



## STANDARD OPERATING PROCEDURE

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|--|------------------------|
| <b>Department:</b> Production (Softgel)            | <b>SOP No.:</b>        |
| <b>Title:</b> Cleaning of Utensils and Accessories | <b>Effective Date:</b> |
| <b>Supersedes:</b> Nil                             | <b>Review Date:</b>    |
| <b>Issue Date:</b>                                 | <b>Page No.:</b>       |

### 1.0 OBJECTIVE:

To lay down the procedure for monitoring of Temperature, Relative Humidity and Differential Pressure in Production Area.

### 2.0 SCOPE:

This procedure is applicable for monitoring of Temperature, Relative Humidity and Differential Pressure in Production Area.

### 3.0 RESPONSIBILITY:

Technician / Officer / Executive / Manager.

Head of Department: To ensure execution & compliance.

Head QA: To ensure the compliance.

### 4.0 PROCEDURE:

#### 4.1 PRECAUTION:

4.1.1 Ensure that all the doors of the process area are properly closed and HVAC system is functional prior to startup of the activity.

4.1.2 Ensure that the Digital hygrometer / Wet and Dry bulb hygrometer being used to monitor the temperature is calibrated and the calibration tag is affixed to the instrument.

#### 4.2 Recording of Minimum and Maximum Temperature and Relative Humidity by using Digital Hygrometer:

4.2.1 Ensure that the digital hygrometer is calibrated and keep at the defined place.

4.2.2 Press the "MODE" key on digital hygrometer then display will show current temperature & RH on screen, Record the reading in the format as per the Annexure - I for Production process area.

4.2.3 Press "MODE" key on digital hygrometer then display will show the minimum temperature & minimum RH on screen, Record the reading in the format as per the Annexure - II for Dispensed Raw material and primary packing material store and Bulk Quarantine in production.

4.2.4 Press "MODE" key on digital hygrometer then display will show the maximum temperature



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& maximum RH on screen, Record the reading in the format as per the Annexure - II for Dispensed Raw material and Primary packing material store and Bulk Quarantine in production area.

4.2.5 Re-Press the “MODE” key on digital hygrometer then display will show again current temperature & RH on screen.

4.2.6 Clean the digital hygrometer by using dry lint free cloth.

4.2.7 **Frequency:**

Record current temperature & RH for a particular area twice in a shift (Beginning of shift and towards end of shift).

4.2.8 Record minimum and maximum temperature and RH for a particular area twice in a shift (Beginning of shift and towards end of shift).

4.2.9 **Limit of Temperature:**

4.2.9.1 For limit of temperature refer Annexure – I, II.

4.2.10 **Limit of Relative Humidity:**

4.2.10.1 For limit of Relative Humidity refer Annexure – I, II.

4.2.11 When the temperature / RH exceed standard limits, inform to head of Department Head QA and engineering department for further rectification and corrective action.

4.2.12 After corrective action note down the temperature / RH in particular annexure-I & annexure - II (wherever it is applicable).

**4.3 Recording of Temperature & Relative Humidity By using Wet and Dry bulb hygrometer:**

4.3.1 Ensure that the Wet and Dry bulb hygrometer is calibrated.

4.3.2 Ensure that sufficient purified water is available in the Wet and Dry bulb hygrometer to keep the wick wet.

4.3.3 Ensure that the top end of the wick covers the mercury bulb completely.

4.3.4 Ensure that the wick is wet and the bottom end is always immersed in purified water.

4.3.5 Check and ensure that there is no scale deposit on the wick. If it is found scale deposited then replace it.

4.3.6 Rotate the Wet and Dry bulb hygrometer in clockwise or anticlockwise for 2 minutes



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such that it will cover entire area in a room.

- 4.3.7 Check and record the dry bulb temperature and wet bulb temperature in the Wet and Dry bulb hygrometer of the respective area and record it as per Annexure -III.
- 4.3.8 Check and record the RH using dry bulb temperature and the difference between dry bulb temperature and wet bulb temperature with the help of Chart and record it as per Annexure - III (wherever it is applicable).
- 4.3.9 **Frequency:**
- 4.3.9.1 Record current temperature & RH for a particular area twice in a shift (Beginning of shift and towards end of shift).
- 4.3.10 **Limit of Temperature:**
- 4.3.10.1 For limit of temperature refer Annexure - III.
- 4.3.11 **Limit of Relative Humidity:**
- 4.3.11.1 For limit of Relative Humidity refer Annexure - III.
- 4.3.12 When the temperature / RH exceed standard limits, inform to head of Department, Head QA and engineering department for further rectification and corrective action.
- 4.3.13 After corrective action note down the temperature / RH in particular annexure - III.
- 4.4 Recording of Differential Pressure(By Magnehelic Gauge):**
- 4.4.1 Ensure that the magnehelic gauge of the concerned area is calibrated.
- 4.4.2 Ensure the zero reading of the magnehelic gauge by opening the door of the concerned area.
- 4.4.3 Officer shall ensure that all the doors are closed properly before recording the reading.
- 4.4.4 Check the reading and record the same in the format shown in the Annexure - IV
- 4.4.5 **Frequency:**
- 4.4.5.1 Record minimum and maximum differential pressure twice in a Shift (Beginning of shift and towards end of shift).
- 4.4.6 **Limit of Differential Pressure:**
- 4.4.6.1 Differential pressure limit for Magnehelic gauge shall be NLT 1.5 mm of WC.
- 4.4.6.2 When the differential pressure exceed standard limits, inform to head of



