



STANDARD OPERATING PROCEDURE OF CLEANING VALIDATION APPLICATION SOFTWARE

SOP No.:

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



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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.

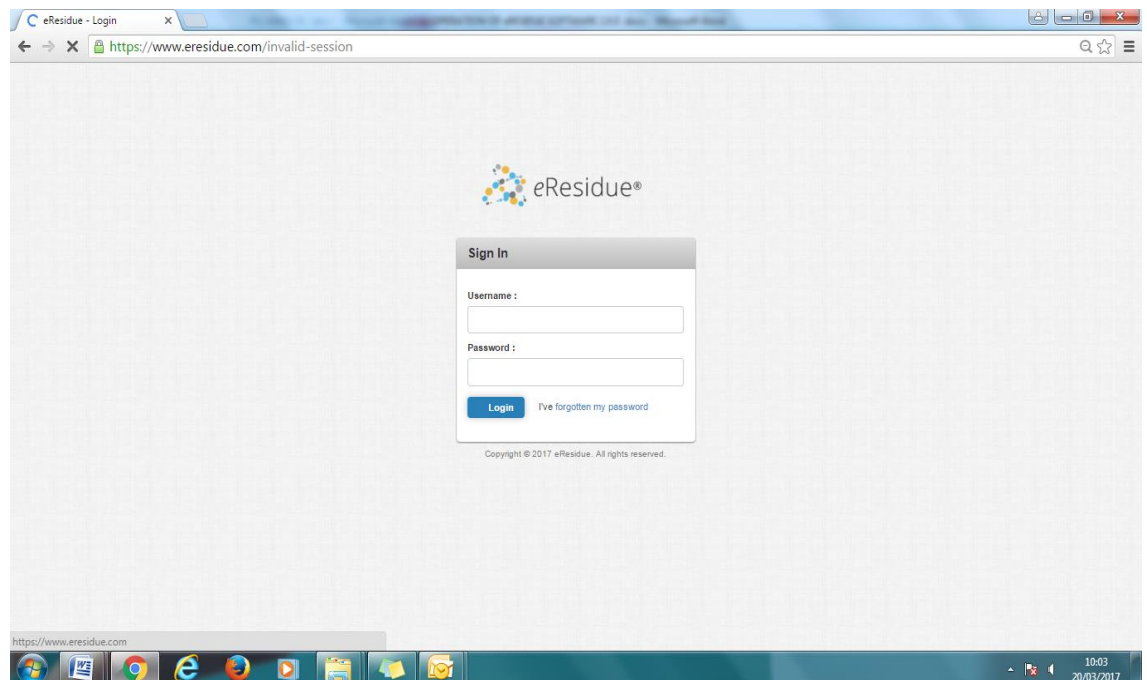
L4c (Rinse): Concentration of residue in the analyzed rinse sample.

- ❖ 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 https://www.eResidue.com/customer_login 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.

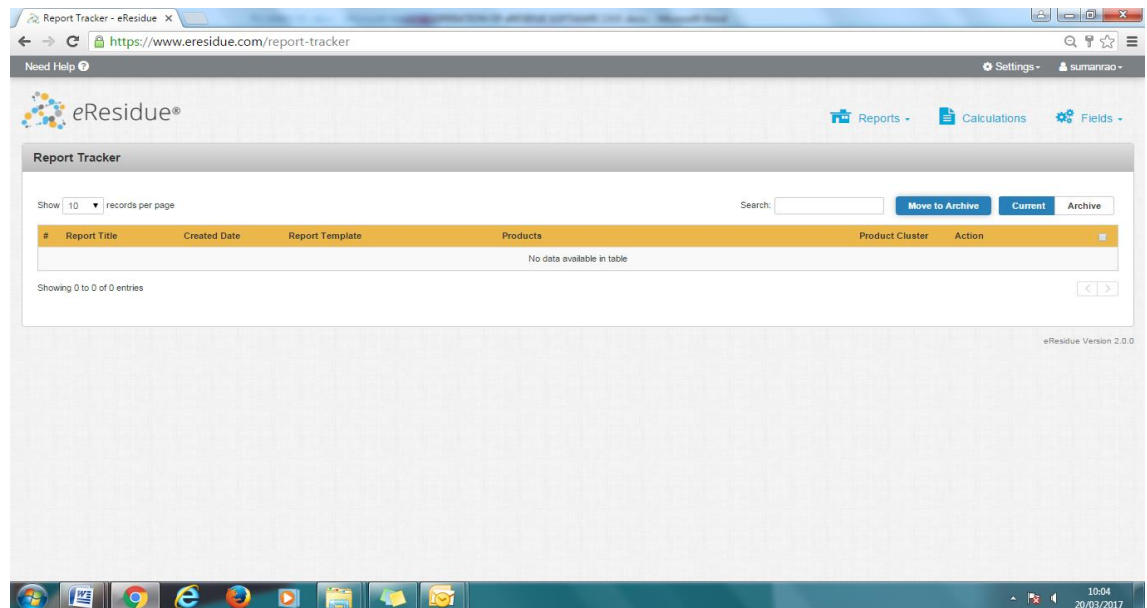
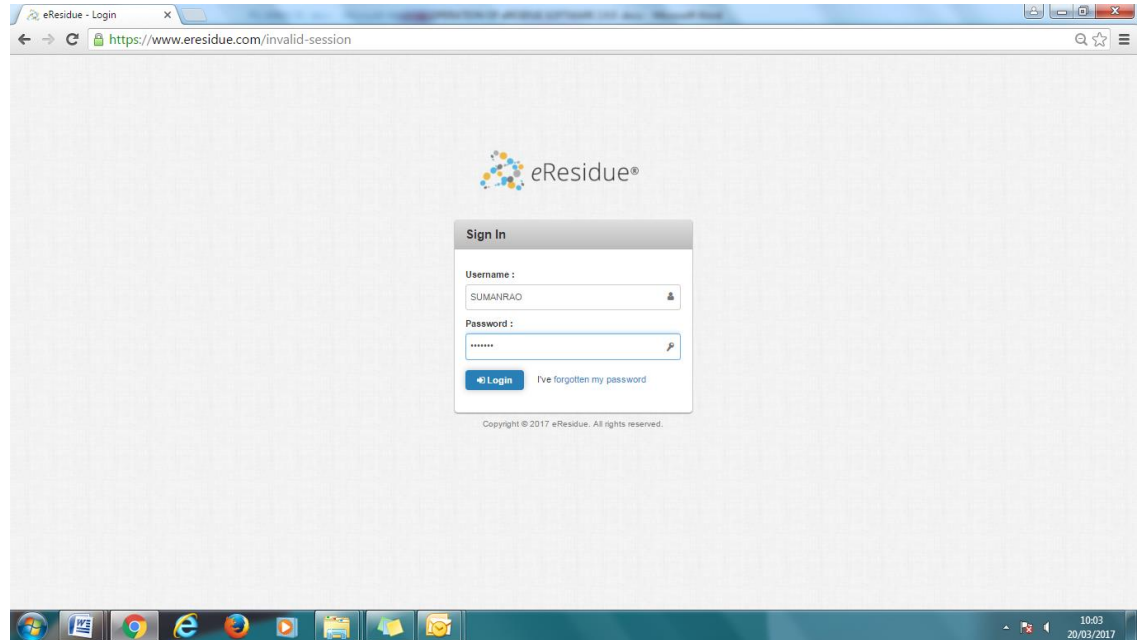




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- ❖ After entering the Username and Password click the Login button. Then the Setup Wizard window shall open. The setup window shall have the following details: Introduction, Facility Profile, Equipment, Product, Upload, Basis of Limit, Default Limit, Signature Policy Report, Calculations and Fields, access setting, universal setting, change password.



- ❖ 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.



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- ❖ 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)

#	First name & Last name	Username	Email Address	Account Permissions	Role	Status	Actions
1	Jendra Kumar Rout	eresidue	eugia.eresidue@eugia.co.in	Reports Menu, Fields Menu, Calculations Menu, Receive report by Email	User	Active	[Edit] [Delete] [Add]
2	Vamshi Darelli	Vamshidarelli	vamshi.darelli@eugia.co.in	Reports Menu, Fields Menu, Calculations Menu, Receive report by Email	User	Active	[Edit] [Delete] [Add]
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	[Edit] [Delete] [Add]
4	Smruti Ranjan Biswal	smrutiranjn	smrutiranjn.biswal@eugia.co.in	Access Settings, Reports Menu, Fields Menu, Facility Profile, Calculations Menu, Delete Data, Receive report by Email	Admin	Active	[Edit] [Delete] [Add]

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.

