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VALIDATION PROTOCOL CUM REPORT

FOR

PERSONAL COMPUTER SYSTEM (PC)

Department   :   **Information Technology**

Protocol No.   :   **xxx**

Effective Date   :

Version No.   :   **00**

Supersede   :   **Nil**

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1.0 TABLE OF CONTENT:

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2.0   REASON FOR QUALIFICATION:

Please tick the appropriate option (√):

New Installation   ☐

Requalification   ☐

Other (Please Specify)

_____   ☐

_____   ☐

_____   ☐

_____   ☐

3.0   DOCUMENT HISTORY:

Revision number	Revision details	Date of revision
00	New Protocol	--------

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4.0   PRE - APPROVAL:

The author signature indicates that this document has been prepared in accordance with **XX company** policies, standards, site – specific SOPs, existing cGMP standard and adequately reflects the tasks and deliverables necessary for qualification of Computer System.

Prepared By/ Function	Designation	Signature	Date
Information Technology			

The reviewer's signature indicates that this document has been verified and it accurately and completely reflects the tasks and deliverables necessary for qualification of Computer System and that the document and information complies with applicable standards, **XX company** policies and cGMP.

Verified By/ Function	Designation	Signature	Date
Information Technology			
Quality Assurance			

The approver's signature indicated that the documentation and contained herein complies with applicable standards, **XX company** policies and cGMP requirements.

Approved By/ Function	Designation	Signature	Date
Quality Assurance			

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5.0 OBJECTIVE:

The objective of this protocol is to define the Qualification requirements and acceptance criteria of the Computer (PC). Successful completion of Qualification requirements will provide assurance that the Computer (PC) was installed, operated and performed as required in the processing environment.

6.0 SCOPE:

The scope of this Qualification protocol is limited to the Qualification of Computer (PC) at the site of XX company Pvt Ltd., used for the GMP activity.

This Qualification protocol is part of validation activity for the Computer (PC) installed, operated and performed at XX company Pvt Ltd.

7.0 RESPONSIBILITIES:

7.1 Information Technology

➢ Shall be responsible to prepare protocol and report.

➢ Assembling the testing data into final report form for Q.A., IT and management approval.

➢ Coordinating the qualification study with the appropriate individuals and departments.

➢ Provide all related software, documents or any other data necessary related to Computer (PC) and provide support related to IT.

7.2 Engineering

➢ Ensure the supporting utility.

7.3 Quality Assurance

➢ Shall be responsible for review and approval of the protocol

➢ Guiding the qualification team using the expertise
➢ Verifying that the study test requirements are completed and prepared for management and Quality Assurance approval
➢ Providing technical assistance during the development of the qualification study and the development of the summary report
➢ Providing personnel to assist in the operation of the equipment during the execution of qualification studies

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8.0 QUALIFICATION TEAM:

Name	Company	Designation	Signature (Full)	Signature (Initials)

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9.0 METHODOLOGY:

S.No.	Tests to be performed	Responsibility
1.	Signature Identification Log	Qualification Team
2.	List of system used for GMP work	Qualification Team
3.	Verification of System Identification	Qualification Team
4.	Verification of System Documentation	Qualification Team
5.	Verification of Environmental Condition-PC	Qualification Team
6.	Verification of Power Utility	Qualification Team
7.	Verification of IT Policy	Qualification Team
8.	Verification of Access and Security	Qualification Team
9.	Verification of PC System Software, Application Software and Hardware	Qualification Team
10.	Verification of Hardware Change Control	Qualification Team
11.	Calibration Record of Standard Instruments Used During Qualification	Qualification Team

9.1 Signature Identification Log:

A signature identification log with full and initial signature shall be prepared and maintained for all the personnel involved directly or indirectly with the qualification activity. Record for the Signature identification shall be maintained as **Annexure-1**.

9.2 List of system used for GMP work:

Objective of this test is to verify the list of the system used for GMP work. Record the observation in **Annexure-2**.

9.3 Verification of System Identification:

Objective:

To describe the identification of the Personal computer (PC). Record the observation in **Annexure-3**.

Procedure:

1. Verify the following information.
    a. Computer System Identification Number
2. Physical location of the system. According to list of system used for GMP

Acceptance Criteria:

1. Actual details should be match with specified details of Computer (PC).
2. Computer (PC) should be available at the location as specified.

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9.4   Verification of System Documentation:

Objective:

To identify the availability of documents, check the accuracy of the document. Record the observation in **Annexure-4**.

