

PROTOCOL No.:



Department	QUALITY ASSURANCE
Unit	
Block	
Software name	eRESIDUE APPLICATION
VERSION	1.0.1

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



TABLE OF CONTENTS				
S.No.	Content	Page No.		
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		



1.0 PRE-APPROVAL:

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

Prepared By	Department	Designation	Sign & Date

Reviewed By	Department	Designation	Sign & Date

Approved By	Department	Designation	Sign & Date



2.0 OBJECTIVE:

The objective of this 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





5.0 **RESPONSIBILITIES:**

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

IDENTIFICATION OF EXECUTORS:

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

6.0 PRE-REQUSITE:

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



7.0 METHODOLOGY:

The 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.

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



PROTOCOL No.:

Tested By Sign/Date

esults	Actual Results	Status
		(Pass/Fall)
ry		
r		
dow		
ed		

C1				G 4 4	a
Step	Description	Expected Results	Actual Results	Status	Screen
No #				(Pass/Fall)	Shot No
7.1.4	Close the window	All mandatory			
	and Open Access	fields in user			
	Settings and	creation window			
	create a new user.	are shown red			
	Click submit	asterisk (*) beside			
	button.	the field.			
7.1.5	Select the	New user should			
	Account	be created with			
	Permissions as	privileges limited			
	reports and	to Reports and			
	Calculations and	Calculations.			
	enter User Name,	User Should receive			
	First Name, Last	an email with a			
	Name and Email	system generated			
	Address and	password.			
				1	1

	Permissions as reports and Calculations and enter User Name, First Name, Last Name and Email Address and Click submit button.	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.		



PROTOCOL No.:

Results	Status	Screen	Tested By
	(Pass/Fall)	Shot No	Sign/Date

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	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 Reset Password				
7.1.15	and click on the link provided in the email.	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.				



PROTOCOL No.:

Tested By

Sign/Date

Screen

Shot No

No #switch and select
the 'off'7.1.20Click on Logout
window should

Description

Remarks:

Step

Meet the Acceptance Criteria [] Yes [] No

open in the default

browser.

Verified by : _____ Date: _____

 Reviewed by :
 Date :



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.

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
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	The settings should be saved.				
	Setup the Time format, Date format and time Zone and click the Save icon.					
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.				



Description

Step

OPERATIONAL QUALIFICATION FOR **eRESIDUE APPLICATION**

PROTOCOL No.:

Screen

Tested By

Expected Results Actual Results Status Change Password window should open.

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

Remarks:

Meet the Acceptance Criteria	ı [] Yes	[] No	
Verified by :		Date:			-
Reviewed by :		Date :			



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

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
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.				Jul
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	eRESIDUE APPLICATIO	ON
Meet the Acc	eptance Criteria [] Yes	[] No
Verified by	: Date:	
Reviewed b	y: Date:	
7.4. VERIFICAT	TION OF BASIS OF LIMIT AND DEFAU	LT L1/L3:

Objective: To verify whether L0 is dose based or health based or lower of the 2, The Calculated L1 and/or L3 is to be used or the calculated value is compared against default limits and the lower value used.

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

Acceptance criteria: Refer acceptance criteria as per Data Sheet-7.4 of this protocol

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
7.4.1	Login to the eResidue application with the full access user	User shall be logged in into the application. Home Page shall be displayed.				
7.4.2	Go to fields and Click on the Basis of Limit	The Basis of Limit window should be displayed				
7.4.3	 Verify that the application allows the user to choose one of the following options: LO to be dose based LO to be health based LO to be based on the lower 	It should be possible to select the radio button against 'LO to be dose based' or 'LO to be health based' or 'LO to be based on the lower value between dose based LO and health based LO'. The field 'LO to be based on the lower				



PROTOCOL No.:

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	 value between dose based LO and health based LO Select 'LO to be based on the lower value between dose based LO and health based LO' with safety factor being '0.001' 	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: No default used. Use calculated value. Use a default value for L1 Use a default value for L3 Use default value for both L1 and L3 	It should be possible to select only one of the radio buttons against the following options: • No default used. Use calculated value • Use a default value for L1 • Use a default value for L3 • Use default value for both L1 and L3				
7.4.6	Click on Logout	Application login window should open in the default browser.				

PHARMA DEVILS	OPERATIONA eRESIDUE	L QUALIFICATION FOR APPLICATION	PROTOCOL No.:
Remarks:			
Meet the Acc	ceptance Criteria [] Yes	[] No	
Verified by	· :	Date:	
Reviewed b	oy :	Date :	_





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.

	Equipment										
	Equipment Name S		Surface Area	Surface Area (Cm ²) E		Equipment Name		Surface A	Surface Area (Cm ²)		
	Equipment P		300,00	300,000		ipment Q		150,	000		
	Equipment R		50,000)	Equ	ipment S		20,0	000		
	Eq	uipment T		15,000)	Equ	ipment U		15,0	000	
	Product Ty	pe: Liquid									
tes	Product Name	Active Concn.	Dosing Frequency	Product dose	Doses per period (min/max)	Batch Size (L) (min/max)	Safety Factor	ADE (mg)	% TOC of Active	Equipment Used	
equisi	А	70 mg/mL	Daily	10 mL	1/1	400/800	0.001	6.5	45	P, Q, R & S	
Pre-r	В	15 mg/mL	Daily	15 mL	1/2	350/800	0.001	2.0	40	P, Q, R & S	
	С	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	
	Product Ty	pe: Cleaning	g Agent								
	Produ	ct Nama			LD50 I	Based					
	110000		L	D50	Body W	Veight	Conversion	n Factor	ADE		
	CA1 900 mg/kg				601	ĸg	0.00	1		0.1 mg	



Data Sheet 7.5	

Step No.	Description	Expected Results	Actual Results	Status (Bass/Fall)	Screen Shot No	Tested By Sign/Data
#	I a sin to the	I I a a a a la a ll da a		(Pass/Fall)	Shot No	Sign/Date
7.3.1	a Regidue	logged in into the				
	enclication with	application Home				
	the full ecoses	application. Home				
	the full access	Page shall be				
7.5.0	user.	displayed.				
7.5.2	Click on Upload	Upload Database				
	1con (located	window should be				
	under Fields in	displayed. On				
	menu bar).	selecting the radio				
	Choose the radio	button against				
	button against	'Upload				
	'Upload	Worksheet', a				
	Worksheet'.	template along with				
		upload instructions				
		should be				
		displayed.				
7.5.3	Click on	A pop-up window				
	Spreadsheet	titled Download				
	Template	Excel Template				
	listed in the	should be				
	Upload	displayed.				
	Worksheet					
	window.					
7.5.4	Click Download	A file				
	icon	'eResidue DB				
		Template' should				
		be downloaded				
755	Click Close	Clicking the Close				
7.5.5	Chek Close	icon should close				
		the pop-up window				
		and file was				
		downloaded				
756	Open the	The unload				
7.5.0	downloaded file	worksheet window				
	in Microsoft	should be				
	Evcel and fill the	displayed				
	data in respective	uispiayeu.				
	toba (Equipment					
	Cleaning Accest					
	Cleaning Agent					
	and Liquid) as			1		



PROTOCOL No.:

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Step No.	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Data
#	per above table			(1 ass/1 all)		Sign/Date
	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	The application				
	icon and select	should display a				
	the saved	pop-up window				
	spreadsheet file	confirming				
	and click the	successful upload.				
	Upload icon.					
7.5.8	Go to Equipment	Equipment entries				
	and verify the	in eResidue				
	equipment entries	application should				
	in eResidue	match with what				
	application	was noted in the				
750		spreadsheet.				
7.5.9	Go to Product \rightarrow	Cleaning agent				
	cleaning agent	application should				
	details of	application should				
	cleaning agent	was noted in the				
	CA1in eResidue	spreadsheet				
	application	spreudoneet.				
7.5.10	Go to Product	Product details in				
1.0.110	and verify the	eResidue				
	details of product	application should				
	eResidue	match with what				
	application	was noted in the				
		spreadsheet.				
7.5.11	Make a duplicate	Spreadsheet file				
	copy of already	should be saved.				
	uploaded					
	spreadsheet,					
	renamed the					
	spreadsheet with					
	different name.					
	Open the					



PROTOCOL No.:

FROI

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
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Verified by : _____ Date: _____

 Reviewed by :
 Date :



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.

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



PROTOCOL No.:

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Step	Description	Expected Results	Observed Results	Status (Dagg/Fall)	Screen Shot No	Tested By Sign/Data
INO #	aquinment for			(Pass/Fall)	Shot No	Sign/Date
	equipment for					
	euit ille					
	surface area from					
	$450\ 000\ \mathrm{cm}^2$ to					
	$86000\mathrm{cm}^2$ and					
	click submit					
	button.					
7.6.7	Try to edit the	Application will not				
	equipment Name.	allow to editing the				
	1 1	equipment name.				
7.6.8	Edit the required	Equipment				
	details and click	summary window				
	update button.	displayed with				
		updated equipment				
		details.				
7.6.9	Click on the	Edit equipment				
	pencil icon	window should be				
	against the	displayed with				
	equipment.	respective				
7 (10		equipment details.				
7.6.10	Click cancel	Equipment				
	button.	Summary window				
7611	Co to aquinment	Delete equipment				
7.0.11	Summery window	Delete equipment				
	and click on the	should be displayed				
	minus icon	with Proceed and				
	against the	Cancel buttons				
	equipment for	Culleer buttons.				
	delete the					
	equipment					
	details.					
7.6.12	Click on proceed	Equipment				
	button.	summary window				
		displayed and				
		respective				
		equipment was				
		deleted in				
		equipment				
		summary.				
7.6.13	Click on the	Delete equipment				



PROTOCOL No.:

Step No #	Description	Expected Results	Observed Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	minus icon	warning message				
	against the	should be displayed				
	equipment.	with Proceed and				
		Cancel buttons.				
7.6.14 Click cancel button.	Click cancel	Equipment				
	button.	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:

Verified by	:		Date:	
Doviowod by		Г	Noto :	
Reviewed by	:	D	Date :	



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-Requ	Pre-Requisites									
Product Name	Product Type	Active Concn.	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	

Step No #	Description	Expected Results	Observed Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
7.7.1	Login to the	User shall be				0
	eResidue	logged in into the				
	application with	application. Home				
	the full access	Page shall be				
	user.	displayed.				
7.7.2	Go to Product	Add new Product				
	summary window	shall be displayed				
	and click on add	with red asterisks				
	Products	(*) are displayed				
		for mandatory				
		fields.				
7.7.3	Create 2 new	Application should				
	products AA &	be save the Product				
	BB as per above	details and this will				
	table and click	be also displayed in				
	submit button.	Product Summary.				
7.7.4	Go to Product	Add new Product				
	summary window	shall be displayed				
	and click on add	with red asterisks				
	Product	(*) are displayed				
		for mandatory				
		fields.				



PROTOCOL No.:

PHARMA DEVILS

Step No #	Description	Expected Results	Observed Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
775	Click cancel	Product Summary		(1 a55/1 all)		Sign/Date
1.1.5	button	window displayed				
7.7.6	Go to Product	Edit Product				
	summary window	window should be				
	and click on the	displayed with				
	pencil icon	respective Product				
	against the	details.				
	Product for edit					
	the Product					
777	Tru to adit the	Application will not				
1.1.1	Product Name	allow to editing the				
	Tioduct Ivanie.	Product name				
7.7.8	Edit the Product	Product summarv				
	AA Active concn	window displayed				
	from 70 mg/mL	with updated				
	to 15 mg/mL and	Product details.				
	click update					
	button.					
7.7.9	Click on the	Edit Product				
	pencil icon	window should be				
	Broduct	respective Product				
	riouuci.	details				
7.7.10	Click cancel	Product Summary				
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	button.	window displayed.				
7.7.11	Go to Product	Delete Product				
	summary window	warning message				
	and click on the	should be displayed				
	minus icon	with Proceed and				
	against the	Cancel buttons.				
	Product for delete					
	details					
7.7.12	Click on proceed	Product summary				
,.,.12	button.	window displayed				
		and respective				
		Product was deleted				
		in Product				
		summary.				
7.7.13	Click on the	Delete Product				
	minus icon	warning message				
	against the	should be displayed				



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	Product Summary				
	button.	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
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Verified by : _____

Date: _____

Reviewed by :_____

Date:_____

[] 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.

	Old MD	Old MDB file shall have the following details									
	Equipment details										
	Equipment Name		Surfac	urface Area (cm ²)		Equipment Name		Surface	Area (cm ²)		
tes	Equipment E1			120,000		E	Equipment E2		65,000		
uisi	Equipment E3			45,000							
ereq	Product Type: Solid										
Pre	Product Name	Active Concn.	Dosing Frequency	Product dose	Doses j perio (min/m	per d ax)	Batch Size (L) (min/max)	% TOC of Active	Equipment Used		
	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		

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
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				



Step

No#

Description

OPERATIONAL QUALIFICATION FOR eRESIDUE APPLICATION

Actual Results

Status

(Pass/Fall)

Expected Results

PROTOCOL No.:

Tested By

Sign/Date

Screen

Shot No

	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.		

р	HARMAT	DEVILS		OPERATIONAL QUALIFICATION FOR eRESIDUE APPLICATION					PROTO	OCOL No.:
]	Remarks:									
-										
-										
-	Meet the Acceptance Criteria [] Yes [] No									
	V	erified by	* :		Da	ate:				
	R	eviewed l	oy:		Date	:				
	7.9. VERIFICATION OF CALCULATIONS:									
	(Objective:	To verify the	t the calcul	ations carried	out by residu	e softwar	e applic	cation	
	F	Procedure:	Refer step d	escription a	s per Data Sh	eet-7.9 of this	s protocol			
	ŀ	Acceptance	e Criteria: Re	fer accepta	nce criteria as	per Data She	et-7.9 of	this pro	tocol.	
	Equipme	nt								
	Equip	ment Na	me S	Surface Ar	ea (cm ²)	Equipment Name		5	Surface A	Area (cm ²)
	Equ	uipment P		300,0	00	Equipment Q			150	,000
	Equ	ipment T		15.00)0)0	Equipi	lient S		20,	000
	Product '	Гуре: Liq	uid	10,00						
re-requisite	Product Name	Active Concn.	Dosing Frequency	Product dose	Doses per period (min/max)	Batch Size (L) (min/max)	Safety Factor	ADE (mg)	% TOC of Active	Equipment Used
P	А	70 mg/mL	Daily	10 mL	1/1	400/800	0.001	6.5	45	P, Q, R & S
	В	15 mg/mL	Daily	15 mL	1/2	350/800	0.001	2.0	40	P, Q, R & S
	С	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



PROTOCOL No.:

Product Type: Cle	eaning Agent					
	LD50 Based					
Product Name	LD50		Body Weight	Conversio Factor	n	ADE
CA1	900 mg/kg		60 kg	0.001		0.1 mg
Rinse						
Rinse Sampling	Swab Sampling					
Rinse volume	Solvent used	A	Amt. of solvent used for desorption		Sur	face Area Sampled
20 L	Water		40 mL			25 cm^2



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 Step 1 - Product Selection, Select Products A & B from the Available Products list. Use the right arrow to transfer it to the Products Selected list Click Next.	Products A and B should be displayed under <i>Products</i> <i>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: • Place tick mark in check box against 'Rinse' • Select radio button against 'individually' for Equipment Sampling	In Step 2-Sampling Method window, following should be the settings: • Check box against 'Rinse' should be selected • Radio button against 'Individually' for Equipment				



Step No

#

Description

• Place tick mark

in check box

OPERATIONAL QUALIFICATION FOR **eRESIDUE APPLICATION**

Actual Results

Status

(Pass/Fall)

Expected Results

category should

Sampling

PROTOCOL No.:

Tested By Sign/Date

Screen

Shot No

	against 'Swab	be selected		
	Select radio	Check box against		
	button against	'Swab' should be		
	'Both' for the	Selected		
	heading Express			
	swah limits as:			
	swab mints as.	Radio button		
		against 'Both'		
		should be selected		
		for the heading		
		Express swab		
		limits as:		
7.9.6	Click on the Next	Rinse Individuel		
	button.	window should be		
		displayed.		
7.9.7	In Rinse-	The radio button		
	Individual	against 'Apply		
	window, select the	volume inter entered		
	radio button	in the first row to all		
	against Apply	other listed		
	volume liter	equipment' should		
	entered in the first	be selectable.		
	row to all other	A volume of 20L		
	Enter Volume as	snould be displayed		
	inter volume as	against an		
708	20. Click on the Next	Step 3 - Swah		
7.9.0	button	accordion window		
	oution.	should be displayed.		
7.9.9	In Swab window.	The radio button		
	select the radio	against $ \Delta$ nnly all 3		
	button against	entries in the first		
	'Apply all 3	row to all the other		
	entries in the first	lists d and dusts!		
	row to all the	insteal products		
	other listed	should be selectable.		
	products'.			
	• Enter in the first	All the entries under		
	box below Solvent	column Solvent		
	Used column	Used should display		



OPERATIONAL QUALIFICATION FOR

PROTOCOL No.:

eRESIDUE APPLICATION

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	'Water'.	'Water'.		())		~-8
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 accord ion window should be displayed.				
7.9.12	Under Limit Calculation heading, select radio button against 'Calculate thelimits 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</i> <i>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				



Step No

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Description

OPERATIONAL QUALIFICATION FOR **eRESIDUE APPLICATION**

Actual Results

Status

(Pass/Fall)

Expected Results

PROTOCOL No.:

Tested By Sign/Date

Screen

Shot No

	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 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.	The check boxes 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.		
7.9.17	Under <i>Step 5 - Report</i> Format, 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		



7.9.19

7.9.20

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.				
	Click Close icon.	Report Tracker window should be displayed.				
	Verify that the	The table in Report				
	Report Name	Tracker window				
	'Qualification	should show an				
	eResidue Test 1',	entry with Products				
	for the	Selected as A & B				
	calculation	and Report title				
	carried out in	noted as				
	earlier steps,	'Qualification				
	appears in Report	eResidue Test 1'.				
	Tracker.					
	Verify that this	This report should				
	report can be	be downloadable as				
	the Report Tracker	a PDF document				
	window	Tracker window				
	Click the Pencil	Calculate Limit				
	edit icon in Report	accordion should				
		displayed with the				

	Report Name 'Qualification eResidue Test 1', for the calculation carried out in earlier steps, appears in Report Tracker.	Tracker window should show an entry with Products Selected as A & B and Report title noted as 'Qualification eResidue Test 1'.		
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</i> <i>Tracker</i> window.		
7.9.22	Click the Pencil edit icon in Report tracker window against 'Qualification eResidue Test1'	Calculate Limit 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		



PROTOCOL No.:

ults	Actual Results	Status

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


Status

(Pass/Fall)

PROTOCOL No.:

Tested By Sign/Date

Screen

Step No #	Description	Expected Results	Actual Results
	but with the report	in Report Tracker	

	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>under</i> Report Title <i>column</i> .		
7.9.30	Download the PDF Report and then open it. Verify that the title 'Qualification eResidue Test 1.1' is captured on the first page of the report	The PDF report should open and show 'Qualification eResidue Test 1.1' as Report title on the first page.		
7.9.31	Verify that the report captures the following information: Product details of	The report should capture the following information: Product details of A		
	A and B Equipment Details of P. O. R & S	and B Equipment Details of P. O. R & S		
	Basis of Limit Default L1 and L3 setting	Basis of Limit Default L1 and L3 setting		
	Settings for Calculation type, TOC Results, Sampling Method, Rinse & Swab Limits and Report Type	Settings for Calculation type, TOC Results, Sampling Method, Rinse & Swab Limits and report type.		
	Limits LO, L1, L2, L3, L4a, L4b, L4c	Limits LO, L1, L2, L3, L4a, L4b, L4c,		



Description

Step No

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OPERATIONAL QUALIFICATION FOR eRESIDUE APPLICATION

Actual Results

Status

Expected Results

PROTOCOL No.:

Tested By

Screen

. . .

#				(Pass/rall)	SHOUND	Sign/Date
	L4a (as TOC), L4b	L4a (as TOC), L4b				
	(as TOC) & L4c	(as TOC) & L4c (as				
	(as TOC)	TOC)				
A calcula	tor/spreadsheet progr	am would be needed fr	om this step onwar	ds to verify th	e limits calc	ulated by
eResidue			_	_		_
7.9.32	Add surface area	Surface Area of P,				
	of P, Q, R & S	Q, R and S should				
		add to				
		300,000+150,000+				
		50,000+ 20,000 =				
		$520,000 \text{ cm}^2$				
7.9.33	Calculate,	1.L1 (calculated) =				
	manually, limits	$0.001 \ge 70 = 0.07$				
	for current	mg/ml (70ppm)				
	product being A,	2. Since the				
	next product	calculated value				
	being the same	is greater than				
	(A).	default 10 ppm.				
		10ppm will be				
		used. $L1 = 0.01$				
		mg/ml (10ppm)				
		3.L2 = 10x0.001 x				
		400 x 1000 =				
		4.000 mg				
		4.L3=				
		4.000/520.000 =				
		0.00769 mg/ cm^2				
		5.Since 0.00769				
		mg/cm2 is				
		greater than				
		0.004 mg/cm2.				
		L3 used = 0.004				
		mg/cm2				
		6 L4a = 0.004x25 =				
		0.1 mg				
		7 L4a (asTOC) =				
		$0.1 \ge 0.45 =$				
		0.045 mg				
		8 I.4b = 0.1/40 =				
		0.0025 mg/ml				
	1	0.0020 mg/m			1	I]



Description

Step No

7.9.34

Calculate,

manually, limits

#

OPERATIONAL QUALIFICATION FOR **eRESIDUE APPLICATION**

Actual Results

Status

(Pass/Fall)

Expected Results

PROTOCOL No.:

Tested By

Screen

Shot No

Sign/Date 9.L4b (as TOC) = 0.0025 x 0.45 = 0.00113 mg/ml 10. L4c: Equipment P 1 = 0.004 x300,000/(20 x1000) = 0.06mg/m! Equipment Q = 0.004 x150,000/(20 x1000) = 0.03mg/ml Equipment R, = 0.004 x 50,000/(20 x1000) = 0.01mg/ml Equipment S = 0.004 x20,000/(20 x1000) = 0.004mg/ml 11. L4c (as TOC): Equipment P $=0.06 \times 0.45 =$ 0.027 mg/ml Equipment Q $=0.03 \times 0.45 =$ 0.0135 mg/ml

> Equipment R = $0.01 \ge 0.45 =$ 0.0045 mg/ml Equipment.S $=0.004 \times 0.45 =$ 0.0018 mg/ml

1. LO (dose based)

= 0.001 x 70 x



OPERATIONAL QUALIFICATION FOR **eRESIDUE APPLICATION**

Actual Results

Status

(Pass/Fall)

Expected Results

PROTOCOL No.:

Tested By Sign/Date

Screen

Shot No

for currerit

Description

product being A, next product B. 2. L0 (health based) = 6.5 mg 3. Since L0 (dose based) is lower, 0.7mg value will be used. 4. L1 (calculated) = 0.7/(15 x2) = 0.023mg/ml ($(23ppm)$ 5. Since 23 ppm is greater than default 10 ppm, value of 10ppm will be used. L1 used = 0.01 mg/ml (10ppm) 6. L2= 0.01 x 350x1000 = 3,500 mg 7. L3 (calc)= 3,500 /520,000 = 0.00673 mg/cm2 8. Since the calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= 0.004x25 = 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =	for currerit	10x1 = 0.7 mg		
next product B. = 6.5 mg 3. Since L0 (dose based) is lower, 0.7mg value will be used. 4. L1 (calculated) = 0.7(15 x2) = 0.023mg/ml (23ppm) 5. Since 23 ppm is greater than default 10 ppm, value of 10ppm will be used. L1 used = 0.01 mg/ml (10ppm) 6. L2= 0.01 x 3500 ng 7. L3 (calc)= 3,500 /520,000 = 0.00673 mg/cm2 8. Since the calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= 0.004x25 = 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =	product being A,	2. L0 (health based)		
3. Since L0 (dose based) is lower, 0.7mg value will be used. 4. L1 (calculated) = 0.7/(15 x2) = 0.023mg/ml (23ppm) 5. Since 23 ppm is greater than default 10 ppm, value of 10ppm will be used. L1 used = 0.01 mg/ml (10ppm) 6. L2= 0.01 x 350x1000 = 3,500 mg 7. L3 (calc)= 3,500 /520,000 = 0.00673 mg/cm2 8. Since the calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a = 0.004x25 = 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =	next product B.	= 6.5 mg		
based) is lower, 0.7mg value will be used. 4. L1 (calculated) = 0.7/(15 x2) = 0.023mg/ml (23ppm) 5. Since 23 ppm is greater than default 10 ppm, value of 10ppm will be used. L1 used = 0.01 mg/ml (10ppm) 6. L2= 0.01 x 350x1000 = 3,500 mg 7. L3 (calc)= 3,500 /520,000 = 0.00673 mg/cm2 8. Since the calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= 0.004x25 = 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		3. Since L0 (dose		
$ \begin{array}{c} 0.7 \text{mg value will} \\ \text{be used.} \\ 4. L1 (calculated) = \\ 0.7/(15 \text{ x2}) = \\ 0.023 \text{mg/ml} \\ (23 \text{ppm}) \\ 5. \text{ Since 23 ppm is} \\ \text{greater than} \\ \text{default 10 ppm,} \\ \text{value of 10 ppm} \\ \text{will be used. L1} \\ \text{used} = 0.01 \\ \text{mg/ml} (10 \text{ppm}) \\ 6. L2 = 0.01 \\ \text{x} \\ 350 \\ x1000 = \\ 3,500 \\ 7.52 \\ 0.00 = \\ 0.00673 \\ \text{mg/cm2} \\ 8. \text{ Since the} \\ \text{calculated L3} \\ \text{value of 0.00673} \\ \text{mg/cm2 is} \\ \text{greater than the} \\ \text{default L3 value} \\ \text{of 0.004 } \\ \text{mg/cm2} \\ 9. L4a = 0.004 \\ \text{x25} = \\ 0.1 \\ \text{mg} \\ 10. L4a (as TOC) = \\ 0.1 \\ x 0.45 = \\ \end{array} $		based) is lower,		
be used. 4. L1 (calculated) = 0.7/(15 x2) = 0.023mg/ml (23ppm) 5. Since 23 ppm is greater than default 10 ppm, value of 10ppm will be used. L1 used = 0.01 mg/ml (10ppm) 6. L2 = 0.01 x 350x1000 = 3,500 mg 7. L3 (calc) = 3,500 /520,000 = 0.00673 mg/cm2 8. Since the calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a = 0.004x25 = 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		0.7mg value will		
4. L1 (calculated) = 0.7/(15 x2) = 0.023mg/ml (23ppm) 5. Since 23 ppm is greater than default 10 ppm, value of 10ppm will be used. L1 used = 0.01 mg/ml (10ppm) 6. L2= 0.01 x 3500 ng 7. L3 (calc)= 3,500 /520,000 = 0.00673 mg/cm2 8. Since the calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a = 0.004x25 = 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		be used.		
$\begin{array}{ c c c c c c c c c c c c c c c c c c c$		4. L1 (calculated) = $(1 - 1)^{-1}$		
$\begin{array}{ c c c c c c c c c c c c c c c c c c c$		0.7/(15 x2) =		
(23ppm) 5. Since 23 ppm is greater than default 10 ppm, value of 10ppm will be used. L1 used = 0.01 mg/ml (10ppm) 6. L2= 0.01 x 350x1000 = 3,500 mg 7. L3 (calc)= 3,500 /520,000 = 0.00673 mg/cm2 8. Since the calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= 0.004x25 = 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		0.023mg/ml		
5. Since 23 ppm is greater than default 10 ppm, value of 10ppm will be used. L1 used = 0.01 mg/ml (10ppm) 6. L2= 0.01 x 350x1000 = 3,500 mg 7. L3 (calc)= 3,500 /520,000 = 0.00673 mg/cm2 8. Since the calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= 0.004x25 = 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		(23ppm)		
greater than default 10 ppm, value of 10ppm will be used. L1 used = 0.01 mg/ml (10ppm) 6. L2= 0.01 x 350x1000 = 3,500 mg 7. L3 (calc)= 3,500 /520,000 = 0.00673 mg/cm2 8. Since the calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= 0.004x25 = 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		5. Since 23 ppm is		
default 10 ppm, value of 10ppm will be used. L1 used = 0.01 mg/ml (10ppm) 6. L2= 0.01 x 350x1000 = 3,500 mg 7. L3 (calc)= 3,500 /520,000 = 0.00673 mg/cm2 8. Since the calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= 0.004x25 = 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		greater than		
value of 10ppm will be used. L1 used = 0.01 mg/ml (10ppm) 6. L2= 0.01 x 350x1000 = 3,500 mg 7. L3 (calc)= 3,500 /520,000 = 0.00673 mg/cm2 8. Since the calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= 0.004x25 = 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		default 10 ppm,		
will be used. L1 used = 0.01 mg/ml (10ppm) 6. $L2=0.01 x$ 350x1000 = 3,500 mg 7. L3 (calc)= 3,500 /520,000 = 0.00673 mg/cm2 8. Since the calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= 0.004x25 = 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		value of 10ppm		
used = 0.01 mg/ml (10ppm) 6. L2= 0.01 x 350x1000 = 3,500 mg 7. L3 (calc)= 3,500 /520,000 = 0.00673 mg/cm2 8. Since the calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= 0.004x25 = 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		will be used. L1		
$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$		used $= 0.01$		
6. $L2=0.01 \text{ x}$ 350x1000 = 3,500 mg 7. $L3 (calc)=3,500$ /520,000 = 0.00673 mg/cm2 8. Since the calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= 0.004x25 = 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		mg/ml (10ppm)		
350x1000 = 3,500 mg 7. L3 (calc) = 3,500 /520,000 = 0.00673 mg/cm2 8. Since the calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a = 0.004x25 = 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		6. $L2 = 0.01 \text{ x}$		
$\begin{array}{c c} 3,500 \text{ mg} \\ 7. \text{ L3 (calc)} = 3,500 \\ /520,000 = \\ 0.00673 \text{ mg/cm2} \\ 8. \text{ Since the} \\ calculated \text{ L3} \\ value of 0.00673 \\ mg/cm2 \text{ is} \\ greater than the \\ default \text{ L3 value} \\ of 0.004 \ mg/cm2, \\ \text{ L3 used is 0.004} \\ mg/cm2 \\ 9. \text{ L4a} = 0.004x25 = \\ 0.1 \text{ mg} \\ 10. \text{ L4a (as TOC)} = \\ 0.1 \text{ x } 0.45 = \\ \end{array}$		$350 \times 1000 =$		
7. L3 (calc)= 3,500 /520,000 = 0.00673 mg/cm2 8. Since the calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= 0.004x25 = 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		3,500 mg		
$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$		7. L3 (calc)= $3,500$		
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$		/520,000 =		
8. Since the calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= $0.004x25 =$ 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		0.00673 mg/cm2		
calculated L3 value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= $0.004x25 =$ 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		8. Since the		
value of 0.00673 mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= $0.004x25 =$ 0.1 mg 10. L4a (as TOC) = 0.1 x $0.45 =$		calculated L3		
mg/cm2 is greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= $0.004x25 =$ 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		value of 0.00673		
greater than the default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= $0.004x25 =$ 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		mg/cm2 is		
default L3 value of 0.004 mg/cm2, L3 used is 0.004 mg/cm2 9. L4a= $0.004x25 =$ 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		greater than the		
of 0.004 mg/cm2 , L3 used is 0.004 mg/cm2 9. L4a= $0.004x25 =$ 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		default L3 value		
L3 used is 0.004 mg/cm2 9. L4a= $0.004x25 =$ 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		of 0.004 mg/cm2,		
mg/cm2 9. L4a= 0.004x25 = 0.1 mg 10. L4a (as TOC) = 0.1 x 0.45 =		L3 used is 0.004		
9. $L4a = 0.004x25 =$ 0.1 mg 10. $L4a$ (as TOC) = 0.1 x 0.45 =		mg/cm2		
$ \begin{array}{c c} 0.1 \text{ mg} \\ 10. \text{ L4a (as TOC)} = \\ 0.1 \text{ x } 0.45 = \end{array} $		9. L4a= 0.004x25 =		
10. L4a (as TOC) = $0.1 \ge 0.45 =$		0.1 mg		
0.1 x 0.45 =		10. L4a (as TOC) =		
		0.1 x 0.45 =		
0.045mg		0.045mg		
11. L4b =		11. $L4b =$		
0.1/40 = 0.0025		0.1/40 = 0.0025		



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Description

OPERATIONAL QUALIFICATION FOR eRESIDUE APPLICATION

Actual Results

Status

(Pass/Fall)

Expected Results

PROTOCOL No.:

Tested By Sign/Date

Screen

mg/ml		
12. L4b (as		
TOC) = 0.0025 x		
0.45 = 0.00113		
mg/ml		
13. L4c:		
Equipment P		
-0.004 x		
300.000/		
$(20 \times 1000) = 0.06$		
(20x1000) = 0.00		
Equipment O		
= 0.004 X		
150,000/(20		
x1000) = 0.03		
mg/ml		
Equipment R		
= 0,004 x		
50,000/(20		
x1000) = 0.01		
mg/ml		
Equipment S		
= 0.004 x		
20,000/(20		
x1000)		
= 0.004 mg/ml		
14. L4c (as		
TOC):		
Equipment P		
= 0.06 x Q.45 =		
0.027 mg/ml		
Equipment Q		
$= 0.03 \times 0.45 =$		
0.0135 mg/ml		
Equipment R		
= 0.01 x Q.45 =		
0.0045 mg/ml		
Equipment S		



#

Description

OPERATIONAL QUALIFICATION FOR **eRESIDUE APPLICATION**

Actual Results

Status

(Pass/Fall)

PROTOCOL No.:

Screen

Shot No

Tested By

Sign/Date

	manually,	0.001 x 15 =		
	limitsfor current	0,015 mg/mi		
	Product being B,	(15ppm)		
	next product	2. Since 15ppm is		
	being the same	higher than		
	(B).	default 1Öppm,		
		10ppm will be		
		used. $L1 = 0.01$		
		mg/mi (10 ppm)		
		3. L2= 10x0.001 x		
		350x1000 =		
		3,500 mg		
		4. L3=		
		3,500/520,000 =		
		0.00673 mg/cm2		
		5. Since the		
		calculated value		
		of 0.00673 is		l

Expected Results

 $= 0.004 \times 0.45$ = 0.0018 mg/ml7.9.35 1. L1 (calculated)-Calculate, of 0.00673 is greater than the default of 0.004 mg/cm^2 , L3. used = 0.004 mg/cm² 6. L4a = 0.004x25

- = 0.1 mg7. L4a (as TOC) = $0.1 \ge 0.40 =$
- 0.04 mg 8. L4b = 0.1/40 =0.0025 mg/mI
- 9. L4b (as TOC) = $0.0025 \ge 0.4 =$ 0.001 mg/ml 10. L4c:

Equipment P



Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
п		= 0.004 x		(1 a 55/1 a 11)		
		300.000/(20 x1000)				
		= 0.06 mg/ml				
		Equipment O				
		= 0.004 x				
		150.000/(20 x1000)				
		= 0.03 mg/ml				
		Equipment R				
		= 0.004 x				
		50,000/(20 x1000) =				
		0.01 mg/ml				
		Equipment S				
		= 0.004 x				
		20,000/(20 x1000) =				
		0.004 mg/ml				
		11. L4c (as TOC):				
		Equipaient P				
		$= 0.06 \ge 0.4 = 0.024$				
		mg/ml Equipment Q				
		$= 0.03 \times 0.4 = 0.012$				
		mg/ml Equipment R				
		= O.OTx 0.4 =				
		0.004 mg/ml				
		Equipment S				
		$= 0.004 \times 0.4 =$				
		0.0016 mg/ml				
7.9.36	Calculate,	1. LO (dose based)				
	manually,	= 0.001 x 15 x 15 x 1				
	limitsfor current	= 0.225 mg				
	product being B,	2. LO (health				
	next product A.	based) = 2.5 mg				
		3. Since LO (dose				
		based) is lower,				
		0.225 mg value				
		will be used. $LI =$				
		0.225 mg/ml				
		4. L1 (calculated) = $0.225/(10 \times 1) =$				
		0.223/(10 X1) =				
		(22.5 mg/m)				
		(22. 3 ppin)				



Description

Step No

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OPERATIONAL QUALIFICATION FOR **eRESIDUE APPLICATION**

Actual Results

Status

(Pass/Fall)

PROTOCOL No.:

Tested By Sign/Date

Screen

Shot No

mg/ml	
6. $L2 = 0.01 \times 400$	
x 1000 = 4,000 mg	
7. L3 =	
4,000/520,000 =	
0.00769 mg/cm2	
8.Since 0.00769	
	mg/ml 6. L2 = 0.01 x 400 x 1000 = 4,000 mg 7. L3 = 4,000/520,000 = 0.00769 mg/cm2 8.Since 0.00769

mg/cm² is greater

than the default 0.004 mg/cm^2 , L3 used = 0.004mg/cm² 9. L4a=0.004 x 25 = 0.1 mg

> 10.L4a(as TOC) - $0.1 \ge 0.40 = 0.04$ mg 11.L4b = 0.1/40 =0.0025 mg/ml 12.L4b (as TOC) = $0.0025 \ge 0.40 =$ 0.001 mg/m!

13.L4c: Equipment Ρ = 0.004 x300,000/(20 x1000) = 0.06 mg/mlEquipment Q

150,000/(20 x1000)

= 0.004 x

= 0.03 mg/ml

22.5ppm is greater than 10ppm, value of 10ppm will be used. L1= 0.01

Expected Results

calculated value of

5. Since the



#

Description

OPERATIONAL QUALIFICATION FOR eRESIDUE APPLICATION

Actual Results

Status

(Pass/Fall)

Expected Results

Equipment R

PROTOCOL No.:

Screen

Shot No

Tested By

Sign/Date

		= 0.004 x		
		50,000/(20 x1000)		
		=0.01 mg/ml		
		Equipment s		
		= 0.004 x		
		20,000/(20 x1000)		
		=0.04 mg/ml		
		14.L4c (as TOC):		
		Equipment P		
		$= 0.06 \ge 0.4 = 0.024$		
		mg/ml		
		Equipment Q		
		$= 0.03 \times 0.4 = 0.012$		
		mg/ml		
		Equipment R		
		= 0.01 x 0.4 =		
		0.004 mg/ml		
		Equipment S		
		=0.004 x 0.4 =		
		0.0016 mg/ml		
7.9.37	Verify that the	The limits LO, L1,		
	limits, as	L2, L3, L4a, L4b		
	calculated in steps	and L4c For A-A,		
	29-33, match that	A-B, B-A and B- B		
	generated by	(Current Product-		
	eResidue in step	Product to be		
	26, report title	manufactured) as		
	being	calculated in steps		
	'Qualification	29-33 should match		

	26, report title	manufactured) as		
	being	calculated in steps		
	'Qualification	29-33 should match		
	eResidue Test 1.1'.	that noted in the		
		PDF document,		
		generated in step 26		
		(Qualification		
		eResidue Test 1.1).		
7.9.38	Click on Default	The Default L1 and		
	L1 and L3 under	L3 field should be		
	Fields icon. Select	set to 'No default		
	the radio button	used. Use calculated		



	DEVILO					
Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	<i>against</i> 'No default used. Use calculated value'.	value'.				
7.9.39	Start a new calculation by clicking the Calculation icon. Under Step 1 - Product Selection, Select Products C & D. Click Next.	Calculate Limit accordion must be displayed. In Step 1 Products selected should be C and D. Step 2 - Sampling Method accordion window should be displayed.				
7.9.40	Continue with the following settings for Step 2 - <i>Sampling Method:</i> • <i>Select radio</i> <i>button against</i> 'Run limits with L4 calculation'. • Place tick mark in check box against ' <i>Rinse'</i> .	In Step 2-Sampling Method, following should be the settings: • Under Sampling Method accordion, radio button for 'Run limits with L4 calculation' should be selected • Check box against 'Rinse' should be selected.				
	 Select radio button against 'Individually' for Equipment Sampling. Place tick mark in check box against 'Swab'. Select radio 	 ' Radio button against 'Individually' for Equipment Sampling category should be selected. Check box against 'Swab' should be selected. 				



	1		1		1	
Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	button against 'Both' for the heading Express swab limits as:.	against 'Both' should be selected for the heading Express swab limits as:.				
7.9.41	Click next Carry out the following steps: • Select the radio button against 'Apply volume liter entered in the first row to all other listed equipment.' • Enter in the first box in volume column the number '20'.	Step 3 - Rinse - Individuai accordion window should be displayed. <i>The radio button</i> <i>against</i> 'Apply volume liter entered in the first row to all other listed equipment.' <i>should be selected</i> . The Volume column, should read '20' for all entries.				
7.9.42	<i>Click</i> Next. 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</i> <i>against</i> 'Apply all 3 entries in the first row to all the other listed products' <i>shoulcl be selected</i> .				
7.9.43	Enter the following details: • Solvent Used:	In Step 3-Swab, the following should be the settings:				



Ctor NI	Decemination		A street D14	6404	Company	TestelD
step No	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Sign/Date
	'Water'.	All entries undér		(1 a bb/ 1 all)		Sign Date
	,, utor i	Solvent Used				
		column should				
	• Amt. of	read 'Water'				
	Solvent Used for					
	Desorption: '40'.	All entries under				
	Select unit as	Amt. of Solvent				
	'mU'.	Used for				
		Desorption column				
	Surface Area	should read '40'				
	Sampled: '25'.	with the units				
	-	being 'mL'.				
		All entries under				
		Surface Area				
		Sampled should				
7044		read '25'.				
7.9.44	<i>Click</i> Next.	Step 4 - Definition				
		accordion window				
	Under Limit	should be				
	Calculation	displayed.				
	heading, select	The radio button				
	radio button	against 'Calculate				
	against 'Calculate	the limits for the				
	the limits for the	active in each				
	active in each	product with every				
	product with every	the same product) as				
	the same modult	the next product'				
	the same product)	should be selected				
	as the next product'					
7.9.45	Under Surface	The radio button				
,	Area Selection	against 'Calculate				
	heading, select	the I 3 limit colely				
	radio button	based on the shared				
	against 'Calculate	surface area				
	the L3 limit solely	between the two				
	based on the	products' should be				
	shared surface	products should be				
	area between the	seleciea.				
	two products'					
		The radio				
	Under IUC	button against				



Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	Results heading, select radio button against 'No'	'No' should be selected.				
7.9.46	<i>Click</i> Next	Step 5 - Report accordion window should be displayed.				
	Enter in the text box against Report Title 'Qualification eResidue Test 2.'	The text box against Report Title should read 'Qualification eResidue Test 2.' On placing a tick				
	In the drop-down list against <i>Signatories,</i> place a tick mark in the check box against	mark in the check box against 'Select All,' all entries in the drop-down list should be selected				
7.9.47	Select the check boxes L1, L2, L3, L4a (Swab Amount), L4b (Swab Conen.) and L4c (Rinse) under heading "Step 5 - Limit Selection."	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.				
7.9.48	Click <i>Submit</i> icon.	A Calculation Status popup window should be displayed with message "Calculation is being setup". Once setup process has been completed, Popup window				



Description

Step No

#

OPERATIONAL QUALIFICATION FOR eRESIDUE APPLICATION

Actual Results

Status

(Pass/Fall)

Expected Results

message "Generated

PROTOCOL No.:

Tested By Sign/Date

Screen

		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).	1. L1 (calculated) = 0.001 x 70: = 0.07 mg/ml 2. L2= 0.07x400x1000 = 28,000 mg 3. L3= 28,000/500,000 = 0.0560 mg/cm2(Equipm ent P+Q+R surface area in		



Sten No	Description	Expected Results	Actual Results	Status	Screen	Tested By
#	Description	Expected Results	Actual Results	(Pass/Fall)	Shot No	Sign/Date
		the denominator)				
7.9.52	Calculate,	1. L0 (dose based)				
	manually, limits L1, L2 and L3 for current product being C, next	$= 0.001 \times 70 \times 10 \times 1 = 0.7$ mg				
	product D.	2. L0 (health based) = 6.5 mg				
		 Since L0 (dose based) is lower, 0.7 mg value will be used. 				
		4. L1 (calculated) = 0.7/(15 x2) = 0.023333 mg/ml				
		5. L2= 0.023333x350x1 000 = 8166.55 mg (round off to 8167 mg)				
		6. L3= 8167/200,000 = 0.0408 mg/cm ²				
7.9.53	Calculate, manually, limits L4a, L4b and L4c based on worst case "next	Equipment S is not used for Product C. Henee not considered				
	product", Current Product being C	Equipment P - Shared only when the same product C is again manufacturad				
		L3 used = 0.0560 mg/cm2 L4a = 0.0560 x 25 = 1.40				
		mg L4b = 1.4/40 = 0.0350 mg/ml L4c = 0.0560 x 300,000/				
		(20 x1000) = 0.840 mg/ml Equipment Q				



