



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Monitoring of Temperature, Relative Humidity & Differential Pressure in Production Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 11

1.0 OBJECTIVE:

To lay down a Procedure for Monitoring of Temperature, Relative Humidity & Differential Pressure in the Production area.

2.0 SCOPE:

This SOP is applicable for Monitoring of Temperature, Relative Humidity & Differential Pressure in Production area and aseptic area.

3.0 RESPONSIBILITY:-

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

⁰ C	Degree Celsius
Hrs	Hour
HVAC	Heating Ventilation and Air Conditioner
Ltd.	Limited
NMT	Not More Than
Pvt	Private
RH	Relative Humidity
RM	Raw Material
SOP	Standard Operating Procedure
ΔP	Differential Pressure
CIP	Clean In Place
SIP	Sterilization In Place.
DTR	Digital Differential Pressure + Temperature + Relative humidity
No.	Number
Sign	Signature.

6.0 PROCEDURE:

6.1 PRECAUTIONS AND ACCEPTANCE CRITERIA:

- 6.1.1** Ensure that the digital Differential Pressure, Temperature and Relative humidity gauges (DTR & DPG Gauges) of Radix, digital hygrometer & other monitoring devices shall be calibrated.
- 6.1.2** Ensure that the digital hygrometer and other temperature monitoring devices shall be placed at hot spot (if available).



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Title: Monitoring of Temperature, Relative Humidity & Differential Pressure in Production Area

SOP No.:		Department:	Production
Revision No.:	00	Effective Date:	
Supersede Revision No.:	Nil	Revision Date:	
		Page No.:	2 of 11

6.1.3 Temperature, Relative Humidity and Differential Pressure of respective areas shall be recorded initially and at frequency of 4 hrs. \pm 30 min. or after any breakdown.

6.1.4 During operation, Monitoring of Temperature, Relative Humidity and Differential Pressure shall be recorded as per respective BMR for area specific along with log books.

6.1.5 In case of material storage minimum and maximum temperature shall be check of previous 24 hrs. at the start of shift by pressing min /max key of respective digital hygrometer and recoding in respective **Annexure's**.

Note: Reset the Digital Hygrometer after taking the minimum and maximum temperature by long press of memory button given in digital hygrometer.

6.1.6 During periodic calibration of digital hygrometer use other calibrated digital hygrometer kept as stand by and records their ID in the remark column.

6.1.7 After receiving of digital hygrometer and other monitoring devises from outside/ calibration agency, previous memory shall be reset before use.

6.2 TEMPERATURE & RELATIVE HUMIDITY MONITORING:

6.2.1 Observe the reading on the LED Display / Digital Display (DTR Gauzes) of Radix/ Digital Hygrometer / Other monitoring devices / Data logger installed in the area.

6.2.2 Record the Temperature and Relative Humidity details of the area in respective **Annexure's**.

6.2.2.1 During operation temperature may excure upto 27°C of following areas:

- Unit Preparation Room (Autoclave Loading / Unloading side)
- Manufacturing Room (CIP/SIP & Water collection, During Batch Manufacturing)
- Filtration Room (CIP/SIP).
- Filling room (CIP/SIP).

6.2.2.2 Handling of Excursions:

6.2.2.2.1 During filling and sealing if excursion is observed out of specified limit related to temperature, Relative humidity and differential pressure then follow the below action:

6.2.2.2.1.1 Clear the filling & sealing track and stop the filling & sealing operation.

6.2.2.2.1.2 Inform to engineering department for rectification of observed excursion.



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STANDARD OPERATING PROCEDURE

Title: Monitoring of Temperature, Relative Humidity & Differential Pressure in Production Area

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	3 of 11	

6.2.2.2.1.3 Wait for 15 min to resume the observed excursion if not rectified raise the Break down slip / SAP, along with incident for further action plan & CAPA.

6.2.2.2.1.4 Record the intervention detail in the respective BMR / Log sheet.

6.2.2.2.1.5 If any monitoring device not working , then follow the below action:

6.2.2.2.1.5.1 Inform to engineering department for rectification of same.

6.2.2.2.1.5.2 If defected monitoring device will not recoverable, initiate the change control for new device along with calibration & ID.

