



STANDARD OPERATING PROCEDURE

Title: Monitoring of Temperature, Relative Humidity & Differential Pressure in Aseptic Area and Controlled Area

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 25

1.0 OBJECTIVE:

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

2.0 SCOPE:

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

3.0 RESPONSIBILITY:

Officer / Executive – Production/ Warehouse

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

°C	Degree Celsius
hrs	Hour
Min	Minutes
HVAC	Heating Ventilation and Air Conditioner
NMT	Not More Than
RH	Relative Humidity
RM	Raw Material
SOP	Standard Operating Procedure
ΔP	Differential Pressure
DTR	Digital Differential Pressure + Temperature + Relative humidity
DPG	Differential Gauze
BMR	Batch Manufacturing Record

6.0 PROCEDURE:

6.1 Monitoring and Recording of Temperature and Relative Humidity by Digital Display (DTR Gauzes) of Radix:

- 6.1.1 Ensure that the digital Differential Pressure, Temperature and Relative humidity gauges shall be calibrated on yearly basis or when required.
- 6.1.2 Ensure that the set the limit of temperature and relative humidity is as per requirement.
- 6.1.3 Monitor the reading of Temperature & Relative Humidity from the digital Temperature and Relative humidity gauges of radix and shall be recorded in respective **Annexure**.



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

6.1.5 If the temperature and relative humidity does not comply the specification, inform to Engineering department to take corrective action.

6.1.6 In warehouse check the minimum and maximum temperature of previous 24 hrs at the start of shift by using digital hygrometer installed at hot spot.

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

6.2 Monitoring and Recording of Temperature and Relative Humidity by Digital Hygrometer:

6.2.1 Ensure that the digital hygrometers are calibrated.

6.2.2 Ensure that the set limit of the digital hygrometers is as per area requirement.

6.2.3 Record the reading of Temperature & Relative Humidity from the display of digital hygrometer and shall be recorded in respective **Annexure**.

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

6.2.5 Check the minimum and maximum temperature of previous 24 hrs at the start of shift by using digital hygrometer installed at hot spot.

6.2.6 Record the reading of minimum and maximum temperature in respective **Annexure**.

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

6.2.8 Check the reading of Temperature & Relative Humidity from the display of digital hygrometer and shall be recorded in respective **Annexure**.

6.2.9 If the temperature and relative humidity does not comply the specification, inform to engineering department through breakdown procedure to take corrective action.

6.3 Measurement of Temperature and Relative Humidity by Data Logger:

6.3.1 Data logger shall be used in Aseptic area wherever required.

6.3.2 Ensure that the data logger is calibrated and check the calibration due date.



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- 6.3.3** Ensure that the Data logger shall be placed in the area, at the designated position (Hot spot).
- 6.3.4** Set the recording interval as per requirement.
- 6.3.5** Take the prints of temperature and relative humidity daily, review the data and keep the record in file.
- 6.3.6** If the temperature and relative humidity does not comply the specification, inform to engineering department through breakdown procedure to take corrective action.
- 6.3.7** After corrective action again check the temperature & relative humidity.

6.4 Acceptance Criteria:

6.4.1 In Dry Powder Injectable Section: Limits of temperature & relative humidity of different areas is given below or as specified in respective BPCR:

Area	Temperature	Relative Humidity	Frequency
			Daily frequency
Vial Filling and Stoppering, Vial Sealing, Buffer Zone, Blending Room.	NMT 25°C	NMT 30%	Initially & at frequency of 4 hrs ± 30 min.
Cooling Zone, Disinfectant filtration & Sterile Corridor	NMT 25°C	NMT 45%	Initially & at frequency of 4 hrs ± 30 min.
Area of grade C and grade D	NMT 25°C	NMT 55%	Initially & at frequency of 4 hrs ± 30 min.

6.4.2 In Liquid Injectable Section: Limits of temperature & relative humidity of different areas is given below:

Area	Temperature	Relative Humidity	Frequency
			Daily frequency
All area of unit preparation, manufacturing, aseptic and grade D.	NMT 25°C	NMT 55%	Initially & at frequency of 4 hrs ± 30 min.



