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# 21 CFR Compliant For Titration, Data Capturing & Calculations SOFTWARE Ш E-BURETT MICROLIT

# Microlit E-Burette Software

A robust software developed by team Microlit in compliance with FDA 21 CFR Part 11 for titration experiments conducted with Microlit E-Burette





# EXPERIENCE PRECISION

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#### Introduction to 21CFR and Its Importance

The FDA 21 CFR Part 11 regulates the use of electronic records and electronic signatures. This regulation is of importance to pharmaceutical, healthcare, and other biological & drug manufacturers.

The 21 CFR (Code of Federal Regulations) Part 11 code has been designed for storing electronic documentation securely with the use of electronic signatures. The 21 CFR demands and ensures data security by validating the electronic instrument, an audit trail for every action, electronic copies of the records, and safe retention of the electronic records.

21 CFR compliance benefits the industries by eliminating the paper record system and increasing the authenticity of data and records via electronic security mechanisms.

Microlit has always upheld the importance of maintaining the validity, reliability and authenticity of the experiments conducted with its high precision liquid handling instruments. Consequently, the Microlit E-Burette software is in compliance with the FDA 21 CFR Part 11.

The users can conduct titration experiments and simultaneously record the experiment readings (titre values) on the E-Burette software. Based on the inputs and the readings received, the software automatically computes the molarity/normality of the analyte.

Furthermore, the software allows the user to perform volumetric titration to create volume standards. The user can also perform assay titration to evaluate the molarity or normality of the analyte. The integrity of the data is protected by implementation of regulations laid down by the FDA.

#### 2. System Compatibility

The E-Burette 21 CFR software is compatible with Windows Operating System only.

#### 3. Software Installation

#### 3.1 Server Setup

Before installing the 21 CFR Part 11 compliant E-Burette Software, you need to set up the server in your LAN or WiFi network. Note that you might have to consult your IT department for the following steps:

#### A. Database Execution

• Download and install the SQL Database Management Studio to the Desktop Sign-up and login with your credentials.

Note: The software is compatible with the free or Express Edition of SQL DBMS.

• Copy the E-Burette Script file available on the provided flash drive to your database studio or double-click on the E-Burette script (*Image 1*).

21 CFR se Share	etup files e View						
<mark> </mark> > 21	1 CFR setup files				~	Ö	P
	Name	Date modified	Туре	Size			
55	Publish	23/11/2020 2:58 pm	File folder				
	JB E_Burette	04/11/2020 1:19 pm	Microsoft SQL Ser	293 KB			
	🔤 setup	15/10/2020 11:46 am	Application	2,496 KB			

(Image 1)

• The script will be opened in the SQL studio. Execute and save the script (Image 2).



(Image 2)

Note: The execution of this script is mandatory for the functioning of the software.

#### B. IIS Configuration

- Choose a Windows system that has to be configured as the Server and which can be accessed wirelessly via LAN or Wifi from other systems in your facility
- Configure IIS (Internet Information Services)

Press the Windows + R button and search for the "inetmgr" (*Image 3*), to check whether your device is configured with IIS or not.



(Image 3)

If configured, an internet information service manager will pop-up on your screen with your desktop details (*Image 4*).



(Image 4)

If IIS is not configured, a pop-up will display "windows cannot find 'inetmgr' ".

Make sure to type the name correctly, and then try again.

To configure the IIS with your system, go to the "Program & Features" section (*Image 5*) and turn on the Windows feature (*Image 6*), and check-mark all the IIS features. Once the changes are applied, do restart your computer.





(Image 6)

To confirm the configuration, press the 'Windows + R' button and search again "inetmgr". If the configuration is completed, Internet Information Services (IIS) Manager will open. (*Image 7*)



(Image 7)

If the configuration is incomplete, a pop-up with "windows cannot find 'inetmgr' " will appear. Please ensure that the required IIS features are already marked. Also, make sure that a dot network framework must be installed compatible with your windows before configuring the IIS. Note: It is recommended that a 4.5.2 dot network framework be installed.

(Image 5)

#### C. Execution of Web Application/Hosting

• Run the Web Application file.

Copy the "Web Application" file provided along with the software in the flash drive (*e.g., publish file; Image 8*), and save it to your Desktop drive (e.g., E or D).

ive (r.)			
Name	Date modified	Туре	Size
Publish	04/11/2020 1:05 pm	File folder	
E_Burette	04/11/2020 1:19 pm	Microsoft SQL Ser	293 KB
Setup	15/10/2020 11:46 a	Application	2,496 KB

(Image 8)

Note: Do not copy the files on primary drive or local disk or window drive.

