



1.0 OBJECTIVE:

1.1. To lay down procedure for operation of cleaning validation application software: eResidue (Version 2.0.0).

2.0 SCOPE:

2.1. This SOP is applicable to cleaning validation application software eResidue (Version 2.0.0).

3.0 **RESPONSIBILITY:**

- 3.1. User: Site QA Validations Executive shall act as User for operating the software.
 - **3.1.1.** Shall be responsible to enter the data of Equipment and Product. Shall be responsible to create facility profile, calculations and updating data in the fields.
 - **3.1.2.** Shall be responsible to select the basis of limit, create the report and download the report.
- **3.2. Administrator**: Instrumentation Engineer/Site QA-Head shall act as Administrator for eResidue software.
 - **3.2.1.** Shall be responsible to create new user by entering the details viz. User name, First Name, Last Name, email address.
 - **3.2.2.** Shall be responsible to edit user details by modifying the Account Permissions.
 - **3.2.3.** Shall be responsible to set Password Options (Password aging, Password length and Password history)
- **3.3. Site QA Validations In charge** shall be responsible to establish and maintain to ensure the compliance to this procedure.

4.0 ACCOUNTABILITY:

4.1. Head Quality Assurance shall be responsible for the implementation / compliance of this SOP.

5.0 ENVIRONMENT, HEALTH & SAFETY:

5.1. Not Applicable

6.0 **PROCEDURE:**

6.1. General procedure

- **6.1.1. eResidue** software is designed to calculate chemical residue limits for pharmaceutical cleaning process validation.
 - eResidue can calculate four types of limits, abbreviated as follows:
 - L0: Safe daily amount (either calculated or entered directly-eResidue)
 - L1: limit in the next product
 - L2: maximum allowable carryover

- L3: limit per surface area
- L4: limit in analytical sample
- The L4 value may be expressed in one of several ways, as follows:
- L4a (Swab amt): Amount of residue per swab (for swab sampling).
- L4b (Swab conc.): Concentration of residue in the extracted swab sample.
- L4c (Rinse): Concentration of residue in the analyzed rinse sample.
- In order to calculate limits, initial data needs to be entered in the eResidue database.
- The eResidue software shall be used for calculation of acceptance limits of chemical residue for Cleaning Procedures validation. The sequential procedure to use the software is as follows.

6.2. Procedure for Operation of eResidue Ver. 2.0.0:

6.2.1. Start up and Login:

- Once company account is created, the application shall send Username and Password via email to the 2 designated Administrators. Administrator shall access <u>https://www.eResidue.com/customer_login</u> in the internet browser (Google chrome or Firefox), login screen shall appear. Login screen shall ask for Username and Password.
- ✤ Administrator shall access the account with temporary password.
- Administrator shall reset the password and log in the account. Administrator shall have all the access including the creation of Users.

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eResidue®	
Sign In	
Username :	
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Copyright © 2017 eResidue. Al rights reserved.	
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After entering the Username and Password click the Login button. Then the Setup Wizard window shall open. The setup window shall have the following details: Introduction, Facility Profile, Equipment, Product, Upload, Basis of Limit, Default Limit, Signature Policy Report, Calculations and Fields, access setting, universal setting, change password.

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- By selecting appropriate 'account details, it shall display the details of 'Administrator account'.
- ◆ To create the user account, Administrator person shall click the 'Access Settings' icon.



The screen for 'Add' icon shall appear. Administrator shall fill the details and provide * the account permissions for the new user.

Note: User shall not be provided the account permission for "Delete"

6.2.2. Fields

The fields menu shall provide access to eResidue modules, Equipment, Product, and * Upload. All the modules shall be accessed by hovering the cursor over Fields on the application screen. (Refer image below)

User	Summary - eResidue 🗙 📃	THE R ADDA OF THE	William States And	ar ben			
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	eResidue®				ra Reports -	Calculation:	5 🍄 Fields
cces	ss Settings						Product
Use	er Summary Options						Upload
show	10 • records per page				Search:	Ехро	t as PDF Add
#	First name & Last name	Username	Email Address	Account Permissions	Role	Status	Actions
1	jitendra Kumar Rout	eresidue	eugia.eresidue@eugia.co.in	Reports Menu, Fields Menu, Calculations Menu, Receive report by Email	User	Active	
2	Vamshi Darelli	Vamshidarelli	vamshi.darelli@eugia.co.in	Reports Menu, Fields Menu, Calculations Menu, Receive report by Email	User	Active	
3	Suman Rao Boinapally	sumanrao	Sumanrao.boinapally@eugia.co.in	Access Settings, Reports Menu, Fields Menu, Facility Profile, Calculations Menu, Delete Data, Receive report by Email	Admin	Active	
4	Smruti Ranjan Biswal	smrutiranjan	smrutiranjan.biswal@eugia.co.in	Access Settings, Reports Menu, Fields Menu, Facility Profile, Calculations Menu, Delete Data, Receive report by Email	Admin	Active	
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www	.eresidue.com/equipment?setup_v	vizard=false					
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6.2.3. Equipment

All equipment entered for the facility and the corresponding details shall be displayed as tables in the Equipment Summary window as shown below.

Equip	oment - eResidue ×	CONTRACTOR OF AN ADDRESS OF TAXABLE	COLUMN REPORT AND	
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Equ	ipment Train			
Show	10 • records per page		Search: Add	Delete Export as XLS Export as PDF
#	Equipment Name	Serial No.	Surface Area	Action
1	25 LITER JACKETED MANUFACTURING VESSEL(MM)	EP210-018	6173.2 sq.cm	
2	AMPOULE & VIAL FILLING MACHINE (MANIFOLD, PUMP, NOZZLE) 3	EP104-012	115.0 sq.cm	
3	50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CEL	EP104-007	11956.0 sq.cm	
4	50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CEL	EP104-006	11956.0 sq.cm	
5	VIAL FILLING MACHINE (FILLING PUMP, FILLING SYRINGE, FILLING	EP210-013	607.0 sq.cm	
6	BUFFER TANK OF FILLING MACHINE (ONCOLOGY)	EP210-013	1127.0 sq.cm	
7	200 LITER JACKETED FILTRATION VESSEL	EP210-017	22896.0 sq.cm	
8	200 LITER JACKETED MANUFACTURING VESSEL	EP210-016	22907.0 sq.cm	
9	BLENDER BIN 15L	EP211-073	3840.9 sq.cm	
10	BLENDER BIN SL	EP211-074	982.49 sq.cm	
				- 10

** Add New Equipment:



• Select Add Equipment option located above the equipment table. A screen shall appear as shown in the following figure. The asterisk (*) indicates compulsory fields.

