



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

<b>Department</b>	<b>QUALITY ASSURANCE</b>
<b>Unit</b>	
<b>Block</b>	
<b>Software name</b>	<b>eRESIDUE APPLICATION</b>
<b>VERSION</b>	<b>1.0.1</b>

<b>Change History</b>			
<b>Date</b>	<b>Supersede version</b>	<b>CC Ref No.</b>	<b>Revision summary</b>
-	-	-	-



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

**TABLE OF CONTENTS**

<b>S.No.</b>	<b>Content</b>	<b>Page No.</b>
1.0	Pre-Approval	4
2.0	Objective	5
3.0	Scope	5
4.0	System Description	5
5.0	Responsibilities	6
6.0	Prerequisite	6
7.0	Methodology	7
8.0	Deviation	75
9.0	Annexure	75
10.0	Summary	76
11.0	Conclusions	76
12.0	Abbreviation	77
13.0	References	77
14.0	Post Approval	78



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

**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.

<b>Prepared By</b>	<b>Department</b>	<b>Designation</b>	<b>Sign &amp; Date</b>

<b>Reviewed By</b>	<b>Department</b>	<b>Designation</b>	<b>Sign &amp; Date</b>

<b>Approved By</b>	<b>Department</b>	<b>Designation</b>	<b>Sign &amp; Date</b>



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

**2.0 OBJECTIVE:**

The objective of this Operational Qualification Protocol is to provide guidelines for verification of eResidue Application Version 1.0.1.

**3.0 SCOPE:**

The operational Qualification study shall be performed for the eResidue Application Version 1.0.1.

This protocol is applicable to operational Qualification of eResidue Application against functional requirements.

**4.0 SYSTEM DESCRIPTION:**

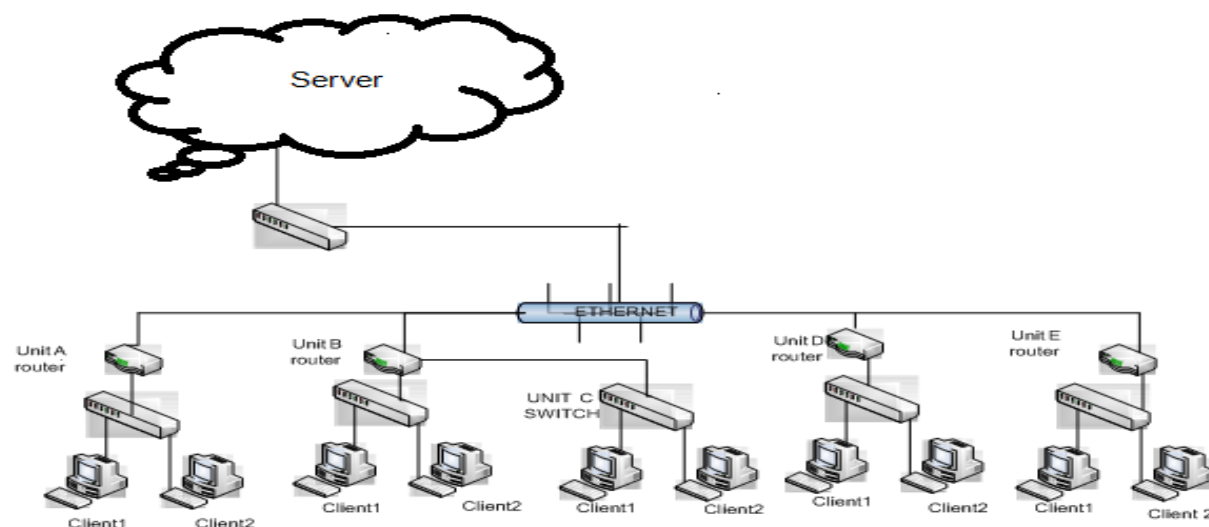
eResidue is the web based application used to calculate residue limits (Maximum Allowable Residue value) in accordance with the following regulations:

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 (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





**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

**5.0 RESPONSIBILITIES:**

<b>Department</b>	<b>Responsibility</b>
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:**

<b>S.No.</b>	<b>Name of the Executor</b>	<b>Dept &amp; Designation</b>	<b>Sign &amp; Date</b>

**6.0 PRE-REQUISITE:**

**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



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

**7.0 METHODOLOGY:**

The satisfactory Operational 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 Operational 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.

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.

**7.1. VERIFICATION OF USER ACCESS CONTROL:**

Objective: To create a new user with different access privileges

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

Acceptance criteria: Refer acceptance criteria as per Data Sheet-7.1 of this protocol.

**Data Sheet 7.1**

<b>Step No #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Actual Results</b>	<b>Status (Pass/Fall)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
7.1.1	Login to the eResidue application with the full access user	User shall be logged in into the application. Home Page shall be displayed.				
7.1.2	Click the pencil icon against the user name listed on the screen. Verify that account Permissions field has full permission.	The designated user should be able to access the application. They should also have full access rights to all features of the application.				
7.1.3	Try to edit the User Name field.	The user name of the user once entered into the Application should not be editable.				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

<b>Step No #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Actual Results</b>	<b>Status (Pass/Fall)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
7.1.4	Close the window and Open Access Settings and create a new user. Click submit button.	All mandatory fields in user creation window are shown red asterisk (*) beside the field.				
7.1.5	Select the Account Permissions as reports and Calculations and enter User Name, First Name, Last Name and Email Address and Click submit button.	New user should be created with privileges limited to Reports and Calculations. User Should receive an email with a system generated password.				
7.1.6	Click the email icon against the user account in Access Settings window. Verify that another email with password is received by user	User should receive another email with password.				
7.1.7	Click on Logout	Application login window should open in the default browser.				
7.1.8	Open the eResidue application link.	Application login window should open in the default browser.				
7.1.9	Enter the user name and password in login window.	Application will ask to change password.				
7.1.10	Enter a new password and confirm password and click submit.	Password changed successfully.				
7.1.11	Click on /Ve forgotten my	pop-up window is displayed.				





**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

<b>Step No #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Actual Results</b>	<b>Status (Pass/Fall)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
	password					
7.1.12	Enter username followed by entering the characters shown in the window. Click Submit icon	A confirmation message is displayed. stating that an email has been sent with details on how to reset the password				
7.1.13	Open the email and click on the link provided in the email.	Reset Password window should displayed.				
7.1.14	Enter a new password and confirm it.	A confirmation message is displayed.				
7.1.15	Using the new password, access eResidue	User should be able to log into eResidue				
7.1.16	Verify that user has access to only the features Reports and Calculations, for which access was granted.	User should only be able to access Report Tracker, Event Summary window under Report menu, and the Calculations menu.				
7.1.17	Verify that the Fields menu features are not accessible.	The features in Fields menu, i.e., Equipaient, Product, should not be accessible.				
7.1.18	Log into eResidue using the access credentials of the primary administrator user. Click Edit icon for user.	Option is available to change the account status for user				
7.1.19	clicking the Enable/Disable 'On/Off' toggle	User account should be inactive state.				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	switch and select the 'off'					
7.1.20	Click on Logout	Application login window should open in the default browser.				

**Remarks:**

---

---

---

---

Meet the Acceptance Criteria [ ] Yes [ ] No

Verified by : \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed by : \_\_\_\_\_ Date : \_\_\_\_\_



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

**7.2. VERIFICATION OF ACCESS CONTROL OPTIONS:**

Objective: To verify the setup the universal settings in the application

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

Acceptance criteria: Refer acceptance criteria as per Data Sheet-7.2 of this protocol.

**Data Sheet 7.2**

<b>Step No #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Actual Results</b>	<b>Status (Pass/Fall)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
7.2.1	Login to the eResidue application with the full access user.	User shall be logged in into the application. Home Page shall be displayed.				
7.2.2	Go to access settings→options tab and set the access control options in eResidue application. Password Aging: 90 Days Password Length: 6 Characters Password History: 3 Setup the Time format, Date format and time Zone and click the Save icon.	The settings should be saved.				
7.2.3	Access Event Summary window from Report menu. Verify that the Date Format and Time Format	The Date Format and Time Format on Event Summary page should matched with the previously saved settings.				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

<b>Step No #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Actual Results</b>	<b>Status (Pass/Fall)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
7.2.4	Access Change password by clicking the username on the top right part of the window.	Change Password window should open.				
7.2.5	Try to change the password with the password length as 4 characters.	Application should not accept the password and enforces the password length.				
7.2.6	Try to change the password within the last 3 passwords.	Application should not accept the password and enforces the password history.				
7.2.7	Click on Logout	Application login window should open in the default browser.				

**Remarks:**

---

---

---

---

Meet the Acceptance Criteria [  ] Yes [  ] No

Verified by : \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed by : \_\_\_\_\_ Date : \_\_\_\_\_



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

**7.3. VERIFICATION OF FACILITY PROFILE:**

Objective: To verify the setup the facility profile in the application

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

Acceptance criteria: Refer acceptance criteria as per Data Sheet-7.3 of this protocol.

**Data Sheet 7.3**

<b>Step No #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Actual Results</b>	<b>Status (Pass/Fall)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
7.3.1	Login to the eResidue application with the full access user.	User shall be logged in into the application. Home Page shall be displayed.				
7.3.2	Go to facility profile. Click the Save icon.	All mandatory fields in user creation window are shown red asterisk (*) beside the field.				
7.3.3	Enter facility description, Manufacturing Type, Master Plan, Policy, Procedure and click the Save icon.	Facility profile should be should be saved.				
7.3.4	Click on Logout	Application login window should open in the default browser.				

