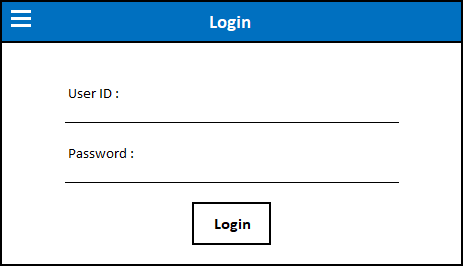
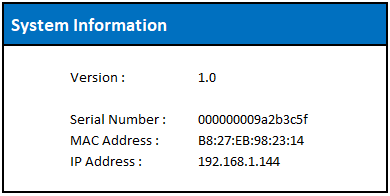
**Sifting**

1. **Purpose:** Active Pharmaceutical Ingredients (API) and excipients are sifted through different sieves to avoid oversized contamination and are mixed.
2. **Login;**



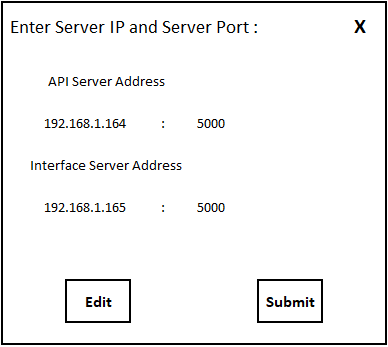
Upon selecting  ‘Drawer menu’, the drawer will display following options;

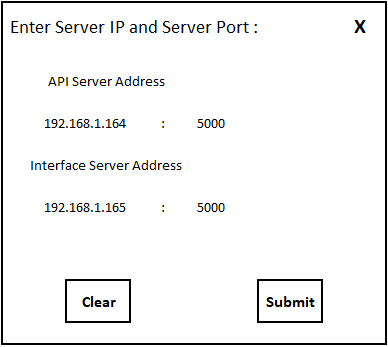
1. **System Information:** The module contains information of the system version, its serial no., MAC Address and respective IP address of HMI in Read Only format.



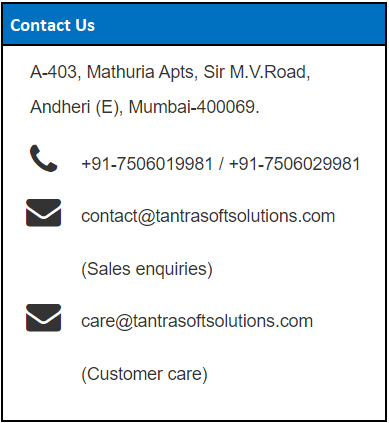
1. **Server IP Configuration:** The module displays API Server Address and Interface Server Address which are editable and accepts numeric values in set format.

* ‘Submit’ button will be disabled till user clicks on ‘Edit’ button. Click on ‘Edit’ button to make changes in API or Interface address and ‘Edit’ button will be replaced with ‘Clear’ button.
* Make required changes and click on ‘Submit’ button and updated data will be saved.

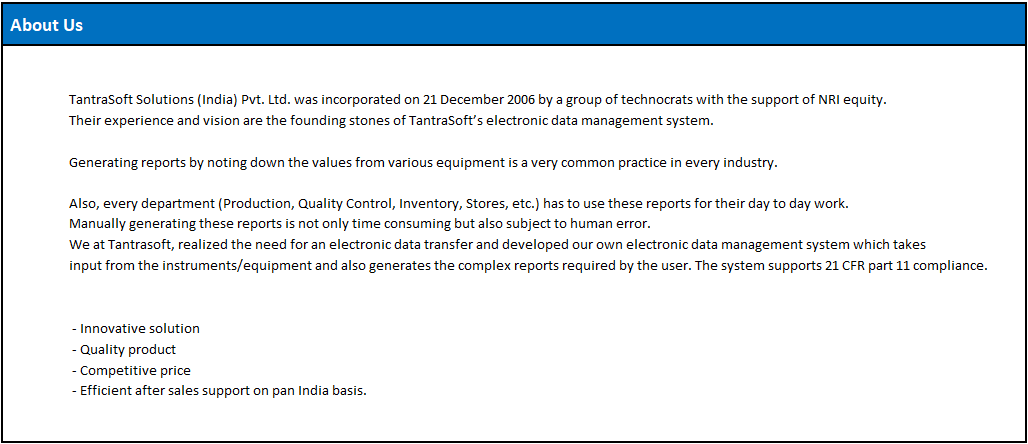




1. **Contact Us:** This module contains contact information of TantraSoft Solutions (India) Private Limited.



1. **About Us:** This module contains information about TantraSoft Solutions (India) Private Limited.



1. **Field Validations;**

|  |  |  |  |
| --- | --- | --- | --- |
| **Field** | **Data Type** | **Character limit** | **Source** |
| User ID | Alpha-numeric and special characters. | Minimum 1 and Maximum 10. | User Master |
| Password | Alpha-numeric and special characters. | Minimum 1 and Maximum 16. | User Master and Password Policy |

