VENDOR:

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FOR

(INCRENCY
IN-PROCESS CHECK
SYSTEM)

SYSTEM NAME : INCRENCY® INPROCESS CHECK SYSTEM

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1. PURPOSE

The purpose of this document is to provide design and parameterization of Incrency Inprocess Check System proposed to be installed at Inventia Ambernath plant.

2. SCOPE

In-Scope (TantraSoft):

The scope of this design document is for Incrency Inprocess Check System to be installed at Inventia, Ambernath.

In-Scope (Inventia):

The design for Power, LAN point and TSH enclosure is in scope. Also, Infrastructure Qualification is covered under installation qualification checks- infrastructure.

3. SYSTEM OVERVIEW

Features of INCRENCY® In-Process Check System:

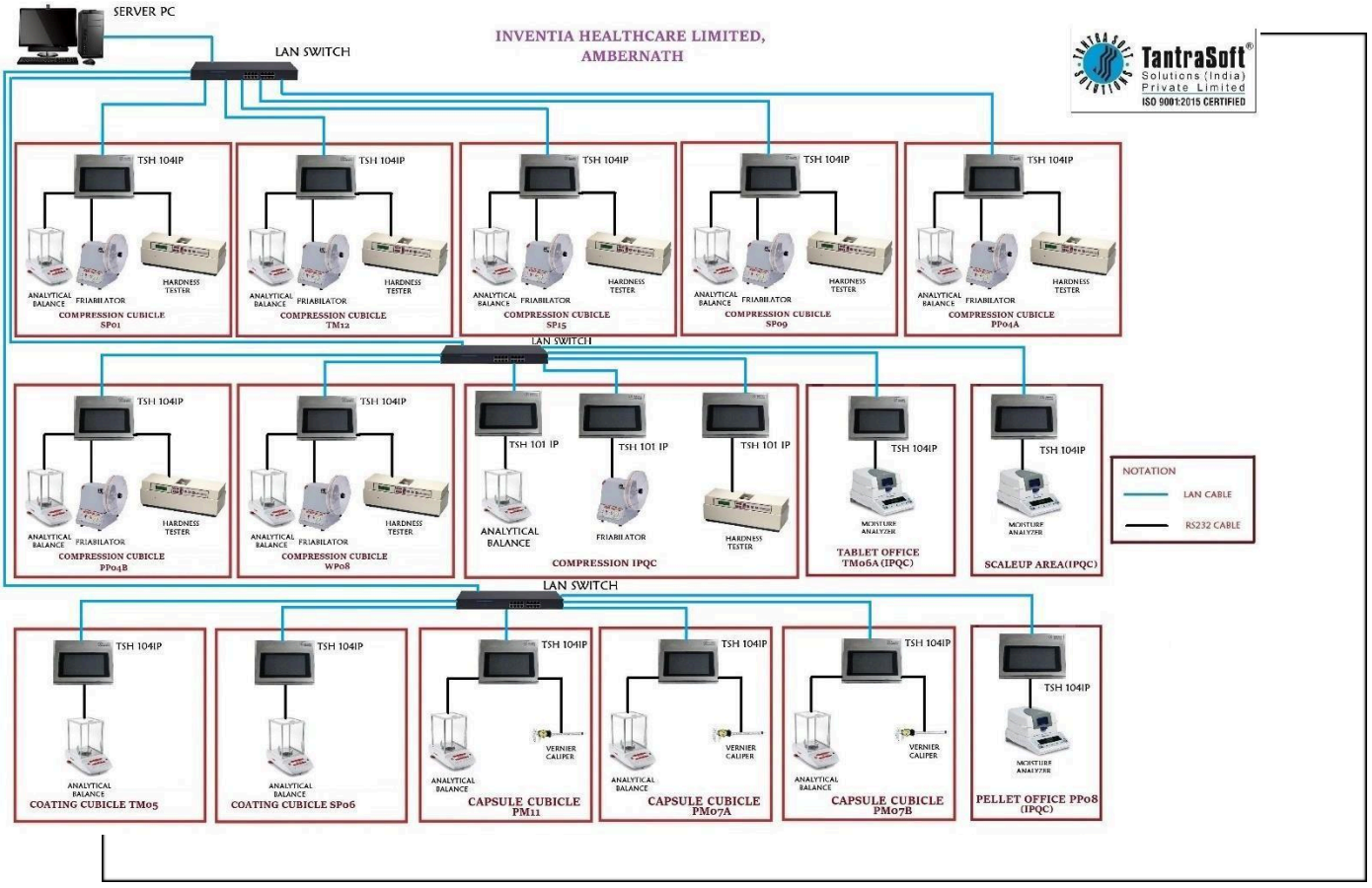
- ✔ INCRENCY® In-Process Check System is a data integrity system, consist of software and hardware.
- ✔ Software is installed on a server and shall be accessible with respected clients.
- ✔ Software consists of master database and generates reports
- ✔ Hardware – Touch Screen Hardware – is installed close to the Instrument and is used for converting the output from Instrument into software in computer via LAN.
- ✔ The test Instrument transfers the values to the system via TSH.
- ✔ The measured values are compared with pre-defined tolerance limits fed in master data.
- ✔ Master data can be maintained for multiple parameters for all stages of product.
- ✔ Visual display indicators of the sample being out of tolerance limit, helps the user to take corrective action.
- ✔ The reports are generated digitally.

Benefits of this system:

- ✔ INCRENCY® In Process Check System can be used via local server by all users in the same network.
- ✔ Thus, eliminates human error.

- ✔ Reports / records are authenticated, customized and Date and time stamped of the server.
- ✔ All the data are permanently stored.
- ✔ All the reports shall be electronically generated and printed reports can be verified manually by signing the documents.
- ✔ Supports features of 21 CFR part 11 compliance and system is developed as per GAMP 5 guidelines.

System Architecture:



4. DETAILED DESIGN

Architectural Description:

- Programming Language – Incrency system is developed in Angular & Node.js, since it is a browser-based application.
- Frontend of application is Angular 6 & 7 whereas backend of application is Node.js 16.14
- Node.js is also being used for data abstraction and interfacing multiple devices with software.
- As an asynchronous event driven JavaScript runtime, Node is designed to build scalable network applications.
- LDAP (Windows authentication) – is to validate user with windows active directory
- Database – MS-SQL 2019 or above is to store information. Root pages: (../~)

  - Style.css

    Type: Cascading Style Sheet
    Purpose: To maintain the same style throughout the application.

  - Sidebar

    Type: component (.ts/.html/.scss)
    Purpose: To maintain the sidebar and menu throughout the application.

  - Header-navigation

    Type: component (.ts/.html/.scss)
    Purpose: To maintain the header throughout the application.

  - authentication/login

    Type: component (.ts/.html/.scss)
    Purpose: This is an entry point for the system.

5. SOFTWARE MODULES

5.1 LOGIN

File extension: .ts (type script)

Type: Angular Web Form
Purpose: Login into the system.

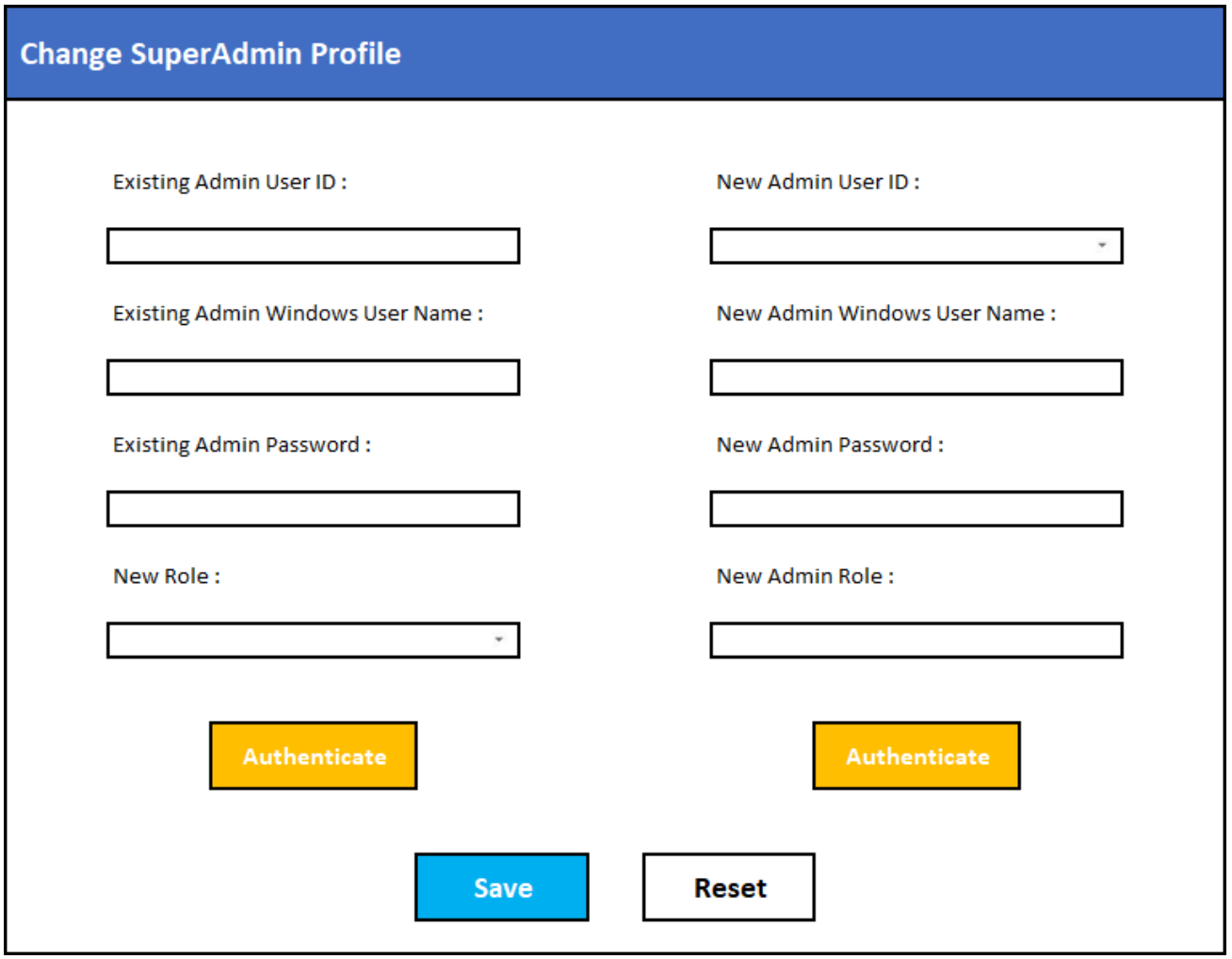
SCREEN 1

Screen 1 : Login

- Enter User ID.
- Enter Password.
- Login into the system.

5.2 CHANGE SUPERADMIN PROFILE

File extension: .ts (type script) Type: Angular Web Form
Purpose: Allows changing profile of Super Admin.



SCREEN 2

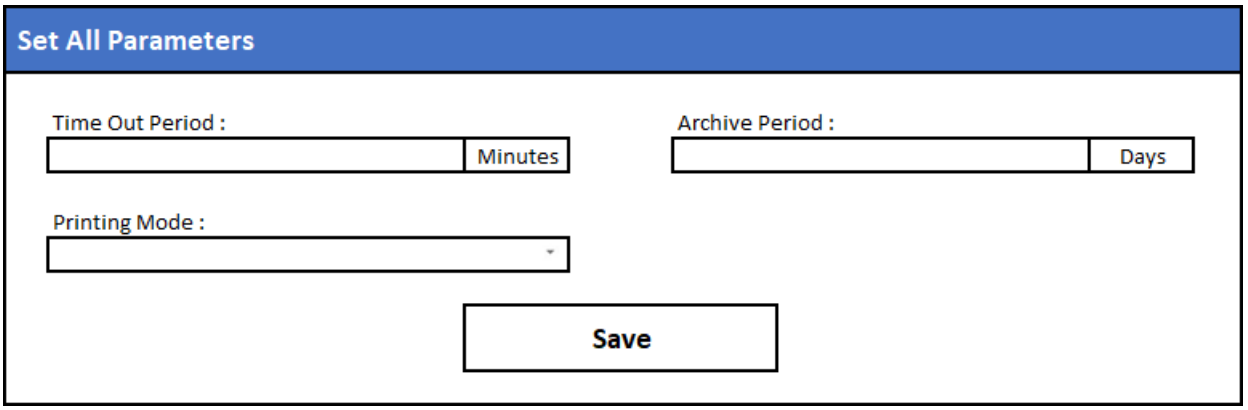
Process

Screen 2 : Change SuperAdmin Profile

- Only accessible by Super Admin.
- Super Admin can transfer Self rights and access privileges to another user.

5.3 PARAMETER SETTING

File extension: .ts (type
script) Type: Angular Web
Form
Purpose: Allows setting all security parameters



SCREEN 3

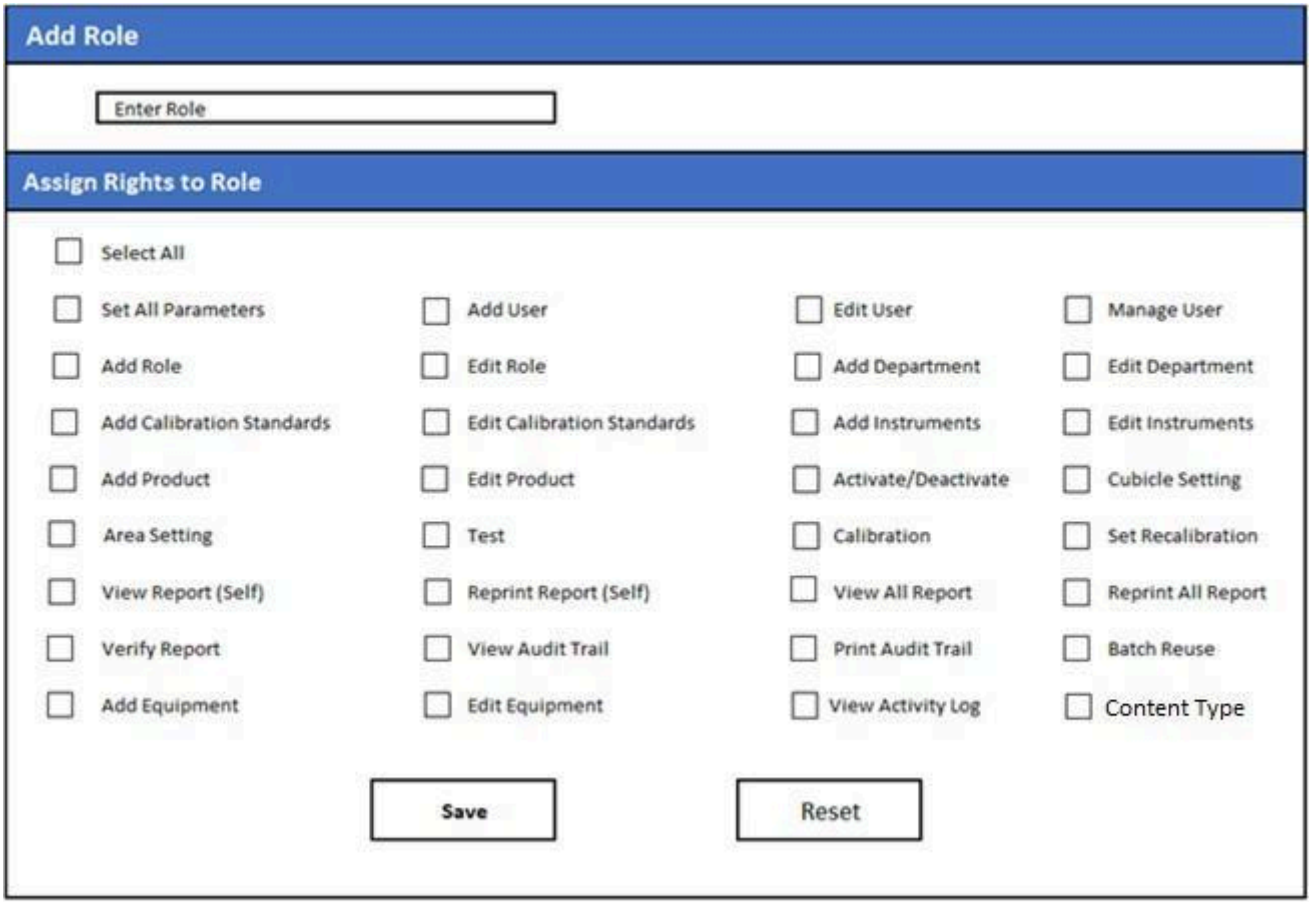
Process

Screen 3 : An authorized user is able to set parameters in the system.

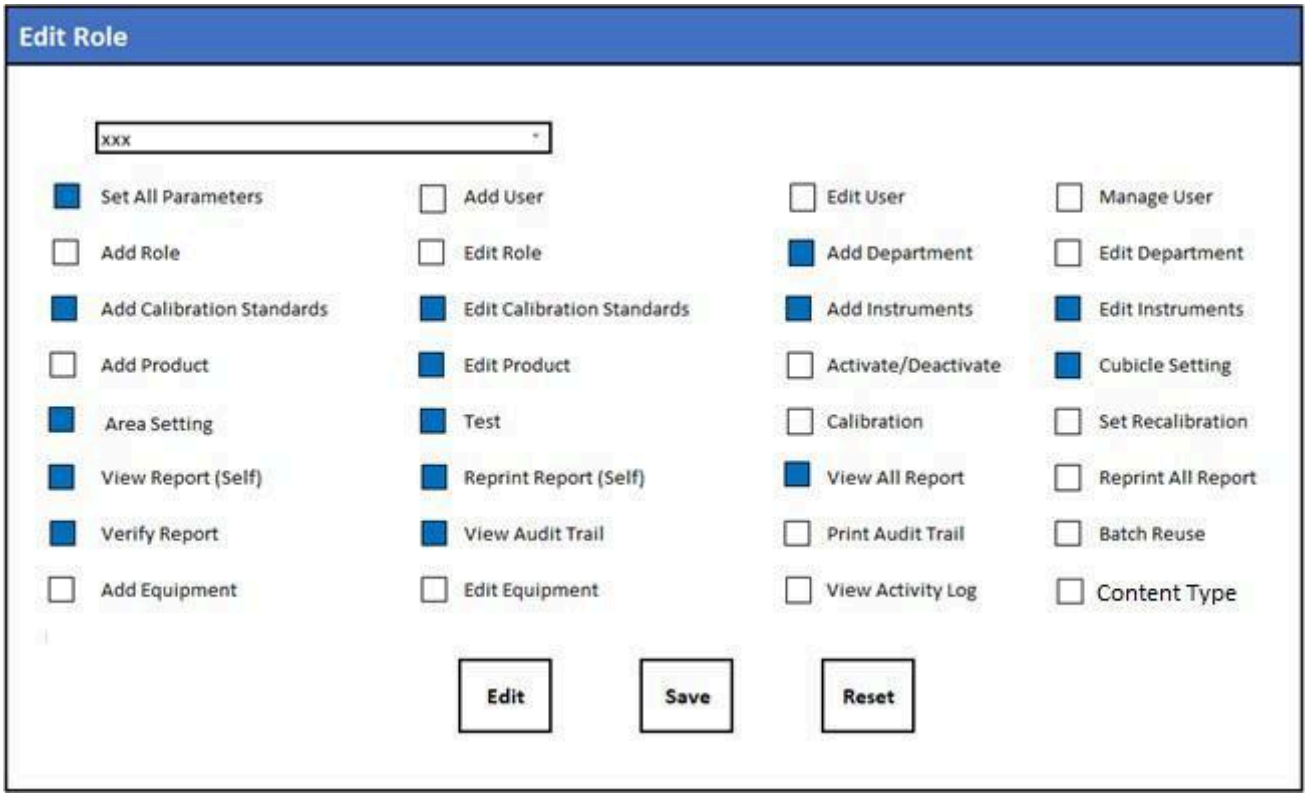
- Time out Period: If the system is idle, i.e., if user is logged into the system and is not using it for time out period (in minutes), the session will expire and the user will be logged out. Data limit: 1. Range: 1 to 9. Field Value: Numeric.
- Archive Period: The reports will be transferred to "archive folder" after set numbered days. Data limit: 3, Range: 1 to 999. Field Value: Numeric.
- Printing Mode: Printing Mode will be Manual, user needs to take the print manually.

5.4 ROLE MANAGEMENT

File extension: .ts (type script) Type: Angular Web Form
Purpose: Allows adding and managing role details.



SCREEN 4



SCREEN 5

Process

Screen 4 : Add Role

Create a role with unique Role name and respective set of rights.

Set of rights assigned to the particular role cannot be repeated for another role.

Roles are later assigned to the user. User gets access of system according to the assigned role. Field Value: Alpha-numeric and Special characters and Data Length: 50.

Screen 5 : Edit Role

Rights assigned to the role can be modified any time.

**Note:

(Batch Reuse) Batch which is ended can be reused in cubicle.

Cubicle/TSH Status can be viewed if 'View Activity Log' right is assigned to user.

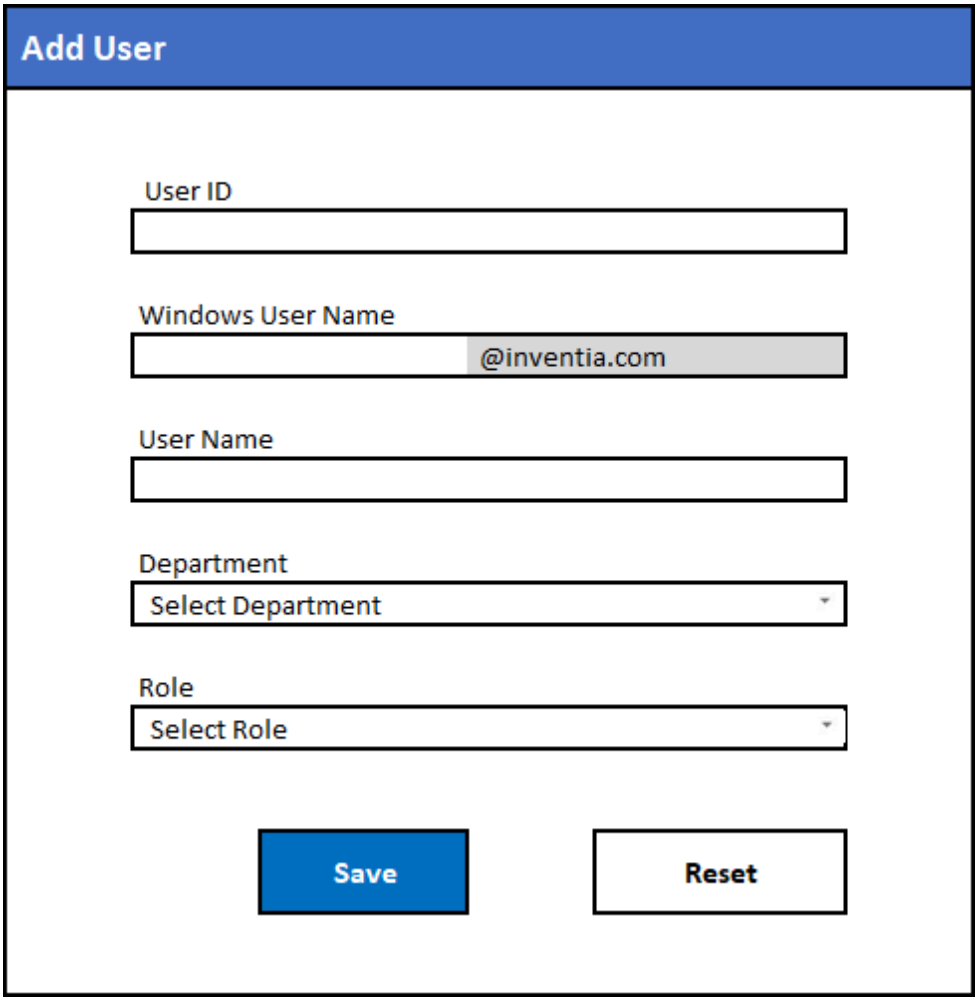
If 'Test' right assigned to any user then automatically 'View Report (Self)' & 'Reprint Report (Self)' right are assigned.

Connected rights / privileges will get selected automatically upon selection of one right.

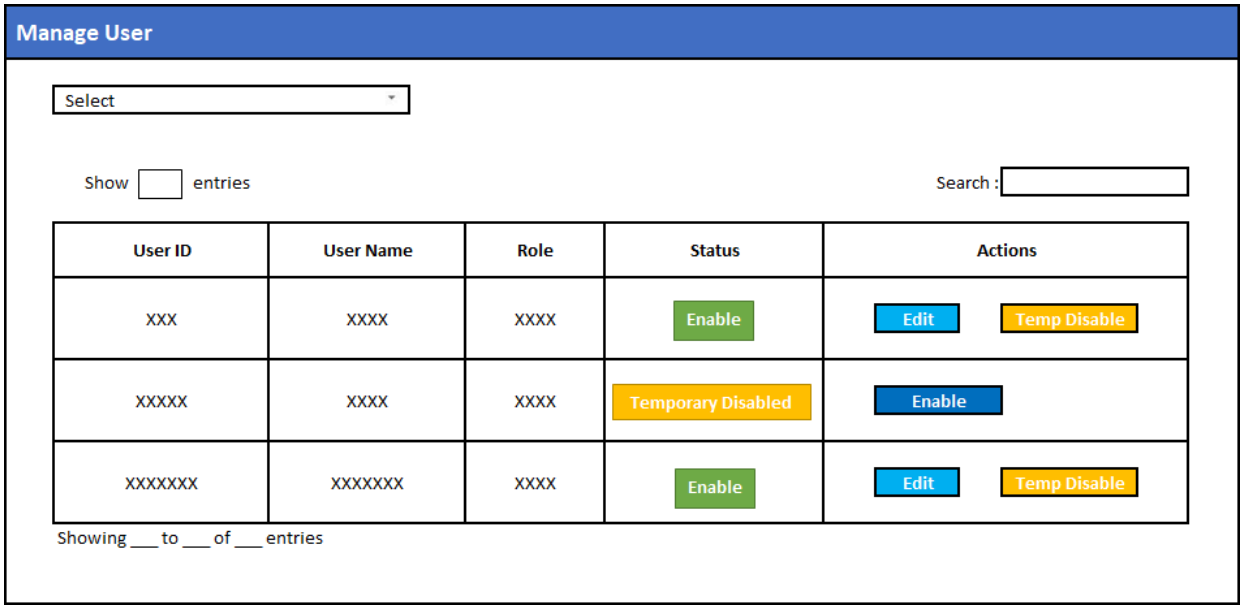
Sr. No	Right / Privilege	Connected Right / Privilege
1.	Print Audit Trail	'View Audit Trail'
2.	Reprint All Report	'View All Report'

5.5 USER MANAGEMENT

File extension: .ts (type
script) Type: Angular Web
Form
Purpose: Allows adding and managing user details.



SCREEN 6



SCREEN 7

Process

Screen 6 : Add User

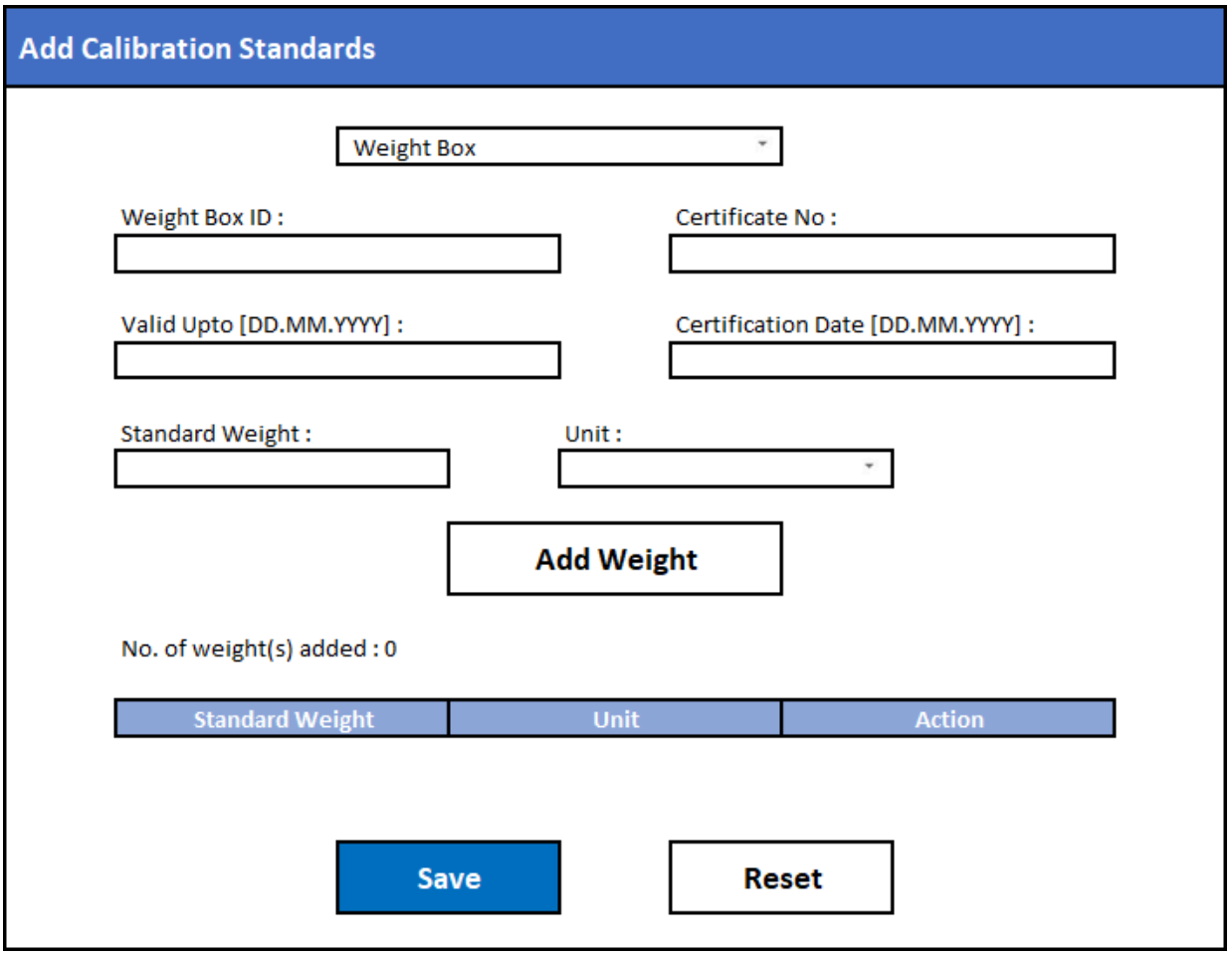
- Authorized user is allowed to add users in the system.
- Unique User ID for every user.
  Data length: 10. Field Value: Alpha-numeric and Special characters.
- Enter Windows username.
  Data length: 100. Field Value: Alpha-numeric and Special characters.
- Enter username.
  Data length: 30. Field Value: Alpha-numeric and Special characters.
- Assign department to the user.
- Assign role to the user.
- On the selection of role, rights assigned to the selected role will be displayed on the right-hand side.
- After filling the details, save details with reason.

Screen 7 : Manage User

- Click on 'Select' dropdown arrow to filter users according to their status - enabled or temporary disabled.
- Click on 'Edit' button, to make changes in role rights and privileges of user.
- Modify role, department and assigned rights.
- Save modified information with remark.
- Authorized user can 'Edit' user(s) who are not logged in the system.
- Authorized user can disable user temporarily through software.
- Temporary disabled users can be enabled by authorized user.
- If User ID is disabled, system will recognize the same and will not allow that user to login.
- Newly created User will be asked to validate upon first login attempt in the system.

5.6 CALIBRATION STANDARDS

File extension: .ts (type script) Type: Angular Web Form
Purpose: Allows adding and managing calibration standards details.



SCREEN 8

Edit Calibration Standards

Weight Box

Weight Box ID : XXX

Certificate No : XXX

Valid Upto [DD.MM.YYYY] : XX.XX.XXXX

Certification date [DD.MM.YYYY] : XX.XX.XXXX

Standard Weight :

Unit :

Add Weight

No. of weight(s) added : 4

Standard Weight	Unit	Action
XX	mg	Remove
XX	mg	Remove
XX	mg	Remove
XX	mg	Remove

Edit **Save** **Reset**

SCREEN 9

View Calibration Standards

Weight Box

Show entries

Search :

Weight Box ID	Certificate No.	Valid Upto	Certification Date	Action
xxx	xxx	xxx	xxx	Weight Detail
xxx	xxx	xxx	xxx	Weight Detail
xxx	xxx	xxx	xxx	Weight Detail

Showing ___ to ___ of ___ entries

SCREEN 10

Process

Screen 8 : Add Calibration Standards

- Weight Box ID: Unique Weight Box ID for weight boxes.
  Data length: 50. Field Value: Alpha-Numeric with special characters.
- Certificate No.: Unique Certificate no. for weight boxes mentioned on the certificate itself. Data length: 50. Field Value: Alpha-Numeric with special characters.
- Valid Up to: Mentioned on certificate of weight box. Date to be selected from calendar.
- Certification Date: Date on which certificate of the weight box was issued. It is always back-dated to be selected from calendar.
- Enter required Calibration Standards.
- Add standard weights for respective Calibration standards.
- Select the unit from the dropdown list.

Screen 9 : Edit Calibration Standards

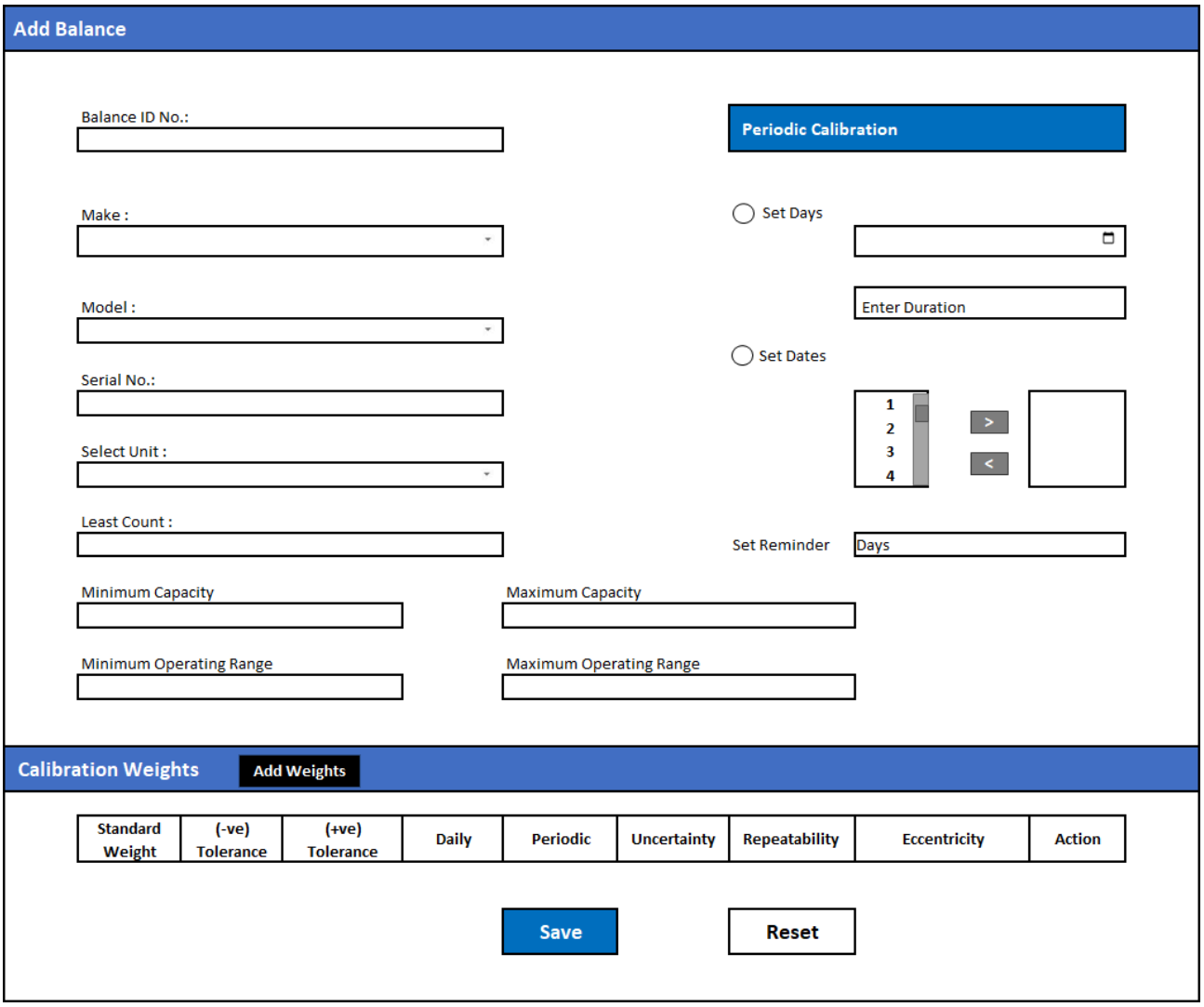
- Calibration Standards can be modified if required.
- Weights can be added or removed from weight box.
- Assigned Weight Box ID in Weight Assignment will not be displayed in dropdown list for edit.