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6.4.3 In Warehouse: Limits of temperature & relative humidity of different areas is given below:

Area	Temperature	Relative Humidity	Frequency	
			Daily frequency	Minimum & Maximum Temperature
Sampling and Dispensing area	NMT 25°C	NMT 55%	Initially & after frequency of 4 hrs ± 30 min.	At start of shift.
Other than Sampling and Dispensing area	NMT 25°C	NA	Initially & after frequency of 4 hrs ± 30 min.	At start of shift.

6.5 Monitoring of Differential Pressure:

6.5.1 Ensure that Magnehelic Gauges/Digital differential pressure gauges (DPG) of radix are calibrated.

6.5.2 Differential Pressure shall be monitored of all areas where magnehelic gauges/ Digital differential pressure gauges (DPG) of radix are installed.

6.5.3 Differential Pressure of concern area shall be monitored by Officer / Executive and record shall be maintained in respective Annexure.

6.5.4 Differential Pressure of respective areas shall be recorded initially and at frequency of 4 hrs ± 30 min. or after any breakdown.

6.5.5 Whenever out of limit results are observed, concern department shall raise the incident report and inform to engineering department through breakdown procedure.

6.6 During periodic calibration of digital hygrometer use other calibrated digital hygrometer kept as stand by and record their ID in the remark column. After receiving of digital hygrometer from outside/ calibration agency, reset the hygrometer before use.

6.7 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.

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

6.7.2 Inform to engineering department for rectification of observed excursion.

6.7.3 Wait for 15 min to resume the observed excursion if not rectified raise the breakdown slip.



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6.7.4 After resuming the observed excursion start the filling and sealing operation.

6.7.5 Record the intervention detail in the respective BMR.

7.0 ANNEXURES:

ANNEXURES No.	TITLE OF ANNEXURE	FORMAT No.
Annexure – I	Temperature & Relative Humidity record (NMT 25°C, NMT 30 %)	
Annexure – II	Temperature & Relative Humidity record (NMT 25°C, NMT 45 %)	
Annexure – III	Temperature & Relative Humidity record (NMT 25°C, NMT 55 %)	
Annexure – IV	Sterile Area Differential Pressure Record (DPI Production)	
Annexure – V	Non Sterile Area Differential Pressure Record (DPI Production)	
Annexure – VI	Non Sterile Area Differential Pressure Record (Warehouse)	
Annexure – VII	Sterile Area Differential Pressure Record (Warehouse)	
Annexure – VIII	Sterile Area Differential Pressure Record (Production, Three Piece Line)	
Annexure – IX	Non Sterile Area Differential Pressure Record (Production, Three Piece Line)	
Annexure – X	Non-Sterile Area Differential Pressure Record (Production, Three Piece Line)	
Annexure-XI	Sterile Area Differential Pressure Record (Production, Three Piece Line)	
Annexure-XII	Non-Sterile Area Differential Pressure Record (Production, Three Piece Line)	
Annexure-XIII	Non-Sterile Area Differential Pressure Record (Production, Three Piece Line)	
Annexure-XIV	Non-Sterile Area Differential Pressure Record (Production, Three Piece Line)	
Annexure-XV	Non-Sterile Area Differential Pressure Record (Production, Three Piece Line)	
Annexure-XVI	Non-Sterile Area Differential Pressure Record (Three Piece Line)	
Annexure-XVIII	Temperature Record (where monitoring of relative humidity is not required.)	
Annexure-XIX	Packing Area Differential Pressure Record (Production)	

ENCLOSURES: SOP Training Record.



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8.0 DISTRIBUTION:

- Controlled Copy No.01 Quality Assurance
- Controlled Copy No.02 Production
- Controlled Copy No.03 Warehouse
- 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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ANNEXURE-IV

STERILE AREA DIFFERENTIAL PRESSURE RECORD (DPI PRODUCTION)

Block:

Month:

Date	Area	Entry Air-lock I (20-25 Pascal)	Entry Air-lock II (40-45 Pascal)	Entry Air-lock III (60-65 Pascal)	Filling Area (60-65 Pascal)	Sealing Area (55-60 Pascal)	Cool Zone (60-65 Pascal)	Disinfect -ant filtration Room (60-65 Pascal)	Blending Area (60-65 Pascal)	Buffer Zone (60-65 Pascal)	Sterile Corridor (50-55 Pascal)	Return Air-lock I (35-40 Pascal)	Return Air-lock II (05-10 Pascal)	Checked By	Verified By QA
	Time														