Procedure:

Identification of the documents:

1. The executor will check whether following specified documents are available or not.
   a. IT Policy
   b. Personal Computer (PC) Specification
   c. Operating System License
   d. Application Software's License
   e. Antivirus License

Check the correctness of the documents:

1. The executor will identify the documents and check that the documents represent the actual installed Computer (PC).
2. The documents should be upgraded as per the latest Computer (PC) configuration.

Acceptance Criteria:

1. The listed documents shall be available.

2. The documents shall provide appropriate information for the actual installed Computer (PC).

9.5   Verification of Power Utility:

Objective:

1. To verify that the electrical utility has been installed and is available as specified.

2. To verify the availability and installation of UPS with the Computer (PC).

   Record the observation in **Annexure-5.**

Procedure:

1. Power on the System and put the multi meter in AC voltage measurement range and measure the voltage at Computer (PC) terminal end.
2. Note down the voltage reading in the test data sheet.
3. Verify the availability of UPS and record its details as specified in test data table.
4. Record the deviations if any, in the deviation report.

Acceptance Criteria:

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1. Recorded measurements for voltage should be match with the specified range.

2. UPS should be available and details should match with the specification.

9.6   Verification of IT Policy:

Objective:

The objective of this test is to verify and check the application of IT Policy on the Personal Computer (PC). Record the observation in **Annexure-6.**

Procedure:

Verify that the following IT policies and check that the policy is applied to the Computer (PC) (As per SOP IT004):
1. Password Policy
    a. Enforce Password History
    b. Maximum Password Age
    c. Minimum Password Length
    d. Password must meet complexity requirements
2. Account Lockout Policy
    a. Account Lockout threshold
3. Account Login Policy
4. Date & Time Policy
5. Mass Storage Policy

Acceptance Criteria:

The IT Policy should be available and applied on Computer (PC).

9.7   Verification of Access and Security:

Objective:

The objective of this test procedure is to verify and record the integrity of the Computer (PC) security. Testing will be performed to verify and record PC's access control. The accessibility to delete / uninstall the specific software will be verified for accuracy. Record the observation in **Annexure-7.**

Procedure:

1. Obtain IT Security Policy for accessibility of the Computer (PC).

2. Attempt to log on to the Computer (PC) with domain Users with correct & wrong password entries.

3. Log in with a specific user profile and attempt to access and delete the different user's profile.

4. Log in with a specific user and attempt to delete / uninstall specific software.

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Acceptance Criteria:

1. Domain user can only access with correct password entry.

2. Access to the Personal Computer (PC) is allowed for domain user only.

3. Software should not be deleted or uninstalled by a specific user.

9.8   Verification of PC System Software, Application Software and Hardware:

Objective:

1. To verify computer system hardware configuration.

2. To verify and record basic information of installed Operating System & Application Software**.**

    Record the observation in **Annexure-8.**

Procedure:

Hardware Configuration Details:

Verify the following information of computer hardware configuration from 'My computer' property or computer system manufacturer tag plate.

1. Name of computer system Manufacturer
2. CPU Specification
    - Computer Processor specification
    - Installed RAM (GB)
    - Hard Drive Specification.

Operating System and Application Software details:

Verify the following information of installed Operating system and Application Software.
1. Operating System Details
    - Name of operating system
    - Version number
    - Installed service pack information
    - Configured Computer name
    - Name of workgroup (if configured)

2. Application Software
    - Name of Application Software
    - Version number

Antivirus Software:

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Verify the following information of the installed antivirus software from software property (about).

1. Name of antivirus Software
2. Version number

Acceptance Criteria:

Computer (PC) system software, application software and hardware configuration should comply as specified.

For each item verified or recorded, indicate the method used in performing the verification in the "Method" column as follows:

VIS - Visual verification of actual installation
CERT -Verification through cross-referencing the manufacturer and model number with information on the manufacturer's/vendor's specification

9.9 Verification of Hardware Change Control:

Objective:

The objective of this test is to verify the change of the Hardware (Major Components) according to needs of the concerned team.

Procedure:

1. When any break down of the Computer (PC), the concerned department personnel shall raise the Service Request Memo.

2. Duly filled Service Request Memo request shall be sent to IT/Computer department. IT/Computer Engineer accepts the intimation and assigns the work to respective technical Assistance or to the outside contractor if required. Approximate date of completion is to given by engineer to the concern department to plan their activities.

3. In case the repair/rectification work is delayed beyond the specified completion date, reason for the same and further course of action shall be mentioned in the remarks column.

