



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Operation and Cleaning of Vial Depyrogenation Tunnel

<b>Department:</b>		<b>Department:</b>	Production
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
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### 1.0 OBJECTIVE:

To lay down a procedure for Operation and Cleaning of Vial Depyrogenating Tunnel.

### 2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Vial Depyrogenating Tunnel (**Make:** Fabtech Technologies Ltd., **Model:** cGMP) at Unit preparation room of Production area in Dry Powder Injectable Section at .....

### 3.0 RESPONSIBILITY:

Officer/Executive – Production

### 4.0 ACCOUNTABILITY:

Head – Production

### 5.0 ABBREVIATIONS:

DPI	Dry Powder Injection
IPA	Iso Propyl Alcohol
IPQA	In Process Quality Assurance
ID No.	Identification Number
QA	Quality Assurance
Ltd.	Limited
MMI	Main Machine Interface
mm	Millimeter
ml	Milliliter
min.	Minute
No.	Number
PD	Production
Pvt.	Private
SOP	Standard Operating Procedure
WFI	Water for Injection
UPS	Uninterrupted Power Supply

### 6.0 PROCEDURE:

#### 6.1 Precautions:

- 6.1.1 To ensure the health and safety of person using the Depyrogenating Tunnel and to train personnel in their proper use.
- 6.1.2 The name of the person responsible for the Depyrogenating Tunnel shall be posted near the depyrogenating tunnel.



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- 6.1.3 No maintenance & cleaning activity shall be performed, during heating mode.
- 6.1.4 Only validated speed & equipment process parameter shall be used as per Annexure-I “Validated Parameter & Conveyor Speed Details of Depyrogenating Tunnel”
- 6.1.5 Depyrogenating Tunnel shall be inspected quarterly as preventive maintenance.
- 6.1.6 Depyrogenating Tunnel shall be qualified periodically i.e. Half yearly.
- 6.1.7 Ensure the availability of power supply before start of operation of depyrogenating tunnel.
- 6.1.8 Two level of users defined for Depyrogenation tunnel.
- 6.1.9 Always use correct user login and password for login.
- 6.1.10 Refer Annexure-IV “List of Safety Alarms and Interlocking” for details of alarms and interlocking.
- 6.1.11 Ensure UPS is working for LAF blower and turbine of Depyrogenating tunnel.
- 6.1.12 Ensure tunnel should be clean.
- 6.1.13 Remove the pre filter of dry zone & cooling zone transfer in filter washing area (Engineering Department) for washing.

### 6.2 User levels:

- 6.2.1 For depyrogenating tunnel, two levels of user are defined.
  - 6.2.2.1 Level 1 (Operator)
  - 6.2.2.2 Level 2 (Supervisor)

For details of user privileges refer respective annexure of SOP “Access Control and Password Policy for Automated Equipments/Systems”

### 6.3 Operation:

- 6.3.1 Cleaning status shall be verified with the help of high beam torch.
- 6.3.2 Validated Recipe Parameter & conveyor speed For 7.5 ml, 10 ml & 20 ml Vial refer as **Annexure-I Titled as “Validated parameter & conveyor speed details of Depyrogenating Tunnel”**.



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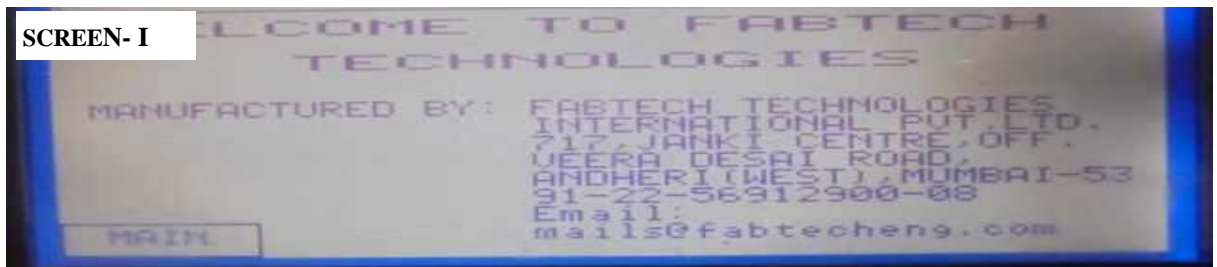
**6.3.3** Refer **Annexure- IV** “List of Safety Alarms and Interlocking” for details of alarms and interlocking available in Depyrogenating tunnel.