**Remarks:**

---

---

---

---





**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

<b>Step No #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Actual Results</b>	<b>Status (Pass/Fall)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
	value between dose based LO and health based LO <ul style="list-style-type: none"><li>• Select 'LO to be based on the lower value between dose based LO and health based LO' with safety factor being '0.001'</li></ul>	value between dose based LO and health based LO' should be selected with safety factor of'0.001'.				
7.4.4	Go to fields and Click on the Default L1/L3.	The Default L1/L3 window should be displayed				
7.4.5	Verify that the application allows the user to choose one of the following options: <ul style="list-style-type: none"><li>• No default used. Use calculated value.</li><li>• Use a default value for L1</li><li>• Use a default value for L3</li><li>• Use default value for both L1 and L3</li></ul>	It should be possible to select only one of the radio buttons against the following options: <ul style="list-style-type: none"><li>• No default used. Use calculated value</li><li>• Use a default value for L1</li><li>• Use a default value for L3</li><li>• Use default value for both L1 and L3</li></ul>				
7.4.6	Click on Logout	Application login window should open in the default browser.				







**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

**7.5. VERIFICATION OF UPLOAD WORKSHEET:**

Objective: To upload the worksheet to the application and verify what is displayed in application

Procedure: Refer step description as per Data Sheet-7.5 of this protocol.

Acceptance criteria: Refer acceptance criteria as per Data Sheet-7.5 of this protocol.

<b>Pre-requisites</b>	<b>Equipment</b>									
	<b>Equipment Name</b>		<b>Surface Area (Cm<sup>2</sup>)</b>			<b>Equipment Name</b>		<b>Surface Area (Cm<sup>2</sup>)</b>		
	Equipment P		300,000			Equipment Q		150,000		
	Equipment R		50,000			Equipment S		20,000		
	Equipment T		15,000			Equipment U		15,000		
	<b>Product Type: Liquid</b>									
	<b>Product Name</b>	<b>Active Conc.</b>	<b>Dosing Frequency</b>	<b>Product dose</b>	<b>Doses per period (min/max)</b>	<b>Batch Size (L) (min/max)</b>	<b>Safety Factor</b>	<b>ADE (mg)</b>	<b>% TOC of Active</b>	<b>Equipment Used</b>
	A	70 mg/mL	Daily	10 mL	1/1	400/800	0.001	6.5	45	P, Q, R & S
	B	15 mg/mL	Daily	15 mL	1/2	350/800	0.001	2.0	40	P, Q, R & S
	C	70 mg/mL	Daily	10 mL	1/1	400/800	0.001	6.5	45	P, Q & R
	D	15 mg/mL	Daily	15 mL	1/2	350/800	0.001	2.0	40	Q, R & S
	<b>Product Type: Cleaning Agent</b>									
	<b>Product Name</b>		<b>LD50 Based</b>						<b>--</b>	
			<b>LD50</b>		<b>Body Weight</b>		<b>Conversion Factor</b>		<b>ADE</b>	
	CA1		900 mg/kg		60 kg		0.001		0.1 mg	



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

**Data Sheet 7.5**

<b>Step No. #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Actual Results</b>	<b>Status (Pass/Fail)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
7.5.1	Login to the eResidue application with the full access user.	User shall be logged in into the application. Home Page shall be displayed.				
7.5.2	Click on Upload icon (located under Fields in menu bar). Choose the radio button against 'Upload Worksheet'.	Upload Database window should be displayed. On selecting the radio button against 'Upload Worksheet', a template along with upload instructions should be displayed.				
7.5.3	Click on Spreadsheet Template listed in the Upload Worksheet window.	A pop-up window titled Download Excel Template should be displayed.				
7.5.4	Click Download icon	A file 'eResidue_DB_Template' should be downloaded.				
7.5.5	Click Close	Clicking the Close icon should close the pop-up window and file was downloaded.				
7.5.6	Open the downloaded file in Microsoft Excel and fill the data in respective tabs (Equipment, Cleaning Agent and Liquid) as	The upload worksheet window should be displayed.				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

<b>Step No. #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Actual Results</b>	<b>Status (Pass/Fall)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
	per above table. Save the file. Login into the application click on upload under Fields in menu bar and select radio button against upload work sheet.					
7.5.7	Click the cloud icon and select the saved spreadsheet file and click the Upload icon.	The application should display a pop-up window confirming successful upload.				
7.5.8	Go to Equipment and verify the equipment entries in eResidue application	Equipment entries in eResidue application should match with what was noted in the spreadsheet.				
7.5.9	Go to Product → cleaning agent and verify the details of cleaning agent CA1 in eResidue application	Cleaning agent details in eResidue application should match with what was noted in the spreadsheet.				
7.5.10	Go to Product and verify the details of product eResidue application	Product details in eResidue application should match with what was noted in the spreadsheet.				
7.5.11	Make a duplicate copy of already uploaded spreadsheet, renamed the spreadsheet with different name. Open the	Spreadsheet file should be saved.				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No. #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	spreadsheet and keeping the entries under Equipment and liquid are same. Delete the Cleaning Agent details and save the file.					
7.5.12	Go to upload option and upload the spreadsheet in to the eResidue application.	The application should warn the user about duplicate Entry.				
7.5.13	Click on Logout	Application login window should open in the default browser.				

**Remarks:**

---

---

---

---

**Meet the Acceptance Criteria** [  ] Yes [  ] No

**Verified by** : \_\_\_\_\_ **Date:** \_\_\_\_\_

**Reviewed by** : \_\_\_\_\_ **Date :** \_\_\_\_\_



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

**7.6. VERIFICATION OF EQUIPMENT:**

Objective: To verify the equipment creation, edit and delete operations in the application.

Procedure: Refer step description as per Data Sheet-7.6 of this protocol.

Acceptance Criteria: Refer acceptance criteria as per Data Sheet-7.6 of this protocol.

**Data Sheet 7.6**

<b>Step No #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Observed Results</b>	<b>Status (Pass/Fall)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
7.6.1	Login to the eResidue application with the full access user.	User shall be logged in into the application. Home Page shall be displayed.				
7.6.2	Go to Equipment summary window and click on add equipment	Add new equipment shall be displayed with red asterisks (*) are displayed for mandatory fields.				
7.6.3	Enter Equipment Name is 'Equipment W', Abbreviation is 'W' & surface area is 450,000 cm <sup>2</sup> and click submit button.	Application should be save the equipment details and this will be also displayed in equipment Summary.				
7.6.4	Go to Equipment summary window and click on add equipment	Add new equipment shall be displayed with red asterisks (*) are displayed for mandatory fields.				
7.6.5	Click cancel button.	Equipment Summary window displayed.				
7.6.6	Go to equipment summary window and click on the pencil icon against the	Edit equipment window should be displayed with respective equipment details.				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

<b>Step No #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Observed Results</b>	<b>Status (Pass/Fall)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
	equipment for edit the equipment surface area from 450,000 cm <sup>2</sup> to 86,000 cm <sup>2</sup> and click submit button.					
7.6.7	Try to edit the equipment Name.	Application will not allow to editing the equipment name.				
7.6.8	Edit the required details and click update button.	Equipment summary window displayed with updated equipment details.				
7.6.9	Click on the pencil icon against the equipment.	Edit equipment window should be displayed with respective equipment details.				
7.6.10	Click cancel button.	Equipment Summary window displayed.				
7.6.11	Go to equipment summary window and click on the minus icon against the equipment for delete the equipment details.	Delete equipment warning message should be displayed with Proceed and Cancel buttons.				
7.6.12	Click on proceed button.	Equipment summary window displayed and respective equipment was deleted in equipment summary.				
7.6.13	Click on the	Delete equipment				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Observed Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	minus icon against the equipment.	warning message should be displayed with Proceed and Cancel buttons.				
7.6.14	Click cancel button.	Equipment Summary window displayed and respective equipment was not deleted in equipment summary.				
7.6.15	Click on Logout	Application login window should open in the default browser.				

**Remarks:**

---

---

---

---

**Meet the Acceptance Criteria** [  ] Yes [  ] No

**Verified by** : \_\_\_\_\_ **Date:** \_\_\_\_\_

**Reviewed by** : \_\_\_\_\_ **Date :** \_\_\_\_\_



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

**7.7. VERIFICATION OF PRODUCT:**

Objective: To verify the product creation, edit and delete operations in the application.

Procedure: Refer step description as per Data Sheet-7.7 of this protocol.

Acceptance Criteria: Refer acceptance criteria as per Data Sheet-7.7 of this protocol.

**Pre-Requisites**

Product Name	Product Type	Active Conc.	Dosing frequency	Product Dose	Doses per period (min/max)	Batch Size (L) (min/max)	ADE (mg)	% TOC of Active	Equipment Used
AA	Liquid	70 mg/mL	Daily	10 mL	1/1	400/800	6.5	45	P, Q, R
BB	Liquid	1 mg/mL	Daily	0.1 mL	1/1	800/2200	2.0	35	Q, R, S

**Data Sheet 7.7**

Step No #	Description	Expected Results	Observed Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
7.7.1	Login to the eResidue application with the full access user.	User shall be logged in into the application. Home Page shall be displayed.				
7.7.2	Go to Product summary window and click on add Products	Add new Product shall be displayed with red asterisks (*) are displayed for mandatory fields.				
7.7.3	Create 2 new products AA & BB as per above table and click submit button.	Application should be save the Product details and this will be also displayed in Product Summary.				
7.7.4	Go to Product summary window and click on add Product	Add new Product shall be displayed with red asterisks (*) are displayed for mandatory fields.				





**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

<b>Step No #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Observed Results</b>	<b>Status (Pass/Fall)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
7.7.5	Click cancel button.	Product Summary window displayed.				
7.7.6	Go to Product summary window and click on the pencil icon against the Product for edit the Product details.	Edit Product window should be displayed with respective Product details.				
7.7.7	Try to edit the Product Name.	Application will not allow to editing the Product name.				
7.7.8	Edit the Product AA Active concn from 70 mg/mL to 15 mg/mL and click update button.	Product summary window displayed with updated Product details.				
7.7.9	Click on the pencil icon against the Product.	Edit Product window should be displayed with respective Product details.				
7.7.10	Click cancel button.	Product Summary window displayed.				
7.7.11	Go to Product summary window and click on the minus icon against the Product for delete the Product details.	Delete Product warning message should be displayed with Proceed and Cancel buttons.				
7.7.12	Click on proceed button.	Product summary window displayed and respective Product was deleted in Product summary.				
7.7.13	Click on the minus icon against the	Delete Product warning message should be displayed				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Observed Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	Product.	with Proceed and Cancel buttons.				
7.7.14	Click cancel button.	Product Summary window displayed and respective Product was not deleted in Product summary.				
7.7.15	Click on Logout	Application login window should open in the default browser.				