Search for "inetmgr" and the internet information services dialog box will pop up. Right-click on the sites then to 'add website' (*Image 9*).



#### (Image 9)

Copy the path of the web application file from the drive and paste it to the physical path. Enter the Site Name (eg. EBurette) and select the Application pool (as applicable).

Bind the IP address along with the port (Image 10).



Note: Static IP address is required to run the application.

To confirm that the application has been hosted:

• Go to the IIS Manager, click on the sites and select your E-Burette file. (Image 11)



• Click on the IP under browser website. (Image 12)

• You will be redirected to the application main page. (Image 13)



(Image 13)

You may also copy the static IP to your browser and it will redirect to the application's main login page if the web hosting is correct.

Note: Please ensure that the E-Burette software setup file has been installed and the license key has been activated correctly before hosting on the server.

#### 3.2 Client/Middleware Setup

#### A. Installation

To access the 21 CFR software, install the middleware setup on the configured system.

To run the software, perform the following steps:

1. Double click on the E-Burette software icon (*Image 14*) to install the E-Burette software file to your desktop.

Name	Date modified	Туре	Size
1 Publish	06-04-2021 13:48	File folder	
21 CFR E_Burette	24-03-2021 13:42	Application	2,885 KB
E_burette	05-04-2021 15:07	Microsoft SQL Ser.,	491 KB



The installation of the software will begin (Image 15).



(Image 15)

2. Click on the next button to let 'InstallShieldWizard' install the E-Burette setup on your computer

(Image 16).



3. Click on the Next button of the 'Install Shield Wizard' to install to this folder or click on the

Change button to install to a different folder (Image 17).

Click Ne:	tion Felder int to install to this folder, or click Change to install to a different folder.
Ø	Install E-Burette Selup to: C:Program Files (x86)Wisrolit 21 CFR\

(Image 17)

4. We recommend modifying the file destination folder, preferably non-window drive (Image 18).

Browse to the destination folder.	3
Look in:	
🚔 Microlit 21 CFR	× 🖻 🖻
	- Lines Lines
Eolder name: D: Vrogram Files (x86)/Mcroit 21.CFR \	



5. Click on the Next button once the destination folder has been selected (Image 19).

Install E-Burette Setup to	0:		
D: \Program Files (x86) \M	licrolit 21 CFR\		Change
	D: Wrogram Files (x86)(4	D: (Program Files (x86)) (Picrolit 21 CFR)	D:\Vrogram Files (x86)\Vicroit 21 CFR\



6. Click on the Install button to install the program (Image 20).

eady to Install the Program		
The wizard is ready to begin insta	llation.	
If you want to review or change a exit the wizard.	my of your installation settings, dick B	ack. Click Cancel to
Current Settings:		
Setup Type:		
Typical		
Destination Folder:		
D:\Program Files (x86) \Microl	t 21 CFR\	
User Information:		
Name: Windows User		
Company:		
l articula		

(Image 20)

7. Click on the Finish button on the device driver installation wizard (Image 21).

🕼 E-Burette Setup - InstallS	hield Wizard	×
	InstallShield Wizard Completed	
MICROLIT		
	The InstallShield Wizard has successfully installed E-Burette Setup. Click Finish to exit the wizard.	
	< Bock Einish Canta	i

(Image .	21)
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8. After successful installation, an icon will appear on your desktop. Double click on the icon and the license key window will appear (*Image 22*).



#### B. Licensing Key

To activate the software licence, enter the 16-digit code provided in the box (Image 23).

Microlit ×	
E-BURETTE SOFTWARE	I MICROLIT
21-CFR Part 11 Compliant	21-CFR Part 11 Compliant
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	Person d
Activate	formation the Signal
(Image 23)	The golf my platored at
ease ensure internet connection while enabling the	Copyright & 3030 ments offed by - indicating technologies (PLLM, Minights-mented

licensing key.

You may log in to the 21 CFR E-BURETTE software on your browser (*Image 24*).

Log in with the credentials provided along with the box and software calibration report and reset your password as per the instructions.

#### 4. Operating 21 CFR Software

#### 4.1 Registration

Open the Microlit 21 CFR E-Burette Software on your browser. Sign-in to start your session with the default registered email address and default password provided in the box. The first sign-in will allow the registered user to update the login password (as a super-admin) by answering the security questions (*Image 25*).

To create/update passwords, it is important to meet the password requirements (Image 26).