**6.3.4** LAF blower and turbine of depyrogenating tunnel are provided with UPS.

**6.3.5** Set the damper of Hot Zone/Sterilization Zone of De-Pyrogenation Tunnel as per vial size by using rod manually.



**6.3.6** Put on the main control switch & following screen shall be display:



**6.3.7** Select “MAIN” as given in **SCREEN -1**, following screen shall be display:



**6.3.8** Select “LOGIN” as given in **SCREEN -2**, following screen will be displayed:



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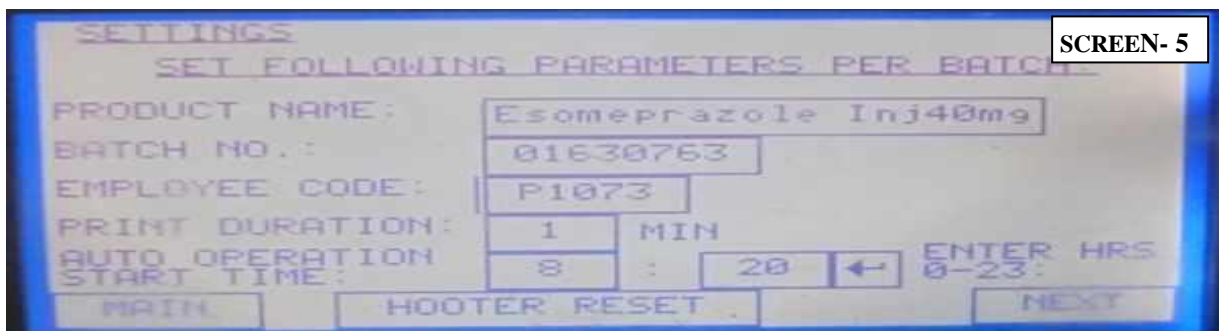
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6.3.9 Enter the password in **SCREEN-3** and then select enter ↵, following screen will display:



6.3.10 Then select “**SETTINGS**” in **SCREEN -4**, following screen shall display:



6.3.11 Enter the Product Name, Batch Number, Employee Code, and Print Duration & Auto Operation Start Time in **SCREEN-5**. Then select “**NEXT**” in **SCREEN-5**, following screen will display:



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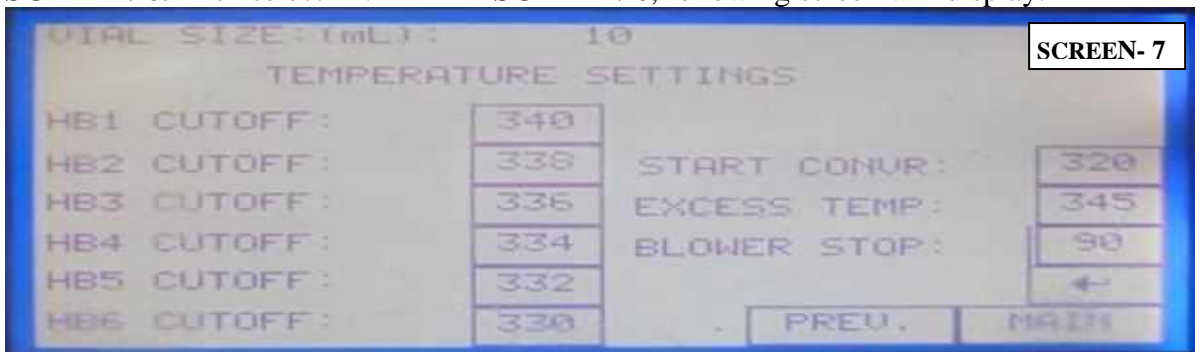
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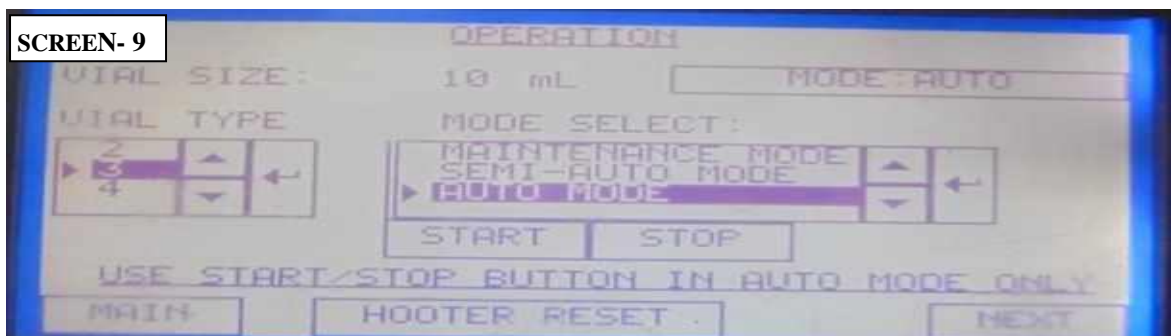
6.3.12 Select and Set the Conveyor Speed and Turbine Motor Speed as per validated parameter in **SCREEN-6**. Then select “NEXT” in **SCREEN-6**, following screen will display.