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	<i>e</i> Residue*	Add Equipment	×	Reports -	Calculations	¢°	Field
quip	ment Summary	Equipment Name*:					
Equ	ipment Train	Equipment Abbreviation:					
how	10 Tecords per page	Surface Area*:	sq.cm	Add Delete	Export as XLS	Export a	s PDF
#	Equipment Name	Surface Area Data Source:	.rea		Act	ion	
1	25 LITER JACKETED MANUFACTURING VESSEL(MM)	Material of Construction:	.cm		2		
2	AMPOULE & VIAL FILLING MACHINE (MANIFOLD, PUMP, NOZZLE) 3		m				
3	50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CEL	Notes:	q.cm				
4	50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CEL		q.cm				
5	VIAL FILLING MACHINE (FILLING PUMP, FILLING SYRINGE, FILLING		<i>"""</i> "		2		
6	BUFFER TANK OF FILLING MACHINE (ONCOLOGY)		Cancel Submit cm		2		
7	200 LITER JACKETED FILTRATION VESSEL	EP210-017	22896.0 sq.cm				
3	200 LITER JACKETED MANUFACTURING VESSEL	EP210-016	22907.0 sq.cm				
9	BLENDER BIN 15L	EP211-073	3840.9 sq.cm				
10	BLENDER BIN 5L	EP211-074	982.49 sq.cm			•	
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- Enter the details as shown in the table below and click Submit to save entry.
- Once all information entered, click Submit. The application shall save the new equipment and this shall be also displayed in the Equipment Summary window.

Edit Equipment:

• Click on the pencil icon, under Actions column, corresponding to the equipment to edit, in the Equipment Summary window. The following window shall appear. After editing, click Update to register details.

8	RAPID MIXER GRANULATION	EP211.002		45994.0 w	n em			
		Edit Equipment		×		2		
9					ą.em			
10	COMPRESSION MACHINE	Equipment Name*:	CONTA BLENDER BIN 30L		ą.cm	2		
1	CONTA BLENDER BIN 75L	Equipment Abbreviation:			q.cm	2		
	CONTA BLENDER BIN 150L	Serial Number/ID:	EP211-073		sq.cm	2		
2		Surface Area*:	5273 sq.cm					
		Surface Area Data Source:			4.cm	2		
24	CONTA BLENDER BIN 30L	Material of Construction:	SS-316		cm			
5	METAL DETECTOR		NA		cm			
6	TABLET DE-DUSTER	Notes:			cm	2		
27	CAPSULE FILLING MACHINE				q.cm	2		
18	TABLET/CAPSULE COUNTING MACHINE			1	cm	2	•	
9	BLISTER PACKING MACHINE		Cance	el Update	q.em	2		
0	TABLET COATING PAN 900MM	EP211-014		120330.0	sq.cm	2		
1	CO-MILL	EP211-003		22490.0 st	q.cm	2		
owin	ng 1 to 31 of 31 entries							1

• Note: Equipment Name cannot be edited.



• Note: For equipments used in prior calculations, the application will not allow the equipment details to be edited, till the associated report listed in Report Tracker has either been archived or deleted.

Delete Equipment:

- Administrator shall select the 'minus' option. The applications confirm the delete request before proceeding.
- For equipments used in prior calculations, the application shall not allow the equipment to be deleted, till the associated report listed in Report Tracker has either been archived or deleted.
- Note: If not associated with any calculation or product.

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18		EP211-002	45994.0 sq.cm	2		
9	FLUID BED ORIER	EP211-004	46516.0 kg.cm	2	0	
0	COMPRESSION MACHINE	EP211-006	10685.0 sq.cm	2	0	
1	CONTA BLENDER BIN 75L	EP211-007	14000.0 sq.cm	2	•	
2	CONTA BLENDER BIN 150L	EP211-008	145211.0 sq.cm	2	-	
3	CONTA BLENDER BIN 100L	Alert	×	2		
4	GONTA BLENDER BIN 30L	Are you sure you want to delete this?	.em	12	•	
ş	METAL DETECTOR		em	2	-	
8	TABLET DE-DUSTER		Cancel Proceed em	22	-	
7	CAPSULE FILLING MACHINE	EP211-015	13615.0 sq.cm	2	-	
8	TABLET/CAPSULE COUNTING MACHINE	EP211-022	6686.0 sq.cm	2	-	
9	BLISTER PACKING MACHINE	EP211-042	10021.0 sq.em	52	•	
0	TABLET COATING PAN 900MM	EP211-014	120330.0 sq.cm	2	-	
1	CO-MIL	EP211-003	22490.0 sq.cm	2	-	
owan	ng 1 to 31 of 31 entries					1
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• Note: If associated with any calculation or product.

	RAPID MIXER GRANULATION	EP211-002	45994.0 sq.cm		2	
19	FLUID BEO DRIER	EP211-004	48516.0 sq.cm	201	-	
20	COMPRESSION MACHINE	EP211-006	10685.0.ng.cm	21	-	
21	CONTA BLENDER BIN 75L	Alert	×	21	-	
22	CONTA BLENDER BIN 150L	This equipment is associated with the following: • METHOTREXATE TABLET 2.5MG (Product)	iq.em	E2 F	-	
23	CONTA BLENDER BIN 100L	ANASTROZOLE TABLET 1mg (Product)	a cm	51 F	-	
24	CONTA BLENDER BIN 30L	LETROZOLE TABLET 2.5MG (Product) AFATANIB TABLET 40MG (Product)	am .	51 F	-	
25	METAL DETECTOR	TOMAXIFIN TABLET 20MG (Product) CAPECITABINE TABLETS 500MG (Product)	em.	22 1	-	
26	TABLET DE-DUSTER	AFATAINIB TABLET 20MG (Product) CAPECITABINE TABLET \$ 150MG (Product)	em	53 F	-	
27	CAPSULE FILLING MACHINE	AFATANIB TABLET 30MG (Product)	a.cm	51 F	-	
28	TABLET/CAPSULE COUNTING MACHINE	To delete, remove links to the above	am an	51 F	-	
29	BLISTER PACKING MACHINE	EP211-042	10021.0 sq.cm	E2 F	-	
30	TABLET COATING PAN 900MM	EP211-014	120330.0 eq.cm	51 F		
31	CO-MILL	EP211-003	22490.0 sq.cm	51 F	3	
ihowin	g 1 to 31 of 31 entries					10
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6.2.4. PRODUCT:

The Product Summary page, as shown in the figure below, lists all products entered into the application. The number of product records to be displayed in a particular page of the Product Summary window shall be varied using the drop-down list. The Search bar shall be used to filter down the list to specific product/s.