(Image 26)

(Image 25)

Sign-in again using your new credentials.

(Image 24)

icintiais.

10

#### 4.2 Onboarding

The first log-in allows the super admin or the registered user to update the company profile, creating and updating new users, assigning the users different roles and permissions.

#### Steps for Onboarding:

#### A. Company Profile Setup (Image 27)

Add your company information and fill in all the required fields (including company name, contact number, email, communication address, and company logo).

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Transfer.		
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Diat/		
-stat@northine		
Sout?		
Bireidž		
De-		
Looky <sup>2</sup>		Printed Spectr
100		The second



#### B. Password Configuration (Image 28)

The changes made will be applied to all the users.

- Password expiration-Depicts the number of days the set password will expire
- Password expiration extension Depicts the number of days allowed for a password reset. It provides extra time for the user to change the password after its expiration.
- Password Uniqueness Depicts the number of recent passwords that cannot be used.
- Auto logout (min.) The minimum time duration after which the account will automatically be logged out if no activity is performed.
- Account disable criteria-This is the total number of unsuccessful login attempts allowed, after which the account will be disabled.

Pessword Exploration* - manage of departments	patienced will expre
н	
exaword Exploration Edmission* - Hamberrin	rpushowed for parameter rates
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Factword Uniquenets* - Number of wooth passo	with their server be used
Sato Logoct (min.)*	
35	
Account Disable Criteria* - Marsher of Assessm	dullagie atterata allocetal
2	

(Image 28)

#### C. SMTP Configuration

The SMTP configuration enables the sending of emails when a user is created (Image 29).

ender Email*	Hosi*	
customercare1@microlit.com	amtp.gmail.com	
lassword*	Port*	
	587	
2 SSL Enable		
Submit		

(Image 29)

- 1. Setting up the SMTP configuration:
- To set SMTP in cPanel, first create an email account on the server.
- In cPanel navigate to the Email Accounts section and create the email account (Image 30).





The c Panel will generate the account. Once you select the details- a domain, a username, and a password, click on the CREATE button (*Image 31*).

nis feat	ture le	ts you creat	e and manage en	nail accounts. Want 1	o learn more? Read our <u>documentation</u>	o≌-	co <sub>Availab</sub>	le 1 Used
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	> (	anel user	Default	✓ Unrestricted	141 34 KB / #	P CHECK EMAIL	#MANASE	D CONNECT DEVICE

(Image 31)

Click on the CONNECT DEVICES to configure the client with the server (Image 32).

his fea	ture lets you create and m	anage email accounts. Want t	o learn more? Read our <u>documentati</u>	on 🗹 -	oo Available	1 Used
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	Account A @ Domain	Restrictions	Storage: Used / Allocated / %			
1	> cpanel_user Draws	✓ Unrestricted	141.34 KB /∞	12 CHECK EMAL	FMANUAGE D	ONNECT DIVICES

(Image 32)

You will find the username, the URL, and the SMTP port number of the outgoing server. Enter these details into the software page to complete the setup (*Image 33*).



#### 2. Setting up SMTP for Gmail-

- The outgoing email (SMTP) server for Gmail: smtp.gmail.com
- Use authentication: YES
- Use secure connection: YES (TLS or SSL depending on your mail client/ website SMTP plugin)
- Username: Your Gmail account (e.g. user@gmail.com)
- Password: Your Gmail password
- Port: 465 (SSL required) or 587 (TLS required)
- 3. Setting up SMTP for Yahoo-
- The outgoing email (SMTP) server for Yahoo: smtp.mail.yahoo.com
- Use authentication: YES
- Use secure connection: YES (TLS or SSL depending on your mail client/ website SMTP plugin)
- Username: Your Yahoo account (e.g. user@yahoo.com)
- Password: Your Yahoo password
- Port: 465 (SSL required) or 587 (TLS required)

#### 4.Setting up SMTP for Hotmail-

- The outgoing email (SMTP) server for Hotmail: smtp.live.com
- Use authentication: YES
- Username: Your Hotmail account (e.g. user@yahoo.com)

Password: Your Hotmail password

Port: 25 or 465

(Image 33)

#### 5. Setting up SMTP for Outlook-

- The outgoing email (SMTP) server for Outlook: smtp-mail.outlook.com
- Sending limits: 3000 emails or 100 recipients a day
- Username: Your Outlook account (e.g. user@outlook.com)
- Password: Your Outlook password
- Port: 587 (With TLS) or 25 (Without TLS/SSL)

#### D. Role Creation & Permissions

This onboarding step allows the super-admin to create or update Roles (or User Types) and assign them the permissions to view other users and their experiments *(Image 34)*. A default configuration is provided which can be further customized, as per the customer's requirement.