4. If the repair /rectification /modification call for Qualification/calibration, Engineer-IT/Computer department initiates the process.

5. Record the deviations based on corrective action / preventive action change control to be initiate.

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9.10 Calibration Record of Standard Instruments Used During Qualification:

Test Instrument	Manufacturer	Tag Number/ Model Number	Calibration Date	Calibration Due Date

10.0 Reference Documents:

S.No.	Name of the Documents	Document Number
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

11.0 List of Abbreviation:

S.No.	Abbreviations	Full Form
1.	CFR	Codes of Federal Regulation
2.	cGMP	Current Good Manufacturing Practices
3.	ID. No.	Identification Number
4.	AC	Alternating Current
5.	DC	Direct Current
6.	RAM	Read Access Memory
7.	P.C.	Personal Computer
8.	CSV	Computer System Validation

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12.0 POST-APPROVAL:

This signature indicates that this document has been compiled in accordance with **XX company**, standards, site – specific SOPs, existing cGMP standard and adequately complies with the tasks and deliverables necessary for qualification of computer system.

Compiled By/ Function	Designation	Signature	Date
Information Technology			

The reviewer's signature indicates that this document has been verified and it accurately and completely complies with the tasks and deliverables necessary for qualification of computer system and that the document and information complies with applicable standards, **XX company policies** and cGMP.

Reviewed By/ Function	Designation	Signature	Date
Information Technology			
Quality Assurance			

The approver's signature indicated that the documentation and contained herein complies with applicable standards, **XX company policies** and cGMP requirements.

Approved By/ Function	Designation	Signature	Date
Quality Assurance			

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ANNEXURE 1
Signature Identification Log

The sheet represents a record of each individual who signs or initials any page included in the Installation & Operational Qualification Protocol. Each person shall be identified by handwritten name, full signature, written initials and department represented

Name	Company	Designation	Signature	Initials	Date

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ANNEXURE 2
List of Computer System used for GMP work

The sheet represents a list of the system used for GMP work.

S.No.	Computer Host Name	Department	Remark

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ANNEXURE 3
Identification of the Personal computer (PC)

Objective:

To describe the identification of the Personal computer (PC).

Procedure:

1. Verify the following information.
    a. Computer Name
    b. Computer Identification Number
2. Also verify the physical location of the system.

References Required:

Observation:

Description	Specified	Actual Observation	Remark
Computer Name			
Identification Number			
Personal Computer (PC) Location			

If any discrepancy has been found, then explain comments in below field.

_____

_____

_____

_____

_____

_____

_____

Remark: The above-mentioned Tests **complies / does not comply** with respect to the acceptance criteria	
Performed By: (Sign/Date)	**Verified By:** (Sign/Date)

(FOR RESTRICTED CIRCULATION ONLY)

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ANNEXURE 4
Verification of System Documentation

Objective:

To identify the availability of documents, check the accuracy of the document.

Procedure:
    Identification of the documents:

    2. The executor will check whether following specified documents are available or not.
        a. IT Policy
        b. Personal Computer (PC) Specification
        c. Operating System License
        d. Application Software's License
        e. Antivirus License

    Check the correctness of the documents:

    3. The executor will identify the documents and check that the documents represent the actual installed Personal Computer (PC).

The documents should be upgraded as per the latest Personal Computer (PC) configuration.

References Required:
PC Manufacturer's Manual

Observation:

Document Title	Availability? (Yes/No)	Remark
IT Policy	Yes / No	
Personal Computer (PC) Specification	Yes / No	
Operating System License	Yes / No	
Application Software License	Yes / No	
Antivirus License	Yes / No	

Remark: The above-mentioned documents **available or not** with respect to the acceptance criteria	
Performed By: (Sign/Date)	**Verified By:** (Sign/Date)

(FOR RESTRICTED CIRCULATION ONLY)

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ANNEXURE 5
Verification of Power Utility

Objective:

3. To verify that the electrical utility has been installed and is available as specified.

4. To verify the availability and installation of UPS with the Personal Computer (PC).

Procedure:
5. Power on the System and put the multi meter in AC voltage measurement range and measure the voltage at Personal Computer (PC) terminal end.
6. Note down the voltage reading in the test data sheet.
7. Verify the availability of UPS and record its details as specified in test data table.
8. Record the deviations if any, in the deviation report.

