	RECORD OF OBSERVATIONS FOR eRESIDUE APPLICATION VERSION 2.0.0	PROTOCOL No.:
PHARMA DEVILS		

RECORD OF OBSERVATIONS

FOR

eRESIDUE APPLICATION

VERSION 2.0.0

PHARMA DEVILS	RECORD OF OBSERVATIONS FOR eRESIDUE APPLICATION VERSION 2.0.0	PROTOCOL No.:

1.0 Identification of executors & verification of training status

Name of the Executor	Department Name	Designation	Sign & Date	Training Details

Note: Attach the training record

Remarks:	
	Verified by Sign & Date:
Remarks:	
	Reviewed by Sign & Date:

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2.0 Qualification status:

Qualification Start Date		Qualification Completed Date	

3.0 Verification of IQ & OQ completion:

Document Name	Document Number	Qualification Status

4.0 Calibration status of the standards used in the Qualification study:

Name of Standard Equipment	ID/Serial No	Calibration Done on	Calibration Due on	Ref Report No	Checked by (sign &Date)

Calibration of Inbuilt Instruments:

Calibration Details				
Name	Location	Id. Number	Done ON	Next Due

Verified By:
Sign & Date

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5.0 RESULTS:

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

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fail)	Screen Shot No	Tested By Sign/Date
5.1.1	Open the eResidue application using Firefox/chrome	Website window should be displayed.				
5.1.2	Login to the eResidue application with the administrator.	Administrator shall be logged in into the application.				
5.1.3	Click on user ID button.	Account details, Change password and logout option shall be displayed.				
5.1.4	Click on Account details button.	Account details window should be displayed user name, Company Name, Address, Site Description, Expiry date, Total No. of products/Equipments are allowed and Report Template. Further should contains additional details like upgrade, Modules				
5.1.5	Click on setting button.	Access setting window should contains User summary and options.				
5.1.6	Click on user summary	First name & Last name, Username, Email Address, Account Permissions, Role, status, Actions, Export as PDF & Add button should be available.				
5.1.7	Click on Universal Settings	General, Limit Terminology, Limit Definition,				

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fail)	Screen Shot No	Tested By Sign/Date
		Signature Policy should be displayed.				
5.1.8	Click on change password button.	Change password window should be displayed with current password, New password, Re-enter password.				
5.1.9	Click on Cancel button	Home page should be displayed.				
5.1.10	Click on Fields	Fields button should contain Equipment, Product and upload options.				
5.1.11	Click on Calculation button	Calculation window should be displayed.				
5.1.12	Click on Reports button	Reports button should contains Calculation Report and Event Log Report options.				
5.1.13	Click on Logout	Application login window should open in the default browser.				
Equipment						
5.1.14	Login to the eResidue application with the user.	User shall be logged in into the application.				
5.1.15	Go to fields and click in equipment.	Equipment summary window is displayed and should contains Equipment and cluster options, Add, Export as XLS/PDF.				
5.1.16	Click on add equipment button in Equipment summary window	Add new equipment window shall be displayed with red asterisks (*) are displayed for mandatory fields.				
5.1.17	Click cancel button.	Equipment Summary				

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fail)	Screen Shot No	Tested By Sign/Date
		Window displayed.				
5.1.18	In equipment summary window and click on the pencil icon against the equipment for edit the equipment details	Edit equipment window should be displayed with respective equipment details.				
5.1.19	Try to edit the equipment Name.	Application will not allow to editing the equipment name.				
5.1.20	Edit the required details and click update button.	Equipment summary window displayed with updated equipment details.				
5.1.21	Click on the pencil icon against the equipment.	Edit equipment window should be displayed with respective equipment details.				
5.1.22	Click cancel button.	Equipment Summary window displayed.				
5.1.23	Click on Logout	Application login window should open in the default browser.				
5.1.24	Login to the eResidue application with the administrator.	Administrator shall be logged in into the application.				
5.1.25	Go to fields and click in equipment.	Equipment summary window is displayed				
5.1.26	Go to equipment summary window and click on the minus icon against the equipment (equipment is not mapped with any product) for	Delete equipment warning message should be displayed with Proceed and Cancel buttons.				

