STANDARD OPERATING PROCEDURE

Department: Quality Control	**SOP No.:**
Title: Operation, Cleaning and Calibration of Walk-in humidity Chamber	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0   OBJECTIVE:

To lay down a procedure for Operation and Calibration of Walk-In Humidity Chamber installed in Quality Control Laboratory.

2.0   SCOPE:

This SOP is applicable for Operation and Calibration of Walk-in Humidity chamber (Make: Newtronics, Model: Nec 2350 rs) in Quality Control laboratory.

3.0   RESPONSIBILITY – Execution - Executive QC.
                          Checking - Assistant Manager QC.

4.0   ACCOUNTABILITY – Manager Quality Control

5.0   PROCEDURE:

5.1   CLEANING PROCEDURE:

Frequency: Daily : Outer Side

            Monthly : Inner Side

5.1.1   Clean the inner and outer walls of the chamber with damp cloth.

5.1.2   Clean the trays and shelves with damp cloth.

5.1.3   Use a dry cloth to clean the LCD, view glass, control panel, and tube light.

5.1.4   Use detergent solution for removing stains, if required.

5.1.5   Maintain the record of cleaning as per Annexure – I.

5.1.6   Maintain the record of cleaning as per Annexure – I for Daily cleaning and as per Annexure – II for Monthly cleaning.

5.2   OPERATING PROCEDURE

5.2.1   Switch on main power of walk-in chamber from the control panel.

5.2..2   "Set value" is displayed on LCD.

5.2.3   Set the desired value of Temperature, Humidity, Printing interval, Date, Month, year, and time of the chamber as it is intended for use.

5.2.4   To set the parameters of the controllers, press SET key to enter in SET mode. Then press (▲) key, level value will start blinking. Enter the level value 2 and press SET key. Displays "Enter PW". Enter default PW value 20 by pressing (▲) key.

STANDARD OPERATING PROCEDURE

Department: Quality Control	**SOP No.:**
Title: Operation, Cleaning and Calibration of Walk-in humidity Chamber	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Set temperature will start blinking. Use (▲) up and (▼) down keys to increase or decrease the SET value of temperature.

5.2.5   The increment or decrement will be step by step of 0.1°C for every press of the key, however if the key is kept pressed continuously the set value will change by 0.1°C for first 10 steps then it will change by 1°C for next 10 steps.If key is kept pressed it will change by 10degree if key is released momentarily in between the step size restarts from 0.1°C.

5.2.5   Set the temperature required (i.e. 25°/40°C) and press again SET key, the set temperature display will be steady and set humidity (%RH) will start blinking. Using (▲) up key and (▼) down keys. Set the required Humidity (i.e.60/75%RH).

5.2.6   After setting the desired value of Temperature & Humidity press again SET key to enter in to printing interval mode. If you do not want to go printing interval mode then press COOL key to terminate the SET MODE.

5.2.7   Once Humidity setting is over, press SET key again, Printing interval is displayed on LCD. (Print interval in minutes).

5.2.8   LCD window fleshes in current print interval setting. Use (▲) up and (▼) down keys to set the required Print interval (10-90 minutes in steps of 10 minutes). Print interval should be kept 60 minutes for controller and 60 minutes for scanner.

5.2.9   Press SET key again to register print interval, Print mode will display on LCD"P mode: Store only" will blink.

5.2.10   Three print mode are available and function of each mode as below.

5.2.11   Print mode "Store only" is only for storage of data specified interval in to memory and no online printing on demand by pressing PRINT key.

5.2.12   Press (▲) display will show Print mode "Store & print" .Printing and storage of data will be stored at programmed interval at the same time printed on to painter connected to the printer port of the instruments (centronic port).

5.2.13   Press (▲) display will show Print mode "Clr Memoy". All data stored in the memory in the memory will be cleared and capacity will be cleared and now be available for the new data, on pressing SET.

5.2.14   Set print mode "Store only" and press SET key to register print mode.

5.2.15   After setting print mode press again SET, Day of the month (DATE) will start blinking. Set desired date with help of (▲) up and (▼) down keys.

STANDARD OPERATING PROCEDURE

Department: Quality Control	**SOP No.:**
Title: Operation, Cleaning and Calibration of Walk-in humidity Chamber	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

5.2.16　Press SET key again, the month will start blinking on the LCD display. Set the desired month with the (▲) up and (▼) down keys.

5.2.17　Press SET key again, the year will be displayed in the LCD display. Set desired year with the help of (▲) up and (▼) down keys.

5.2.18　Press SET key to register Date, Month, &Year and entering clock Programming mode.

5.2.19　After setting Date, Month & Year LCD will blinking "hour" of the day will start blinking. Set desired Hour with help of (▲)up and (▼) down keys .

5.2.20　Press SET key again, the "Minute" will start blinking on the LCD display. Set desired Minute with the (▲)up and (▼) down keys.

5.2.21　Press SET key again, the "second" will be displayed in the LCD display. Set desired Second with the help of (▲) up and (▼) down keys.

5.2.22　Press again to return set value display.

5.2.23　When boiler, heater and compressor start functioning, a green light shall be displayed against each key.

5.2.24　When water level in boiler goes down, at"BLL" a green light start blinking and sounds alarm.

5.2.25　Take printing of data next day by pressing print key "Enter level" is display on LCD.Then press (▲) key level value will start blinking. Enter the level value 1 and press SET key". Enter PW" is displayed. Enter PW value 10 by pressing (▲) key and take printout of controller.

5.2.26　Press "SCANNER" key to take out the print out of the scanner by again repeating the above step.

　　　Set (Print mode) to "Clr Memory". Using SET key. This will clear an old data and store new data after printing, as print mode returns to "Store Only" mode automatically.

5.2.27　To go into the scanner mode press SCANR key. It will display temperature and humidity of all 8 channels one by one. To hold on any particular channel press HOLD key.

5.3　CALIBRATION PROCEDURE:

　Frequency : Once in 6 months.

　Note: Calibration of the instrument is to be carried out by third party

6.0　SAFETY & PRECAUTIONS:

　Not Applicable.

	PHARMA DEVILS	
	QUALITY CONTROL DEPARTMENT	

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Operation, Cleaning and Calibration of Walk-in humidity Chamber	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

7.0   REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & Date

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

QA   : Quality Assurance

No.   : Number

QC   : Quality Control

°C   : Degree Centigrade

M   : Month

RH   : Relative Humidity

Annexure I: Daily Cleaning Record for Walk-in Humidity Chamber

Annexure II: Monthly Cleaning Record for Walk-in Humidity Chamber

STANDARD OPERATING PROCEDURE

Department: Quality Control	**SOP No.:**
Title: Operation, Cleaning and Calibration of Walk-in humidity Chamber	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-I

DAILY CLEANING RECORD FOR WALK-IN HUMIDITY CHAMBER

NAME OF THE INSTRUMENT: WALK-IN HUMIDITY CHAMBER
MAKE   :
MODEL NO   :
IDENTIFICATION NO.   :

Date of Cleaning	Cleaned By	Time		Checked by	Remarks
		From	**To**		

STANDARD OPERATING PROCEDURE

Department: Quality Control	**SOP No.:**
Title: Operation, Cleaning and Calibration of Walk-in humidity Chamber	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE-II

MONTHLY CLEANING RECORD FOR WALK-IN HUMIDITY CHAMBER

NAME OF THE INSTRUMENT: WALK-IN HUMIDITY CHAMBER
MAKE   **:**
MODEL NO   **:**
IDENTIFICATION NO.   **:**

Date of Cleaning	Cleaned By	Time		Checked by	Remarks
		From	**To**		