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Description

OPERATIONAL QUALIFICATION FOR **eRESIDUE APPLICATION**

Actual Results

Status

(Pass/Fall)

Expected Results

- Used when either

PROTOCOL No.:

Tested By Sign/Date

Screen

	1	
	manufacturad,	
	current product	
	being C. L3 used	
	will be lower of the	
	2 L3s calculated (C-	
	C and C-D).	
	L3 used $= 0.0408$	
		1

		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).		
		L3 used $= 0.0408$		
		mg/cm2		
		L4a = 0.0408 x 25 =		
		1.02 mg		
		L4b = 1.02/40 =		
		0.0255 mg/ml		
		L4c = 0.0408 x		
		150.000/ (20 x1000)		
		= 0.306 mg/ml		
		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).		
		L3 used $= 0.0408$		
		mg/ cm2		
		L4a = 0.0408 x 25 =		
		1.02 mg		
		L4b = 1.02/40 =		
		0.0255 mg/ml		
		L4c =0.0408 x		
		50,000/(20 x1000) =		
		0.102 mg/ml		
7.9.54	Calculate,	1.L1 (calculated) =		
	manually, limits	0.001 x 15 =		



#

Description

OPERATIONAL QUALIFICATION FOR **eRESIDUE APPLICATION**

Actual Results

Status

(Pass/Fall)

Expected Results

PROTOCOL No.:

Tested By Sign/Date

Screen

	L1, L2 and L3 for	0.015 mg/ml		
	current product	2.L2=		
	being D, next	0.015x350x1000		
	product being the	= 5,250 mg		
	same (D).	3.L3=		
		5250/220,000 =		
		0.02386 mg/cm2		
		(Equipment Q+R+S		
		surface area in the		
		denominator)		
7.9.55	Calculate,	1.LO (dose based)		
	manually, limits	= 0.001 x 15 x		
	L1, L2 and L3 for	$15x \ 1 = 0.225 \ mg$		
	current product	2.LO (health based)		
	product C	= 2.0 mg		
	product C.	3.Since L0 (dose		
		based) is lower,		
		0.225 mg value		
		will be usecl.		
		L0=0.225 mg/ml		
		4.L1 (calculated) =		
		0.225/(10 x1) =		
		0.0225 mg/ml		
		5.L2=		
		0.0225x400x100		
		0 = 9,000 mg		
		6.L3=		
		9,000/200,000 =		
		0.0450 mg/cm^2		
7.9.56	Calculate,	Equipment P is not		
	manually, limits	used for Product D.		
	L4a, L4b and L4c	Henee not		
	based on worst	considered		
	case "next	Equipment Q - Used		
	product", Current	either when the		
	Product being D	same product D is		
		again manufactured		
		or when Product C		
		1s next product		
		manufactured,		



PROTOCOL No.:

PHARMA DEVILS

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
		current product being D. L3 used will be lower of the 2 L3s calculated (D-C and D-D).				
		L3 used = 0.02386 mg/cm ² L4a = 0.02386×25 = 0.597 mg L4b = $0.597/40$ = 0.0149 mg/ml L4c = $0.02386 \times 150,000/(20 \times 1000)$				
		= 0.179 mg/ml 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). L3 used = 0.02386 mg/cm ² L4a = 0.02386×25 = 0.597 mg L4b = $0.597/40$ =				
		0.0149 mg/ml L4c = 0.02386 x 50,000/(20 x1000) = 0.05965 mg/ml				
		Equipment S - Shared only when the same product D is again manufactured				



Actual Results

Status

(Pass/Fall)

Expected Results

PROTOCOL No.:

Tested By Sign/Date

Screen

Shot No

		L3 (B-B) = 0.02386		
		mg/cm ²		
		$L4a = 0.02386 \times 25$		
		= 0.597 mg		
		$I_{4b} = 0.597/40 =$		
		0.0149 mg/ml		
		$I_{4c} = 0.02386 \text{ x}$		
		$20.000/(20 \times 1000) =$		
		0.0239 mg/ml		
7.9.57	Verify that the	The limits LO, L1		
112101	limits as	L2 L3 L4a L4b		
	calculated in steps	and I_{4c} for $C_{-}C_{-}C_{-}$		
	46-52 match that	D D-C and D-D		
	noted in report	(Current (Cleaned)		
	generated in step	Product- Product to		
	45 (Qualification	be manufactured) as		
	eResidue Test 3)	calculated in steps		
	by eResidue	46-52 should match		
	by citosiduo.	that noted in the		
		PDF document		
		generated in step 45		
7.9.58	Go to Report	On clicking		
1.9.80	Tracker window	"Move to		
	Place a tick mark	Archive" icon the		
	in the checkbox	Archive Icon, the		
		report		
		"Qualification		
	Qualification	eResidue Test 3"		
	eResidue Test 3.	should not be		
	Click the "Move	displayed in the		
	to Archive" icon.	Current Report:		
		Tracker window.		
	From "Select	The Qualification		
	Folder" drop-	a Pasidua Tast 3		
	down menu,	rement should be		
	Select "Archive".			
	Verify that the	displayed in the		
	Qualification	Archive window.		
	eResidue Test 3			
	report is available			
	there			
7.9.59	Change the ADE	ADE of Product A,		
	value noted to:	B and D should		
	Product A - 0.23	change to 0.23 mg.		

PHARMA DEVILS

Step No

#

Description



PROTOCOL No.:

Step No Description **Expected Results Actual Results Status** Screen **Tested By** Shot No Sign/Date # (Pass/Fall) 0.18 mg and 0.40 mg Product B - 0.18 mg mg Product D - 0.40 mg 7.9.60 Click Calculate Limit "Calculation" icon accordion must be on the top right displayed corner of the window. 7.9.61 Under Step 1 -Products A, B and Product Selection, D should be Select Products A. displayed under Products Selected. B & D. Step 2 - Sampling Click Next. Method accordion window should be displayed. In the Step 2 -7.9.62 The radio button Sampling Method against 'Run limits window, select the with L4 calculation' radio button 'Run should be selectable limits with L4 under the heading calculation'. Step 2 - Sampling Method. 7.9.63 Continue with the *In* Step 2-Sampling following Method. settings following should be for Step 2 the settings: Sampling Method: • Check box • Place tick against 'Rinse' mark in check should be box against selected 'Rinse'. • Radio button • Select radio against 'As button against Train' for 'As Train' for Equipment Equipment Sampling



PROTOCOL No.:

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	Sampling.	category should				
	Place tick	be selected.				
	mark in check	Check box				
	box against	against 'Swab'				
	'Swab'.	should be				
	Select radio	selected				
	button against	Radio button				
	'Both' for the	against 'Both'				
	heading	should be				
	Express swab	selected for the				
	limits as:	heading Express				
		swab limits as:				
7.9.64	Click on the Next	Step 3-Rinse-Train				
	button.	accordion window				
		should be displayed				
7.9.65	In Step 3 - Rinse -	The radio button				
	Train <i>window</i> ,	against 'Apply				
	select the radio	volume liter entered				
	button against	in the first row to all				
	'Apply volume	the other listed				
	liter entered in the	Product' should be				
	first row to all the	selected				
	other listed					
	Product'.	A volume of '20'				
	Enter Volume as	should be displayed				
	'20'.	against all product				
70.00		listed				
/.9.66	Click on the Next	Step 3 - Swab				
		accordion window				
	In Swah window	should be displayed.				
	select the radio					
	button against	The radio button				
	'Apply all 3	against 'Apply all 3				
	entries in the first	entries in the first				
	row to all the	row to all the other				

listed products'

All the entries

under column

should be

selectable.

other listed

Enter in the first

box below Solvent

products'.

7.9.67



Step No Description

OPERATIONAL QUALIFICATION FOR **eRESIDUE APPLICATION**

Status

PROTOCOL No.:

Tested By

Screen

Step No #	Description	Expected Results	Actual Results
	Used column	Solvent Used	
	'water'. Enter in	should display	
	the first box below	'water'. All entries	
	Amt. of Solvent	under column Amt.	
	used for	of Solvent used for	
	Desorption value	Desorption should	
	<i></i>		

#			(Pass/Fall)	Shot No	Sign/Date
	Used column	Solvent Used			
	'water'. Enter in	should display			
	the first box below	'water'. All entries			
	Amt. of Solvent	under column Amt.			
	used for	of Solvent used for			
	Desorption value	Desorption should			
	of '40' and choose	display '40' with the			
	the unit as 'ml'.	units being 'mL'.			
		All entries under			
	Enter in the first	column Surface			
	box below Surface	should read the			
	Area Sampled the	value '25'.			
	value '25'.				
.9.68	Click Next.	<i>Step 4 -</i>			
	TT 1 T 1	Definition			
	Under Limit	accordion			
	heading select	window should			
	radio button	be displayed.			
	against 'Calculate	The radio button			
	the limits for the	against 'Calculate			
	active in each	the limits for the			
	product with every	active in each			
	product (including	product with			
	as the next	EVERY product			
	product'.	(including the same			
	I	product) as the next			
		product' should be			
		selected.			

	product'.	(including the same product) as the next product' <i>should be</i> <i>selected</i> .		
7.9.69	<i>Under</i> Surface Area Selection heading, select radio button against 'Calculate the L3 limit based on the lowest total equipment train surface area between the two	The radio button against 'Calculate the L3 limit based on the lowest total equipment train surface area between the two products' should be selected.		



