STANDARD OPERATING PROCEDURE	
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1.0   OBJECTIVE:
To lay down a procedure for User Creation, Activation and Deactivation for Software Application.

2.0   SCOPE:
This SOP is applicable to all the manufacturing sites.

3.0   RESPONSIBILITY:
CIT (Officer / Executive): Preparation of this SOP.

CQA (Officer / Executive): Distribution, Retrieval, Archival and Destruction of this SOP.
                        Preparation of User list for Software Application.

CIT (Operating Manager): Training and effective implementation of this SOP.
                        To review the list of Users for Software Application.

CQA (CQA (Operating Manager): Distribution to Respective department of this SOP.

Respective Department (User): Prepared the Requisition for User ID Creation, Activation, Deactivation.

1.0   ACCOUNTABILITY:

Head CQA: Authorization, Ensure distribution of this SOP.
                Custodian of soft and hard copy of all Master Corporate SOP's.

Head CIT: Approval and to ensure the effective implementation of this SOP.
                To ensure the User Creation, Activation and Deactivation for Software Application.

4.0   ABBREVIATIONS:

BIMS	Batch Issuance and management System
BOM	Bill of Material
ECC	Enterprise Resource Planning (ERP) Central Component
LIMS	Laboratory Information and Management System
Ltd.	Limited
No.	Number
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
Qty.	Quantity
S.No.	Serial Number
SAP	Systems, Applications, Product in Data Processing
SOP	Standard Operating Procedure

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5.0   PROCEDURE :

5.1   All Users shall be well trained for BIMS and QMS Amplelogic Software for Operation and data creations.

5.2   All Users shall be operating SAP, LIMS, BIMS and QMS etc. in his/her individual login.

5.3   When user or others shall be require to User ID Creation / Deactivation send a request to IT administrator for same, as per **Annexure-I** Titled **"Requisition for User ID Creation, Activation and Deactivation".**

5.4   All Users shall be well aware to his/her privileges.

5.5   Login shall be creating department wise.

5.6   Before user creation shall be verified person properly trained or not, before user creation IT person /Department Head shall be trained in respective area.

5.7   Department Head of respective area (QA/ Warehouse/Production/PPIC etc.) shall be intimate to Head IT or Designee for User creation of person.

5.8   Head IT shall be creating user after conformation of Department Head.

5.9   Manager /Designee shall ensure that logical access to the software, being used in the plants, is restricted to authorized personnel only.

5.10   User shall be assigned unique identification code and password for the accessing of Software for entry purpose.

5.11   QA administrator shall be responsible to provide authorization that is revoking and allotting the privileges as out lined in table.

5.12   User shall perform activities on departments by using to assigned unique ID and Password.

5.13   Software wise "List of User" shall be as per **Annexure-II**.

5.14   The users name and ID created date and time shall mentioned in **Annexure-II** Title as **"List of User for Software Application".**

5.15   New user shall raise the request for user creation as per **Annexure-III** Titled as **"User Creation"** and same shall be approved by Department HOD /Designee, submitted to the administrator for assigning user ID with password by IT administrator.

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5.16 If user left the organization or transfer to other section/transfer to other Plants, user will raise the request for user deletion/disable purpose as per **Annexure-IV**. Titled as **"User Deletion/ Modification"** and same shall Approved by Head QA**.**

5.17 The user ID and password shall be granted by administrator after completion the all training program and or recommendation of section in-charge or manager.

    5.17.1 The user access rights and privileges for various functions shall be configured by the administrator in the workstations, based on the functions availability in the software.

    5.17.2 **User Responsibilities:**

    5.17.2.1 User login in first time in workstation, user must be change his password at first login, in order to maintain the secrecy of his password.

    5.17.2.2 User group password shall be at least 6 characters long, contain both alpha and numeric with special character combination in order to avoid easy detection of password.

    5.17.2.3 User group password shall have an expiry period of 90 days, after which the user shall have to change his password.

    5.17.2.4 User shall be allowed a maximum 3 attempts of login into computerized lab instrument. After 3 unsuccessful attempts to login, the user ID shall be locked automatically.

    5.17.2.5 In case of user ID is locked/disable then raises the request for ID unlocked/enable purpose as **Annexure-III**. The IT administrators unlock user ID and password and verifying the reason and training shall be imparted to all concern persons.

6.0 **REFERENCES:**
Qualification Documents

7.0 **ANNEXURES:**

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Requisition For User ID Creation, Activation and Deactivation	
Annexure-II	List of User For Software Application	
Annexure-III	User Creation	
Annexure-IV	User Deletion / Modification	

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8.0 DISTRIBUTION:

- Controlled Copy 01   Corporate Information Technology
- Controlled Copy 02   Corporate Quality Assurance
- Master Copy   Corporate Quality Assurance

9.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control Number	Details of Changes	Reason for Change	Effective Date	Updated By
00		New SOP	Introduction of New SOP		

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ANNEXURE – I
REQUISITION FOR USER ID CREATION, ACTIVATION AND DEACTIVATION

USER PARTICULARS

Name of User:--   Employee Code:-----------------------------

Department:---   Designation:----------------------------------

Immediate Supervisor:--

Reason for ID Creation / Deactivation:--

Prepared By (User):--------------------   Approved By (HOD): --------------
(Sign & Date):------------------------------   (Sign & Date):------------------------------

Activity performed By (IT):------------------   Verified By (HOD):-----------------------
(Sign & Date):-------------------------------------   (Sign & Date):------------------------------

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ANNEXURE – II
LIST OF USER FOR SOFTWARE APPLICATION

Plant:

Name of Software: SAP / LIMS / BIMS / QMS

S.No.	User Name	User ID	Designation	Date	Privilege	Remarks

Prepared By Operating Officer IT	Checked By Operating Manager IT	Approved By Head IT

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ANNEXURE – III
USER CREATION FORMAT

USER PARTICULARS:	**Plant :**

Name   :
ACS No. :
DOJ   :
Dept.   :
Designation :
Email ID :
Mob. No. :
Immediate Superior:

	Prepared By User Department	Checked By User Department HOD	Approved By Head IT
Name			
Sign			
Date			

Comments by IT:
User Created / Not Created for routine use.

Done By   **Reviewed By**
(Sign & Date)   **(Sign & Date)**

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ANNEXURE – IV
USER DELETION / MODIFICATION

USER PARTICULARS	Plant :

Name :	
ACS No. :	
D.O.J :	
Dept. :	
Designation :	
Email ID :	
Mob. No. :	
Immediate Superior:	

	Prepared By User Department	Checked By User Department HOD	Approved By Head IT
Name			
Sign			
Date			

Review Comments by IT:
User Deleted / Modified for routine use.

Done By
(Sign & Date)

Reviewed By
(Sign & Date)