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fail)	Screen Shot No	Tested By Sign/Date
	delete the equipment details.					
5.1.27	Click on the minus icon against the equipment (equipment is mapped with any product).	If the equipment is mapped with any product, Product(s) mapped to this equipments warning message should be displayed with Close button.				
5.1.28	Click close button.	Equipment Summary window displayed and respective equipment was not deleted in equipment summary.				
5.1.29	Click on Logout	Application login window should open in the default browser.				
Product						
5.1.30	Login to the eResidue application with the user.	User shall be logged in into the application.				
5.1.31	Go to fields and click on product.	Product summary window shall be displayed Product and Cluster options with add, Export as XLS/PDF buttons.				
5.1.32	In Product summary window, click on add Product.	Add Product window shall be displayed with product name and product type fields with asterisks (*) are displayed for mandatory fields.				
5.1.33	Click on cancel button in Add Product window.	Product summary window shall be displayed				
5.1.34	In Product summary window, click on	Add Product window shall be displayed with				

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fail)	Screen Shot No	Tested By Sign/Date
	add Product.	product name and product type fields with asterisks (*) are displayed for mandatory fields.				
5.1.35	Enter Product Name and select the product type and click on submit.	Detailed add product window shall be displayed with asterisks (*) are displayed for mandatory fields.				
5.1.36	Click cancel button.	Product Summary window displayed.				
5.1.37	In Product summary window, click on add Product.	Add Product window shall be displayed with product name and product type fields with asterisks (*) are displayed for mandatory fields.				
5.1.38	Enter Product Name and select the product type and click on submit.	Detailed add product window shall be displayed with asterisks (*) are displayed for mandatory fields.				
5.1.39	Enter all required details and click submit button.	Application should be save the Product details and this will be also displayed in Product Summary				
5.1.40	In 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.				
5.1.41	Try to edit the Product Name.	Application will not allow to editing the Product name.				
5.1.42	Edit the any required Product details and click update button.	Product summary window displayed with updated Product details.				
5.1.43	Click on the	Edit Product				

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fail)	Screen Shot No	Tested By Sign/Date
	pencil icon against the Product.	window should be displayed with respective Product details.				
5.1.44	Click cancel button.	Product Summary window displayed.				
5.1.45	Click on Logout	Application login window should open in the default browser.				
5.1.46	Login to the eResidue application with the Administrator.	U Administrator shall be logged in into the application.				
5.1.47	Go to fields and click on product.	Product summary window shall be displayed.				
5.1.48	In 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.				
5.1.49	Click cancel button.	Product Summary window displayed and respective Product was not deleted in Product summary.				
5.1.50	Click on Logout	Application login window should open in the default browser.				
Upload						
5.1.51	Login to the eResidue application with the user	User shall be logged in into the application.				
5.1.52	Go to fields and Click on the upload to verify the existing option availability	Upload Input Data window should be displayed to upload the work sheet.				
5.1.53	Click on Logout	Application login				

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fail)	Screen Shot No	Tested By Sign/Date
		window should open in the default browser.				
Calculation						
5.1.54	Login to the eResidue application with the user.	User shall be logged in into the application.				
5.1.55	Click Calculation icon on the top right corner of the window.	Calculation Limit accordion must be displayed.				
5.1.56	Under Step 1 – Report:	Enter in the report title against Report Title box. Residue Limit Report Template should be selected default as Worst case matrix.				
5.1.57	Limit Selection: Select the check boxes L0, 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) under heading Step 1 - Limit Selection.	The check boxes L0, 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) under heading Step 5 - Limit Selection should be selected.				
5.1.58	Under Step 1 – Sampling Method: For Rinse sampling - Place tick mark in check box against Individual equipment For Swab Sampling: Select radio	• Radio button against 'Individual Equipment should be selected. • Radio button against 'Both' should be selected for				

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fail)	Screen Shot No	Tested By Sign/Date
	button against 'Both' for the heading Express swab limits as:	the heading Express swab limits as:				
5.1.59	Under Step 1 – Email Report, select the check box against 'Send report via Email' and select one of the email addresses from the Dropdown list.	Email address should be selected.				
5.1.60	Clickonthe Next button.	Step 2 - Product Selection accordion window should be displayed.				
5.1.61	Under Step 2 - Product Selection, Select required Products/Clusters selections from the Available Products list. Use the right arrow to transfer it to the Products Selected list Click Next.	Selected products should be displayed under Products Selected list.				
5.1.62	Clickonthe Next button.	Step 3 – Rinse Specification-Individual Equipment accordion window should be displayed.				
5.1.63	In step-3 Rinse Specification-Individual Equipment select the radio button against 'Apply volume litre entered in the first row to all other listed equipment'. Enter Volume in	volume litter entered in the first row to all other listed equipment' should be selectable. Entered volume should be displayed against all equipment listed				

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fail)	Screen Shot No	Tested By Sign/Date
	first equipment.					
5.1.64	Clickonthe Next button.	Step 3 – Swab Specification accordion window should be displayed.				
5.1.65	In Swab Specification, select the radio button against 'Apply all 3 entries in the first row to all the other listed products'. • Enter the required solvent name in the first box below Solvent Used column.	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 same.				
5.1.66	Enter in the first box below Amt. of Solvent used for Desorption value and choose the unit as 'mL'. Enter in the first box below Surface Area Sampled the value.	All Entries under column Amt. Of solvent used for desorption should display same as first with the units being 'ml'. All entries under column surface area sampled should read the value same as first.				
5.1.67	Clickonthe Next button.	*Step 4 – Definition* accordion window should be displayed.				
5.1.68	Under Matrix Definition, select radio button against 'Calculate the limits for the active in each product with only every other product as the next product'	The radio button against 'Calculate the limits for the active in each product with only every other product as the next product'should be selected.				