1. **Validations Messages;**

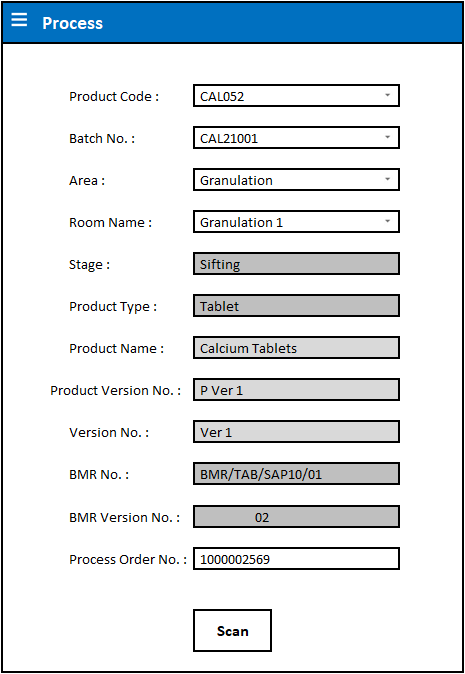
|  |  |  |  |
| --- | --- | --- | --- |
| **Field** | **Scenario** | **Validation messages** | **Co-relation** |
| User ID | Enter **incorrect** User ID. | Incorrect Credentials. | * Audit Trail for Unauthorized Login * Activity Log |
| Enter **inactive** User ID.  (Temporary / Permanent disabled User ID) | User Disabled. Contact Authorized Person. | * Audit Trail for Unauthorized Login * Activity Log |
| Enter User ID with which, a user is already logged in on software. | User Already Active on Software. | * Activity Log |
| Enter User ID with which, a user is already logged in on another hardware. | User Already Active on Hardware / another terminal. | * Activity Log |
| Password | Enter **correct** User ID and **incorrect** Password. | Incorrect Credentials. | * Audit Trail for Unauthorized Login * Activity Log |
| Enter **correct** User ID and **correct** Password (password is about to expire in the system). | Password Expires in <no. of days> Days.   * Change Password * Continue | * Audit Trail for Change Password (if user choose to change their password) * Activity Log |
| Enter **correct** User ID and **correct** Password (password has expired in the system). | Password Expired. Change Password.  (User will be directed to Change Password window). | * Audit Trail for Change Password * Activity Log |
| * Attempt to login multiple times with **correct** User ID and incorrect Password. * Attempt to login with **correct** User ID and **incorrect** Password when a disabled user has got enabled in the system. | User Locked for <Lock Period>.  (User will get locked for ‘Lock Period’). | * Audit Trail for Unauthorized Login * Activity Log |
| * Attempt to login with **newly created** User ID and Password. * Attempt to login when user has got their password changed in the system by Admin / Authorized User. * Attempt to login with **correct** User ID and **correct** Password when a disabled user has got enabled in the system. * Attempt to login with **correct** User ID and **correct** Password after no. of days set in ‘Non Login Period’. | Change Password  (User will be directed to Change Password window). | * Audit Trail for Change Password * Activity Log |
| * Attempt to login multiple times with **correct** User ID and **incorrect** Password and exhaust ‘Auto Enable Chances’. * Attempt to login with **correct** User ID and **incorrect** Password after no. of days set in ‘Non Login Period’. | Auto Enable Chances Exhausted. Contact Authorized Person. | * Activity Log |

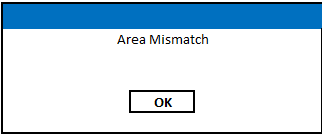
\***Auto Enable Chances -** If the password entered is incorrect for a set number of attempts, User ID will get locked for seconds set in lock period. The user will be allowed to login for no. of attempts set in auto enable chances in spite of keying in incorrect password.

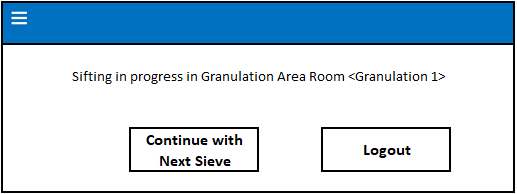
\***Lock Period -** If the user enters incorrect passwords for set number of times, he is locked for number of seconds set in lock period. The user can still try logging in after lock period for no. of attempts set in auto enable chances.

\***Non-Login Period -** If the user is not logged into the system for a set number of days, he will get disabled and will be forced to change the password on his next login attempt.

1. **Screen Design upon Successful Login;**







1. **Field Validations;**

|  |  |  |  |
| --- | --- | --- | --- |
| **Field Name** | **Field Validation** | **Character Limit** | **Source** |
| Product Code | Dropdown selection. | NA | As set in <Product Master> (Will display Product Codes for which applicable stage has not been completed). |
| Batch No. | Dropdown selection. | NA | Material Batches fully Dispensed for Product.  **OR**  As set in <Batch Setting>. |
| Area | Dropdown selection. | NA | As set in <Area Master>. |
| Room Name | Dropdown selection. | NA | As set in <Area Master>. |
| Stage | Dropdown selection (applicable only when more than one stage assigned in <Area Master>; Otherwise the field will be disabled and stage assigned in <Area Master> will be displayed). | NA | As set in <Area Master>. |
| Product Type | Field disabled. | NA | Product Name will be displayed as set in <Product Master>. |
| Product Name | Field disabled. | NA | Product Name will be displayed as set in <Product Master>. |
| Product Version No. | Field disabled. | NA | Product Version No. will be displayed as set in <Product Master>. |
| Version No. | Field disabled. | NA | Version No. will be displayed as set in <Product Master>. |
| BMR No. | Field disabled. | NA | BMR No. will be displayed as set in <Product Master>. |
| BMR Version No. | Field disabled. | NA | BMR Version No. will be displayed as set in <Product Master>. |
| Process Order No. | Alpha-numeric and special characters. | Minimum 1 and maximum 20. | Material Batches fully Dispensed for Product. |

\*If Dispensing is linked with Granulation, Batch No. and Process Order No. will be displayed automatically as per dispensed Product data. Otherwise, provision to manually enter data.

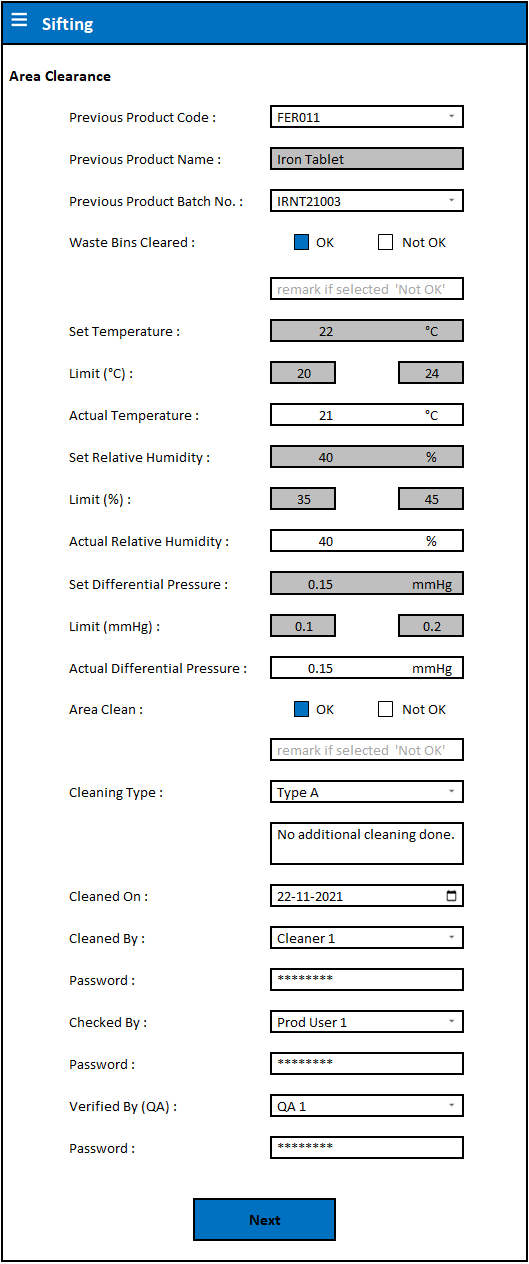
1. **Validation Messages;**

|  |  |  |  |
| --- | --- | --- | --- |
| **Field** | **Scenario** | **Validation** | **Co-relation** |
| Batch No. | Enter an invalid batch no. | ‘Batch No. does not exist’ message will get displayed.  (Process Order No. will not be displayed for entered data). | Dispensing Table. |