Frequency: Every 4 Hrs± 30 Min / breakdown



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ANNEXURE-V

NON-STERILE AREA DIFFERENTIAL PRESSURE RECORD (DPI PRODUCTION)

Block:

Month:

Date	Area → ↓ Time	Vial De- cartoni- ng (5- 10 Pascal)	Vial Loading (10-15 Pascal)	Air Lock-I of Vial Washin g (20-25 Pascal)	Air Lock-II of Vial Washing (40-45 Pascal)	Vial Washin g and Depyro- genation (50-55 Pascal)	Air Lock-I of Unit Prep. (20-25 Pascal)	Air Lock-II of Unit Prep. (40-45 Pascal)	Unit Prep. Room (50-55 Pascal)	Equip. Washing (40-45 Pascal)	Dress Washing (40-45 Pascal)	Disinf. Prep. (40-45 Pascal)	Materi- -al Entry (20-25 Pascal)	Checked By	Verified By QA

Frequency: Every 4 Hrs± 30 Min/breakdown



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ANNEXURE-VI

NON-STERILE AREA DIFFERENTIAL PRESSURE RECORD (WAREHOUSE)

Block:

Month:

Date	Area →	Sampling Air Lock-I (15-20 Pascal)	Sampling Air Lock-II (35-40 Pascal)	Sampling Room (45-50 Pascal)	Under test/Approved RM store (10-15 Pascal)	Dispensing Air Lock-I (15-20 Pascal)	Dispensing Air Lock-II (35-40 Pascal)	Dispensing Room (50-55 Pascal)	Checked By	Verified By QA
	↓ Time									

Frequency: Every 4 Hrs± 30 Min/ breakdown



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ANNEXURE-VII

STERILE AREA DIFFERENTIAL PRESSURE RECORD (WAREHOUSE)

Block:

Month:

Date	Area →	Sampling Entry Air Lock-I (15- 20 Pascal)	Sampling Entry Air Lock-II (35-40 Pascal)	Sampling Entry Air Lock-III (55- 60 Pascal)	Sterile RM Sampling Room (50-55 Pascal)	Sampling Return Air Lock-I (35- 40 Pascal)	Sampling Return Air Lock- II (15-20 Pascal)	Sterile RM Store (25-30 Pascal)	Checke d By	Verified By QA
	Time ↓									

Frequency: Every 4 Hrs±30 Min / breakdown



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ANNEXURE-VIII

STERILE AREA DIFFERENTIAL PRESSURE RECORD (PRODUCTION, THREE PIECE LINE)

Block:

Month:

Date	Area	Filling Room (60-65 Pascal)	Filtration -01 (55-60 Pascal)	Filtration -02 (55-60 Pascal)	Vial Staging Room (50-55 Pascal)	Machine Tools and tubing (50-55 Pascal)	Unloading (50-55 Pascal)	Sterile Corridor (40-45 Pascal)	Entry Air-lock III (35-40 Pascal)	Entry Air-lock II (20-25 Pascal)	Entry Air-lock I (05-10 Pascal)	Passage -1 (40-45 Pascal)	Return Air-lock I (25-30 Pascal)	Return Air-lock II (10-15 Pascal)	Disinfectant filtration Room (50-55 Pascal)	Checked By	Verified By QA
	Time																

Frequency: Every 4 Hrs±30 Min / breakdown



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ANNEXURE-IX

NON-STERILE AREA DIFFERENTIAL PRESSURE RECORD (PRODUCTION, THREE PIECE LINE)

Block:

Month:

Date	Area →	Vial Decartoning (20-25 Pascal)	P/L Entry to Decartoning (05-10 Pascal)	Scrap Out (05-10 Pascal)	Mat. Entry To Decartoning(05-10 Pascal)	Disinf. Prep. (20-25 Pascal)	P/L Entry to Dis. Prep. (05-10 Pascal)	Entry Material Sterile (05-10 Pascal)	Unit Prep. Room (30-35 Pascal)	Equip. Washing (20-25 Pascal)	Air Lock-II of Unit Prep. (20-25 Pascal)	P/L-1 Ent. to UPR(05-10 Pascal)	Checked By	Verified By QA
	Time ↓													

Frequency: Every 4 Hrs ± 30 Min/ breakdown



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ANNEXURE-X

NON-STERILE AREA DIFFERENTIAL PRESSURE RECORD (PRODUCTION, THREE PIECE LINE)

Block:

Month:

Date	Area →	Garment wash & preparation (05-10 Pascal)	Mfg. -I (40-45 Pascal)	Mfg. -II (40-45 Pascal)	Mfg Corridor (30-35 Pascal)	P/L-2 Entry to mfg-1&2 (20-25 Pascal)	Return Change room mfg. area(05-10 Pascal)	P/L-1 Entry to mfg-1&2 (05-10 Pascal)	Material entry. Mfg. 1&2 (05-10 Pascal)	CIP & SIP Room (05-10 Pascal)	Checked By	Verified By QA
	Time ↓											

Frequency: Every 4 Hrs± 30 Min / breakdown



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ANNEXURE-XII

NON-STERILE AREA DIFFERENTIAL PRESSURE RECORD (PRODUCTION Q-BLOCK THREE PIECE LINE)

Block:

Month:

Date	Area →	Mal For Dis.Pre. (15-20 Pascal)	Pal For Dis.Pre. (15-20 Pascal)	Dis.Pre. Room (50-60 Pascal)	Dis.Filtr. Room (80-90 Pascal)	Sterile Material Entry (15-20 Pascal)	Checked By	Verified By QA
	↓ Time							

Frequency: Every 4 Hrs± 30 Min/ breakdown



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ANNEXURE-XIII

NON-STERILE AREA DIFFERENTIAL PRESSURE RECORD (PRODUCTION, THREE PIECE LINE)

Block:

Month:

Date	Area →	Equip. Wash (30-35 Pascal)	Unit Prep. (50-60 Pascal)	Unit Prep. PAL-01 (15-20 Pascal)	Unit Prep. A/L-2 (35-45 Pascal)	Garment Wash Room(15-20Pascal)	Garment Wash PAL-2(25- 35 Pascal)	Checked By	Verified By QA
	Time ↓								

Frequency: Every 4 Hrs±30 Min / breakdown



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ANNEXURE-XIV

NON-STERILE AREA DIFFERENTIAL PRESSURE RECORD (PRODUCTION, THREE PIECE LINE)

Block:

Month:

Date	Area →	Mfg. -I (65-75 Pascal)	Mfg. -II (65-75 Pascal)	PAL-1 Entry to mfg (05-10 Pascal)	PAL-2 Entry to mfg (30-35 Pascal)	Mfg Corridor (50-60 Pascal)	CIP Room (05-10 Pascal)	Checked By	Verified By QA
	Time ↓								

Frequency: Every 4 Hrs± 30 Min / breakdown



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ANNEXURE-XV

NON-STERILE AREA DIFFERENTIAL PRESSURE RECORD (PRODUCTION, THREE PIECE LINE)

Block:

Month:

Date	Area →	Decart. PAL-01 (15-20 Pascal)	Disp. Material. MAL (15-20 Pascal)	Visual Insp. PAL-01 (10-15 Pascal)	Visual Insp. PAL-02 (30-35 Pascal)	Visual Insp. Room (50-60 Pascal)	Vial Staging (80-90 Pascal)	Vial Decartoning (35-45 Pascal)	Checked By	Verified By QA
	Time ↓									

Frequency: Every 4 Hrs±30 Min / breakdown



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ANNEXURE-XVII

STERILE AREA DIFFERENTIAL PRESSURE RECORD (PRODUCTION, THREE PIECE LINE)

Block:

Month:

Date	Area → ↓ Time	Filling Room (80-90 Pascal)	Filtration-1 (80-90 Pascal)	Filtration-2. (80-90 Pascal)	Aseptic Passage (65-75 Pascal)	Tools & Tubing (80-90 Pascal)	Unloading (80-90 Pascal)	Checked By	Verified By QA

Frequency: Every 4 Hrs±30 Min / breakdown



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ANNEXURE-XVIII TEMPERATURE RECORD

Area:

Block:

Month:

Temperature Limit: NMT 25°C

Date	Time	Equipment ID No:			Remark
		Temperature (°C)	Checked By	Verified By QA	
		Minimum:			
		Maximum:			
		Minimum:			
		Maximum:			

Frequency: Every 4 hrs ± 30 Min / breakdown