#	Equipment Name	Serial No.	Surface Area	Action
1	25 LITER JACKETED MANUFACTURING VESSEL(MM)	EP210-018	6173.2 sq cm	[Edit] [Delete] [Add]
2	AMPOULE & VIAL FILLING MACHINE (MANIFOLD, PUMP, NOZZLE) 3--	EP104-012	115.0 sq cm	[Edit] [Delete] [Add]
3	50 LITERS JACKETED TANK WITH IN-BUILD OIPISIP AND LOAD CEL...	EP104-007	11956.0 sq cm	[Edit] [Delete] [Add]
4	50 LITERS JACKETED TANK WITH IN-BUILD OIPISIP AND LOAD CEL...	EP104-006	11956.0 sq cm	[Edit] [Delete] [Add]
5	VIAL FILLING MACHINE (FILLING PUMP, FILLING SYRINGE, FILLING...	EP210-013	607.0 sq cm	[Edit] [Delete] [Add]
6	BUFFER TANK OF FILLING MACHINE (ONCOLOGY)	EP210-013	1127.0 sq cm	[Edit] [Delete] [Add]
7	200 LITER JACKETED FILTRATION VESSEL	EP210-017	22696.0 sq cm	[Edit] [Delete] [Add]
8	200 LITER JACKETED MANUFACTURING VESSEL	EP210-016	22907.0 sq cm	[Edit] [Delete] [Add]
9	BLENDER BIN 15L	EP211-073	3840.9 sq cm	[Edit] [Delete] [Add]
10	BLENDER BIN 5L	EP211-074	982.49 sq cm	[Edit] [Delete] [Add]

- ❖ **Add New Equipment:**



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

#	Equipment Name	Equipment ID	Surface Area	Action
1	25 LITER JACKETED MANUFACTURING VESSEL(MM)			
2	AMPOULE & VIAL FILLING MACHINE (MANIFOLD, PUMP, NOZZLE) >			
3	50 LITERS JACKETED TANK WITH IN-BUILD CIP&IP AND LOAD CEL.			
4	50 LITERS JACKETED TANK WITH IN-BUILD CIP&IP AND LOAD CEL.			
5	VIAL FILLING MACHINE(FILLING PUMP, FILLING SYRINGE, FILLING.			
6	BUFFER TANK OF FILLING MACHINE (ONCOLOGY)			
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 5L	EP211-074	982.49 sq.cm	

- 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.

#	Equipment Name	Equipment ID	Surface Area	Action
18	RAPID MIXER GRANULATION	EP211-002	45994.0 sq.cm	
19	FLUID BED DRIER			
20	COMPRESSION MACHINE			
21	CONTA BLENDER BIN 75L			
22	CONTA BLENDER BIN 150L			
23	CONTA BLENDER BIN 100L			
24	CONTA BLENDER BIN 30L			
25	METAL DETECTOR			
26	TABLET DE-DUSTER			
27	CAPSULE FILLING MACHINE			
28	TABLET/CAPSULE COUNTING MACHINE			
29	BLISTER PACKING MACHINE			
30	TABLET COATING PAN 900MM	EP211-014	120330.0 sq.cm	
31	CO-MILL	EP211-003	22490.0 sq.cm	

- **Note:** Equipment Name cannot be edited.



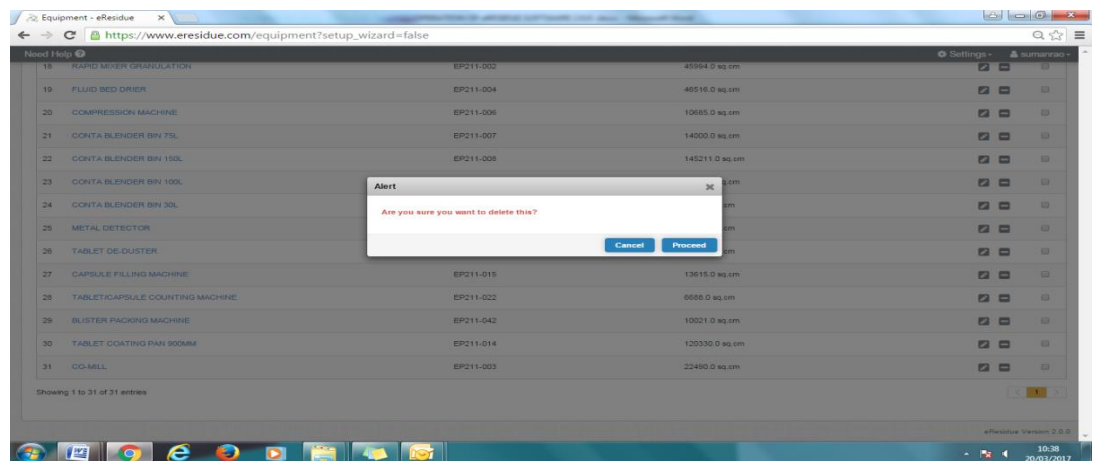
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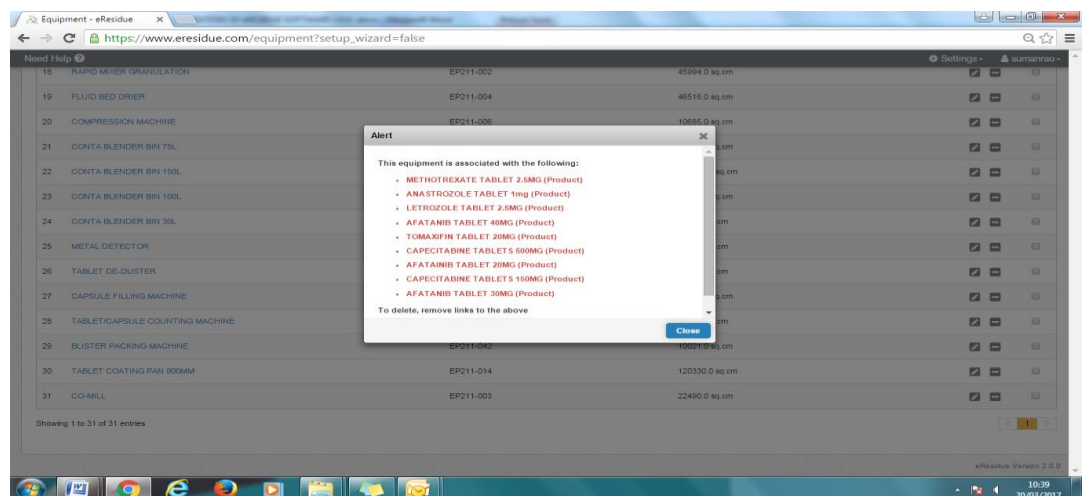
- **Note:** For equipments used in prior calculations, the application will not allow the equipment details to be edited, till the associated report listed in Report Tracker has either been archived or deleted.

❖ 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.



- **Note:** If associated with any calculation or product.





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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.

#	Product Name	Product Type	Equipment Train	Equipment	Action
1	PQ OF 2.0.0	Solid	-	CO-MILL, BLISTER PACKING MACHINE, SAMPLING ROD	[Icons]
2	DOXORUBICIN HCL INJECTION ...	Liquid	-	200 LITER JACKETED MANUFACTURING VESSEL, 200 LITER JACKETED FILTR...more	[Icons]
3	MELPHALAN FOR INJECTION 50...	Liquid	-	200 LITER JACKETED FILTRATION VESSEL, BUFFER TANK OF FILLING MACH...more	[Icons]
4	CLOFARABINE INJECTION 1MG/ML	Liquid	-	200 LITER JACKETED FILTRATION VESSEL, BUFFER TANK OF FILLING MACH...more	[Icons]
5	TESTOSTERONE CYPIONATE IN...	Liquid	-	50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FAC...more	[Icons]
6	HYDROXY PROGESTERONE CA...	Liquid	-	50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FAC...more	[Icons]
7	TESTOSTERONE ENANTHATE I...	Liquid	-	50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FAC...more	[Icons]
8	PROGESTERONE INJECTION 50...	Liquid	-	50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FAC...more	[Icons]
9	HYDROXY PROGESTERONE CA...	Liquid	-	50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FAC...more	[Icons]
10	MEDROXYPROGESTERONE ACET...	Liquid	-	50 LITERS JACKETED TANK WITH IN-BUILD CIP/SIP AND LOAD CELL FAC...more	[Icons]