(Image 34)

1. Role Creation (Image 35)

The software has a default configuration of roles- Super Admin > Admin > Analyst. The user can

modify it as per the requirement.

Follow the given steps to create a new role:

- Enter the role name you wish to create.
- Mark the checkbox and assign the permissions of which other roles this new role can create.

If you do not wish to assign this new role the permission to create other roles, leave the marks unchecked.

- Click on the 'Submit' button after completion.
- If you do not want to change/create any role, click on the 'Next' button.





#### 2. Permissions (Image 36)

The default roles (super admin, admin, and analyst) have been assigned the permissions which can be modified by the user. The Super Admin has ALL permissions, the Admin has TREE permissions, and the Analyst has no permissions.

#### Role View Rights-

- Only Show Own Users- Allows the new users or existing users to view/edit only the users they have created.
- Show Tree Users- Allows the new users or existing users to view/edit all users with roles that the user can create.

\*Tree: Includes all users with roles that the new role can create.

Experiment View Rights-

- Only Show Own Users- Allows the new users or existing users to view the experiment reports of only the users they have created.
- Show Tree Users- Allows the new users or existing users to view/review experiment reports of all the users with roles that the user can create

\*Tree: Includes all users with roles that the new role can create.



E. Navigation Permissions

The navigation permissions allow the super admin to assign and authorize the navigation controls to the users created (*Image 37*).

	CHRORENUS-Map 3 of 5
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Bank Reset for Delia 8	

(Image 37) 16

#### The super admin can authorize what controls the users can have access to.

The super admin has access to all the controls, by default (Image 38).

	ONBOARDING - Step 5 of 5
avigation Control Accentrations to	User Roles
Please select menu options that will be visible to Super Admin r	ole.
Navigation Menu*	
OSelect Al:	
• Dashboard	
o 🖬 Dashboard	
O User Management	
e 🖬 Add User	
Configuration	
<ul> <li>Maxigation Control</li> </ul>	
<ul> <li>Password Configuration</li> </ul>	
e 🗹 Authorize System	
<ul> <li>SMTP Configuration</li> </ul>	
e Company Profile	
Evantiments	
- Element SOR	
o Craste de View Experimente	
e 🖾 Review Experiments	
• 🗆 Audit Trail	
e 🖾 Audit Trail	
Finish Reset to Osfault	



Once done, click on the 'Finish' button.

#### 4.3 Dashboard

The dashboard is the main page or the home page which will open whenever the users login (if they have been assigned the dashboard under navigation control) (*Image 39*).

				Vidushi Srivas
Profile			6	
User Profile				<b>9</b> .
Name	Email	Role	Vidushi	
Vichushi Scivestava	vidushi@micralit.com	Super Admin	Supe	r Admin
Current Password*	New Password*	Confirm Password*	Profile	Sign
Current Research	Paramaterid	Confirm Pasaword	in avere i	
Sutmit Reset				
Password Requirements!				
Password must be between a to 15 characters. Password should contains at least one lowercase letter				
Password should contains at least one uppercase letter				

(Image 39)

The user can access the profile and change the password by clicking on the name in the top right corner. The user can also sign out from here.

#### 4.4 User Management

User management enables users to add, edit, view, or disable any new or a particular user

(Image 40).

E BURETTE SUPTIMARE 21-DR for 11 Constant	-				1	🔘 Viduahi Situadas
(C)	New User					
~	Name*		Creail*		Araign Role*	
MINIMUM	3anjay		and generatives		latert	*
	Login with Authorized St	sten ardy"			Cal sult	
Destance	Rate				t krant per tegna aper Terreti ver Suppor Admin	
	Current Users					4.0
	Name	Rola	Local	Last Lègin Time	Action	
	Viduchi Shirastava	Super Admin	iduali@nicisht.com	4/03/2020 12:19:56 (%)	New Datal Lats Cashie	

(Image 40)

A list of all active and inactive users can be accessed.