1. **Workflow;**

* Login with valid User ID and Password.
* Upon successful login, ‘Process’ window will get displayed.
* Select ‘Product Code’ and ‘Batch No’ from dropdown list.
* Product details (Product Name, Product Version No. and Version No.), BMR No. and BMR Version No. will automatically get displayed in respective fields as set in <Product Master> upon Selection of ‘Product Code’ from dropdown list.
* Select ‘Area’ and ‘Room’ from dropdown list.
* Select appropriate ‘Stage’ name from dropdown list if available. (Stage will be selected automatically as explained in field validations)
* Enter Process Order No. manually.
* Select ‘Scan’ button to scan the area barcode.
* [If area details selected are matching with scanned information, process will be allowed to start. Otherwise message will be displayed.](#AreaMismatch)
* If more than one stage is assigned in an area, option to select stage will be displayed.
* [If sifting has already begun for selected product – batch and another user logs in through a different HMI, they will be notified of the same and will be given option to begin sifting with another sieve (option will only appear if sifting is ‘Simultaneous’).](#SiftingInProcess)
* User can ‘Continue with Next Sieve’ to sift materials through other sieve set in <Product Master>.

1. Area Clearance form.



1. **Field Validations;**

|  |  |  |  |
| --- | --- | --- | --- |
| **Field Name** | **Field Validation** | **Character Limit** | **Source** |
| Previous Product Code | Dropdown selection. | NA | As set in <Product Master>. |
| Previous Product Name | Auto Display. Field disabled. | NA | As set in <Product Master>. |
| Previous Product Batch No. | Dropdown selection. | NA | From <Database>. |
| Waste Bins Cleared (OK / Not OK) | Check box selection. | NA | NA. |
| Temperature | Numeric and decimal values. | Range from 0.001 to 999.999. | NA |
| Set & Limits | Auto Display. Fields disabled. | NA | As set in <Area Master>. |
| Relative Humidity | Numeric and decimal values. | Range from 0.001 to 999.999. | NA |
| Set & Limits | Auto Display. Fields disabled. | NA | As set in <Area Master>. |
| Differential Pressure | Numeric and decimal values. | Range from 0.001 to 999.999. | NA |
| Set & Limits | Auto Display. Fields disabled. | NA | As set in <Area Master>. |
| Area Clean (OK / Not OK) | Check box selection. | NA | NA |
| Cleaning Type | Dropdown selection.  Manual entry for remark (alpha-numeric and special characters). | Remark only in case of any additional cleaning done. | NA |
| Cleaned On | Date selection from calendar. | NA | Calendar. |
| Cleaned By | Dropdown selection. | NA | From <User Master>. |
| Password | Alpha-numeric and special characters. | Minimum 1 and maximum 16. | As per limits set in <Password Policy>. |
| Checked By | Dropdown selection. | NA | From <User Master>. |
| Password | Alpha-numeric and special characters. | Minimum 1 and maximum 16. | As per limits set in <Password Policy>. |
| Verified By (QA) | Dropdown selection. | NA | From <User Master>. |
| Password | Alpha-numeric and special characters. | Minimum 1 and maximum 16. | As per limits set in <Password Policy>. |

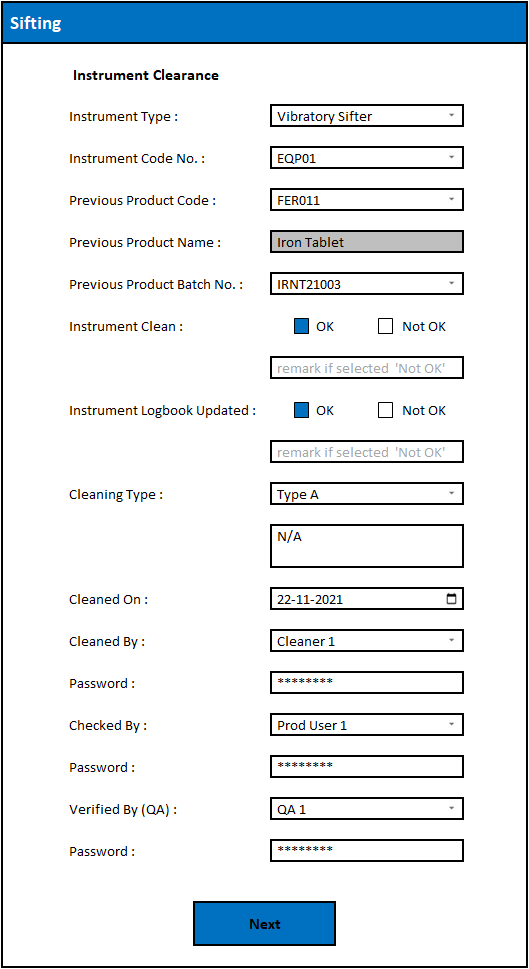
1. **Validation Messages;**

|  |  |  |  |
| --- | --- | --- | --- |
| **Field Name** | **Scenario** | **Validation** | **Co-relation** |
| Waste Bins Cleared (OK / Not OK) | Select ‘Not OK’. | User will not be allowed to proceed further. Will be asked to enter remark, file deviation record, enter QA credentials and will be directed to ‘Process’ window. | * Cleaning Log * Activity Log |
| Temperature | Enter Actual temperature beyond tolerance. | User will not be allowed to proceed further. Will be asked to enter remark, file deviation record, enter QA credentials and will be directed to ‘Process’ window. | * Activity Log |
| Relative Humidity | Enter Actual Relative Humidity beyond tolerance. | User will not be allowed to proceed further. Will be asked to enter remark, file deviation record, enter QA credentials and will be directed to ‘Process’ window. | * Activity Log |
| Differential Pressure | Enter Actual Relative Humidity beyond tolerance. | User will not be allowed to proceed further. Will be asked to enter remark, file deviation record, enter QA credentials and will be directed to ‘Process’ window. | * Activity Log |
| Area Clean (OK / Not OK) | Select ‘Not OK’. | User will not be allowed to proceed further. Will be asked to enter remark, file deviation record, enter QA credentials and will be directed to ‘Process’ window. | * Cleaning Log * Activity Log |
| Cleaned On | Attempt to select future date from calendar. | User will not be allowed to select future dates (all future dates will be disabled). | NA |
| Password | Attempt to feed in incorrect password for selected User ID. | User will not be allowed to proceed further until a correct password has been entered.  \*User will be disabled after entering incorrect password for no. of attempts set in <Set All Parameters>. | * Audit Trail for Unauthorized Login * Activity Log |