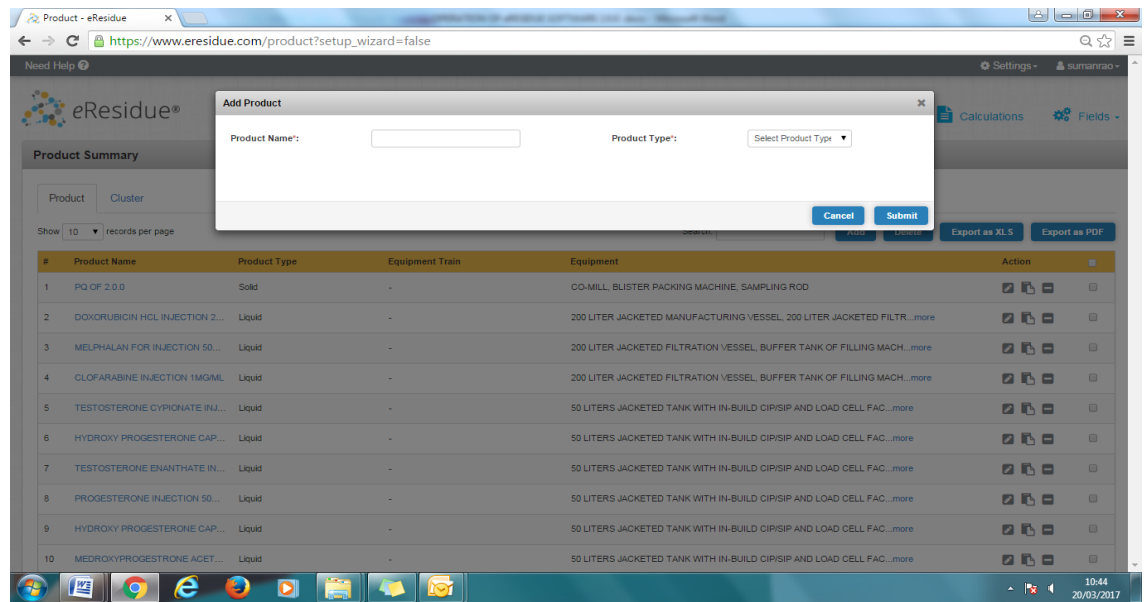
❖ Add New Product:

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

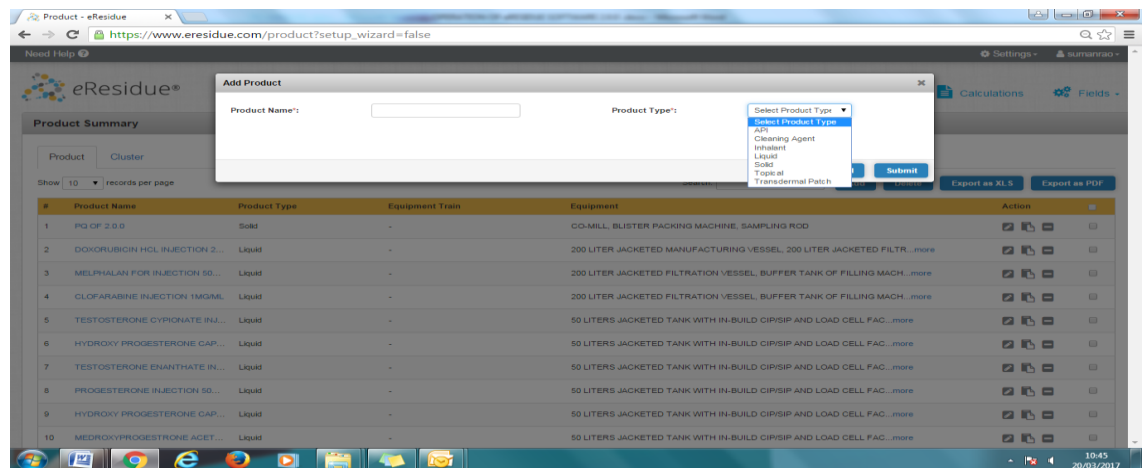


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Fields marked with an asterisk (*) indicate mandatory fields. The first step shall be to enter the Product Name. Select Product Type from drop-down menu. Product Type options are – API, Cleaning agent, Inhalants, Liquids, Solids, Topical and Transdermal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



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

❖ **Product type - Solid/ Liquid/ Inhalant:**

The following window shall appear 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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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.

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:



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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.

Note: The Product Name cannot be edited.

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



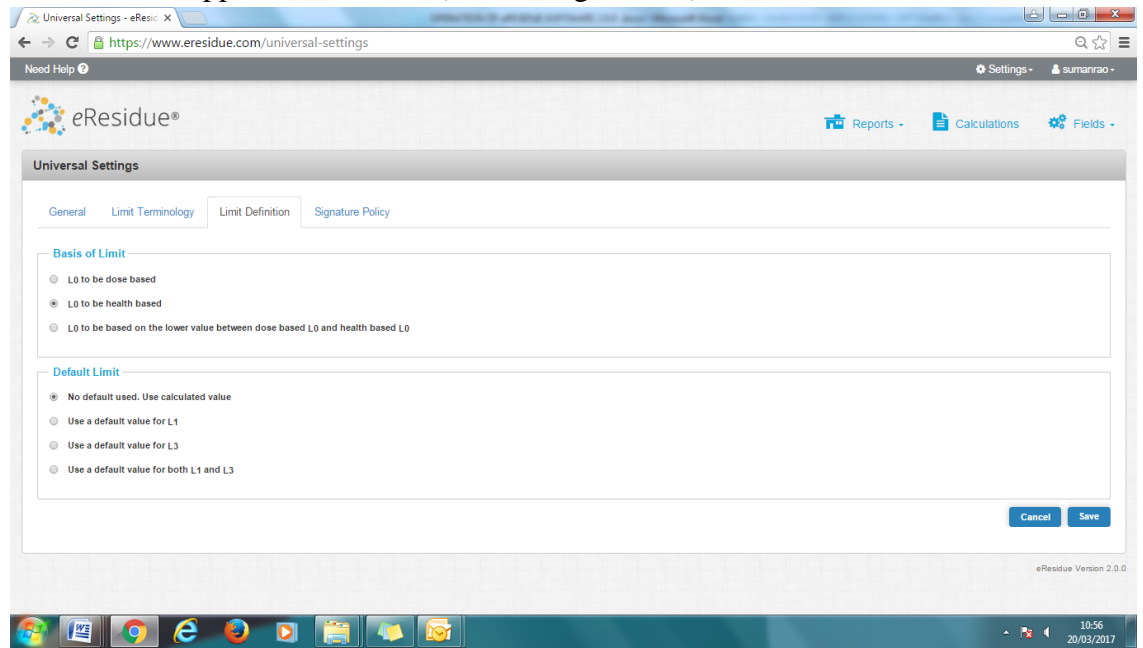
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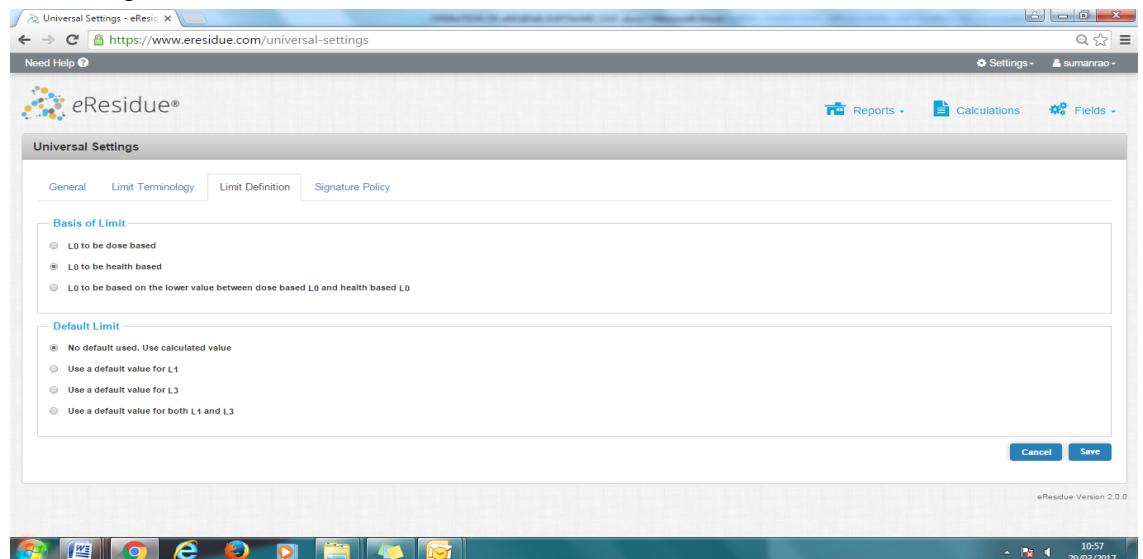
Note: For products used in prior calculations, the application will not allow the details to be deleted, till the associated report listed in Report Tracker has either been archived or deleted.