A. Add User (Image 41)

- To add a new user, go to the 'User Management' section. Enter the name, email address, and select the roles which you may want to assign (from the drop-down).
- Login with authorized system only. To ensure data security, while creating a user, authorize the system to restrict the logins from authorized desktops only.
- The one who is creating the user, can disable it or change the assigned roles.

ew User		
Name*	Email."	Assign Role"
Rajesh	info@microlit.com	Operator 🛩
Login with Authorized System only*		Select Admin Analyst
ALO DA		Operator Super Admin

(Image 41)

B. Edit Users (Image 42)

- Click on the 'Edit' button to amend or update the changes to an existing user.
- It allows the authorized user to change the role, name, or email address.

Name*		Small*		Assign Role"
Sarjay		wipprouple.com		Anatyst
Login with Authorized 5	gsten avlg"			
ADD Tent Users				
AD0 ent Users				
ADD ent Users M Podtva	Bala	truit	Last Lugin Time	Action

(Image 42)

#### C. View Users (Image 43)

#### • Click on the 'View Detail' button to view the details of existing users.

Name"		Email*		Azzign Kole*	
Sanjay		info@microlit.com	5	analyst	3
Login with Authorized	System only"				
-					
(ADD)					
ADD					
0CA					
400 urrent Users					
400 Urrent Users					
urrent Users					
ADD Lurrent Users Active Inactive	Hole	Dual	Last Legin Time	Action	

(Image 43)

#### D. Disable Users (Image 44)

Click on the 'Disable' button to disable the existing users.

New User					
Name*		Email"		Assign Hole"	
Sanjay		infe@microlit.com		Analyst	Ŷ
Login with Authorized S	system only*				
Current Users Active Inactive					
Name	Role	Email	Last Login Time	Action	
Vidushi Srivastave	Super Admin	viduahi@microlit.com	4/03/2021 12:19:50 PH	Men Detail Tall Disable	

4.5 Configuration

(Image 44)

#### A. Navigation Control

Allows to assign or reassign the navigation permissions to the users (Image 45).

Vidiam Scheretze	0			•	AT 120 Part 11 December
				Navigation Control hear respect control was	(B)
		Permission	Autgood	Andreas Burbert	
	and an	Referitaria -	*)	-bas-	an investori -
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				Champhet (and Champhet (and Champhet Nature Champhet Nature Champh	
				Clear Server (1999)	



B. Password Configuration (similar to the onboarding step 2)

This allows the user to set the accounts password activity. The changes applied here will be

applicable to all the existing users.

#### C. Authorize System

To enhance data security, you may authorize certain systems to operate this software (*Image 46*).

If any user has been created with *Login with Authorized System* only option checked, he/she will only be able to login with authorized systems.

Note: To authorize the system, the E-Burette connectivity with the system is mandatory.

21-OR Ret 11 Certains	-			💮 Vidashi brivastav
(CO) Mandal Drivestows	Add Authorized System			
	General Details			
	Gystom Name*		System Seriel No."	
	Consult Nexu		Sealing.	
	Dat System Details			
	Ruthorized System List			
	Adlive modive			
	System Harne	Serial No.	Action	
	Nortazi	W/285352-27	Diamin defen	
	060470743334FH	SIMPLIFIC	Date Date	

(Image 46)

D. SMTP Configuration (similar to onboarding step 3)

This setting allows the user to change SMTP configuration which will be used to send emails to all users from the software application.

\*Refer to onboarding step 3 on how to set the SMTP for different domains.

#### E. Company Profile (Similar to onboarding step 1)

Users with permission to view this configuration option may make any required changes to the company details which include the company's address, logo and contact information.

#### F. Role Creation and Configuration

Access to this option allows the creation of a new role or edition of an existing one. It is similar to on-boarding step 4.

The user can view the details of the assigned permissions by clicking on the 'View Detail' button (*Image 47*).



One can view the role configuration- role name, assigned user view and experiment view rights, and assigned role creation permission. This information can be modified by clicking on the 'Edit' button (*Image 48*).

Role Name		
Admin		
User View Rights		
Show Tree Users		
Experiment View Rights		
Show Tree Reports		
Allowed Role List		
Analyst		

(Image 48)

#### 4.6 Experiments

#### A. Create SOP

SOPs/Standard Operating Procedures maintain consistency and help carry out the procedures correctly and promptly. These procedures can be viewed by all users in the system.

To create a new SOP for your experiment:

- Click on Create SOPs
- Enter the SOP title
- Enter the Steps
- Click on Submit

You may also view or print/edit/delete any steps after the SOP is saved (Image 49).