**Remarks:**

---

---

---

---

**Meet the Acceptance Criteria** [ ] Yes [ ] No

**Verified by** : \_\_\_\_\_ **Date:** \_\_\_\_\_

**Reviewed by** : \_\_\_\_\_ **Date:** \_\_\_\_\_



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

**7.8. VERIFICATION OF DATABASE FILE UPLOAD FROM RESIDUE DESKTOP SOFTWARE:**

Objective: To verify the upload of database file (Residue desktop application) in eResidue application

Procedure: Refer step description as per Data Sheet-7.8 of this protocol.

Acceptance Criteria: Refer acceptance criteria as per Data Sheet-7.8 of this protocol.

<b>Pre-requisites</b>	<b>Old MDB file shall have the following details</b>							
	<b>Equipment details</b>							
	<b>Equipment Name</b>		<b>Surface Area (cm<sup>2</sup>)</b>		<b>Equipment Name</b>		<b>Surface Area (cm<sup>2</sup>)</b>	
	Equipment E1		120,000		Equipment E2		65,000	
	Equipment E3		45,000		--			
	<b>Product Type: Solid</b>							
	<b>Product Name</b>	<b>Active Conc.</b>	<b>Dosing Frequency</b>	<b>Product dose</b>	<b>Doses per period (min/max)</b>	<b>Batch Size (L) (min/max)</b>	<b>% TOC of Active</b>	<b>Equipment Used</b>
	P1	23 mg/g	Daily	10 g	1/2	250/1200	45	E1, E2 & E3
	P2	18 mg/g	Daily	6 g	1/3	650/2200	35	E1, E2 & E3

**Data Sheet 7.8**

<b>Step No #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Actual Results</b>	<b>Status (Pass/Fail)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
7.8.1	Login to the eResidue application with the full access user	User shall be logged in into the application. Home Page shall be displayed.				
7.8.2	Access Upload Database window from Fields in menu bar. Select radio button against Old MDB.	On selecting the Select radio button against Old MDB, the application should provide a window detailing the process to upload the database file.				
7.8.3	Download	The Database				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

<b>Step No #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Actual Results</b>	<b>Status (Pass/Fall)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
	database converter application on to your desktop and install it. Open the converter application	converter application should be open.				
7.8.4	Select the .mdb file and convert it as a excel file and save it a location.	File should be saved in the location.				
7.8.5	Click on Upload, under Fields in menu bar. Select radio button against Upload Old MDB. Click the Cloud icon and select the saved Excel file. Click the Upload icon.	The Upload Old MDB window should be displayed. The application should confirm that the upload was successful.				
7.8.6	Go to Equipment and verify the equipment entries in eResidue application	Equipment entries in eResidue application should match with what was noted in the spreadsheet.				
7.8.8	Go to Product and verify the details of product eResidue application	Product details in eResidue application should match with what was noted in the spreadsheet.				
7.8.19	Click on Logout	Application login window should open in the default browser.				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

**Remarks:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Meet the Acceptance Criteria [ ] Yes [ ] No

Verified by : \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed by : \_\_\_\_\_ Date : \_\_\_\_\_

**7.9. VERIFICATION OF CALCULATIONS:**

Objective: To verify that the calculations carried out by residue software application

Procedure: Refer step description as per Data Sheet-7.9 of this protocol.

Acceptance Criteria: Refer acceptance criteria as per Data Sheet-7.9 of this protocol.

<b>Equipment</b>										
<b>Equipment Name</b>		<b>Surface Area (cm<sup>2</sup>)</b>		<b>Equipment Name</b>		<b>Surface Area (cm<sup>2</sup>)</b>				
Equipment P		300,000		Equipment Q		150,000				
Equipment R		50,000		Equipment S		20,000				
Equipment T		15,000		--						
<b>Product Type: Liquid</b>										
Pre-requisites	<b>Product Name</b>	<b>Active Conc.</b>	<b>Dosing Frequency</b>	<b>Product dose</b>	<b>Doses per period (min/max)</b>	<b>Batch Size (L) (min/max)</b>	<b>Safety Factor</b>	<b>ADE (mg)</b>	<b>% TOC of Active</b>	<b>Equipment Used</b>
	A	70 mg/mL	Daily	10 mL	1/1	400/800	0.001	6.5	45	P, Q, R & S
	B	15 mg/mL	Daily	15 mL	1/2	350/800	0.001	2.0	40	P, Q, R & S
	C	70 mg/mL	Daily	10 mL	1/1	400/800	0.001	6.5	45	P, Q & R
	D	15 mg/mL	Daily	15 mL	1/2	350/800	0.001	2.0	40	Q, R & S



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

**Product Type: Cleaning Agent**

Product Name	LD50 Based			--
	LD50	Body Weight	Conversion Factor	ADE
CA1	900 mg/kg	60 kg	0.001	0.1 mg
<b>Rinse</b>				
<b>Rinse Sampling</b>	<b>Swab Sampling</b>			
<b>Rinse volume</b>	<b>Solvent used</b>	<b>Amt. of solvent used for desorption</b>		<b>Surface Area Sampled</b>
20 L	Water	40 mL		25 cm <sup>2</sup>



PHARMA DEVILS

OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION

PROTOCOL No.:

Data Sheet 7.9

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
7.9.1	Login to the eResidue application with the full access user.	User shall be logged in into the application. Home Page shall be displayed.				
7.9.2	Click Calculation icon on the top right corner of the window.	Calculate Limit accordion must be displayed.				
7.9.3	Under <i>Step 1 - Product Selection</i> , Select Products A & B from the <i>Available Products</i> list. Use the right arrow to transfer it to the <i>Products Selected</i> list Click Next.	Products A and B should be displayed under <i>Products Selected</i> list.  Step 2 - Sampling Method accordion window should be displayed				
7.9.4	In the Step 2 - Sampling Method window, select the radio button Run limits with L4 calculation.	The radio button against Run limits with L4 calculation should be selectable under the heading Step 2-Sampling Method.				
7.9.5	Continue with the following settings in Step 2 - Sampling Method window: <ul style="list-style-type: none"><li>Place tick mark in check box against 'Rinse'</li><li>Select radio button against 'individually' for Equipment Sampling</li></ul>	In Step 2-Sampling Method window, following should be the settings: <ul style="list-style-type: none"><li>Check box against 'Rinse' should be selected</li><li>Radio button against 'Individually' for Equipment</li></ul>				



PHARMA DEVILS

OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION

PROTOCOL No.:

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	<ul style="list-style-type: none"><li>Place tick mark in check box against 'Swab</li><li>Select radio button against 'Both' for the heading Express swab limits as:</li></ul>	<ul style="list-style-type: none"><li>Sampling category should be selected</li><li>Check box against 'Swab' should be Selected</li><li>Radio button against 'Both' should be selected for the heading Express swab limits as:</li></ul>				
7.9.6	Click on the <i>Next</i> button.	Rinse Individual window should be displayed.				
7.9.7	In Rinse-Individual window, select the radio button against 'Apply volume liter entered in the first row to all other listed equipment'. Enter Volume as '20'.	The radio button against 'Apply volume liter entered in the first row to all other listed equipment' should be selectable. A volume of 20L should be displayed against all equipment listed				
7.9.8	Click on the Next button.	Step 3 -Swab <i>accordion window should be displayed.</i>				
7.9.9	In Swab window, select the radio button against 'Apply all 3 entries in the first row to all the other listed products'.  <ul style="list-style-type: none"><li>Enter in the first box below Solvent Used column</li></ul>	The radio button against 'Apply all 3 entries in the first row to all the other listed products' should be selectable.  All the entries under column Solvent Used should display				





**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

<b>Step No #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Actual Results</b>	<b>Status (Pass/Fall)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
	'Water'.	'Water'.				
7.9.10	Enter in the first box below Amt. of Solvent used for Desorption value of '40' and choose the unit as 'mL'.  Enter in the first box below Surface Area Sampled the value '25'	All Entries under column Amt. Of solvent used for desorption should display 40 with the units being 'ml'. All entries under column surface area sampled should read the value '25'.				
7.9.11	Click Next	Step 4 - Definition accordion window should be displayed.				
7.9.12	Under Limit Calculation heading, select radio button against 'Calculate the limits for the active in each product with every product (including the same product) as the next product'	The radio button against 'Calculate the limits for the active in each product with EVERY product (including the same product) as the next product' should be selected.				
7.9.13	Under <i>TOC Results</i> heading, select radio button against 'Yes'	The radio button against 'Yes' should be selected.				
7.9.14	Click the Next button.	Step 5 - Report accordion window should be displayed.				
7.9.15	Enter in the text box against Report Title 'Qualification eResidue Test 1'. In the drop-down list against	The text box against Report Title should read 'Qualification eResidue Test 1' On placing a tick mark in the check				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

<b>Step No #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Actual Results</b>	<b>Status (Pass/Fall)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
	Signatories, place a tick mark in the check box against 'Select All'.	box against 'Select All,' all entries in the drop-down list should be selected				
7.9.16	Select the check boxes <i>L1, L2, L3, L4a (Swab Amount), L4b (Swab Conen.), L4c (Rinse), L4a as TOC (Swab Amount), L4b as TOC (Swab Conen.) and L4c as TOC (Rinse)</i> under heading <i>Step 5 - Limit Selection</i> .	The check boxes <i>L1, L2, L3, L4a (Swab Amount), L4b (Swab Conen.), L4c (Rinse) L4a as TOC (Swab Amount), L4b as TOC (Swab Conen.) and L4c as TOC (Rinse)</i> under heading <i>Step 5 - Limit Selection</i> should be selected.				
7.9.17	Under <i>Step 5 - Report Format</i> , select the check box against 'Send report to Email' and select one of the email addresses from the Dropdown list.	Email address should be selected.				
7.9.18	Click Submit icon.	A Calculation Status popup window should be displayed with message "Calculation is being setup". Once setup process has been completed, Popup window should show the message "Generated report will appear on Report Tracker. Please download it from there." Page. The popup window				



