



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

INSTALLATION QUALIFICATION OF COMPUTER SYSTEM

Department: Information Technology

Protocol No.

Title: Installation Qualification of Computer System

Effective Date:

Installation Qualification Report

For

Personal Computer



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1.0 Introduction:

1.1 **Purpose:** The purpose of this document is to provide documentary evidence to ensure that the Installation qualification completed successfully.

1.2 **Scope:** The scope of this document is to provide summary and details of attachments of the Performed installation qualification for PC use in Warehouse.

1.3 **Reference Documents:** SOP “Validation of GxP Computerized System”.

2.0 System Description:

The system is a PC that provides server based security and interface to the use of software connected to an analytical instrument to execute their function.

In Installation Qualification, the system is used to check proper installation of components (Hardware & Software) of the system with proper utility.

3.0 Roles & Responsibilities:

The following department personal involving in activity shall be responsible:

Roles	Responsibilities
QC/IT (Executive/Officer)	Preparation of this report
QC (Operating Manager)	Review of this report
QA (Operating Manager)	Review of this report
QA (Head)	Approval of this report

4.0 General Instruction:

4.1 Good documentation practices shall be followed during documentation.

4.2 Do not leave any blank spaces. Use NA where ever applicable.

5.0 Pre-requisite:

5.1 Annexure I “Installation Qualification Test Script for PC” should be executed.

5.2 All attachments related to execute document should be available.

6.0 Installation Qualification Strategy:

NA

7.0 Installation Qualification Procedure:

NA



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8.0 Installation Qualification Error/Incident Reporting:

8.1 The installation qualification for PC has been successfully executed and no discrepancy found during execution. All tests have been executed and evidence is captured and attached.

8.2 Overall Test Status: Pass.

9.0 Error/Incident Log:

S.No.	Test Script Number	Incident/Deviation	Description of the Incident/Deviation	Incident/Deviation Number	Status (Open/Closed)
NA	NA	NA	NA	NA	NA

10.0 Attachment/Annexure:

Attachment No.	Title
Attachment 1	Installation Qualification Test Script for PC
Attachment 2	Installation Qualification Test Script for PC

11.0 Revision History:

Revision	Revised by	Revised on	Reason for Change
00	NA	NA	NA



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12.0 Approval & Authorization:

Prepared By:

Signature indicates that this document is accurate and complete and it complies with current standards and regulatory requirement and adequately address the intended purpose and scope.

QC/IT Officer/Executive			
	Name, Designation	Signature	Date

Reviewed by:

Signature indicates that this document has been reviewed and it is accurate, complete and contains the necessary degree of detail to accomplish the intended purpose.

QC Operating Manager			
	Name, Designation	Signature	Date
QA Operating Manager			
	Name, Designation	Signature	Date

Approved by:

Signature indicates that this document complies with the computer system validation policy; and that the documentation and information contained herein complies with applicable regulatory requirements.

Head QA			
	Name, Designation	Signature	Date



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13.0 Abbreviations:

- Gxp** : Good “x” Practice, “x” means
- GEP** : Good Engineering Practice
- GMP** : Good Manufacturing Practice
- GLP** : Good Laboratory Practice
- GCP** : Good Clinical Practices
- GDP** : Good Distribution / Documentation Practice
- GCLP** : Good Control Laboratory Practice
- GCSVP** : Good Computer System Validation Practice
- GSP** : Good Storage Practice
- GTP** : Good Transportation Practice
- GAMP** : Good Automated Manufacturing Practice