❖ 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



- Three options are available to choose how the application would handle L0:



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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.

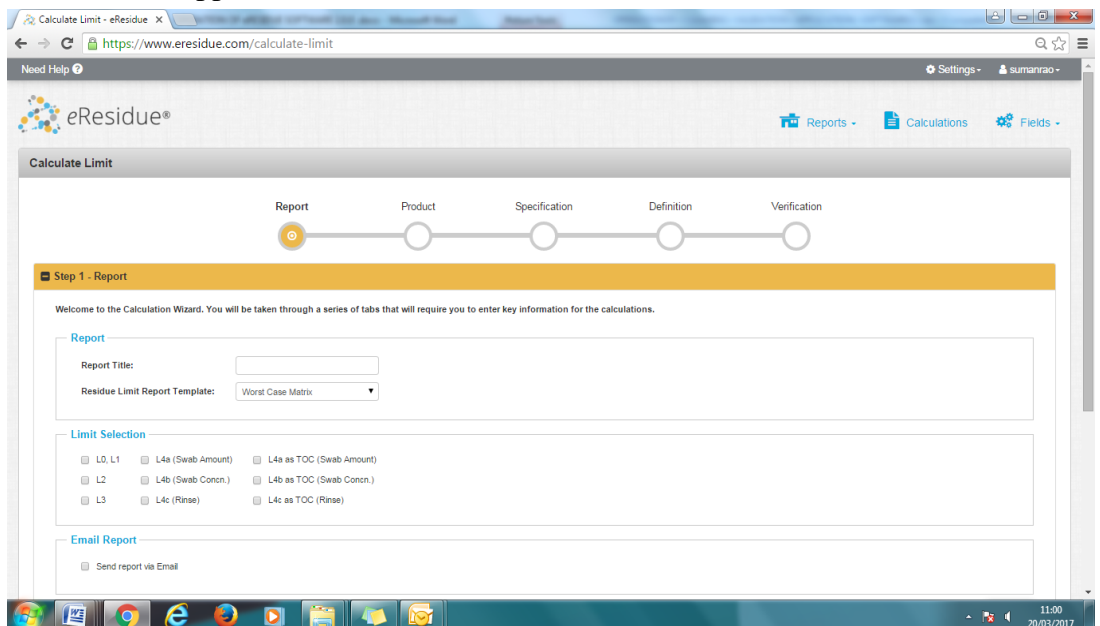
3. L0 to be based on lower of dose based L0 or health based L0: If you select this option, L0 value for the above two will be calculated and the lower of the two will be used in limit calculations.

❖ **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.



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.

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



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- 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

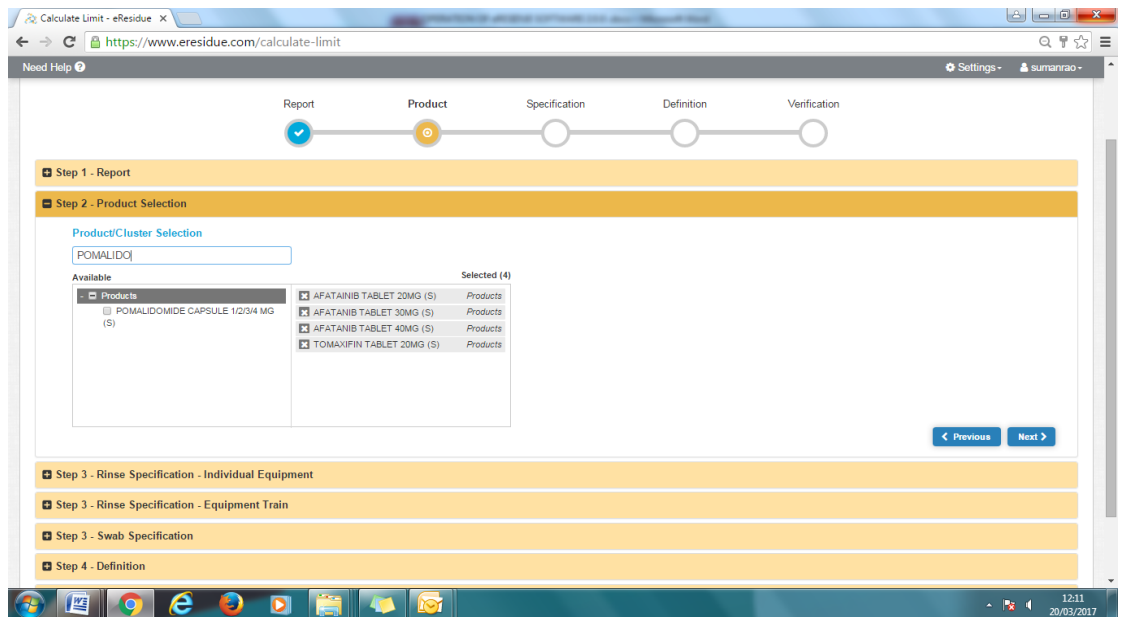
❖ **Step-2:**

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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Select the products of interest and use the selection box by click on the box (✓) 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-

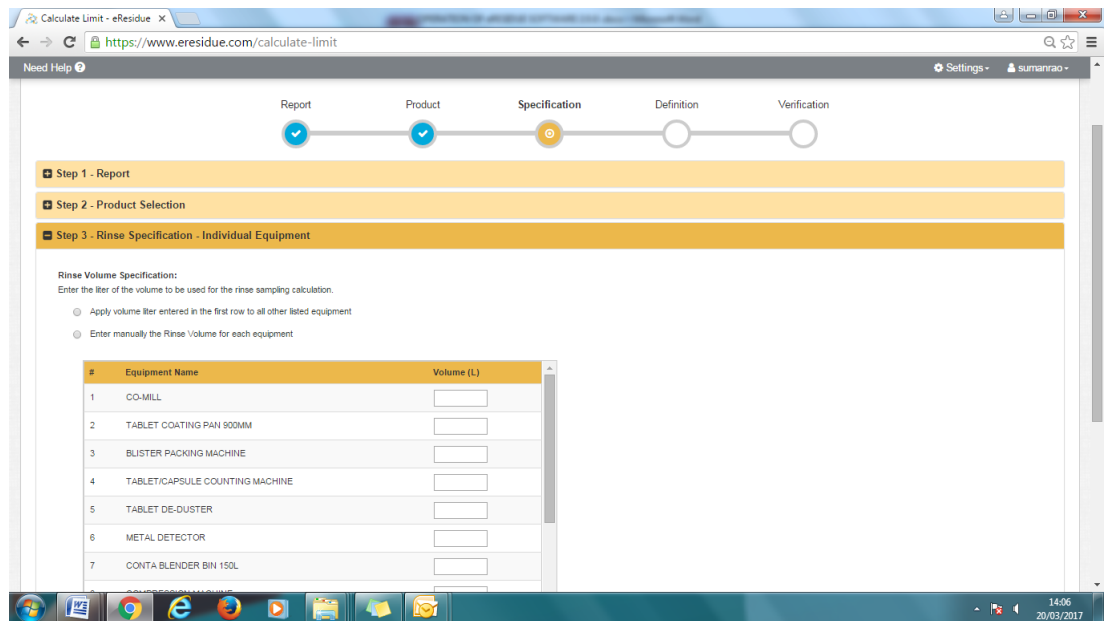
Equipment volume information: This section of the Calculate Limit is available if you have chosen to run limits with L4 calculation and have chosen Rinse sampling.

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



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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

Rinse Specification- Equipment Train:

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.



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The screenshot shows the 'Calculate Limit - eResidue' application interface. The 'Rinse Volume Specification' step is active, displaying a table for product selection and volume input.