1. **Workflow;**

* Select ‘Previous Product Code’ from dropdown list and ‘Previous Product Name’ will be displayed automatically in the field.
* Select ‘Previous Product Batch No.’ from <database>.
* Check if ‘Waste Bins’ are clear and select relevant option (if bins ‘Not Cleared’, enter remark, file deviation record, enter QA credentials and user will be logged out).
* Check and enter Area Temperature, Relative Humidity and Differential Pressure to be as per limits set in ‘Area Master’.
* Check if area is clean and enter remark if ‘Not Clean’.
* Select appropriate ‘Cleaning Type’ from dropdown list and enter appropriate remark if any additional cleaning is done.
* Select ‘Cleaned On’ date from calendar.
* Select ‘Cleaned By’, ‘Checked By’ and ‘Verified By’ user details from dropdown list which will be available as per department from <User Master> and enter respective passwords.
* Click on ‘Next’ button to finish ‘Area Clearance’ save entered details and begin ‘Instrument Clearance’.
* Cleaning record of area will be generated in Reports module in software.

1. **Instrument Clearance;**



1. **Field Validations;**

|  |  |  |  |
| --- | --- | --- | --- |
| **Field Name** | **Field Validation** | **Character Limit** | **Source** |
| Instrument Type | Dropdown selection. | NA. | As per <Area Master>. |
| Instrument Code No. | Dropdown selection. | NA. | As per <Area Master>. |
| Previous Product Code | Dropdown selection. | NA. | As per <Product Master>. |
| Previous Product Name | Auto Display. Field disabled. | NA | As set in <Product Master>. |
| Previous Product Batch No. | Dropdown selection. | NA. | From <Database>. |
| Instrument Clean (OK / Not OK) | Check box selection. | NA | NA. |
| Instrument Logbook Updated (OK / Not OK) | Check box selection. | NA | NA. |
| Cleaning Type | Dropdown selection.  Manual entry for remark (alpha-numeric and special characters). | Remark only in case of any additional cleaning done. | NA |
| Cleaned On | Date selection from calendar. | NA | Calendar. |
| Cleaned By | Dropdown selection. | NA | From <User Master>. |
| Checked By | Dropdown selection. | NA | From <User Master>. |
| Verified By (QA) | Dropdown selection. | NA | From <User Master>. |
| Passwords | Alpha-numeric and special characters. | Minimum 1 and maximum 16. | As per limits set in <Password Policy>. |

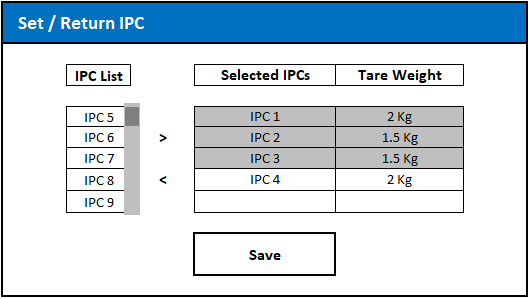
1. **Validation Messages;**

|  |  |  |  |
| --- | --- | --- | --- |
| **Field Name** | **Scenario** | **Validation** | **Co-relation** |
| Instrument Clean (OK / Not OK) | Select ‘Not OK’. | User will not be allowed to proceed further. Will be asked to enter remark, file deviation record, enter QA credentials and will be directed to ‘Process’ window. | * Cleaning Log * Activity Log |
| Instrument Logbook Updated (OK / Not OK) | Select ‘Not OK’. | User will not be allowed to proceed further. Will be asked to enter remark, file deviation record, enter QA credentials and will be directed to ‘Process’ window. | * Cleaning Log * Activity Log |
| Cleaned On | Attempt to select future date from calendar. | User will not be allowed to select future dates (all future dates will be disabled). | NA |
| Password | Attempt to feed in incorrect password for selected User ID. | User will not be allowed to proceed further until a correct password has been entered.  \*User will be disabled after entering incorrect password for no. of attempts set in <Set All Parameters>. | * Audit Trail for Unauthorized Login * Activity Log |

1. **Workflow;**

* Select ‘Instrument Type’ and appropriate ‘Instrument Code No.’ from dropdown list (which will be fetched from <Area Master>).
* Select ‘Previous Product Code’ from dropdown list and ‘Previous Product Name’ will be displayed automatically in the field.
* Enter ‘Previous Product Batch No.’ in the field manually.
* Check if Instrument is clean and select relevant option (enter remark if ‘Not OK’).
* Check if ‘Instrument Logbook’ is updated (enter remark if ‘Not OK’).
* Select appropriate ‘Cleaning Type’ from dropdown list and enter appropriate remark if any additional cleaning is done.
* Select ‘Cleaned On’ date from calendar.
* Select ‘Cleaned By’, ‘Checked By’ and ‘Verified By’ user details from dropdown list which will be available as per department from <User Master> and enter respective passwords.
* Click on ‘Next’ button to finish clearance of selected Instrument and begin for next one.
* The process of ‘Instrument Clearance’ will repeat till all (Fixed and Portable) Instrument assigned in Area Master are cleaned.
* Cleaning record of Instrument will be generated in Reports module in software.

