PERFORMANCE QUALIFICATION

FOR

eRESIDUE APPLICATION

VERSION 2.0.0

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR eRESIDUE APPLICATIONVERSION 2.0.0	PROTOCOL No.:

Department	**Quality Assurance**
Unit	
Block	
Software name	**eResidue Application**
Version	**2.0.0**

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 Performance Qualification protocol is to define the Qualification requirements and acceptance criteria for the eResidue Application.

Approval of this document implies that reviewers are confident that following the execution of this protocol, the resulting system will be considered fully-tested and eligible for further stage of implementation.

3.0 SCOPE:

The Performance Qualification study shall be performed for the eResidue Application version 2.0.0.

This protocol shall be applicable and executed in all formulation units and subsidiaries and its where eResidue Application is being implemented.

The scope of this protocol is to perform the Performance Qualification of eResidue Application against User requirements Specifications along with additional features as below.

- Updated Equipment and Product module
- Added Equipment Train to club equipment
- Added Product Cluster, to club products
- Updated Upload feature that provides the ability to upload equipment and product through a spreadsheet
- Moved “Access Settings” to “Settings” menu
- Created Universal Settings module
- Calculation workflow has been reorganized with same functionality.

Reference Change Control No: ……

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:

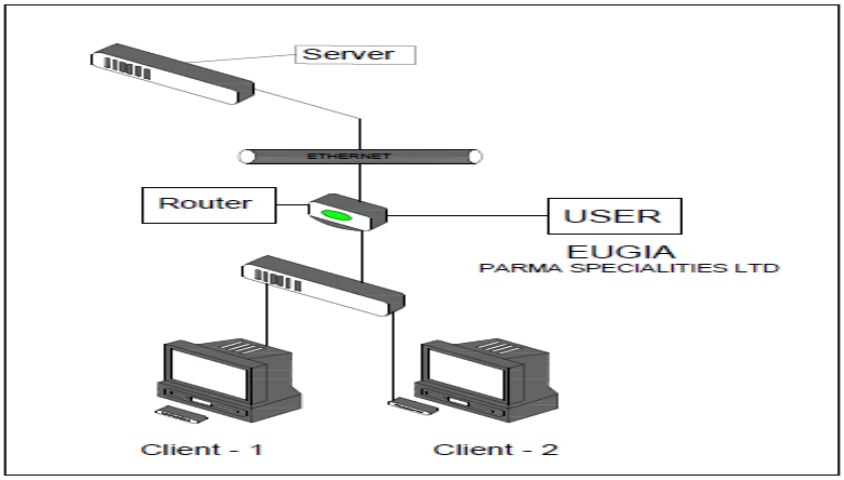
US21CFR Part 211.67 Subpart D

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 Dally Exposure (ADE) or Permitted Dally Exposure (PDE) residue carryover limits for various combinations of products manufactured using defined equipment.

eResidue is a multi-tenant application, used by multiple end user organizations over a standard web browser interface. Access to the application is restricted by User name and Password.



5.0 RESPONSIBILITIES:

Department	Responsibility
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.

5.1. Identification of Executors: The personnel involved in the execution of this protocol shall be recorded with their Name, Designation, Signature and Date in **Annexure-1** "Identification of Executors".

5.2. Qualification Status – To be recorded in **Annexure-1.**

6.0 PRE-REQUSITE:

6.1. 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.

6.2. Verification of IQ & OQ completion:

Before Performance Qualification, the completion of the IQ and OQ shall be verified with respect to the Recording of observation.

6.3. Verification of Calibration status of master and accessory equipments (if any):

Check the calibration status of the master equipment/instruments used in the calibration process the traceability certificated shall be verified with in record of observation.

6.4. Calibration (if any):

All measuring & controlling devices should be calibrated like Conductivity Meter, Pressure Gauges, ORP Sensor, ORP Transmitter, Level Sensor and Pressure Transmitter, etc.

6.5. Precautions:

Safety aspects of operation of equipment and system and process mentioned in the respective SOP / Specification must be ensured.

7.0 METHODOLOGY:

- The satisfactory Performance Qualification of eResidue Application shall be verified by executing the Qualification studies described in this protocol. The successfully executed protocol documents that the eResidue Application is satisfactorily tested for its functionality.

- The Performance Qualification of eResidue Application shall be verified functionally by executing the test data sheets provided in this protocol. The test data sheets will be used to document functionality of eResidue Application.

- The individual test cases will define the procedural test steps required to execute the approved Protocol test scenario.

- Each test will be manually executed. Test results will be documented by the test executor at the time of execution. All associated test data will be captured.

- A Protocol summary report will be prepared summarizing all test results, protocol and testing deviations and conclusions determined from the Qualification testing results.

7.1. VERIFICATION OF ERESIDUE APPLICATION PERFORMANCE AND FUNCTIONALITY WITH RESPECT TO THE REQUIREMENTS AND PROCEDURES:

To verify the eResidue Application performance and functionality with respect to the requirements and procedures.

8.0 DEVIATION (IF ANY):

8.1. Record the deviations occurred during the execution of program and their justifications, corrective & preventive actions taken shall be recorded in Record of observations **Annexure-1**

9.0 SUMMARY & CONCLUSION:

9.1. Record the Summary and conclusion shall be recorded in Record of observations. **Annexure-2**

10.0 ANNEXURES:

S.No.	Name of Annexure	Annexure No.
1.	Record of Observations	Annexure-1
2.	Summary Report	Annexure-2

11.0 ABBREVIATIONS:

Title	Abbreviations
PQ	Performance Qualification
ADE	Acceptable Dally Exposure
PDE	Permitted Dally Exposure
GMP	Good Manufacturing Practice

12.0 REFERENCES:

- Manual