



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Operation and Monitoring of Walk-in Stability Chamber	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for operation and monitoring of Walk-in stability chambers.

2.0 SCOPE:

This procedure is applicable for operation and monitoring of Walk-in stability chamber (Mack Pharmatech) used in Quality Control department.

3.0 RESPONSIBILITY:

Executive, Officer – Quality control
Head –Quality control

4.0 PROCEDURE:

4.1 Operation:

4.1.1 Connect the equipment to the main power.

4.1.2 Switch on the main electric supply.

4.1.3 The display will show MACK PHARMATECH Tab. Now set other parameter as given below.

4.1.4 After pressing tab it will show on HMI date at left hand top corner and time on right hand top corner.

4.1.5 Temperature (°C) & Humidity (%RH) process value (PV) display in red colour and Set Value (SV) will display in green colour, located in middle on HMI.

4.2 Setting temperature & humidity

4.2.1 Go to HMI and press on set value which is shown in the green colour. Enter the password.

4.2.2 Enter the set value (SV) which will display in green colour.

4.3 Print frequency setting:

4.3.1 Go to HMI press on MENU.

4.3.2 Go to option print frequency, press on it and enter password.

4.3.3 Change the master print frequency and scanner print frequency, both shall be same.

4.3.4 After changing print frequency press on “BACK” again press on “BACK”. It will display HMI main screen.



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4.4 Procedure for Charging and Pullout of sample

- 4.4.1 On HMI display, click CHAMBER LIGHT ON before enter in to the chamber.
- 4.4.2 Open the door After pressing MENU tab on HMI and then press DOOR OPEN and enter the Password then open the door with the help of handle provided.
- 4.4.3 Enter in to stability chamber for Charging and pullout the stability sample as per procedure.
- 4.4.4 After completion of work, Open the door from inside by pressing blue colour button.
- 4.4.5 In case blue colour button not working, then open the door by pressing green colour push button in emergency case only.

4.5 Procedure for handling of breakdown condition

- 4.5.1 If temperature and Humidity deviates $\pm 2.0^{\circ}\text{C}$ & $\pm 5\%$ from set temperature & Humidity, equipment starts giving beep sound till set temperature attained. Pressing "ALARM ACK" switch can stop alarm.
- 4.5.2 Whenever alarm activated by the system, it will in turn activate buzzer and indicator light.
- 4.5.3 Acknowledge the alarm to run the set condition.
- 4.5.4 If again alarm activated, inform to engineering department for rectification.
- 4.5.5 Monitor the temperature & Humidity by take out the print out daily for a period of 24 hrs. and also monitor the temperature & humidity manually on daily basis as per Annexure-I.
- 4.5.6 Rectify Any type of problem within 24 hours.

4.6 CALIBRATION

- 4.6.1 Calibration of chamber should be done once in a year.
- 4.6.2 Calibration of Stability chamber shall be done through approved outside engineer or company engineer with the help of data logger and under the observation of QC Executive/Officer.

4.7 PRECAUTION

- 4.7.1 Take the precaution that there should not occur power failure.
- 4.7.2 Do not disturb set value of temperature, print frequency and other parameters.
- 4.7.3 Do not switch off chamber while running condition.
- 4.7.4 All walk in type Stability chambers open door shall be closed immediately after entry and exit.



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4.7.5 Also ensure that the water supply to its boiler tank is proper and this should be monitored on daily basis.

4.8 Cleaning:

4.8.1 Clean the equipment with a lint free cloth.

4.8.2 **Frequency:** Outer surface daily and inner surface once in a month. (Refer Annexure -II).

5.0 ANNEXURE (S):

Annexure-I- Daily temperature & humidity record of Walk-In Stability chamber

Annexure-II- Cleaning record of Walk-In Stability Chamber

6.0 REFERENCE (S):

Nil

7.0 ABBREVIATION (S)/DEFINITION (S):

QC: Quality Control

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No
1	00	---	---	New SOP	-



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ANNEXURE I

DAILY TEMPERATURE & HUMIDITY RECORD OF WALK-IN STABILITY CHAMBER

S.No.	Date	Morning			Evening			Done by	Checked by
		Time	Temp.	humidity	Time	Temp.	humidity		

Checked By:



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ANNEXURE II
CLEANING RECORD OF WALK-IN STABILITY CHAMBER

CLEANING RECORD OF WALK-IN STABILITY CHAMBER			
AREA	QUALITY CONTROL	EQUIPMENT	WALK IN STABILITY CHAMBER
MONTH		EQUIPMENT LOCATION	STABILITY LAB

INSTRUMENT ID. : _____

S.No.	Date	Cleaning status		Cleaned by	Checked by	Remark
		Outer surface	Inner surface			

*If performed write: √ If not performed write: NA