Assign IPCs for Stage;



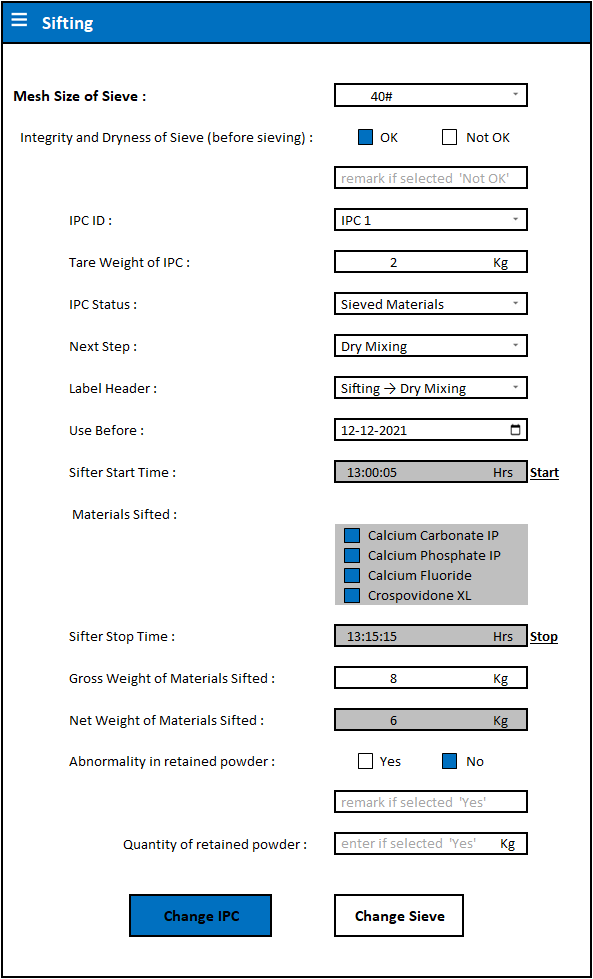
1. **Field Validations;**

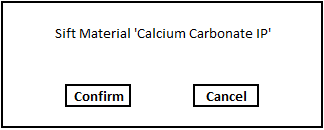
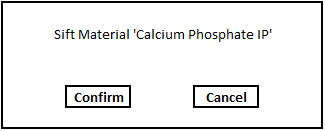
|  |  |  |  |
| --- | --- | --- | --- |
| **Field Name** | **Field Validation** | **Character Limit** | **Source** |
| IPC List | Scroll selection. | NA | The list will be fetched from <IPC Master>. |
| “**<**” and “**>**” buttons | IPCs can be selected or deselected using these buttons (Multiple entries can be selected). | NA | NA |
| Tare Weight | Numeric and Decimal values. | Range from 0.001 to 999.999. | Tare Weight of IPCs will be captured automatically upon selection from <IPC Master>. |

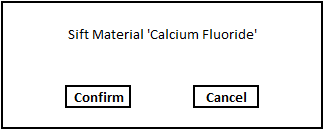
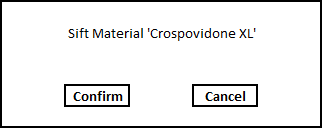
1. **Workflow;**

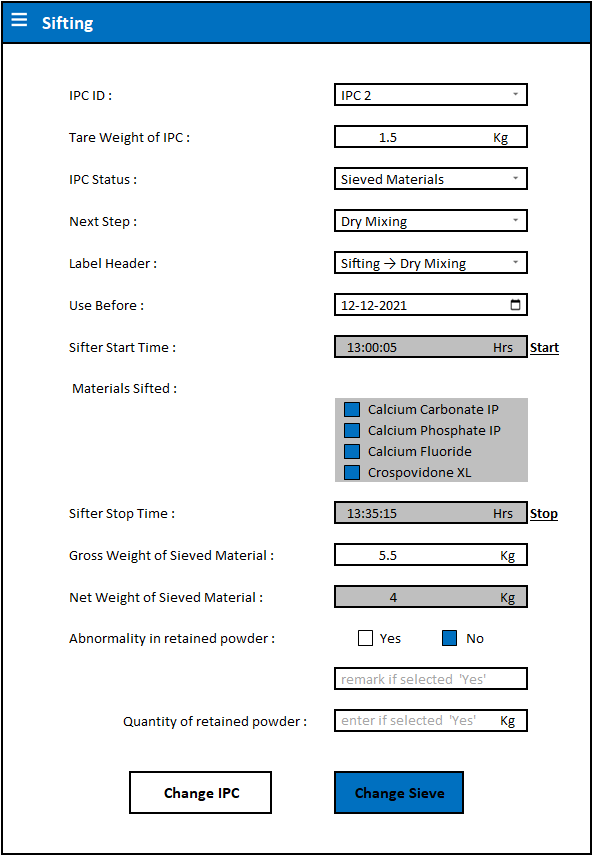
* Upon successful completion of all Instrument assigned in Area Master, User will be asked to assign IPCs for stage.
* IPCs can be selected or deselected by using ‘**>**’ or ‘**<**’ buttons.
* Selected IPCs will get displayed in ‘Selected IPCs’ column and their ‘Tare Weight’ will get fetched from IPC master and will be displayed in next column.
* Assign required number of IPCs and ‘Save’ the details; post which user will be directed to stage.