PHARMA DEVILS

OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION

PROTOCOL No.:

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		should also then display 'Close' icon.				
7.9.19	Click <i>Close</i> icon.	Report Tracker window should be displayed.				
7.9.20	Verify that the Report Name ' <i>Qualification eResidue Test 1</i> ', for the calculation carried out in earlier steps, appears in <i>Report Tracker</i> .	<i>The table in Report Tracker window should show an entry with Products Selected as A &amp; B and Report title noted as 'Qualification eResidue Test 1'.</i>				
7.9.21	Verify that this report can be downloaded from the Report Tracker window.	This report should be downloadable as a PDF document from the <i>Report Tracker</i> window.				
7.9.22	Click the Pencil edit icon in Report tracker window against 'Qualification eResidue Test1'	<i>Calculate Limit</i> accordion should displayed with the product selected being A&B				
7.9.23	Verify that if the steps 2-18 were to be again executed, without any changes, the application will warn the user that the report title is a duplicate	The application should warn the user that the Report title already exists and should not allow calculation to be carried out.				
7.9.24	Verify that if the steps 2-18 were to be again executed but with a new Report title, the	When a new Report title is assigned and the calculation submitted, the application should				



PHARMA DEVILS

OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION

PROTOCOL No.:

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	application will warn the user that the calculation is a duplicate.	warn the user that the calculation is a duplicate.				
7.9.25	Click Limit Calculation Report icon under Reports menu.	Report Tracker window should be displayed when Limit Calculation Report icon is clicked under Reports menu.				
7.9.26	Click the Minus icon against 'Qualification eResidue Test 1.	On clicking the Minus icon against 'Qualification eResidue Test 1, a pop-up Delete Calculation window should appear asking for confirmation to delete the report.				
7.9.27	Click Proceed icon in Delete Calculation window.	Confirmation Required pop-up window must be displayed asking for username and password.				
7.9.28	Enter username and password in the Confirmation Required pop-up window and click Submit icon.	On entering username and password, without any error, in the Confirmation Required pop-up window, the report 'Qualification eResidue Test 1' should be deleted. It should not appear in the Report Tracker window.				
7.9.29	Verify that if the steps 2-18 were to be again executed	'Qualification eResidue Test 1.1' should be displayed				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	but with the report title entered as 'Qualification eResidue Test 1.1', the application will execute the calculation and the report will be displayed in Report Tracker window.	<i>in</i> Report Tracker <i>under</i> Report Title <i>column.</i>				
7.9.30	Download the PDF Report and then open it. Verify that the title ' <i>Qualification eResidue Test 1.1</i> ' is captured on the first page of the report	The PDF report should open and show ' <i>Qualification eResidue Test 1.1</i> ' as Report title on the first page.				
7.9.31	Verify that the report captures the following information: Product details of A and B Equipment Details of P, Q, R & S Basis of Limit Default L1 and L3 setting Settings for Calculation type, TOC Results, Sampling Method, Rinse & Swab Limits and Report Type Limits LO, L1, L2, L3, L4a, L4b, L4c	The report should capture the following information: Product details of A and B Equipment Details of P, Q, R & S Basis of Limit Default L1 and L3 setting Settings for Calculation type, TOC Results, Sampling Method, Rinse & Swab Limits and report type. Limits LO, L1, L2, L3, L4a, L4b, L4c,				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	L4a (as TOC), L4b (as TOC) & L4c (as TOC)	L4a (as TOC), L4b (as TOC) & L4c (as TOC)				
A calculator/spreadsheet program would be needed from this step onwards to verify the limits calculated by eResidue						
7.9.32	Add surface area of P, Q, R & S	Surface Area of P, Q, R and S should add to $300,000 + 150,000 + 50,000 + 20,000 = 520,000 \text{ cm}^2$				
7.9.33	Calculate, manually, limits for current product being A, next product being the same (A).	1.L1 (calculated) = $0.001 \times 70 = 0.07 \text{ mg/ml (70ppm)}$ 2.Since the calculated value is greater than default 10 ppm, 10ppm will be used. L1 = 0.01 mg/ml (10ppm) 3.L2 = $10 \times 0.001 \times 400 \times 1000 = 4,000 \text{ mg}$ 4.L3 = $4,000 / 520,000 = 0.00769 \text{ mg/cm}^2$ 5.Since 0.00769 mg/cm <sup>2</sup> is greater than 0.004 mg/cm <sup>2</sup> , L3 used = 0.004 mg/cm <sup>2</sup> 6.L4a = $0.004 \times 25 = 0.1 \text{ mg}$ 7.L4a (asTOC) = $0.1 \times 0.45 = 0.045 \text{ mg}$ 8.L4b = $0.1 / 40 = 0.0025 \text{ mg/ml}$				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		9.L4b (as TOC) = $0.0025 \times 0.45 =$ $0.00113 \text{ mg/ml}$ 10. L4c: Equipment P $1. = 0.004 \times$ $300,000 / (20$ $\times 1000) = 0.06$ $\text{mg/m!}$ Equipment Q $= 0.004 \times$ $150,000 / (20$ $\times 1000) = 0.03$ $\text{mg/ml}$ Equipment R , = $0.004 \times$ $50,000 / (20$ $\times 1000) = 0.01$ $\text{mg/ml}$ Equipment S $= 0.004 \times$ $20,000 / (20$ $\times 1000) = 0.004$ $\text{mg/ml}$ 11. L4c (as TOC): Equipment P $= 0.06 \times 0.45 =$ $0.027 \text{ mg/ml}$ Equipment Q $= 0.03 \times 0.45 =$ $0.0135 \text{ mg/ml}$ Equipment R = $0.01 \times 0.45 =$ $0.0045 \text{ mg/ml}$ Equipment.S $= 0.004 \times 0.45 =$ $0.0018 \text{ mg/ml}$				
7.9.34	Calculate, manually, limits	1. LO (dose based) $= 0.001 \times 70 \times$				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	for currerit product being A, next product B.	<p>10x1= 0.7 mg</p> <p>2. L0 (health based) = 6.5 mg</p> <p>3. Since L0 (dose based) is lower, 0.7mg value will be used.</p> <p>4. L1 (calculated) = <math>0.7/(15 \times 2) = 0.023\text{mg/ml}</math> (23ppm)</p> <p>5. Since 23 ppm is greater than default 10 ppm, value of 10ppm will be used. L1 used = 0.01 mg/ml (10ppm)</p> <p>6. L2= <math>0.01 \times 350 \times 1000 = 3,500 \text{ mg}</math></p> <p>7. L3 (calc)= <math>3,500 / 520,000 = 0.00673 \text{ mg/cm}^2</math></p> <p>8. Since the calculated L3 value of 0.00673 mg/cm<sup>2</sup> is greater than the default L3 value of 0.004 mg/cm<sup>2</sup>, L3 used is 0.004 mg/cm<sup>2</sup></p> <p>9. L4a= <math>0.004 \times 25 = 0.1 \text{ mg}</math></p> <p>10. L4a (as TOC) = <math>0.1 \times 0.45 = 0.045\text{mg}</math></p> <p>11. L4b = <math>0.1/40 = 0.0025</math></p>				





PHARMA DEVILS

OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION

PROTOCOL No.:

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		mg/ml 12. L4b (as TOC) = $0.0025 \times 0.45 = 0.00113$ mg/ml 13. L4c: Equipment P = $0.004 \times 300,000 / (20 \times 1000) = 0.06$ mg/ml Equipment Q = $0.004 \times 150,000 / (20 \times 1000) = 0.03$ mg/ml Equipment R = $0.004 \times 50,000 / (20 \times 1000) = 0.01$ mg/ml Equipment S = $0.004 \times 20,000 / (20 \times 1000) = 0.004$ mg/ml 14. L4c (as TOC): Equipment P = $0.06 \times Q.45 = 0.027$ mg/ml Equipment Q = $0.03 \times 0.45 = 0.0135$ mg/ml Equipment R = $0.01 \times Q.45 = 0.0045$ mg/ml Equipment S				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		$= 0.004 \times 0.45$ $= 0.0018 \text{mg/ml}$				
7.9.35	Calculate, manually, limits for current Product being B, next product being the same (B).	<ol style="list-style-type: none"> <li>1. L1 (calculated)-  <math>0.001 \times 15 = 0,015 \text{ mg/mi}</math>            (15ppm)</li> <li>2. Since 15ppm is higher than default 10ppm, 10ppm will be used. L1 = 0.01 mg/mi (10 ppm)</li> <li>3. L2= <math>10 \times 0.001 \times 350 \times 1000 = 3,500 \text{ mg}</math></li> <li>4. L3=  <math>3,500 / 520,000 = 0.00673 \text{ mg/cm}^2</math></li> <li>5. Since the calculated value of 0.00673 is greater than the default of 0.004 <math>\text{mg/cm}^2</math>, L3 used = 0.004 <math>\text{mg/cm}^2</math></li> <li>6. L4a = <math>0.004 \times 25 = 0.1 \text{ mg}</math></li> <li>7. L4a (as TOC) =  <math>0.1 \times 0.40 = 0.04 \text{ mg}</math></li> <li>8. L4b = <math>0.1 / 40 = 0.0025 \text{ mg/ml}</math></li> <li>9. L4b (as TOC) =  <math>0.0025 \times 0.4 = 0.001 \text{ mg/ml}</math></li> <li>10. L4c: Equipment P</li> </ol>				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		$= 0.004 \times 300,000 / (20 \times 1000)$ $= 0.06 \text{ mg/ml}$ <b>Equipment Q</b> $= 0.004 \times 150,000 / (20 \times 1000)$ $= 0.03 \text{ mg/ml}$ <b>Equipment R</b> $= 0.004 \times 50,000 / (20 \times 1000) = 0.01 \text{ mg/ml}$ <b>Equipment S</b> $= 0.004 \times 20,000 / (20 \times 1000) = 0.004 \text{ mg/ml}$ 11. L4c (as TOC): <b>Equipaient P</b> $= 0.06 \times 0.4 = 0.024 \text{ mg/ml}$ <b>Equipment Q</b> $= 0.03 \times 0.4 = 0.012 \text{ mg/ml}$ <b>Equipment R</b> $= 0.01 \times 0.4 = 0.004 \text{ mg/ml}$ <b>Equipment S</b> $= 0.004 \times 0.4 = 0.0016 \text{ mg/ml}$				
7.9.36	Calculate, manually, limits for current product being B, next product A.	1. LO (dose based) $= 0.001 \times 15 \times 15 \times 1 = 0.225 \text{ mg}$ 2. LO (health based) = 2.5 mg 3. Since LO (dose based) is lower, 0.225 mg value will be used. L1 = 0.225 mg/ml 4. L1 (calculated) = $0.225 / (10 \times 1) = 0.0225 \text{ mg/ml}$ (22.5ppm)				