Entries in the Product Summary page shall be sorted in ascending or descending order (i.e. the order in which they were added) and the order of display shall be toggled by clicking the column headings (Product Name, Product Type, Equipments, etc.). The column heading in the table corresponds to the product details when a new entry is made.

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Show	10 records per page			Search: Add Delete Export a	as XLS Export a	IS PDF
#	Product Name	Product Type	Equipment Train	Equipment	Action	
1	PQ OF 2.0.0	Solid		CO-MILL, BLISTER PACKING MACHINE, SAMPLING ROD		
2	DOXORUBICIN HCL INJECTION	Liquid	-	200 LITER JACKETED MANUFACTURING VESSEL, 200 LITER JACKETED FILTRmore	0 6 8	
3	MELPHALAN FOR INJECTION 50	Liquid	-	200 LITER JACKETED FILTRATION VESSEL, BUFFER TANK OF FILLING MACH more	060	
4	CLOFARABINE INJECTION 1MG/ML	Liquid	-	200 LITER JACKETED FILTRATION VESSEL, BUFFER TANK OF FILLING MACH more	0 6 8	
5	TESTOSTERONE CYPIONATE IN	Liquid		50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FACmore	060	
6	HYDROXY PROGESTERONE CA	Liquid	-	50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FAC more	0 6 8	
7	TESTOSTERONE ENANTHATE I	Liquid	-	50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FAC more	060	
8	PROGESTERONE INJECTION 50	Liquid	-	50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FAC more	0 6 8	
9	HYDROXY PROGESTERONE CA	Liquid	-	50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FACmore	060	
10	MEDROXYPROGESTRONE ACET	Liquid	-	50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FACmore		
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***** Add New Product:

To add a product to eResidue, click Add Product, to include products manufactured in the facility. The following pop-up window shall be displayed.



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d He	elp 🛛				🖨 Settings - 🛛 🛔	sumanra
	eResidue®	Add Product		×	Calculations	Fields
rod	uct Summary	Product Name*:		Product Type*: Select Product Type •		
Pro	duct Cluster			Cancel Submit	Export as XLS Expo	ort as PDF
#	Product Name	Product Type	Equipment Train	Equipment	Action	=
1	PQ OF 2.0.0	Solid		CO-MILL, BLISTER PACKING MACHINE, SAMPLING ROD	060	
2	DOXORUBICIN HCL INJECTION 2	Liquid		200 LITER JACKETED MANUFACTURING VESSEL, 200 LITER JACKETED FILTRmore	260	
3	MELPHALAN FOR INJECTION 50	Liquid		200 LITER JACKETED FILTRATION VESSEL, BUFFER TANK OF FILLING MACH more	060	
4	CLOFARABINE INJECTION 1MG/ML	. Liquid		200 LITER JACKETED FILTRATION VESSEL, BUFFER TANK OF FILLING MACH more	000	
5	TESTOSTERONE CYPIONATE INJ	. Liquid		50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FACmore	0 6 0	
6	HYDROXY PROGESTERONE CAP	. Liquid		50 LITERS JACKETED TANK WITH IN-BUILD CIPISIP AND LOAD CELL FACmore	0 6 0	
7	TESTOSTERONE ENANTHATE IN	. Liquid		50 LITERS JACKETED TANK WITH IN-BUILD CIPISIP AND LOAD CELL FACmore	060	
8	PROGESTERONE INJECTION 50	Liquid		50 LITERS JACKETED TANK WITH IN-BUILD CIPISIP AND LOAD CELL FACmore	0 6 0	
9	HYDROXY PROGESTERONE CAP	. Liquid		50 LITERS JACKETED TANK WITH IN-BUILD CIPISIP AND LOAD CELL FACmore	0 6 0	

Fields marked with an asterisk (*) indicate mandatory fields. The first step shall be to enter the Product Name. Select Product Type from drop-down menu. Product Type options are – API, Cleaning agent, Inhalants, Liquids, Solids, Topical and Transdermal patch.

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id He	elp 🚱					🕸 Settings - 🛛	🛔 sumanrao
	eResidue®	Add Product			×	Calculations	Fields
Pro	uct Summary oduct Cluster	Product Name*:		Product Type*:	Select Product Type Cleaning Agent Inhalant Lägud Topic al Trensdermal Patch Trensdermal Patch	Export as XLS Exp	ort as PDF
	Product Name	Product Type	Equipment Train	Equipment		Action	
1	PQ OF 2.0.0	Solid		CO-MILL, BLISTER PACKING MACHI	NE, SAMPLING ROD	260	
2	DOXORUBICIN HCL INJECTION 2	. Liquid		200 LITER JACKETED MANUFACTUR	RING VESSEL, 200 LITER JACKETED FILTR more		
3	MELPHALAN FOR INJECTION 50	Liquid		200 LITER JACKETED FILTRATION \	ESSEL, BUFFER TANK OF FILLING MACH more	260	
4	CLOFARABINE INJECTION 1MG/ML	. Liquid		200 LITER JACKETED FILTRATION V	ESSEL, BUFFER TANK OF FILLING MACH more	260	
5	TESTOSTERONE CYPIONATE INJ	Liquid		50 LITERS JACKETED TANK WITH IN	-BUILD CIP/SIP AND LOAD CELL FACmore	260	
6	HYDROXY PROGESTERONE CAP.	Liquid		50 LITERS JACKETED TANK WITH IN	-BUILD CIP/SIP AND LOAD CELL FACmore	260	
7	TESTOSTERONE ENANTHATE IN	. Liquid		50 LITERS JACKETED TANK WITH IN	HBUILD CIP/SIP AND LOAD CELL FACmore	260	
8	PROGESTERONE INJECTION 50	Liquid		50 LITERS JACKETED TANK WITH IN	N-BUILD CIP/SIP AND LOAD CELL FACmore	260	
9	HYDROXY PROGESTERONE CAP	. Liquid		50 LITERS JACKETED TANK WITH IN	HBUILD CIP/SIP AND LOAD CELL FACmore	260	
10	MEDROXYPROGESTRONE ACET	Liquid		50 LITERS JACKETED TANK WITH IN	N-BUILD CIP/SIP AND LOAD CELL FAGmore		
						· 194 4	

The subsequent sections shall assist in defining the fields for different product types.