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Department, Head QA and engineering department for further rectification and corrective action.

4.4.6.3 After corrective action note down the differential pressure in particular Annexure - IV.

4.4.6.4 The differential pressure recording revealed has to be recorded by officer or concerned responsible person.

### 5.0 ANNEXURE (S) :

Annexure - I : Temperature & Relative Humidity Record (By Digital Hygrometer).

Annexure - II : Minimum & Maximum Temperature & Relative Humidity Record (By Digital Hygrometer).

Annexure - III : Temperature & Relative Humidity Record (By wet and dry bulb Hygrometer).

Annexure - IV: Differential Pressure Record.

### 6.0 REFERENCE (S):

SOP: Preparation, approval, distribution control, revision and Destruction of Standard Operating Procedure (SOP).

### 7.0 ABBREVIATION (S) /DEFINITION (S):

QA : Quality assurance

% : Percentage

°C : Degree Celsius.

WC : Water Column.

RH : Relative Humidity

NLT : Not Less Than

HVAC : Heating Ventilation Air Conditioning

### REVISION CARD

| S.No. | REVISION No. | REVISION DATE | DETAILS OF REVISION | REASON (S) FOR REVISION | REFERENCE CHANGE CONTROL No. |
|-------|--------------|---------------|---------------------|-------------------------|------------------------------|
|       |              |               |                     |                         |                              |



# PHARMA DEVILS

PRODUCTION DEPARTMENT

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### ANNEXURE 1 TEMPERATURE AND RELATIVE HUMIDITY RECORD (BY DIGITAL HYGROMETER)

|                   |                  |                               |  |
|-------------------|------------------|-------------------------------|--|
| <b>Department</b> |                  | Reference SOP No.             |  |
| <b>Area</b>       |                  | Digital Hygrometer ID.<br>No. |  |
| <b>Frequency</b>  | Twice in a Shift | Month / Year                  |  |

| Date | Time | Temperature (°C) | Relative Humidity (%) | Checked By | Remark |
|------|------|------------------|-----------------------|------------|--------|
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- 1. Limit of Temperature & Relative Humidity:**  $22 \pm 3^\circ\text{C}$  &  $50 \pm 5\%$  respectively.
- 2. For Low Relative Humidity area:** Inspected Capsule, Before Inspection Quarantine, Inspection-I, Inspection-II, Encapsulation, Encapsulation Feeding and Blister Packing-I  
Relative Humidity range 30 to 40%.
- 3. For Very Low Relative Humidity area:** Drying room Relative Humidity range 13 to 23 %.
- 4. For Low Temperature area:** Encapsulation and Encapsulation Feeding Temperature range  $18 \pm 3^\circ\text{C}$ .



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### ANNEXURE II

**MINIMUM AND MAXIMUM TEMPERATURE AND RELATIVE HUMIDITY RECORD  
(BY DIGITAL HYGROMETER)**

| <b>Department</b> |      |                  |     | Reference SOP No.          |     |                   |            |
|-------------------|------|------------------|-----|----------------------------|-----|-------------------|------------|
| Area              |      |                  |     | Digital hygrometer ID. No. |     |                   |            |
| Frequency         |      | Twice in a Shift |     | Month / Year               |     |                   |            |
| Date              | Time | Temp. (°C)       |     | RH (%)                     |     | Data Cleared /Set | Checked By |
|                   |      | Min              | Max | Min                        | Max |                   |            |
|                   |      |                  |     |                            |     |                   |            |
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**Note:** Limit for Temperature and RH.

- Area (Dispensed Raw Material Store, Dispensed Raw Material Hold, Primary Packing Material Store, Primary Packing Material Hold, Medicament and Gelatin Hold): Temperature and RH Limit are 22±3°C & 50±5% respectively.
- Area (Before Inspection Quarantine and Inspected Capsules): Temperature and RH Limit are 22±3°C & 30 to 40% respectively.