PHARMA DEVILS

OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION

PROTOCOL No.:

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		<p>5. Since the calculated value of 22.5ppm is greater than 10ppm, value of 10ppm will be used. <math>L1 = 0.01</math> mg/ml</p> <p>6. <math>L2 = 0.01 \times 400 \times 1000 = 4,000</math> mg</p> <p>7. <math>L3 = 4,000/520,000 = 0.00769</math> mg/cm<sup>2</sup></p> <p>8. Since 0.00769 mg/cm<sup>2</sup> is greater than the default 0.004 mg/cm<sup>2</sup>, <math>L3</math> used = 0.004 mg/cm<sup>2</sup></p> <p>9. <math>L4a = 0.004 \times 25 = 0.1</math> mg</p> <p>10. <math>L4a</math> (as TOC) – <math>0.1 \times 0.40 = 0.04</math> mg</p> <p>11. <math>L4b = 0.1/40 = 0.0025</math> mg/ml</p> <p>12. <math>L4b</math> (as TOC) = <math>0.0025 \times 0.40 = 0.001</math> mg/m!</p> <p>13. <math>L4c</math>: Equipment P = <math>0.004 \times 300,000/(20 \times 1000) = 0.06</math> mg/ml Equipment Q = <math>0.004 \times 150,000/(20 \times 1000) = 0.03</math> mg/ml</p>				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		Equipment R $= 0.004 \times 50,000 / (20 \times 1000)$ $= 0.01 \text{ mg/ml}$ Equipment s $= 0.004 \times 20,000 / (20 \times 1000)$ $= 0.04 \text{ mg/ml}$ 14.L4c (as TOC): Equipment P $= 0.06 \times 0.4 = 0.024 \text{ mg/ml}$ Equipment Q $= 0.03 \times 0.4 = 0.012 \text{ mg/ml}$ Equipment R $= 0.01 \times 0.4 = 0.004 \text{ mg/ml}$ Equipment S $= 0.004 \times 0.4 = 0.0016 \text{ mg/ml}$				
7.9.37	Verify that the limits, as calculated in steps 29-33, match that generated by eResidue in step 26, report title being <i>'Qualification eResidue Test 1.1'</i> .	The limits LO, L1, L2, L3, L4a, L4b and L4c For A-A, A-B, B-A and B- B (Current Product- Product to be manufactured) as calculated in steps 29-33 should match that noted in the PDF document, generated in step 26 ( <i>Qualification eResidue Test 1.1</i> ).				
7.9.38	<i>Click on Default L1 and L3 under Fields icon. Select the radio button</i>	<i>The Default L1 and L3 field should be set to 'No default used. Use calculated</i>				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

<b>Step No #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Actual Results</b>	<b>Status (Pass/Fall)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
	<i>against 'No default used. Use calculated value'.</i>	value'.				
7.9.39	<p>Start a new calculation by clicking the Calculation icon.</p> <p><i>Under Step 1 - Product Selection, Select Products C &amp; D.</i></p> <p><i>Click Next.</i></p>	<p><i>Calculate Limit</i> accordion must be displayed.</p> <p>In Step 1 Products selected should be C and D.</p> <p>Step 2 - Sampling Method accordion window should be displayed.</p>				
7.9.40	<p>Continue with the following settings for Step 2 - <i>Sampling Method:</i></p> <ul style="list-style-type: none"> <li>• <i>Select radio button against 'Run limits with L4 calculation'.</i></li> <li>• Place tick mark in check box against <i>'Rinse'.</i></li> <li>• Select radio button against <i>'Individually'</i> for Equipment Sampling.</li> <li>• Place tick mark in check box against <i>'Swab'.</i></li> <li>• Select radio</li> </ul>	<p><i>In Step 2-Sampling Method, following should be the settings:</i></p> <ul style="list-style-type: none"> <li>• <i>Under Sampling Method accordion, radio button for 'Run limits with L4 calculation' should be selected</i></li> <li>• <i>Check box against 'Rinse' should be selected.</i></li> <li>• <i>' Radio button against 'Individually' for Equipment Sampling category should be selected.</i> <ul style="list-style-type: none"> <li>• <i>Check box against 'Swab' should be selected.</i></li> </ul> </li> <li>• <i>Radio button</i></li> </ul>				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	button against <i>'Both'</i> for the heading <i>Express swab limits as:.</i>	against <i>'Both'</i> should be selected for the heading <i>Express swab limits as:.</i>				
7.9.41	<p>Click next</p> <p>Carry out the following steps:</p> <ul style="list-style-type: none"> <li>• <i>Select the radio button against 'Apply volume liter entered in the first row to all other listed equipment.'</i></li> <li>• <i>Enter in the first box in volume column the number '20'.</i></li> </ul>	<p>Step 3 - Rinse - Individuai accordion window should be displayed.</p> <p><i>The radio button against 'Apply volume liter entered in the first row to all other listed equipment.' should be selected.</i></p> <p>The Volume column, should read '20' for all entries.</p>				
7.9.42	<p>Click Next.</p> <p>Select the radio button against <i>'Apply all 3 entries in the first row to all the other listed products'</i></p>	<p>Step 3 - Swab accordion window should be displayed.</p> <p><i>The radio button against 'Apply all 3 entries in the first row to all the other listed products' should be selected.</i></p>				
7.9.43	<p>Enter the following details:</p> <ul style="list-style-type: none"> <li>• Solvent Used:</li> </ul>	<p>In Step 3-Swab, the following should be the settings:</p>				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	<p>'Water'.</p> <ul style="list-style-type: none"> <li>• Amt. of Solvent Used for Desorption: '40'. <i>Select unit as 'mU'.</i></li> <li>• Surface Area Sampled: '25'.</li> </ul>	<p>All entries under <i>Solvent Used</i> column should read 'Water'.</p> <p>All entries under <i>Amt. of Solvent Used for Desorption</i> column should read '40' with the units being 'mL'.</p> <p>All entries under <i>Surface Area Sampled</i> should read '25'.</p>				
7.9.44	<p><i>Click Next.</i></p> <p><i>Under Limit Calculation heading, select radio button against 'Calculate the limits for the active in each product with every product (including the same product) as the next product'.</i></p>	<p><i>Step 4 - Definition</i> accordion window should be displayed.</p> <p><i>The radio button against 'Calculate the limits for the active in each product with every product (including the same product) as the next product' should be selected.</i></p>				
7.9.45	<p><i>Under Surface Area Selection heading, select radio button against 'Calculate the L3 limit solely based on the shared surface area between the two products'.</i></p> <p><b>Under TOC</b></p>	<p><i>The radio button against 'Calculate the L3 limit solely based on the shared surface area between the two products' should be selected.</i></p> <p>The radio button against</p>				





PHARMA DEVILS

OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION

PROTOCOL No.:

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	<i>Results</i> heading, select radio button against 'No'	'No' should be selected.				
7.9.46	<i>Click Next</i>  Enter in the text box against Report Title ' <i>Qualification eResidue Test 2.</i> '  In the drop-down list against <i>Signatories</i> , place a tick mark in the check box against ' <i>Select All.</i> '	<i>Step 5 - Report</i> accordion window should be displayed.  The text box against Report Title should read ' <i>Qualification eResidue Test 2.</i> '  On placing a tick mark in the check box against ' <i>Select All,</i> ' all entries in the drop-down list should be selected				
7.9.47	<i>Select the check boxes L1, L2, L3, L4a (Swab Amount), L4b (Swab Conen.) and L4c (Rinse) under heading "Step 5 - Limit Selection."</i>	<i>The check boxes L1,L2, L3, L4a (Swab Amount), L4b (Swab Conen.) and L4c (Rinse) under heading "Step 5 - Limit Selection" should be selected. The check boxes L4a as TOC (Swab Amount), L4b as TOC (Swab Conen.) and L4c as TOC (Rinse) should not be selectable.</i>				
7.9.48	<i>Click Submit icon.</i>	A Calculation Status popup window should be displayed with message "Calculation is being setup". Once setup process has been completed, Popup window should show the				



