



PHARMA DEVILS

**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

**PERFORMANCE QUALIFICATION
REPORT
FOR
STERILIZING & DEPYROGENATING
TUNNEL**

EQUIPMENT ID. No.	
LOCATION	Vial Washing and De-Pyrogenation
DATE OF QUALIFICATION	
SUPERSEDES REPORT No.	NIL



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**PERFORMANCE QUALIFICATION REPORT
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STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

CONTENTS

S.No.	TITLE	PAGE No.
1.0	Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Equipment Details	6
6.0	System Description	6
7.0	Pre-Qualification Requirements	8
8.0	Tests & Checks	11
9.0	Documents To Be Attached	36
10.0	Non Compliance	36
11.0	Deviation From Pre-Defined Specification, If Any	36
12.0	Change Control, If Any	36
13.0	Review (Inclusive of follow up action, If Any)	37
14.0	Conclusion	37
15.0	Recommendation	37
16.0	Abbreviations	38
17.0	Post Approval	39



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**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

1.0 PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



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**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

2.0 OBJECTIVE:

The objective of this Report is to establish that Sterilization & Depyrogenating tunnel meets the following criteria:

The Sterilization and Depyrogenating tunnel performs as per the pre-defined parameters and/or quality attributes.

3.0 SCOPE:

- The Report covers all aspects of Performance Qualification for the Sterilizing and Depyrogenating Tunnel (**Make – Fabtech Technologies Pvt. Ltd.**) installed in the Vial Washing & Depyrogenating of
- This report provides all the relevant information of the performance qualification activity, In-process observations and analytical data of testing of collected samples



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**PERFORMANCE QUALIFICATION REPORT
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STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the verification and evaluation of performed tests results.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Initiation, Approval Compilation and Authorization of the Performance Qualification.• Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity.• Monitoring of Performance Qualification.
Production	<ul style="list-style-type: none">• Review of Report.• To co-ordinate and support Performance Qualification Activity.
Quality Control	<ul style="list-style-type: none">• Review of Report.• Analytical Support (Microbiological Testing / Analysis)
Engineering	<ul style="list-style-type: none">• Reviewing of qualification Report for correctness, completeness and technical excellence• Responsible for trouble shooting (if occurred during execution).• Maintenance & preventive maintenance as per schedule.



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**PERFORMANCE QUALIFICATION REPORT
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STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

5.0 EQUIPMENT DETAILS:

Equipment Name	Sterilizing and De-pyrogenating Tunnel
Equipment ID.
Manufacturer's Name	Fabtech Technologies Int. Pvt. Ltd.
Supplier's Name	cGMP Model
Model	Fabtech Technologies Int. Pvt. Ltd.
Location of Installation	Vial Washing and Depyrogenating Tunnel

6.0 PRE – QUALIFICATION REQUIREMENTS:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of Sterilizing and De-pyrogenating Tunnel.
- SOP for Preventive Maintenance Sterilizing and De-pyrogenating Tunnel.



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**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

7.0 TESTS AND CHECKS:

7.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	Executed and approved Design Qualification document				
2.	Executed and approved Installation Qualification document				
3.	Executed and approved Operational Qualification document				
4.	PQ Protocol approved				
5.	SOP for Operation & Cleaning of Sterilizing and De-pyrogenating Tunnel				
6.	SOP for Preventive Maintenance Sterilizing and De-pyrogenating Tunnel				

**Checked By
(Production)**

Sign/Date:

Verified By

(Quality Assurance)

Sign/Date:

Inference:

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**Reviewed By
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Sign/Date:



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FOR
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PROTOCOL No.:

7.2 Air velocity measurement:

Date of Test	
Name of Instrument Used for Testing	Digital Anemometer
Calibrated on	
Calibration due on	

HEPA Filter No.	Location	Velocity [FPM]					Average Velocity [FPM]	Done By Sign & Date
		V1	V2	V3	V4	V5		
1.	Drying Zone							
2.	Sterilizing Zone							
3.	Cooling & Stabilizing Zone							

Acceptance Criteria

The Average measured clean air velocity at downstream of filter face.

- **Drying Zone:** 120 ft. / min. \pm 20% (96 to 144 ft. / min.)
- **Sterilizing Zone:** 150 ft. / min. \pm 20% (120 to 180 ft. / min.)
- **Cooling & Stabilizing Zone:** 120 ft. / min. \pm 20% (96 to 144 ft. / min.)

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FOR
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PROTOCOL No.:

7.3 Filter Integrity Test (PAO Test) Of HEPA Filter:

Date of Test	
Name of Instrument	Aerosol Photometer
Calibrated on	
Calibration due on	

S.No.	HEPA Filter Location	Filter Size	Observed Downstream Concentration	Done By Sign & Date
1.	Drying Zone	610×460×50		
2.	Sterilization Zone	610×460×150		
3.	Sterilization Zone	610×460×150		
4.	Cooling Zone	610×460×50		
5.	Cooling Zone	610×460×50		

Acceptance Criteria:

The PAO Penetration Leak Through HEPA Filters Should Not Be Greater Than 0.03% of The Upstream PAO Concentration

**Checked By
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Sign/Date:

**Verified By
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Sign/Date:



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FOR
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PROTOCOL No.:

7.4 Non – viable particle count test:

Date of Test	
Name of Instrument used for Testing	
Calibrated on	
Calibration due on	