Screen 10 : View Calibration Standards

- Added standard weight details can be viewed.

5.7 BALANCE MASTER

File extension: .ts (type script) Type: Angular Web Form
Purpose: Allows adding and managing balance details.



SCREEN 11

Edit Balance

Balance ID No. :

Make :

Model :

Serial No. :

Select Unit :

Least Count :

Minimum Capacity

Maximum Capacity

Minimum Operating Range

Maximum Operating Range

Periodic Calibration

Set Days

Enter Duration

Set Dates

1
2
3
4

Set Reminder Days

Calibration Weights Add Weights

Standard Weight	(-ve) Tolerance	(+ve) Tolerance	Daily	Periodic	Uncertainty	Repeatability	Eccentricity	Action
xx	xx	xx	xx	xx	xx	xx	xx	Remove
xx	xx	xx	xx	xx	xx	xx	xx	Remove
xx	xx	xx	xx	xx	xx	xx	xx	Remove
xx	xx	xx	xx	xx	xx	xx	xx	Remove

Edit Save Reset

SCREEN 12

View Balance

Show entries

Search :

Balance ID No.	Make	Model	Serial No.	Unit	Least Count	Minimum Capacity	Maximum Capacity	Minimum Operating Range	Maximum Operating Range	Date	Duration	Reminder	View Weights	Action
XXX	XXX	XXX	XXX	g	X.XXX	X.XXX	XXX	X.XXX	XXX	XX.XX.XXXX	X	X	View	Activate
XXXX	XXXX	XXXX	XXXX	mg	X.XXX	X.XXX	XXX	X.XXX	XXX	XX.XX.XXXX	X	X	View	Deactivate
XX	XX	XX	XX	mg	X.XXX	X.XXX	XXX	X.XXX	XXX	XX.XX.XXXX	X	X	View	Deactivate
XXX	XXX	XXX	XXX	g	X.XXX	X.XXX	XXX	X.XXX	XXX	XX.XX.XXXX	X	X	View	Activate

Showing ___ to ___ of ___ entries

SCREEN 13

Process

Screen 11 : Add Balance

Balance ID No.: Add balance details with unique Balance Code No.

Data length: 25. Field Value: Alpha-Numeric with special characters.

Make: Select Name/details of the manufacturer of balance from dropdown list.

Model: Select Model details of the balance from dropdown list.

Serial No.: Enter unique Serial No. of balance.

Data length: 50. Field Value: Alpha-Numeric with special characters.

Select Unit from dropdown list.

Enter Least Count.

Data Range: 0.00001 to 99999.99999. Field Value: Numeric and Decimal.

Enter Minimum and Maximum Capacity.

Data Range: 0.00001 to 99999.99999. Field Value: Numeric and Decimal.

Enter Minimum and Maximum Operating Range.

Data Range: 0.00001 to 99999.99999. Field Value: Numeric and Decimal.

Set periodic calibration date and duration.

According to set calibration period/date, calibration will be asked on TSH.

Set Reminder is considered as number of days before due date of calibration (periodic calibration).

Calibration Weights: The weights to be added and saved for different types of calibration along with standard/negative/positive tolerances.

Screen 12 : Edit Balance

Balance details can be edited, if required.

Standard weights can be added or removed.

Only inactive balance will be available in dropdown list for edit.

Once activated, balance details will not be available for edit.

Screen 13 : View Balance

Balance details can be viewed.

Balance can be activated or deactivated.

'Deactivate' button will be disabled if balance are assigned in an area/cubicle.

'Activate/Deactivate' button will be disabled for self-added balance.

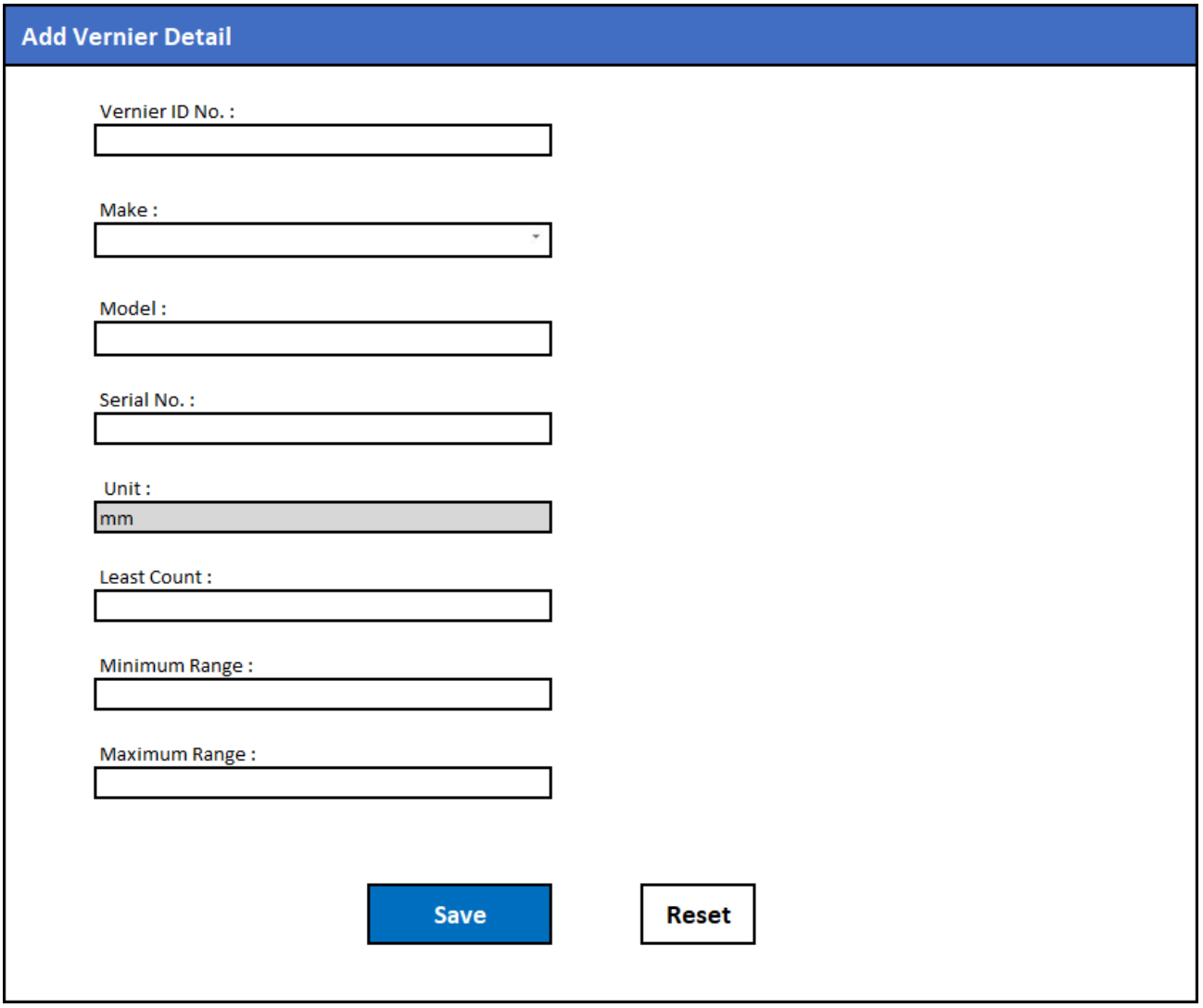
*Note :

Only 2 weights will be accepted for daily calibration (Refer Daily Calibration Report).

Eccentricity, Repeatability, Uncertainty can be skipped. Only selected tests will be displayed on report.

5.8 VERNIER MASTER

File extension: .ts (type script) Type: Angular Web Form
Purpose: Allows managing Vernier master.



SCREEN 14

Edit Vernier Detail

Vernier ID No. :

Make :

Model :

Serial No. :

Unit :
mm

Least Count :

Minimum Range :

Maximum Range :

Edit | Save | Reset

SCREEN 15

View Vernier Detail

Show entries Search :

Vernier ID No.	Make	Model	Serial No.	Unit	Least Count	Minimum Range	Maximum Range	Action
XXX	XXX	XXX	XXX	mm	X.XX	X.XX	XX	Activate
XXX	XXX	XXX	XXX	mm	X.XXX	X.XXX	XX	Deactivate
XXX	XXX	XXX	XXX	mm	X.XX	X.XX	XX	Deactivate
XXX	XXX	XXX	XXX	mm	X.XXX	X.XXX	XX	Activate

Showing __ to __ of __ entries

SCREEN 16

Screen 14 : Add Vernier

- Add Vernier details with unique Vernier ID No. It consists of minimum 1 and maximum 25 alpha-numeric and special characters.
- Select Make details of Vernier Caliper from dropdown list.
- Enter Model details consisting of minimum 1 and maximum 50 alpha-numeric and special characters.
- Enter unique Vernier Serial No. consisting of minimum 1 and maximum 50 alpha-numeric and special characters.
- Unit for Vernier will be selected as 'mm' by default and the field will be disabled.
- Enter Least Count of Vernier Caliper consisting of numeric and decimal values ranging between 0.00001 and 99999.99999.
- Enter Minimum and Maximum Range consisting of numeric and decimal values ranging between 0.00001 and 999.99999.
- Save details with remark.

Screen 15 : Edit Vernier

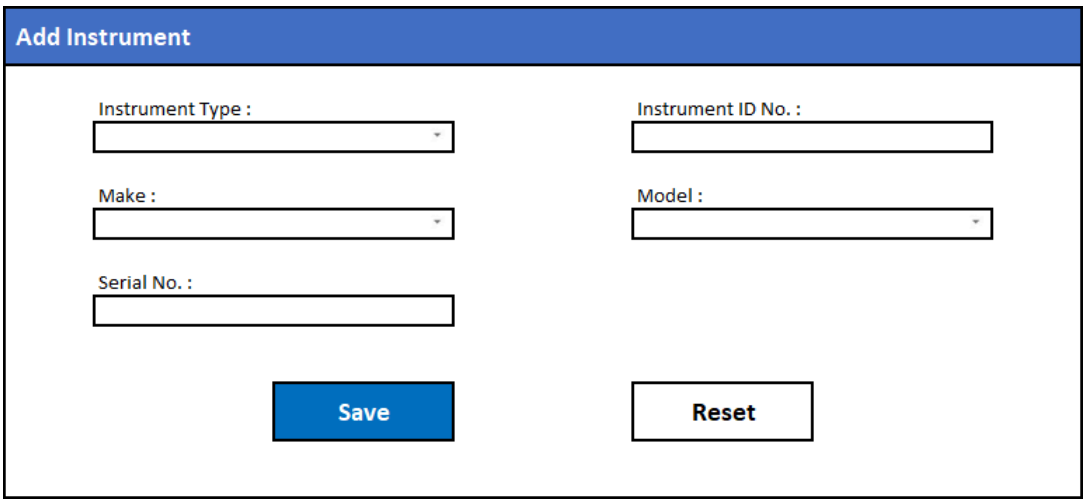
- Vernier details can be edited if required.
- Only 'Inactive' Vernier Calipers will reflect in dropdown list for edit.
- Once activated, Vernier details will not be available for edit.

Screen 16 : View Vernier

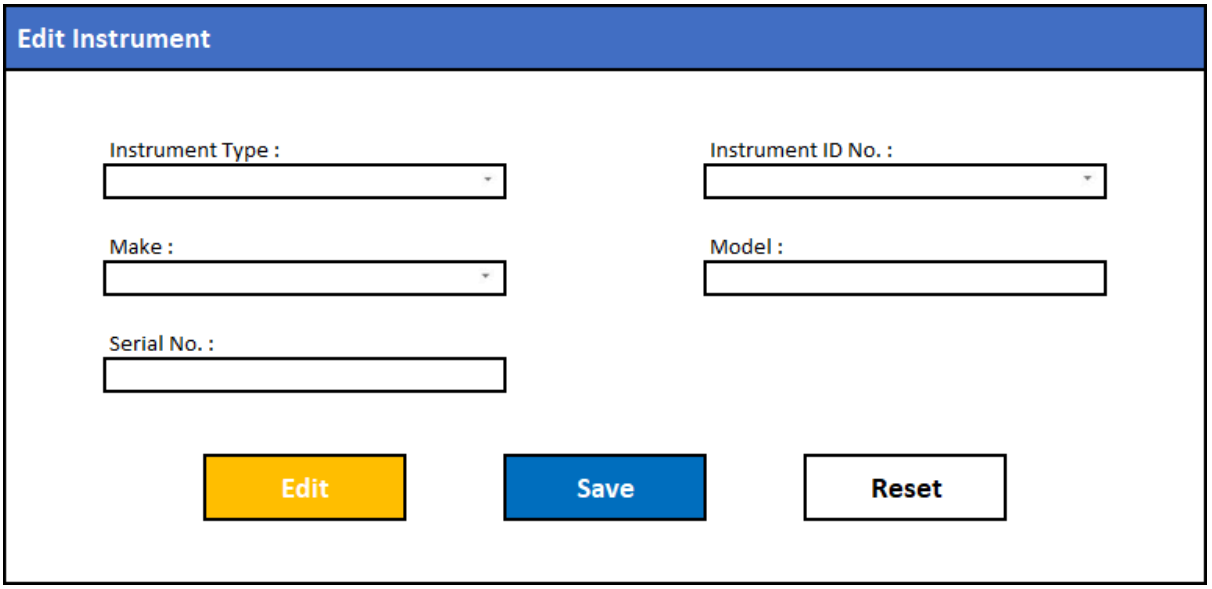
- Vernier details can be viewed.
- 'Deactivate' button will be disabled for Vernier Calipers that are assigned in an area/cubicle.
- 'Activate/Deactivate' buttons will be disabled for self-added Vernier Caliper details.

5.9 OTHER INSTRUMENT MASTER

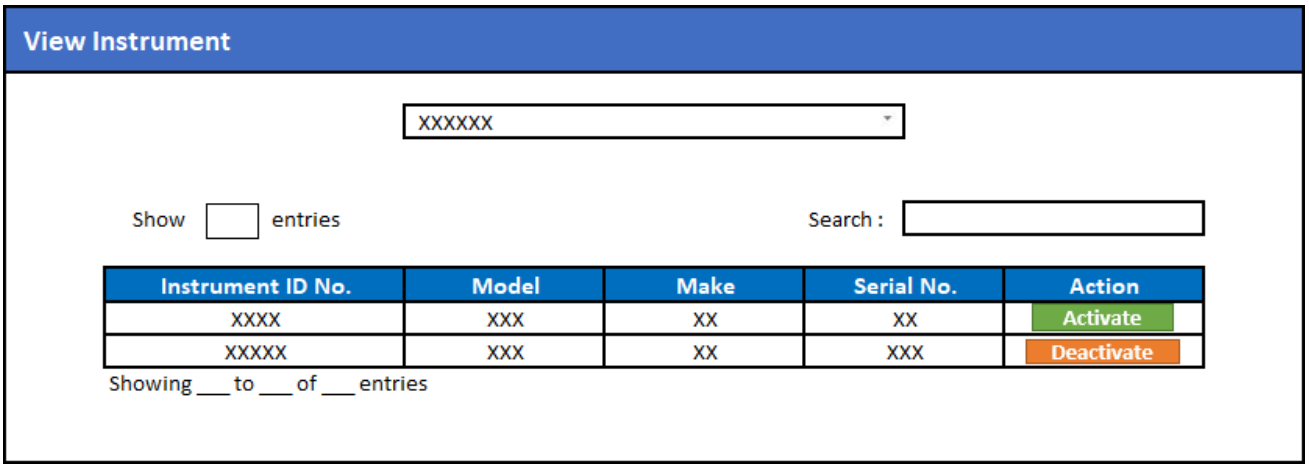
File extension: .ts (type script) Type: Angular Web Form
Purpose: Allows adding and managing other instruments details.



SCREEN 17



SCREEN 18



SCREEN 19

Process

Screen 17 : Add Instrument

Select Instrument Type from dropdown list.

Enter unique Instrument ID No.

Data length: 25, Field Value: Alpha-numeric and Special characters.

Enter details of the manufacturer of instrument.

Data length: 50. Field Value: Alpha-numeric and Special characters.

Enter Model details of instrument.

Data length: 50. Field Value: Alpha-numeric and Special characters.

Enter unique Serial No. of instrument.

Data length: 50. Field Value: Alpha-numeric and Special characters.

Save instrument details.

Screen 18 : Edit Instrument

Instrument(s) details can be modified if required.

Only inactive Instrument(s) will be available in dropdown list for edit.

Once activated, Instrument(s) details will not be available for edit.

Screen 19 : View Instrument

Instrument(s) details can be viewed.

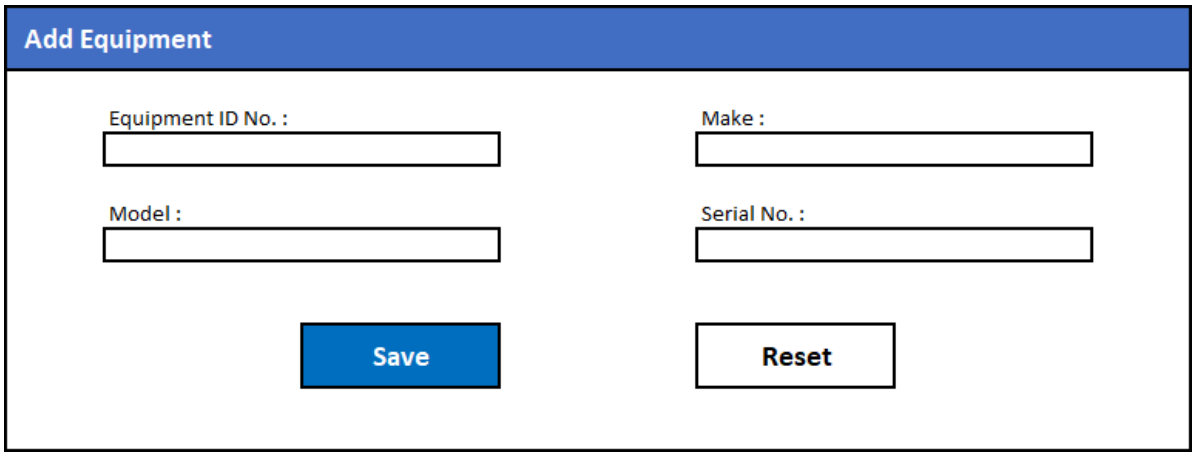
Instrument(s) can be activated or deactivated.

'Deactivate' button will be disabled if Instrument(s) are assigned in an area/cubicle.

'Activate/Deactivate' button will be disabled for self-added instrument(s).

5.10 EQUIPMENT MASTER

File extension: .ts (type script) Type: Angular Web Form
Purpose: Allows adding and managing equipment details.



SCREEN 20

SCREEN 21

View Equipment

Show [ ] entries Search : [ ]

Equipment ID No.	Make	Model	Serial No	Action
xxx	xxx	xxx	xxx	Activate
xxx	xxx	xxx	xxx	Deactivate

Showing ___ to ___ of ___ entries

SCREEN 22

Process

Screen 20 : Add Equipment

Enter unique Equipment ID No.

Data length: 25, Field Value: Alpha-numeric and Special characters.

Enter details of the manufacturer of Equipment.

Data length: 50. Field Value: Alpha-numeric and Special characters.

Enter Model details of Equipment.

Data length: 50. Field Value: Alpha-numeric and Special characters.

Enter unique Serial No. of Equipment.

Data length: 50. Field Value: Alpha-numeric and Special characters.

Save Equipment details.

Screen 21 : Edit Equipment

Equipment details can be edited if required.

Only inactive Equipment will be available in dropdown list for edit.

Once activated, Equipment details will not be available for edit.

Screen 22 : View Equipment

Equipment details can be viewed.

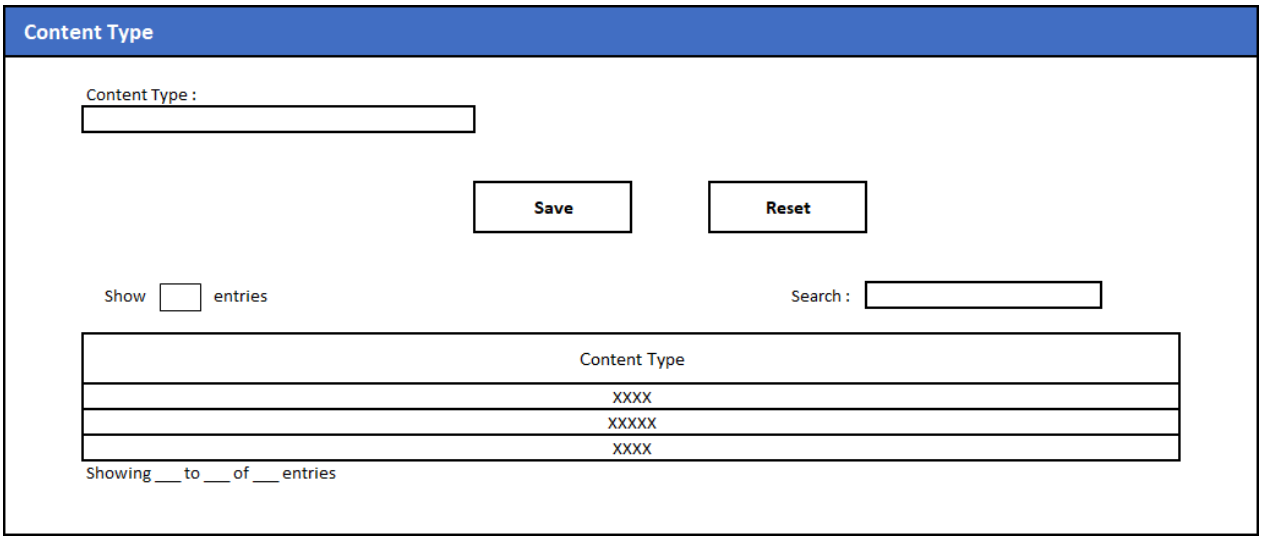
Equipment(s) can be activated or deactivated.

'Deactivate' button will be disabled if Equipment are assigned in an area/cubicle.

'Activate/Deactivate' button will be disabled for self-added equipment.

5.11 CONTENT TYPE

File extension: .ts (type script) Type: Angular Web Form
Purpose: Allows adding Content Type details for Multi-Component Capsules.



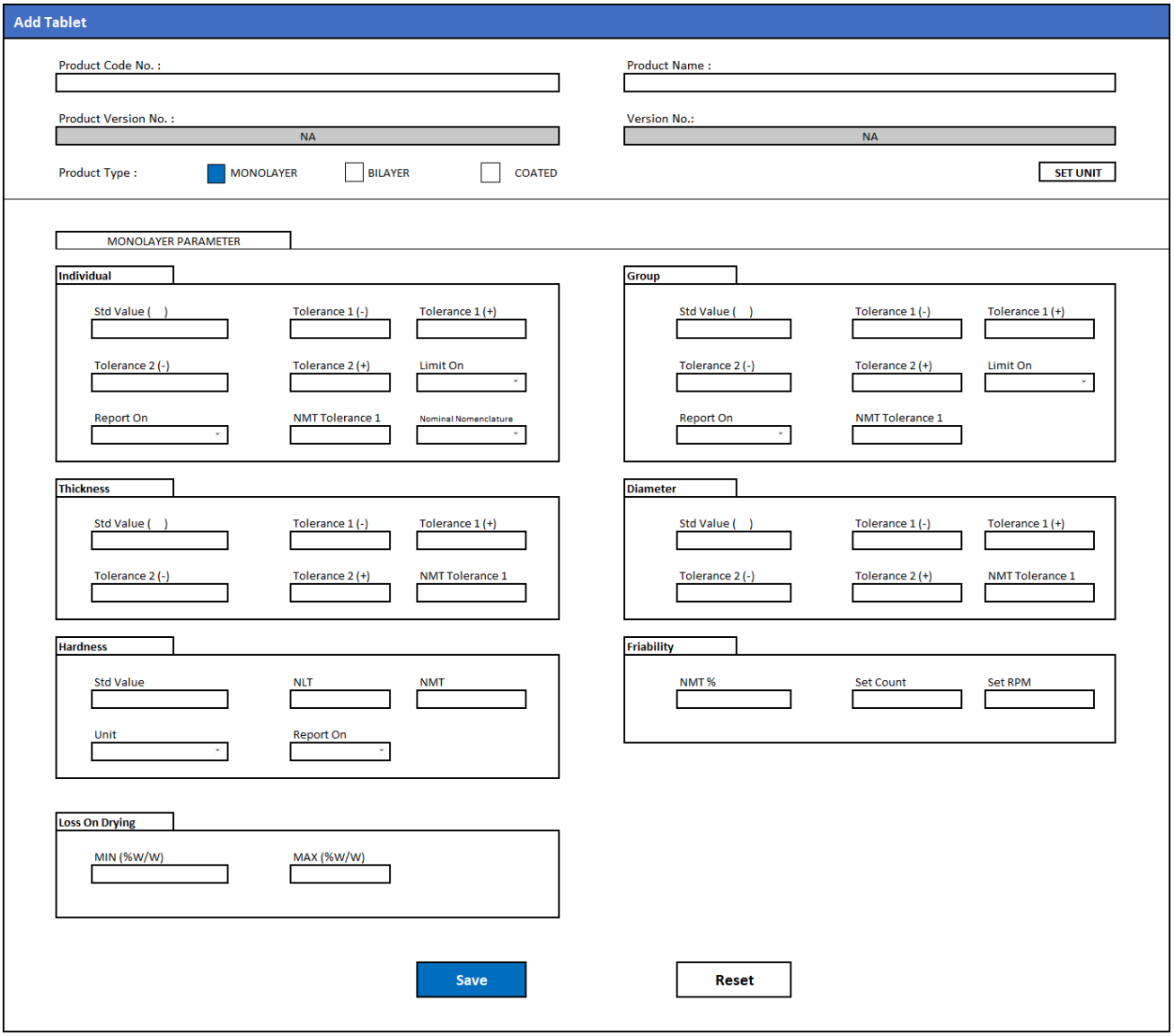
SCREEN 23

Screen 23 : Add Content Type

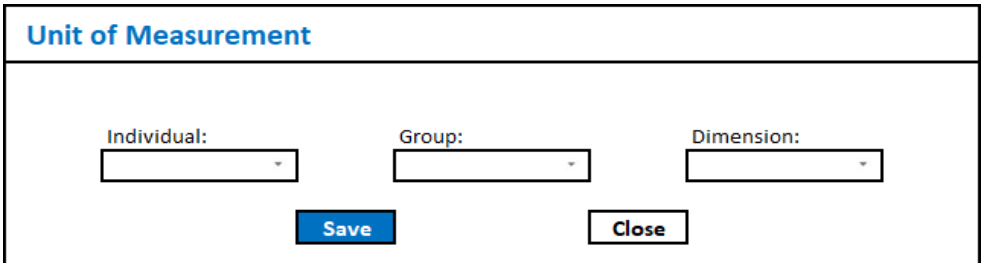
Add "Content Type" which is to be assigned to each content of a Multi-Content Capsule in Add Capsule module. The field accepts minimum 1 and maximum 25 alpha-numeric and special characters.

5.12 PRODUCT MASTER (TABLET)

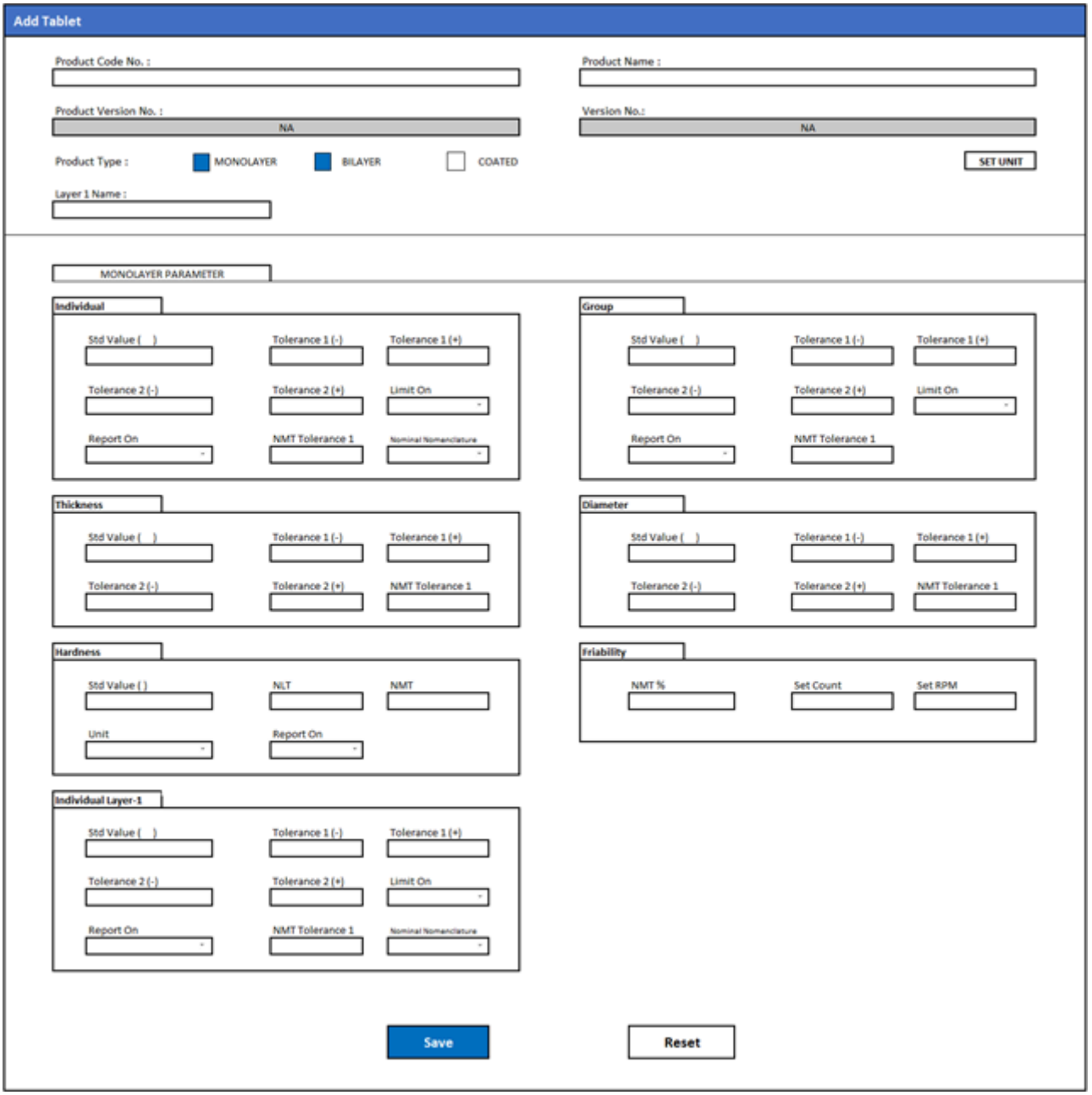
File extension: .ts (type script) Type: Angular Web Form
Purpose: Allows adding and managing product (tablet) details.