6.3.13 Select and Set all the parameter given in **SCREEN-7** as per validated parameter. Then select “MAIN” in **SCREEN-7**, following screen will display:



6.3.14 Select “OPERATION” in **SCREEN-8**, following screen will display:








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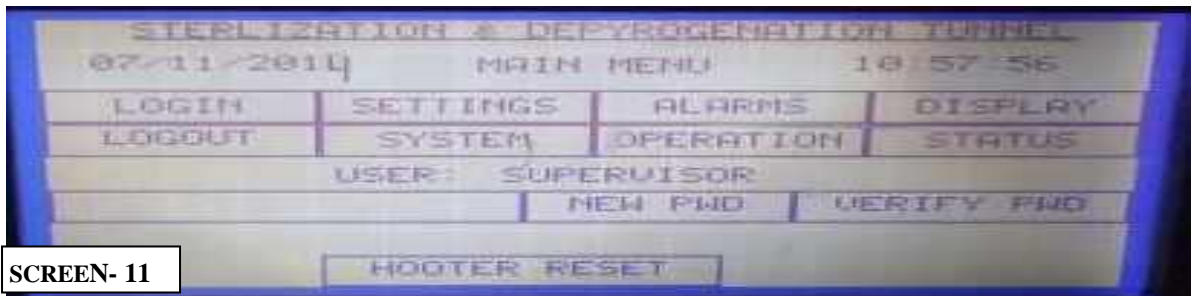
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6.3.15 Select “**AUTO MODE**” in **SCREEN-9** and then enter  and again select “**START**”, following screen will display:

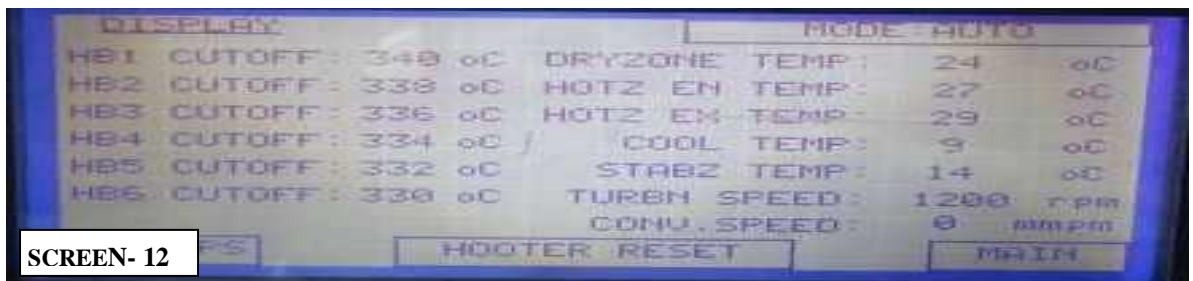


6.3.16 Select “**HOOPER RESET**” and then “**MAIN**” in **SCREEN-10**, following screen will display:



6.3.17 Now Sterilization and depyrogenating tunnel is start. After achieving the temperature of sterilization zone at 320°C, conveyor will start. Then vials washing needs to be started and feed into tunnel for sterilization & depyrogenation.

