



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Sterilizing and Depyrogenation Tunnel	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for Operation and Cleaning of Sterilizing and Depyrogenation Tunnel.

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Sterilizing and Depyrogenation Tunnel (Make: **Truiking**) in Production area at

3.0 RESPONSIBILITY:

Officer/Executive – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 DEFINITION:

Not Applicable

6.0 PROCEDURE:

6.1 Put on the main switch control

6.2 Welcome screen shall display.

6.3 Push the login button enter the User ID and password.

6.4 On The Pre Heat Fan, Cooling Fan, Heating Fan, Conveyor Belt Motor, Exhausting Fan. Set the all parameters



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Sterilizing and Depyrogenation Tunnel	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

6.4.1 Set the Recipe for 1ml, 2ml, 3ml, 5ml & 10ml ampoule and fixed recipe parameter as per Table No.1.

TABLE No. – 01

Parameter	Set value				
	1 ml Ampoule	2 ml Ampoule	3 ml Ampoule	5 ml Ampoule	10 ml Ampoule
Hot Zone Set Point Temperature	320°C	320°C	320°C	320°C	320°C
Hot Zone Temperature Overshoot	350°C	350°C	350°C	350°C	350°C
Conveyor Start Temperature	310°C	310°C	310°C	310°C	310°C
Conveyor Stop Temperature	300°C	300°C	300°C	300°C	300°C
Conveyor Speed	75mm/min.	95mm/min.	100mm/min	110mm/min	120mm/min.
Cooling Zone Overshoot Temperature	30°C	30°C	30°C	30°C	30°C
Data Logging in Minute	1 minute	1 minute	1 minute	1 minute	1 minute
Night Mode Hot Zone Temperature	50°C	50°C	50°C	50°C	50°C
Recipe Type	GO	GO	GO	GO	GO

Set the Recipe for 2ml, 10ml, 20ml & 30ml vial and fixed recipe parameter as per Table No.2

TABLE NO. - 02

Parameter	Set value			
	2 ml vial	10 ml vial	20 ml vial	30 ml vial
Hot Zone Set Point Temperature	320°C	320°C	320°C	320°C
Hot Zone Temperature Overshoot	350°C	350°C	350°C	350°C
Conveyor Start Temperature	310°C	310°C	310°C	310°C
Conveyor Stop Temperature	300°C	300°C	300°C	300°C
Conveyor Speed	100 mm/min.	120 mm/min.	130 mm/min.	140 mm/min.
Cooling Zone Overshoot Temperature	30°C	30°C	30°C	30°C
Data Logging in Minute	1 minute	1 minute	1 minute	1 minute
Night Mode Hot Zone Temperature	50°C	50°C	50°C	50°C
Recipe Type	GO	GO	GO	GO



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Sterilizing and Depyrogenation Tunnel	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 6.4.2** To start the tunnel and simultaneously switch “ON” the Heater Bank MCB to start Heating of Tunnel.
- 6.4.3** Switch off the MCB Heater bank & Tunnel will go under cooling mode.
- 6.4.4** Blower and exhaust of the tunnel should be kept on till reaching the temperature of Hot Zone at 60°C and switch off to stop the machine.
- 6.4.5** Record the operation details in Format, Titled “**Equipment Log**” as per SOP.
- 6.4.6** **CLEANING:**
- 6.4.7** **Cleaning Procedure (Before & End of Operation) Daily:**
- 6.4.8** Clean the tunnel conveyor by lint free cloth followed by 70% IPA in running mode of conveyor to clean entire surface with operation machine.
- 6.4.9** Open the bolt of dry zone cover plate with the help of the key
- 6.4.10** Remove the SS cover plate for cleaning of conveyor belt.
- 6.4.11** Start the conveyor with PLC to select the “Maintenance” tab on PLC
- 6.4.12** Set the conveyor speed in manual mode at 150mm/minute for cleaning purpose
- 6.4.13** Damped the lint free moping pad with 70% IPA solution for cleaning of conveyor belt shown in fig. as under.
- 6.4.14** Conveyor belt shall be clean to cover entire surface of conveyor in operation mode.
- 6.4.15** Outer surface of tunnel to be cleaning with help of dry lint free duster.
- 6.4.16** Production Officer/Executive shall check the conveyor cleaning by using High Beam Torch & verified by IPQA Officer/Executive and cleanness should be pass as per visual clean criteria. Shown in fig. as under.
- 6.4.17** **Cleaning Frequency:** Weekly



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Sterilizing and Depyrogenation Tunnel	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 6.4.18** Open the Dry Zone & Cooling Zone both side cover and clean the Tunnel by using vacuum cleaner.
- 6.4.19** Clean the pre-filters of Tunnel with WFI as well as with air jet weekly followed by air drying.
- 6.4.20** Repeat the Conveyor Cleaning procedure step from point no. **6.4.8** to **6.16.1.1**
- 6.4.21** **Product Change Over:**
- 6.4.22** Open the both side cover of the sterilizing and Depyrogenation tunnel.
- 6.4.23** Adjust the height of the both dampers (hot zone cover and tunnel out feed) and adjust the height by measurement with scale by rotating the knob of the tunnel.
- 6.4.24** After adjustment of damper height according to vial size, lock the damper rotating knob.
- 6.4.25** Record the daily & weekly cleaning details in Format No. Titled “**Equipment Log**” as per SOP by putting remark cleaning as “Daily Cleaning/Weekly Cleaning”.

6.4.26 ABBREVIATIONS:

°C	Degree Celsius
IPA	Isopropyl Alcohol
LI	Liquid Injection
Ltd.	Limited
MCB	Miniature Circuit Breaker
Min	minutes
ml	milliliter
mm	millimeter
MMI	Man Machine Interface
PLC	Programmable Logical Controller
QA	Quality Assurance
SOP	Standard Operating Procedure



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Sterilizing and Depyrogenation Tunnel	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Temp.	Temperature
WC	Water Column
WFI	Water for Injection
IPQA	In process Quality Assurance

6.4.27 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Set Parameter List of Differential Pressure Limit and Temperature	

6.4.28 DISTRIBUTION:

- Controlled Copy No.1 Head Production
- Master Copy Quality Assurance Department

6.4.29 REFERENCES:

- SOP Titled “Equipment Log”

6.4.30 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Operation and Cleaning of Sterilizing and Depyrogenation Tunnel

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

ANNEXURE – I

SET PARAMETER LIST OF DIFFERENTIAL PRESSURE LIMIT AND TEMPERATURE

PARAMETERS	DIFFERENTIAL PRESSURE LIMIT	TEMPERATURE LIMIT
Pressure Differentials (Pre heating Zone)	100-300 Pa	80°C - 110°C
Pressure Differentials (Heating Zone)	150-350 Pa	310°C - 350°C
Pressure Differentials (Cooling Zone)	80-250 Pa	25°C - 30°C