Observation:

Description	Specified	Actual Observation	Actual as per Specified? (Yes/No)
Voltage rating	230 VAC ± 5%		Yes / No
UPS Details	Make:	Make:	Yes / No

Remark: The above-mentioned documents **available or not** with respect to the acceptance criteria
Performed By: (Sign/Date)	**Verified By:** (Sign/Date)

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ANNEXURE 6
Verification of IT Policy

Objective:

The objective of this test is to verify and check the application of IT Policy on the Personal Computer (PC).

Procedure:

Verify that the following IT policies and check that the policy is applied to the Personal Computer (PC):
6. Password Policy
    a. Enforce Password History
    b. Maximum Password Age
    c. Minimum Password Length
    d. Password must meet complexity requirements
7. Account Lockout Policy
    a. Account Lockout threshold
8. Account Login Policy
9. Date & Time Policy
10. Mass Storage Policy

Observation:

Policy Description	Specified	Actual result	Meet Acceptance Criteria (Yes/No)?
Enforce Password History	10 Passwords		
Maximum Password Age	45 Days		
Minimum Password Length	7 Characters		
Password must meet complexity requirements	Enable		
Account Lockout threshold	5 Invalid Logon Attempts		
Account Login Policy	Account must login with correct user ID & password		
Date & Time Policy			
Mass Storage Policy			

Remark: The above-mentioned documents **available or not** with respect to the acceptance criteria	
Performed By: (Sign/Date)	**Verified By:** (Sign/Date)

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ANNEXURE 7
Verification of Access and Security

Objective:

The objective of this test procedure is to verify and record the integrity of the Personal Computer (PC) security. Testing will be performed to verify and record PC's access control. The accessibility to delete / uninstall the specific software will be verified for accuracy.

Procedure:
1. Attempt to log on to the Personal Computer (PC) with domain Users with correct & wrong password entries.
2. Log in with a specific user profile and attempt to access and delete the different user's profile.
3. Log in with a specific user and attempt to delete / uninstall specific software.

Observation:

Password Entry

S. No.	Domain User Name	Correct User password entry Allowed? (Yes/No)	Wrong User password entry Allowed? (Yes/No)	Acceptance Criteria Met? (Yes/No)	Remark
1.		Yes / No	Yes / No	Yes / No	
2.		Yes / No	Yes / No	Yes / No	
3.		Yes / No	Yes / No	Yes / No	

Security of the User Profile

Other User Can Access the folder? (Yes / No)	Other User Can Delete the folder? (Yes / No)	Acceptance Criteria Met? (Yes/No)	Remark
Yes / No	Yes / No	Yes / No	

Security of the Software

Software Name	User can Uninstall / Delete the software (Yes / No)	Acceptance Criteria Met? (Yes/No)	Remark
	Yes / No	Yes / No	
	Yes / No	Yes / No	
	Yes / No	Yes / No	
	Yes / No	Yes / No	
	Yes / No	Yes / No	
	Yes / No	Yes / No	

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ANNEXURE 8
Verification of PC System Software, Application Software and Hardware

1. Objective:

The objective of this test procedure is to verify and record the computer system hardware configuration and to verify and record basic information of installed Operating System & Application Software**.**

Procedure:

1. Personal computer (PC) system software, application software and hardware configuration should comply as specified.

Observation:

Verification of computer System Hardware:

Description	Acceptance Criteria	Actual Observation	Meet Acceptance Criteria (Yes/No)?
Name of manufacturer			
Processor	Intel Core 2 Duo or Higher		
Random Access Memory (RAM)	At least 2 GB		
Hard drive Capacity	Minimum 40 GB		

Verification of computer System Software & Application Software:

Description	Acceptance Criteria	Actual Observation	Meet Acceptance Criteria (Yes/No)?
Operating System			
Operating System	Microsoft Windows 11 Professional		
Version of Operating System	2025		
Service Pack Version (if installed)	Service Pack 1		
Name of Computer			
Computer System Domain Name			
Application Softwares			
Name of Application	Name:	Name:	

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Description	Acceptance Criteria	Actual Observation	Meet Acceptance Criteria (Yes/No)?
Software 1 & Version	Version:	Version:	
Name of Application Software 2 & Version	Name:	Name:	
	Version:	Version:	
Name of Application Software 3 & Version	Name:	Name:	
	Version:	Version:	
Name of Application Software 4 & Version	Name:	Name:	
	Version:	Version:	
Name of Application Software 5 & Version	Name:	Name:	
	Version:	Version:	
Name of Application Software 6 & Version	Name:	Name:	
	Version:	Version:	