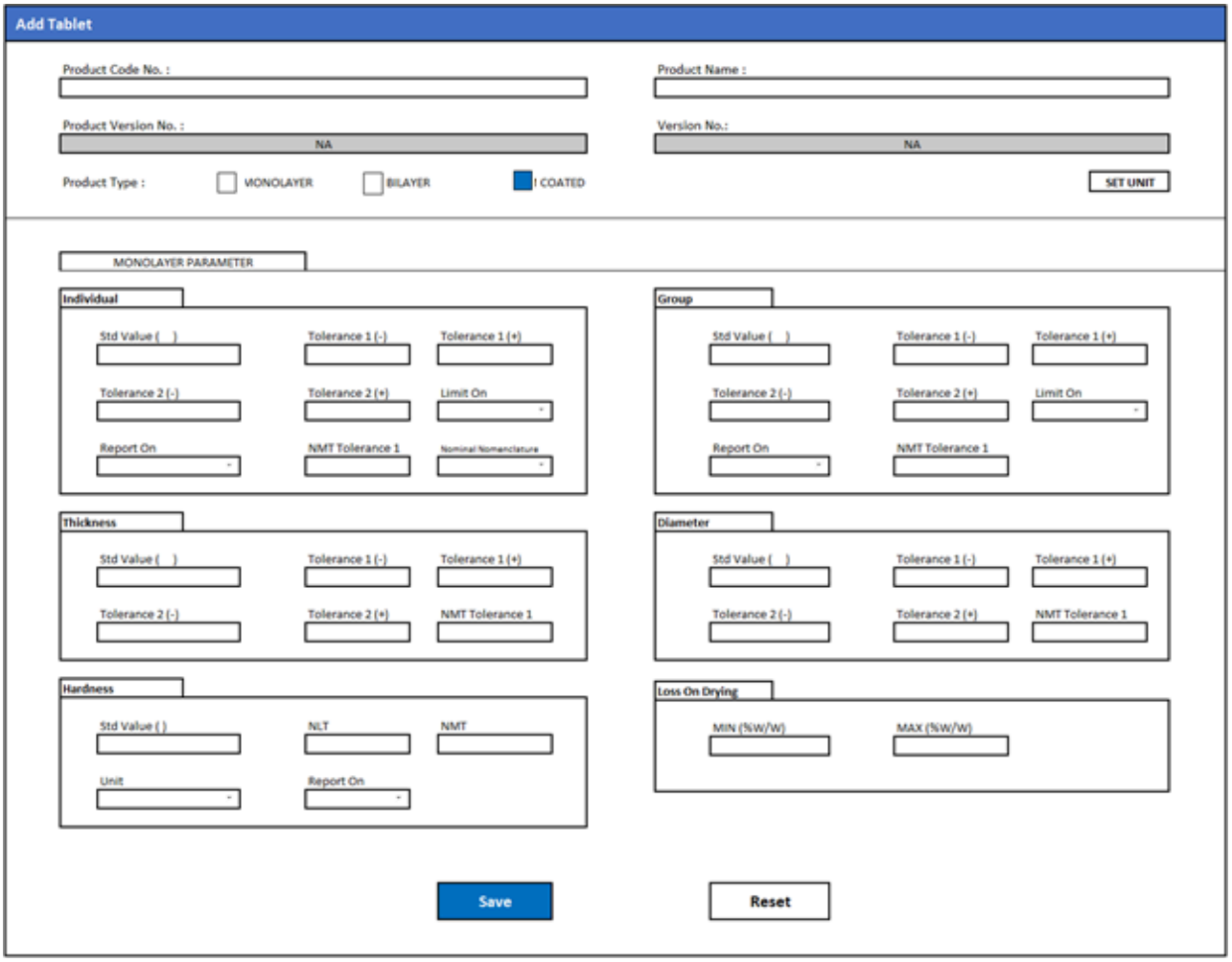
SCREEN 24



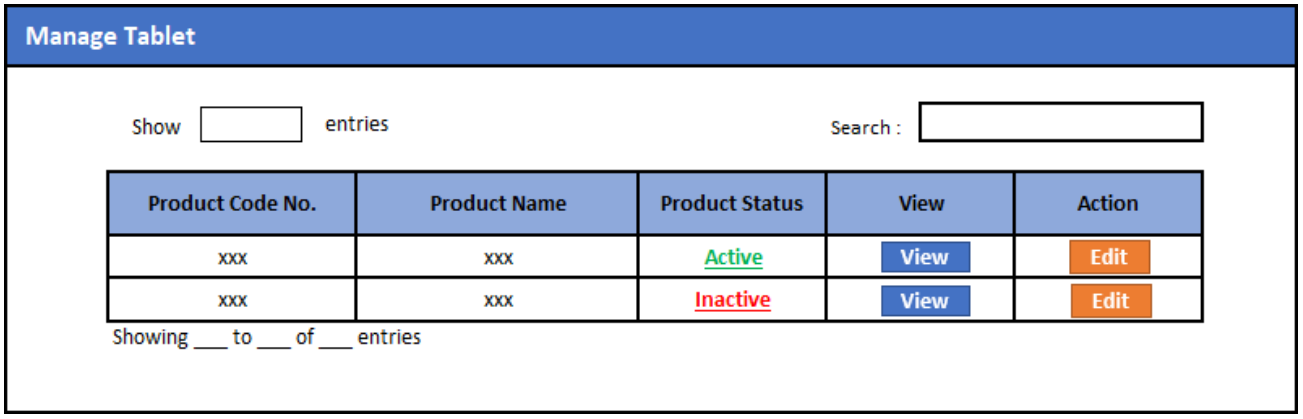
SCREEN 25


Add Tablet
Product Code No. :
Product Name :
Product Version No. :
NA
Version No.:
NA
Product Type :
MONOLAYER
BILAYER
COATED
SET UNIT
Layer 1 Name :
MONOLAYER PARAMETER
Individual
Std Value ( )
Tolerance 1 (-)
Tolerance 1 (+)
Tolerance 2 (-)
Tolerance 2 (+)
Limit On
Report On
NMT Tolerance 1
Nominal Nomenclature
Group
Std Value ( )
Tolerance 1 (-)
Tolerance 1 (+)
Tolerance 2 (-)
Tolerance 2 (+)
Limit On
Report On
NMT Tolerance 1
Thickness
Std Value ( )
Tolerance 1 (-)
Tolerance 1 (+)
Tolerance 2 (-)
Tolerance 2 (+)
NMT Tolerance 1
Diameter
Std Value ( )
Tolerance 1 (-)
Tolerance 1 (+)
Tolerance 2 (-)
Tolerance 2 (+)
NMT Tolerance 1
Hardness
Std Value ( )
NLT
NMT
Unit
Report On
Friability
NMT %
Set Count
Set RPM
Individual Layer-1
Std Value ( )
Tolerance 1 (-)
Tolerance 1 (+)
Tolerance 2 (-)
Tolerance 2 (+)
Limit On
Report On
NMT Tolerance 1
Nominal Nomenclature
Save
Reset

SCREEN 26



SCREEN 27



SCREEN 28

Edit Tablet

Product Code No. : XXX

Product Name : XXX

Product Version No. : NA

Version No.: NA

Product Type : [x] MONOLAYER [ ] BILAYER [ ] COATED

MONOLAYER PARAMETER

Individual

Std Value ( )	Tolerance 1 (-)	Tolerance 1 (+)
XXX	XXX	XXX
Tolerance 2 (-)	Tolerance 2 (+)	Limit On
XXX	XXX	XXX
Report On	NMT Tolerance 1	Nominal Nomenclature
XXX	XXX	XXX

Group

Std Value ( )	Tolerance 1 (-)	Tolerance 1 (+)
XXX	XXX	XXX
Tolerance 2 (-)	Tolerance 2 (+)	Limit On
XXX	XXX	XXX
Report On	NMT Tolerance 1	
XXX	XXX	

Thickness

Std Value ( )	Tolerance 1 (-)	Tolerance 1 (+)
XXX	XXX	XXX
Tolerance 2 (-)	Tolerance 2 (+)	NMT Tolerance 1
XXX	XXX	XXX

Diameter

Std Value ( )	Tolerance 1 (-)	Tolerance 1 (+)
XXX	XXX	XXX
Tolerance 2 (-)	Tolerance 2 (+)	NMT Tolerance 1
XXX	XXX	XXX

Hardness

Std Value ( )	NLT	NMT
XXX	XXX	XXX
Unit	Report On	
XXX	XXX	

Friability

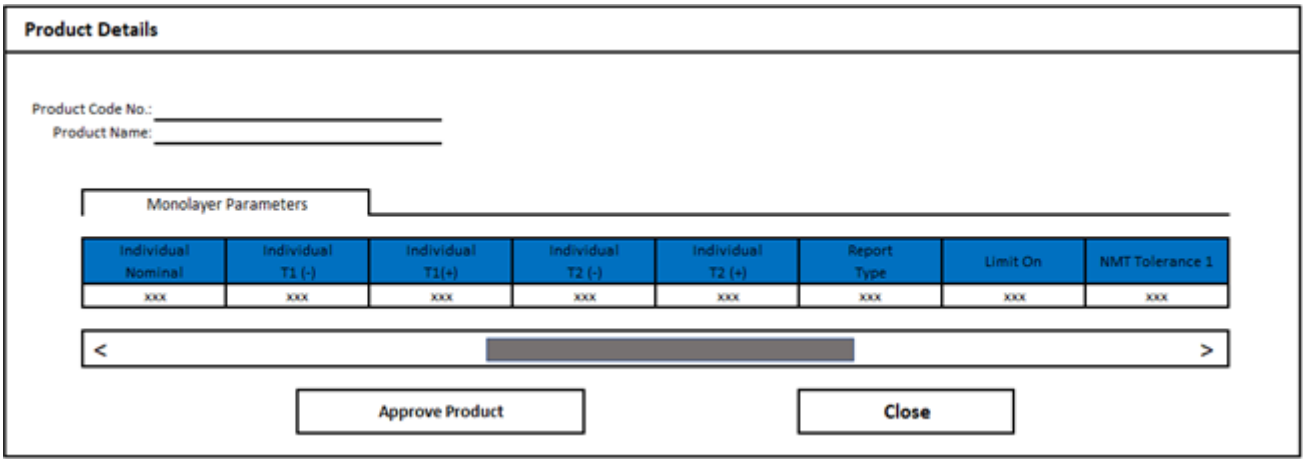
NMT %	Set Count	Set RPM
XXX	XXX	XXX

Loss On Drying

MIN (%W/W)	MAX (%W/W)
XXX	XXX

Save Reset

SCREEN 29



SCREEN 30

Process

Screen 24 , 26 and 27: Add Product (TABLET)

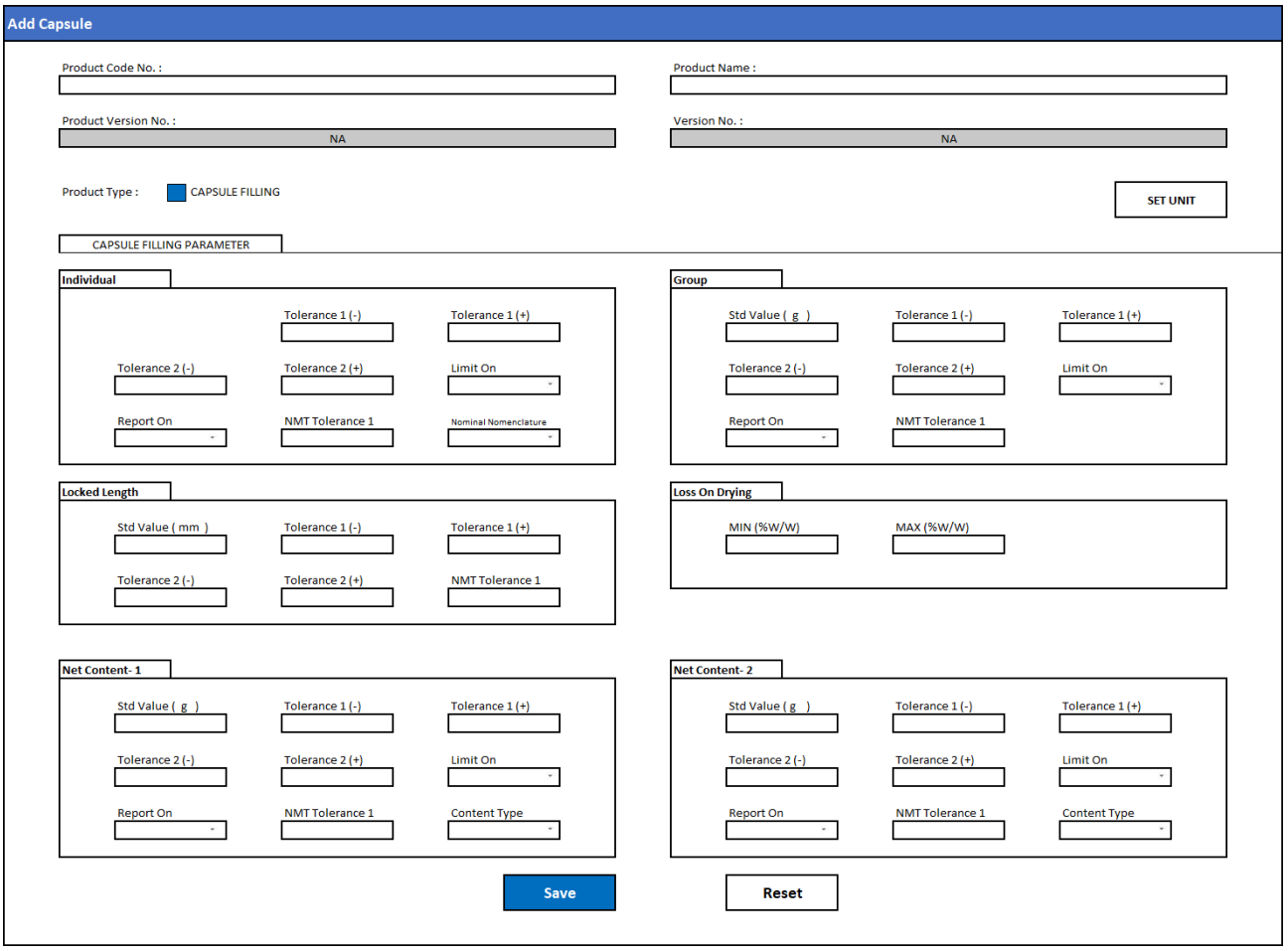
- Enter tablet details (Product Code No., Product Name etc.)
  Data Length: 25 Data type : Alpha-Numeric with special character.
  For Product Name, Data Length: 250 Data type : Alpha-Numeric with special character.
- Select product type (Monolayer, Bilayer, Coated or Granulation).
- Select "Select Unit" to set Unit of Measurement for Individual, Group and Dimension parameters. (Screen 25).
- Unit for Individual Layer 1 will be considered as per unit selected for 'Individual' parameters respectively.
- Fill tolerance details for respective parameters.
- Save tablet details in the system with remark.

Screen 28 ,29 and 30: Manage Product (TABLET)

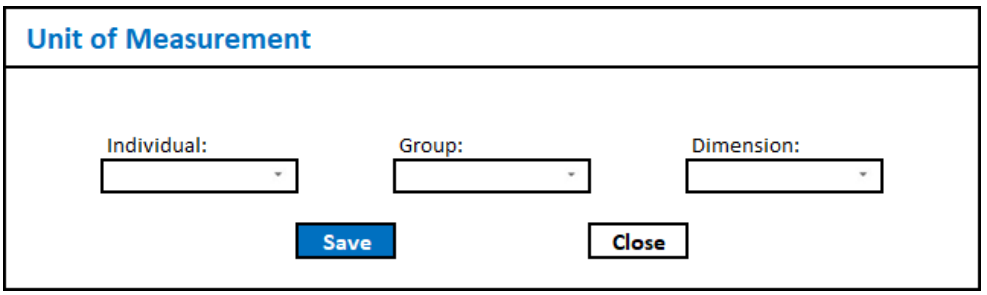
- Product assigned to any cubicle will not be allowed to modify/edit.
- Product status will be displayed as active or inactive.
- Product should be 'Approved (activated)' before assigning to cubicle by authorized user (Activate/ Deactivate right).
- Products which are no more in use can be deactivated.
- Approved product cannot be edited after the first weighment/test is done.
- User will not be allowed to 'Approve/Deactivate' self-added product details in the system.

5.13 PRODUCT MASTER (CAPSULE)

File extension: .ts (type script) Type: Angular Web Form
Purpose: Allows adding and managing product (tablet) details.



SCREEN 31



SCREEN 32

Manage Capsule

Show [ ] entries Search : [ ]

Product Code No.	Product Name	Product Status	View	Action
xxx	xxx	Active	View	Edit
xxx	xxx	Inactive	View	Edit

Showing ___ to ___ of ___ entries

SCREEN 33

Edit Capsule

Product Code No. : xxx
Product Name : xxx
Product Version No. : NA
Version No. : NA
Product Type : CAPSULE FILLING

CAPSULE FILLING PARAMETER

Individual

	Tolerance 1 (-) xxx	Tolerance 1 (+) xxx
Tolerance 2 (-) xxx	Tolerance 2 (+) xxx	Limit On xxx
Report On xxx	NMT Tolerance 1 xxx	Nominal Nomenclature xxx

Group

Std Value (g) xxx	Tolerance 1 (-) xxx	Tolerance 1 (+) xxx
Tolerance 2 (-) xxx	Tolerance 2 (+) xxx	Limit On xxx
Report On xxx	NMT Tolerance 1 xxx	

Locked Length

Std Value (mm) xxx	Tolerance 1 (-) xxx	Tolerance 1 (+) xxx
Tolerance 2 (-) xxx	Tolerance 2 (+) xxx	NMT Tolerance 1 xxx

Loss On Drying

MIN (%W/W) xxx	MAX (%W/W) xxx

Net Content- 1

Std Value (g) xxx	Tolerance 1 (-) xxx	Tolerance 1 (+) xxx
Tolerance 2 (-) xxx	Tolerance 2 (+) xxx	Limit On xxx
Report On xxx	NMT Tolerance 1 xxx	Content Type xxx

Net Content- 2

Std Value (g) xxx	Tolerance 1 (-) xxx	Tolerance 1 (+) xxx
Tolerance 2 (-) xxx	Tolerance 2 (+) xxx	Limit On xxx
Report On xxx	NMT Tolerance 1 xxx	Content Type xxx

Save Reset

SCREEN 34

Product Details

Product Code No. : _____

Product Name : _____

Capsule Filling Parameters

Individual Nominal	Individual T1 Neg	Individual T1 Pos	Individual T2 Neg	Individual T2 Pos	Report Type	Limit On	Nominal Nomenclature

< >

Approve Product Close

SCREEN 35

Screen 31 and 32: Add Product (CAPSULE)

Enter Capsule details (Product Code No., Product name.)

Enter Product Code No.

Data length: 25 Data type: Alpha-Numeric with special character.

Enter Product Name.

Data length: 250 Data type: Alpha-Numeric with special character.

Select "Set Unit" to set Unit of Measurement for Individual, Group and Dimension parameters.

Enter Product parameter details (Std. value, Tolerances etc).

Data Length: 0.00001 to 99999.99999 Numbers with Decimal.

Save Capsule details in the system.

Screen 33 34 and 35 : Manage Product (CAPSULE)

Product assigned to any cubicle will not be allowed to modify/edit.

Product status will be displayed as 'Active' or 'Inactive'.

Product should be 'Approved (activated)' before assigning to cubicle.

Products which are no more in use can be deactivated.

**Note:

1. For 'Individual' parameter 'Std Wt.' value will not be added in product master. 'Tolerance' value to be entered in percentage for Individual, Content-1, Content-2. Empty standard weight can be added in cubicle setting as per batch (refer cubicle setting).

The value of Individual Standard Weight will be calculated in backend with formula as follows:

Case1: Both content

Individual (Std Wt.)= [Content-1 (Std Wt.)+ Content-2 (Std Wt.)+ Empty (Std Wt.)]

Case2: One content

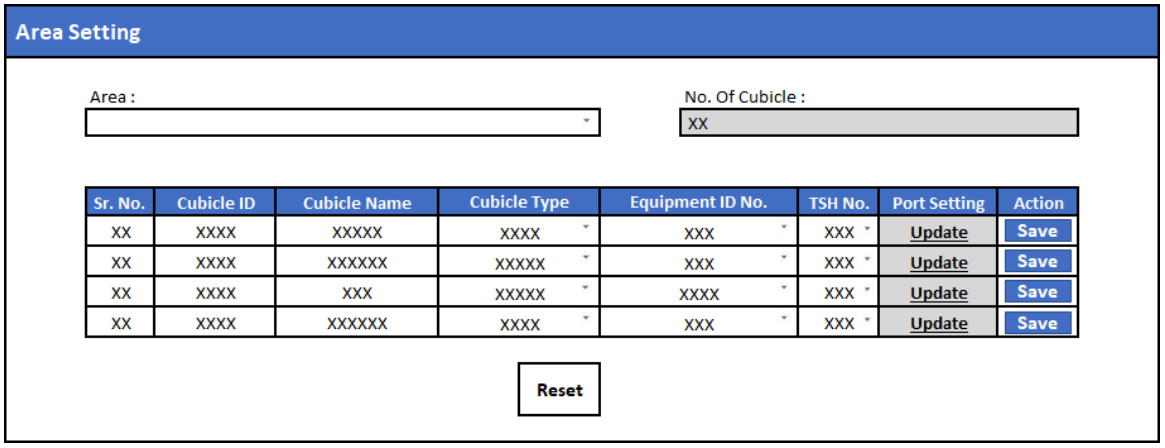
Individual (Std Wt.)= [Content (Std Wt.)+ Empty (Std Wt.)]

Limits will be calculated using, above Standard weight of capsule and percentage entered in product master.

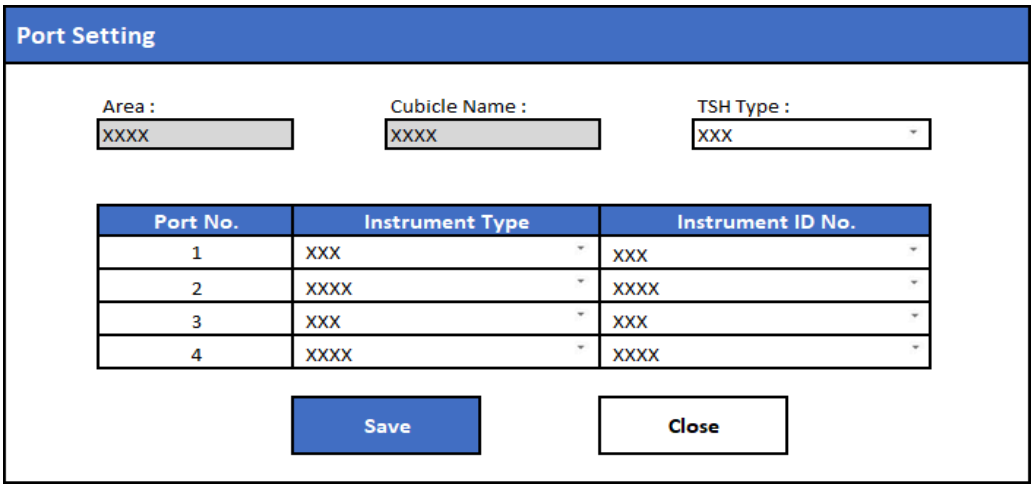
2. If only one tolerance is applicable then add value in Tolerance 2 and add 0 in tolerance 1.

5.14 AREA SETTING

File extension: .ts (type script) Type: Angular Web Form
Purpose: Allows managing area setting details.



SCREEN 36



SCREEN 37

Process

Screen 36 : Area Setting

- Enter Area details like Cubicle name, Cubicle type etc.
- Equipment ID No. to be selected from dropdown list.
- Select the TSH No. from dropdown list.
- Save the details first then perform Port Setting for Cubicle where instrument will be assigned to respective TSH.

Screen 37 : Port Setting

- Select TSH type.
- According to the TSH type, ports will get enabled.

- Assign Instrument to the respective port.

*Note: In Port Setting 'Instrument Type' and 'Instrument ID No.' can be save as 'None'.

5.15 CUBICLE SETTING

File extension: .ts (type
script) Type: Angular Web
Form
Purpose: Allows managing cubicle setting details.

Cubicle Setting

Area :
XXXXX

Sr. No.	Cubicle Name	Cubicle Type	TSH No.	Product Code No.	Batch No.	Batch Status	Action
XX	XXX	XXX	XXX	XXXX	XXX	Running	Show Detail
XX	XXX	XXX	XXX	XXXX	XXX	Assigned	Show Detail
XX	XXX	XXX	XXX	XXXX	XXX	Not Started	Show Detail
XX	XXX	XXX	XXX	XXXX	XXX	Resumed	Show Detail
XX	XXX	XXX	XXX	XXXX	XXX	Paused	Show Detail
XX	XXX	XXX	XXX	XXXX	XXX	No Batch	Show Detail

SCREEN 38

Cubicle Setting for Compression and Coating

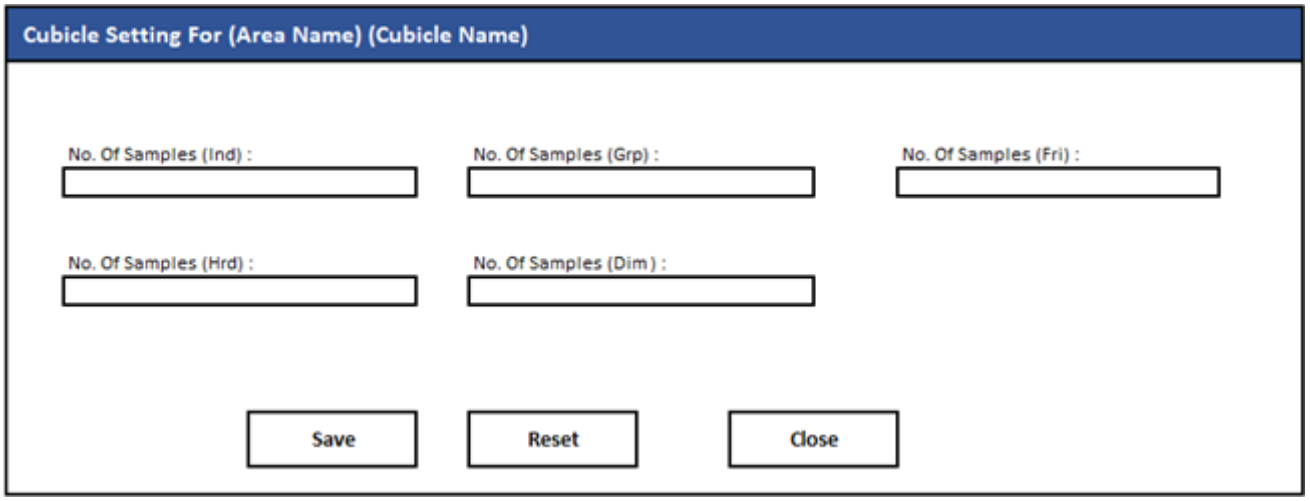
Cubicle Setting For (Area Name) (Cubicle Name)

Cubicle Type :
Equipment ID No. :

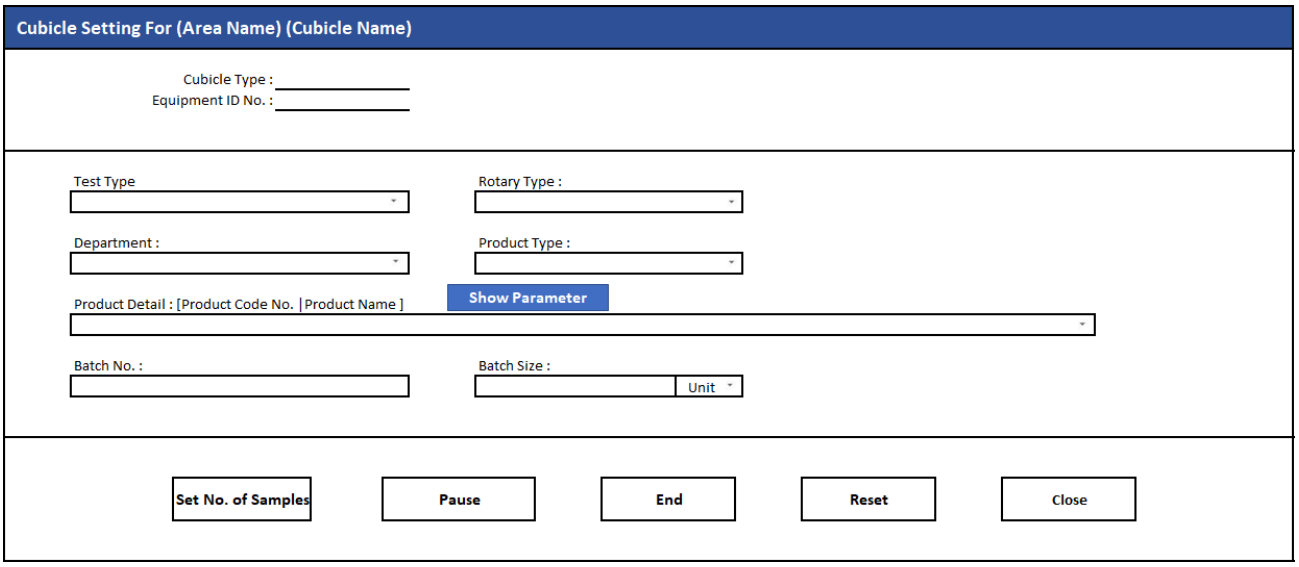
Test Type
Rotary Type :
Department :
Product Type :
Product Detail : [Product Code No. | Product Name]
Show Parameter
Batch No. :
Batch Size :
Unit

Set No. of Samples | Update | Pause | End | Reset | Close

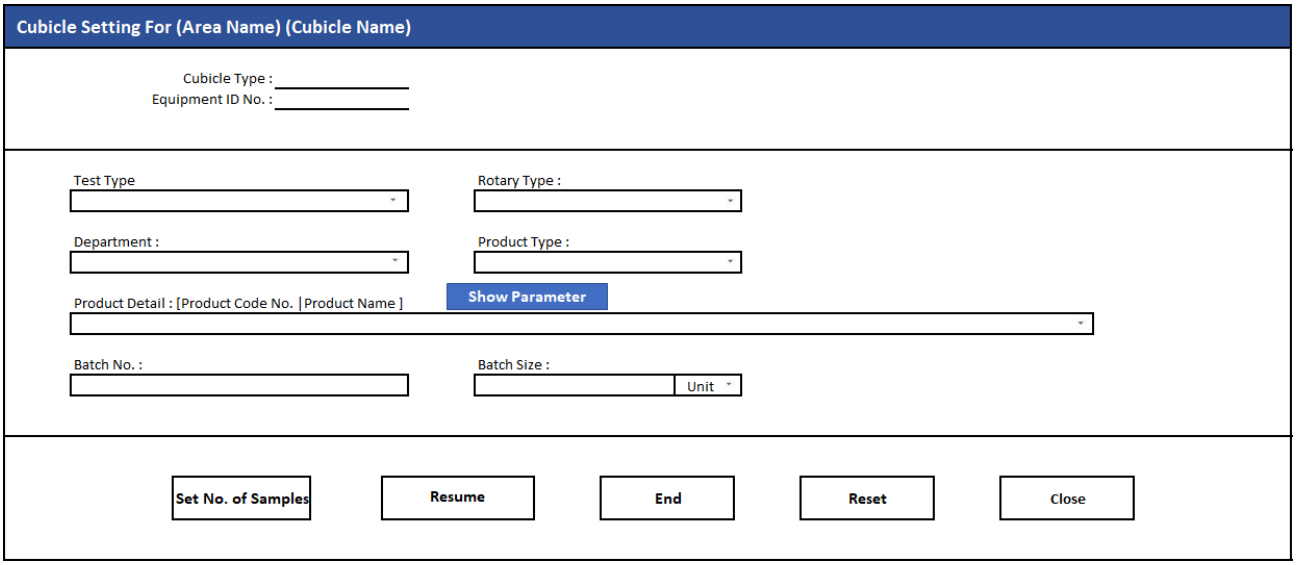
SCREEN 39



SCREEN 40



SCREEN 41



SCREEN 42

Process

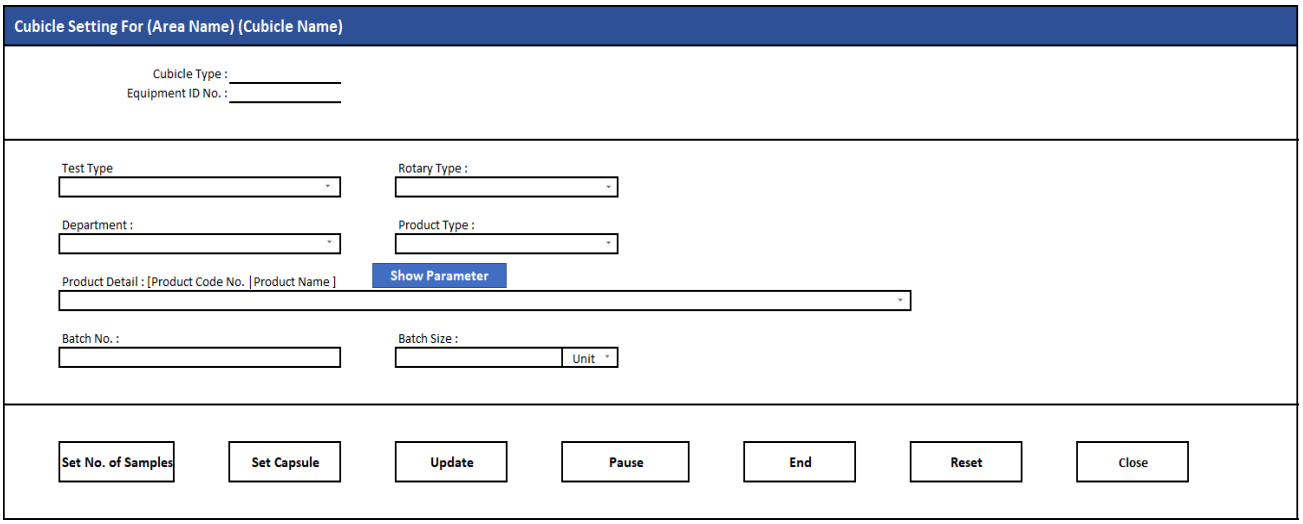
Screen 38 : Cubicle Setting

- Select Area.
- List of cubicles will display whose area setting has been done.
- Click on show detail where batch details will be visible.

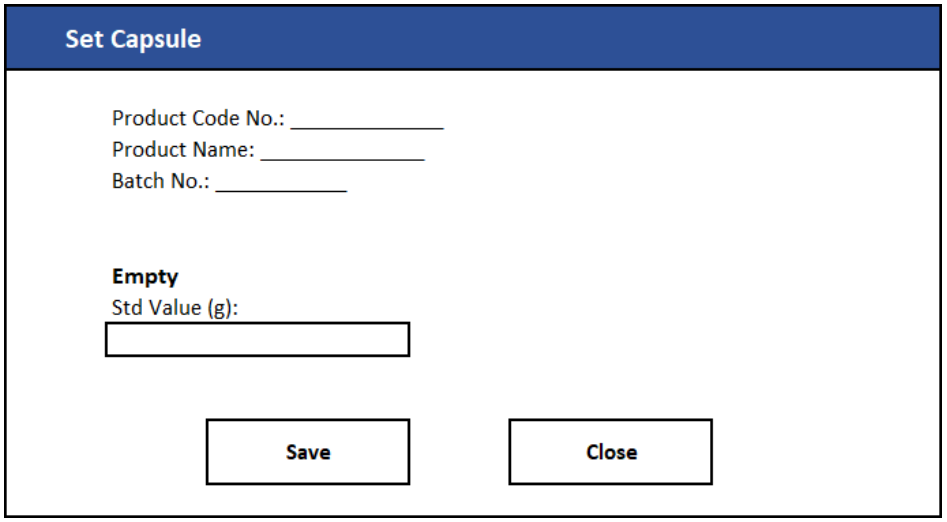
Screen 39 , 40, 41, and 42 : Batch Start/End/Pause/Resume/Close

- Select Test Type (Initial/Inprocess).
- Select Rotary Type (NA/Double).
- Select Department.
- Select Product Type.
- Select Product to be assigned to the cubicle.
- Enter Batch Number.
- Enter Batch Size.
- Select 'Set No. of Samples' Add 'No. of Samples' as per the test. User cannot proceed without entering no of samples. User can add '0' as no. of samples. (User have to add at least 1 test 'No. of Samples' above 0.)
- Batch can be paused in case of any breakdown between the running batch(es). Once a batch is paused, user can shift it to another cubicle.
- Paused batch can be resumed and batch can be started where it was left.
- Batch end will release the batch and will allow setting new batch.

For Capsule filling



SCREEN 43

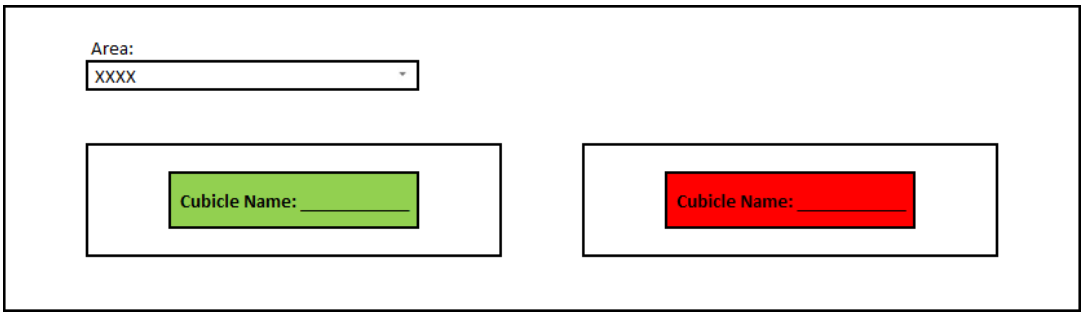


SCREEN 44

*Note: In Capsule filling area user will add 'Standard Weight' of 'Empty', to be used to calculate standard weight of whole capsule (Individual's standard weight)(refer 'Add Product Capsule')

5.16 CUBICLE /TSH STATUS

File extension: .ts (type
script) Type: Angular Web
Form
Purpose: Allows managing cubicle/TSH status details.



SCREEN 45

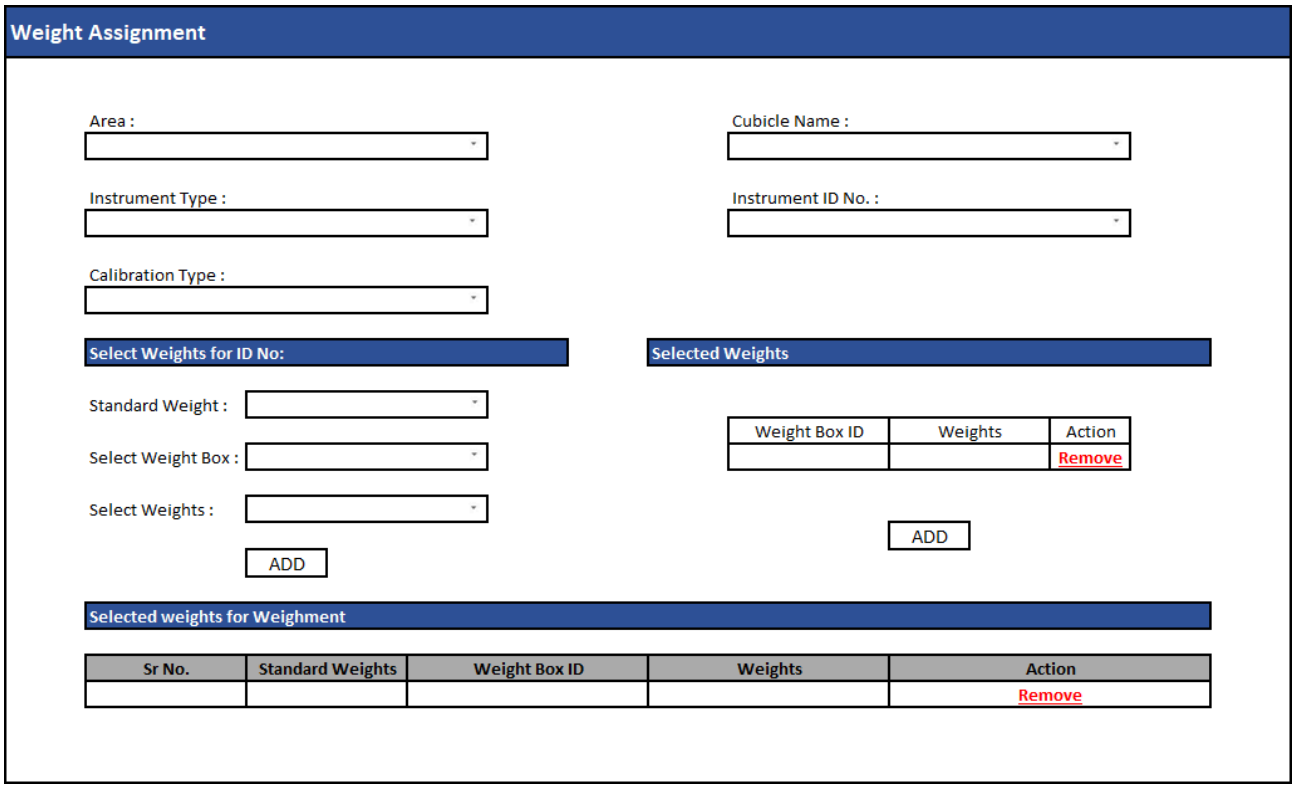
Process

Screen 45 : Cubicle/TSH status

- It displays the cubicle name in green where weighment/test is ongoing.
- It displays the cubicle name in red where no weighment/test is ongoing.