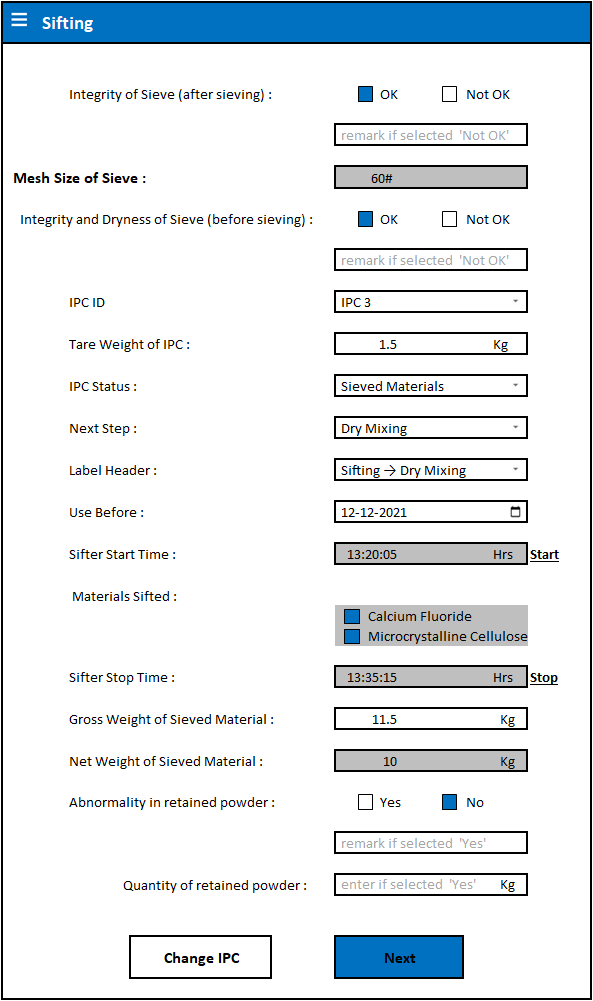
1. **Process;**

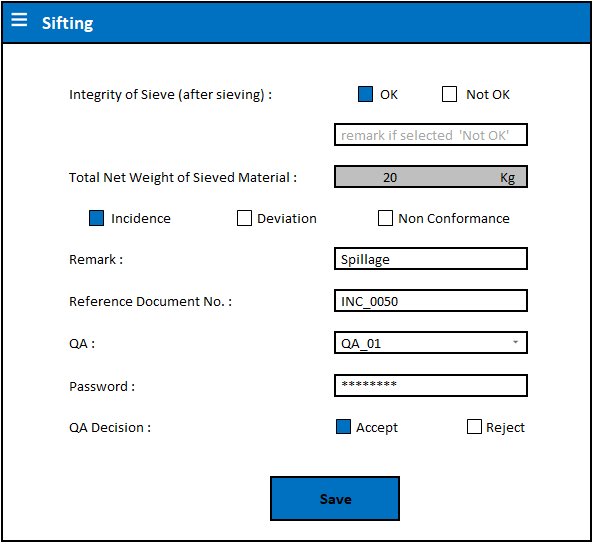








1. **Field Validations;**

|  |  |  |  |
| --- | --- | --- | --- |
| **Field Name** | **Field Validation** | **Character Limit** | **Source** |
| Mesh Size of Sieve | Dropdown selection from <Product Master>. (Mesh Size selection enabled in case of multiple sieves set in <Product Master>). | NA | As set in <Product Master>. |
| Integrity and Dryness of Sieve before sieving (OK / Not OK) | Check box selection. | NA | NA. |
| IPC ID | Dropdown selection as per IPCs assigned for stage. | NA | As set in [‘Assign IPC for Sifting’](#AssignIPC). |
| Tare Weight of IPC | Fetched automatically when IPCs assigned for stage. | Range 0.001 to 999.999. | As set in [‘Assign IPC for Sifting](#AssignIPC)’. |
| IPC Status | Dropdown selection. | NA | From <Status Master>. |
| Next Step | Dropdown selection. | NA | From <Next Step Master>. |
| Label Header | Dropdown selection. | NA | From <Label Header Master>. |
| Use Before | Future date to be selected from calendar. | NA | Calendar. |
| Sifter Start Time | Server time will be captured upon clicking ‘Start’ button. | Time will be captured of server upon click on ‘Start’ button in HH:MM:SS format. | Server. |
| Materials Sifted | Check box selection for respective material as sifting progresses. | NA | List of materials to be sifted will be fetched from <Product Master>. |
| Sifter Stop Time | Server time will be captured upon clicking ‘Stop’ button. | Time will be captured of server upon click on ‘Start’ button in HH:MM:SS format. | Server. |
| Gross Weight of Materials Sifted | Manual entry consisting of numeric and decimal values. | Range 0.001 to 999.999. | Weighing / IPC Balance. |
| Net Weight of Materials Sifted | The field will be disabled. Net weight will be calculated automatically upon receiving Gross Weight. | NA | Tare and Gross Weights of IPC. |
| Abnormality in retained powder (Yes / No) | Check box selection. | NA | NA. |
| Quantity of retained powder | To be filled manually only if any abnormality found in sifted materials. It is expressed in numeric and decimal values. | Range 0.001 to 999.999. | Sifted Materials. |
| Integrity of Sieve after sieving | Check box selection. | NA | NA. |
| Total Net Weight of Sieved Materials | Will be calculated automatically and the field will be disabled. | NA | Tare and Gross Weights of IPCs. |
| Incidence/Deviation/Non Conformance | Check box selection. | NA | NA. |
| Reference Document No. | To be filled only if any incidence/deviation/non conformance. | Minimum 1 and maximum 20 alpha-numeric and special characters. | NA. |
| ‘Change IPC’ button. | Select ‘Change IPC’ to add new IPCs for sifting from assigned lot. | NA | NA. |
| ‘Change Sieve’ button. | Once required materials are passed through one sieve, ‘Change Sieve’ button can be selected to pass materials through another sieve. | NA | NA. |
| ‘Next’ button. | Button will be enabled only upon successful usage of all sieves set in <Product Master>. | NA | NA. |
| QA Login | Dropdown selection. | NA | <User Master>. |
| Password | Alpha-numeric and special characters. | Minimum 1 and maximum 16. | As per limits set in <Password Policy>. |
| QA Decision | Checkbox selection. | NA | NA. |

1. **Validation Messages;**

|  |  |  |  |
| --- | --- | --- | --- |
| **Field Name** | **Scenario** | **Validation** | **Co-relation** |
| Integrity and Dryness of Sieve before sieving (OK / Not OK) | Select ‘Not OK’ option. | User will not be allowed to proceed further. Will be asked to enter remark, file deviation record, enter QA credentials and will be directed to ‘Process’ window. | * Report * Activity Log |
| Abnormality in retained powder (Yes / No) | Select ‘Yes’ option. | User will be asked to enter remark, fill in Quantity of retained powder, file deviation record, enter QA credentials and user will be directed to ‘Process’ window. | * Report * Activity Log |
| Integrity of Sieve after sieving | Select ‘Not OK’ option. | User will not be allowed to proceed further. Will be asked to enter remark, file deviation record, enter QA credentials and will be directed to ‘Process’ window. | * Report * Activity Log |
| Incidence/Deviation/Non Conformance | Select ‘Yes’ option. | Enter respective record no., enter QA credentials and enter QA decision. | * Incidence / Deviation / Non Conformance Record * Report * Activity Log |
| Reference Document No. | Select ‘Yes’ option for Incidence/Deviation/Non Conformance | User will be asked to fill Reference document no. along with QA credentials and user will be directed to ‘Process’ window. | * Incidence / Deviation / Non Conformance Record * Report * Activity Log |