Product type - Solid/ Liquid/ Inhalant:

The following window shall appears when choose Solid, Liquid or Inhalant as Product Type. *Refer Annexure I "Field Description when Product type is Solid, Liquid or Inhalant"* while entering the data in fields.



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d Hel	p 😡					🖨 Settings -	🕯 sumann
	eResidue®	Add Product				× Calculations	Field
		Product Name*:	PRODUCT 1	Product Type*:	Liquid		
rodu	ct Summary	Active Ingredient Name:					
Prod	fuet Cluster	Dosing Frequency*:	Daily	Active Concentration:	mg/g 🔻		
		Dose Based On*:	Product •	Single Dose of Product*:	g		-
how	10 v records per page	Minimum Doses per Period*:		Maximum Doses per Period*:		Export as XLS Expo	ort as PD
#	Product Name	Minimum Batch*:	kg	% TOC of Active:	%	Action	
1	PQ OF 2.0.0	Basis of Limit Determination				260	
2	DOXORUBICIN HCL INJECTION	2 🔲 Dose Based Limit				0 6 0	
3	MELPHALAN FOR INJECTION 50	Health Based Limit				260	
4	CLOFARABINE INJECTION 1MG	Equipment/Bracket/Train Sel	ection			2 R C	
5		Available		Selected (0)			
0		+ Equipment					
7		N					
8	PROGESTERONE INJECTION 50	5.					
9	HYDROXY PROGESTERONE CA	(F					
10	MEDROXYPROGESTRONE ACE	т					

Once all details entered, click Submit to save the entry or Cancel to exit. Once the entry is saved, it appears on the Product list. You can repeat the process to add more products. Once all fields are complete, Click Submit to save the entry or Cancel to exit. Once the entry is saved, it appears on the Product Summary page as the latest entry.

Product type - Cleaning Agent:

Choose cleaning agent from the Product type menu, then the window shall expands as shown below.

-	C A https://www.orosie	ue com (product?cotup. w	vizard = falco			0.0
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ed He	n an				Settings - a	sumanra
	<i>e</i> Residue®	Add Product		× 🗈 ca	Iculations 🛱	Fields
		Product Name*:	PRODUCT 1	Product Type*: Cleaning Agent		
rod	uct Summary	Basis of Limit Determination				
Pro	duct Cluster	LD50 Based				
		Health Based Limit				
Show	10 Trecords per page			Ехро	rt as XLS Expe	ort as PDF
#	Product Name				Action	
1	PQ OF 2.0.0			Cancel	2 6 0	
2	DOXORUBICIN HCL INJECTION 2	Liquid		200 LITER JACKETED MANUFACTURING VESSEL, 200 LITER JACKETED FILTRmore	260	
3	MELPHALAN FOR INJECTION 50.	Liquid		200 LITER JACKETED FILTRATION VESSEL, BUFFER TANK OF FILLING MACH more	00	
4	CLOFARABINE INJECTION 1MG/	IL Liquid		200 LITER JACKETED FILTRATION VESSEL, BUFFER TANK OF FILLING MACH more	260	
5	TESTOSTERONE CYPIONATE IN	Liquid		50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FAGmore	260	
6	HYDROXY PROGESTERONE CAP	Liquid		50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FACmore	260	
7	TESTOSTERONE ENANTHATE IN	Liquid		50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FAC more	260	
3	PROGESTERONE INJECTION 50.	Liquid		50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FAC more	260	
	HYDROXY PROGESTERONE CAP	Liquid		50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FAGmore	260	
9						

Once all fields are complete, Click Submit to save the entry or Cancel to exit Add Product. The saved entry shall appear on the Product Summary page.

Product Edit:



Click on the 'pencil' icon, under Actions column, corresponding to the product to be edited, in the Product Summary window. The following window shall appear.

The Product Name cannot be edited.

id He	lp 😡							_			© Settings		sumanna
	eResidue*	Edit Product								×	Calculations		O Elolite
		Product Name*:	PQ OF 2	0.0		Product Type*:		Solid	•		Calculations		Tienus
rodu	ict Summary	Active Ingredient Name:											
Pro	duct Cluster	Dosing Frequency*:	Monthly		•	Active Concentra	ition:		mg/g				
		Dose Based On*:	Product		•	Single Dose of Pi	roduct";	9	g				
now	10 • records per page	Minimum Doses per Period":	9			Maximum Doses Period':	per	9			Export as XLS	Expo	it as PDF
#	Product Name	Minimum Batch*:	9	kg		% TOC of Active:		10	%		Action		
5	PQ OF 2.0.0	Basis of Limit Determination									82 IC		
2	DOXORUBICIN HCL INJECTION	Dose Based Limit									12 IC		
3	MELPHALAN FOR INJECTION 50	Health Based Limit										-	
4		Toxicological Basis*:	ADE		•	Comments	PQ OF 2.0				P2 11-		
		Health Based Limit *:	9	mg		111				_			
		Equipment/Bracket/Train Sele	stion										
6	HYDROXY PROGESTERONE CA	Available				Selected (3)							
7	TESTOSTERONE ENANTHATE	+ Equipment			CO-MILL	Equipment				_	12 IC		
8	PROGESTERONE INJECTION 50				BLISTER PACKING MACHINE SAMPLING ROD	Equipment Equipment					2 10	-	
9	HYDROXY PROGESTERONE CA										20	-	
												-	

After editing click the Update to register details.

Note: For products used in prior calculations, the application shall not allow its details to be edited, till the associated report listed in Report Tracker has either been archived or deleted.

Delete Product:

Administrator shall delete the product listed by selecting 'minus' icon. The applications

confirms the delete request (refer image below) before proceeding.

