	INSTALLATION QUALIFICATION FOR eRESIDUE APPLICATION	PROTOCOL No.:
PHARMA DEVILS		

INSTALLATION QUALIFICATION FOR eRESIDUE APPLICATION

Department	QUALITY ASSURANCE
Block Location	
Software Name	eRESIDUE APPLICATION
Version	

PHARMA DEVILS	INSTALLATION QUALIFICATION FOR eRESIDUE APPLICATION	PROTOCOL No.:

Change History

Date	Supersede version	CC Ref No.	Revision summary
-	-	-	-

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1.0 PRE-APPROVAL:

Signing of approval page of this document indicates the Qualification approach described in this document. If any modification approach becomes necessary, a revision through change control shall be prepared, checked and approved. This document cannot be executed unless approved

Prepared By	Department	Designation	Sign & Date

Reviewed By	Department	Designation	Sign & Date

Approved By	Department	Designation	Sign & Date

2.0 OBJECTIVE:

The objective of this Installation qualification protocol is to define the qualification requirements and acceptance criteria for the eResidue Application Version 1.0.1.

3.0 SCOPE:

The Installation Qualification study shall be performed for the eResidue Application Version 1.0.1. This protocol is applicable to installation qualification of eResidue Application Version 1.0.1 against requirements.

4.0 SYSTEM DESCRIPTION:

eResidue is the web based application used to calculate residue limits (Maximum Allowable Residue value) in accordance with the following regulations:

US21CFR Part 211.67 Subpart D

Eudralex-Volume 4 Good Manufacturing Practice (GMP) Guidelines, Annex 15.

PIC/S Guide to Good Manufacturing Practice for Medicinal Products, Annex 15

The Application calculates dose based /10 PPM or health based (Acceptable Daily Exposure (ADE) or Permitted Daily Exposure (PDE)) residue carryover limits for various combinations of products manufactured using defined equipment

5.0 RESPONSIBILITIES:

Department	Responsibility
Engineering	Execute the validation activity and provide necessary support for the proper installation of the system
Service Engineer	Commissioning & Installation of the system as per the specifications
User department	Participate and provide necessary support for the qualification activity. Review of the compiled data, Qualification report and its compliance to meet the acceptance criteria of the protocol.
Quality Assurance	Monitoring and reviewing the validation activities Preparation of qualification protocol & summary. Training and approval of the protocol.

IDENTIFICATION OF EXECUTORS:

S.No.	Name of The Executor	Dept & Designation	Sign & Date

6.0 PRE-REQUSITE:

Training: Before processing for the qualification, the respective validation team shall be trained on the concept of validation. The training document shall be verified and shall be satisfactory.

7.0 METHODOLOGY:

The following qualification activities for the Installation Qualification are listed. Successful execution of the activities listed shall complete the Installation Qualification of eRESIDUE APPLICATION.

Following Parameters shall be tested.

Verification of client system hardware configuration

Verification of client system software configuration

Verification of internet connectivity in client system

Verification of web url access in client system

7.1. VERIFICATION OF CLIENT SYSTEM HARDWARE CONFIGURATION:

Objective: To verify and record the Hardware components and its configurations against the requirements

Procedure: Refer step description as per Data Sheet-7.1 of this protocol.

Acceptance Criteria: Observed results shall be match with Specifications of this protocol.

Data Sheet 7.1

S.No.	Description	Specification	Observed Results	Verified By Sign/Date
1.	Processor	I3 or above		
2.	RAM	4 GB RAM or above		

Remarks:

_____

_____

_____

_____

   Meet the Acceptance Criteria   [   ] Yes   [   ] No

   Verified by   : _____   Date: _____

   Reviewed by : _____   Date :_____

7.2. VERIFICATION OF CLIENT SYSTEM SOFTWARE CONFIGURATION:

Objective: To verify and record the software configurations against the requirements

Procedure: Refer step description as per Data Sheet-7.2 of this protocol.

Acceptance criteria: Observed results shall be match with Specifications of this protocol.

Data Sheet 7.2

S.No #	Description	Specification	Observed Results& Screen Shot No	Verified By Sign/Date
1	Operating System	Windows 7 or higher		
2	Microsoft Excel	Microsoft Excel 2007 or higher		
3	Mozilla	Version 42 or higher		
4	Google Chrome	Version 46 or higher		

Remarks:

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Meet the Acceptance Criteria   [   ] Yes   [   ] No

Verified by   : _____   Date: _____

Reviewed by : _____   Date :_____

7.3. VERIFICATION OF INTERNET CONNECTIVITY IN CLIENT SYSTEM:

Objective: To verify and record the internet connectivity in client system against the requirements

Procedure: Refer step description as per Data Sheet-7.3 of this protocol.

Acceptance criteria: Observed results shall be match with Specifications of this protocol.

Data Sheet 7.3

S No #	Description	Specification	Observed Results& Screen Shot No	Verified By Sign/Date
1	Internet Connection	Should be present		
2	Bandwidth	1Mbps or higher		

Remarks:

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_____

Meet the Acceptance Criteria   [   ] Yes   [   ] No

Verified by   : _____   Date: _____

Reviewed by : _____   Date :_____

7.4. VERIFICATION OF WEB URL ACCESS IN CLIENT SYSTEM:

Objective: To verify and record the web URL access in client system.

Procedure: Refer step description as per Data Sheet-7.4 of this protocol.

Acceptance Criteria: Observed results shall be match with Specifications of this protocol.

Data Sheet 7.4

S.No #	Description	Specification	Observed Results& Screen Shot No	Verified By Sign/Date
1	Web URL (Access)	Should be access from client		

Remarks:

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_____

Meet the Acceptance Criteria   [   ] Yes   [   ] No

Verified by   : _____   Date: _____

Reviewed by : _____   Date :_____

8.0 DEVIATION (IF ANY):

8.1. Deviation:

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8.2. Impact on operation:

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8.3. Justification for acceptance:

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9.0 ANNEXURES:

S.No.	Name of Annexure	Annexure No.

10.0 SUMMARY:

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11.0 CONCLUSION:

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12.0 ABBREVIATIONS:

Abbreviation	Description
IQ	Installation Qualification
RAM	Random Access Memory
CC	Change Control
Ref.	Reference
ADE	Acceptable Daily Exposure
PDE	Permitted Daily Exposure
PPM	Part per Million

13.0 REFERENCES:

- Eudralex-Volume 4 Good Manufacturing Practice (GMP) Guidelines, Annex 15.
- PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PE 009-11), Annex 15
- eResidue Manual

14.0 POST APPROVAL:

Signing of Report page of this document indicates the acceptance of Qualification approach described in this document.

Prepared By	Department	Designation	Sign & Date

Reviewed By	Department	Designation	Sign & Date

Approved By	Department	Designation	Sign & Date