5.17 WEIGHT ASSIGNMENT

File extension: .ts (type script) Type: Angular Web Form
Purpose: Allows managing weight assignment standards details.



SCREEN 46

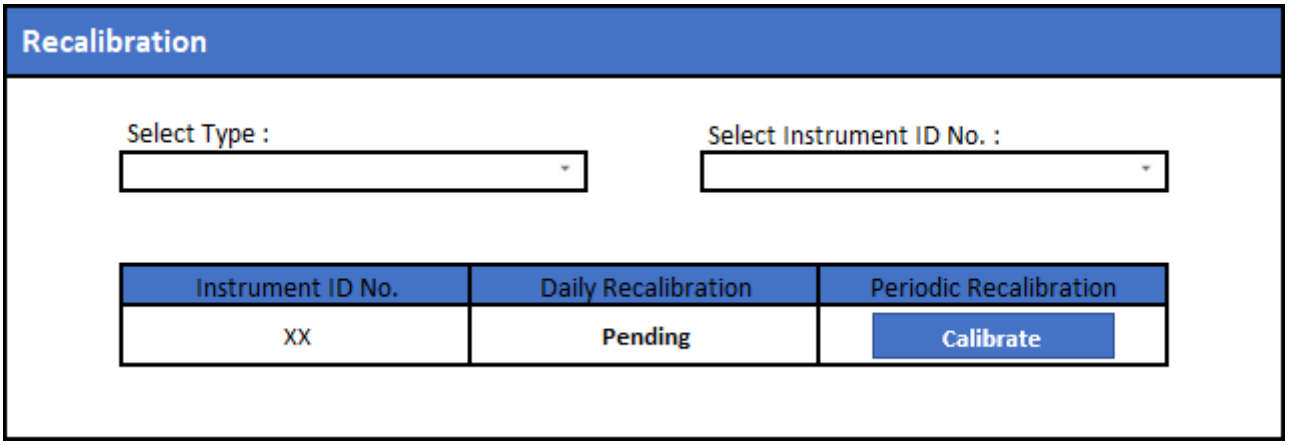
Process

Screen 46 : Set Weight Assignment

- It displays standard weights added for selected Instrument assigned to the cubicle.
- Weights from calibration box should be assigned to standard weights.
- Weight must be assigned before proceeding for calibration of Instrument.
- If calibration is in process for a particular active balance assigned in the cubicle of an area, then that Area Name/Cubicle Name will not reflect in dropdown list for Weight Assignment.

5.21 RECALIBRATION SETTING

- File extension: .ts (type script) Type: Angular Web Form
  Purpose: Allows managing recalibration setting.



SCREEN 47

Process

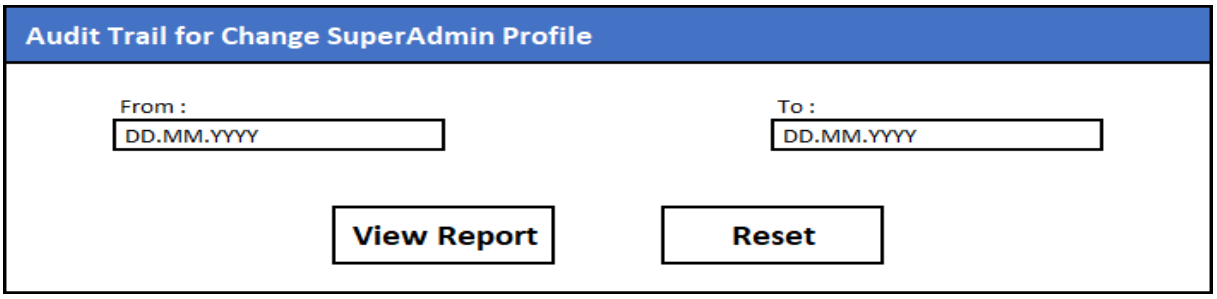
Screen 47 : Recalibration

- Recalibration can be set for Instrument which needs to be calibrated again before its next due date.
- Instrument ID No. list will be displayed according to the selected type.
- For recalibration, scheduled calibration should be performed first.

5.18 AUDIT TRAIL

File extension: .ts (type script) Type: Angular Web Form
Purpose: Allows viewing audit trail reports.

*Note : To view Audit Trail report user can select date range of maximum 7 days.



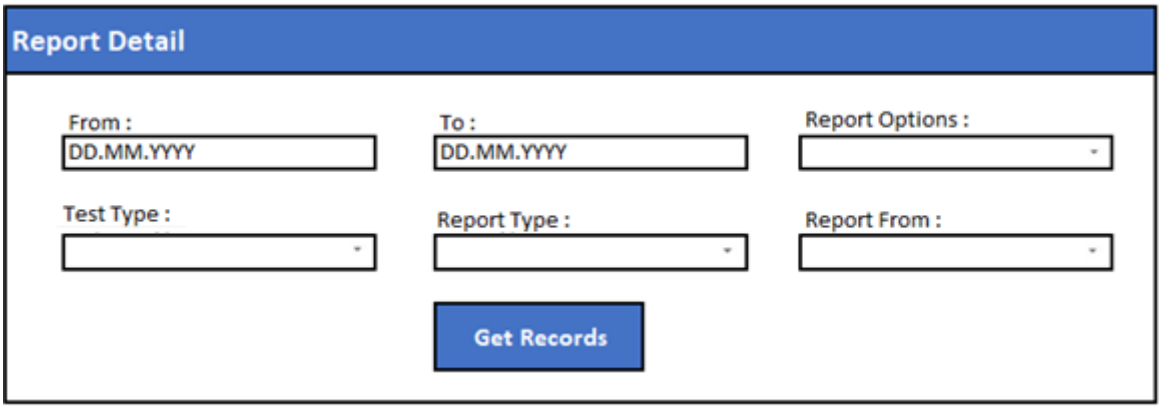
SCREEN 48

- Select From Date and To Date.
- Click on 'View Report' button to view Audit trail report for selected input.
- Click on 'Reset' button to reset the form.

*Note : Audit Trail reports for all master modules are generated in respective audit trail modules

5.19 TABLET REPORT DETAILS

File extension: .ts (type script) Type: Angular Web Form
Purpose: Allows viewing tablet reports.



SCREEN 49

Screen 49 : Report Detail TABLET

Select Date Range.

Select 'Report Options' from dropdown list: Individual, Group, Thickness, Diameter, Hardness, Friability, LOD, Individual Layer 1.

Select 'Test Type' from dropdown list: Initial or Inprocess.

Select 'Report Type' from dropdown list: Complete or Incomplete.

Select 'Report From' from dropdown; Current or Archive.

Click on 'Get Records' button.

List of records which comes under selected input will be displayed.

**Note:

For weighment tests, digits after decimal point will be as per least count entered in Balance Master thought-out the report. Values on Graph will always be in 4 digits irrespective of least count.

For Dimension and Hardness tests, digits after decimal point will be 2. Values on Graph will always be in 2 digits

For Loss on Drying and Friability decimal point will be 3.

Cubicle ID will be displayed as per entered in area setting.

Tests Reports can be verified anytime but printing of report is allowed after verification only.

Header table will be repeated in case of multiple pages report.

Batch No	BFG Code No.	Product Name	Date	Time	Side	User Name	Print No	Action	OPC
PB20737	31005860	ABAC (SULFATE) LAMI DISP TAB 120/60 mg	04.01.2023	13:01:58	LHS	Samadhan Sonawale	1	View	POST TO OPC
PB20737	31005860	ABAC (SULFATE) LAMI DISP TAB 120/60 mg	04.01.2023	13:11:24	RHS	Samadhan Sonawale	1	View	POST TO OPC
PB20702	31004331	AMLODIPINE BESYLATE 10 mg TABLETS USP	04.01.2023	17:30:21	NA	Ravindra Chavan	1	View	POST TO OPC
PB20737	31005860	ABAC (SULFATE) LAMI DISP TAB 120/60 mg	04.01.2023	20:05:33	LHS	Narendra Mhatre	1	View	POST TO OPC

Showing 1 to 10 of 435 entries First Previous 1 2 3 4 5 ... 44 Next Last

User can send Reports data from software to OPC tags by clicking on 'POST TO OPC'.

Post To OPC: This is manual provision to send data to OPC tags for selected report. Data in report will be posted to OPC tags related to instrument used to generate the report.

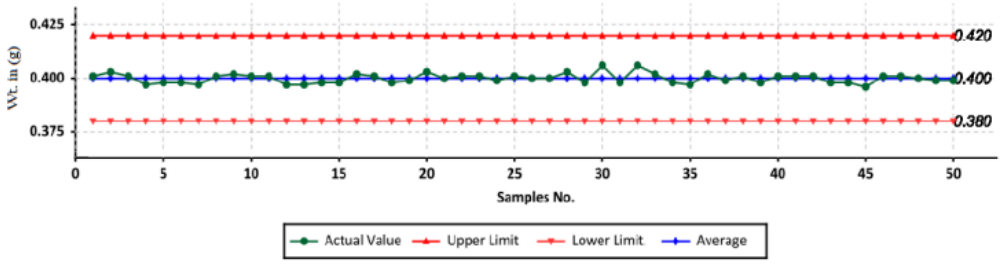
COMMPRESSION

INDIVIDUAL WEIGHT VARIATION REPORT

inventia

INITIAL INDIVIDUAL WEIGHT VARIATION REPORT

Product Name	Paracetamol Tablet		
Batch No.	BT 20	**Date**	01/Feb/2023
Product Code No.	PRD 18	**Start Time**	08:15:06
No. of Samples	50	**End Time**	08:25:06
Equipment ID No.	EQ 65	**Cubicle ID**	SP01
Balance ID No.	BCCD 9	**Performed By**	Sail
Standard Weight of Tablets (g)	0.4000	**Side**	LHS
Std. Limit 1 (g)	NA		NA
Std. Limit 2 (g)	None of tablets by ±5.00 %		0.3800 - 0.4200



Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)
1	0.4010	2	0.4030	3	0.4010	4	0.3970	5	0.3980
6	0.3980	7	0.3970	8	0.4010	9	0.4020	10	0.4010
11	0.4010	12	0.3970	13	0.3970	14	0.3980	15	0.3980
16	0.4020	17	0.4010	18	0.3980	19	0.3990	20	0.4030
21	0.4000	22	0.4010	23	0.4010	24	0.3990	25	0.4010
26	0.4000	27	0.4000	28	0.4030	29	0.3980	30	0.4060
31	0.3980	32	0.4060	33	0.4020	34	0.3980	35	0.3970
36	0.4020	37	0.3990	38	0.4010	39	0.3980	40	0.4010
41	0.4010	42	0.4010	43	0.3980	44	0.3980	45	0.3960
46	0.4010	47	0.4010	48	0.4000	49	0.3990	50	0.3990

Test Results

Average Weight of Tablets (g)	0.4000	**Standard Deviation**	0.0022
Minimum Weight (g)	0.3960	**No. of Tablets Above Limit (1)**	NA
Maximum Weight (g)	0.4060	**No. of Tablets Below Limit (1)**	NA
Minimum %	1.00	**No. of Tablets Above Limit (2) 0.4200**	0
Maximum %	1.50	**No. of Tablets Below Limit (2) 0.3800**	0

Result: Complies

Checked By : Raj
Date : 01/Feb/2023

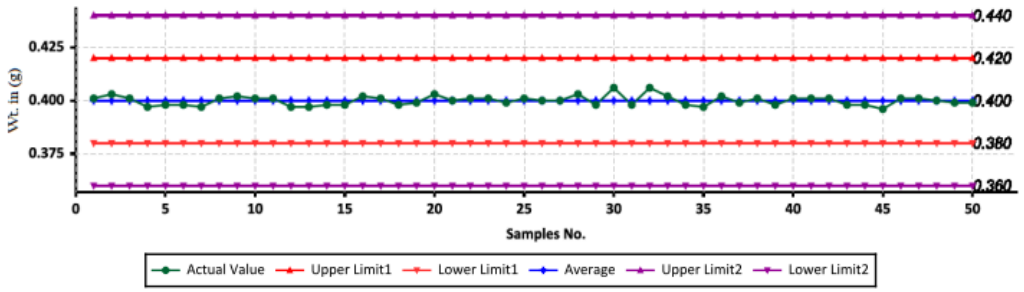
This document is Confidential, electronically generated by Raj 20/Feb2023 10:07:39

INDIVIDUAL WEIGHT VARIATION REPORT (Two Tolerance)

inventia

INITIAL INDIVIDUAL WEIGHT VARIATION REPORT

Product Name	Paracetamol Tablet		
Batch No.	BT 20	**Date**	01/Feb/2023
Product Code No.	PRD 18	**Start Time**	08:15:06
No. of Samples	50	**End Time**	08:25:06
Equipment ID No.	EQ 65	**Cubicle ID**	SP01
Balance ID No.	BCCD 9	**Performed By**	Sail
Standard Weight of Tablets (g)	0.4000	**Side**	LHS
Std. Limit 1 (g)	NMT 2 tablets by ±5.00 %		0.3800 - 0.4200
Std. Limit 2 (g)	None of tablets by ±10.00 %		0.3600 - 0.4400



Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)
1	0.4010	2	0.4030	3	0.4010	4	0.3970	5	0.3980
6	0.3980	7	0.3970	8	0.4010	9	0.4020	10	0.4010
11	0.4010	12	0.3970	13	0.3970	14	0.3980	15	0.3980
16	0.4020	17	0.4010	18	0.3980	19	0.3990	20	0.4030
21	0.4000	22	0.4010	23	0.4010	24	0.3990	25	0.4010
26	0.4000	27	0.4000	28	0.4030	29	0.3980	30	0.4060
31	0.3980	32	0.4060	33	0.4020	34	0.3980	35	0.3970
36	0.4020	37	0.3990	38	0.4010	39	0.3980	40	0.4010
41	0.4010	42	0.4010	43	0.3980	44	0.3980	45	0.3960
46	0.4010	47	0.4010	48	0.4000	49	0.3990	50	0.3990

Test Results

Average Weight of Tablets (g)	0.4000	**Standard Deviation**	0.0022
Minimum Weight (g)	0.3960	**No. of Tablets Above Limit (1) 0.4200**	0
Maximum Weight (g)	0.4060	**No. of Tablets Below Limit (1) 0.3800**	0
Minimum %	1.00	**No. of Tablets Above Limit (2) 0.4400**	0
Maximum %	1.50	**No. of Tablets Below Limit (2) 0.3600**	0

Result: Complies

Checked by : Raj
Date : 01/Feb/2023

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INCOMPLETE INDIVIDUAL WEIGHT VARIATION REPORT

inventia

INITIAL INDIVIDUAL WEIGHT VARIATION REPORT

Product Name	Paracetamol Tablet		
Batch No.	BT 20	**Date**	01/Feb/2023
Product Code No.	PRD 18	**Start Time**	08:15:06
No. of Samples	50	**End Time**	08:25:06
Equipment ID No.	EQ 65	**Cubicle ID**	SP01
Balance ID No.	BCCD 9	**Performed By**	Sail
Standard Weight of Tablets (g)	0.4000	**Side**	LHS
Std. Limit 1 (g)	NA		NA
Std. Limit 2 (g)	None of tablets by ±5.00 %		0.3800 - 0.4200

Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)
1	0.4010	2	0.4030	3	0.4010	4	0.3970	5	0.3980
6	0.3980	7	0.3970	8	0.4010	9	0.4020	10	0.4010
11	0.4010	12	0.3970	13	0.3970	14	0.3980	15	0.3980

Result: Aborted Test

TEST

Checked By : Raj
Date : 01/Feb/2023

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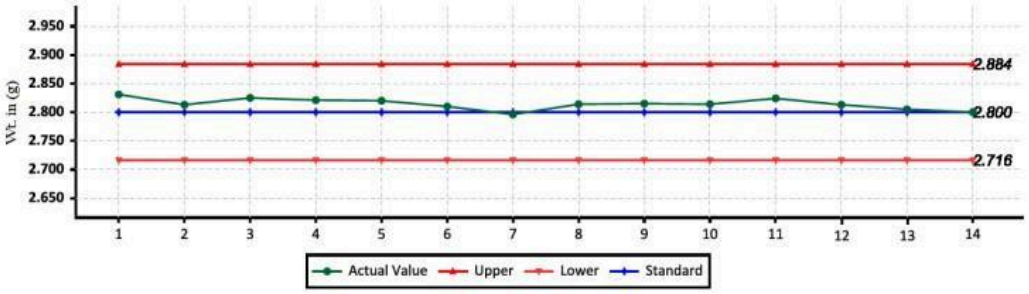
GROUP WEIGHT VARAIATION REPORT

inventia

INPROCESS GROUP WEIGHT VARIATION REPORT

Product Name	Paracetamol Tablets		
Batch No.	03	**Balance ID No.**	TS/356
Product Code No.	PRD 15	**Equipment ID No.**	EQ 3
Std. Group Wt. of Tablets (g)	2.8000	**Cubicle ID**	SP01
Std. Lower Limit (g)	2.7160(-3.00%)	**Std. Upper Limit (g)**	2.8840(+3.00%)



Test	Date	Time	Side	No. of Samples Tested	Group Weight (g)	Average Weight (g)	Test Result	Performed By
1.	01/Feb/2023	20:35:09	Single	20	2.8310	0.1415	Complies	Sagar Patel
2.	01/Feb/2023	21:01:29	Single	20	2.8130	0.1407	Complies	Sagar Patel
3.	01/Feb/2023	21:32:04	Single	20	2.8250	0.1413	Complies	Sagar Patel
4.	01/Feb/2023	21:41:49	Single	20	2.8210	0.1416	Complies	Sagar Patel
5.	01/Feb/2023	22:02:03	Single	20	2.8200	0.1410	Complies	Sagar Patel
6.	01/Feb/2023	22:23:55	Single	20	2.8100	0.1405	Complies	Sagar Patel
7.	02/Feb/2023	03:54:35	Single	20	2.7960	0.1398	Complies	Sagar Patel
8.	02/Feb/2023	04:21:36	Single	20	2.8140	0.1407	Complies	Sagar Patel
9.	02/Feb/2023	04:54:01	Single	20	2.8150	0.1408	Complies	Sagar Patel
10.	02/Feb/2023	05:21:37	Single	20	2.8140	0.1407	Complies	Sagar Patel
11.	02/Feb/2023	05:53:43	Single	20	2.8240	0.1412	Complies	Sagar Patel
12.	02/Feb/2023	06:23:50	Single	20	2.8130	0.1407	Complies	Sagar Patel
13.	02/Feb/2023	06:54:24	Single	20	2.8050	0.1403	Complies	Sagar Patel
14.	02/Feb/2023	07:21:26	Single	20	2.8000	0.1400	Complies	Sagar Patel

Test Results

Average Group Wt. of Tablets (g)	2.8143	**Average Wt. of Tablets (g)**	0.1408
Min Group Wt. of Tablets (g)	2.7960	**Min Wt. of Tablets (g)**	0.1398
Max Group Wt. of Tablets (g)	2.8310	**Max Wt. of Tablets (g)**	0.1416
No. of Samples Below Limit	0	**No. of Samples Above Limit**	0

Result: Complies

Checked By : Sayli Patel
Date : 05/Feb/2023

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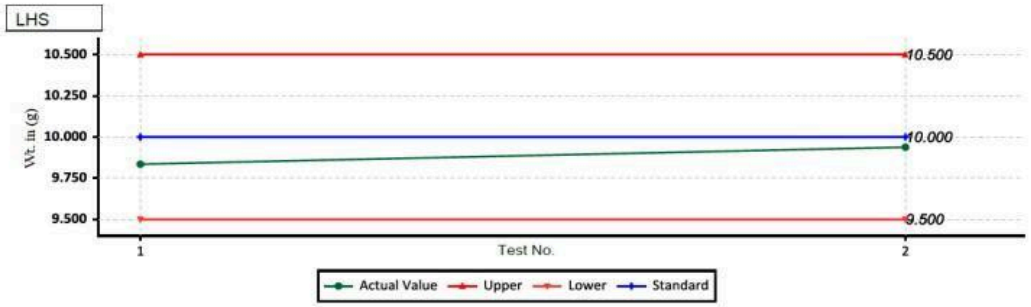
GROUP WEIGHT VARIATION REPORT (Double Rotary)

inventia

INITIAL GROUP WEIGHT VARIATION REPORT

Product Name	Paracetamol Tablets		
Batch No.	BT 121	**Balance ID No.**	BCD 6
Product Code No.	PRD 12	**Equipment ID No.**	EQ 26
Std. Group Wt. of Tablets (g)	10.0000	**Cubicle ID**	SP01
Std. Lower Limit (g)	9.5000(-0.50%)	**Std. Upper Limit (g)**	10.5000(+0.50%)



Test	Date	Time	Side	No. of Samples Tested	Group Weight (g)	Average Weight (g)	Test Result	Performed By
1.	20/Jan/2023	10:25:06	LHS	20	9.8350	0.4918	Complies	Raj
2.	20/Jan/2023	10:26:24	RHS	20	10.1260	0.5063	Complies	Raj
3.	20/Jan/2023	12:16:55	LHS	20	9.9380	0.4969	Complies	Raj
4.	20/Jan/2023	12:17:10	RHS	20	10.1100	0.5055	Complies	Raj

Test Results

Average Group Wt. of Tablets (g)	10.0022	**Average Wt. of Tablets (g)**	0.5001
Min Group Wt. of Tablets (g)	9.8350	**Min Wt. of Tablets (g)**	0.4918
Max Group Wt. of Tablets (g)	10.1260	**Max Wt. of Tablets (g)**	0.5063
No. of Samples Below Limit	0	**No. of Samples Above Limit**	0

Result: Complies

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Date : 05/Feb/2023

Page 1 of 1

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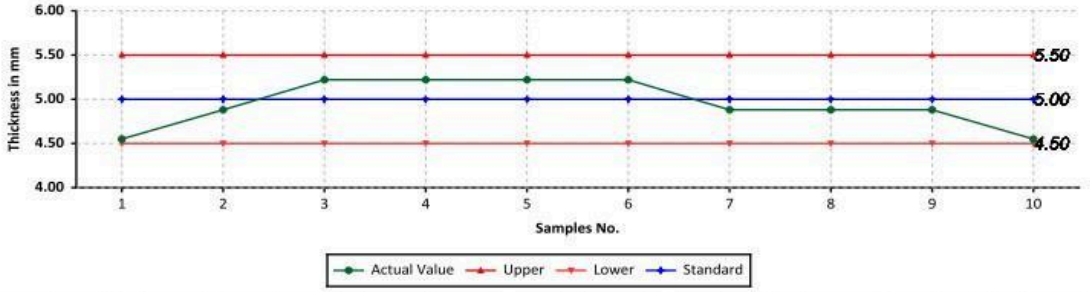
**Note: If any of the Test results is Not Complies then 'Result' will be Not Complies.

THICKNESS VARIATION REPORT (Hardness Tester)

inventia

INITIAL THICKNESS VARIATION REPORT

Product Name	Paracetamol Tablets		
Batch No.	BTH123	**Date**	19/Aug/2023
Product Code No.	BFG - 101	**Start Time**	14:16:32
No. of Samples	10	**End Time**	14:23:32
Equipment ID No.	EQP123	**Cubicle ID**	SP01
Hardness Tester ID No.	VCN-202	**Performed By**	Sail
Standard Thickness (mm)	5.00	**Side**	LHS
Std. Lower Limit (mm)	4.50	**Std. Upper Limit (mm)**	5.50



Sample No.	Thickness (mm)	Sample No.	Thickness (mm)	Sample No.	Thickness (mm)	Sample No.	Thickness (mm)	Sample No.	Thickness (mm)
1	4.55	2	4.88	3	5.22	4	5.22	5	5.22
6	5.22	7	4.88	8	4.88	9	4.88	10	4.55

Test Results

Average Thickness (mm)	4.95	**Standard Deviation**	0.27
Minimum Thickness (mm)	4.55	**No. of Tablets Below Limit**	0
Maximum Thickness (mm)	5.22	**No. of Tablets Above Limit**	0

Result: Complies

Checked By : kumkum
Date : 19/Aug/2023

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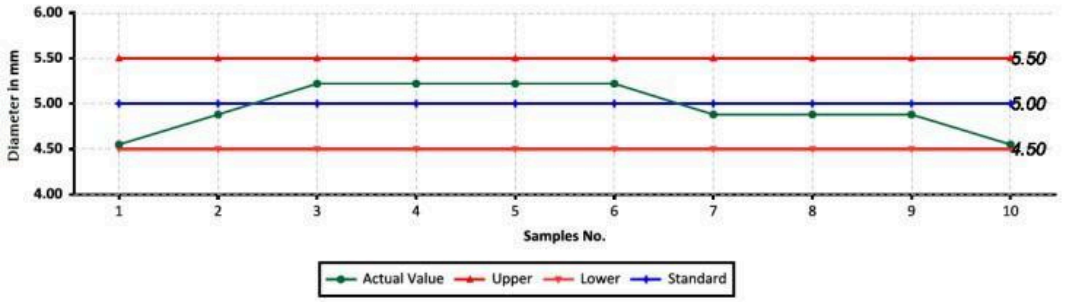
DIAMETER VARIATION REPORT (Hardness Tester)

inventia

INPROCESS DIAMETER VARIATION REPORT

Product Name	Paracetamol Tablets		
Batch No.	BTH123	**Date**	19/Aug/2023
Product Code No.	BFG - 101	**Start Time**	14:16:32
No. of Samples	10	**End Time**	14:23:32
Equipment ID No.	EQP123	**Cubicle ID**	SP01
Hardness Tester ID No.	VCN-202	**Performed By**	Sail
Standard Diameter (mm)	5.00	**Side**	LHS
Std. Lower Limit (mm)	4.50	**Std. Upper Limit (mm)**	5.50



Sample No.	Diameter (mm)	Sample No.	Diameter (mm)	Sample No.	Diameter (mm)	Sample No.	Diameter (mm)	Sample No.	Diameter (mm)
1	4.55	2	4.88	3	5.22	4	5.22	5	5.22
6	5.22	7	4.88	8	4.88	9	4.88	10	4.55

Test Results

Average Diameter (mm)	4.95	**Standard Deviation**	0.27
Minimum Diameter (mm)	4.55	**No. of Tablets Below Limit**	0
Maximum Diameter (mm)	5.22	**No. of Tablets Above Limit**	0

Result: Complies

Checked By : kumkum
Date : 19/Aug/2023

Page 1 of 1

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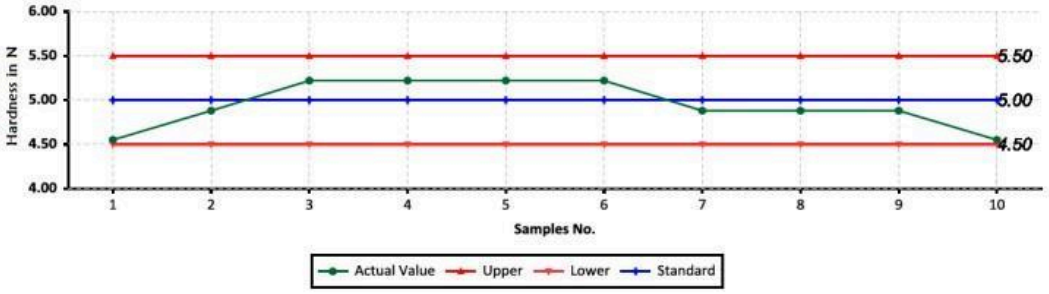
HARDNESS VARIATION RECORD

inventia

INITIAL HARDNESS VARIATION REPORT

Product Name	Paracetamol Tablets		
Batch No.	BTH123	**Date**	19/Aug/2023
Product Code No.	BFG - 101	**Start Time**	14:16:32
No. of Samples	10	**End Time**	14:23:32
Equipment ID No.	EQP123	**Cubicle ID**	SP01
Hardness Tester ID No.	VCN-202	**Performed By**	Sail
Standard Hardness(N)	5.00	**Side**	LHS
Std. Lower Limit (N)	4.50	**Std. Upper Limit (mm)**	5.50



Sample No.	Hardness (N)	Sample No.	Hardness (N)	Sample No.	Hardness (N)	Sample No.	Hardness (N)	Sample No.	Hardness (N)
1	4.55	2	4.88	3	5.22	4	5.22	5	5.22
6	5.22	7	4.88	8	4.88	9	4.88	10	4.55

Test Results

Average Hardness (N)	4.95	**Standard Deviation**	0.27
Minimum Hardness (N)	4.55	**No. of Tablets Below Limit**	0
Maximum Hardness (N)	5.22	**No. of Tablets Above Limit**	0

Result: Complies

Checked By : kumkum
Date : 19/Aug/2023

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FRIABILITY TEST REPORT (SINGLE ROTARY)

inventia

INITIAL FRIABILITY TEST REPORT

Product Name	Paracetamol Tablet		
Batch No.	Batch_3303	**Date**	21/Jan/2023
Product Code No.	33033	**Start Time**	16:47:13
Equipment ID No.	763	**End Time**	16:52:15
Friabilator ID No.	14962	**Cubicle ID**	SP01
Set Count	100	**Set RPM**	25
Std. Limit NMT (% W/W)	1.00	**Performed By**	Sail

Test Results

Actual Count	100	**Actual RPM**	25

Side	**Single**
Initial Weight of Samples	2.540
Weight After Test	2.530
Friability (%)	0.390

Result: Complies

Checked By : kanchan
Date : 21/Jan/2023

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FRIABILITY TEST REPORT (DOUBLE ROTARY)

inventia

INPROCESS FRIABILITY TEST REPORT

Product Name	Paracetamol Tablet		
Batch No.	Batch_3303	**Date**	21/Jan/2023
Product Code No.	33033	**Start Time**	16:47:13
Equipment ID No.	763	**End Time**	16:52:15
Friabilator ID No.	14962	**Cubicle ID**	SP01
Set Count	100	**Set RPM**	25
Std. Limit NMT (% W/W)	1.00	**Performed By**	Sail

Test Results

Actual Count	100	**Actual RPM**	25

Side	**LHS**	**Side**	**RHS**
Initial Weight of Samples	2.540	**Initial Weight of Samples**	2.540
Weight After Test	2.530	**Weight After Test**	2.530
Friability (%)	0.390	**Friability (%)**	0.390

Result: Complies

Checked By : kanchan
Date : 21/Jan/2023

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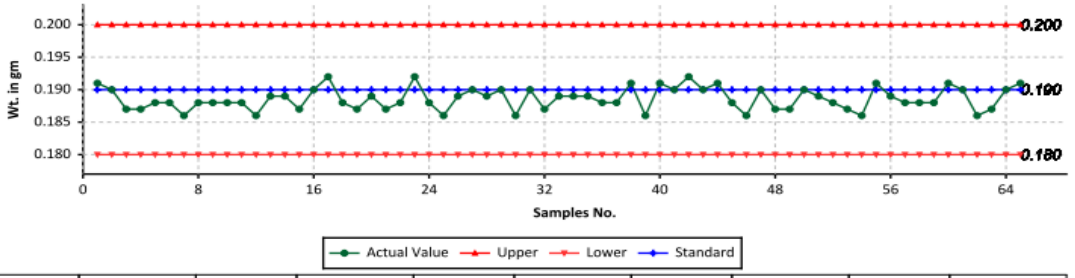
INDIVIDUAL LAYER 1 WEIGHT VARIATION REPORT

inventia

INITIAL INDIVIDUAL LAYER 1 WEIGHT VARIATION REPORT

Product Name	Paracetamol Tablet		
Layer Name	CT 00		
Batch No.	BT 20	**Date**	01/Jan/2023
Product Code No.	PRD 18	**Start Time**	08:15:06
No. of Samples	50	**End Time**	08:25:06
Equipment ID No.	EQ 65	**Cubicle ID**	SP01
Balance ID No.	BCCD 9	**Performed By**	Sail
Standard Weight of Tablets (g)	0.1900	**Side**	LHS
Std. Limit 1 (g)	NA		NA
Std. Limit 2 (g)	None of tablets by ±5.00 %		0.1800 - 0.2000



Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)
1	0.1910	2	0.1900	3	0.1870	4	0.1870	5	0.1880
6	0.1880	7	0.1860	8	0.1880	9	0.1880	10	0.1880
11	0.1880	12	0.1860	13	0.1890	14	0.1890	15	0.1870
16	0.1900	17	0.1920	18	0.1880	19	0.1870	20	0.1890
21	0.1870	22	0.1880	23	0.1920	24	0.1880	25	0.1860
26	0.1890	27	0.1900	28	0.1890	29	0.1900	30	0.1860
31	0.1900	32	0.1870	33	0.1890	34	0.1890	35	0.1890
36	0.1880	37	0.1880	38	0.1910	39	0.1860	40	0.1910
41	0.1900	42	0.1920	43	0.1900	44	0.1910	45	0.1880
46	0.1860	47	0.1900	48	0.1870	49	0.1870	50	0.1900
51	0.1890	52	0.1880	53	0.1870	54	0.1860	55	0.1910
56	0.1890	57	0.1880	58	0.1880	59	0.1880	60	0.1910
61	0.1900	62	0.1860	63	0.1870	64	0.1900	65	0.1910

Test Results

Average Weight of Tablets (g)	0.1886	**Standard Deviation**	0.0017
Minimum Weight (g)	0.1860	**No. of Tablets Above Limit (1)**	NA
Maximum Weight (g)	0.1920	**No. of Tablets Below Limit (1)**	NA
Minimum %	2.11	**No. of Tablets Above Limit (2) 0.2000**	0
Maximum %	1.05	**No. of Tablets Below Limit (2) 0.1800**	0

Result: Complies

Checked by : Sagar Patel
Date : 05/Jan/2023

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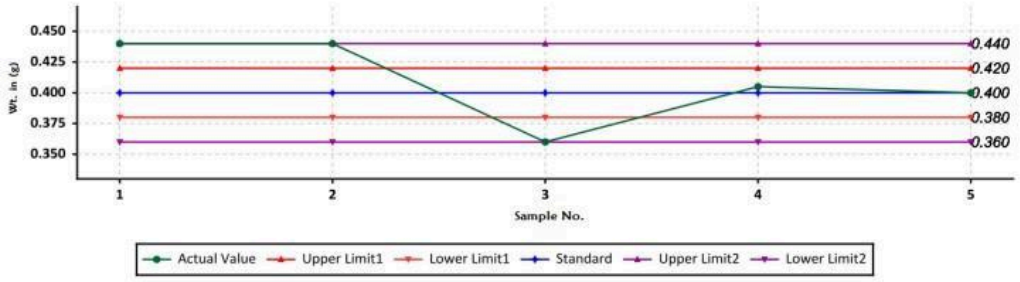
INDIVIDUAL BILAYER WEIGHT VARIATION REPORT

inventia

INPROCESS CHECK REPORT FOR BILAYER TABLET

Product Name	Paracetamol Tablet		
Batch No.	BT 20	**Date**	18/Nov/2023
Product Code No.	PRD 18	**Start Time**	08:15:06
No. of Samples	5	**End Time**	08:45:26
Equipment ID No.	EQ 65	**Cubicle ID**	SP01
Balance ID No.	BCCD 9	**Performed By**	Sail
Standard Weight of Tablets (g)	0.4000		
Std. Limit 1 (g)	NMT 3 tablets by ±5.00 %		0.3800 - 0.4200
Std. Limit 2 (g)	None of tablets by ± 10.00 %		0.3600 - 0.4400



Sample No.	Weight of Bilayer (g)	Layer 1 (g)	Layer 2 (g)	Sample No.	Weight of Bilayer (g)	Layer 1 (g)	Layer 2 (g)
1	0.4400	0.2200	0.2200	2	0.4400	0.2200	0.2200
3	0.3600	0.1800	0.1800	4	0.4050	0.2025	0.2025
5	0.4000	0.2000	0.2000				

Test Results

Weight of Bilayer (g)		Layer 1 (g)		Layer 2 (g)	
Total Weight	= 2.0450	Total Weight	= 1.0225	Total Weight	= 1.0225
Average	= 0.4090	Average	= 0.2045	Average	= 0.2045
Minimum	= 0.3600	Minimum	= 0.1800	Minimum	= 0.1800
Maximum	= 0.4400	Maximum	= 0.2200	Maximum	= 0.2200

Result: Complies

Checked By : kumkum
Date : 18/Nov/2023

Page 1 of 1

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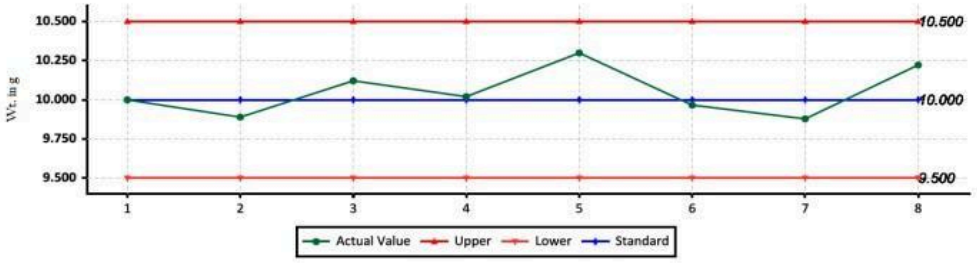
**Note: Limits of only bilayer tablets will be displayed. Graph and Result will be as per Weight of Bilayer tablet.