6.2.2.2.1.5.3 New addition / deletion of monitoring device shall be handled through SOP.

S.No.	Area	Monitoring Frequency: Initially & at frequency of 4 hrs. \pm 30 min. and as per respective BMR in operation		Annexure Reference for recording
		Temperature	%RH	
1	Filling Room -01	NMT 25°C	NMT 60%	ANNEXURE-I
	Filling Room -02			
	Filtration Room -01			
	Filtration Room -02			
	Disinfectant filtration Room			
	Machine Tool Room			
	Cooling zone			
2	Unit Preparation Area	NMT 25°C	NMT 60%	ANNEXURE-II
	Manufacturing Room -01			
	Manufacturing Room -02			
	Granule Day store	NMT 25°C	NA	ANNEXURE-II
	RM Day Store			
	Disinfectant Preparation room			
3	Packing Area	NMT 25°C	NA	ANNEXURE-VI
	FG Quarantine	NMT 25°C		
	Unloading Area			



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STANDARD OPERATING PROCEDURE

Title: Monitoring of Temperature, Relative Humidity & Differential Pressure in Production Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	4 of 11

6.3 DIFFERENTIAL PRESSURE:

- 6.3.1** Ensure that Magnehelic Gauges are calibrated.
- 6.3.2** Differential Pressure shall be monitored of all areas, where Magnehelic gauges / DTR displays are installed.
- 6.3.3** Differential Pressure of concern Area shall be monitored by Officer / Executive concern area, and record shall be maintained as per concern Annexure.
- 6.3.4** Differential Pressure of respective areas shall be recorded initially, at every 4 Hours \pm 30 min.
- 6.3.5** Whenever out of limit results are observed, immediate inform to engineering department for corrective action. If differential pressure of classified area, return to it's, define limit, within 15 minutes, then record physical parameter as per defined interval.
- 6.3.6** In case physical parameter not in limit for more than 15 min. concern dept. shall fill the incident report and inform to Engineering department through breakdown intimation Slip / SAP procedure.

Note: 1. In case of Holidays / Non-Working Days / if there is no Activity , Temperature and Relative Humidity will not be recorded in the respective Annexure of Production.

2. In case any activities performed on Holidays / Non-Working Days, Temperature and Relative Humidity shall be recorded in the respective Annexure of Production.

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure – I	Temperature & Relative Humidity record (NMT 25°C, NMT 60 %)	
Annexure- II	Differential Pressure Record Production (Filling & Holding Area)	
Annexure- III	Differential Pressure Record Production Area-I	
Annexure- IV	Differential Pressure Record Production Area-II	
Annexure – V	Temperature & Relative Humidity record (NMT 25°C, NMT 60 %)	
Annexure- VI	Temperature Record (PACKING)	

ENCLOSURES: SOP Training Record.



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STANDARD OPERATING PROCEDURE

Title: Monitoring of Temperature, Relative Humidity & Differential Pressure in Production Area

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	5 of 11	

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By



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STANDARD OPERATING PROCEDURE

Title: Monitoring of Temperature, Relative Humidity & Differential Pressure in Production Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	6 of 11

ANNEXURE-I

TEMPERATURE & RELATIVE HUMIDITY RECORD (NMT 25°C, NMT 60 %)

Block:

Month:

Limits:	Temperature: NMT 25°C	Relative Humidity: NMT 60%
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Date	Area → ↓ Time	Filling Room-01		Filling Room-02		Filtration Room-01		Filtration Room-02		Disinfectant filtration Room		Machine Tool Room		Cooling zone		Checked By	Verified By QA
		Temp.	RH	Temp.	RH	Temp.	RH	Temp.	RH	Temp.	RH	Temp.	RH	Temp.	RH		

Frequency: Every 4 Hours ± 30 min.



