



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Digital Hygrometer	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning and Operation of Digital Hygrometer, Make Testo and Rotronic.

2.0 SCOPE:

2.1 The procedure is applicable to the cleaning and operation of Digital Hygrometer Make Testo and Rotronic in production and Store department.

3.0 RESPONSIBILITY:

- 3.1 Technical associate, Officer, Executive (Production/Store): Operation & Recording of Temperature and RH
- 3.2 Manager (Production/Store): SOP compliance.

4.0 DEFINITION(S):

4.1 NA

5.0 PROCEDURE:

5.1 Cleaning:

- 5.1.1 Clean the Digital hygrometer display and body with dry lint free cloth by gently wipe.
- 5.1.2 Cleaning is to be performed once at the start of shift or after every change over.

5.2 Operation of Digital Hygrometer (Testo):

- 5.2.1 Ensure the calibration status of Testo digital hygrometer place at predefined location.
- 5.2.2 Ensure the battery status of Testo digital hygrometer, if battery is low a battery icon appears on the display. Battery shall be replaced whenever battery status is indicating as low.
- 5.2.3 MODE button provided to get the Minimum and Maximum temperature and RH of area. At press one it will show the minimum temperature and RH, again press the MODE button for the Maximum temperature.
- 5.2.4 Current temperature and RH is always displayed by the Testo digital hygrometer.
- 5.2.5 Temperature and RH recording is to be followed as per QA SOP, "Monitoring of Temperature, Relative Humidity and differential Pressure" and respective Annexure (For Process Areas/Quarantine Areas).



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Digital Hygrometer	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.2.6 After each recording of the observation press and hold the SET button till its memory is clear for past history in case the digital hygrometer is installed in quarantine areas.

5.2.7 In case of process areas after ever change over or Type-B cleaning reset the memory of digital hygrometer by press and hold SET button.

5.3 Operation of Digital Hygrometer (Rotronic):

5.3.1 Ensure the calibration status of Rotronic digital hygrometer place at predefined location.

5.3.2 Ensure the battery status of digital hygrometer, if battery is low a battery icon appears on the display. Battery shall be replaced whenever battery status is indicating as low.

5.3.3 Press "MODE" button once to get the minimum temperature and RH of area. Display will shown "MIN" which indicate minimum temperature of area from last reset time.

5.3.4 Press "MODE" button twice to get the maximum temperature and RH of area. Display will shown "MAX" which indicate maximum temperature of area from last reset time.

5.3.5 Press the "MODE" button four times to get the current temperature and RH. Display will shown any no message.

5.3.6 Temperature and RH recording is to be followed as per QA SOP, "Monitoring of Temperature, Relative Humidity and differential Pressure" and respective Annexure (For Process Areas/Quarantine Areas).

5.3.7 Follow 5.3.3 and hold the SET button for 2 seconds to clear minimum value. To clear maximum value follow 5.3.4 and hold set button for 2sec. Hold the SET button till its memory is clear for past history.

5.3.8 In case the digital hygrometer is installed in quarantine area, reset the memory every four hours. In case the digital hygrometer is installed in process area, memory to be reset after ever change over or Type-B cleaning.

6.0 ABBREVIATION (S):

6.1 NA

7.0 REFERENCES(S):

7.1 **SOP:** Monitoring of Temperature, Relative Humidity and differential Pressure" for usage of Annexures.

8.0 ANNEXURE(S):

8.1 NA

9.0 DISTRIBUTION:

9.1 Master Copy : Quality Assurance

9.2 Controlled Copy (S): Production department (02), Quality Assurance (01)



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Digital Hygrometer	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

9.3 Reference copy (S): Production department

10.0 REVISION HISTORY:

S. No.	Version No.	Change Control No.	Reason (s) for Revision	Details of Revision	Effective Date
1.	00		New SOP	NA	