GROUP BILAYER WEIGHT VARIATION REPORT

inventia

INPROCESS GROUP REPORT FOR BILAYER TABLET

Product Name	Paracetamol Tablet		
Batch No.	BT 21	**Balance ID No.**	BCD 6
Product Code No.	PRD 12	**Equipment ID No.**	EQ 26
Std. Group Wt. of Tablets (g)	10.0000	**Cubicle ID**	SP01
Std. Lower Limit (g)	9.5000(-0.50%)	**Std. Upper Limit (g)**	10.5000(+0.50%)



Test	Date	Time	No. of Samples Tested	Group Weight (g)	Average Weight (g)	Test Result	Performed By
1.	20/Jan/2023	10:25:06	10	9.9990	0.9999	Complies	Raj
2.	20/Jan/2023	12:04:24	10	9.8890	0.9889	Complies	Raj
3.	20/Jan/2023	12:16:55	10	10.1210	1.0121	Complies	Raj
4.	20/Jan/2023	12:19:10	10	10.0200	1.0020	Complies	Raj
5.	20/Jan/2023	12:19:43	10	10.2990	1.0299	Complies	Raj
6.	20/Jan/2023	12:20:03	10	9.9660	0.9966	Complies	Raj
7.	20/Jan/2023	12:27:32	10	9.8780	0.9878	Complies	Raj
8.	20/Jan/2023	16:13:25	10	10.2220	1.0222	Complies	Raj

Test Results

Average Group Wt. of Tablets (g)	10.0493	**Average Wt. of Tablets (g)**	1.0049
Min Group Wt. of Tablets (g)	9.8780	**Min Wt. of Tablets (g)**	0.9878
Max Group Wt. of Tablets (g)	10.2990	**Max Wt. of Tablets (g)**	1.0121
No. of Samples Below Limit	0	**No. of Samples Above Limit**	0

Result: Complies

Checked By : Sayli Patel
Date : 23/Jan/2023

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LOSS ON DRYING TEST REPORT

inventia

INPROCESS LOSS ON DRYING TEST REPORT

Product Name	Paracetamol Tablets		
Batch No.	BT 25	**Date**	15/Jan/2023
Product Code No.	PRD 5	**Start Time**	12:37:17
Moisture analyzer ID No.	MA 86	**End Time**	12:40:17
Duration	10 min	**Cubicle ID**	SP01
Lot No.	15	**Performed By**	Sail
Min. Std. Limit (% w/w)	0.00	**Max. Std. Limit (% w/w)**	0.50
Set Temperature (°C)	60.0		

Test Results	
Initial Weight of sample (g)	2.464
Final Weight of sample (g)	2.460
Loss on Drying (% w/w)	0.160

Result: Complies

Checked By: Sagar Patel
Date : 15/Jan/2023

Page 1 of 1

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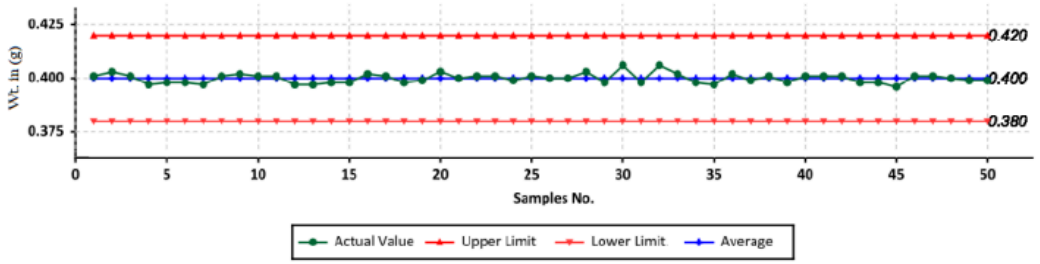
*Note: For LOD Start Time: When string is started to receive, End Time: When complete string is received.
*Note: For Compression, Coating and Capsule same format will be used.

COATING
INDIVIDUAL WEIGHT VARIATION REPORT

inventia

INITIAL INDIVIDUAL WEIGHT VARIATION REPORT

Product Name	Paracetamol Tablet		
Batch No.	BT 20	**Date**	01/Feb/2023
Product Code No.	PRD 18	**Start Time**	08:15:06
No. of Samples	50	**End Time**	08:25:06
Equipment ID No.	EQ 65	**Cubicle ID**	SP01
Balance ID No.	BCCD 9	**Performed By**	Sail
Standard Weight of Tablets (g)	0.4000	**Lot No.**	1A
Std. Limit 1 (g)	NA		NA
Std. Limit 2 (g)	None of tablets by ±5.00 %		0.3800 - 0.4200



Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)
1	0.4010	2	0.4030	3	0.4010	4	0.3970	5	0.3980
6	0.3980	7	0.3970	8	0.4010	9	0.4020	10	0.4010
11	0.4010	12	0.3970	13	0.3970	14	0.3980	15	0.3980
16	0.4020	17	0.4010	18	0.3980	19	0.3990	20	0.4030
21	0.4000	22	0.4010	23	0.4010	24	0.3990	25	0.4010
26	0.4000	27	0.4000	28	0.4030	29	0.3980	30	0.4060
31	0.3980	32	0.4060	33	0.4020	34	0.3980	35	0.3970
36	0.4020	37	0.3990	38	0.4010	39	0.3980	40	0.4010
41	0.4010	42	0.4010	43	0.3980	44	0.3980	45	0.3960
46	0.4010	47	0.4010	48	0.4000	49	0.3990	50	0.3990

Test Results

Average Weight of Tablets (g)	0.4000	**Standard Deviation**	0.0022
Minimum Weight (g)	0.3960	**No. of Tablets Above Limit (1)**	NA
Maximum Weight (g)	0.4060	**No. of Tablets Below Limit (1)**	NA
Minimum %	1.00	**No. of Tablets Above Limit (2) 0.4200**	0
Maximum %	1.50	**No. of Tablets Below Limit (2) 0.3800**	0

Result: Complies

Checked By : Raj
Date : 01/Feb/2023

Page 1 of 1

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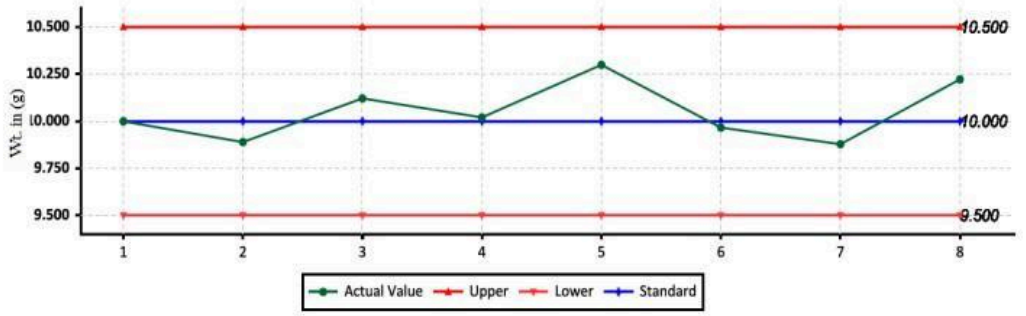
**Note: Inprocess Individual Weight Variation report will have similar format to Initial Weight Variation report.

GROUP WEIGHT VARIATION REPORT

inventia

INPROCESS GROUP WEIGHT VARIATION REPORT

Product Name	Paracetamol Tablets		
Batch No.	BT 21	**Balance ID No.**	BCD 6
Product Code No.	PRD 12	**Equipment ID No.**	EQ 26
Std. Group Wt. of Tablets (g)	10.0000	**Cubicle ID**	SP01
Std. Lower Limit (g)	9.5000(-0.50%)	**Std. Upper Limit (g)**	10.5000(+0.50%)
Lot No.	1A		



Test	Date	Time	No. of Samples Tested	Group Weight (g)	Average Weight (g)	Test Result	Performed By
1.	20/Jan/2023	10:25:06	10	9.9990	0.9999	Complies	Raj
2.	20/Jan/2023	12:04:24	10	9.8890	0.9889	Complies	Raj
3.	20/Jan/2023	12:16:55	10	10.1210	1.0121	Complies	Raj
4.	20/Jan/2023	12:19:10	10	10.0200	1.0020	Complies	Raj
5.	20/Jan/2023	12:19:43	10	10.2990	1.0299	Complies	Raj
6.	20/Jan/2023	12:20:03	10	9.9660	0.9966	Complies	Raj
7.	20/Jan/2023	12:27:32	10	9.8780	0.9878	Complies	Raj
8.	20/Jan/2023	16:13:25	10	10.2220	1.0222	Complies	Raj

Test Results

Average Group Wt. of Tablets (g)	10.0493	**Average Wt. of Tablets (g)**	1.0049
Min Group Wt. of Tablets (g)	9.8780	**Min Wt. of Tablets (g)**	0.9878
Max Group Wt. of Tablets (g)	10.2990	**Max Wt. of Tablets (g)**	1.0121
No. of Samples Below Limit	0	**No. of Samples Above Limit**	0

Result: Complies

Checked By : Sayli Patel
Date : 23/Jan/2023

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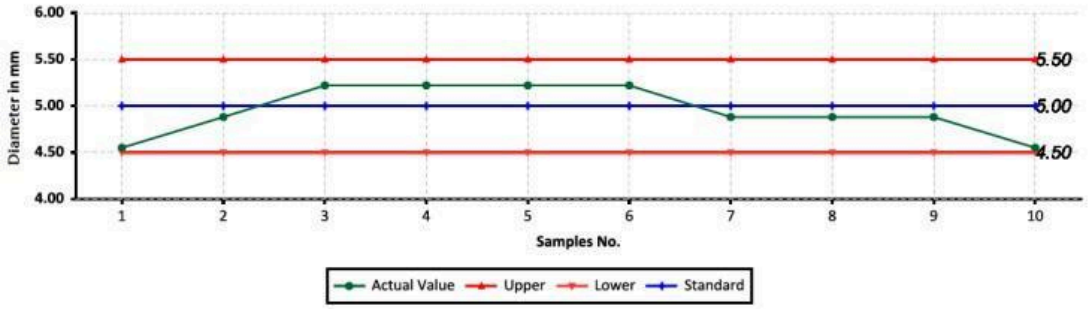
DIAMETER VARIATION REPORT

inventia

INITIAL DIAMETER VARIATION REPORT

Product Name	Paracetamol Tablets		
Batch No.	BTH123	**Date**	19/Aug/2023
Product Code No.	BFG - 101	**Start Time**	14:16:32
No. of Samples	10	**End Time**	14:23:32
Equipment ID No.	EQP123	**Cubicle ID**	SP01
Hardness Tester ID No.	VCN-202	**Performed By**	Sail
Standard Diameter (mm)	5.00	**Lot No.**	1A
Std. Lower Limit (mm)	4.50	**Std. Upper Limit (mm)**	5.50



Sample No.	Diameter (mm)	Sample No.	Diameter (mm)	Sample No.	Diameter (mm)	Sample No.	Diameter (mm)	Sample No.	Diameter (mm)
1	4.55	2	4.88	3	5.22	4	5.22	5	5.22
6	5.22	7	4.88	8	4.88	9	4.88	10	4.55

Test Results

Average Diameter (mm)	4.95	**Standard Deviation**	0.27
Minimum Diameter (mm)	4.55	**No. of Tablets Below Limit**	0
Maximum Diameter (mm)	5.22	**No. of Tablets Above Limit**	0

Result: Complies

Checked By : kumkum
Date : 19/Aug/2023

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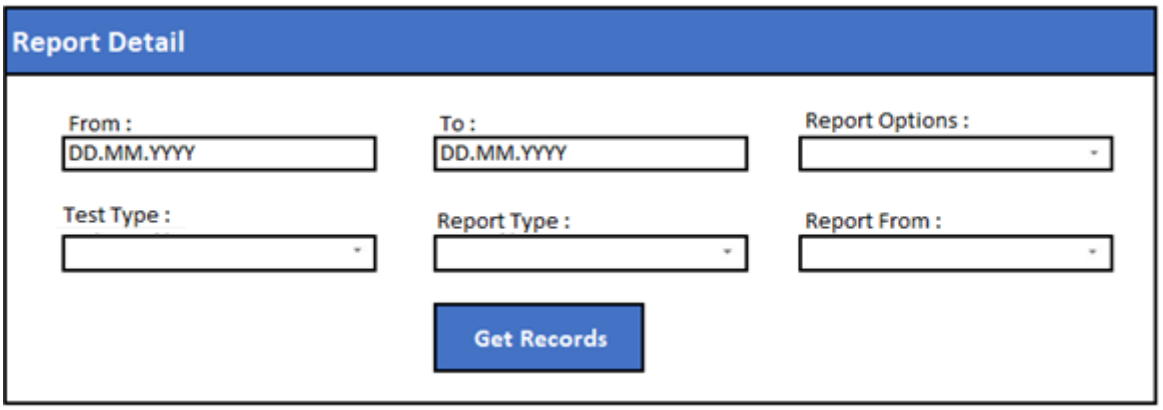
5.20 CAPSULE REPORT DETAILS



SCREEN 50

Screen 50 Report Detail CAPSULE

Select Date Range.

Select 'Report Options' from dropdown list: Individual, Group, Locked Length, Net Weight Content-1 and Net Weight Content-2.

Select 'Test Type' from dropdown list: Initial/Inprocess

Select 'Report Type' from dropdown list: Complete or Incomplete.

Select 'Report From' from dropdown; Current or Archive.

Click on 'Get Records' button.

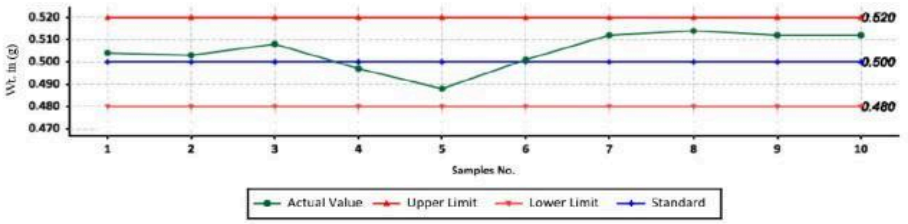
List of records which comes under selected input will be displayed.

INDIVIDUAL WEIGHT VARIATION REPORT

inventia

INITIAL INDIVIDUAL WEIGHT VARIATION REPORT

Product Name	Multi Vitamin Capsule		
Batch No.	BT 20	**Date**	01/Jan/2023
Product Code No.	PRD 18	**Start Time**	08:15:06
No. of Samples	50	**End Time**	08:25:06
Equipment ID No.	EQ 65	**Cubicle ID**	SP01
Balance ID No.	BCCD 9	**Performed By**	Sail
Standard Weight of Capsules (g)	0.5000		
Std. Limit 1 (g)	NA		NA
Std. Limit 2 (g)	None of capsules by ±0.02 %		0.4800 - 0.5200



Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)
1	0.5040	2	0.5030	3	0.5080	4	0.4970	5	0.4880
6	0.5010	7	0.5120	8	0.5140	9	0.5120	10	0.5120

Test Results

Average Weight of Capsules (g)	0.5051	**Standard Deviation**	0.0082
Minimum Weight (g)	0.4880	**No. of Capsules Above Limit (1)**	NA
Maximum Weight (g)	0.5140	**No. of Capsules Below Limit (1)**	NA
Minimum %	2.11	**No. of Capsules Above Limit (2) 0.5200**	0
Maximum %	2.80	**No. of Capsules Below Limit (2) 0.4800**	0

Result: Complies

Checked By : Sid
Date : 20/Jan/2023

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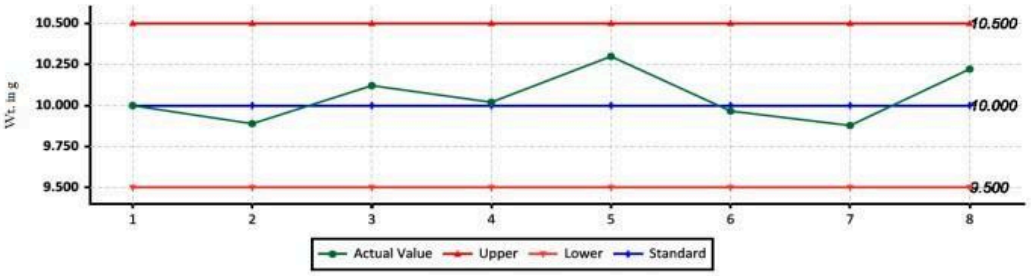
GROUP WEIGHT VARIATION REPORT

inventia

INPROCESS GROUP WEIGHT VARIATION REPORT

Product Name	Multivitamin Capsule		
Batch No.	BT 21	**Balance ID No.**	BCD 6
Product Code No.	PRD 12	**Equipment ID No.**	EQ 26
Std. Group Wt. of Capsules (g)	10.0000	**Cubicle ID**	SP01
Std. Lower Limit (g)	9.5000(-0.50%)	**Std. Upper Limit (g)**	10.5000(+0.50%)



Test	Date	Time	No. of Samples Tested	Group Weight (g)	Average Weight (g)	Test Result	Performed By
1.	20/Jan/2023	10:25:06	10	9.9990	0.9999	Complies	Raj
2.	20/Jan/2023	12:04:24	10	9.8890	0.9889	Complies	Raj
3.	20/Jan/2023	12:16:55	10	10.1210	1.0121	Complies	Raj
4.	20/Jan/2023	12:19:10	10	10.0200	1.0020	Complies	Raj
5.	20/Jan/2023	12:19:43	10	10.2990	1.0299	Complies	Raj
6.	20/Jan/2023	12:20:03	10	9.9660	0.9966	Complies	Raj
7.	20/Jan/2023	12:27:32	10	9.8780	0.9878	Complies	Raj
8.	20/Jan/2023	16:13:25	10	10.2220	1.0222	Complies	Raj

Test Results

Average Group Wt. of Capsules (g)	10.0493	**Average Wt. of Capsules (g)**	1.0049
Min Group Wt. of Capsules (g)	9.8780	**Min Wt. of Capsules (g)**	0.9878
Max Group Wt. of Capsules (g)	10.2990	**Max Wt. of Capsules (g)**	1.0121
No. of Samples Below Limit	0	**No. of Samples Above Limit**	0

Result: Complies

Checked By : Sayli Patel
Date : 23/Jan/2023

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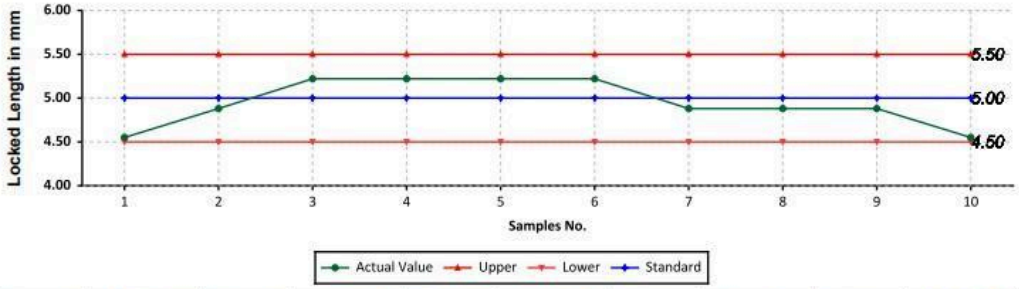
LOCKED LENGTH VARIATION REPORT

inventia

INPROCESS LOCKED LENGTH VARIATION REPORT

Product Name	Multivitamin Capsules		
Batch No.	BTH123	**Date**	19/Aug/2023
Product Code No.	BFG - 101	**Start Time**	14:16:32
No. of Samples	10	**End Time**	14:23:32
Equipment ID No.	EQP123	**Cubicle ID**	SP01
Vernier Code No.	VCN-202	**Performed By**	Sail
Standard Locked length (mm)	5.00		
Std. Lower Limit (mm)	4.50	**Std. Upper Limit (mm)**	5.50



Sample No.	Locked Length (mm)	Sample No.	Locked Length (mm)	Sample No.	Locked Length (mm)	Sample No.	Locked Length (mm)	Sample No.	Locked Length (mm)
1	4.55	2	4.88	3	5.22	4	5.22	5	5.22
6	5.22	7	4.88	8	4.88	9	4.88	10	4.55

Test Results

Average Locked Length (mm)	4.95	**Standard Deviation**	0.27
Minimum Locked Length(mm)	4.55	**No. of Capsules Below Limit**	0
Maximum Locked Length (mm)	5.22	**No. of Capsules Above Limit**	0

Result: Complies

Checked By : kumkum
Date : 19/Aug/2023

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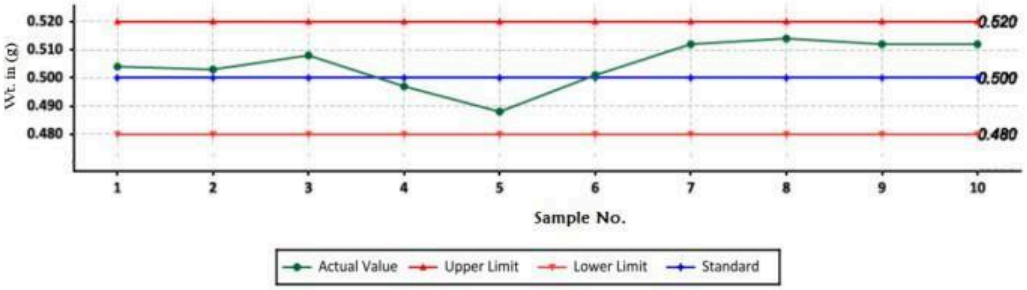
NET WEIGHT CONTENT- 1 REPORT

inventia

INITIAL NET WEIGHT CONTENT-1 REPORT

Product Name	VITAMIN CAPSULES		
Content Name	BX 10		
Batch No.	BT 20	**Date**	20/Jan/2023
Product Code No.	PRD 40	**Start Time**	16:10:01
No. of Samples	10	**End Time**	16:11:01
Equipment ID No.	EQ 6	**Cubicle ID**	SP01
Balance ID No.	BCD 46	**Performed By**	Sail
Standard Weight of Capsules (g)	0.5000		
Std. Limit 1 (g)	NA		NA
Std. Limit 2 (g)	None of capsules by ±0.02 %		0.4800 - 0.5200



Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)
1	0.5040	2	0.5030	3	0.5080	4	0.4970	5	0.4880
6	0.5010	7	0.5120	8	0.5140	9	0.5120	10	0.5120

Test Results

Average Weight of Capsules (g)	0.5051	**Standard Deviation**	0.0082
Minimum Weight (g)	0.4880	**No. of Capsules Above Limit (1)**	NA
Maximum Weight (g)	0.5140	**No. of Capsules Below Limit (1)**	NA
Minimum %	2.40	**No. of Capsules Above Limit (2) 0.5200**	0
Maximum %	2.80	**No. of Capsules Below Limit (2) 0.4800**	0

Result: Complies

Checked By : Raj
Date : 20/Jan/2023

Page 1 of 1

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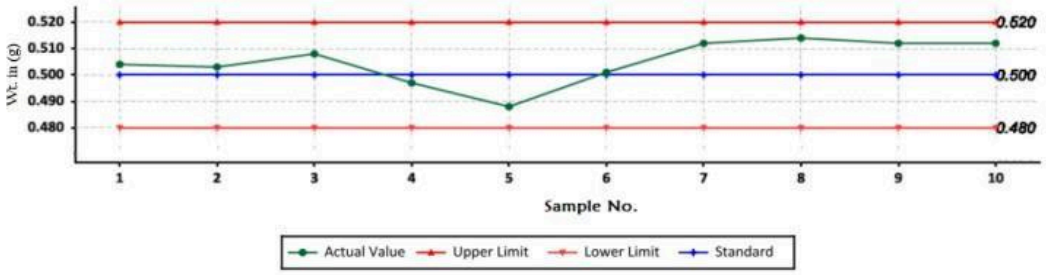
**Note: 'Content Name' will be 'Content Type'.

NET WEIGHT CONTENT- 2 REPORT

inventia

INPROCESS NET WEIGHT CONTENT-2 REPORT

Product Name	VITAMIN CAPSULES		
Content Name	AX 01		
Batch No.	BT 20	**Date**	20/Jan/2023
Product Code No.	PRD 40	**Start Time**	16:10:01
No. of Samples	10	**End Time**	16:11:01
Equipment ID No.	EQ 6	**Cubicle ID**	SP01
Balance ID No.	BCD 46	**Performed By**	Sail
Standard Weight of Capsules (g)	0.5000		
Std. Limit 1 (g)	NA		NA
Std. Limit 2 (g)	None of capsules by ±0.02 %		0.4800 - 0.5200



Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)	Sample No.	Weight in (g)
1	0.5040	2	0.5030	3	0.5080	4	0.4970	5	0.4880
6	0.5010	7	0.5120	8	0.5140	9	0.5120	10	0.5120

Test Results

Average Weight of Capsules (g)	0.5051	**Standard Deviation**	0.0082
Minimum Weight (g)	0.4880	**No. of Capsules Above Limit (1)**	NA
Maximum Weight (g)	0.5140	**No. of Capsules Below Limit (1)**	NA
Minimum %	2.40	**No. of Capsules Above Limit (2) 0.5200**	0
Maximum %	2.80	**No. of Capsules Below Limit (2) 0.4800**	0

Result: Complies

Checked By : Raj
Date : 20/Jan/2023

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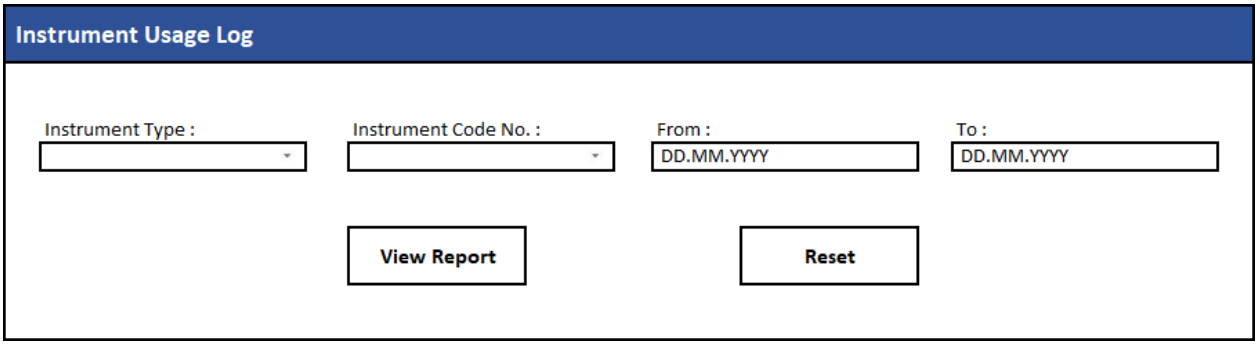
5.21 INSTRUMENT USAGE LOG

File extension: .ts (type script) Type: Angular Web Form
Purpose: Allows viewing Instrument Usage Log reports.



SCREEN 51

Process

Screen 51 : Instrument Usage Log

- Every Instrument's usage gets logged.
- Instrument usage log report can be viewed.

5.22 USER STATUS REPORT

File extension: .ts (type script) Type: Angular Web Form
Purpose: Allows viewing user status reports.

SCREEN 52

Process

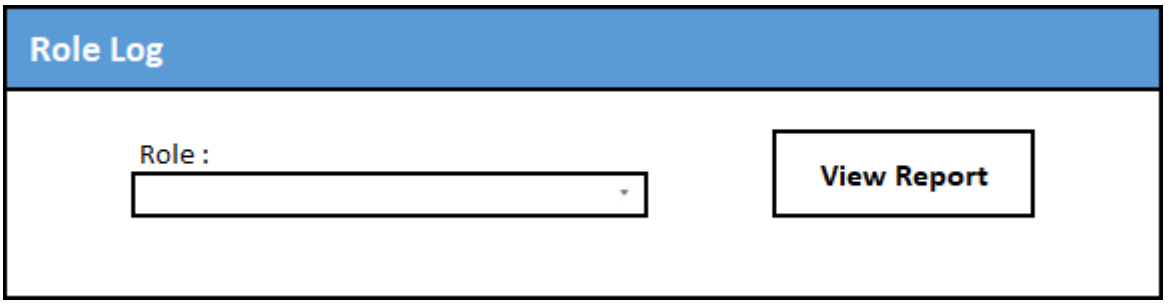
Screen 52 : User Status Report

- Select status and click on View Report.
- According to the selected status list of users displays.

- This report can be viewed and printed.

5.23 ROLE LOG REPORT

File extension: .ts (type script) Type: Angular Web Form
Purpose: Allows viewing role log reports



SCREEN 53

Process

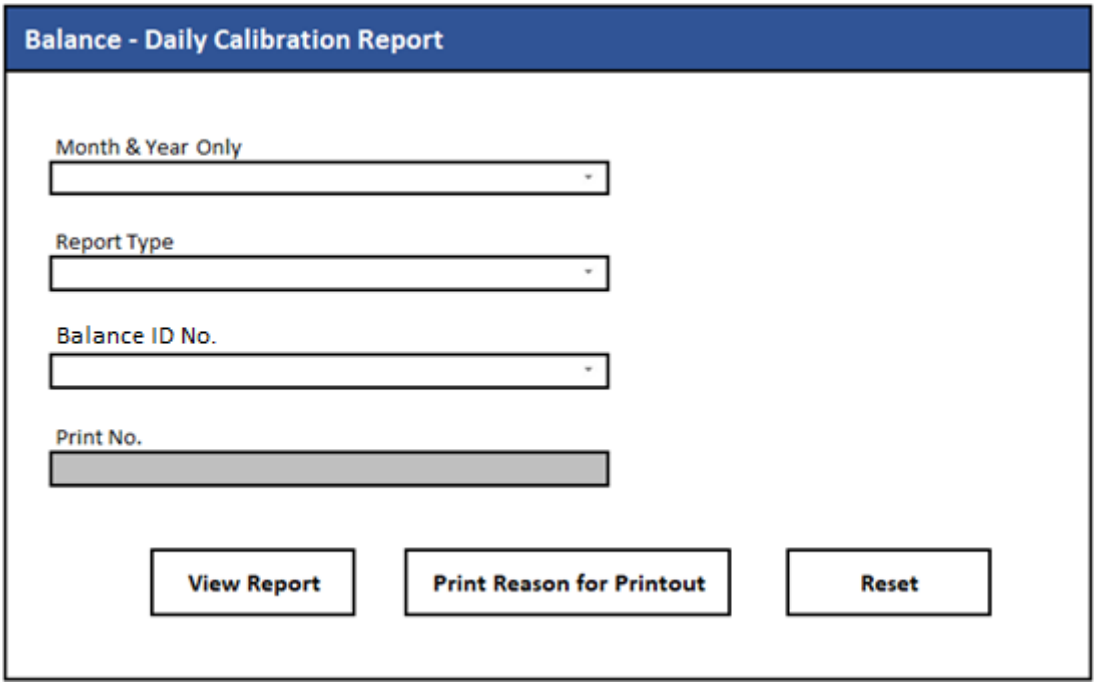
Screen 53 : Role Log Report

- Select role and click on View Report.
- According to the selected role report will display.
- This report can be viewed /printed.

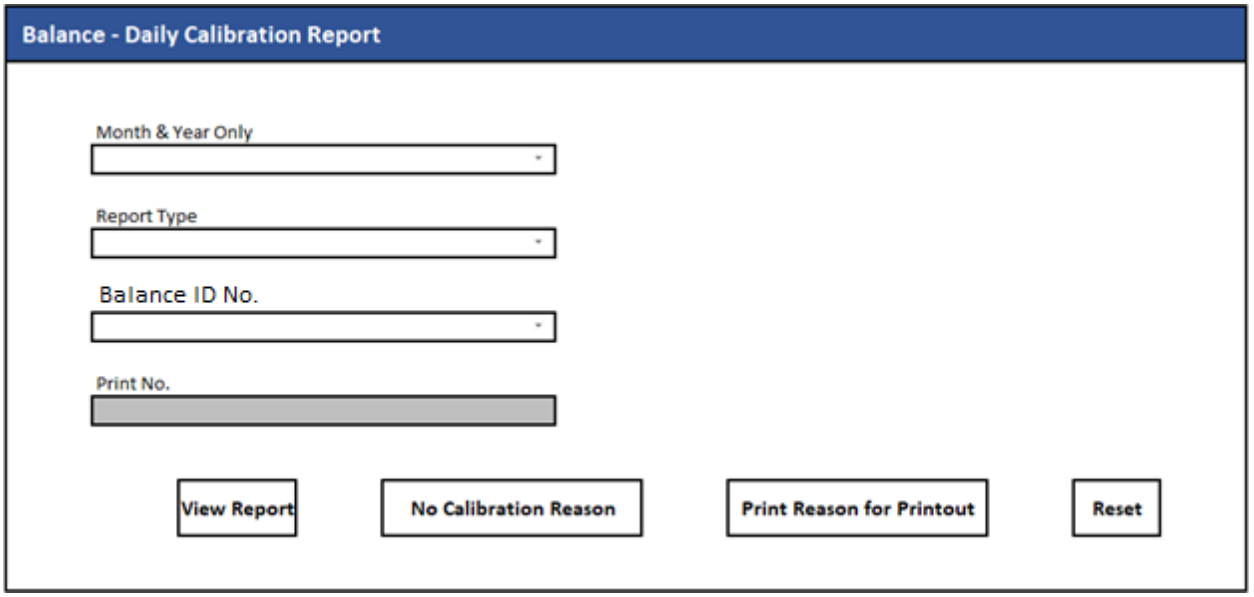
**User having Audit Trail rights will only be able to view/print Instrument Usage Log, Role Log & User Status.