->	C A https://www.eresidu	e.com/product?setup_wiz	ard=false			Q ·
d He	sip @	intern, productivetap_int			🕸 Settings - 🛔	suman
	eResidue®			n Reports -	Calculations	Fiel
odu	uct Summary					
Pro	duct Cluster					
ow [10 • records per page		Alert	Add Delete	Export as XLS Expor	rt as PDI
	Product Name	Product Type	Are you sure you want to delete this?		Action	
	PQ OF 2.0.0	Solid		IPLING ROD	260	
	DOXORUBICIN HCL INJECTION 2	Liquid		Cancel Proceed ESSEL, 200 LITER JACKETED FILTRmo	. 26.0	
	MELPHALAN FOR INJECTION 50	Liquid		200 LITER JACKETED FILTRATION VESSEL, BUFFER TANK OF FILLING MACH more	- 260	
	CLOFARABINE INJECTION 1MG/ML	Liquid		200 LITER JACKETED EILTRATION VESSEL BUEEER TANK OF EILLING MACH. mm		
	TESTOSTERONE CYPIONATE INJ	Liquid		50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FAC more	260	
	TESTOSTERONE CYPIONATE INJ HYDROXY PROGESTERONE CAP	Liquid		SO LITERS JACKETED TANK WITH IN-BUILD CIPISIP AND LOAD CELL FACmore SO LITERS JACKETED TANK WITH IN-BUILD CIPISIP AND LOAD CELL FACmore		
	TESTOSTERONE CYPIONATE INJ., HYDROXY PROGESTERONE CAP.,. TESTOSTERONE ENANTHATE IN.,.	Liquid Liquid Liquid		SO LITERS JACKETED TANK WITH IN-BUILD CIPISIP AND LOAD CELL FACmore SO LITERS JACKETED TANK WITH IN-BUILD CIPISIP AND LOAD CELL FACmore SO LITERS JACKETED TANK WITH IN-BUILD CIPISIP AND LOAD CELL FACmore		
	TESTOSTERONE CVPIONATE INJ. HYDROXY PROGESTERONE CAP TESTOSTERONE ENANTHATE IN PROGESTERONE INJECTION 50	Liquid Liquid Liquid		50 LITERS JACKETED TANK WITH IN-BUILD CIPISIP AND LOAD CELL FACmore 50 LITERS JACKETED TANK WITH IN-BUILD CIPISIP AND LOAD CELL FACmore 50 LITERS JACKETED TANK WITH IN-BUILD CIPISIP AND LOAD CELL FACmore 50 LITERS JACKETED TANK WITH IN-BUILD CIPISIP AND LOAD CELL FACmore		
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Note: For products used in prior calculations, the application will not allow the details to be deleted, till the associated report listed in Report Tracker has either been archived or deleted.

Basis of Limit:

• Access the Basis of Limit module by hovering the cursor over Limit Definition on the application screen. (Refer image below)



• Define the L0 value as mention in common procedure for Cleaning Validation Program QAD-010-current version

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👔 eResidue®	📷 Reports - 📑 Calculations 🛭 📽 Fields -
niversal Settings	
General Limit Terminology Limit Definition Signature Policy	
Basis of Limit L0 to be dose based L0 to be health based L0 to be health based L0 to be based on the lower value between dose based L0 and health based L0	
Default Limit We default under and the estimated value	
Ve a default value for L1	
Use a default value for both L1 and L3	
	Cancel Save
	eResidue Version 2

• <u>Three options are available to choose how the application would handle L0:</u>



1. L0 to be dose based: Select this option for calculations for dose based. The Safety factor can either be defined as 0.001 or alternatively the radio button against other can be selected to define a custom safety factor.

2. L0 to be health based: Select this option if the L0 is to be health based.

3. L0 to be based on lower of dose based L0 or health based L0: If you select this option, L0 value for the above two will be calculated and the lower of the two will be used in limit calculations.

✤ Default Limit:

No Default is used. Use calculated value: Select this option to only consider the calculated values for L1 and L3. Click Save to register preferences.

Calculation:

This section shall be accessed by clicking the Calculation Icon. The following pop-up window shall appear.

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eResidue®					Reports -	Calculations	🕸 Fields
ulate Limit							
	Report	Product	Specification	Definition	Verification		
	0	-0	—0—	—0—	———————————————————————————————————————		
Step 1 - Report							
Welcome to the Calculation Wizard. You w	Ⅲ be taken through a series of tab:	s that will require you to	o enter key information for the ca	lculations.			
Welcome to the Calculation Wizard. You w Report Report Title: Residue Limit Report Template:	III be taken through a series of tab	s that will require you to	o enter key information for the ca	lculations.			
Welcome to the Calculation Wizard. You w Raport Report Title: Residue Limit Report Template: Limit Selection	III be taken through a series of tab	s that will require you to	p enter key information for the ca	liculations.			
Welcome to the Calculation Wizard. You w Report Report Title: Residue Limit Report Template: Limit Selection U.U.U.U.U.U.U.U.U.U.U.U.U.U.U.U.U.U.U.	Ill be taken through a series of tab Worst Case Matrix Uta as TOC (Swab Amount) L4a as TOC (Swab Amount) Uta as TOC (Swab Amount) Uta as TOC (Swab Amount)	s that will require you to	o enter key information for the ca	liculations.			
Welcome to the Calculation Wizard. You w Report Report Title: Residue Limit Report Template: Limit Selection L L L1 L4e (Swab Amount) L2 L4b (Swab Concn.) L3 L4c (Rinse)	III be taken through a series of tab Worst Case Matrix • L4a as TOC (Swab Amount) L4b as TOC (Swab Concn.) L4c as TOC (Rine)	s that will require you to	o enter key information for the ca	iculations.			
Welcome to the Calculation Wizard. You w Report Report Title: Residue Limit Report Template: Limit Selection L0, L1 L4a (Swab Amount) L2 L4b (Swab Conon,) L3 L4c (Rinee) Email Report	III be taken through a series of tab Worst Case Matrix • L4a as TOC (Swab Amount) L4a as TOC (Swab Concn.) L4c as TOC (Rinee)	s that will require you to	o enter key information for the ca	iculations.			

The Calculate Limit window shall have different sections arranged in an accordion, as shown in the above picture, user shall move to the subsequent sections only after completing the requisite fields in the current section.

Step-1:

Report: This part of the Calculate Limits accordion defines various aspects of the report generated by the application. It includes selection for the formal report title, selection of worst case, selection of limits, send email report via mail option.

- a. Report: The first section in the Report allows the user to assign report title,
- b. Limit Selection: In this section, the user can check boxes for limit Values that should appear on the Limit Calculation report



generated by the application.

- c. Sampling Method: Depending on the selection made on this screen, the application will present varying screens for information entry.
 - **Rinse:** the application will request you to define how rinse sampling will be performed.

