



PHARMA DEVILS

**SUMMARY REPORT OF PERFORMANCE
QUALIFICATION OF eRESIDUE APPLICATION
VERSION 2.0.0**

REPORT No.:

**SUMMARY REPORT
OF
PERFORMANCE QUALIFICATION
OF
eRESIDUE APPLICATION
VERSION 2.0.0**



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1.0 REPORT APPROVAL:

Performance qualification is verified that all test cases required by the protocol are completed, reconciled and included in the summary report.

Signatures in the block below indicate that all items in this qualification report have been reviewed and found to be acceptable.

Prepared By	Department	Designation	Sign & Date

Reviewed By	Department	Designation	Sign & Date

Approved By	Department	Designation	Sign & Date



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2.0 OBJECTIVE:

The Objective of this summary report of performance qualification of eRESIDUE Application is to summaries the executed validation parameters which provide high degree of confidence that the eRESIDUE Application performing according with pre-determined acceptance criteria.

3.0 SCOPE:

This summary report is applicable to eRESIDUE Application located at Innovation Center QA Office.

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:

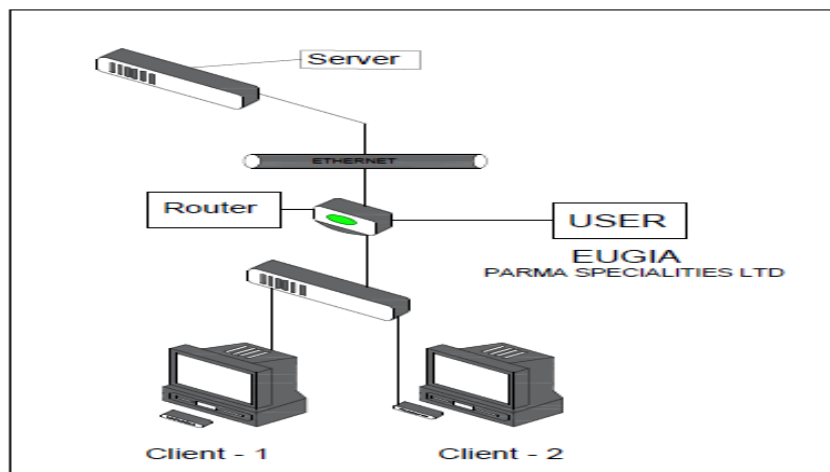
US21CFR Part 211.67 Subpart D

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

PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PE 009-11), 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.





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5.0 QUALIFICATION STATUS:

5.1. Equipment / Instrument Details:

Department	Quality Assurance
Block Location	
Name of the Supplier / Manufacturer	eRESIDUE
Version	2.0.0

5.2. Qualification Status

Date of qualification started	
Date of qualification completed	

6.0 SUMMARY OF RESULTS:

Performance qualification protocol of “eRESIDUE Application” is executed all test required by the protocol are completed, reconciled and included in summary report. Results are reviewed and found satisfactory.

Reference Test No	Reviewed & Check Points	Meeting Requirement (Yes / No)
7.1	Verification of eResidue application performance and functionality with respect To the requirements and procedures	YES

7.0 LIST OF ATTACHMENT:

NA



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8.0 CONCLUSION:

- The performance qualification of eRESIDUE Application (Version 2.0.0) was carried out as per the pre approved protocol.
- The personnel who were involved in the performance qualification have been trained on the respective protocol and SOP's.
- In the part of performance qualification below parameter has been performed and results were found satisfactory as per the acceptance criteria.

❖ Verification of Eresidue Application (Version 2.0.0) Performance and Functionality with Respect To The Requirements And Procedures.

- From the above finding of summary it is concluded that eRESIDUE Application is capable of carrying out for MACO Calculation for Cleaning Validation Study..
- Hence it is recommended to operate and use the eRESIDUE Application (Version 2.0.0) for further MACO calculation for Cleaning Validation Study.

9.0 ABBREVIATIONS:

Title	Abbreviations
PQ	Performance Qualification
MACO	Maximum Allowable Carry Over
IC	Innovation center
NA	Not Applicable