#	Product Name	Volume (L)
1	TOMAXIFIN TABLET 20MG	<input type="text"/>
2	AFATANIB TABLET 20MG	<input type="text"/>
3	AFATANIB TABLET 30MG	<input type="text"/>
4	AFATANIB TABLET 40MG	<input type="text"/>

Swab Specification

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

The screenshot shows the 'Calculate Limit - eResidue' application interface. The 'Swab Sampling Specification' step is active, displaying a table for product selection and swab sampling parameters.

#	Product Name	Solvent Used	Amt. of Solvent Used for Desorption	Surface Area Sampled
1	TOMAXIFIN TABLET 20MG	<input type="text"/>	<input type="text"/> mL	<input type="text"/> sq.cm
2	AFATANIB TABLET 20MG	<input type="text"/>	<input type="text"/> mL	<input type="text"/> sq.cm
3	AFATANIB TABLET 30MG	<input type="text"/>	<input type="text"/> mL	<input type="text"/> sq.cm
4	AFATANIB TABLET 40MG	<input type="text"/>	<input type="text"/> mL	<input type="text"/> sq.cm

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.



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- **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.

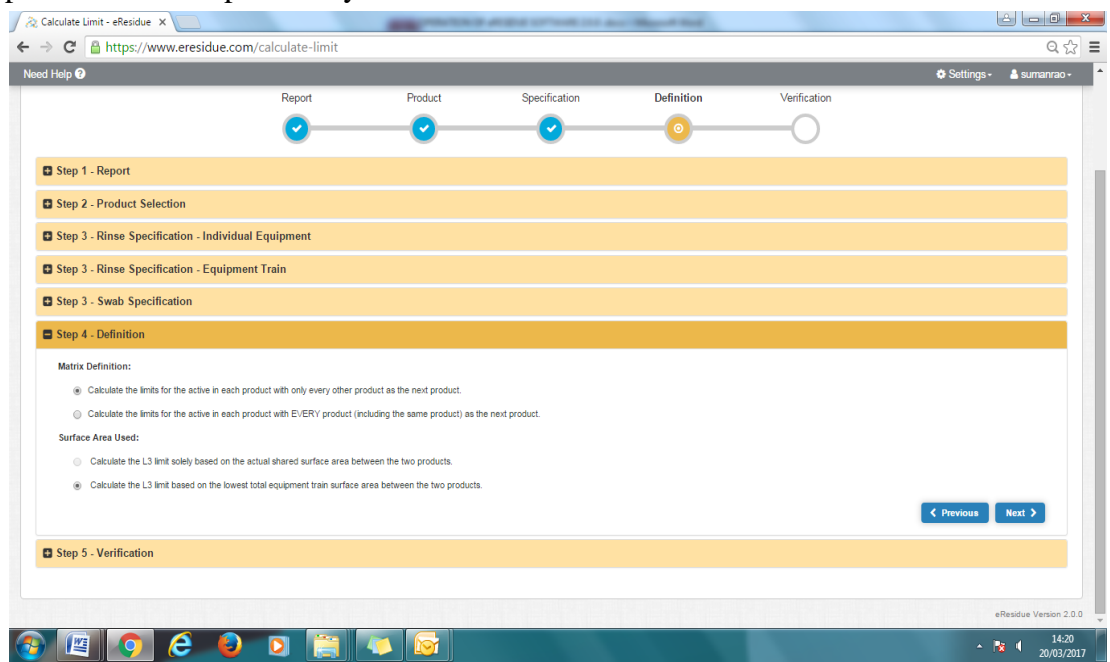
- **Enter manually the information:**

The last option expects all product information to be done manually. Once the information has entered, click Next to proceed to Step 4.

❖ **Step4-:**

Definition:

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





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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.

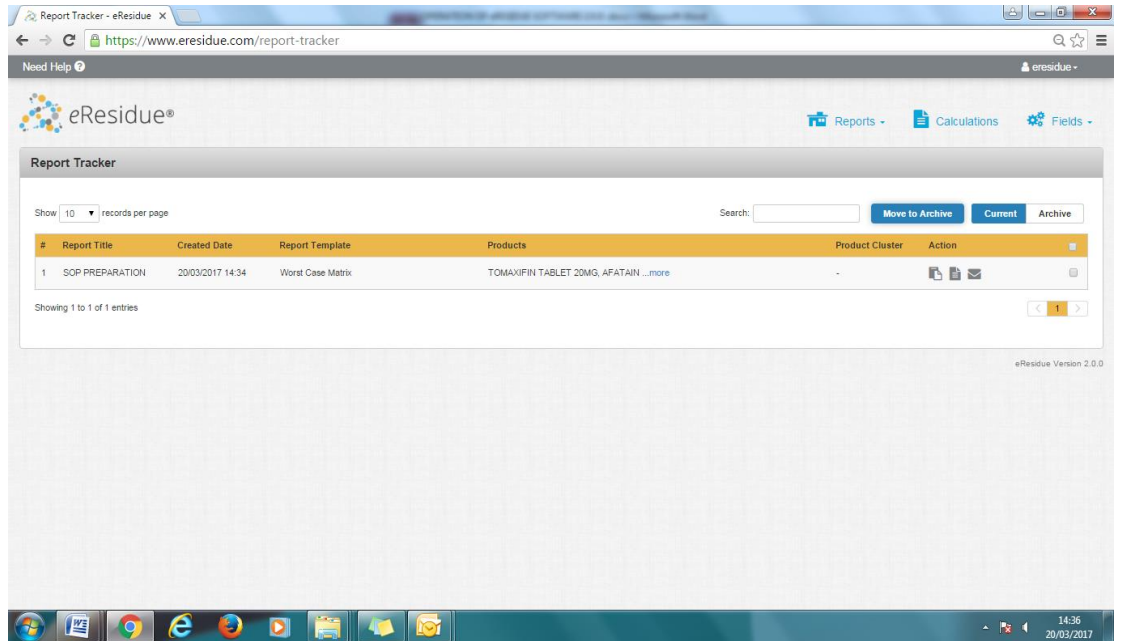
Access this window by clicking **Calculation Report** in the **Reports** menu.



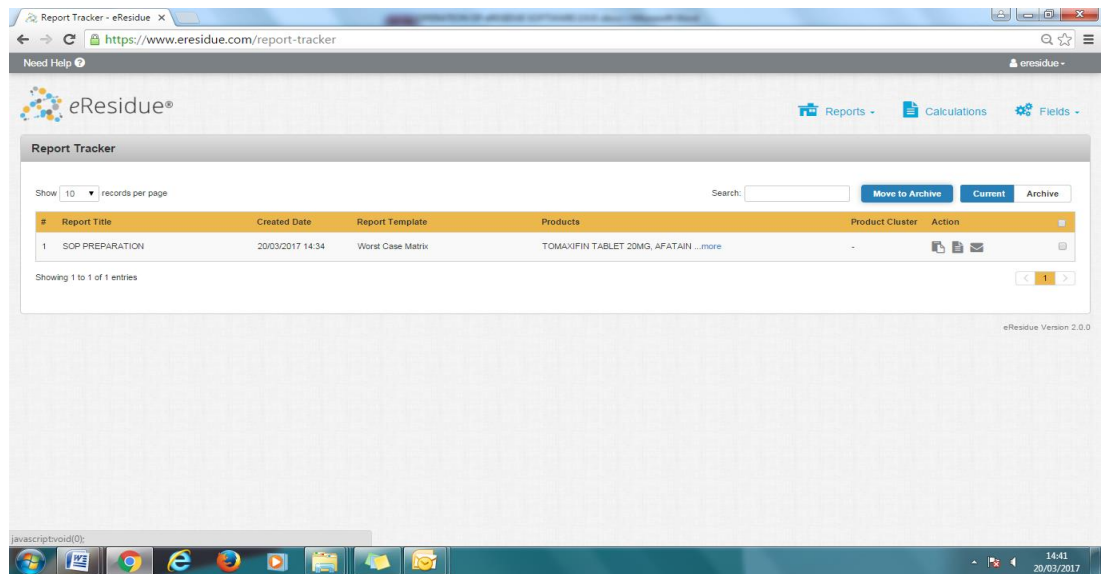
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The Current folder is displayed by default. You can use the drop-down list to select the Archive folder (see image below), where archived reports can be accessed.