5.24 CALIBARTION REPORT

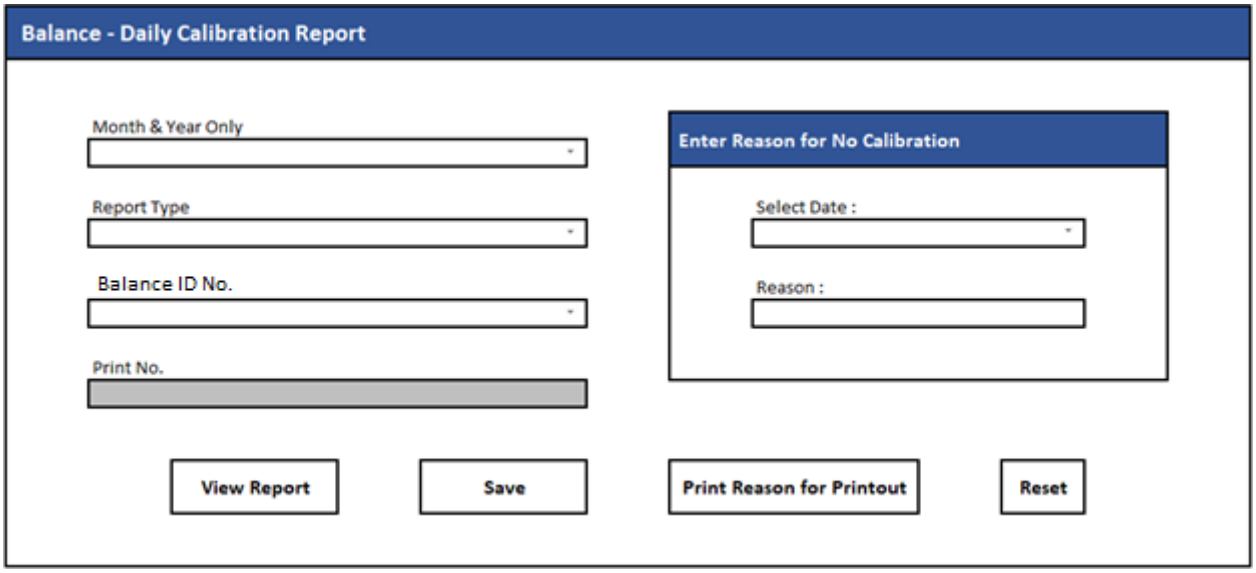
File extension: .ts (type
script) Type: Angular Web
Form
Purpose: Allows viewing calibration reports



SCREEN 54



SCREEN 55



SCREEN 56

SCREEN 57

Process

Screen 54 : Daily – Balance Calibration Report:

- Select Month and Year.
- Select Report Type.
- Select Balance ID No.
- Click on 'View Report' to View Daily Balance Calibration Report.
- After the report is displayed, click on 'Print Report' button to print the report.

Screen 55 & 56 Reason for No-Calibration:

- Once all the details are filled, "No Calibration Reason" button appears (This is mainly used for situations when the Daily calibration is not performed for a particular day.
- When the "No Calibration Reason" button is pressed, the user will get an option to select the date in which the daily calibration is not performed.
- Select the date on which daily calibration is not done.
- Enter the reason for the same.
- Click on 'Save' button.
- Once the changes are saved, the user will be able to view the reason for no calibration by opening the Daily Calibration report for the said month. Username will be reflected in 'Reviewed By' column.

Screen 57 : Periodic Balance Calibration Report:

- Select date range.
- Select Report Type.
- Select Balance ID No.
- Click on 'Get Records' button to displayed records for selected input.
- Click on 'View' button for a particular record to view the report.
- After the report is displayed, click on 'Print Report' to print the report.

DAILY PERFORMANCE CHECK OF WEIGHING BALANCE :

inventia

Annexure – II
Daily performance check of weighing balance

Instrument ID No.: BCN_202	Min. operating range: 0.0020	Make: Mettler
Capacity (g): 320.0000	Max. operating range: 300.0000	Month/ Year: December/ 2023
Least count (g): 0.0010	Area: Compression	Location: SP01

Standard weight (g)	Tolerance	Permissible limit (g)
0.0200	(+/- 0.0010)	0.0190 - 0.0210
256.0000	(+/- 1.0000)	255.0000 - 257.0000

Adjust the sprit level and zero error before commencing the operation.

Date	Time	Zero Error	Spirit Level	Standard weight (g)		Observed wt. (g)	Performed by	Checked by	Remark
01/Dec/2023	09:02:00	0.0	OK	Lower	0.0200	0.0210	Sail	Raj	OK
				Upper	256.0000	256.1000	Sail	Raj	OK
02/Dec/2023	09:02:50	0.0	OK	Lower	0.0200	0.0210	Raj	Sail	OK
				Upper	256.0000	256.0000	Raj	Sail	OK
03/Dec/2023	NA	NA	NA	Lower	NA	NA	NA	NA	Holiday
				Upper	NA	NA	NA	NA	Holiday
04/Dec/2023	09:05:00	0.0	OK	Lower	0.0200	0.0210	Sail	Raj	OK
				Upper	256.0000	256.0000	Sail	Raj	OK
05/Dec/2023	09:02:50	0.0	OK	Lower	0.0200	0.0200	Raj	Sail	OK
				Upper	256.0000	256.0000	Raj	Sail	OK
06/Dec/2023	09:10:00	0.0	OK	Lower	0.0200	0.0210	Sail	Raj	OK
				Upper	256.0000	256.5000	Raj	Sail	OK
07/Dec/2023	09:08:00	0.0	OK	Lower	0.0200	0.0200	Sail	Raj	OK
				Upper	256.0000	257.0000	Raj	Sail	OK
08/Dec/2023	09:05:00	0.0	OK	Lower	0.0200	0.0210	Sail	Raj	OK
				Upper	256.0000	256.0000	Sail	Raj	OK
09/Dec/2023	09:02:50	0.0	OK	Lower	0.0200	0.0200	Raj	Sail	OK
				Upper	256.0000	256.0000	Raj	Sail	OK
10/Dec/2023	NA	NA	NA	Lower	NA	NA	NA	NA	Holiday
				Upper	NA	NA	NA	NA	Holiday

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MONTHLY/QUARTERLY/REPEATABILITY AND FULL-SCALE PERFORMANCE CHECK OF WEIGHING BALANCE :

inventia

Annexure III

(Critical Balance/Non-Critical Balance)

Monthly / Quarterly / Repeatability and full-scale performance check of weighing balance

Instrument ID.: BCN_202	**Min. operating range:**0.002	**Make:** Mettler
Capacity(g): 320.000	**Max. operating range:**300.000	**Month/ Year:** Jan/2024
Least count(g): 0.001	**Area:**Compression	**Location:** SP01
Performance checked on:15/Jan/2024		**Performance due on:**15/Feb/2024

Tolerance:+/- Least count of the balance OR+/- 0.1 % of Standard weight whichever is higher and value should be rounded off on lower side as per display capacity of balance.

Standard weights for calibration (g)	Tolerance (g)	Permissible Limits (g)
0.020	± 0.001	0.019 - 0.021
10.000	- 0.002 + 0.005	9.998 - 10.005
20.000	- 0.005 + 0.004	19.995 - 20.004
30.000	- 0.006 + 0.008	29.994 - 30.008
40.000	- 0.006 + 0.007	39.994 - 40.007
64.000	- 0.002 + 0.004	63.998 - 64.004
160.000	- 0.005 + 0.004	159.995 - 160.004
200.000	± 0.004	199.996 - 200.004
256.000	- 0.004 + 0.004	255.996 - 256.004

Note: 1. Adjust zero error before commencing the weighing operation.

2. Check against standard weights on quarterly.

Date	Time	Spirit Level (Ok/ Not Ok)	Zero Error	Standard weights kept on the balance (g)	Readings shown (g)	Performed by	Checked by
15/Jan/2024	11:41	OK	0.0	0.020	0.020	Abhishek	Sail
				10.000	10.000	Abhishek	Sail
				20.000	20.000	Abhishek	Sail
				30.000	30.000	Abhishek	Sail
				40.000	40.000	Abhishek	Sail
				64.000	64.000	Abhishek	Sail
				160.000	160.000	Abhishek	Sail
				200.000	200.000	Abhishek	Sail
				256.000	256.000	Abhishek	Sail

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Annexure III

(Critical Balance/Non-Critical Balance)

Monthly / Quarterly / Repeatability and full-scale performance check of weighing balance

2. Uncertainty test:

Sr. No.	Standard Weight (g)	Reading displayed on the balance (g)	Remarks
1	0.020	0.020	Ok
2	0.020	0.020	Ok
3	0.020	0.020	Ok
4	0.020	0.020	Ok
5	0.020	0.020	Ok
6	0.020	0.020	Ok
7	0.020	0.020	Ok
8	0.020	0.020	Ok
9	0.020	0.020	Ok
10	0.020	0.020	Ok
Mean		0.020	-
Standard Deviation (S.D.)		0.000	-

Uncertainty = $\frac{3 \times S.D.}{\text{Reported Standard weight (g)}} \times 100 = 0.000$

Acceptance criteria : Value of uncertainty should be NMT 0.001 g.

Remark : Complies

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Annexure III

(Critical Balance/Non-Critical Balance)

Monthly / Quarterly / Repeatability and full-scale performance check of weighing balance

3. Repeatability test:

Sr. No.	Standard Weight (g)	Reading displayed on the balance (g)	Remarks
1	0.020	0.020	Ok
2	0.020	0.020	Ok
3	0.020	0.020	Ok
4	0.020	0.020	Ok
5	0.020	0.020	Ok
6	0.020	0.020	Ok
7	0.020	0.020	Ok
8	0.020	0.020	Ok
9	0.020	0.020	Ok
10	0.020	0.020	Ok
Mean		0.020	-
Standard Deviation (S.D.)		0.000	-

$$\textbf{Repeatability (\%)} = \frac{2 \times S.D.}{\text{Reported Standard weight (g)}} \times 100 = 0.000$$

Acceptance criteria : Repeatability is NMT 0.10 %

Remark : Complies

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Date : 15/Jan/2024 **Date :** 15/Jan/2024

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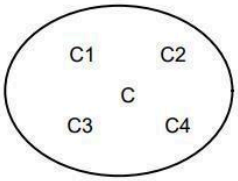
Annexure III

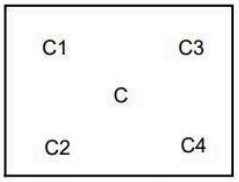
(Critical Balance/Non-Critical Balance)

Monthly / Quarterly / Repeatability and full-scale performance check of weighing balance

4. Eccentricity test :

Note: Adjust zero error before commencing the weighing operation .





Sr No.	Standard Weight (g)	Position	Reading displayed by the balance (g)	Deviation from center =X-C	Remark
1	0.020	C	0.020	------	Ok
2	0.020	C1	0.020	0.000	Ok
3	0.020	C2	0.020	0.000	Ok
4	0.020	C3	0.020	0.000	Ok
5	0.020	C4	0.020	0.000	Ok

Where, X=C1, C2, C3, C4 i.e. different corners of the balance.

Acceptance criteria : Deviation is not more than 0.05%.

Remark: Complies

Comment: _____

Performed By: Abhishek **Checked By:** Sail

Date : 15/Jan/2024 **Date :** 15/Jan/2024

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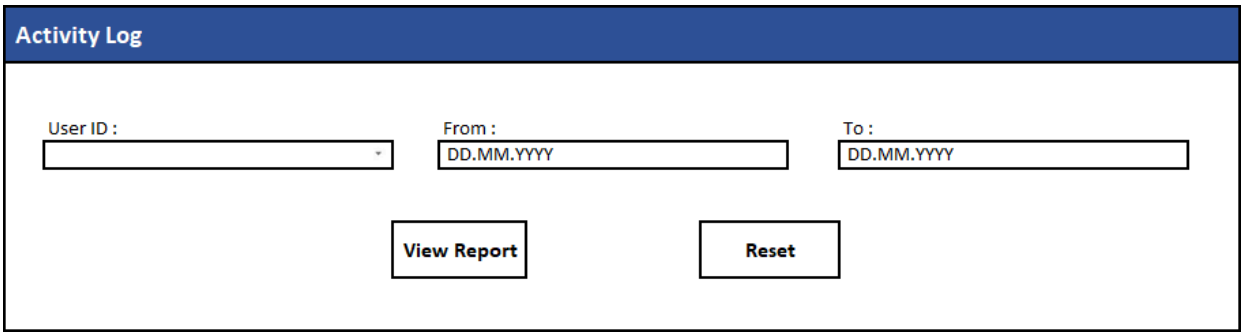
**Note: Area will be displayed as set in area setting and Location will be cubicle name.

5.25 ACTIVITY LOG

File extension: .ts (type
script) Type: Angular Web
Form
Purpose: Allows viewing activity log.



SCREEN 58

Process

Screen 58 : View activity log

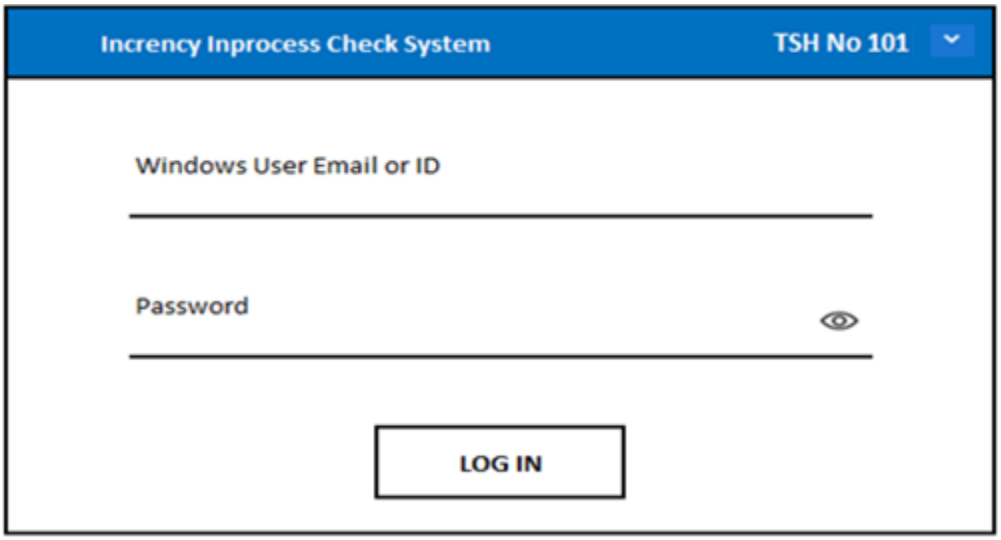
- Select User ID from dropdown, select date range and view report.
- Every activity performed on software and /gets logged with date time stamp with respective user ID.

***Note:

- To view Activity log report user can select date range of maximum 7 days.

6. HARDWARE MODULES

6.1 LOGIN



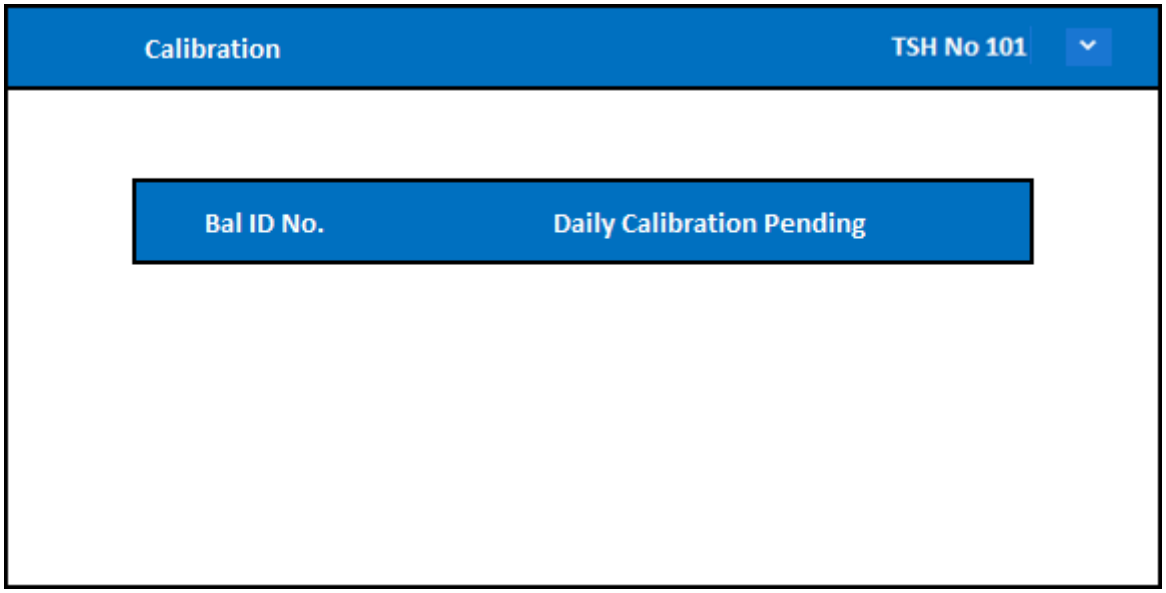
SCREEN 59

Screen 59 : Login on TSH

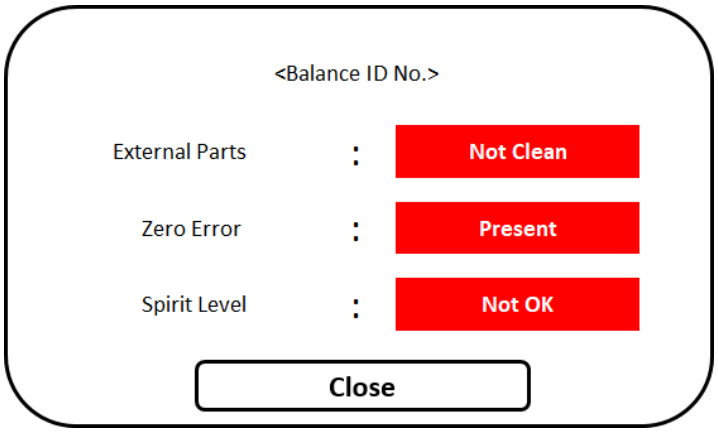
Enter User ID and Password.

Select "Login" button to login.

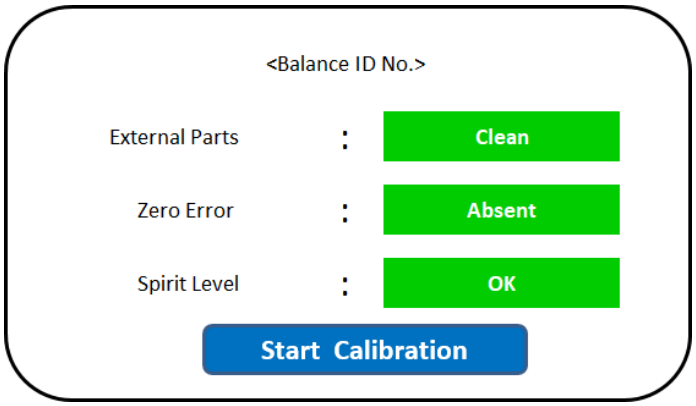
6.2 DAILY CALIBRATION



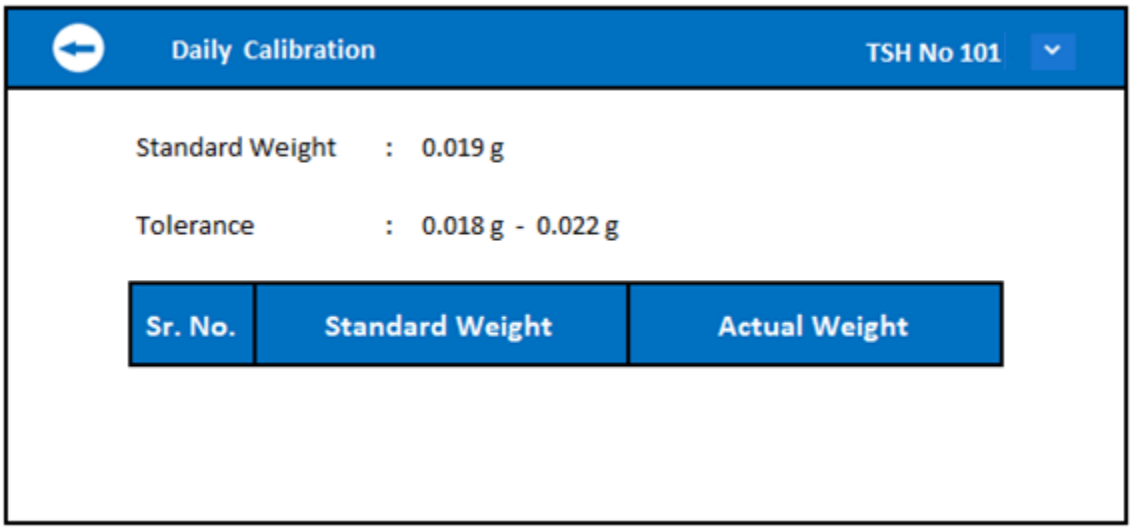
Screen 60



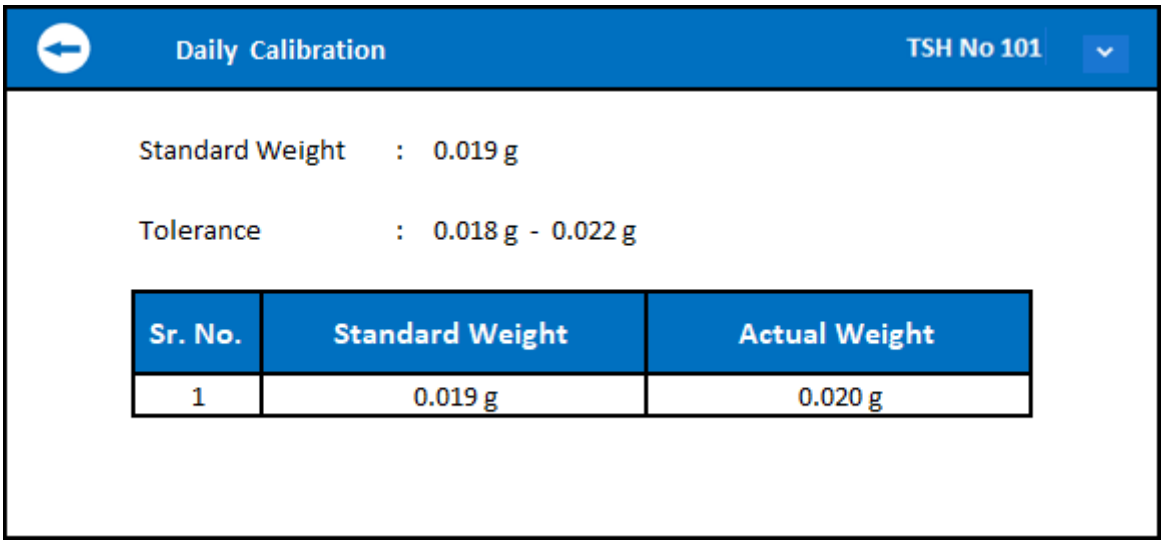
Screen 61



Screen 62



Screen 63



Screen 64

Daily Calibration **TSH No 101**

Standard Weight : 30.000 g

Tolerance : 28.070 g - 31.020 g

Sr. No.	Standard Weight	Actual Weight
2	30.000 g	30.000 g
1	0.020 g	0.020 g

Calibration Successful **Ok**

Screen 65

SCREEN 60 : Daily Calibration Pending

- The system will alert the user every day at 7 AM to perform Daily Calibration of Balance.
- Daily Calibration skip able time will be 12 AM to 7 AM.

SCREEN 61 and Screen 62: Verification checks

- The user verifies if:
  - i. External parts are Not Clean/ Clean.
  - ii. Zero Error Absent/Present.
  - iii. Spirit Level Not OK/ OK.

SCREEN 63 , Screen 64 and Screen 65: Daily Calibration.

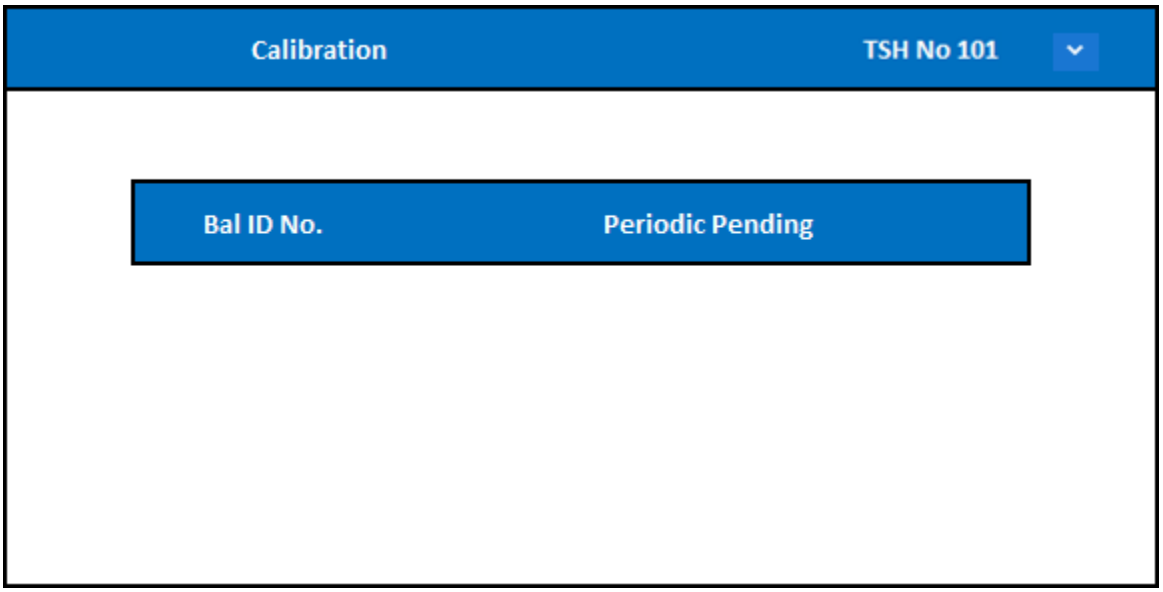
- The system will ask for weights for Daily Verification as per set sequence in software.
- Upon successful completion, 'Calibration Successful' message will pop up on screen and user will be directed to Calibration .
- Calibration power backup will be provided.

*Note:

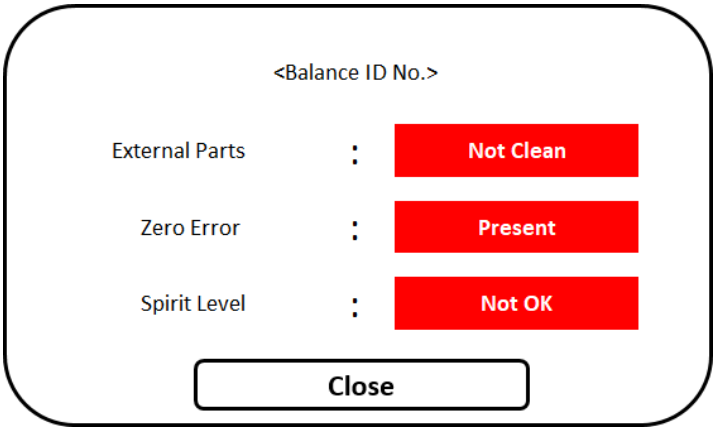
User will have to verify report before proceeding further.

Whenever periodic calibration is due, system will not ask for Daily Calibration will only ask for Periodic Calibration.

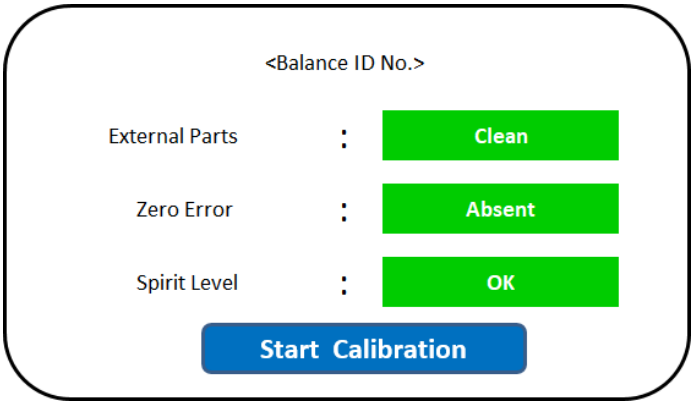
6.3 PERIODIC CALIBRATION



Screen 66



Screen 67



Screen 68

Periodic Calibration TSH No 101

Standard Weight : 44.000 g

Tolerance : 43.988 g - 45.099 g

Sr. No.	Standard Weight	Actual Weight
1	44.000 g	44.000 g

Screen 69

Periodic Calibration TSH No 101

Standard Weight : 124.000 g

Tolerance : 123.988 g - 125.099 g

Sr. No.	Standard Weight	Actual Weight
5	124.000 g	124.000 g
4	120.000 g	120.000 g
3	100.000 g	100.000 g
2	55.000 g	55.000 g
1	44.000 g	44.000 g

Calibration Successful **Ok**

Screen 70

SCREEN 66 : Periodic Pending

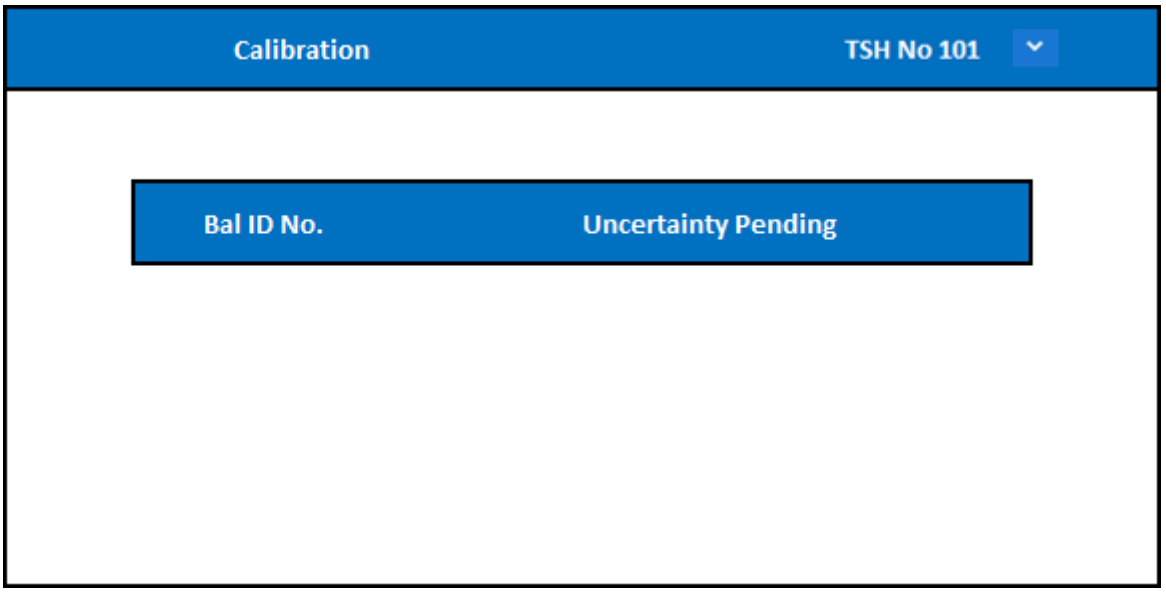
- The system will alert the user to perform Periodic Calibration of Balance.

SCREEN 67 and Screen 68 : Verification checks

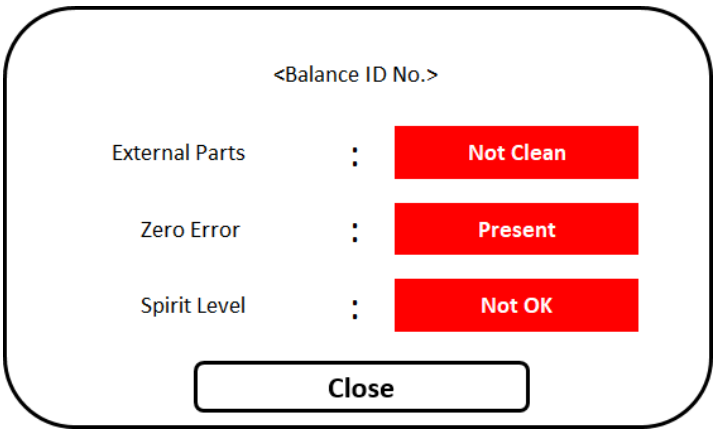
- The user verifies if:
  - i. External parts are Clean/Not Clean.
  - ii. Zero Error Absent/Present.
  - iii. Spirit Level OK/NOT OK.

SCREEN 69 and Screen 70 : Periodic Calibration

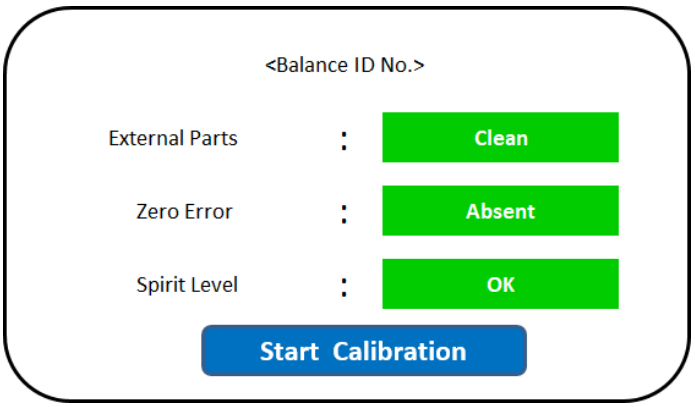
- The system will ask for weights for Periodic Calibration as per set sequence in software.
- After Calibration completed clicking on 'OK' button user will be directed to Calibration Screen.



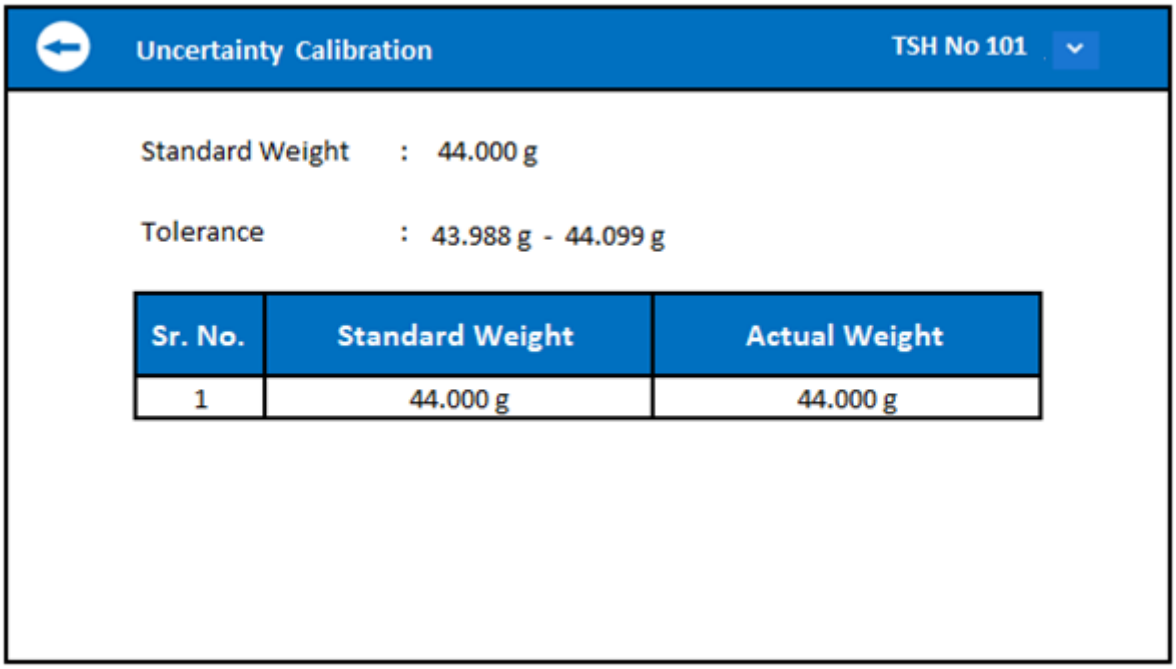
Screen 71



Screen 72



Screen 73



Screen 74

Uncertainty Calibration TSH No 101

Standard Weight : 44.000 g

Tolerance : 43.988 g - 44.099 g

Sr. No.	Standard Weight	Actual Weight
10	44.000 g	44.000 g
9	44.000 g	44.000 g
8	44.000 g	44.000 g
7	44.000 g	44.000 g
6	44.000 g	44.000 g

Calibration Successful **Ok**

Screen 75

SCREEN 71Uncertainty Calibration Pending

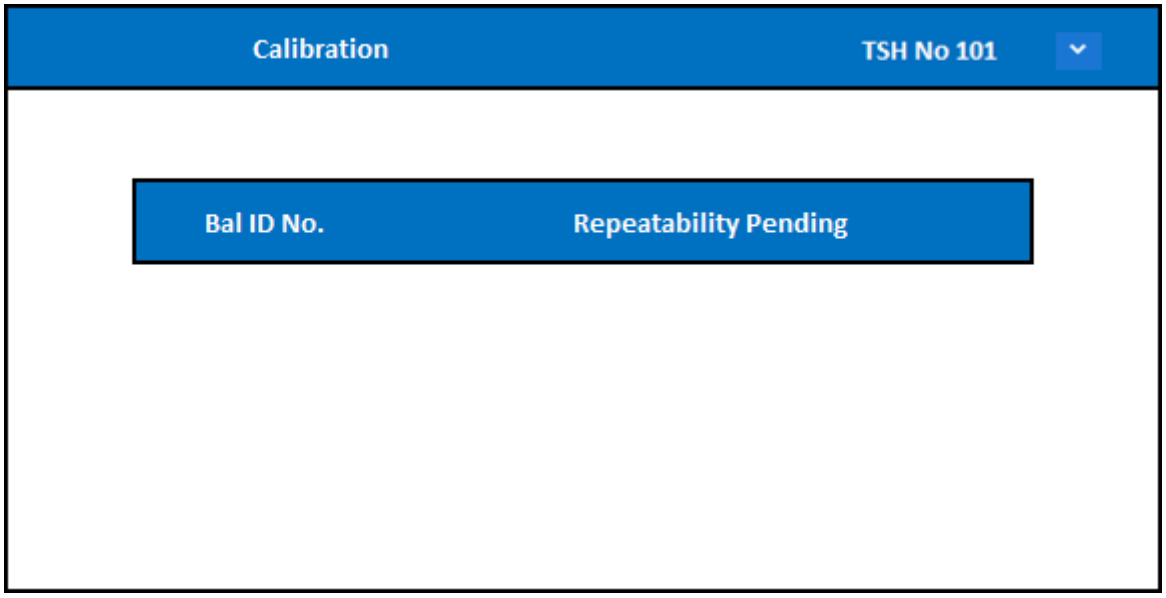
- The system will alert the user to perform Uncertainty Calibration of Balance.