31-CH for 11 Gorgline		(i) Viciusiai Srivestave
Violastid Schreidare	Create SOPs	
	SOPs Details	
NAME REPORTED	SOP THE"	
	Acid with fine heutislipation	
Con Management	Steps*	
a contraction .	Step 3	Ads
· toperments	Dag 1	0
	Step 2	8
	silbert Back	



#### B. Create or view experiment

To create a new experiment:

• Click on "Start New Experiment" button (Image 50).

Experiments			Rort Here Experiment
Quick Search			
Experiment List			
Ny Experimenta All Experimenta			
Experiment Name	Author	Experiment Date	Action

(Image 50)

Note: The E-Burette connectivity is mandatory for the experiment (Image 50).

• Depending on the type of experiment you want to perform, you may choose either 'Start Volumetric Titration' or 'Start Assay Titration'. Select the available com port to establish the connection between the E-Burette and the software (*Image 51*).

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EDATE DEVISION	COMI	*	B860	×
· Unertoant	Deputy Deputy		Stop Eits'	
	7	*	0	*
	Hanty'		Derimal Places'	
Contection 1	Name	*		
Concernant (				
an evente trail	Slart Volumencian Tenzifor Start Apper, Zimahon			

(Image 51)

If the connection is successful, it will redirect you to the experiment page (Image 52).

Serial No. :	Velume Range :	Statua :	
1902/298	40 mi	Sconected	
	restrument its (Optional)		
	manifestant ()		
la al			
Equivalent Weight Pact	ar Of Titsaut	Average Titse Value (mil)	
		Pector Value Of Titrant	
(1446) (1446)			
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The experiment page will automatically capture the device details (model number, serial number of the device, volume range of the burette, and its status). The user may additionally enter the Batch Number and Instrument ID.

The user may then enter the experiment title and experiment description to start the experiment.

They may also enter additional experiment notes for future reference.

Note: The fields marked with '\*' are mandatory.

#### A. Volumetric Titration

It is used to prepare and standardize the different volume standards.

It helps in calculating the factor value of the analyte which can then be used to calculate the

assay (Image 53).

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	-				

(Image 53)

#### There are 5 inputs and outputs relevant to Volumetric Titrations (Image 54).

ht Of Analyte (mg)	Equivalent Weight Factor Of Titrant	Average Titre Value (mil)	
al Molarity/Normality Of Yitrant (M/N)		Factor Value OF Vitrant	
Scilla .	Tites Water Indi	Date	Time

(Image 54)

1. Weight Of Analyte- The substance which is used to prepare the standard solution.

The user will have to enter its weight in mg.

2. Equivalent Weight Factor Of Titrant- It is the gram equivalent weight of the substance which is used to prepare the standard solution. This is a unitless quantity.

3. Actual Molarity/Normality of Titrant- The actual/calculated molarity or normality of the titrant, of which standard solutions need to be prepared. This must be entered by the user.

The default unit considered is Molar or Normal.

4. Average Titre Value- This is the total average value of the titration performed. These values will be fetched when readings are added to the software by clicking the ADD button from the E-Burette panel. The unit of average titer value is in ml.

5. Factor Value of Titrant- This is the ratio of two concentrations. The actual value of the titrant is calculated to the theoretical value of the titrant (given). Once the input values are entered by the user and titre values are transferred to the software, the factor value will be calculated automatically.

Once all required readings have been transferred from the E-Burette, the user may SAVE the experiment report.

#### **B. Assay Titration**

(Image 55).

The assay titration is used for titrating and evaluating the biological samples

0 Barrish Marris



The first step is to select whether the user wants to titre blank or not (Image 56).

and configuration and the second	Do you want to titre blank?	and the second sec	
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(Image 56) Assay titrations have the following 6 inputs and outputs (Image 57):

54. No.	Titre Value (ml)	Date	Time
erage Titre Value Of Blank (ml) 0.0000	Average Titre Value Of Sample (ml)	Assay Of Analyte %	

*(Image 57)* **1. Weight Of Analyte-** The substance of which assay needs to be performed.

Please enter its weight in grams

2. Equivalent Weight Factor Of Analyte- It is the gram equivalent weight of the substance of which assay needs to be performed. This is a unit less quantity.

3. Factor Value of Titrant- The factor value used here is calculated at the time of preparation of volumetric standards. It is the ratio of two concentrations, therefore, this is a unit less quantity.

23

**4.** Average Titre Value of Blank- This is the total average value of the blank titration performed. These values will be fetched when readings are transferred by clicking on the ADD button from the E-Burette panel.

This is automatically calculated by the software. The unit of average titer value is in ml. **5. Average Titre Value of Sample-** This is the total average value of the sample titration performed. These values will be fetched when readings are transferred by clicking on the ADD button from the E-Burette panel.