PHARMA DEVILS

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		message “Generated report will appear on Report Tracker. Please download it from there.” Page. The popup window should also then display ‘Close’ icon.				
7.9.49	Download the PDF Report from Report Tracker window, created in earlier step, and then open it. Verify that the title ‘Qualification eResidue Test 2’ is captured on the first page of the report.	It should be possible to download the PDF report from. Report tracker window. The PDF report should open and show ‘qualification eResidue Test 2’ as report title on the first page.				
7.9.50	Calculate the total surface area of equipment shared between C and D.	Equipment Q and R are shared by products C and D. The shared surface area should therefore be $= 150,000 + 50,000 = 200,000 \text{ cm}^2$				
7.9.51	Calculate, manually, limits L1, L2 and L3 for current product being C, next product being the same (C).	<ol style="list-style-type: none"><li>1. L1 (calculated) = <math>0.001 \times 70 = 0.07 \text{ mg/ml}</math></li><li>2. L2 = <math>0.07 \times 400 \times 1000 = 28,000 \text{ mg}</math></li><li>3. L3 = <math>28,000 / 500,000 = 0.0560 \text{ mg/cm}^2</math> (Equipment P+Q+R surface area in</li></ol>				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		the denominator)				
7.9.52	Calculate, manually, limits L1, L2 and L3 for current product being C, next product D.	1. L0 (dose based) $= 0.001 \times 70 \times 10 \times 1 = 0.7$ mg 2. L0 (health based) $= 6.5$ mg 3. Since L0 (dose based) is lower, 0.7 mg value will be used. 4. L1 (calculated) = $0.7 / (15 \times 2) = 0.023333$ mg/ml 5. L2 = $0.023333 \times 350 \times 1000 = 8166.55$ mg (round off to 8167 mg) 6. L3 = $8167 / 200,000 = 0.0408$ mg/cm <sup>2</sup>				
7.9.53	Calculate, manually, limits L4a, L4b and L4c based on worst case "next product", Current Product being C	Equipment S is not used for Product C. Hence not considered Equipment P - Shared only when the same product C is again manufacturad L3 used = 0.0560 mg/cm <sup>2</sup> L4a = $0.0560 \times 25 = 1.40$ mg L4b = $1.4 / 40 = 0.0350$ mg/ml L4c = $0.0560 \times 300,000 / (20 \times 1000) = 0.840$ mg/ml Equipment Q				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		<p>- Used when either Product C or D is the next product manufacturad, current product being C. L3 used will be lower of the 2 L3s calculated (C-C and C-D).</p> <p>L3 used = 0.0408 mg/cm<sup>2</sup></p> <p>L4a = 0.0408 x 25 = 1.02 mg</p> <p>L4b = 1.02/40 = 0.0255 mg/ml</p> <p>L4c = 0.0408 x 150,000/ (20 x1000) = 0.306 mg/ml</p> <p>Equipment R - Used when either product C or Product D is the next product manufacturad, current product being C. L.3 used will be lower of the 2 L3s calculated (C-C and C-D).</p> <p>L3 used = 0.0408 mg/ cm<sup>2</sup></p> <p>L4a = 0.0408 x 25 = 1.02 mg</p> <p>L4b = 1.02/40 = 0.0255 mg/ml</p> <p>L4c =0.0408 x 50,000/(20 x1000) = 0.102 mg/ml</p>				
7.9.54	Calculate, manually, limits	1.L1 (calculated) = 0.001 x 15 =				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	L1, L2 and L3 for current product being D, next product being the same (D).	0.015 mg/ml 2.L2= $0.015 \times 350 \times 1000 = 5,250 \text{ mg}$ 3.L3= $5250 / 220,000 = 0.02386 \text{ mg/cm}^2$ (Equipment Q+R+S surface area in the denominator)				
7.9.55	Calculate, manually, limits L1, L2 and L3 for current product being D, next product C.	1.LO (dose based) = $0.001 \times 15 \times 15 \times 1 = 0.225 \text{ mg}$ 2.LO (health based) = 2.0 mg 3.Since L0 (dose based) is lower, 0.225 mg value will be used. $L0 = 0.225 \text{ mg/ml}$ 4.L1 (calculated) = $0.225 / (10 \times 1) = 0.0225 \text{ mg/ml}$ 5.L2 = $0.0225 \times 400 \times 100 = 9,000 \text{ mg}$ 6.L3 = $9,000 / 200,000 = 0.0450 \text{ mg/cm}^2$				
7.9.56	Calculate, manually, limits L4a, L4b and L4c based on worst case "next product", Current Product being D	Equipment P is not used for Product D. Hence not considered Equipment Q - Used either when the same product D is again manufactured or when Product C is next product manufactured,				



PHARMA DEVILS

OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION

PROTOCOL No.:

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		<p>current product being D. L3 used will be lower of the 2 L3s calculated (D-C and D-D).</p> <p>L3 used = 0.02386 mg/cm<sup>2</sup> L4a = 0.02386 x 25 = 0.597 mg L4b = 0.597/40 = 0.0149 mg/ml L4c = 0.02386 x 150,000/(20 x1000) = 0.179 mg/ml</p> <p>Equipment R - Used either when the same product D is again manufactured or when Product C is next product manufactured, current product being D. L3 used will be lower of the 2 L3s calculated (D-C and D-D).</p> <p>L3 used = 0.02386 mg/cm<sup>2</sup> L4a = 0.02386 x 25 = 0.597 mg L4b = 0.597/40 = 0.0149 mg/ml L4c = 0.02386 x 50,000/(20 x1000) = 0.05965 mg/ml</p> <p>Equipment S - Shared only when the same product D is again manufactured</p>				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		$L3 (B-B) = 0.02386 \text{ mg/cm}^2$ $L4a = 0.02386 \times 25 = 0.597 \text{ mg}$ $L4b = 0.597/40 = 0.0149 \text{ mg/ml}$ $L4c = 0.02386 \times 20,000/(20 \times 1000) = 0.0239 \text{ mg/ml}$				
7.9.57	Verify that the limits as calculated in steps 46-52 match that noted in report, generated in step 45 (Qualification eResidue Test 3) by eResidue.	The limits LO, L1, L2, L3, L4a, L4b and L4c for C-C, C-D, D-C and D- D (Current (Cleaned) Product- Product to be manufactured) as calculated in steps 46-52 should match that noted in the PDF document, generated in step 45.				
7.9.58	<p>Go to Report Tracker window. Place a tick mark in the checkbox against Qualification eResidue Test 3. Click the "Move to Archive" icon.</p> <p>From "Select Folder" drop-down menu, Select "Archive". Verify that the Qualification eResidue Test 3 report is available there</p>	<p>On clicking "Move to Archive" icon, the report "Qualification eResidue Test 3" should not be displayed in the Current Report: Tracker window.</p> <p>The Qualification eResidue Test 3 report should be displayed in the Archive window.</p>				
7.9.59	Change the ADE value noted to: Product A - 0.23	ADE of Product A, B and D should change to 0.23 mg,				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	mg Product B - 0.18 mg Product D - 0.40 mg	0.18 mg and 0.40 mg				
7.9.60	Click "Calculation" icon on the top right corner of the window.	Calculate Limit accordion must be displayed				
7.9.61	Under Step 1 - Product Selection, Select Products A, B & D.  <i>Click Next.</i>	Products A, B and D should be displayed under <i>Products Selected.</i>  Step 2 - Sampling Method accordion window should be displayed.				
7.9.62	In the Step 2 - Sampling Method window, select the radio button 'Run limits with L4 calculation'.	The radio button against ' <i>Run limits with L4 calculation</i> ' should be selectable under the heading <i>Step 2 - Sampling Method.</i>				
7.9.63	Continue with the following settings for Step 2 - Sampling Method: <ul style="list-style-type: none"> <li>Place tick mark in check box against '<i>Rinse</i>'.</li> <li>Select radio button against 'As Train' for Equipment</li> </ul>	<i>In Step 2-Sampling Method,</i> following should be the settings: <ul style="list-style-type: none"> <li>Check box against 'Rinse' should be selected</li> <li>Radio button against 'As Train' for Equipment Sampling</li> </ul>				





PHARMA DEVILS

OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION

PROTOCOL No.:

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	Sampling. <ul style="list-style-type: none"><li>Place tick mark in check box against 'Swab'.</li><li>Select radio button against 'Both' for the heading Express swab limits as:</li></ul>	category should be selected. <ul style="list-style-type: none"><li>Check box against 'Swab' should be selected</li><li>Radio button against 'Both' should be selected for the heading Express swab limits as:</li></ul>				
7.9.64	Click on the <i>Next</i> button.	Step 3-Rinse-Train accordion window should be displayed				
7.9.65	<i>In Step 3 - Rinse - Train window, select the radio button against 'Apply volume liter entered in the first row to all the other listed Product'. Enter Volume as '20'.</i>	<i>The radio button against 'Apply volume liter entered in the first row to all the other listed Product' should be selected</i>  <i>A volume of '20' should be displayed against all product listed</i>				
7.9.66	Click on the <i>Next</i> button.  In Swab window, select the radio button against 'Apply all 3 entries in the first row to all the other listed products'.	Step 3 - Swab accordion window should be displayed.  The radio button against 'Apply all 3 entries in the first row to all the other listed products' should be selectable.				
7.9.67	Enter in the first box below <i>Solvent</i>	All the entries under column				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

<b>Step No #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Actual Results</b>	<b>Status (Pass/Fall)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
	<p><i>Used column 'water'. Enter in the first box below Amt. of Solvent used for Desorption value of '40' and choose the unit as 'ml'.</i></p> <p><i>Enter in the first box below Surface Area Sampled the value '25'.</i></p>	<p><i>Solvent Used should display 'water'. All entries under column Amt. of Solvent used for Desorption should display '40' with the units being 'mL'. All entries under column Surface Area Sampled should read the value '25'.</i></p>				
7.9.68	<p><i>Click Next.</i></p> <p><i>Under Limit Calculation heading, select radio button against 'Calculate the limits for the active in each product with every product (including the same product) as the next product'.</i></p>	<p><i>Step 4 - Definition accordion window should be displayed.</i></p> <p><i>The radio button against 'Calculate the limits for the active in each product with EVERY product (including the same product) as the next product' should be selected.</i></p>				
7.9.69	<p><i>Under Surface Area Selection heading, select radio button against 'Calculate the L3 limit based on the lowest total equipment train surface area between the two</i></p>	<p><i>The radio button against 'Calculate the L3 limit based on the lowest total equipment train surface area between the two products' should be selected.</i></p>				



PHARMA DEVILS

OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION

PROTOCOL No.:

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	products.  Under <b>TOC</b> Results heading, select radio button against 'No'	The radio button against 'No' should be selected.				
7.9.70	Click the <i>Next</i> button.  <i>Enter in the text box against Report Title 'Qualification eResidue Test 3'.</i>  In the drop-down list against <i>Signatories</i> , place a tick mark in the check box against ' <i>Select All</i> '.	<i>Step 5 - Report</i> accord ion window should be displayed.  <i>The text box against Report Title should read 'Qualification eResidue Test 3'</i>  On placing a tick mark in the check box against ' <i>Select All</i> ,' all entries in the drop-down list should be selected.				
7.9.71	<i>Select the check boxes</i> L1, L2, L3, L4a (Swab Amount), L4b (Swab Conen.) and L4c (Rinse) under heading Step 5 - Limit Selection.	<i>The check boxes</i> L1, L2, L3, L4a (Swab Amount), L4b (Swab Conen.) and L4c (Rinse) under heading Step 5 - Limit Selection should be selected.				
7.9.72	Click <i>Submit</i> icon. Click Close icon once the calculation setup is over in the calculation Status popup window	A Calculation Status popup window should be displayed with message "Calculation is being setup". Once setup process has been completed, Popup window				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		should show the message “Generated report will appear on Report Tracker. Please download it from there.” Page. The popup window should also then display ‘Close’ icon.				
7.9.73	Download the PDF Report from Report Tracker window, created in earlier step, and then open it. Verify that the title ‘Qualification eResidue Test 3’ is captured on the first page of the report.	It should be possible to download the PDF report from. Report tracker window. The PDF report should open and show ‘qualification eResidue Test 3’ as report title on the first page.				
7.9.74	<p>Add surface area of P, Q, R &amp; S for Products A</p> <p>Add surface area of P, Q &amp; R for Product B</p> <p>Add surface area of Q, R &amp; S for Product D</p>	<p>Surface Area of P, Q, R &amp; S should add to: 300,000+150,000+50,000+20,000 = 520,000 cm<sup>2</sup></p> <p>Surface Area of P, Q, R &amp; S should add to: 300,000+150,000+50,000+20,000 = 520,000 cm<sup>2</sup></p> <p>Surface Area of Q, R &amp; S should add to: 150,000+50,000+20,000 = 220,000 cm<sup>2</sup></p>				
7.9.75	Calculate,	LO (dose based)				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	manually, limits for current product being A, next product being the same (A).	$= 0.001 \times 70 \times 10 \times 1 = 0.7 \text{ mg}$ L0 (health based) = 0.23 mg Since L0 (health based) is lower, 0.23mg value will be used. L1 (calculated) = $0.23 / (10 \times 1) = 0.023 \text{ mg/ml}$ L2 = $0.023 \times 400 \times 1000 = 9,200 \text{ mg}$ L3 = $9,200 / 520,000 = 0.01769 \text{ mg/cm}^2$				
7.9.76	Calculate, manually, limits for current product being A, next product B.	L0 (dose based) = $0.001 \times 70 \times 10 \times 1 = 0.7 \text{ mg}$ L0 (health based) = 0.23 mg Since L0 (health based) is lower, 0.23mg value will be used. L1 (calculated) = $0.23 / (15 \times 2) = 0.007667 \text{ mg/ml}$ L2 = $0.007667 \times 350 \times 1000 = 2683.45 \text{ mg}$ (round off to 2683 mg) L3 = $2683 / 520,000 = 0.00516 \text{ mg/cm}^2$				
7.9.77	Calculate, manually, limits for current product being A, next Product D	LO (dose based) = $0.001 \times 70 \times 10 \times 1 = 0.7 \text{ mg}$ L0 (health based) =				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		0.23 mg Since L0 (health based) is lower, 0.23 mg value will be used. $L1 \text{ (calculated)} = 0.23 / (15 \times 2) = 0.007667 \text{ mg/ml}$ $L2 = 0.007667 \times 350 \times 1000 = 2683.45 \text{ mg}$ $L3 = 2683.45 / 220,000 = 0.0122 \text{ mg/cm}^2$				
7.9.78	Calculate, manually, Rinse limits L4c, for P, Q, R and S equipment train used by Products A and B.	$L3 \text{ for A-B is } 0.00516 \text{ mg/cm}^2$ , which is lower than $0.053846 \text{ mg/cm}^2$ for A-A. $L4c \text{ for P, Q, R and S equipment train} = 0.00516 \times 520,000 / (20 \times 1000) = 0.134 \text{ mg/ml}$				
7.9.79	Calculate, manually, Rinse limits L4c, for Q, R and S equipment train used by Product D	$L4c \text{ for Q, R and S equipment train} = 0.0122 \times 220,000 / (20 \times 1000) = 0.134 \text{ mg/ml}$				
7.9.80	Calculate, manually, Swab limits for current product A	$L3 \text{ for A-B is the lowest } (0.00516 \text{ mg/cm}^2)$ in comparison to L3 for A-A and A-D. This will be used for				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		<p>all equipment.</p> <p>For Equipment P, Q, R and S each:  <math>L4a = 0.00516 \times 25 = 0.129 \text{ mg}</math>  <math>L4b = 0.129/40 = 0.00323 \text{ mg/ml}</math></p>				
7.9.81	Calculate, manually, limits for current product being B, next product being the same (B).	<p>LO (dose based) = <math>0.001 \times 15 \times 15 \times 1 = 0.225 \text{ mg}</math></p> <p>LO (health based) = <math>0.18 \text{ mg}</math></p> <p>Since LO (health based) is lower, 0.18 mg value will be used.</p> <p>L1 (calculated) = <math>0.18 / (15 \times 2) = 0.006 \text{ mg/ml}</math></p> <p>L2 = <math>0.006 \times 350 \times 1000 = 2,100 \text{ mg}</math></p> <p>L3 = <math>2,100 / 520,000 = 0.00404 \text{ mg/cm}^2</math></p>				
7.9.82	Calculate, manually, limits for current product being B, next product A.	<p>L0 (dose based) = <math>0.001 \times 15 \times 15 \times 1 = 0.225 \text{ mg}</math></p> <p>L0 (health based) = <math>0.18 \text{ mg}</math></p> <p>Since L0 (health based) is lower, 0.18 mg value will be used. L1 = <math>0.18 \text{ mg/ml}</math></p> <p>L1 (calculated) =</p>				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		$0.18/(10 \times 1) = 0.018 \text{ mg/ml}$ $L2 = 0.018 \times 400 \times 1000 = 7,200 \text{ mg}$ $L3 = 7,200 / 520,000 = 0.01385 \text{ mg/cm}^2$				
7.9.83	Calculate, manually, limits for current product being B, next product D.	$L0 \text{ (dose based)} = 0.001 \times 15 \times 15 \times 1 = 0.225 \text{ mg}$  $L0 \text{ (health based)} = 0.18 \text{ mg}$ Since L0 (health based) is lower, 0.18 mg value will be used. $L1 = 0.18 \text{ mg/ml}$  $L1 \text{ (calculated)} = 0.18 / (15 \times 2) = 0,006 \text{ mg/ml}$  $L2 = 0.006 \times 350 \times 1000 = 2,100 \text{ mg}$  $L3 = 2,100 / 220,000 = 0.009545 \text{ mg/cm}^2$				
7.9.84	Calculate, manually, Rinse limits L4c, for P, Q, R and S equipment train used by Products A and B	$L3 \text{ for B-B is } 0.00404 \text{ mg/cm}^2$ , which is lower than $0.01385 \text{ mg/cm}^2$ for B-A. $L4c \text{ for P, Q, R and S equipment train} = 0.00404 \times 520,000 / (20 \times 1000) = 0.1050 \text{ mg/ml}$				
7.9.85	Calculate,	$L4c \text{ for Q, R and S}$				