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



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#	Report Title	Created Date	Report Template	Products	Action
1	MACO LIMIT OF ONCOLOGY BLOCK OSD L...	11/02/2017 14:41	Version-1 Template	TOMAXIFIN TABLET 20MG, METHOTR...more	[Icons]
2	MACO LIMIT FOR HORMONE BLOCK INJECT...	11/02/2017 15:02	Version-1 Template	TESTOSTERONE CYPIONATE INJECTI...more	[Icons]
3	NEW MACO LIMIT AS PER ADE VALUE FOR...	16/02/2017 13:02	Version-1 Template	LETRAZOLE TABLET 2.5MG, TOMAXI...more	[Icons]
4	NEW MACO LIMIT AS PER ADE VALUE FOR...	21/02/2017 16:35	Version-1 Template	AZACITIDINE FOR INJECTION 100M...more	[Icons]
5	NEW MACO LIMIT AS PER ADE VALUE FOR...	16/02/2017 11:02	Version-1 Template	AZACITIDINE FOR INJECTION 100M...more	[Icons]
6	NEW MACO LIMIT AS PER ADE VALUE FOR...	16/02/2017 12:49	Version-1 Template	AFATAINIB TABLET 20MG, AFATANI...more	[Icons]
7	NEW MACO LIMIT FOR ONCOLOGY BLOCK L...	16/02/2017 10:21	Version-1 Template	AZACITIDINE FOR INJECTION 100M...more	[Icons]
8	MACO LIMIT AS PER ADE VALUE FOR ONC...	14/02/2017 18:23	Version-1 Template	AZACITIDINE FOR INJECTION 100M...more	[Icons]
9	MACO LIMIT FOR ONCOLOGY BLOCK LINE...	11/02/2017 16:32	Version-1 Template	AZACITIDINE FOR INJECTION 100M...more	[Icons]
10	MACO LIMIT FOR ONCOLOGY BLOCK LINE...	11/02/2017 14:33	Version-1 Template	AZACITIDINE FOR INJECTION 100M...more	[Icons]

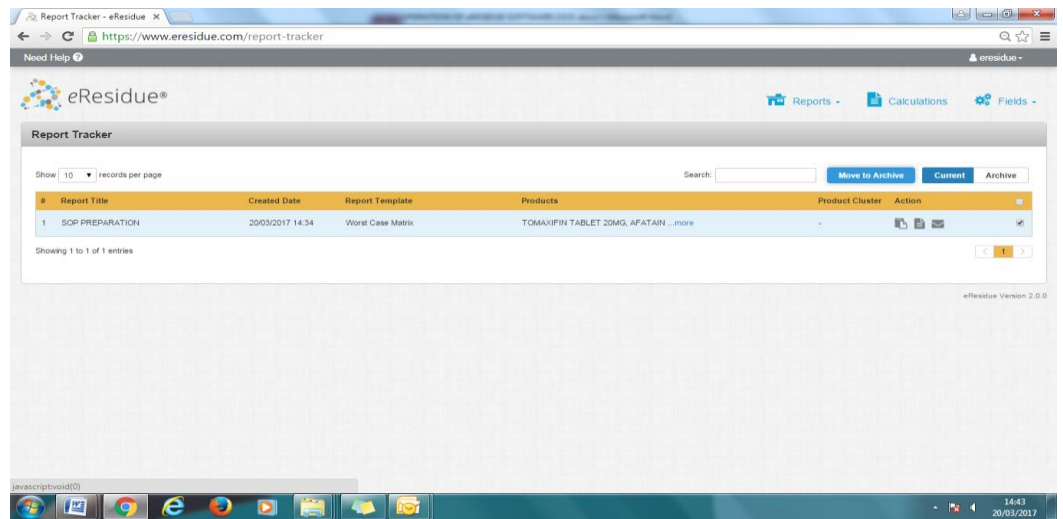
- **Email Report:** A copy of the selected report can be sent via email, on clicking the mail icon
- **Delete:** The selected report can be deleted, by clicking the minus icon.
- **Edit:** eResidue allows the user to take a set of conditions on the basis of which a particular report was generated and 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.



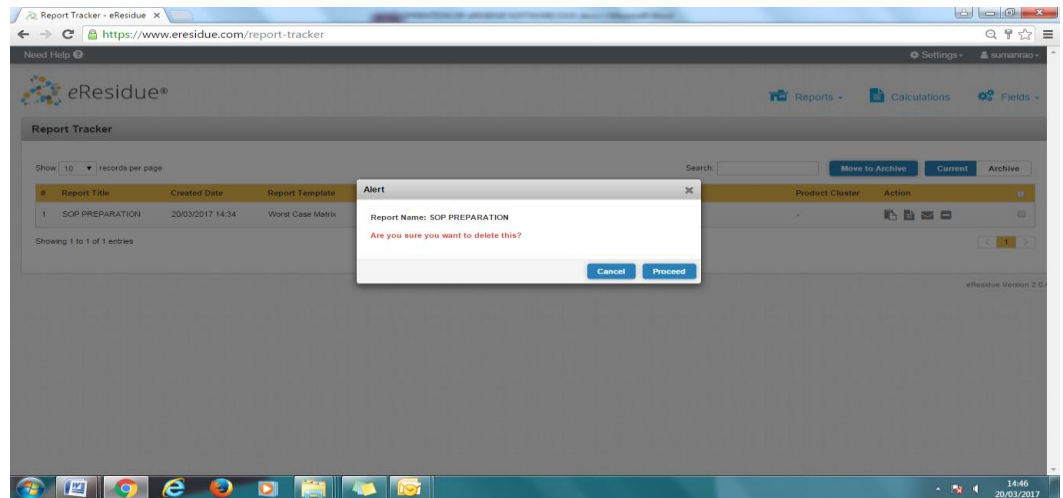
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User can use the action buttons to email/ generate report. Administrator can use the action buttons to delete the report click the 'minus' button. A delete confirmation pop-up window appears. Click Yes to proceed with report deletion.



The Report document created by eResidue is in PDF format.

❖ **Event Log Report:**

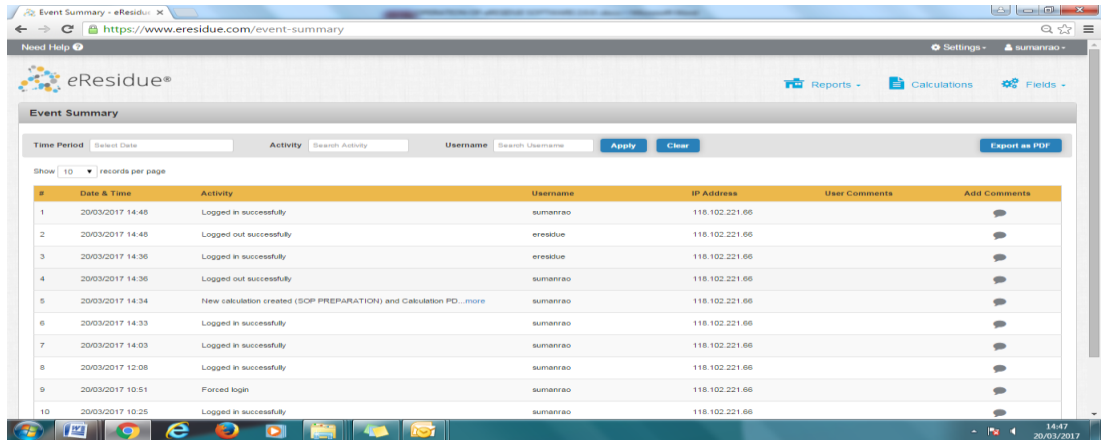
The eResidue Event Summary, as shown below, is a record of any significant occurrence or activity in the application. (Refer image below)



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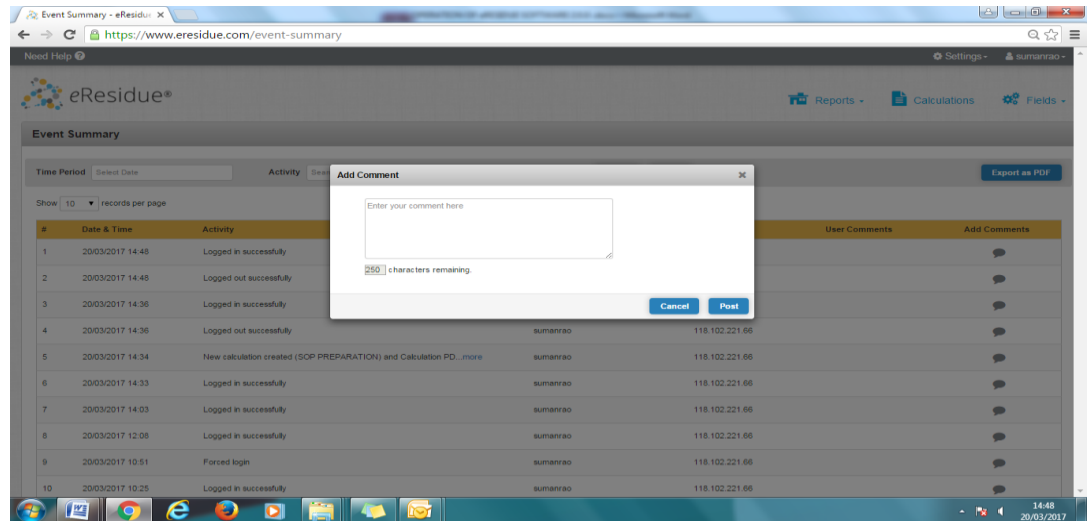
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The **Event Summary** is displayed as a table and cannot be modified. Search for specific event shall be done based on time frame, activity or username.