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PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Monitoring of Temperature, Relative Humidity & Differential Pressure in Production Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	7 of 11

ANNEXURE-II DIFFERENTIAL PRESSURE RECORD PRODUCTION (FILLING & HOLDING AREA)

Block:

Month:

Date	Area →	Entry A/L-I Aseptic area (05-15 Pascal)	Entry Air- lock II (15-30 Pascal)	Entry Air- lock III (15-30 Pascal)	A/L- III- Aseptic corrido r (05-15 Pascal)	Machine Tool Room (05-15 Pascal)	Filtratio n Room- I (05- 15 Pascal)	Filtration Room- II (05-15 Pascal)	Cool Zone (05-15 Pascal)	Disinfect -ant filtration Room 05-15 Pascal)	Filling Room- I (05-15 Pascal)	Filling Room- II (05-15 Pascal)	Return Air- lock -II (05 - 15 Pascal)	Return Air- lock- III (15- 30 Pascal)	Return A/L- III with corrido r (05- 15) Pascal	Checked By	Verified By QA
	Time ↓																

Frequency: Every 4 Hours ± 30 min.



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STANDARD OPERATING PROCEDURE

Title: Monitoring of Temperature, Relative Humidity & Differential Pressure in Production Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	8 of 11

ANNEXURE-III DIFFERENTIAL PRESSURE RECORD OF PRODUCTION AREA - I

Block:

Month:

Date	Area → ↓ Time	PAL-1 Mfg. -01 (05 - 15 Pascal)	PAL-02 Mfg. -01 (15- 30 Pascal)	Mfg.- 01 Room 05- 15	PAL-01 Mfg.- 02 (05 -15 Pascal)	PAL-02 Mfg.-02 (15 -30 Pascal)	Mfg.- 02 Room (05- 15 Pascal)	PAL-01 Garment washing (05-15 Pascal)	PAL-02 Unit Prep. (15 -30 Pascal)	Unit Prep. & Sterilizati on (05-15 Pascal)	Garment Washing (05 -15 Pascal)	Equip. Washing (05- 15 Pascal)	Checked By	Verified By QA

Frequency: Every 4 Hours ± 30 min.



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STANDARD OPERATING PROCEDURE

Title: Monitoring of Temperature, Relative Humidity & Differential Pressure in Production Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	9 of 11

ANNEXURE-IV

PURE & CURE HEALTHCARE PVT. LTD.

HARIDWAR
PRODUCTION

DIFFERENTIAL PRESSURE RECORD OF PRODUCTION AREA -II

Block:

Month:

Date	Area →	PAL-01 Disinfectant preparation (05 -15 Pascal)	Disinfectant. Prep. Room (15- 30 Pascal)	PAL-01 Raw material store (05- 15 Pascal)	PAL Granule feeding (05 -15 Pascal)	Granule Feeding room (05- 15 Pascal)	Production Accessory Room (05- 15 Pascal)	PAL-01 scrap out (05- 15 Pascal)	Primary Change Room- 02 (15- 30 Pascal)	Buffer Room (05 - 15 Pascal)	Buffer Room to Grade D corridor (05 - 15 Pascal)	Checked By	Verified By QA
	↓ Time												

Frequency: Every 4 Hours ± 30 min.



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SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	10 of 11	

ANNEXURE-V

PURE & CURE HEALTHCARE PVT. LTD.
HARIDWAR
PRODUCTION

TEMPERATURE & RELATIVE HUMIDITY RECORD (NMT 25°C, NMT 60 %)

Block: L Block

Month:

Limits:	Temperature: NMT 25°C	Relative Humidity: NMT 60%
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Date	Area → ↓ Time	Unit Preparation Area		Manufacturing Room -01		Manufacturing Room -02		Disinfectant Preparation Room		Granule Day store		RM Day Store		Checked By	Verified By QA
		Temp.	RH	Temp.	RH	Temp.	RH	Temp.	RH	Temp	RH	Temp.	RH		

Frequency: Every 4 Hours ± 30 min.



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PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Monitoring of Temperature, Relative Humidity & Differential Pressure in Production Area

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	11 of 11	

ANNEXURE-VI TEMPERATURE RECORD (PACKING)

Block:

Month:

Limits:	Temperature: NMT 25°C
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Date	Area ↓ Time	Un-Loading Area	Packing Area	Day FG Store	Checked By	Verified By
		Temperature (°C)	Temperature (°C)	Temperature (°C)		

Frequency: Every 4 Hours ± 30 min.