



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Prevention of Unauthorized access to Electronic Records	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To establish a procedure for prevention of unauthorized access to electronic records for maintaining the security & confidentiality of the electronic data.

2.0 SCOPE:

This procedure shall be applicable to Quality Control Department.

3.0 RESPONSIBILITY -Execution - Executive QC.

Checking - Assistant Manager QC

4.0 ACCOUNTABILITY- Manager Quality Control

5.0 PROCEDURE:

- 5.1 The respective section heads shall prepare the list of the instruments/ equipments, in consultation with - Manager Quality Control, that require password protection(Annexure I).
- 5.2 Manager Quality Control or his designee shall create the user and reviewer account as per the discussed details (like no. of instruments, no. of users, documentation, etc.).
- 5.3 After creating the user and reviewer account Manager Quality Control shall assign the password to user and reviewer and authorize them for their respective responsibilities.
- 5.4 The password shall have atleast 5 alphanumeric characters; the alphabets can be in capital/ small. For e.g. ABCs1 / bhk45e , etc.
- 5.5 Manager Quality Control shall inform the password to the individual separately.
- 5.6 The password shall be changed, after every six months or as and when required, by Manager QC to maintain the integrity of the system.
- 5.7 Manager Quality Control shall maintain the records of the password (Annexure II).

6.0 SAFETY & PRECAUTIONS:

Not Applicable

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & Date



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8.0 DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/ Date	By	Sign/ Date

9.0 REFERENCES:

Not Applicable

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

No. : Number

QC : Quality Control

ANNEXURES:

Annexure I: List of Instrument required password protection

Annexure II: Record of passwords