SCREEN 72 and 73 : Verification checks

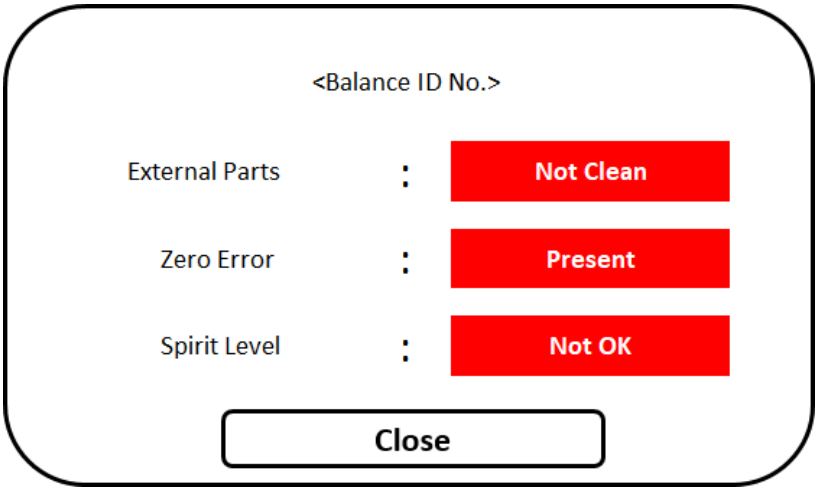
- The user verifies if:
  - i. External parts are Clean/Not Clean.
  - ii. Zero Error Absent/Present.
  - iii. Spirit Level OK/NOT OK.

SCREEN 74 and 75: Uncertainty Calibration

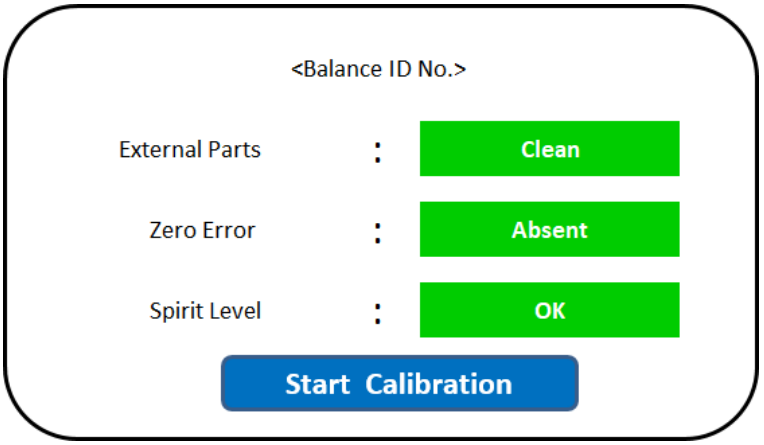
- The system will ask for weights for Uncertainty Calibration as per set sequence in software.
- After Calibration completed clicking on 'OK' button user will be directed to Calibration Screen.



Screen 76



Screen 77



Screen 78

Repeatability Calibration TSH No 101

Standard Weight : 44.000 g

Tolerance : 43.988 g - 44.099 g

Sr. No.	Standard Weight	Actual Weight
1	44.000 g	44.000 g

Screen 79

Repeatability Calibration TSH No 101

Standard Weight : 44.000 g

Tolerance : 43.988 g - 44.099 g

Sr. No.	Standard Weight	Actual Weight
10	44.000 g	44.000 g
9	44.000 g	44.000 g
8	44.000 g	44.000 g
7	44.000 g	44.000 g
6	44.000 g	44.000 g

Calibration Successful **Ok**

Screen 80

SCREEN 76 : Repeatability Pending

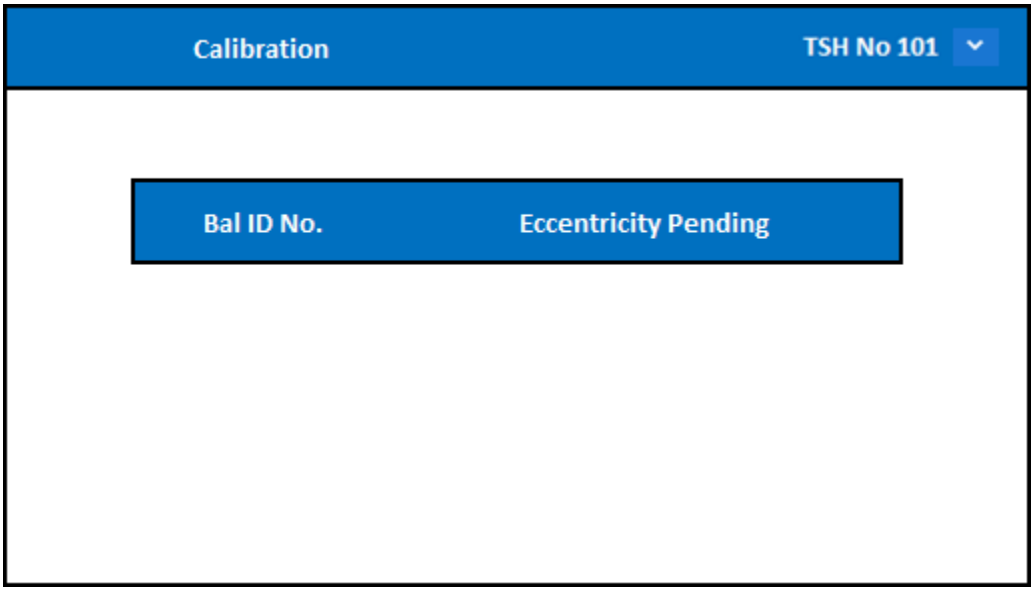
- The system will alert the user to perform Repeatability Calibration of Balance.

SCREEN 77 and 78 : Verification checks

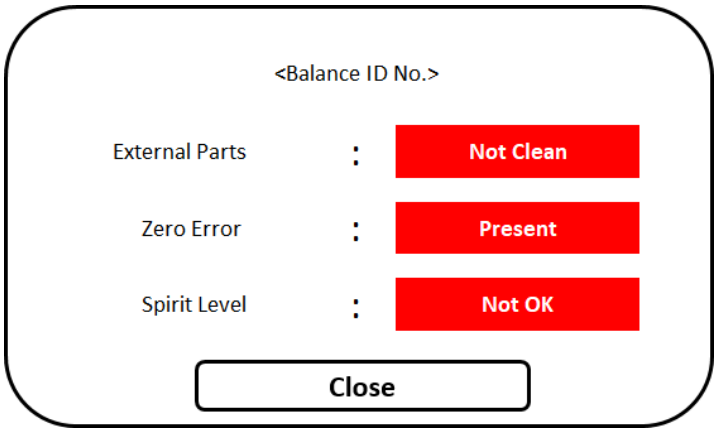
- The user verifies if:
  - i. External parts are Clean/Not Clean.
  - ii. Zero Error Absent/Present.
  - iii. Spirit Level OK/NOT OK.

SCREEN 79 , and SCREEN 80 : Repeatability Calibration

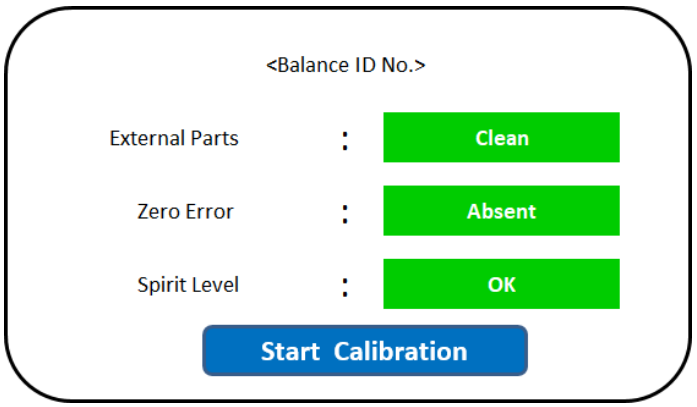
- The system will ask for weights for Repeatability Calibration as per set sequence in software.
- After Calibration completed clicking on 'OK' button user will be directed to Calibration Screen.



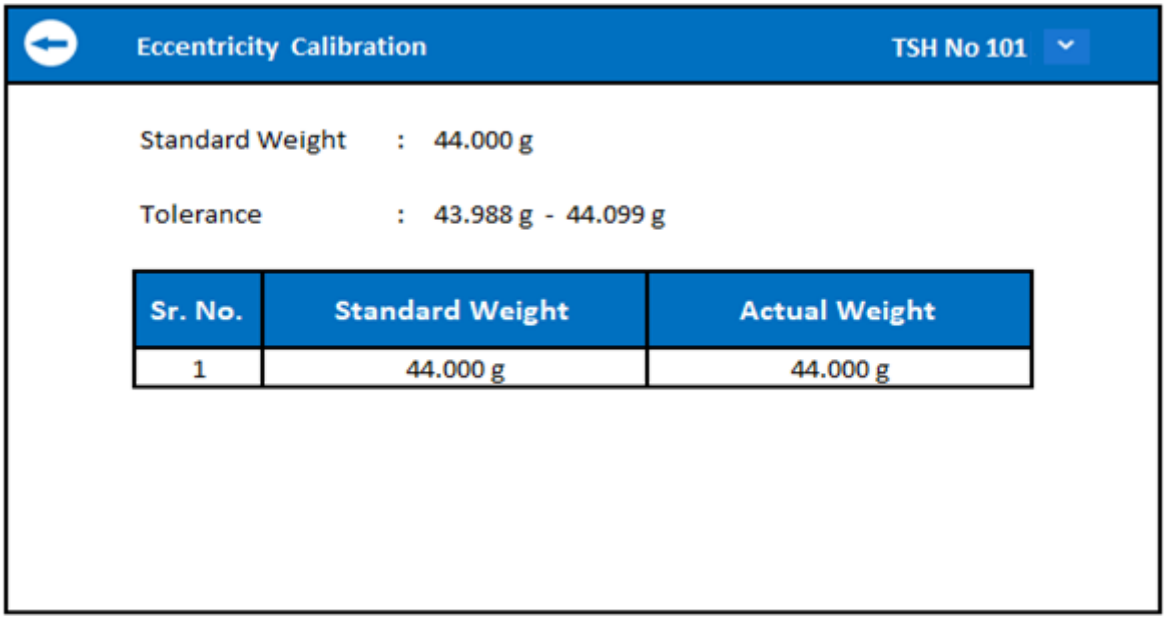
Screen 81



Screen 82



Screen 83



Screen 84

Eccentricity Calibration **TSH No 101**

Standard Weight : 44.000 g

Tolerance : 43.988 g - 44.099 g

Sr. No.	Standard Weight	Actual Weight
5	44.000 g	44.000 g
4	44.000 g	44.000 g
3	44.000 g	44.000 g
2	44.000 g	44.000 g
1	44.000 g	44.000 g

Calibration Successful **Ok**

Screen 85

SCREEN 81: Eccentricity Pending

- The system will alert the user to perform Eccentricity Calibration of Balance.

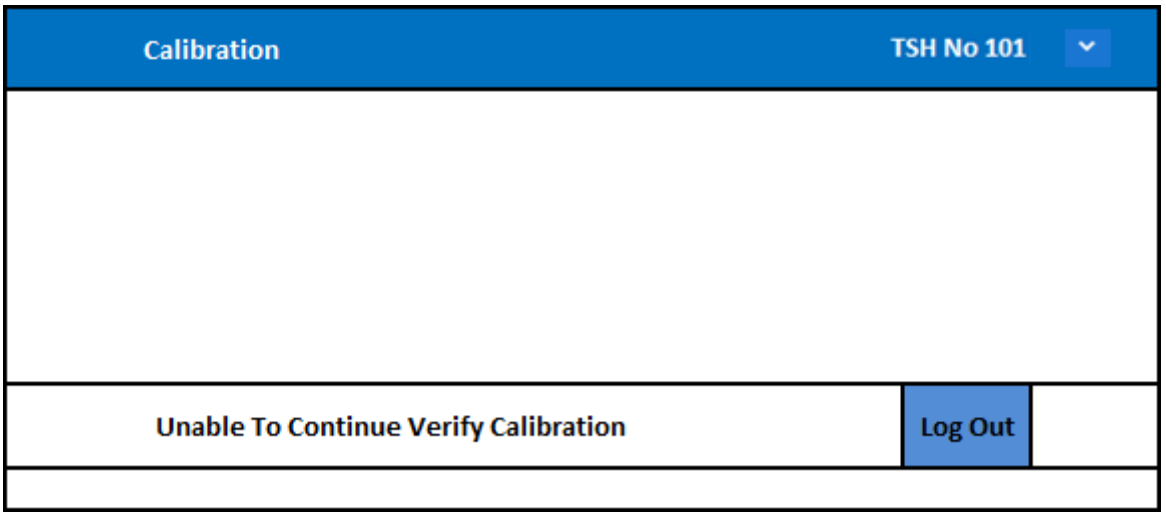
SCREEN 82 and SCREEN 83: Verification checks

- The user verifies if:
  - i. External parts are Clean/Not Clean.
  - ii. Zero Error Absent/Present.
  - iii. Spirit Level OK/NOT OK.

SCREEN 84 and SCREEN 85 : Eccentricity Calibration

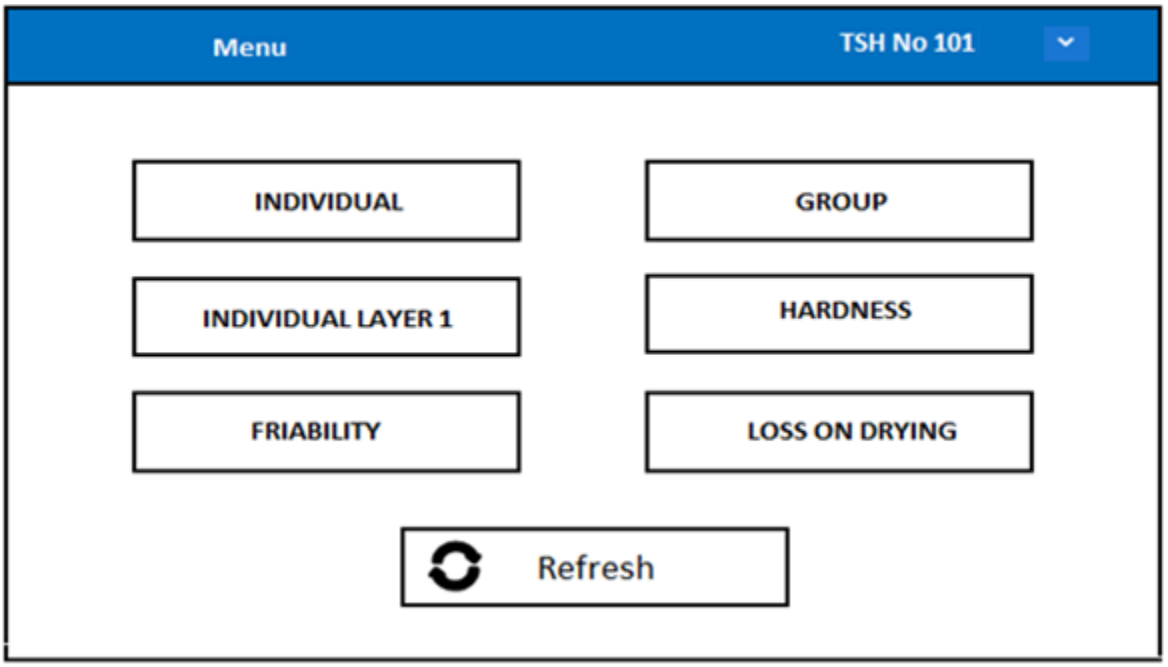
- The system will ask for weights for Eccentricity Calibration as per set sequence in software.
- After Calibration completed clicking on 'OK' button user will be directed to Calibration Screen and if "No Calibration pending' then user will be redirected to menu screen.

CALIBRATION FAILURE/ CALIBRATION SUCCESSFUL



- The system will ask to verify calibration on software.
- The system won't let the user perform any action further until he has verified the calibration report on software.
- Press 'Logout' to navigate to login screen.

6.4 MENU (TABLET)



Screen 86

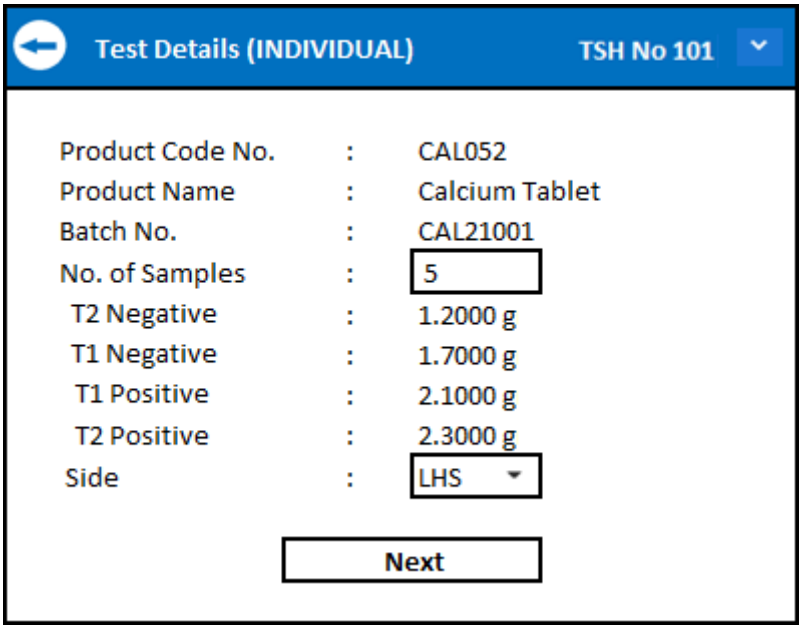
Screen 86 : Menu

User can select test type and proceed for test.

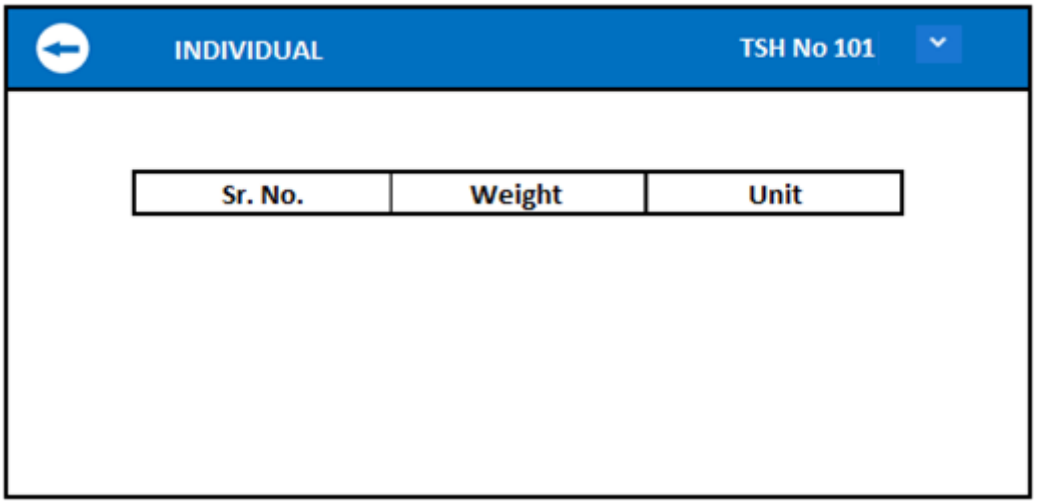
**Note:

- For Compression tests 'Side' will be applicable.
- For Coating tests 'Side' will not be applicable, Lot no. will be applicable.
- For Loss on Drying 'Lot no.' will be applicable.

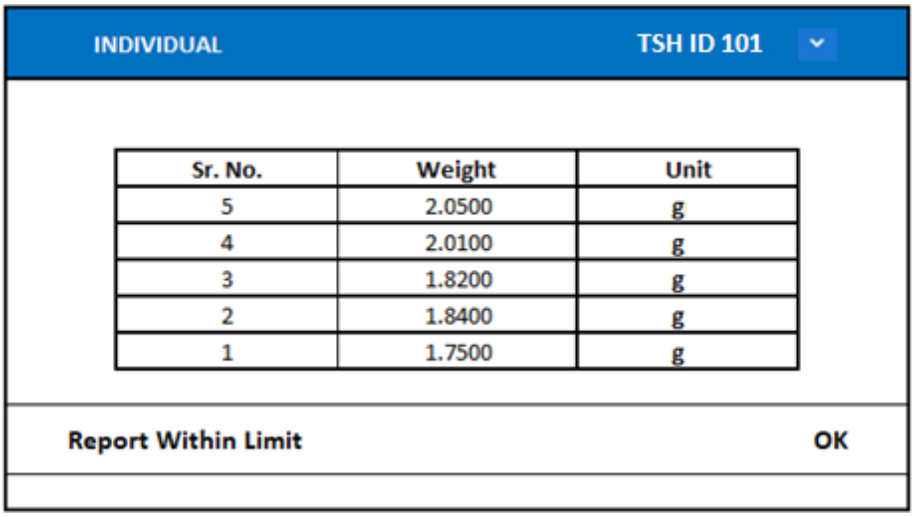
TEST
TABLET
INDIVIDUAL WEIGHT VARIATION
flow explained below will be applicable for following: (Monolayer: Initial and Inprocess)
(layer 1: Initial)
(Bilayer: Initial)



Screen 87



Screen 88



Screen 89

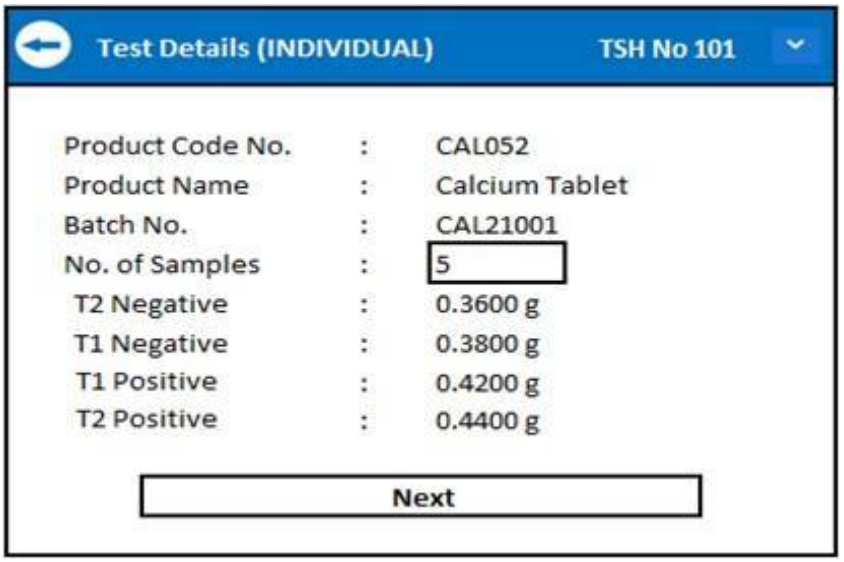
SCREEN 87 Start Test (Verify details)

- Before starting the test, the system will display Batch details such as Product Code No., Product Name, Batch No., No. of Samples, Side, T1 Negative, T1 Positive, T2 Positive and T2 Negative.
- Upon confirming the above details, the user can proceed to perform Individual Weight Variation.

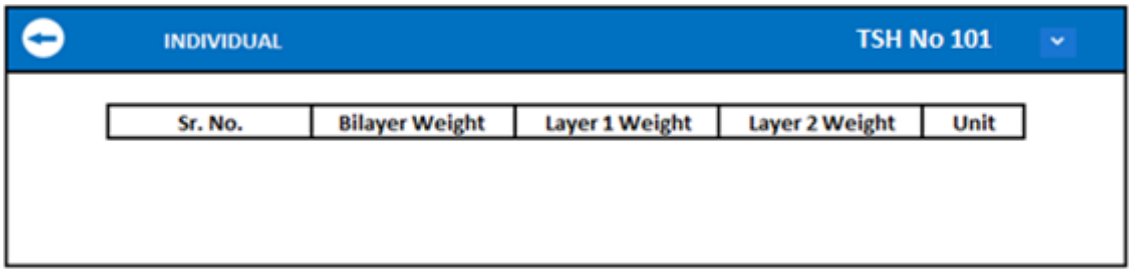
SCREEN 88 and SCREEN 89 : Test

- After Confirming the Product-Batch details, the system will ask for weight of samples.
- Weight received for each sample is displayed with the corresponding Sample Number.
- Upon successful completion, test result will be displayed at the bottom of the field with OK button.

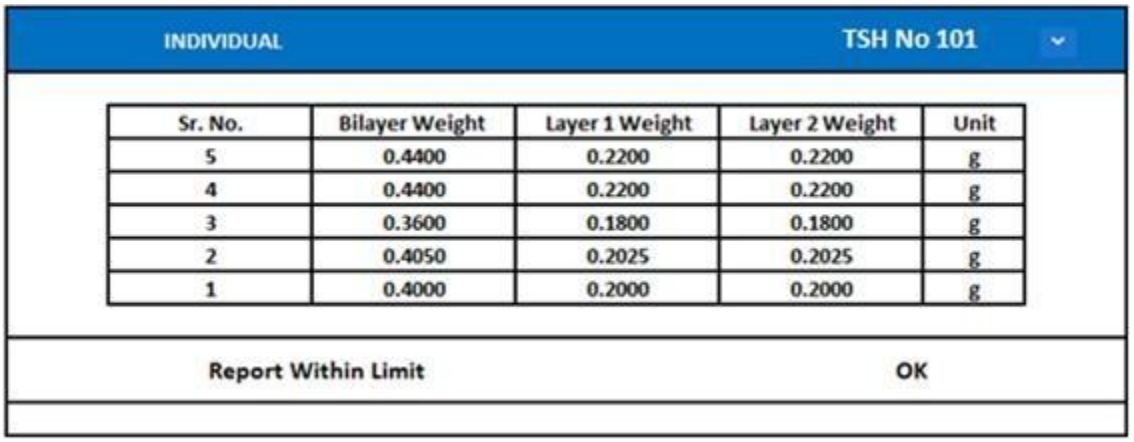
INDIVIDUAL WEIGHT VARIATION flow explained below will be applicable for (Bilayer: Inprocess test)



Screen 90



Screen 91



Screen 92

SCREEN 90 Start Test (Verify details)

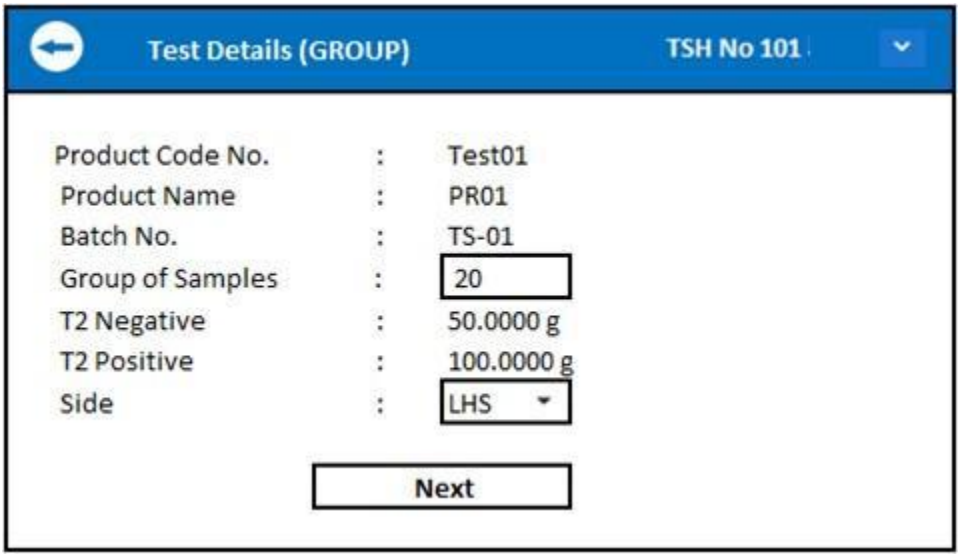
Note: Only tolerances of bilayer tablet will be displayed which will be used to compare the received bilayer weights and display result accordingly.

- Before starting the test, the system will display Batch details such as Product Code No., Product Name, Batch No., No. of Samples, Side, T1 Negative, T1 Positive, T2 Positive and T2 Negative.
- Upon confirming the above details, the user can proceed to perform Individual Weight Variation (Bilayer).

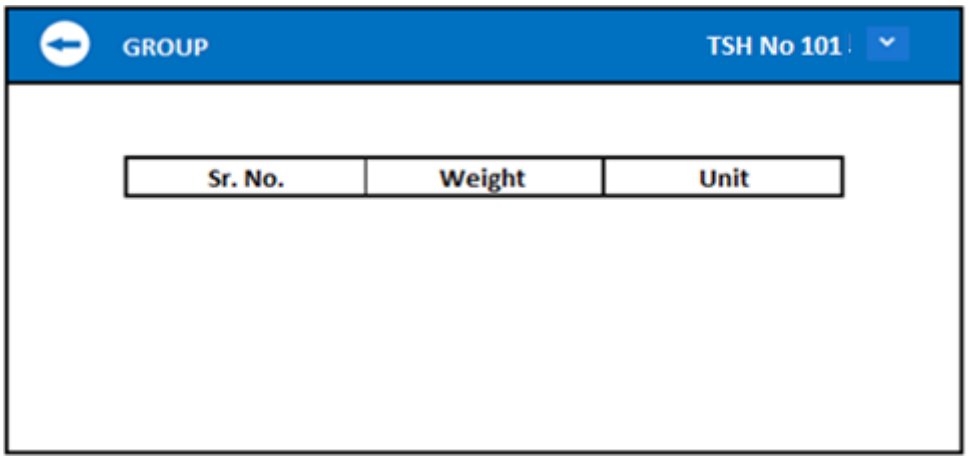
SCREEN 91 and SCREEN 92 : Test

- After Confirming the Product-Batch details, the system will ask for weight of samples as per following sequence.
- Weight of Bilayer tablet, weight of layer 1 and weight of layer 2.
- Weights received for each sample are displayed with the corresponding Sample Number.
- Upon successful completion, test result will be displayed at the bottom of the field with OK button.

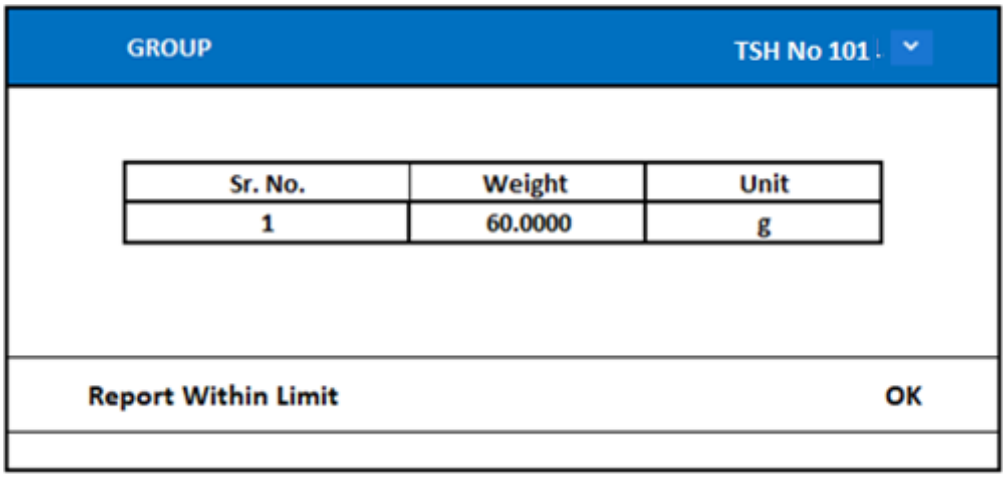
GROUP WEIGHT VARIATION (applicable for all types of product)



Screen 93



Screen 94



SCREEN 93 & 94 : Start Test (Verify details)

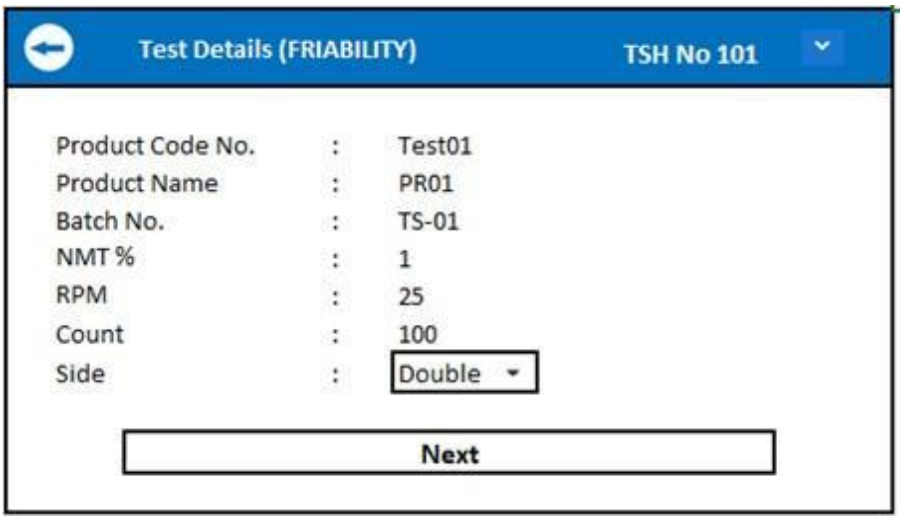
- Before starting the test, the system will display Batch details such as Product Name, Batch No., Server date and time, Side, number of samples, T2 Negative, T2 Positive.
- Upon confirming the above details, the user can proceed to perform Group Weight Variation.