6.3.18 Select “**DISPLAY**” in **SCREEN-11** to see the all parameters which was set, following screen will display:



6.3.19 To stop the tunnel after completion the activity select “**MAIN**” in **SCREEN -12**, following screen will display:



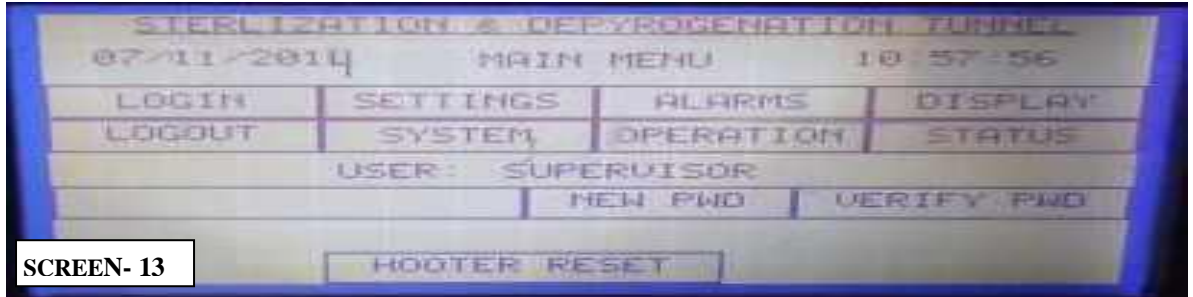
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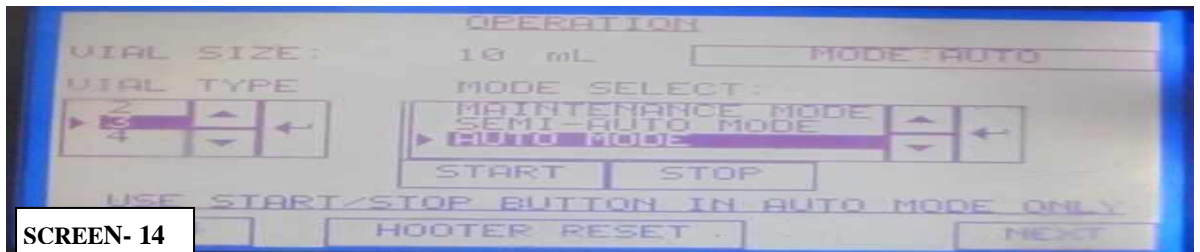
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SCREEN- 13

6.3.20 Select “OPERATION” in SCREEN-13, following screen will display:



SCREEN- 14

6.3.21 Select “STOP” in SCREEN-14. Then all heaters will be stopped but blower of drying zone, sterilization zone, cool zone & stabilizing zone will run till getting the temperature of sterilization zone at 90°C. After getting the temperature of sterilization zone at 90°C, all the blower will be stopped automatically.

6.3.22 Put the main supply OFF by control switch.

6.3.23 Equipment configuration & related parameters shall be referred as **Annexure-II** Titled as “**Configuration & Parameter Details of Depyrogenating Tunnel Details (DPI)**”.

### 6.4 Monitoring and Data recording:

6.4.1 Temperature, conveyor speed, pressure differential of all zones and printout will be monitored at the time of start and every one hour by Production & QA staff. It should be within validated parameters.

6.4.2 Data should be recorded in BMR.

6.4.3 Printout will be checked after completion the batch and it will be attached in BMR after signing.

### 6.5 Cleaning:

6.5.1 Cleaning procedure of Conveyor & Outer surface of Tunnel (at the end of each Operation):

6.5.1.1 In case of Conveyor:

6.5.1.1.1 Set the conveyor speed 200 mm/minute for cleaning purpose as given in SCREEN – 6.



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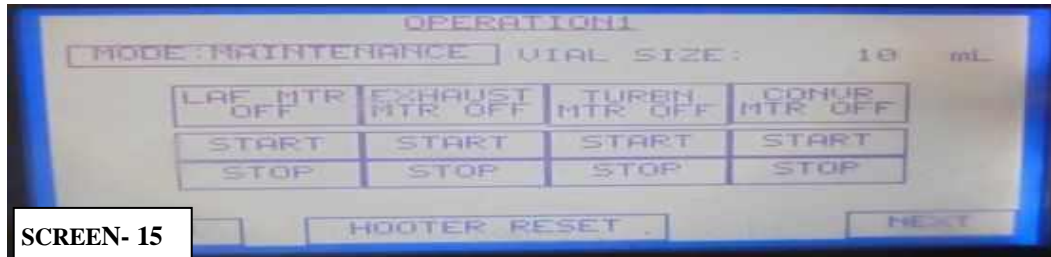
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6.5.1.1.2 Select the “**MAINTENANCE MODE**” as given in for cleaning purpose as given in **SCREEN – 8**, following screen will displayed:



6.5.1.1.3 Select “**START**” below conveyor motor off in **SCREEN-15**.

6.5.1.1.4 Clean the tunnel conveyor by lint free cloth followed by 70% IPA in running mode of conveyor to clean entire surface with operation machine.

6.5.1.1.5 Open the Screw of dry zone cover plate with the help of key / screwdriver.

6.5.1.1.6 Remove the SS cover plate for cleaning of conveyor belt.

6.5.1.1.7 Damped the lint free moping pad with 70% IPA solution and clean the conveyor belt shown in Picture -1.



**Picture-1**

6.5.1.1.8 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.



6.5.1.2 **In case of Outer surface:** Ensure that tunnel is in cool condition prior to cleaning.





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6.5.1.2.1 Mopping of all outer surfaces to be done with 70% IPA as following steps.



Drying zone cleaning



Sterilizing zone cleaning



Cooling & Stabilizing zone cleaning

6.5.1.2.2 Tunnel should be cleaned after completion of batch activity.

6.5.1.2.3 In case of no production activity, tunnel should be cleaned once in working day.

### 6.5.2 Weekly Cleaning of Equipment (Once in a week):

6.5.2.1 Open the Dry Zone & Cooling Zone both side cover and throughout the cleaning of **Tunnel**.

6.5.2.2 Remove the pre filter of dry zone & cooling zone and put in poly bag transfer in filter washing area (Engineering Department).

6.5.2.3 Clean the pre-filters of Tunnel with WFI as well as with air jet weekly followed by air drying.

6.5.2.4 For weekly cleaning follow the steps as mentioned in **Annexure-III** Titled as “**Pictorial steps for weekly cleaning of Depyrogenating Tunnel of DPI Section**”.

6.5.2.5 Record the Operation and cleaning detail in “**Machine Utilization Record**” as per SOP by putting remark cleaning as “Daily cleaning / Weekly Cleaning”.

## 7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Validated Parameter & Conveyor Speed Details of Depyrogenating Tunnel	
Annexure-II	Configuration & Parameter Details of Depyrogenating Tunnel Details (DPI)	
Annexure-III	Pictorial steps for weekly cleaning of Depyrogenating Tunnel of DPI Section	
Annexure-IV	List of Safety Alarms and Interlocking	

**ENCLOSERS:** SOP Training Record

## 8.0 DISTRIBUTION:

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





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### ANNEXURE – I

#### VALIDATED PARAMETER & CONVEYOR SPEED DETAILS OF DEPYROGENATING TUNNEL

**Equipment ID:**

**Make:** Fabtech Technologies Ltd. / cGMP Model

**Block:** .....

**Located at:** DPI, Unit preparation room

Parameter	Set value		
	7.5 ml	10 ml	20 ml
Hot Zone Temperature Overshoot	350	350	350
Conveyor Start Temperature	320	320	320
Conveyor Stop Temperature	315	315	315
Conveyor Speed	110 mm/min	110 mm/min	110 mm/min
Print Int.	60 sec.	60 sec.	
Heater-1	340 <sup>0</sup> C	340 <sup>0</sup> C	
Heater-2	338 <sup>0</sup> C	338 <sup>0</sup> C	
Heater-3	336 <sup>0</sup> C	336 <sup>0</sup> C	
Heater-4	334 <sup>0</sup> C	334 <sup>0</sup> C	
Heater-5	332 <sup>0</sup> C	332 <sup>0</sup> C	
Heater-6	330 <sup>0</sup> C	330 <sup>0</sup> C	
Auto Off	90 <sup>0</sup> C	90 <sup>0</sup> C	