The options are:

- i. Individually: where rinse sampling shall be sampled individually for each equipment item (Refer Step 1) or
- ii. As train: where the rinse sampled from the entire equipment train. (Refer Step 1)
- Click on the radio button that identifies the process used for this set of calculations.
- **Swab:** Use the swab technique for sampling; choose to express the swab limits:
 - i. Amount of residue per swab (L4a)
 - ii. Concentration limit in the liquid (such as water or solvent) the swab is extracted into (L4b)
 - iii. Both (L4a and L4b)
- d. In this section, the user can check boxes for limit values that should appear on the Limit Calculation report generated by the application.
- e. Report Format: This section allows the user to email the report after calculations. A drop down menu with "Select Mail' appears where email recipients may be selected
- Step-2:

Product Selection: Select the products for which residue limit calculations shall be performed. All the products entered shall be listed in the Available Products box. Alternatively, user can search for the products using the Product Selector. (Figure below)



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	Report Product		Specification	Definition	Verification	
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Step 1 - Report						
Step 2 - Product Selection						
- •						
Product/Cluster Selection						
POMALIDO						
Available		Selected (4)				
- Products	AFATAINIB TABLET 20MG (S)	Products				
POMALIDOMIDE CAPSULE 1/2/3/4 M	G AFATANIB TABLET 30MG (S)	Products				
(S)	AFATANIB TABLET 40MG (S)	Products				
	TOMAXIFIN TABLET 20MG (S)	Products				
						< Previous Next >
Step 3 - Rinse Specification - Individual E	quipment					
Step 3 - Rinse Specification - Equipment I	rain					
Step 3 Swah Specification						

Select the products of interest and use the selection box by click on the box $(\sqrt{})$ to move the desired products to the Products Selected box. Use the cross sign (X) to move selected products back to the main product list.

Click Next to proceed to the next section of the Calculate Limit accordingly.

***** Step-3:

Rinse Specification- individual equipment-

Equipment volume information: This section of the Calculate Limit is available if you have chosen to run limits with L4 calculation and have chosen Rinse sampling.

Rinse –Individually: If you have selected the rinse sampling to be done individually for each equipment item, then the following window appears.



Help 🕐							Settings -	🔒 sumanra
	Repo	rt	Product	Specification	Definition	Verification		
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Step 1 - Re	port							
Step 2 - Pro	oduct Selection							
Step 3 - Rin	ase Specification - Individual Equipment	nt						
Rinse Volum	e Specification:							
Rinse Volum Enter the liter	e Specification: of the volume to be used for the rinse sampling cal	culation.						
Rinse Volum Enter the liter	e Specification: of the volume to be used for the rinse sampling cal volume liter entered in the first row to all other liste	culation. d equipment						
Rinse Volum Enter the liter Apply Enter	e Specification: of the volume to be used for the rinse sampling cal volume liter entered in the first row to all other liste manually the Rinse Volume for each equipment	culation. d equipment						
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Rinse Volum Enter the liter O Enter 1	e Specification: of the volume to be used for the rinse sampling cal volume itere entered in the first row to all other late manually the Rinse Volume for each equipment Equipment Name CO-MILL	culation. d equipment	Volume (L)	ŕ				
Rinse Volum Enter the liter Apply Enter 1 2	e Specification: of the volume to be used for the rine sampling cal volume iter entered in the first row to all other list manually the Rine Volume for each equipment Equipment Name COMILL TABLET COATING PAN 900MM	culation. d equipment	Volume (L.)					
Rinse Volum Enter the liter Apply Enter 1 2 3	e Specification: of the volume to be used for the rinse sampling cal volume liter entered in the first row to all other lite manually the Rinse Volume for each equipment Equipment Name CO-MILL TABLET COATING PAN SOOMM BUISTER PACKING MACHINE	sulation. d equipment	Volume (L)					
Rinse Volum Enter the liter Enter Enter	e Specification: of the volume to be used for the inve sampling cal volume Rer entered in the first row to al other like menually the Rine Volume for each equipment Equipment Name CO-MILL TABLET COATING PAN SOOMM BLISTER PACKING MACHINE	:ubtion. d equipment	Volume (L)					
Rinse Volum Enter the liter Apply Enter 1 2 3 4	e Specification: of the volume to be used for the rinse sampling cal volume Rer entered in the first row to al other list enumulay the Rinse Volume for each equipment Equipment Name CO-MILL TABLET COATING PAN 900MM BLISTER PACKING MACHINE TABLETICAPSULE COUNTING MACHINE	:ubtion. d equipment	Volume (L)	Î				
Rinse Volum Enter the iter Apply Enter 1 2 3 4 5	e Specification: of the volume to be used for the rinse sampling cal volume iter entered in the first row to al other list manually the Rinse Volume for each equipment Equipment Name CO-MILL TABLET COATING PAN 900MM BLISTER PACKING MACHINE TABLET CAPSULE COUNTING MACHINE TABLET DE-DUSTER	culation. d equipment	Volume (L)					
Rinse Volum Enter the iter Apply Enter 1 2 3 4 5 6	Specification: of the values to be used for the rines sampling call volume iter entered in the first row to all other fille manually the Rinne Volume for each equipment Equipment Name COMILL TABLET COATING PAN 900MM BLISTER PACKING MACHINE TABLET CAPSULE COUNTING MACHINE TABLET DE-DUSTER METAL DETECTOR	culdion. d equipment	Volume (L)	Î				

Note that the unit is Liters.

Select one option based on the requirement:

- 1. Apply volume liter entered in the first row to all other listed equipment OR
- 2. Enter manually the rinse volume of each equipment.

Click Next to continue

<u>Rinse Specification- Equipment Train:</u>

This option in the Calculate Limit accordion is only available if you have selected rinse sampling based on equipment train. eResidue provides 2 options to define the volume of rinse sample collected for each product.

- 1. Apply volume liter entered in the first row to all the other listed products.
- 2. Enter manually the Rinse Volume for each product.



Calculate Limi	t-eResidue ×	and the second s	
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d Help 😮			🗢 Settings - 🛛 🛔 sumanrad
Step 2 - F	Product Selection		
🗄 Step 3 - F	Rinse Specification - Individual Equipment		
🖬 Step 3 - F	Rinse Specification - Equipment Train		
Rinse Vol	ume Specification:		
Enter volun	ne to be used for the rinse sampling calculation		
Ap	ply volume liter entered in the first row to all the other listed p	roducts	
En	ter manually the rinse volume for each product		
#	Product Name	Volume (L)	
1	TOMAXIFIN TABLET 20MG		
2	AFATAINIB TABLET 20MG		
3	AFATANIB TABLET 30MG		
4	AFATANIB TABLET 40MG		
			< Previous Next >
Stop 3	Swah Specification		
a step s - t	Swab Specification		
Step 4 - L	Definition		
Step 5 - \	/erification		
			eResidue Version
WE			14

Swab Specification

This section of the Calculate Limit accordion is available if run limits with L4 calculation and have chosen swab sampling.