C

OPERATIONAL QUALIFICATION FOR eRESIDUE APPLICATION

C4a- NI	Degeniter		Stat	Carro	TestelD	
Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
"	products.	The radio button				
	Under TOC Results heading.	against 'No' should be selected.				
	select radio button against 'No'					
7.9.70	Click the <i>Next</i> button.	Step 5 - Report accord ion window should be displayed.				
	<i>Enter in the text</i> <i>box against</i> Report Title 'Qualification eResidue Test 3'.	<i>The text box against</i> Report Title <i>should</i> <i>read</i> 'Qualification eResidue Test 3'				
	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 'Select All,' all entries in the drop-down list should be selected.				
7.9.71	Select the check boxes LI, L2, L3, L4a (Swab Amount), L4b (Swab Conen.) and L4c (Rinse) under heading Step 5 - Limit Selection.	The check boxes 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				



7.9.75

Calculate,

#

Description

OPERATIONAL QUALIFICATION FOR **eRESIDUE APPLICATION**

Actual Results

Status

(Pass/Fall)

PROTOCOL No.:

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	It should be possible		
	PDF Report from	to download the		
	Report Tracker	PDF report from.		
	window, created	Report tracker		
	in earlier step, and	window. The PDF		
	then open it.	report should open		
	Verify that the	and show		
	title 'Qualification	'qualification		
	eResidue Test 3'	eResidue Test 3' as		
	is captured on the	report title on the		
	first page of the	first page.		
	report.			
7.9.74	Add surface area	Surface Area of P,		
	of P, Q, R & S for	Q, R & S should		
	Products A	add to:		
		300,000+150,000+5		
	Add surface area	0,000+20,000 =		
	of P, Q & R for	$520,000 \text{ cm}^2$		
	Product B			
		Surface Area of P.		

Expected Results

Q, R & S should add to: Add surface area 300,000+150,000+5 of Q, R & S for 0,000+20,000 =Product D $520,000 \text{ cm}^2$

> Surface Area of Q, R & S should add

150,000+50,000+20 $,000 = 220,000 \text{ cm}^2$ LO (dose based)

to:



Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	manually, limits	= 0.001 X 70 x 10 x				
	for current	1 = 0.7 mg				
	product being A,	L0 (health based) =				
	next product	0.23 mg				
	being the same	Since L0 (health				
	(A).	based) is lower,				
		0.23mg value will				
		be used.				
		L1 (calculated) =				
		0.23/(10x1)				
		= 0.023 mg/ml				
		L2 =				
		0.023x400x1000				
		= 9,200 mg				
		L3 = 9,200/520,000				
		$= 0.01/69 \text{ mg/cm}^2$				
7.9.76	Calculate,	L0 (dose based) =				
	manually, limits	0.001 x 70 x 10 x 1				
	for current	= 0.7 mg L0				
	product being A,	(health based) =				
	next product B.	0.23 mg Since L0				
		(health based) is				
		lower, 0.23mg				
		value will be used.				
		L1 (calculated) =				
		0.23/(15 x2) =				
		0.007667 mg/ml				
		$L^2 =$				
		0.00/00/X350X 1000 - 2682.45 ma				
		1000 = 2085.45 mg				
		(100110 011 to 2005				
		1.3 = 2683 /				
		520,000 = 0.00516				
		mg/cm ²				
7.9.77	Calculate,	LO (dose based) =				
	manually, limits	0.001 x 70 x 10 x 1				
	for current product	= 0.7 mg				
	being A, next	L0 (health based) =				
	Product D	, · · · · · · · · · · · · · · · · · · ·				



#

Description

OPERATIONAL QUALIFICATION FOR eRESIDUE APPLICATION

Actual Results

Status

(Pass/Fall)

Expected Results

Since L0 (health

0.23 mg

PROTOCOL No.:

Tested By Sign/Date

Screen

		based) is lower, 0.23 mg value will be used. L1 (calculated) = 0.23/(15 x2) = 0.007667 mg/ml L2 = 0.007667x350x 1000 = 2683.45 mg L3 = $2683.45 /$ 220,000 = 0.0122 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 for A-B is 0.00516 mg/cm ² , which is lower than 0.053846 mg/cm ² for A- A. L4c for P, Q, R and S equipment train = 0.00516 x 520,000 / (20 x) 1000) = 0.134 mg/ml		
7.9.79	Calculate, manually, Rinse limits L4c, for Q, R and S equipment train used by Product D	L4c for Q, R and S equipment train = 0.0122x220,000/ (20x1000) = 0.134 mg/ml		
7.9.80	Calculate, manually, Swab limits for current product A	L3 for A-B is the lowest (0.00516 mg/cm ²) in comparison to L3 for A-A and A-D. This will be used for		



#

Description

product A.

OPERATIONAL QUALIFICATION FOR eRESIDUE APPLICATION

Actual Results

Status

(Pass/Fall)

Expected Results

For Equipment P, Q, R and S each:

all equipment.

= 0.18 mg

mg/ml

Since L0 (health based) is lower, 0.18 mg value will be used. L1= 0.18

L1 (calculated) =

PROTOCOL No.:

Screen Shot No **Tested By**

Sign/Date

		$L4a = 0.00516 \ge 25$		
		= 0.129 mg		
		L4b = 0.129/40 =		
		0.00323 mg/ml		
7.9.81	Calculate,	LO		
	manually, limits	(dose		
	for current product	based) =		
	being B, next	0.001 x		
	product being the	15x15x1		
	same (B).	= 0.225		
		mg		
		LO (health based) =		
		0.18 mg		
		Since L0 (health		
		based) is lower,		
		0.18 mg value will		
		be used.		
		L1 (calculated) =		
		0.18/(15x2) = 0.006		
		mg/ml		
		L2=		
		$0.006 \times 350 \times 1000 =$		
		2,100 mg		
		L3=2,100/520,000		
		$= 0.00404 \text{ mg/cm}^2$		
7.9.82	Calculate,	L0 (dose based) =		
	manually, limits	$0.001 \times 15 \times 15 \times 1 =$		
	hoing P next	0.225 mg		
	being B, next	L0 (health based)		



Description

Step No

OPERATIONAL QUALIFICATION FOR **eRESIDUE APPLICATION**

Actual Results

Status

PROTOCOL No.:

Tested By Sign/Date

Screen

#	-		(Pass/Fall)	Shot No
		0.18/(10x1) =		
		0.018 mg/ml		
		L2 = 0.018 x 400 x		
		1000 = 7,200 mg		
		L3 = 7,200 /520,000		
		$= 0.01385 \text{ mg/cm}^2$		
7.9.83	Calculate,	L0 (dose		
	manually, limits	based) =		
	for current product	0.001 x		
	being B, next	15x15x1 =		
	product D.	0.225 mg		
		L0 (health based) = 0.18 mg Since L0 (health based) is lower, 0.18 mg value will be used. L1 = 0.18 mg/ml		

Expected Results

		value will be used. L1 = 0.18 mg/ml		
		L1 (calculated) = 0.18/(15x2) = 0,006 mg/ml		
		L2 = 0.006x350x1000 = 2,100 mg		
		L3 = 2,100/220,000 = 0.009545 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 for B-B is 0.00404 mg/cm ² , which is lower than 0.01385 mg/cm ² for B- A. L4c for P, Q, R and S equipment train = $0.00404 \times 520,000$ / (20 x 1000) =		
7.9.85	Calculate,	L4c for Q, R and S		



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 x 220,000 / (20x1000) = 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 ²) 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 mg/cm^2				
7.9.88	Calculate, manually, limits for current product being D, next product A.	LO (dose based) = 0.001 x 15 x 15 x 1 = 0.225 mg LO (health based) = 0.40 mg				



Description

Step No

#

OPERATIONAL QUALIFICATION FOR eRESIDUE APPLICATION

Actual Results

Status

(Pass/Fall)

Expected Results

Since LO (dose based) is lower, 0.225 mg value will

= 0.131 mg/ml

be used.