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)



Event Log table details:

Column 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



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Column 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.

#	First name & Last name	Username	Email Address	Account Permissions	Role	Status	Actions
1	Jitendra Kumar Rout	eresidue	evgia.eresidue@evgia.co.in	Reports Menu, Fields Menu, Calculations Menu, Receive report by Email	User	Active	
2	Vamshi Dereb	vamshidereb	vamshi.dereb@evgia.co.in	Reports Menu, Fields Menu, Calculations Menu, Receive report by Email	User	Active	
3	Suman Rao Boinapally	sumanrao	Sumanrao.boinapally@evgia.co.in	Access Settings, Reports Menu, Fields Menu, Facility Profile, Calculations Menu, Delete Data, Receive report by Email	Admin	Active	
4	Smruti Ranjan Biswal	smrutiranj	smrutiranj.biswal@evgia.co.in	Access Settings, Reports Menu, Fields Menu, Facility Profile, Calculations Menu, Delete Data, Receive report by Email	Admin	Active	

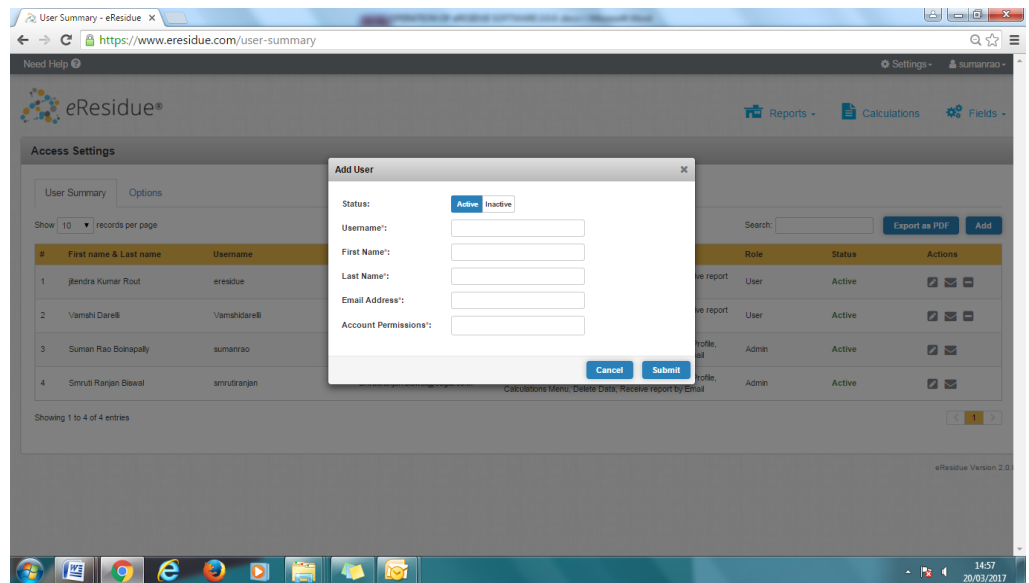
Create User: Click the Create User button to assign a new user to your eResidue application. (Refer screenshot below)



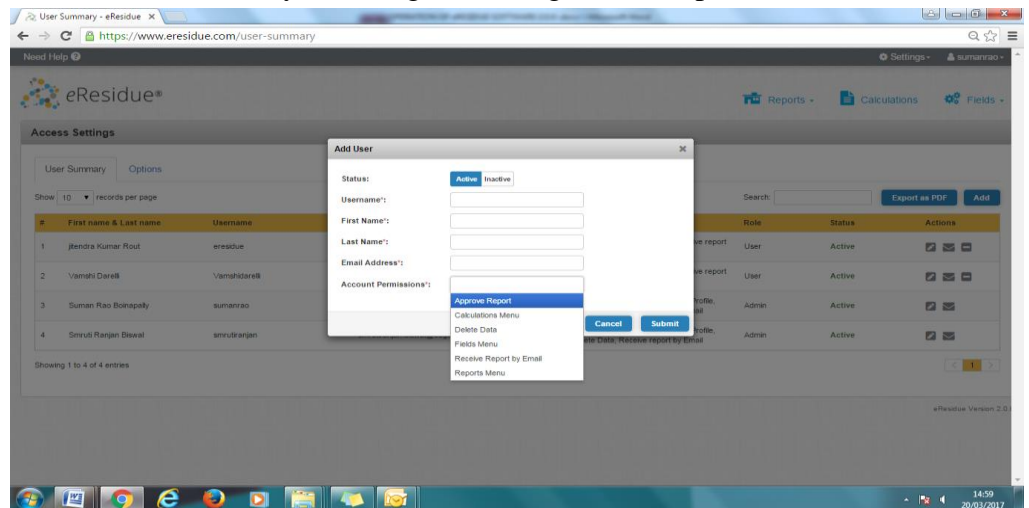
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Click the drop down menu to reveal Account Permissions. Either select all or choose from the list by checking the box against the option.



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

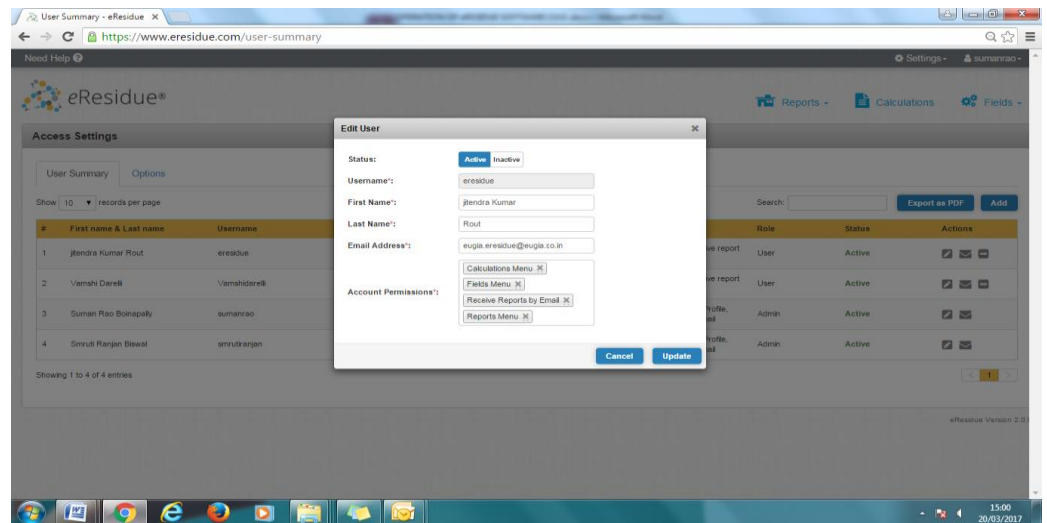
Edit user details: On the Home tab, the admin can edit user access using the 'pencil' icon under action column corresponding to the name of the user. The edit user window appears as shown below. The Username cannot be changed and Account Permission can be modified.