This is automatically calculated by the software. The unit of average titer value is in ml.6. Assay of Analyte- This is final output and is calculated when all the input values are entered by the user. Once the experiment is complete, the user may SAVE the report.

#### C. Edit Experiments and Versions

The author can make changes to any previously performed experiment.

Any edit will create a new version of the same experiment while retaining the original version for back traceability.

Note: The edits can be made with the same type of experiments. For example, edits made to a volumetric titration will be volumetric titration only. The same is applicable for assay titrations. It has to be noted that blank computation cannot be edited.

To make an edit to an experiment:

• Click on the 'View' button of the experiment performed (Image 58).

Experiments			Start New Experiment
Quick Search			
Experiment List Ny Experiment All Experiments			
Experiment Name	Author	Experiment Data	Action
Assay Titration	Viduzhi Srivatava	4/03/2021 12:55:18 PM	Warm

(Image 58)

• Click on the 'Edit' button and it will redirect you to the performed experiment (Image 59).

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		Author	Deper	Intent Date	Action
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• You can add or delete the readings by clicking on 'X' (Image 60).



(Image 60)

The user can save the changes by clicking on 'SAVE'.

The user can click on the 'BACK' button if they don't want to make any changes. It will redirect them to the main page of the experiment.

The changes made to the experiment will be saved as a new version (Image 61).



(Image 61)

Note: The edits will always be made to the most recent versions.

(Image 59)

#### D. Experiment Reports

- To view the experiment report, go to the experiment list and click on the 'View' button corresponding to the relevant experiment (*Image 62*).
- You may also 'Quick Search' your experiments.

veriments						Start from Experien
ick Search						
periment List						
Experimenta Al Experim	enta					
Femariment Name			Author		Experiment Date	Arting
Experiment Name			Author	Giventava	Experiment Date	Action
Experiment Name Volumatric Titration			<b>Author</b> Vidushi	Srivastava	Experiment Date	Action
Experiment Name Volumetric Tetration Experiment Version	Status	Reviewed By	Author Vidush Revisived Data	Srivestava Experiment Da	Experiment Date 4/05/2001 12:44:25 PM nte Action	Action .

(Image 62)

• The experiment report will include the company details (as entered by the user), print time and date, device detail (device id, device capacity), author details, creation date, reviewer information, and other experiment computation details (*Image 63*).

			Inner 2456: Print Tesel 1/07/2021/4/221
		Chemical Industry Karsi Road, Lodesee 220026, India Email: vituabi@infosell.com Phone: 07022242004	
			Device 61:0033356 Device Capacity: 51:00 Author: 50030 Creation Date: 25/06/2022
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Note: Since this is an electronically generated report, therefore, no signature is required.

• You may print the experiment report or save it as a pdf to your desktop by clicking on the 'Print' button (*Image 64*).

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#### E. Review Experiment:

Users may review any experiment that they have access to, according to the Experiment View permissions set during the creation of their role.

The review section contains a list of reviewed and not-reviewed experiments (Image 65).

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• To review an experiment- click on the 'View Detail' button of the relevant experiment and click on 'View' button to open the report. Click on the 'Review' button (*Image 66*).

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(Image 66)

A dialog box will appear, where you may approve or reject the experiment. You may also enter a remark as feedback to the author or for future reference (*Image 67*).

Approve	C Reject
Reviewer Comment	
Test Run Successful!	
Submit Back	
Subline Udde	

#### (Image 67)

• After reviewing the experiment, the review status will be visible on the report along with

the reviewer's details, review date / time and reviewer's comment (Image 68).

	Chemical Industry Kuri Rood, Lucknew 20026, India Ensile industry (individ), or Phane: 07072302504	
experiment test		Besice ktr. 68333366 Besice Capacity: 5275 Active: vibush Creation Date: 20196-0021
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Expariment Not	95	
S. No.	Readings for Sample	Date / Time
1	1.89000 mi	29,06/2021/14:49:14
Review Status: A Reviewed Dy: Wil Review Date/Tim Reviewer Commo	genoed oditi 34 eesteve e: 1,077,070,015-e8 PM web: Teat rvn nuodesefwilij/	

(Image 68)

• Once the experiment has been reviewed, its status will be updated in the list of experiments

#### section (Image 69).

xperiment List						
ly Experiments All Experi	monts					
Experiment Name			Author	Exper	riment Date	Action
Testing Volumetric Triation			Statesh	7/04/	2021 11:39:26 AM	View
Experiment Version	Status	Reviewed By	Reviewed Date	Experiment Date	Action	
¥ 1.0	Approved	Vidushi Srivestave	7/64/2021	7/04/2021	West	660
Reviewer Comment: Test	Run Successful!					