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C	https://www.eresidue.com	/calculate-limit			Q
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Step 2 -	Product Selection				
Step 3 -	Rinse Specification - Individual	Equipment			
Step 3 -	Rinse Specification - Equipmen	t Train			
Step 3 -	- Swab Specification				
Enter the : A A A A A C A C A	solvent used, amount of solvent and Suffa lpply all 3 entries in the first row to all the o lpply only the "Solvent used" and "Amount lpply only the "Sufface Area Sampled" fror Enter manually the information	ue area sampled for each of the listed ther listed products " from the first row to all the other liste m the first row to all the other listed pro	products d products ducts		
#	Product Name	Solvent Used	Amt. of Solvent Used for Desorption	Surface Area Sampled	
1	1 TOMAXIEIN TABLET 20MG				
1	2 AFATAINIB TABLET 20MG		mL V	sq.cm	
1	TOMAXIFIN TABLET 20MG AFATAINIB TABLET 20MG AFATANIB TABLET 30MG		mL ·	sq.cm	
1 2 3 4	TOMAXIFIN TABLET 20MG AFATANIB TABLET 20MG AFATANIB TABLET 30MG AFATANIB TABLET 40MG		mL •	sq.cm	
1 2 3 4	TOMAXIFIN TABLET 20MG AFATAINIB TABLET 20MG AFATANIB TABLET 30MG AFATANIB TABLET 40MG AFATANIB TABLET 40MG		mL •	sq.cm sq.cm sq.cm	C Previous Next 3
1 2 3 4 Step 4 -	TOMAXIFIN TABLET 20MG AFATAINIB TABLET 20MG AFATANIB TABLET 30MG AFATANIB TABLET 40MG Definition			sq.cm	🤇 Previous 🛛 Next 🗲
1 2 3 4 Step 4 - Step 5 -	TOMAXIFIN TABLET 20MG AFATANIB TABLET 20MG AFATANIB TABLET 20MG AFATANIB TABLET 30MG Definition Verification			sq.cm	🤇 Previous 🛛 Next 🗲

In order to collate the swab sampling information, the application provides 4 options

• Apply all 3 entries in the first row to all the other listed products:

The application takes the entries in the first row for Solvent Used; Amt. of Solvent used for Desorption and Surface Area Sampled and applies to the products listed below it in subsequent rows. Enter data only for the first row.



• Apply only the "solvent used "and "amount" from the first row to all the other listed products:

The application takes the entries in the first row for Solvent Used, Amt. of Solvent used for Desorption and applies to the products listed below it in subsequent rows. The data for Surface Area Sampled shall be entered manually for all the products.

• Apply only the "surface area sampled" from the first row to all the other listed products:

The application takes the entries in the first row for Surface Area Sampled and applies to the products listed below it in subsequent rows. The data for Solvent Used and Amt. of Solvent used for Desorption is entered manually for all the products.

• Enter manually the information:

The last option expects all product information to be done manually.

Once the information has entered, click Next to proceed to Step 4.

Step4-: <u>Definition:</u>

The Definition section addresses whether the Limit calculation shall also include the product that was previously manufactured or not.

Help 🕐						Settings -	🔒 sumanra
	Report	Product	Specification	Definition	Verification		
	~	·	<u> </u>	0	———————————————————————————————————————		
Step 1 - Report							
Step 2 - Product Selection							
Step 3 - Rinse Specification - Indi	vidual Equipment						
Step 3 - Rinse Specification - Equ	ipment Train						
Step 3 - Swab Specification							
Step 4 - Definition							
Matrix Definition:							
 Calculate the limits for the active in e 	ach product with only every other p	product as the next product.					
 Calculate the limits for the active in elements 	each product with EVERY product (including the same product) as	the next product.				
Surface Area Used:							
 Calculate the L3 limit solely based of 	in the actual shared surface area b	etween the two products.					
 Calculate the L3 limit based on the 	lowest total equipment train surface	area between the two product	s.				
						Previous	Next >
Step 5 - Verification							
							ERESIQUE VERSIO



Limit Calculation: Two options are available:

- 1. Calculate the limits for the active in each product with only every other product as the next product: The application calculates limits where the current product and the next product are not the same.
- 2. Calculate the limits for the active in each product with EVERY product (including the same product) as the next product: If this option selected, the application also calculates limits for cases where the current and the next manufactured product are the same. It also calculates limits for cases where the next manufactured product is different from the current product.

Step4-:

Verification:

In this step the input data of calculation shall show like report title, Calculation type, limits selected, selected product/cluster.

Once the information has verified, click on calculation icon to proceed the MACO calculation.

Note: If any changes is required in any step from step-01 to step -05, Click 'Previous' to do so. Otherwise click 'Calculate'

6.2.5. **REPORT**:

The Report section of the eResidue application allows user to access:

- Calculation Report
- Event Log Report
 - Calculation Report: All calculations carried out using eResidue application are stored in the database and the Report Tracker window provides the user the ability to access the report, without again repeating the same calculation.

Access this window by clicking **Calculation Report** in the **Reports** menu.





The Actions menu in the Report Tracker window allows the user to carry out the following:



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ро	rt Tracker					
ow	10 • records per page				Search:	Current Archive
	Report Title Cre	ated Date	Report Template	Products		Action
	MACO LIMIT OF ONCOLOGY BLOCK OSD LI 11/0	02/2017 14:41	Version-1 Template	TOMAXIFIN TABLET 20MG, METHOTRmore		
	MACO LIMIT FOR HORMONE BLOCK INJECT 11/0	02/2017 15:02	Version-1 Template	TESTOSTERONE CYPIONATE INJECTImore		
	NEW MACO LIMIT AS PER ADE VALUE FOR 16/0	02/2017 13:02	Version-1 Template	LETROZOLE TABLET 2.5MG, TOMAXImore		
	NEW MACO LIMIT AS PER ADE VALUE FOR 7 21/0	02/2017 16:35	Version-1 Template	AZACITIDINE FOR INJECTION 100Mmore		
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	MACO LIMIT FOR ONCOLOGY BLOCK LINEr 11/0	2/2017 16:32	Version-1 Template	AZACITIDINE FOR INJECTION 100Mmore		
0	MACO LIMIT FOR ONCOLOGY BLOCK LINEr 11/0	02/2017 14:33	Version-1 Template	AZACITIDINE FOR INJECTION 100Mmore		

- Email Report: A copy of the selected report can be sent via email, on clicking the mail icon
- **Delete:** The selected report can be deleted, by clicking the minus icon.
- Edit: eResidue allows the user to take a set of conditions on the basis of which a particular report was generated and edit it, so as to generate a new calculation. By clicking the pencil icon, the application takes the user back to the calculation menu. As the user goes from one step to the other, the application displays the recorded information from the previous calculation. One then can change the number of products or the sampling criteria or the definition and recalculate. A new report name has to be provided otherwise the application will not proceed with the calculation. The number of reports to be displayed can be chosen using the drop-down list **Show per page.** The **Search** bar can be used to filter down the list to specific reports.
- eResidue also provides the option to archive reports. To archive, select the report of interest and place a tick mark in the check box (right end of the row). Click the **Move to Archive** icon. This action moves the selected Report file to **Archive** folder.
- The default folder in the Report Tracker window is **Current folder.** You can use the drop-down list to select the Archive folder (see image below), where archived reports can be accessed.