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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 –

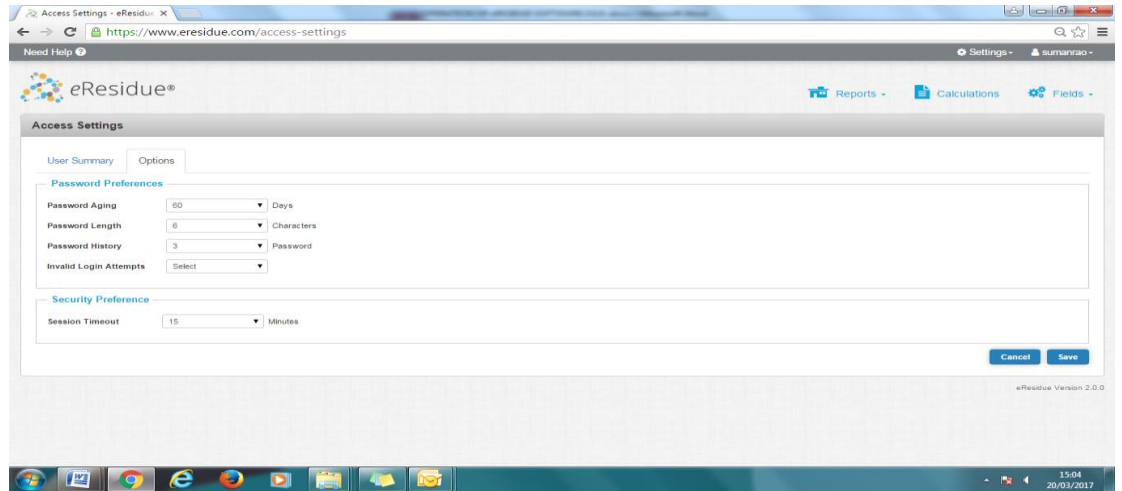
1. Password Aging – allows the Admin to set a specified period (60 days) after which the user is Prompted to create a new password..
2. Password Length – this field determines the least number of characters that can make up a password for a user account. Admin shall set a value 6 characters.
3. Password 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

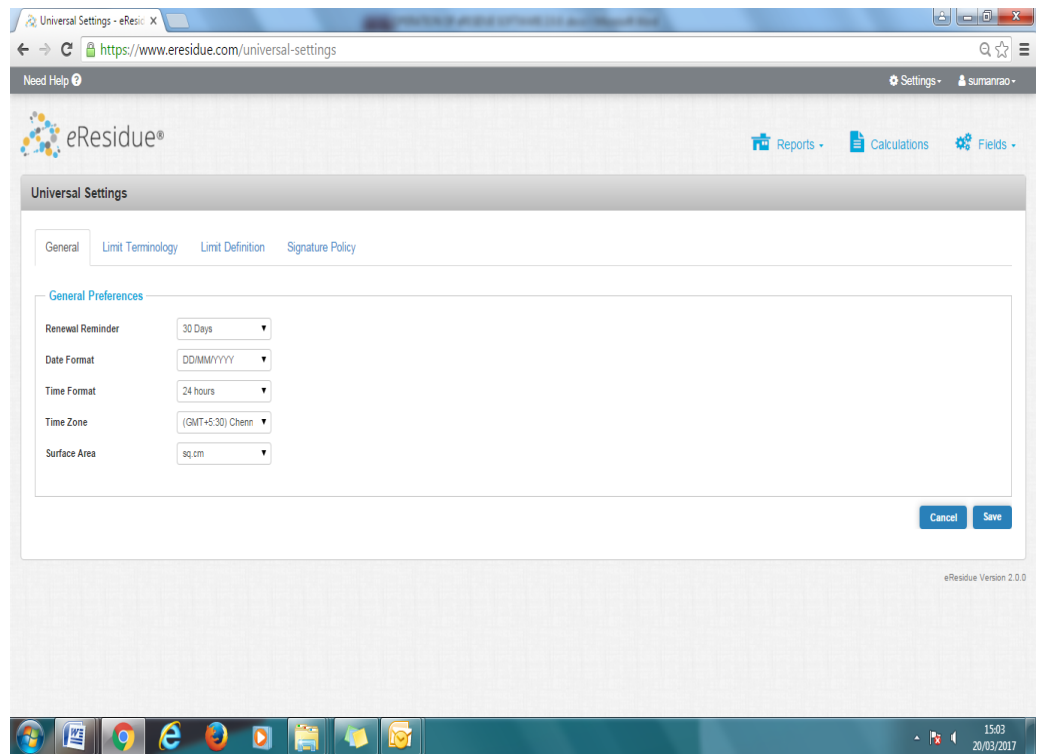
The General Preferences, refer image below, accessible by drop-down menu, include:

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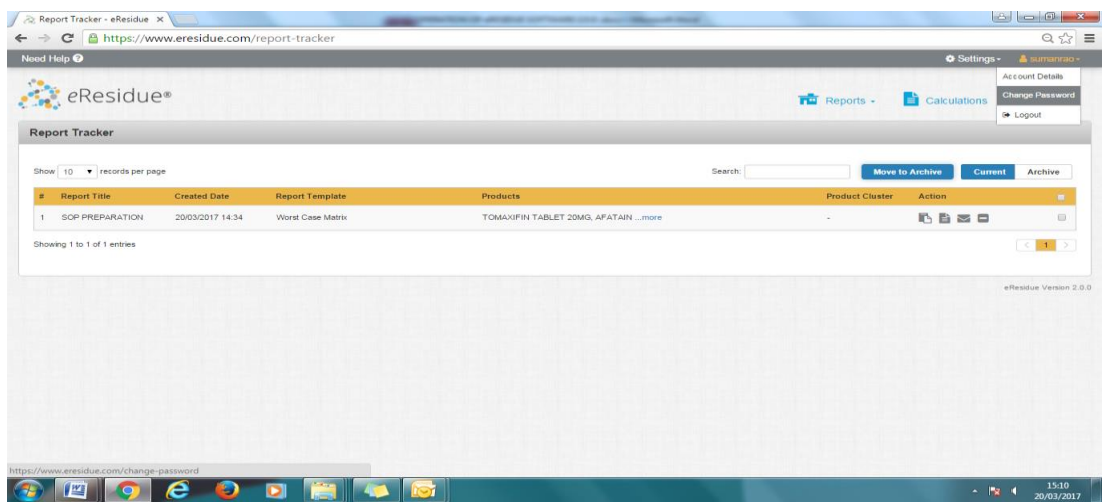
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Click Save to store options or Cancel to retain default settings.

❖ Change Password:

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

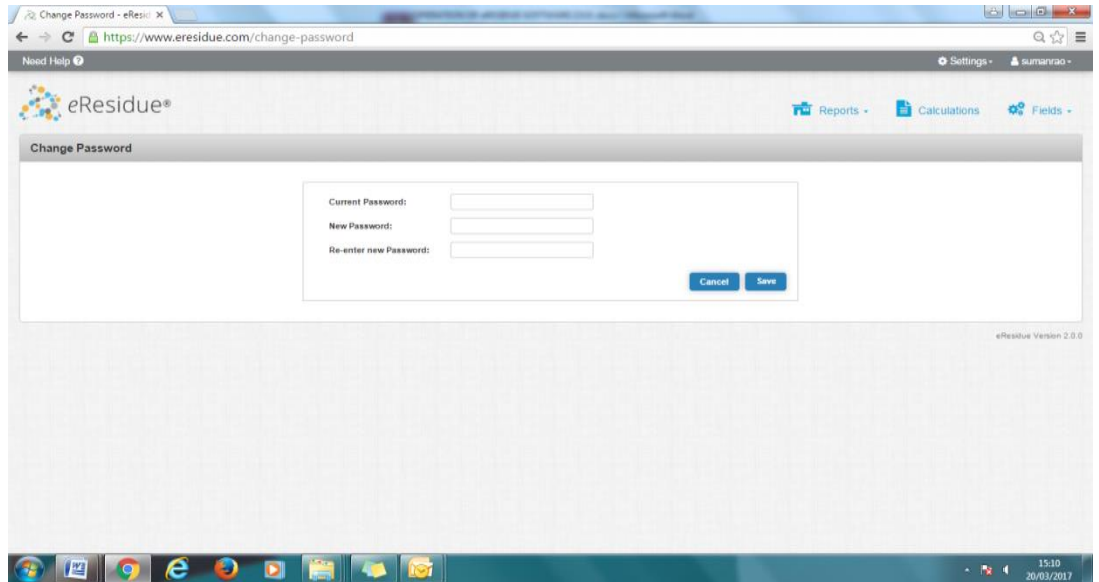


To change password, enter the current password and then new password. Retype new password and the Save to proceed. (Refer image below.)



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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