1. **Workflow;**

* Mesh Size selection for ‘Sifting’ stage will be enabled in case of multiple mesh sizes selected in <Product Master> to sift materials through more than one sieve (if only one mesh size set in <Product Master>, mesh size selection will be disabled).
* Check integrity and dryness of selected sieve before sieving. If ‘Not OK’, enter remark, file deviation record, enter QA credentials and begin from Instrument Clearance again.
* Select IPC ID from assigned IPCs, Tare Weight will be displayed from ‘Assign IPCs for Sifting’ (if any change in Tare Weight, enter the same), select ‘Status’, ‘Next Step’ and ‘Label Header’ for IPC and select ‘Use Before’ date for materials to be sifted from calendar.
* Start Vibratory Sifter and click on ‘Start’ button to note ‘Sifter Start Time’.
* Check respective check box and confirm to sift materials and material names will get disabled as sifting progresses.
* Stop the Sifter and click on ‘Stop’ button to note ‘Sifter Stop Time’.
* Weigh filled IPC, enter its Filled / Gross Weight in the field and its net weight will be calculated automatically and respective label will be generated.
* Check for any abnormality in sifted materials. If any found, enter remark and mention relevant quantity.
* Select ‘Continue’ option to select new IPC details (from list of assigned IPCs) to continue sifting of various other materials. Or else, select ‘Change Sieve’ option to sieve materials through another sieve set in <Product Master>.
* Before changing sieve, check for integrity of the first sieve after sieving. If ‘Not OK’, enter remark, file deviation record, enter QA credentials and begin from Instrument Clearance again.
* If integrity of sieve after sieving found OK, change sieve, check its integrity and dryness before sieving. If found ‘Not OK’, enter remark, file deviation record, enter QA credentials and begin from Instrument Clearance again.
* Repeat the same process from selecting IPC ID, Tare Weight, Status, etc. to check of abnormalities till all the materials are sifted.
* Upon successful completion sieving materials through all sieves set in <Product Master>, ‘Next’ option will be enabled. User will be asked to check integrity of sieve after sieving. If ‘Not OK’, enter remark, file deviation record, enter QA credentials and begin from Instrument Clearance again.
* Manually enter weights of all the containers filled with sifted materials. Net weight will be calculated automatically.
* File ‘Incidence/Deviation/Non Conformance’ if applicable. QA might ‘Accept’ or ‘Reject’ the incidence / deviation depending upon severity of issue. (User can proceed further if QA accepts or will be directed to ‘Process’ window if QA rejects the issue).
* Select ‘Save’ option to generate label.

1. **Reports;**

Area Clearance Report will be generated for all passed condition as follows;

**Area Clearance log.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sr. No.** | **Checkpoint** | **Observation** | **Verified By** | |
| **Production** | **QA** |
| 1. | Previous Product Code. No. | FER011 |  |  |
| 2. | Previous Product Name | Iron Tablet |  |  |
| 3. | Previous Product Batch No. | IRNT21003 |  |  |
| 4. | Waste Bins Cleared | OK |  |  |
| 5. | Set Temperature | 22°C  20°C - 24°C |  |  |
| 6. | Actual Temperature | 21°C |  |  |
| 7. | Set Relative Humidity | 40%  35% - 45% |  |  |
| 8. | Actual Relative Humidity | 40% |  |  |
| 9. | Set Differential Pressure | 0.15 mmHg  0.1 mmHg - 0.2 mmHg |  |  |
| 10. | Actual Differential Pressure | 0.15 mmHg |  |  |
| 11. | Area Clean | OK |  |  |
| 12. | Cleaning Type | Type A |  |  |
| 13. | Cleaned On | 22/12/2021 |  |  |
| 14. | Cleaned By | Cleaner 1 |  |  |
| 15. | Checked By | Prod User 1 |  |  |
| 16. | Verified By (QA) | QA1 |  |  |

**Failed Area Clearance Log;**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sr. No.** | **Checkpoint** | **Observation** | **Verified By** | |
| **Production** | **QA** |
| 1. | Previous Product Code. No. | FER011 |  |  |
| 2. | Previous Product Name | Iron Tablet |  |  |
| 3. | Previous Product Batch No. | IRNT21003 |  |  |
| 4. | Waste Bins Cleared | Not OK |  |  |
| 5. | Deviation Reference Document No. | DEV\_0102 |  |  |
| 6. | QA | QA01 |  |  |
| 7. | QA Decision | Reject |  |  |

**Instrument Clearance log.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sr. No.** | **Checkpoint** | **Observation** | **Verified By** | |
| **Production** | **QA** |
| 1. | Instrument Type | Vibratory Sifter |  |  |
| 2. | Instrument Code No. | EQP01 |  |  |
| 3. | Previous Product Code. No. | FER011 |  |  |
| 4. | Previous Product Name | Iron Tablet |  |  |
| 5. | Previous Product Batch No. | IRNT21003 |  |  |
| 6. | Instrument Clean | OK |  |  |
| 7. | Instrument Logbook Updated | OK |  |  |
| 8. | Cleaning Type | Type B |  |  |
| 9. | Cleaned On | 22/12/2021 |  |  |
| 10. | Cleaned By | Cleaner 1 |  |  |
| 11. | Checked By | Prod User 1 |  |  |
| 12. | Verified By (QA) | QA1 |  |  |

**Failed Instrument Clearance Log;**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sr. No.** | **Checkpoint** | **Observation** | **Verified By** | |
| **Production** | **QA** |
| 1. | Instrument Type | Vibratory Sifter |  |  |
| 2. | Instrument Code No. | EQP01 |  |  |
| 3. | Previous Product Code. No. | FER011 |  |  |
| 4. | Previous Product Name | Iron Tablet |  |  |
| 5. | Previous Product Batch No. | IRNT21003 |  |  |
| 6. | Instrument Clean | OK |  |  |
| 7. | Instrument Logbook Updated | Not OK |  |  |
| 8. | Deviation Reference Document No. | DEV\_0104 |  |  |
| 9. | QA | QA01 |  |  |
| 10. | QA Decision | Reject |  |  |

