event where parameters change, procedures are in place to	Upon Loss and Restoration of Utility. The Instrument will respond as expected as the backup policy is applied.		

S.No.	Test Step	Expected Results	Actual results	Pass/Fail	Reference
		address recovery of operational parameters.			
8.	Alarms, Interlocks and Safety Ergonomics Verification	Safety and ergonomics assessment form has been completed and approved. Alarms/ Interlocks/ and Safety functions meet design specification.	Safety Ergonomics assessment form is completed and approved. Safety functions meets the design specifications.		
9.	Sequence of Operations	The sequence operation Meets the design specification.	Sequence of Operations meets design specifications		

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:

10.0 RECORDED VERIFICATIONS DURING INSTALLATION QUALIFICATION:

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

- Describe the system to be validated.
- Verify and document that each major /Critical component is installed as specified.
- Measure and record temperature and humidity of the room where the computer system is installed.
- Verify that the electrical utility has been installed and is available as specified/Required.
- Verify physical and logical security available in the Computer System and Installed Software.
- Verify that the operating system software, antivirus software and other required software are installed in the computer system.
- Verify user operation training record.

b. Test Method: Record the results in the appropriate row of test table, where possible, screenshots or other documented evidence may be included as supporting evidence and attached to this document with appropriate document number and other sequential information.

c. Acceptance Criteria: All expected results must match the Actual result.

10.1 TEST STEPS: Hardware, Software and Documentation requirement.

S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
1.	Clint Station Identification	Computer Name	.....		
		Location of System	INSTRUMENT ROOM		
		Purpose of system	For HPLC		
		Manufacturer	Hewlett-Packard		
		User	Administrator		
2.	Verification of System Hardware and Interface Components	Computer Type	Desktop PC		
		CPU Type	Intel Core i5-8500 @ 3.00GHz		
		Motherboard Name	.....		
		System Memory/ Type/Speed	8+8 GB/ DDR4 SDRAM/ 1333.3 MHz		
		Monitor	Compaq 8191		
		Keyboard	.....		
		Mouse	HP USB Optical Mouse		
		Drive Capacity	Toshiba DT01ACA100 1000GB/7200 RPM		
		Primary IP Address	.....		
		BIOS Version	DMI Based Version 3.2		
		Wake-Up Type	Normal		

PHARMA DEVILS

IT DEPARTMENT

INSTALLATION QUALIFICATION FOR COMPUTER SYSTEM

Name of Item: Computer System	**Protocol No**.:.....
Functional Area: IT	**Page No.:** 13 of 18

S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
		Boot-Up State	Secure Boot		
		Power Supply State	Ok		
		Thermal State	Ok		
		Error Detection/ Correction	Ok		
		Current Power Source	AC		
		Battery	NO		
		Battery Type	NA		
		Chassis Cooling Fan	OK		
		Power Supply Fan	OK/1559 RPM		
		Automatic Clock control	OK		
3.	Verification of System Physical and Logical Security	Physical Security	System Should be Installed in lock and key Room		
		Logical Security	System Usage Should be as per User And Administrator Level		
4.	Verification Of Operating System-Software	OS Name	Windows 10 Professional		
		OS Provider	Microsoft Corporation		
		OS Version	Microsoft Windows 64 bit OS		
		Virus/ Malware Detection software	Integrated Windows Defender		
5.	Verification of User Training Records	User Training Record For Operation	Proper Training records shall be available.		
6.	Environmental Conditions	Temperature	10°C to 25°C		
		Relative Humidity	55% ±5%		

INSTALLATION QUALIFICATION FOR COMPUTER SYSTEM

Name of Item: Computer System	**Protocol No**.:.....
Functional Area: IT	**Page No.:** 14 of 18

S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
7.	Power Utilities	Computer system Power Supply	AC 220 V		
		Earthing Voltage	Less than 3 volt.		
		Power Backup	UPS Supply Available		
HPLC SOFTWARE REQUIREMENTS					
8.	Name of Clint Application Software For HPLC	Identification of Software Used HPLC	Empower		
9.	Version No.	Identification Current Version of the Software used.	3.0		
10.	Manufactured By	Identification of Manufacturer of Software	Waters		
DOCUMENTATION REQUIREMENTS					
11.	Hardware and Software Manual	Manuals contain critical details of the Instrument and Application Software.	Manuals of Hardware , Operating System and Application Software shall be available.		
12.	Vendor Document	Purchase Order and Vendor Approval and DQ,IQ,OQ Documents.	All the documents provided by the vendor shall be available and reviewed.		
13.	Application Software License Copy /Media	Copy of genuine license of software and media in which application	All the Software used must have a current and genuine license of software shall be available along with the available along with the Media in which Software is Stored.		

S.No.	Test Step	Description	Expected Results	Actual Results	Pass/Fail
		software in available and stored.			
14.	Training Records	Training of operation of all the related users of the Instrument and Software.	Each User of the Software and Hardware shall be Trained for the operation and handling of the Computer system and applicable Software.		

Comments/Remarks:

- Data recorded from the system and room tag plates matches with the data specified in test data table.
- All the required records are available and found in place.
- Physical Installation of the computerized system is verified and details are recorded. Observed results are found satisfactory.
- The computerized system room environmental conditions measured ad found within the limit.
- Power supply to the computerized system is within the limit.
- At least Two access level groups are available to login and access the computer system and Application software.
- User training for the system operation is available.

Actual result meets acceptance criteria:

- (Yes/No) _____

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

Comments / Deviations:		

11.0 COMPUTER SYSTEM VALIDATION (Hardware and Software):

Qualification	Test	Test Result	Meet Acceptance Criteria	Initial & Date
	Verification of System Identity			
	Verification of System Documents			
	Verification of System Hardware and Interface Components			

Installation Qualification	Verification of Environmental Conditions			
	Verification of Utilities Requirements			
	Verification of System and Software Physical and Logical Security			
	Verification of Application Software Installed in System			
	Verification of User Operation Training Records			

12.0 DISCREPANCY REPORT:

12.1 Discretion of Deficiency and its Classification:

S.No.	Discrepancy/ Deficiency	Category

13.1 Recommended Corrective Action Plan And Person Responsible:

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)

13.2 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:

13.0 ACCEPTANCE CRITERIA:

Installation 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.

14.0 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.

15.0 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.

16.0 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

Acronym	Description
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
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

Acronym	Description
NA	Not Applicable
OQ	Operational 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

17.0 LIST OF SUPPORTING DOCUMENTS:

S.No.	Description of Attachment	Annexure No.	Checked By Sign. / Date

18.0 DOCUMENT POST APPROVAL:

PHARMA DEVILS

IT DEPARTMENT

INSTALLATION QUALIFICATION FOR COMPUTER SYSTEM

Name of Item: Computer System	**Protocol No**.:.....
Functional Area: IT	**Page No.:** 25 of 18

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				