PROTOCOL No.:

Tested By Sign/Date

Screen

		L1 (calculated) = 0.225/(10x 1) = 0.0225 m g/ml		
		L2 = 0.0225x400x 1000 = 9,000 mg L3 = 9.000 /220.000		
		$= 0.04091 \text{ mg/cm}^2$		
7.9.89	Calculate,	LO (dose		
	manually, limits	based) $= 0.001$		
	for current	x 15x15x1 =		
	product being D,	0.225 mg		
	next product B.	L0 (health based) =		
		0.40 mg Since L0		
		(dose based) is		
		lower, 0.225 mg		
		value will be used.		
		L1 (calculated) =		
		$0.225/(15 \times 2) =$		
		0.0075 mg/ml		
		L2 = 0.0075x350x		
		1000 = 2,625 mg		
		L3 = 2,625 /220,000		
		$= 0.01193 \text{ mg/cm}^2$	 	
7.9.90	Calculate,	L3 for D-B is		
	manually, Rinse	0.01193 mg/cm^2 ,		
	limits L4c, for P,	which is lower		
	Q, R and S	than 0.04091		
	equipment train	mg/cm^2 for B-A.		
	used by Products	L4c for P, Q, R		
	A and B	and S equipment		
		train		
		= 0.01193 x		
		220,000 / (20 x		
		1000)	1	



PROTOCOL No.:

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



C

OPERATIONAL QUALIFICATION FOR eRESIDUE APPLICATION

Step No	Description	Expected Results	Actual Results	Status	Screen	Tested By
#				(Pass/Fall)	Shot No	Sign/Date
	calculation.	Step 2 - Sampling Method				
7.9.96	Continue with the following settings in <i>Step 2 -</i> <i>Sampling Method</i> window: • Place tick mark in check box against <i>'Rinse'</i>	 In Step 2 - Sampling Method, following should be the settings: Check box against 'Rinse' should be selected Radio button against 'Individually' for Equipment 				
	 Select radio button against 'Individually' for Equipment Sampling. Place tick mark in check box against 'Swab' Select radio 	Equipment Sampling category should be selected • Check box against 'Swab' should be selected • Radio button against 'Both' should be selected for the heading				
	button against 'Both' for the heading Express swab limits as:	Express swab limits as:				
7.9.97	Click on the <i>Next</i> button.	Rinse Individuai window should be displayed.				
	<i>In</i> Rinse- Individual <i>window, select the</i> <i>radio button</i> <i>against</i> 'Apply volume liter entered in the first row to all other	The radio button against 'Apply volume liter entered in the first row to all other listed equipment should be selectable.				



Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	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</i> <i>against</i> 'Apply all 3 entries in the first row to all the other listed products' <i>should be</i> <i>selectable</i> .				
7.9.99	Enter in the first box below Solvent Used co I u m n 'Wa te r' Enter in the first box beJow Amt. of Solvent used for Desorption va lue 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</i> <i>column</i> Amt. of Solvent used for Desorption should display '40' with the units being 'mL' All entries under column <i>Surface</i> <i>Area Sampled</i> should read the value '25'.				
7.9.100	<i>Click</i> Next. Under TOC Results heading, select radio button	Step 4 - Definition accord ion window should be displayed. The radio button				



PROTOCOL No.:

PHARMA DEVILS

Step No #	Description	Expected Results	Actual Results	Status (Pass/Fall)	Screen Shot No	Tested By Sign/Date
	Click the <i>Next</i> button	be selected. Step 5 - Report accordion window should be displayed				
7.9.101	<i>Enter in the text</i> <i>box against</i> Report Title 'Qualification eResidue Test 4'.	<i>The text box against</i> Report Title <i>should</i> <i>read</i> 'Qualification eResidue Test 4'				
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 'Select All,' all entries in the drop-down list should be selected				
7.9.103	Select the check boxes L1, L2, L3, L4a (Swab Amount), L4b (Swab Conen.) and L4c (Rinse) under heading Step 5 - Limit Selection.	The check boxes L7, L2, L3, L4ai (Swab Amount), L4b (Swab Conen.) and L4c (Rinse) under heading Step 5 - Limit Selection should be selected				
7.9.104	Click Submit icon. Click Close icon once the calculation setup is over in the Calculation Status popup window and the Close 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				



PROTOCOL No.:

PHARMA DEVILS **Step No** Description **Expected Results Actual Results Status** Screen **Tested By** Sign/Date # (Pass/Fall) Shot No should also then display 'Close' icon. Download the It should be possible 7.9.105 PDF Report from to download the **Report Tracker** PDF report from. window. created Report tracker in earlier step, and window. The PDF then open it. report should open Verify that the and show title 'Qualification 'qualification eResidue Test 2' eResidue Test 2' as is captured on the report title on the first page of the first page. report. 7.9.106 1.L0 (ADI based) Calculate, manually, limits = 900 x 60 xL1, L2 and L3 for 1/1000 = 54 mg2.L0 (health based) Cleaning agent = 0.1 mgCA1, next Product 3.Since L0 (health Α based) is lower, 0.1 mg will be used. 4.L1 (calculated) = 0.1/(10x1) =0.0100 mg/ml 5.L2 = 0.0100x 400x 1000 = 4000 mg6.L3=4000/500,000 $= 0.00800 \text{ mg/cm}^2$ 7.9.107 1. L0 (ADI based) Calculate, manually, limits $= 900 \times 60 \times 10^{-10}$ L1, L2 and L3 for 1/1000 = 54 mg2. L0 (health based) Cleaning agent = 0.1 mgCA1. next Product 3. Since L0 (health В based) is lower, 0.1 mg will be

used.

4. L1 (calculated) = 0.1/(15x2) = 0.003333 mg/ml



#

Description

OPERATIONAL QUALIFICATION FOR eRESIDUE APPLICATION

Actual Results

Status

(Pass/Fall)

Expected Results

5. L2= 0.003333 x

PROTOCOL No.:

Tested By Sign/Date

Screen

		350 x 1000 =		
		1166.55 mg		
		(round off to		
		1167mg)		
		6. L3=		
		1167/220,000 =		
		0.00530 mg/cm^2		
7.9.108	Calculate,	Equipment P - Used		
	manually, limits	when product A is		
	L4a, L4b and L4c	nèxt Product. L3		
	based on worst	(D-A) = 0.00800		
	case "next	mg/cm ²		
	Product", Current			
	Product being	$I_{4a} = 0.00800 \times 25$		
	Cleaning agent	= 0.200 mg		
	CA1	1.4h = 0.200/40		
		L40 = 0.200/40 =		
		0.00500 mg/m		
		L4c = 0.00800 x		
		300,000/(20 x1000)		
		= 0.120 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).		
		I_{3} used = 0.00530		
		m_{α}/cm^{2}		
		L4a = 0.00530 x		
		25 = 0.1325 mg		
		L4b = 0.1325/40 =		
		0.00331 m g/ml		
		L4c = 0.00530 x		
		150,000/(20		
		x1000) = 0.0398 m		


Step No

#

Description

report, generated

eResidue Test 4),

in step 103 (Qualification

by eResidue.

Product to be

manufactured) as

calculated in steps

104-106 should match that noted in the PDF document,

OPERATIONAL QUALIFICATION FOR **eRESIDUE APPLICATION**

Actual Results

Status

(Pass/Fall)

PROTOCOL No.:

Screen

Shot No

Tested By

Sign/Date

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/cm2	
$L4a = 0.00530 \ge 25$	
= 0.1325 mg	
L4b = 0.1325/40 =	
0.00331 m g/ml	

Expected Results

g/ml

		101 manataetare or		1 1	
		A and B. L3 used			
		will be lower of the			
		2 L3s calculated			
		(CA1-A and CA1-			
		B).			
		L3 used = 0.00530			
		mg/cm2			
		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 ²			
		L4a = 0.00530 x			
		25 = 0.1325 mg			
		L4b = 0.1325/40 =			
		0.00331 m g/ml			
		$I_{4c} = 0.00530 \text{ x}$			
		$20.000/(20 \times 1000)$			
		-0.00530 m g/m			
79109	Verify that the				
7.7.107	limits as	The limits L0, L1,			
	calculated in steps	L2, L3, L4a, L4b			
	104-106 matches	and L4c for CA1-			
	that noted in	A and CA1-B			
	report generated	(Cleaning Agent-			



Step No

Remarks:

#

Description

OPERATIONAL QUALIFICATION FOR eRESIDUE APPLICATION

Actual Results

Status

(Pass/Fall)

PROTOCOL No.:

Tested By

Sign/Date

Screen

Shot No

generated in step 103 (*Qualification eResidue Test* 4), by eResidue

Meet the Acceptance Criteria	[] Yes	[] No
Verified by :		Date:		

Expected Results

 Reviewed by : _____
 Date: _____

8.0 DEVIATION (IF ANY):



OPERATIONAL QUALIFICATION FOR eRESIDUE APPLICATION

9.0 ANNEXURES:

S.No.	Name of Annexure	Annexure No.

10.0 SUMMARY:

11.0 CONCLUSION:



OPERATIONAL QUALIFICATION FOR eRESIDUE APPLICATION

12.0 ABBREVIATIONS:

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

13.0 REFERENCE:



OPERATIONAL QUALIFICATION FOR eRESIDUE APPLICATION

14.0 POST APPROVAL:

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

Prepared By	Department	Designation	Sign & Date

Reviewed By	Department	Designation	Sign & Date

Approved By	Department	Designation	Sign & Date