**IPC Labels;**

**GRANULATION**

**SIFTING → DRY MIXING**

**PRODUCT NAME:** CALCIUM TABLET **PRODUCT CODE:** CAL052

**BATCH NO.:** 210045 **STATUS:** SIEVED MATERIALS

**NEXT STEP:** DRY MIXING

**IPC ID:** IPC 1 **GROSS WEIGHT:** 8 Kg

**IPC NO.:** 1 of 3 **TARE WEIGHT:** 2 Kg

**USE BEFORE:** 12/12/2021 **NET WEIGHT:** 6 Kg

**DATE:** 10/12/2021

**SIGNATURE:**

**GRANULATION**

**SIFTING → DRY MIXING**

**PRODUCT NAME:** CALCIUM TABLET **PRODUCT CODE:** CAL052

**BATCH NO.:** 210045 **STATUS:** SIEVED MATERIALS

**NEXT STEP:** DRY MIXING

**IPC ID:** IPC 1 **GROSS WEIGHT:** 5.5 Kg

**IPC NO.:** 2 of 3 **TARE WEIGHT:** 1.5 Kg

**USE BEFORE:** 12/12/2021 **NET WEIGHT:** 4 Kg

**DATE:** 10/12/2021

**SIGNATURE:**

**GRANULATION**

**SIFTING → DRY MIXING**

**PRODUCT NAME:** CALCIUM TABLET **PRODUCT CODE:** CAL052

**BATCH NO.:** 210045 **STATUS:** SIEVED MATERIALS

**NEXT STEP:** DRY MIXING

**IPC ID:** IPC 1 **GROSS WEIGHT:** 11.5 Kg

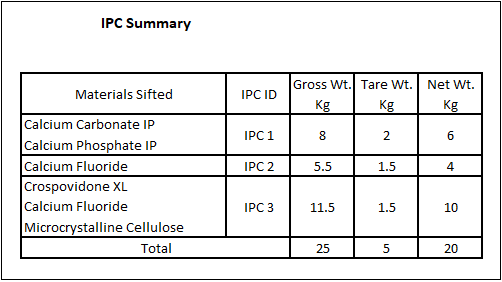
**IPC NO.:** 3 of 3 **TARE WEIGHT:** 1.5 Kg

**USE BEFORE:** 12/12/2021 **NET WEIGHT:** 10 Kg

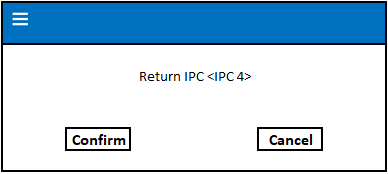
**DATE:** 10/12/2021

**SIGNATURE:**

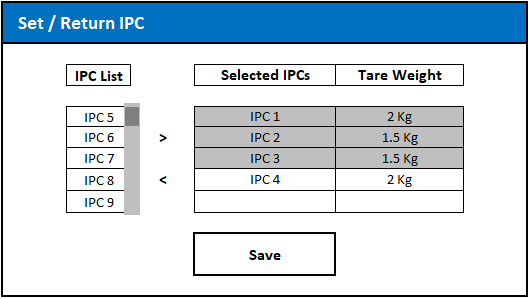
A consolidated IPC Summary report will also be generated upon saving the data;



If an IPC has been assigned for stage and has not been used throughout, system will not allow user to proceed further and will ask user to return the IPC so that it can be assigned for next stage / process. The following window will be displayed;



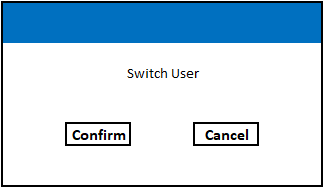
During an ongoing Sifting stage, new IPCs can be assigned and assigned but unused IPCs can be returned through ‘Drawer menu – Set / Return IPC’ module.

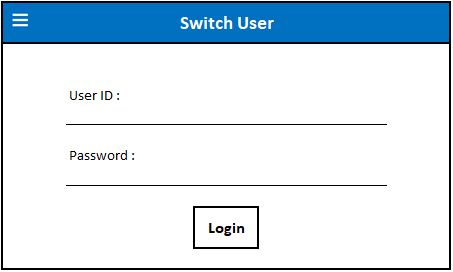


* To assign new IPC during an ongoing process, select IPC ID from IPC List and click on ‘>’ button.
* To return a particular IPC, select relevant IPC ID from Selected IPCs list and click on ‘<’ button.
* ‘Save’ details after assigning / returning the IPCs.

**\*NOTE:** ‘<’ button will be disabled for used IPCS. This means no action can be performed for used IPC IDs.

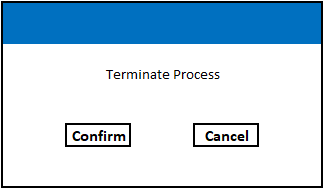
Option to ‘Switch User’ during an ongoing process is also provided in ‘Drawer menu’.

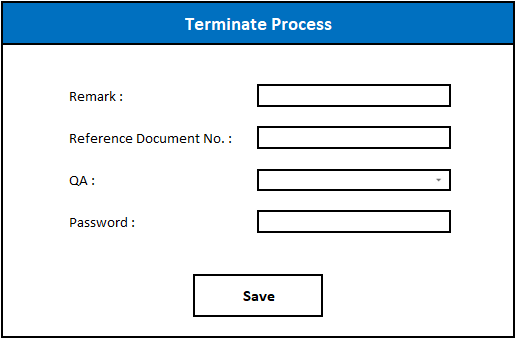




* Upon ‘Confirm’, new user credentials will be asked.
* Enter valid User ID and Password and click on ‘Login’ button to successfully login and continue process.
* Old user will be logged out.

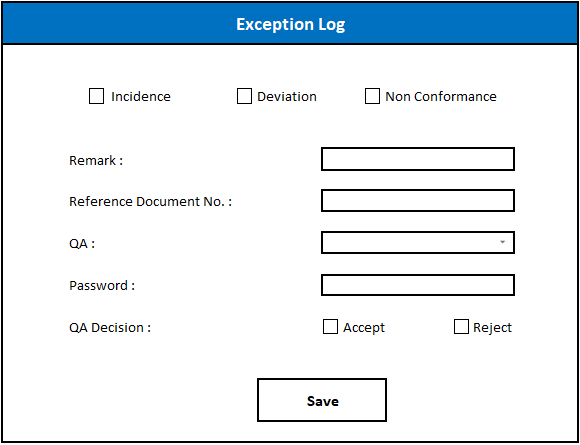
User can ‘Terminate / Abort’ the process if required.





* Upon ‘Confirm’, QA credentials along with reason and reference document details will be asked.
* Enter QA credentials and ‘Save’ the details; the batch will be aborted and user will be directed to ‘Process’ window.

File ‘Incidence / Deviation / Non Conformance’ details during ongoing process under ‘Exceptions Log’.



* Select relevant type of exception.
* Briefly mention its details in ‘Remark’ field, enter respective ‘Reference Document No.’ in the field.
* Provide QA User ID and Password and select QA Decision – ‘Accept’ or ‘Reject’ and ‘Save’ the details.
* Batch will be aborted and User will be directed to ‘Process’ window if QA has ‘Rejected’ the exception.
* User will be able to proceed if QA ‘Accepts’ the exception.

1. **Flowchart;**