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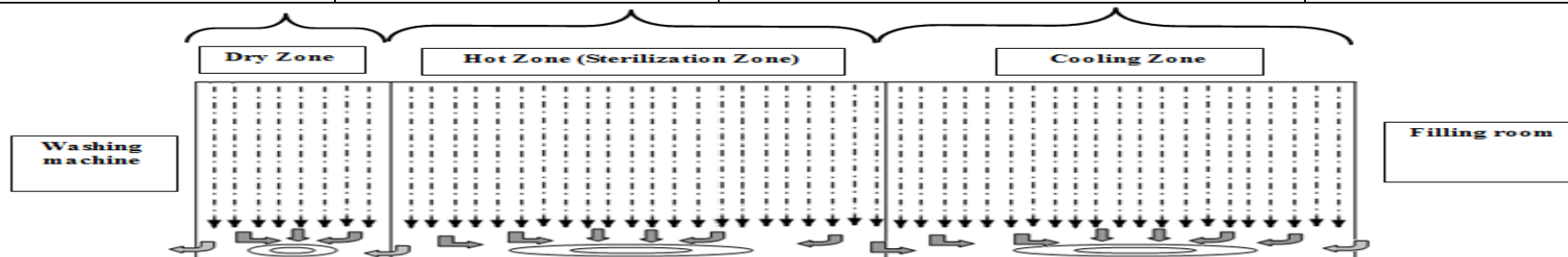
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### ANNEXURE –II

#### CONFIGURATION & PARAMETER DETAILS OF STERILIZING AND DE-PYROGENATING TUNNEL DETAILS (DPI)

<b>Equipment ID.:</b>	<b>Model :</b> cGMP Model	<b>Manufacturer's Name:</b> Fabtech Technologies Ltd.	<b>Conveyor Width :</b> 450 mm
<b>Total Conveyor Length:</b> 3600 mm	<b>Dry zone Length :</b> 710 mm	<b>Hot Zone (Sterilization Zone) :</b> 1490 mm	<b>Cooling zone Length :</b> 1400 mm



Parameter	Dry Zone	Hot Zone (Sterilization Zone)	Cooling Zone	Stabilizing Zone	Pack size	Vial Diameter	Conveyor speed
<b>Velocity</b>	90-110 feet/min	120-150 feet/min.	90-110 feet/min.		5 ml	25 mm	110 mm/min.
<b>DP</b>	05-15 mm of Hg	15-25 mm of Hg	05-15 mm of Hg		7.5 ml	25 mm	110 mm/min.
<b>Temp.</b>	50 to 110°C	320 to 350°C	25 to 50°C	NMT 30	10 ml	25 mm	110 mm/min.
<b>No. of HEPA</b>	01	02	02		20 ml	28 mm	110 mm/min.





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### ANNEXURE –III

### Pictorial Steps for Weekly Cleaning of Depyrogenating Tunnel (DPI Section)



Open side panel of drying zone



Remove SS panel



Open side panel of cooling & stabilizing zone



Remove side panel of cooling & stabilizing zone



Drying zone cleaning (using 70% IPA)



Conveyor cleaning (upper side)



Conveyor cleaning (Lower side)



Cooling & Stabilizing zone cleaning (inside)



Open screw of Pre-filter grill



Remove Pre-filter grill



Remove Pre-filter for cleaning



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Install Pre-filter (after cleaning)



Install Pre-filter grill (after cleaning)



Screw fixing after Pre-filter installation



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### ANNEXURE –IV

### List of Safety Alarms and Interlocking

S.No.	Component	Response from Depyrogenating Tunnel
1.	Maximum accumulation at feeding Point	Conveyor off.
2.	Heater Safety Switch off	“Heater safety switch off” fault displayed on MMI with alarm
3.	Drying zone high temperature	“Drying zone temperature high” fault displayed on MMI with alarm
4.	Cooling zone low temperature	“Cooling zone temperature low” fault displayed on MMI with alarm
5.	Cooling zone air velocity low	“Cooling zone air velocity low” fault displayed on MMI with alarm consequently conveyor stopped.
6.	Infeed Proximity switch off	“Infeed Proximity switch OFF” fault displayed on MMI with alarm
7.	Outfeed Proximity switch off	“Outfeed Proximity switch OFF” fault displayed on MMI with alarm
8.	Motor trip	“Drying zone motor trip” fault displayed on MMI with alarm