(Image 69)

#### 4.7 Audit Trail

Audit trail records minute-to-minute details and activity performed on the software.

The following major actions are included in the audit trail (not exhaustive):

- 1. User Login and Logout Activity
- 2. Company Profile Modifications
- 3. Password and Configuration Updation
- 4. Creating and Disabling User(s)
- 5. Permission Modifications and Authorizations
- 6. Created and Updated SOP
- 7. New Experiments
- 8. Failed Experiments
- 9. Reviewed Experiments

Note that the audit trail can only be accessed by users who have been granted access during user creation. The 'Quick Search' option allows you to filter and view the data as required (*Image 70*).

Audit ⊺rail	1			
Quick Searc	h			
From?		To*	Action	
25,62,2	81	64/03/2025	Gei Res	orts
Sr. Ne.	Action	Values	User	Date
1	UserLegin	Viduahi Seivastava : Log-(n	Vidushi Srivastava (1)	4/90/2021 1:39:09 #0
2	User Sign-Out	Viduahi Selvastava : Sign-Cut	Viduati Srivantava (1)	4/03/2021 1:98:53 PM
3	Experiment 7 Approved	Esperiment Name: , Status Approved	Vidualii Srivastava (1)	4/99/29211.33.14 PM
4	Experiment 7 Created	Experiment Name: Testing User, Experiment Notes: Testing on 04,02,2023, Model No: 11 - 25, Benel/No: 19900259, Volume Range: 25 ml	Aait(3)	4/90/2021.5:31:54 PM
3	User Login	Asif Login	Auf (3)	4/08/2021 1 29:59 PM
6	Persward 3 Updated		Asif(3)	4/00/20211.2546 PM
7	User2 Updated	Name: Sanjay, Email: Info@microlit.com, Role is: 3	Vidushi Srivantava (1)	4/03/20211:25:04 PM
8	illiaer 3 Added	Name, Auf Email contenencere@microlit.com, Role id 3	Yiduuhi Shkastava (1)	4/08/20211:24:35 PM
9	34TP Configuration Updated	sender: customercare@microlR.com, bastamip.gmail.com, port: 507, Password: *******	Yidushi Srivantava (1)	4/93/2021.1.22:54 PM
10	Experiment 6 Created	Experiment Name: Volumetric Titration, Experiment Notes Apd + Base = Salt, Model No: Ti - 25, SenaiNo +9640199, Williams Bases 25 ml	Viduzh Srvastava (1)	4/08/2021 12:58:58 PM

(Image 70)

### 5. Troubleshooting -

S. No.	Problem	Possible Cause	Solution
1	Cannot open the E-Burette script	SQL DBMS unavailable	Download, install and login to execute the script.
		IIS not configured	Refer to the IIS configuration section of the manual
2	Windows cannot find 'inetmgr'	Dot Network Framework not installed	Download and install Dot net framework to configure IIS. Recommended is 4.5.2.
		Dynamic IP is present	Static IP binding is mandatory
3	Unable to host web application/ redirect to main application	The web application physical path is 'Physical drive' or 'Local disk'.	The web application file must not be copied to main drive or local disk
	page	Middleware software uninstalled	To execute the software, install and run the middleware software (21 CFR E-Burette setup file)
4	Unable to login in to the web application	E-Burette Script not executed	Run and execute the E-Burette script. Refer to instruction manual
	Unable to access the Licence	No internet connectivity	High Speed Internet connectivity is mandatory to retrieve licence key
5	key	Already activated	Contact the manufacturer for purchasing additional licenses
6	Unable to view experiment report and role with 'Tree' access	Role creation permission not assigned	Contact your super- admin or admin to reassign the roles
7	Unable to login to other system	Permission restricted to 'login with authorized system only'	Contact your super- admin or admin to authorize your system
8	Unable to select com port/ edit an experiment	E-Burette is not connected	Connect the E-Burette with the system you are working with.
9	No value displayed in factor/ assay	The required input fields are not filled	Calculation is based on the inputs, so please enter the required values
		Licence key already activated or invalid	Check with your super-admin and manufacturer
10	Unable to connect E-Brette	USB port access restricted or unavailable	Check the port connection to which E-burette is connected or Contact your IT support.