	DECODING PHARMA	
	QUALITY ASSURANCE DEPARTMENT	

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Restricted use (Password Protected) of System	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0   OBJECTIVE:

To lay down a procedure for restricted use (password protected) of system.

2.0   SCOPE:

This procedure is applicable to the restricted use of BMS software, Stability chamber, water PLC system and all PLC system but not limited to, which are used in …….

3.0   RESPONSIBILITY:

HOD: All Concerned Department

QA Head

4.0   DEFINITION(S):

NA

5.0   PROCEDURE:

5.1   BMS:

5.1.1   BMS software is used for operation of HVAC system.

5.1.2   Operation of HVAC system is protected by password in BMS software.

5.1.3   Password is given for opening of computer of BMS software.

5.1.4   BMS software has three modes by password levels for handling of HVAC system as follows:

5.1.4.1   Operator mode:

> ➢ Edit of controlling parameter.

5.1.4.2   Engineer mode:

> ➢ Edit of controlling

> ➢ Edition of alarm limits.

5.1.4.3   Manager mode:

> ➢ All functions of engineer user level.

> ➢ Edition of configuration parameters

> ➢ Application user edition / deletions.

5.2   Stability chamber:

5.2.1   Stability chamber is used for storage of drugs for stability study in different temperature and

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humidity.

5.2.2   QC Manager sets parameters such as temperature and humidity in presence of QA Manager.

5.2.3   Stability chamber is protected by password for restriction.

5.2.4   QC Manager can only open the password and change the parameters in presence of QA Manager if any regulatory or Pharmacopoeial requirement.

5.3   Water PLC system:

5.3.1   Water PLC system software has two modes for handling of purified as well as water for injection system as follows:

5.3.1.1   Operator/Engineer mode:

> ➤ Monitoring the parameters/alarms

> ➤ Report preview/prints

5.3.1.2   Manager mode:

> ➤ Monitor the parameters/alarms

> ➤ Report preview/prints

> ➤ System setting-Data logging, communication

> ➤ Creation/deletion of users of operator/engineer

5.4   Other PLC system which is used in equipment, not limited to:

5.4.1   PLC software has three modes for handling of equipment as follows:

5.4.1.1   Operator mode:

> ➤ Monitor the operation of equipment.

5.4.1.2   Supervisor mode:

> ➤ Monitor & control the operation of equipment

5.4.1.3   Manager mode:

> ➤ Monitor & control the operation of equipment.

> ➤ Change the parameters, setting and programming as per requirement.

5.5   Password shall expired when aging period become over as defined in respective qualification protocol.

5.6   According to aging period, password shall be changed by user.

5.7   If aging period become over, old password cannot work so that HOD/Manager can edit new password for user.

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5.8   To further control the unauthorized access, provision for idle session timeout and account lockout upon falsification attempt is also provide wherever applicable.

5.9   Permitted duration for idle session shall be permitted and after session time out, fresh challenge shall be made for user name and password.

5.10   For all critical system, minimum length of password, maximum tenor of password is defined.

5.11   Password for printed labeling:

5.11.1   Incase of label printed, two passwords are provided for printing.

5.11.2   One password for printed which can done by respective officer

5.11.3   Second password for reprinting the same, which can done by HOD.

5.11.4   If any mistake in label print, respective officer shall go to HOD for reprinting with proper justification.

6.0   ABBREVIATION(S):

BMS : Building Management System

HVAC : Heating and Ventilating Air Conditioner

PLC : Programmable Logic Controller

QA : Quality Assurance

QC : Quality Control

7.0   REFERENCE(S):

NA

8.0   ANNEXURE(S):

Nil

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9.0   REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION