

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

SOD No 4		Department:	Production
SOF No.:		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 gauzes 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 gauzes of radix and shall be recorded in respective **Annexure**.



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

SOD No .		Department:	Production
SOF No.:		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	2 of 25

- **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.



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

SOD No .		Department:	Production
SOF No.:		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	3 of 25

- **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:

mnoroturo	Relative	Frequency
mperature	Humidity	Daily frequency
ИТ 25°С	NMT 30%	Initially & at frequency of $4 \text{ hrs} \pm 30$
		min.
ИТ 25°С	NMT 45%	Initially & at frequency of $4 \text{ hrs} \pm 30$
		min.
ИТ 25°С	NMT 55%	Initially & at frequency of $4 \text{ hrs} \pm 30 \text{ min.}$
	mperature 1T 25°C 1T 25°C 1T 25°C	mperatureRelative Humidity4T 25°CNMT 30%4T 25°CNMT 45%4T 25°CNMT 55%

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

A moo	Tomporature	Relative	Frequency
Area	Temperature	Humidity	Daily frequency
All area of unit preparation, manufacturing, aseptic and grade D.	NMT 25°C	NMT 55%	Initially & at frequency of $4 \text{ hrs} \pm 30 \text{ min.}$



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

 Department:
 Production

SOD No .		Department:	Production
SOF No.:		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	4 of 25

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

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

6.5 Monitoring of Differential Pressure:

- **6.5.1** Ensure that Maganehelic Gauges/Digital differential pressure gauzes (DPG) of radix are calibrated.
- **6.5.2** Differential Pressure shall be monitored of all areas where magnehelic gauges/ Digital differential pressure gauzes (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 \pm 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.





PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

SOD No .		Department:	Production
SOF No.:		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	5 of 25

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.



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

SOD No .		Department:	Production	
SOF No.:		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	6 of 25	

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



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

 Department:
 Production

SOD No .	Department:		Production		
SOF NO.:		Effective Date:			
Revision No.:	00	Revision Date:			
Supersede Revision No.:	Nil	Page No.:	7 of 25		

ANNEXURE-I TEMPERATURE, RELATIVE HUMIDITY RECORD

Area:	•••••	Block:	Month:
Limits:	Temperature: NMT 25°C	Relative Humidity:	NMT 30 %

		Te	emperature & Re	lative Humidit	y	_	
Date	Time	Equipment ID No	D:	1		Remark	
Dute	Time	Temperature (°C)	% RH	Checked By	Verified By QA		

Frequency: Every 4 hrs±30 min / breakdown



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

 Department:
 Production

SOD No .		Department:	Production	
SOF NO.:		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	8 of 25	

ANNEXURE-II TEMPERATURE, RELATIVE HUMIDITY RECORD

Area:	•••••	Block:	Month:		
Limits:	Temperature: NMT 25°C	Relative Humidity:	NMT 45 %		

		Те	emperature & Re	lative Humidit	y	_	
Date	Time	Equipment ID No):			Remark	
Date	Time	Temperature (°C)	% RH	Checked By	Verified By QA	Keinark	

Frequency: Every 4 hrs ± 30 Min / breakdown



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

 Department:
 Production

SOD No .		Department:	Production	
SOF NO.:		Effective Date:		
Revision No.:	00	Revision Date:		
Supersede Revision No.:	Nil	Page No.:	9 of 25	

ANNEXURE-III TEMPERATURE, RELATIVE HUMIDITY RECORD

Area:	•••••••••••	Block:	Month:		
Limits:	Temperature: NMT 25°C	Relative Humidity:	NMT 55 %		

		Te	emperature & Re	lative Humidit	y		
Date	Time	Equipment ID No):	1		Remark	
Dute	Time	Temperature (°C)	% RH	Checked By	Verified By QA		

Frequency: Every 4 hrs.± 30 Min/breakdown

		44					PHAR	MA DEI	/ILS						
							PRODUCT	ION DEPART	MENT						
	STANDARD OPERATING PROCEDURE														
Title	Fitle: Monitoring of Temperature, Relative Humidity & Differential Pressure in Aseptic Area and Controlled Area														
SOP	SOP No.: Production														
						<u> </u>]	Effective I	Date:					
Kevis Super	Revision No.: 00 Supercode Devision No.: Nil						1	Revision L Page No ·	Date:		10 of 25				
Super	scue Re		0			11	ANI	NEXURE-	IV			10 01 25	I		
				STERIL	E AREA	DIFFERF	INTIAL I	PRESSUR	E RECOI	RD (DPI H	PRODUC	ΓION)			
Bloc	k:	•••••	•••										Month:	•••••	•••
Date	Area Time	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)	Blendi- ng Area (60-65 Pascal)	Buffer Zone (60-65 Pascal)	Sterile Corrido r (50-55 Pascal)	Return Air-lock I (35-40) Pascal)	Return Air-lock II (05-10) Pascal)	Checke d By	Verified By QA
													_		
													<u> </u>		
													<u> </u>		
E			20 11. /	1											
Freque	ency: Ev	ery 4 Hrs	3± 30 Min /	breakdown											

	PHARMA DEVILS													
						PRODUCTI	ON DEPART	MENT						
	STANDARD OPERATING PROCEDURE													
Title: Mon	toring of	f Tempera	ature, Rel	ative Hun	nidity & I	Different	ial Press	ure in As	septic Area	and Cont	rolled A	rea		
SOP No.:	SOP No.:							Departme Effective l	nt: Date:]	Production	1		
Revision No.	Revision No.: 00]	Revision I	Date:					
Supersede R	Supersede Revision No.: Nil]	Page No.:			11 of 25				
						ANN	EXURE			DDODUC				
		l	NON-STE	RILE ARE	LA DIFFE	RENTIAI	_ PRESS	URE REC	CORD (DPI	PRODUC	FION)			
Block:	•••••	•••									Γ	Month:	•••••	
Date Area	Vial	Vial	Air	Air	Vial	Air	Air	Unit	Equip.	Dress	Disinf.	Materi	Checked	Verified
	De-	Loading	Lock-I	Lock-II	Washin	Lock-I	Lock-	Prep.	Washing	Washing	Prep.	-al Entry	By	By QA
	-ng (5-	(10-15 Pascal)	Washin	Washing	g and Depyro	Prep.	Unit	(50-55	(40-45 Pascal)	(40-45 Pascal)	(40-45 Pascal)	(20-25		
	10	,	g (20-25	(40-45	g-	(20-25	Prep.	Pascal)	,	,		Pascal)		
Time	Pascal)		Pascal)	Pascal)	enation	Pascal)	(40-45 Bessel)							
1 me					(30-33 Pascal)		1 ascal)							
	\backslash				,									
Frequency: E	Voru / Ur	$\sim 20 \text{ Min}/$	braakdawn											
Frequency: E	very 4 mis	s± 50 mill/	DIEakuowi	l										

	(PHARMA	DEVILS						
				PRODUCTION D	EPARTMENT						
			STAND	ARD OPERA	TING PROCE	DURE					
Title: Monito	oring of Te	mperature, Relativ	ve Humidity a	& Differential l	Pressure in Ase	otic Area and	Controlled Area	1			
SOP No.:					Department Effective Da	: ite:	Production				
Revision No.:			00		Revision Da	te:					
Supersede Rev	Supersede Revision No.: Nil				Page No.:		12 of 25				
ANNEXURE-VI NON-STERILE AREA DIFFERENTIAL PRESSURE RECORD (WAREHOUSE)											
Block:	•••••						Mor	ıth:	••••		
Date Time	Sampl Air Lo (15-2 Pasca	ling Sampling ck-I Air Lock-II 20 (35-40 al) 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		
Frequency: Eve	ery 4 Hrs± 30) Min/ breakdown									

	PHARMA DEVILS												
	PRODUCTION DEPARTMENT STANDARD OPERATING PROCEDURE												
	STANDARD OPERATING PROCEDURE												
Title: N	Ionitoring	of Te	mperatu	re, Relative Hur	nidity & Differ	ential Pres	ssure i	n Aseptic Are	ea and	l Contr	rolled Area		
SOP No.	.:						Depar	rtment:		F	Production		
Effective Date: Revision No.: 00 Revision Date:													
Superse	de Revision	No.:			00 Nil		Page	No.:			13 of 25		
Buperse	ANNEXURE-VII												
	STERILE AREA DIFFERENTIAL PRESSURE RECORD (WAREHOUSE)												
Block:	Block:												
Date	Area Time	San Ent Locl 20 I	npling ry Air x-I (15- Pascal)	Sampling Entry Air Lock-II (35-40 Pascal)	Sampling Entry Air Lock-III (55- 60 Pascal)	Sterile Sampl Room (: Pasca	RM ling 50-55 al)	Sampling Return Air Lock-I (35- 40 Pascal)	Sam Ret Air I II (1 Pas	pling turn Lock- 15-20 scal)	Sterile RM Store (25-30 Pascal)	Checke d By	Verified By QA
Frequenc	ey: Every 4 F	Hrs±30	Min / bro	eakdown									

	PHARMA DEVILS PRODUCTION DEPARTMENT															
								PRODU	CTION DEP	PARTMENT						
						ST	FANDA	RD OF	PERAT	ING P	ROCEI	DURE				
Title	: Mon	itoring	of Temp	perature	, Relati	ve Hun	idity &	Differe	ential Pr	essure i	n Asep	tic Area a	and Cont	rolled A	rea	
SOP	No.:									Depa Effec	rtment: tive Dat	e:		Production	L	
Revis	ion No.	.:				0	0			Revis	sion Dat	e:				
Super	sede R	evision	No.:			N	il			Page	No.:			14 of 25		
								AN	NEXUR	E-VIII			·			
	STERILE AREA DIFFERENTIAL PRESSURE RECORD (PRODUCTION, THREE PIECE LINE)															
Bloc	Block:															
Date	Area Filling Room (60-65 Filtration (60-65 Pascal)Filtration Filtration Filtration (50-55 															
Freque	ency: E	very 4 H	Irs±30 M	in / breal	kdown										<u> </u>	
1		j														

	PHARMA DEVILS PRODUCTION DEPARTMENT													
	PRODUCTION DEPARTMENT STANDARD OPERATING PROCEDURE													
					ST	ANDARI	D OPERA	ATING P	ROCED	URE				
Title:	Monito	oring of '	Temperat	ure, Relat	ive Humi	dity & Di	ifferential	Pressure	in Asepti	c Area ar	d Controlle	ed Area		
SOP N	lo ·							Dep	artment:		Produ	iction		
D · · ·	NT							Effe	ctive Date:					
Revisi	on No.: Todo Boy	vicion No	•		00 Niji	1		Rev	ision Date:		15 0	f 25		
Supers	seue rev	/151011 INU.	••		111		ANNEX	Tage	e INU.:		150	1 23		
		N	ION-STE	RILE ARE	A DIFFER	RENTIAL	PRESSUR	E RECOR	RD (PROD	UCTION,	THREE PIE	ECE LINE)		
	INVIN-5 I ERILE AREA DIFFERENTIAL PRESSURE RECORD (PRODUCTION, THREE PIECE LINE)													
Block	Block:													
Date	Area Time	Vial De- cartonin g (20-25 Pascal)	P/L Entry to Decartoni ng (05-10 Pascal)	Scrap Out (05-10 Pascal)	Mat. Entry To Decartoni ng(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
Freque	ncy: Eve	ery 4 Hrs	± 30 Min/ 1	breakdown		1	1	1	1		1	1	1	LJ

				1	PHARMA	DEVILS					
					PRODUCTION DE	EPARTMENT					
			S	TANDAR	D OPERAT	FING PRO	OCEDURE				
Title: Monitoring of	of Temp	erature, Re	elative Hun	nidity & D	ifferential P	ressure in	Aseptic Are	a and Co	ontrolled Area		
SOP No ·				-		Depart	ment:		Production		
501 110						Effectiv	e Date:				
Revision No.:	Ŧ		<u> </u>	00		Revisio	n Date:		16 605		
Supersede Revision N	NO.:		N	11		Page No	0.:		16 of 25		
	NON-S	STERILE A	REA DIFFE	RENTIAL	PRESSURE	JKE-A RECORD (PRODUCTI	ON THR	EE PIECE LIN	JE)	
	11011 0				INLODUKL		INODUCII	.01., 111		(1)	
Block:	••••						•		N	<u>Ionth:</u>	•••••
Date Area Gal wa pre on 0 Pa	arment ash & eparati (05-10 Pascal	MfgI (40-45 Pascal)	MfgII (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)	Materia entry. Mf 1&2 (05-10 Pascal)	l cg. CIP & SIP Room (05- 10 Pascal)	Checked By	Verified By QA
Frequency: Every 4 Hr	rs± 30 M	lin / breakdo	wn								

	PHARMA DEVILS PRODUCTION DEPARTMENT												
						PRC	DUCTIC	ON DEPART	MENT				
						STANDARD	OPEI	RATIN	G PF	ROCEDURE			
Title: M	onitoring	g of Tei	nperatu	ure, Relativ	e Hı	umidity & Diffe	erenti	ial Press	ure i	n Aseptic Area an	d Controlled Area		
SOP No.:	:								Depar	rtment:	Production		
Revision	No ·					00		1	Effect	tive Date: ion Date:			
Supersed	e Revisio	n No.:				Nil]	Page 1	No.:	17 of 25		
		~					ANN	EXURE-	XI			·	
		S	TERILI	E AREA DI	FE	RENTIAL PRES	SUR	E RECO.	RD (I	PRODUCTION, TH	REE PIECE LINE		
Block:		•••••									Ν	Aonth:	
	Area	Aseptic	PAL-1	Aseptic PA	L-2	Aseptic PAL-3	Retu	irn Air Lo	ock-1	Return Air Lock-2	Return Air Lock-3	Checked By	Verified By
		(15-20	Pascal	(35-45 Pase	al)	(50-60 Pascal)	(5	00-60 Pasc	cal	(35-45 Pascal)	(15-20 Pascal)		QA
Date													
	▼ \												
	Time												
Eno are are		1 II. 2	O Min /	haaledare									
r requent	cy: Every	4 mrs± 3	U IVIIN /	oreakdown									



				PHARMA	DEVILS				
				PRODUCTION D	EPARTMENT				
			STANDA	RD OPERA	TING PROCE	DURE			
Title: Monitori	ng of Tem	perature, Relative H	Iumidity & I	Differential I	Pressure in Ase	ptic Area and C	Controlled Are	ea	
SOP No ·					Department		Production		
					Effective Da	ite:			
Revision No.:	NT.		00		Revision Da	ite:	10 - £ 25		
Supersede Revis	ion No.:		IN1I	ANNEVI	Page No.:		19 of 25		
	NON-9	STERILE AREA DI	FFERENTIA	ANNEAU L PRESSURF	RECORD (PRO	DUCTION TH	REE PIECE L	INE)	
	110111								
Block:	••••							Month:	•••••
Date	Area Time	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

Frequency: Every 4 Hrs±30 Min / breakdown

	Colton			PHAR	MA DEVILS				
4				PRODUCT	ION DEPARTMENT				
				STANDARD OPH	ERATING PROCE	DURE			
Title: M	Ionitoring	g of Tempera	ture, Relative I	Humidity & Differen	tial Pressure in Asep	tic Area and	Controlled Area		
SOP No.	:				Department: Effective Dat	te•	Production		
Revision	No.:			00	Revision Dat	te:			
Supersed	le Revision	n No.:		Nil	Page No.:		20 of 25		
				ANN	EXURE-XIV				
		NON-STE	RILE AREA DI	FFERENTIAL PRESS	URE RECORD (PRO	DUCTION, TH	IREE PIECE LII	NE)	
Block: .	• • • • • • • • • • • • •	•••••					Ν	Aonth:	
	Area	MfgI	MfgII	PAL-1 Entry to mfg	PAL-2 Entry to mfg	Mfg Corridor	CIP Room		Verified By
Date		(65-75 Pascal)	(65-75 Pascal)	(05-10 Pascal)	(30-35 Pascal)	(50-60 Pascal	(05-10 Pascal)	Checked By	QA QA
	Time								
Frequen	ncy: Every	4 Hrs± 30 Min	/ breakdown						

(C)				PHAI	RMA DEI	/tLs				
				PRODUC	CTION DEPART	MENT				
			STAN	DARD OP	ERATIN	G PROCEE	DURE			
Title: Monitoring of	<u>Femperat</u>	ure, Relativ	e Humidity	y & Differe	ntial Press	ure in Asept	ic Area an	d Controlled	Area	
SOP No ·]	Department:		Product	tion	
]	Effective Date	2.			
Revision No.:			00			Revision Date	:	21 60	25	
Supersede Revision No.	•		IN11	A N		rage No.:		21 of 2	25	
N	ON-STER	RILE AREA	DIFFEREN	TIAL PRES	SURE REG	A V CORD (PROI	DUCTION,	THREE PIEC	CE 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
Frequency: Every 4 Hrs	s±30 Min /	breakdown								

a de la d	Color.			PHA	RMA DE	EVILS				
~				PRODU	UCTION DEPAR	RTMENT				
				STANDARD O	PERATI	NG PR	OCEDURE			
Title: Mo	onitoring of	Tei	mperature, Relative	Humidity & Differ	ential Pres	ssure in	Aseptic Area and	d Co	ontrolled Area	
SOP No.:						Depart	tment:		Production	
Revision N	No ·			00		Effectiv	ve Date: on Date:			
Supersede	e Revision No	D.:		Nil		Page N	lo.:		22 of 25	
			NON-STERII	AN LE AREA DIFFEREN	NNEXURE	-XVI ESSURF	E RECORD (WAR	E HO	DUSE)	
Block:		••••							Mont	h:
Date	Area Time	۲ ۲	Sampling Entry Air Lock-I (15-20 Pascal)	Sampling Entry Air Lock-II (35-45 Pascal)	Proces Area/Disj Area (5 Pasc	ssing pensing 50-60 al)	Under Test/Appro Area (10-15 Pasc	oved al)	Checked By	Verified By QA
Frequenc	vv• Every A H	rs+2	0 Min/ breakdown							
ricquein	. y• Every 4 II	u 5±0								

	PHARMA DEVILS PRODUCTION DEPARTMENT												
			PRODUC	CTION DEPARTMEN	T								
		STA	NDARD OP	ERATING I	PROCEDU	U RE							
Title: Monitoring	g of Temperatu	re, Relative Humid	lity & Differe	ntial Pressure	in Aseptic	Area and	Controlled A	Area					
SOP No.:				Dep Fffe	artment:		Productio	n					
Revision No.:		00		Rev	ision Date:								
Supersede Revision	n No.:	Nil		Pag	e No.:		23 of 25						
			ANN	NEXURE-XVI	[
	STERILE	AREA DIFFEREN	TIAL PRESSU	RE RECORD	(PRODUCT	TION, THR	EE PIECE LI	NE)					
Block:	•••••							Month:					
Date	Area	Filling Room (80-90 Pascal)	Filtration-1 (80-90 Pascal)	Filtration-2. (80-90	Aseptic Passage (65-75	Tools &Tubing (80-90	Unloading (80-90	Checked By	Verified By QA				
	Time		(Pascal)	Pascal)	Pascal)	Pascal)						
D	<u> </u>	1.1											
r requency: Every	4 Hrs±30 Min / b	oreakdown											



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

 Sop Notion
 Department:
 Production

SOD No.		2 ·p	110000
SOF NO.:		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	24 of 25

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



PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

SOD No .		Department:	Production
SOF NO.:		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	25 of 25

ANNEXURE-XIX PACKING AREA DIFFERENTIAL PRESSURE RECORD (PRODUCTION)

Area:

Section:

Month:

Differential Pressure Limit for Three piece: NLT 60 Pascal

Differential Pressure Limit for FFS: NLT 55 Pascal

Differential Pressure Limit for DPI: NLT 60 Pascal

Date Tim		ID No:			
	Time	Differential Pressure (Pascal)	Checked By	Verified By QA	Remark

Frequency: Every 4 hrs ± 30 Min / breakdown