Screen 95 : Test

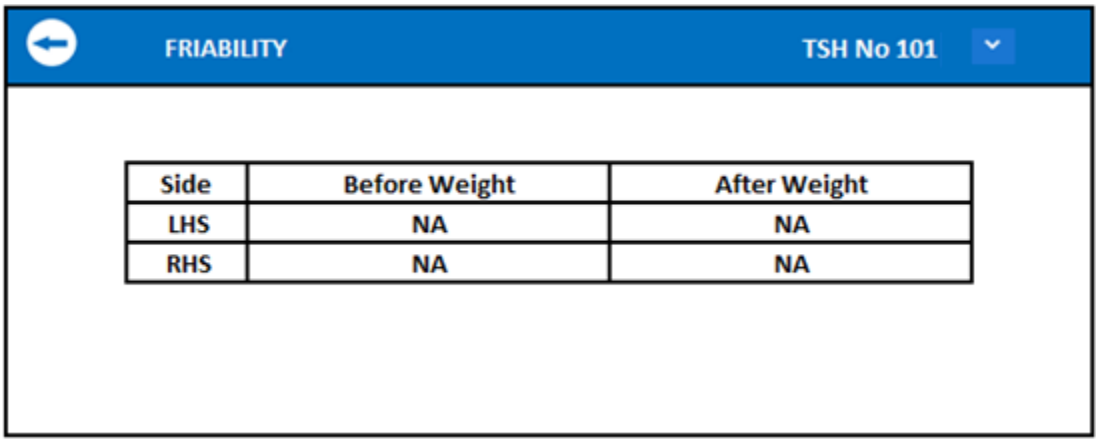
- After Confirming the Product-Batch details, the system will ask for weight of samples.
- Weight received for each sample is displayed with the corresponding Sample Number.
- Upon successful completion, test result will be displayed at the bottom of the field with OK

*Note: For Group double rotary test after completion of LHS test user will be directly asked to perform RHS test.

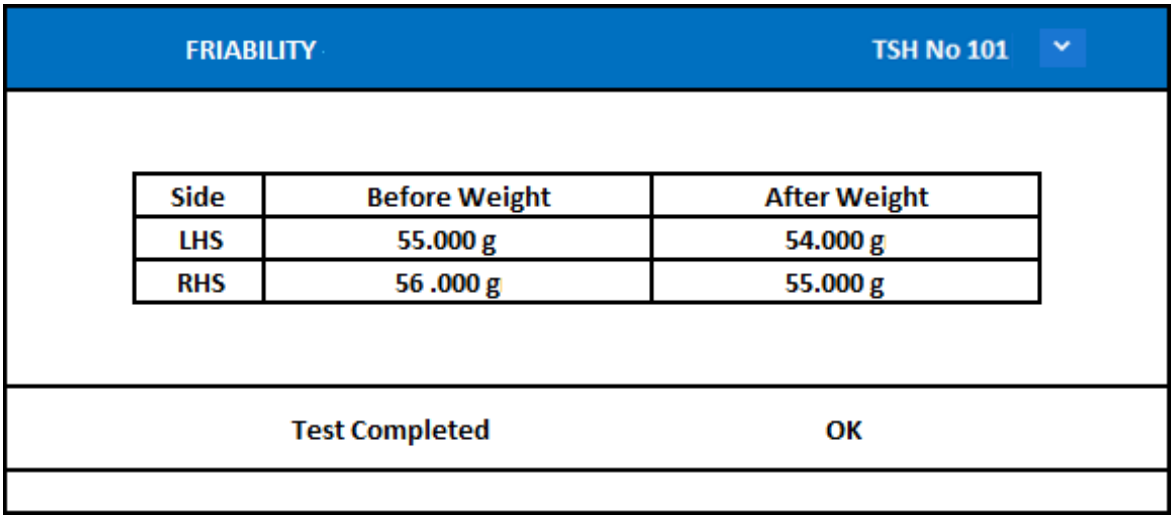
FRIABILITY



Screen 96



Screen 97



Screen 98

SCREEN 96 : Start Test (Verify details)

- Before starting the test, the system will display Batch details such as Product Code No., Product Name, Batch No., Side (Single/Double), NMT%, Set Count and Set RPM.
- Upon confirming the above details, the user can proceed to perform Friability Test.

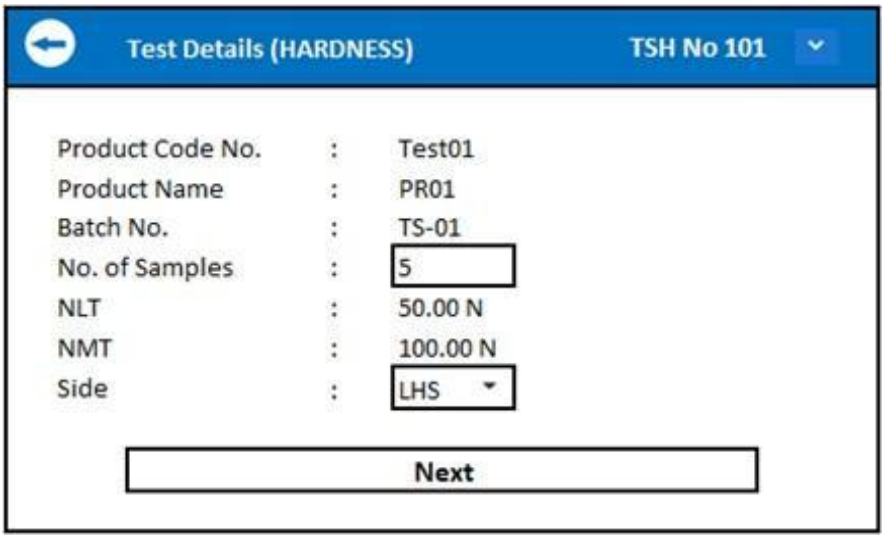
SCREEN 97 : Before Test Weighment

- After Confirming the Product-Batch details, the system will ask for measurements of samples.

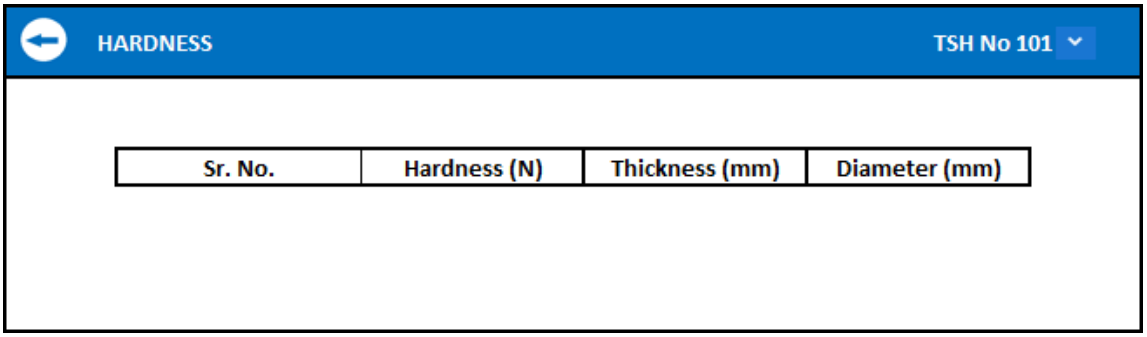
SCREEN 98 : After Test Weighment

- Upon receiving the measurements, the system will save Friability Test details and report will be generated.

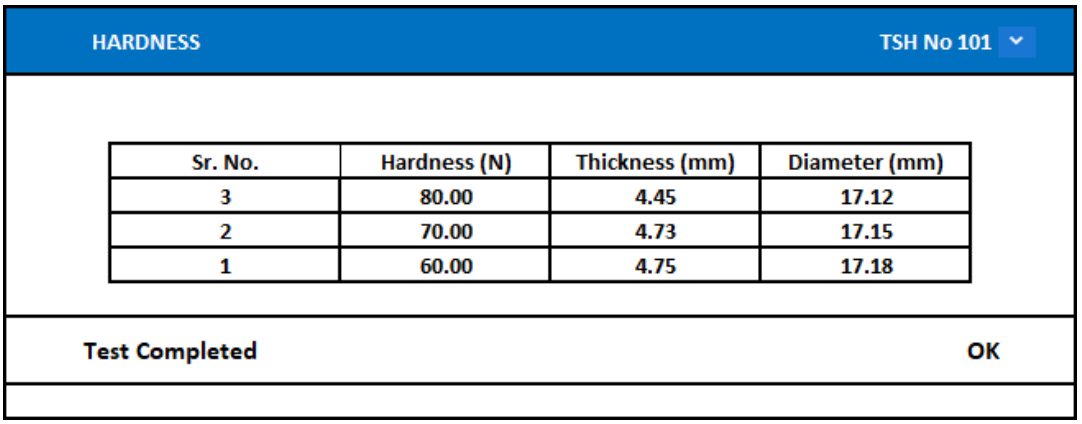
HARDNESS TEST



Screen 99



Screen 100



Screen 101

SCREEN 99 : Start Test (Verify details)

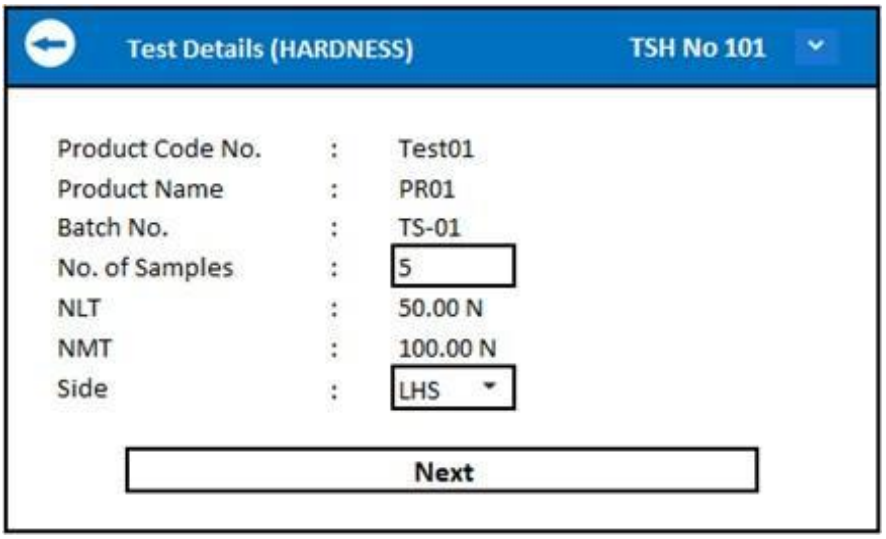
- Before starting the test, the system will display Batch details such as Product Code No., Product Name, Batch No., NLT and NMT.
- Select Side (Single/LHS/RHS) from dropdown.
- Upon confirming the above details, the user can proceed to perform Hardness Variation.

SCREEN 100 and 101 : Test

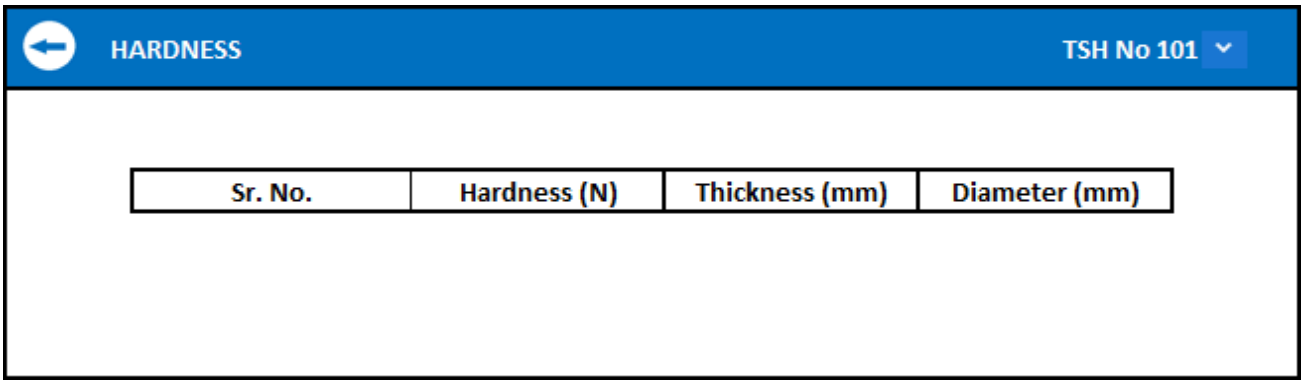
- After Confirming the Product-Batch details, the system will ask for measurement of samples.
- Measurement received for each sample is displayed with the corresponding Sample Number.
- Upon successful completion, test result will be displayed at the bottom of the field with OK button.

Note : Separate report will be generated for hardness , thickness, diameter. (Refer report section)

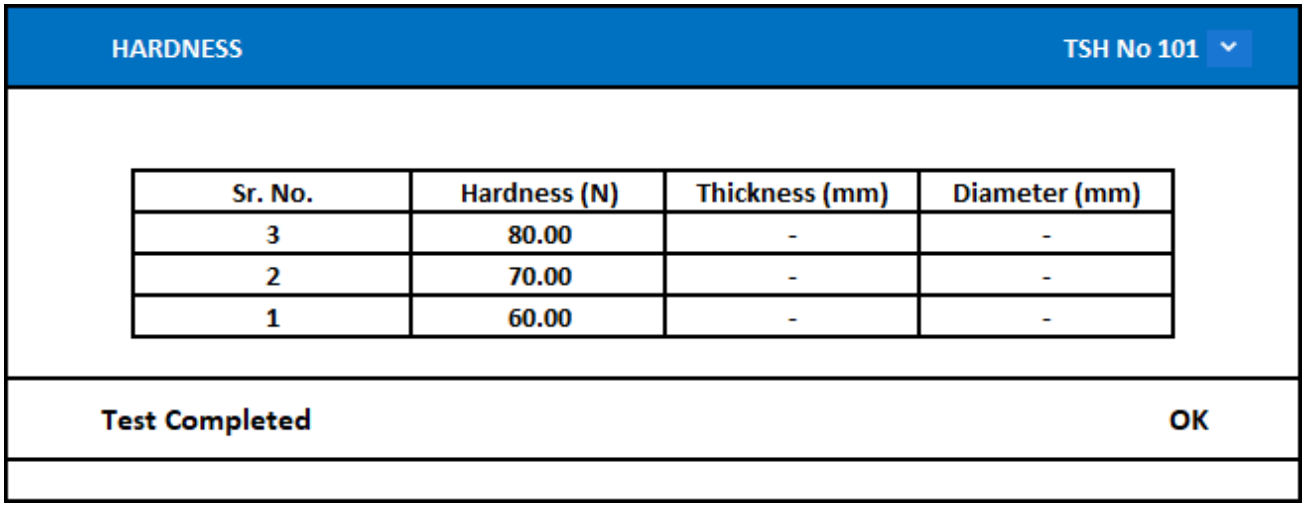
HARDNESS TEST (Only Hardness readings received)



Screen 102



Screen 103



Screen 104

Screen 102 : Start Test (Verify details)

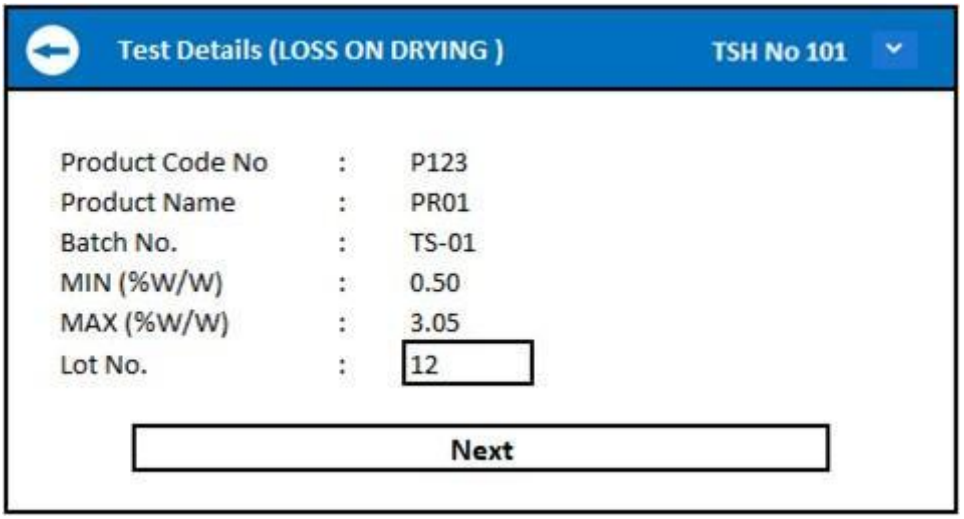
- Before starting the test, the system will display Batch details such as Product Code No., Product Name, Batch No., NLT and NMT.
- Select Side (Single/LHS/RHS) from dropdown.
- Upon confirming the above details, the user can proceed to perform Hardness Variation.

Screen 103 and 104 : Test

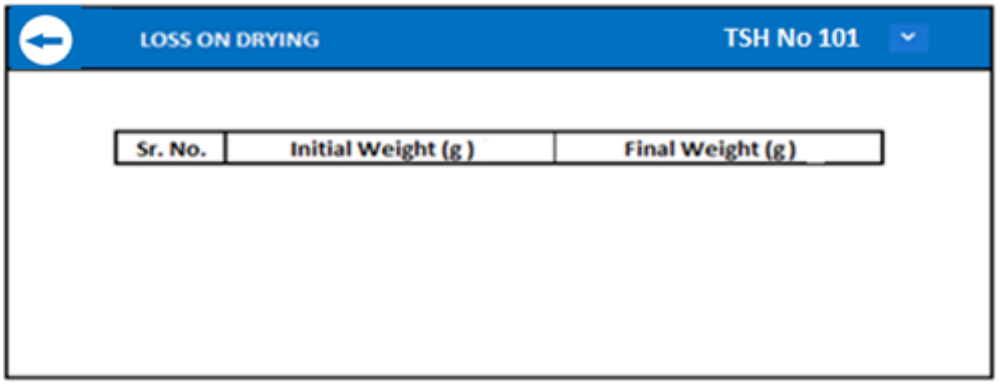
- After Confirming the Product-Batch details, the system will ask for measurement of samples.
- Measurement received for each sample is displayed with the corresponding Sample Number.
- Upon successful completion, test result will be displayed at the bottom of the field with OK button.

*Note: For coated tablets similar screens will be applicable except side. There will be entry for Lot no.

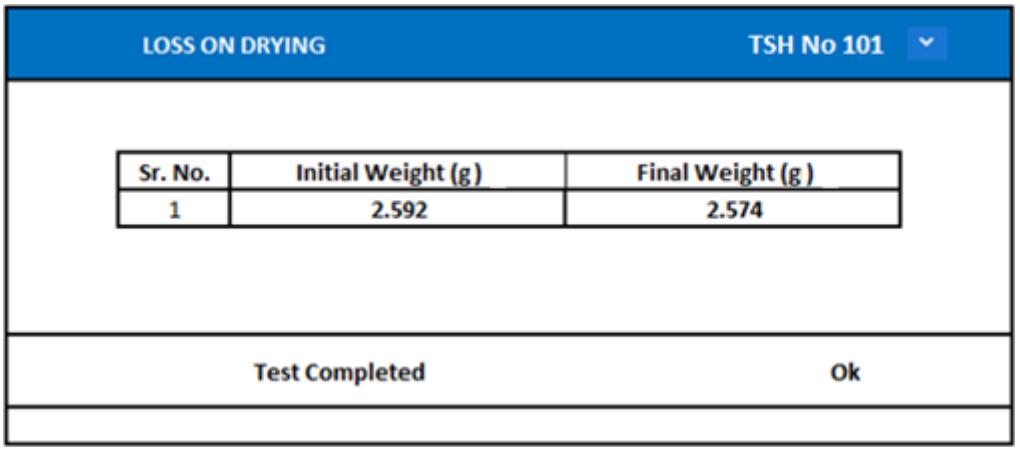
LOD



Screen 105



Screen 106



Screen 107

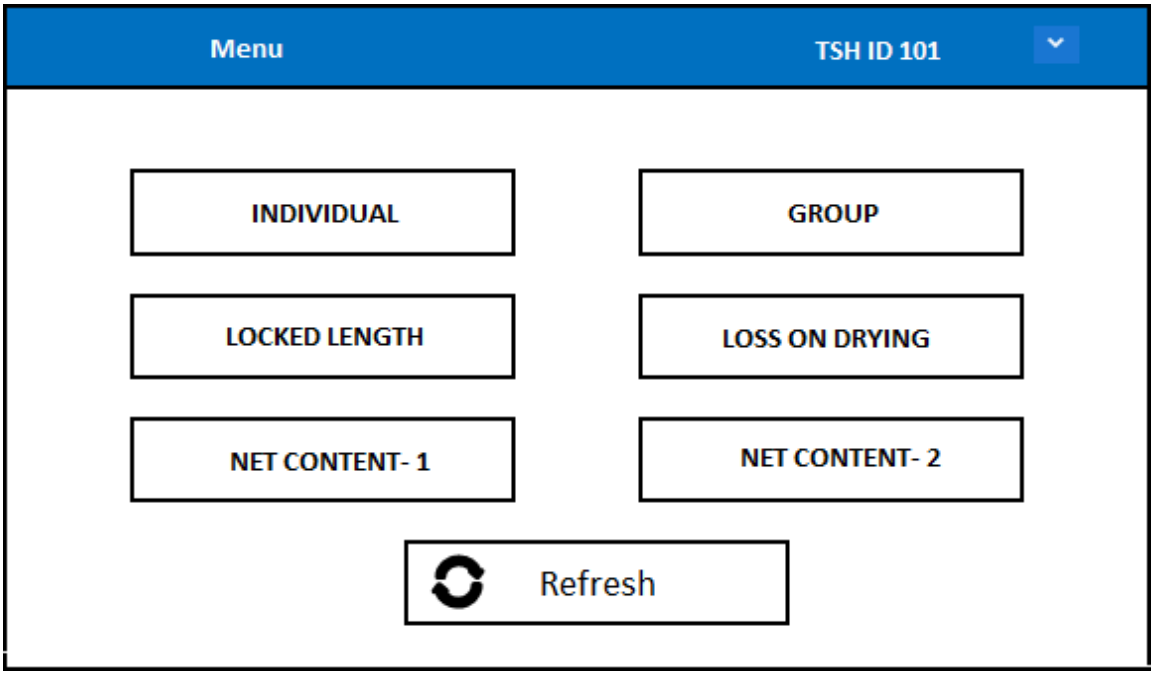
Screen 105 : Start Test

- Before starting the test, the system will display Batch details such as Product Code No., Product Name, Batch No., MIN (%W/W) and MAX (%W/W), Lot No.
- Upon confirming the above details, the user can proceed to perform Test.

Screen 106 and Screen 107 : Test

- After Confirming the Product-Batch details, the system will ask for weight of samples.
- Once data is transferred from Moisture Analyzer to TSH, the TSH will then parse and send data to software for further processing.
- Weight received for each sample is displayed with the corresponding Sample Number.
- Upon successful completion, test result will be displayed at the bottom of the field with OK button.

6.5 MENU (CAPSULE)

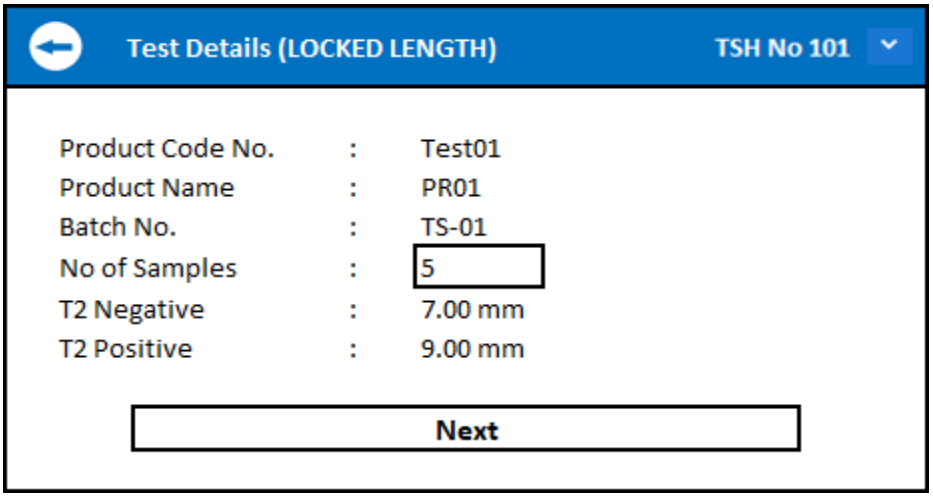


Screen 108

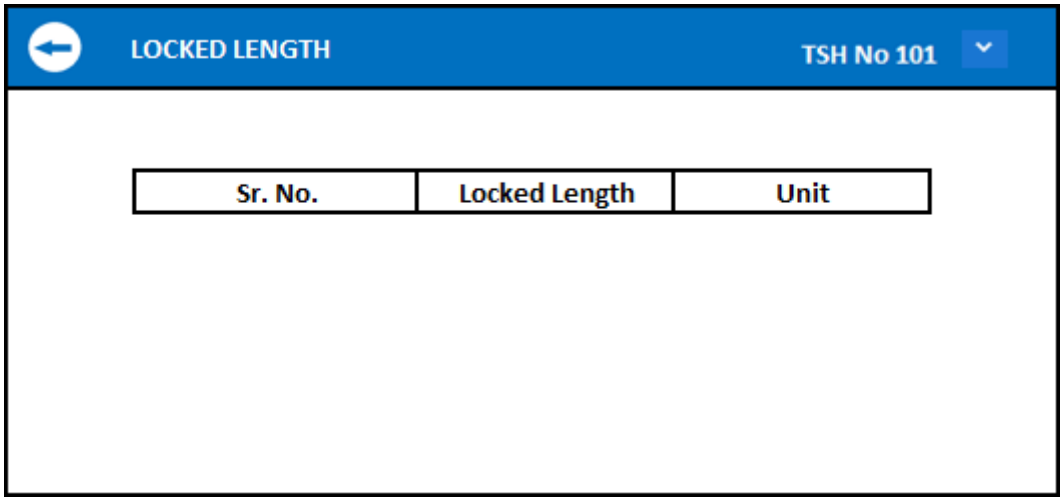
Screen 108 : Menu

User can select test type and proceed for test.

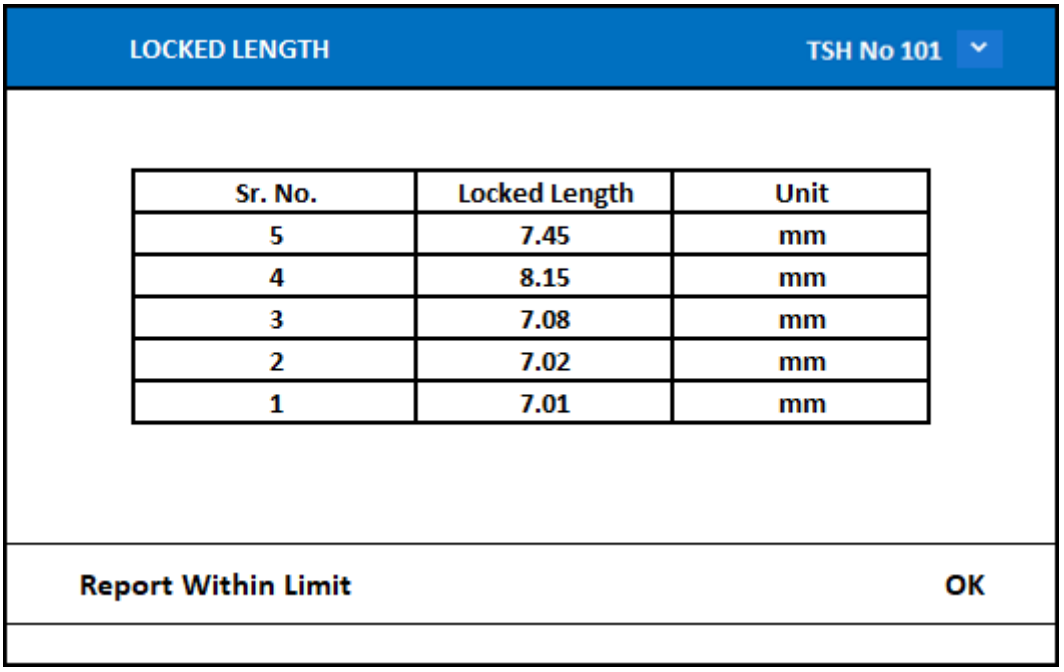
LOCKED LENGTH



Screen 109



Screen 110



Screen 111

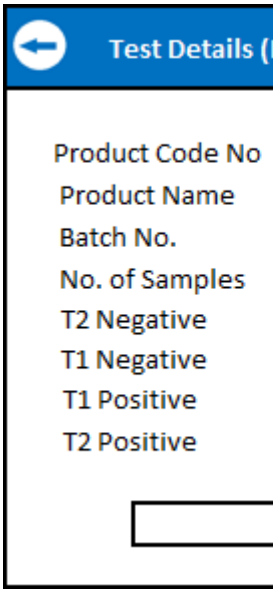
SCREEN 109 Start Test (Verify details)

- Before starting the test, the system will display Batch details such as Product Code No., Product Name, No. of samples, Batch No., Side, T2 Negative, T2 Positive.
- Upon confirming the above details, the user can proceed to perform Locked length Variation.

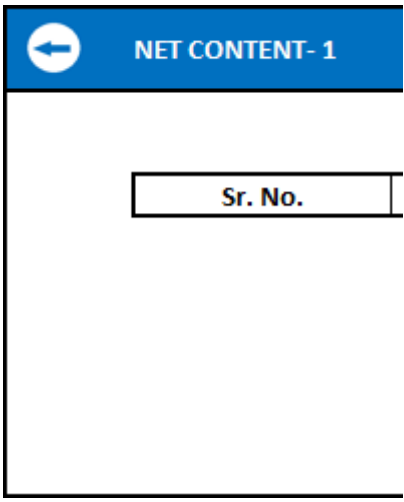
SCREEN 110 and SCREEN 111 : Test

- After Confirming the Product-Batch details, the system will ask for Measurement of samples.
- Measurement received for each sample is displayed with the corresponding Sample Number.
- Upon successful completion, test result will be displayed at the bottom of the field with OK button.

CONTENT- 1



Screen 112



Screen 113

NET CONTENT- 1 TSH No 101

Sr. No.	Weight	Unit
5	2.0500	g
4	2.0100	g
3	1.8200	g
2	1.8400	g
1	1.7500	g

Report Within Limit OK

Screen 114

SCREEN 112 Start Test (Verify details)

- Before starting the test, the system will display Batch details such as Product Code No., Product Name, Batch No., No. of Samples, T1 Negative, T1 Positive, T2 Positive and T2 Negative.
- Upon confirming the above details, the user can proceed to perform Net Weight Content-1.

SCREEN 113 and SCREEN 114 : Test

- After Confirming the Product-Batch details, the system will ask for weight of samples.
- Weight received for each sample is displayed with the corresponding Sample Number.
- Upon successful completion, test result will be displayed at the bottom of the field with OK button.

*Note: Net Content-2 Screen will be similar as per Content- 1 test.

7. VALIDATION

- Blank entries will not be allowed to save.
- None of the TSHs can be allowed to repeat.
- Menus can be accessed by authorized users only.
- At any given time, a user can access the system only from one terminal.
- Cubicle setting should be done properly to perform weighment.
- Weighment can be performed only if batch is started.
- User should not be allowed to Activate/Approve/Deactivate self-added Instruments/Equipment/Products in the system.
- Instruments/Equipment/Products that are assigned to cubicle should not be allowed to edit.
- Once Equipment or any Instrument is activated, it cannot be edited (even upon deactivation). [Except Balance and Vernier]

8. MS-SQL SCHEMA

Display Balance details from following table.

Table: tbl_balance

Field	Type
Id	INTEGER
Bal_Model	STRING(50)
Bal_Make	STRING(50)
Bal_SrNo	STRING(50)
Bal_ID	STRING(50)
Bal_Dept	STRING(50)
Bal_LeastCnt	DECIMAL(10,5)
Bal_MaxCap	DECIMAL(10,5)
Bal_MinCap	DECIMAL(10,5)
Bal_Unit	STRING(5)
Bal_CalbStoreType	INTEGER
Bal_CalbDates	STRING(100)
Bal_CalbDuration	INTEGER
Bal_CalbDueDt	DATEONLY
Bal_CalbDueDtL	DATEONLY
Bal_CalbDueDtU	DATEONLY
Bal_CalbDueDtR	DATEONLY
Bal_CalbDueDtE	DATEONLY
Bal_IsCalibFail	INTEGER
Bal_CalbReminder	INTEGER
locked	INTEGER
editCounter	INTEGER
Bal_MaxoptRange	DECIMAL(10,5)
Bal_MinoptRange	DECIMAL(10,5)
IsNewBalance	INTEGER
IsBinBalance	INTEGER
Bal_isActivate	INTEGER
Bal_DP	INTEGER
userID	STRING(200)
Bal_DSNW	DECIMAL(10,5)
Bal_IsApproved	INTEGER
Bal_ApprovedBy	STRING(200)
Bal_CalbDueMonth	DATEONLY
Bal_Location	STRING(50)
Bal_Status	STRING(50)
Bal_FormNo	STRING(50)
Bal_VersionNo	STRING(50)
Bal_ChangeWt	INTEGER

*Likewise maintained separate table for all equipment.

Display product details from following table.

Table: tbl_product_master

Field	Type
Id	INTEGER
ProductId	STRING(25)
ProductName	STRING(300)
ProductType	INTEGER
ProductVersion	STRING(50)
Version	STRING(50)
IsActive	INTEGER
BatchSize	STRING(100)
BatchUnit	STRING(10)
IsBilayer	INTEGER
IsBilayerLbl	STRING(50)
IsCoated	INTEGER
IsGranulation	INTEGER
IsCompress	INTEGER
NominalNomenclature	STRING(50)
Locked	INTEGER
userID	STRING(200)
ActivateChance	INTEGER
ISBfGChecked	INTEGER
ISPrdVersionChecked	INTEGER
ISVersionChecked	INTEGER

Display area list from following table.

Table: tbl_cubicle_area

Field	Type
RecNo	INTEGER
Area	STRING(100)
Flag	INTEGER
TSHNos	INTEGER
TSHFrom	INTEGER
TSHTo	INTEGER

After selecting area fetch cubicle related data from following table.

Table: tbl_cubical	
Field Sys_CubicNo Sys_RptType Sys_CubicName	T y

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e
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G
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R
I
N
T
E
G
E
R
S
T
R
I
N
G
(
1
0
0
)

Sys_RoomNo	STRING(100)
Sys_Location	STRING(100)
Sys TSHNo	STRING(100)
Sys_MachineCode	STRING(70)
Sys_MfgCode	STRING(100)
Sys_RotaryType	STRING(10)
Sys_BalID	STRING(100)
Sys_VernierID	STRING(100)
Sys_HardID	STRING(100)
Sys_FriabID	STRING(100)
Sys_MoistID	STRING(100)
Sys_PHID	STRING(100)
Sys_ConductID	STRING(100)
Sys_DOID	STRING(100)
Sys_Batch	STRING(30)
Sys_ProductCodeNo	STRING(100)
Sys_ProductName	STRING(300)
Sys_BatchSize	STRING(100)
Sys_BatchSizeUnit	STRING(20)
Sys_Stage	STRING(500)
Sys_CubType	STRING(50)
Sys_DataMode	INTEGER(1)
Sys_Version	STRING(50)
Sys_PVersion	STRING(50)
Sys_DailyBalRecalib	INTEGER
Sys_PeriodicBalRecalib	INTEGER
locked	INTEGER
editCounter	INTEGER
Sys_MAStage	STRING(200)
Sys_PortNo	INTEGER
Sys_Port1	STRING(200)
Sys_Port2	STRING(200)
Sys_Port3	STRING(200)
Sys_Port4	STRING(200)
Sys_Plant	STRING(100)
Sys_dept	STRING(200)
Sys_LotNo	STRING(200)
Sys_Area	STRING(200)
Sys_media	STRING(50)
Sys_IPQCType	STRING(100)
Sys_Validation	INTEGER
Sys_PrinterName	STRING(1000)
Sys_CalibInProcess	INTEGER(1)
Sys_flagAlert	INTEGER(1)
Sys_cubTypes	STRING(200)

Audit Trail Table for User related operations

Table: tbl_audit_users

Field	Type
RecNo	INTEGER
Dt	DATEONLY
Tm	TIME
Userid	STRING(50)
Username	STRING(255)
OldRole	STRING(50)
NewRole	STRING(50)
ACT	STRING(50)
KeyCode	STRING(5000)
KeyValue	STRING(5000)
RightAdded	STRING(5000)
RightRemoved	STRING(5000)
Remark	STRING(500)
OldDepartment	STRING(150)
NewDepartment	STRING(150)

*Likewise maintained separate table for all actions.