User can use the action buttons to email/ generate report. Administrator can use the action buttons to delete the report click the 'minus' button. A delete confirmation pop-up window appears. Click Yes to proceed with report deletion.

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The Report document created by eResidue is in PDF format.

***** Event Log Report:

The eResidue Event Summary, as shown below, is a record of any significant occurrence or activity in the application. (Refer image below)



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	20/03/2017 14:36	Logged in successfully	eresidue	118.102.221.66		
	20/03/2017 14:36	Logged out successfully	sumanrao	118.102.221.66		,
	20/03/2017 14:34	New calculation created (SOP PREPARATION) and Calculation PDmore	sumanrao	118.102.221.66		-
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	20/03/2017 14:03	Logged in successfully	sumanrao	118.102.221.66		*
	20/03/2017 12:08	Logged in successfully	sumanrao	118.102.221.66		
	20/03/2017 10:51	Forced login	sumanrao	118.102.221.66		

The **Event Summary** is displayed as a table and cannot be modified. Search for specific event shall be done based on time frame, activity or username.

Users shall add comments by clicking the blue balloon in the add comment column. Once the comment is entered for a particular event, it is visible in the corresponding User comments field. (Refer image below)

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6	20/03/2017 14:33	Logged in successfully	sumanrao	118.102.221.66		9
7	20/03/2017 14:03	Logged in successfully	sumanrao	118.102.221.66		9
8	20/03/2017 12:08	Logged in successfully	sumanrao	118.102.221.66		9
9	20/03/2017 10:51	Forced login	sumanrao	118.102.221.66		9
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Event Log table details:

Colum Heading	Description
#	Serial Number
Date & Time	Date and Time when event/ activity occurred
Activity	Activity that was recorded during operation
User Name	Name of user who accessed and/or worked on the application
IP Address	System IP address from which the application was accessed





Colum Heading	Description
User Comments	User recorded comments; added using column 'Add
	Comment'
Add Comments	Click here to add comments.

***** Settings:

All application settings shall be accessed by hovering the cursor over the username. The various options available are- Access Settings, Universal setting Account Details, Facility Profile and Change Password.

• Access Settings:

The Access Settings page will display Home and Option tabs.

Access Settings – Home: The Home tab, as shown in the figure below, lists all users assigned to eResidue, their First & Last name, User Name, Email address, Account Permissions, user Status and administrator Actions.

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	Vamshi Darelli	Vamshidarelli	vamshi.darelli@eugia.co.in	Reports Menu, Fields Menu, Calculations Menu, Receive report by Email	User	Active	
	Suman Rao Boinapally	sumanrao	Sumanrao.boinapally@eugia.co.in	Access Settings, Reports Menu, Fields Menu, Facility Profile, Calculations Menu, Delete Data, Receive report by Email	Admin	Active	
	Smruti Ranjan Biswal	smrutiranjan	smrutiranjan.biswal@eugia.co.in	Access Settings, Reports Menu, Fields Menu, Facility Profile, Calculations Menu, Delete Data, Receive report by Email	Admin	Active	
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Create User: Click the Create User button to assign a new user to your eResidue application. (Refer screenshot below)





Click the drop down menu to reveal Account Permissions. Either select all or choose from the list by checking the box against the option.

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Click Submit to add user to list or Cancel to exit.

Edit user details: On the Home tab, the admin can edit user access using the 'pencil' icon under action column corresponding to the name of the user. The edit user window appears as shown below. The Username cannot be changed and Account Permission can be modified.





The Edit User Details window also allows you to disable the user permission. Once a user access is disabled by sliding the button from active to inactive, a warning is raised that the user account will be archived and cannot be enabled. To confirm, click Proceed else Cancel. You can also delete the details and the user using the 'minus' option.

Access Settings – Options

The Password Options, accessible by drop-down menu, includes -

- 1. Password Aging allows the Admin to set a specified period (60 days) after which the user is Prompted to create a new password..
- 2. Password Length this field determines the least number of characters that can make up a password for a user account. Admin shall set a value 6 characters.
- 3. Password History the number of unique new passwords that must be associated with a user account before an old password can be reused. Remembrance of old password shall be set as 3.

The system uses a default logout or session expires automatically if the application had been inactive for 15 minutes. You will be directed to the login screen to access the system after session expires from inactivity.





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Universal Settings – General

The General Preferences, refer image below, accessible by drop-down menu, include:

- 1. Renewal reminder allows you to set a reminder on how many days in advance you would like to be prompted to renew your eResidue account.
- 2. Time format allows you to set the time display format; 24 hours.
- 3. Date format -the date format can be customized here using the drop down menu.
- 4. Time zone select the time zone appropriate to your location
- 5. Surface area- Select the unit of measurement for calculation.



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Click Save to store options or Cancel to retain default settings.

Change Password:

You can access the Change Password option from the options revealed by clicking the username.

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To change password, enter the current password and then new password. Retype new password and the Save to proceed. (Refer image below.)





7.0 **REFERENCES:**

7.1. User's Guide Version 2.0.0 eRESIDUE, Cleaning Validation Technologies

8.0 ABBREVIATIONS:

Abbreviation	Description
ADE	Acceptable Daily Exposure
ID	Identification
PDE	Permitted Daily Exposure
PPM	Parts per million

9.0 LIST OF ANNEXURES:

S.No.	Name of Annexure	Annexure No.	Format No.	No. of Pages
1	Field Description and Type of Entry for Solid and Liquid Products	Annexure-01		2

10.0 CHANGE HISTORY:

S.No.	Supersede No.	Effective Date	CC Ref No.	Revision Summary