**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	manually, Rinse limits L4c, for Q, R and S equipment train used by Product D	equipment train = $0.009545 \times 220,000 / (20 \times 1000)$ = 0.105 m g/ml				
7.9.86	Calculate, manually, Swab limits for current product A	L3 for B-B is the lowest (0.00404 mg/cm <sup>2</sup> ) in comparison to L3 for B-A and B-D. This will be used for all equipment.  For Equipment P, Q, R and S each: L4a = $0.00404 \times 25$ = 0.101 mg L4b = $0.101/40$ = 0.00252 mg/ml				
7.9.87	Calculate, manually, limits for current product being D, next product being the same (D).	LO (dose based) = $0.001 \times 15 \times 15 \times 1$ = 0.225 mg LO (health based) = 0.40 mg Since LO (dose based) is lower, 0.225 mg value will be used. L1 (calculated) = $0.001 \times 15$ = 0.015 m g/ml L2= $0.015 \times 350 \times 1000$ = 5,250 mg L3= $5,250/220,000$ = 0.02386 m g/cm <sup>2</sup>				
7.9.88	Calculate, manually, limits for current product being D, next product A.	LO (dose based) = $0.001 \times 15 \times 15 \times 1$ = 0.225 mg LO (health based) = 0.40 mg				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		Since LO (dose based) is lower, 0.225 mg value will be used. $L1 \text{ (calculated)} = 0.225 / (10 \times 1) = 0.0225 \text{ m g/ml}$  $L2 = 0.0225 \times 400 \times 1000 = 9,000 \text{ mg}$ $L3 = 9,000 / 220,000 = 0.04091 \text{ mg/cm}^2$				
7.9.89	Calculate, manually, limits for current product being D, next product B.	$LO \text{ (dose based)} = 0.001 \times 15 \times 15 \times 1 = 0.225 \text{ mg}$ $L0 \text{ (health based)} = 0.40 \text{ mg}$ Since L0 (dose based) is lower, 0.225 mg value will be used. $L1 \text{ (calculated)} = 0.225 / (15 \times 2) = 0.0075 \text{ mg/ml}$ $L2 = 0.0075 \times 350 \times 1000 = 2,625 \text{ mg}$ $L3 = 2,625 / 220,000 = 0.01193 \text{ mg/cm}^2$				
7.9.90	Calculate, manually, Rinse limits L4c, for P, Q, R and S equipment train used by Products A and B	$L3 \text{ for D-B is } 0.01193 \text{ mg/cm}^2$ , which is lower than $0.04091 \text{ mg/cm}^2$ for B-A. $L4c \text{ for P, Q, R and S equipment train} = 0.01193 \times 220,000 / (20 \times 1000) = 0.131 \text{ mg/ml}$				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
7.9.91	Calculate, manually, Rinse limits L4c, for Q, R and S equipment train used by Product D	L4c for Q, R and S equipment train = 0.02386 x 220,000 / (20x1000) = 0.263 mg/ml				
7.9.92	Calculate, manually, Swab limits for current product D	L3 for D-B is the lowest (0.0119 mg/cm <sup>2</sup> ) in comparison to L3 for D-A and D-D. This will be used for all equipment.  For Equipment P, Q, R and 5 each: L4a = 0.01193 x 25 = 0.2983 mg L4b = 0.2983/40 = 0.00746 mg/ml				
7.9.93	Start a new calculation by clicking the <i>Calculation</i> icon.	<i>Calculate Limit</i> accordion must be displayed.				
7.9.94	Under <i>Step 1 - Product Selection</i> , Select Products A, B & CA1 from the <i>Available Products</i> list. Use the right arrow to transfer it to the <i>Products Selected</i> list.  Click Next	Products A, B and CA1 should be displayed under <i>Products Selected</i> .  Step 2 - Sampling Method accordion window should be displayed				
7.9.95	<i>In the Step 2 - Sampling Method</i> window, select the radio button 'Run limits with L4	The radio button against ' <i>Run limits with L4 calculation</i> ' should be selectable under the heading				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	calculation'.	<i>Step 2 - Sampling Method</i>				
7.9.96	<p>Continue with the following settings in <i>Step 2 - Sampling Method</i> window:</p> <ul style="list-style-type: none"> <li>Place tick mark in check box against '<i>Rinse</i>'</li> <li>Select radio button against '<i>Individually</i>' for Equipment Sampling.</li> <li>Place tick mark in check box against 'Swab'</li> <li>Select radio button against 'Both' for the heading Express swab limits as:</li> </ul>	<p><i>In Step 2 - Sampling Method, following should be the settings:</i></p> <ul style="list-style-type: none"> <li>Check box against 'Rinse' should be selected</li> <li>Radio button against</li> <li>'Individually' for Equipment Sampling category should be selected</li> <li>Check box against 'Swab' should be selected</li> <li>Radio button against '<i>Both</i>' should be selected for the heading <i>Express swab limits as:</i></li> </ul>				
7.9.97	<p>Click on the <i>Next</i> button.</p> <p><i>In Rinse-Individual window, select the radio button against 'Apply volume liter entered in the first row to all other</i></p>	<p><i>Rinse Individuai</i> window should be displayed.</p> <p><i>The radio button against 'Apply volume liter entered in the first row to all other listed equipment should be selectable.</i></p>				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fail)	Screen Shot No	Tested By Sign/Date
	listed equipment. Enter Volume as '20'.	A volume of '20' should be displayed against all equipment listed				
7.9.98	Click on the <i>Next</i> button.  In Swab window, select the radio button against 'Apply all 3 entries in the first row to all the other listed products'.	Step 3 -Swab accordion window should be displayed.  <i>The radio button against 'Apply all 3 entries in the first row to all the other listed products' should be selectable.</i>				
7.9.99	Enter in the first box below Solvent Used column 'Water'.  Enter in the first box below Amt. of Solvent used for Desorption value of '40' and choose the unit as 'ml'.  Enter in the first box below Surface Area Sampled the value '25'	All the entries under column Solvent Used should display 'Water'.  <i>All entries under column Amt. of Solvent used for Desorption should display '40' with the units being 'mL'</i>  All entries under column <i>Surface Area Sampled</i> should read the value '25'.				
7.9.100	Click Next.  Under <b>TOC</b> Results heading, select radio button against 'No'.	<i>Step 4 - Definition</i> accordion window should be displayed.  The radio button against 'No' should				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

<b>Step No #</b>	<b>Description</b>	<b>Expected Results</b>	<b>Actual Results</b>	<b>Status (Pass/Fall)</b>	<b>Screen Shot No</b>	<b>Tested By Sign/Date</b>
	Click the <i>Next</i> button	be selected. <i>Step 5 - Report</i> accordion window should be displayed				
7.9.101	<i>Enter in the text box against Report Title 'Qualification eResidue Test 4'.</i>	<i>The text box against Report Title should read 'Qualification eResidue Test 4'</i>				
7.9.102	In the drop-down list against <i>Signatories</i> , place a tick mark in the check box against <i>'Select All'</i> .	On placing a tick mark in the check box against <i>'Select All,'</i> all entries in the drop-down list should be selected				
7.9.103	<i>Select the check boxes L1, L2, L3, L4a (Swab Amount), L4b (Swab Conen.) and L4c (Rinse) under heading Step 5 - Limit Selection.</i>	<i>The check boxes L7, L2, L3, L4ai (Swab Amount), L4b (Swab Conen.) and L4c (Rinse) under heading Step 5 - Limit Selection should be selected</i>				
7.9.104	Click <i>Submit</i> icon. Click <i>Close</i> icon once the calculation setup is over in the Calculation Status popup window and the <i>Close</i> icon are visible.	A Calculation Status popup window should be displayed with message "Calculation is being setup". Once setup process has been completed, Popup window should show the message "Generated report will appear on Report Tracker. Please download it from there." Page. The popup window				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		should also then display 'Close' icon.				
7.9.105	Download the PDF Report from Report Tracker window, created in earlier step, and then open it. Verify that the title 'Qualification eResidue Test 2' is captured on the first page of the report.	It should be possible to download the PDF report from. Report tracker window. The PDF report should open and show 'qualification eResidue Test 2' as report title on the first page.				
7.9.106	Calculate, manually, limits L1, L2 and L3 for Cleaning agent CA1, next Product A	1.L0 (ADI based) = 900 x 60 x 1/1000 = 54 mg 2.L0 (health based) = 0.1 mg 3.Since L0 (health based) is lower, 0.1 mg will be used. 4.L1 (calculated) = 0.1/(10x1) = 0.0100 mg/ml 5.L2= 0.0100x 400 x 1000 = 4000 mg 6.L3= 4000/500,000 = 0.00800 mg/cm <sup>2</sup>				
7.9.107	Calculate, manually, limits L1, L2 and L3 for Cleaning agent CA1, next Product B	1. L0 (ADI based) = 900 x 60 x 1/1000 = 54 mg 2. L0 (health based) = 0.1 mg 3. Since L0 (health based) is lower, 0.1 mg will be used. 4. L1 (calculated) = 0.1/(15x2) = 0.003333 mg/ml				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		5. $L2 = 0.003333 \times 350 \times 1000 = 1166.55 \text{ mg}$ (round off to 1167mg) 6. $L3 = 1167/220,000 = 0.00530 \text{ mg/cm}^2$				
7.9.108	Calculate, manually, limits L4a, L4b and L4c based on worst case "next Product", Current Product being Cleaning agent CA1	Equipment P - Used when product A is next Product. $L3 (D-A) = 0.00800 \text{ mg/cm}^2$  $L4a = 0.00800 \times 25 = 0.200 \text{ mg}$ $L4b = 0.200/40 = 0.00500 \text{ mg/ml}$ $L4c = 0.00800 \times 300,000/(20 \times 1000) = 0.120 \text{ mg/ml}$  Equipment Q - Used for manufacture of A and B. L3 used will be lower of the 2 L3s calculated (CA1-A and CA1-B). $L3 \text{ used} = 0.00530 \text{ mg/cm}^2$ $L4a = 0.00530 \times 25 = 0.1325 \text{ mg}$ $L4b = 0.1325/40 = 0.00331 \text{ m g/ml}$ $L4c = 0.00530 \times 150,000/(20 \times 1000) = 0.0398 \text{ m}$				





**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		<p>g/ml Equipment R - Used for manufacture of A and B. L3 used will be lower of the 2 L3s calculated (CA1-A and CA1-B). L3 used = 0.00530 mg/cm<sup>2</sup> L4a = 0.00530 x 25 = 0.1325 mg L4b = 0.1325/40 = 0.00331 m g/ml L4c= 0.00530 x 50,000/(20 x1000) = 0.0133 mg/ml Equipment S - Used when product B is next product manufactured. L3(CA1 - B) = 0.00530 mg/cm<sup>2</sup> L4a = 0.00530 x 25 = 0.1325 mg L4b = 0.1325/40 = 0.00331 m g/ml L4c= 0.00530 x 20,000/(20 x1000) = 0.00530 m g/ml</p>				
7.9.109	Verify that the limits as calculated in steps 104-106 matches that noted in report, generated in step 103 ( <i>Qualification eResidue Test 4</i> ), by eResidue.	The limits L0, L1, L2, L3, L4a, L4b and L4c for CA1-A and CA1-B (Cleaning Agent-Product to be manufactured) as calculated in steps 104-106 should match that noted in the PDF document,				



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		generated in step 103 ( <i>Qualification eResidue Test 4</i> ), by eResidue				

**Remarks:**

---

---

---

---

Meet the Acceptance Criteria [ ] Yes [ ] No

Verified by : \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed by : \_\_\_\_\_ Date: \_\_\_\_\_

**8.0 DEVIATION (IF ANY):**





**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

**12.0 ABBREVIATIONS:**

<b>Abbreviations</b>	<b>Description</b>
OQ	Operational Qualification
ADE	Acceptable Daily Exposure
PDE	Permitted Daily Exposure
PPM	Part per Million
CC	Change Control
Ref.	Reference

**13.0 REFERENCE:**



**PHARMA DEVILS**

**OPERATIONAL QUALIFICATION  
FOR  
eRESIDUE APPLICATION**

**PROTOCOL No.:**

**14.0 POST APPROVAL:**

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

<b>Prepared By</b>	<b>Department</b>	<b>Designation</b>	<b>Sign &amp; Date</b>

<b>Reviewed By</b>	<b>Department</b>	<b>Designation</b>	<b>Sign &amp; Date</b>

<b>Approved By</b>	<b>Department</b>	<b>Designation</b>	<b>Sign &amp; Date</b>