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fail)	Screen Shot No	Tested By Sign/Date
5.1.69	Under Surface area used, select radio button against ,Calculate the L3 limit solely based on the actual shared surface area between the two products'	The radio button against 'Calculate the L3 limit solely based on the actual shared surface area between the two products''should be selected.				
5.1.70	Clickonthe Next button.	Step 5 – Verification accordion window should be displayed.				
5.1.71	Under Verification, the preview dispalying Report title, Calculation type, Limit Selected, Selected products/cluster	Report title, Calculation type, Limit Selected, Selected products/cluster should be displayed.				
5.1.72	Click on the Calculate button.	A Calculation Status popup window should be displayed.				
Reports						
5.1.73	Login to the eResidue application with the user.	User shall be logged in into the application.				
5.1.74	Go to reports and click on limit calculation report.	Reprt tracker accordion must be displayed.				
5.1.75	Verify that the Report for the calculation carried out in earlier steps, appears in Report Tracker.	The table in Report Tracker window should show the Report Title, Created Date, Report Template, Products, Products Cluster, Action, Move to Archive, Current and Archive buttons.				
5.1.76	Click on download icon against the	This report should be downloaded as a PDF document.				

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fail)	Screen Shot No	Tested By Sign/Date
	selected report.					
5.1.77	Verify that this report can be downloaded from the Report Tracker window.	This report should be downloadable as a PDF document from the Report Tracker window.				
5.1.78	Click the copy icon in Report tracker window.	Calculate Limit accordion should displayed with the Report.				
5.1.79	Click on mail icon against the selected report.	Send mail accordion should display with select mail option, send and cancel buttons.				
5.1.80	Click on cancel button.	Report tracker accordion must be displayed.				
5.1.81	Click on mail icon against the selected report.	Send mail accordion should display with select mail option, send and cancel buttons.				
5.1.82	Select required emails and click on send button.	Emails send to the selected emails and Report tracker accordion must be displayed.				
5.1.83	Click on Logout	Application login window should open in the default browser.				
5.1.84	Login to the eResidue application with the administrator.	Administrator shall be logged in into the application.				
5.1.85	Click Calculation Report icon under Reports menu.	Report Tracker window should be displayed when Calculation Report icon is clicked under Reports menu.				
5.1.86	Click the Minus icon against report.	On clicking the Minus icon against report, A pop-up Alert asking for cònfirmation to				

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fail)	Screen Shot No	Tested By Sign/Date
		delete the report.				
5.1.87	Click Proceed icon in Delete Calculation window.	Confirmation Required pop-up window must be displayed asking for password and Comments				
5.1.88	Click on Logout	Application login window should open in the default browser.				
Event Log Report						
5.1.89	Login to the eResidue application with the user.	User shall be logged in into the application.				
5.1.90	Click Event Log Report icon under Reports menu.	Event Summary window should be displayed with the activities list and should contains the options like Time Period, Activity, User name, Export as PDF.				
5.1.91	In event summary window, Click on blue balloon button in the add comments column.	Add comments window shall be opened.				
5.1.92	Enter comments and click on cancel button in add comments window.	Event Summary window should be displayed without update the entered comments.				
5.1.93	In event summary window, Click on blue balloon button in the add comments column.	Add comments window shall be opened.				
5.1.94	Enter comments and click on post button in add comments	Event Summary window should be displayed with update the entered				

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fail)	Screen Shot No	Tested By Sign/Date
	window.	comments.				
5.1.95	In event summary window, Verify the event logs for each activity during PQ.	Event summary window should displayed the each event done during PQ.				
5.1.96	Click on Logout	Application login window should open in the default browser.				
5.1.97	Run the eResidue application with existing data	Application should run without interruption due inclusion of additional features.				
5.1.98	Verify the current Calculated data with existing report	Calculations results i.e. L0, L1, L2, L3, L4 should be same.				

Remarks:

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Meet the Acceptance Criteria   [   ] Yes   [   ] No

Verified by   : _____   Date: _____

Reviewed by : _____   Date: _____

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6.0 DEVIATION (if any):

6.1. Deviation:

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6.2. Impact on operation:

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6.3. Justification for acceptance:

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7.0 ABBREVIATIONS:

ABBREVIATIONS	DESCRIPTION
IQ	Installation Qualification
NA	Not Applicable
No.	Number
OQ	Operational Qualification
ppb	Parts Per Billion
ppm	Part Per Million
PQ	Performance Qualification
SOP	Standard Operating Procedure

8.0 ANNEXURES:

S.No.	Name of Attachment	Attachment No.