HEPA Filter No.	HEPA Filter Location	Location	Particle Size	Particle Count Location			Average	Done By Sign & Date
				Cycle 1	Cycle 2	Cycle 3		
1.	Drying Zone	L1	≥0.5 μ					
			≥5.0 μ					
2.	Sterilizing Zone	L2	≥0.5 μ					
			≥5.0 μ					
		L3	≥0.5 μ					
			≥5.0 μ					
3.	Cooling & Stabilizing Zone	L4	≥0.5 μ					
			≥5.0 μ					
		L5	≥0.5 μ					
			≥5.0 μ					

**Checked By
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Sign/Date:

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(Quality Assurance)**
Sign/Date:

Inference:

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FOR
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PROTOCOL No.:

Name of Area	Recovery Time of Each Location (Acceptance Criteria: NMT 20 Minutes)		
	Location No.	Area Recovery Time	Area Uncontrolled Time
Vial Washing & Sterilization	First Floor, I-Block		
Average Recovery Time			

**Checked By
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PROTOCOL No.:

7.6 Differential Pressure Record:

Magnehelic Gauge ID. No.	
Date of Calibration	
Calibration due date	
Acceptance Criteria	

Date	Differential Pressure	Observation					
		Morning		Afternoon		Evening	
		Time	Pressure (Pa)	Time	Pressure (Pa)	Time	Pressure (Pa)

**Checked By
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Sign/Date:**

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(Quality Assurance)
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FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

Pre- Calibration of Sensor at 350°C

Acceptance criteria:

Temperature should not be fluctuating more than $\pm 1^\circ\text{C}$ from the mean of temperatures shown by the calibrated thermometer during the data-logging period.

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(Production)**

Sign/Date:

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Sign/Date:

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**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

Post Calibration of Sensor at 350°C

Date	Time	CH-1	CH-2	CH-3	CH-4	CH-5	CH-6	CH-7	CH-8	CH-9	CH-10	CH-11	CH-12

Acceptance criteria:

Temperature should not be fluctuating more than $\pm 1^\circ\text{C}$ from the mean of temperatures shown by the calibrated thermometer during the data-logging period.

**Checked By
(Production)**

Sign/Date:

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Sign/Date:

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**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

7.9 Heat Distribution Study For Empty Chamber:

Test Instrument Name	
Sensors type & Qty.	
Model No	
Make	
Calibration done Date	
Calibration due Date	

Empty Heat Distribution Cycle Parameter:

Parameters	Set Value	Observed Value		
		1 st Cycle	2 nd Cycle	3 rd Cycle
Cycle Start Date / Time				
Relative Humidity of Area				
No. of In - built Temp. Sensors	05			
No. of external placed Temp. Sensors	12			
Set Point 1 (Heater Bank 1 cut off)	330 ⁰ C			
Set Point 2 (Heater Bank 1 cut off)	332 ⁰ C			
Set Point 3 (Heater Bank 1 cut off)	334 ⁰ C			
Set Point 4 (Heater Bank 1 cut off)	336 ⁰ C			
Set Point 5 (Heater Bank 1 cut off)	338 ⁰ C			
Set Point 6 (Heater Bank 1 cut off)	345 ⁰ C			
Conveyor Start Temp.	310 ⁰ C			
Conveyor Stop Temp.	305 ⁰ C			
Conveyor Belt Speed	140 mm/min			



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**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

Parameters	Set Value	Observed Value		
		1 st Cycle	2 nd Cycle	3 rd Cycle
Pressure differentials (Drying Zone)	05-15 mm wc			
Pressure differentials (Sterilization Zone)	17-25 mm wc			
Pressure differentials (Cooling Zone)	05-15 mm wc			
Minimum Avg. Temperature (Sensor No.& its Location)				
Maximum Avg. Temperature(Sensor No.& its Location)				
Total Cycle Time				
Sterilization Zone Exposure Time				
Result				
Cold Spot (external placed Temp. Sensors)				
Cycle End Date / Time				

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Sign/Date:**

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(Quality Assurance)
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**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

7.10 Heat Distribution Study For Loaded Chamber:

Test Instrument Name	
Sensors type & Qty.	
Model No	
Make	
Calibration done Date	
Calibration due Date	
Vial Size	

Loaded heat distribution cycle parameter:

Parameters	Set Value	Observed Value		
		1 st Cycle	2 nd Cycle	3 rd Cycle
Cycle Start Date / Time				
Relative Humidity of Area				
No. of external placed Temp. Sensors	12			
No. of In - built Temp. Sensors	05			
Set Point 1 (Heater Bank 1 cut off)	330 ⁰ C			
Set Point 2 (Heater Bank 1 cut off)	332 ⁰ C			
Set Point 3 (Heater Bank 1 cut off)	334 ⁰ C			
Set Point 4 (Heater Bank 1 cut off)	336 ⁰ C			
Set Point 5 (Heater Bank 1 cut off)	338 ⁰ C			
Set Point 6 (Heater Bank 1 cut off)	345 ⁰ C			
Conveyor Start Temp.	310 ⁰ C			
Conveyor Stop Temp.	305 ⁰ C			



PHARMA DEVILS

**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

Parameters	Set Value	Observed Value		
		1 st Cycle	2 nd Cycle	3 rd Cycle
Conveyor Belt Speed	120 mm / minute			
Pressure differentials (Drying Zone)	05-15 mm wc			
Pressure differentials (Sterilization Zone)	17-25 mm wc			
Pressure differentials (Cooling Zone)	05-15 mm wc			
Minimum Avg. Temperature (Sensor No.& its Location)				
Maximum Avg. Temperature(Sensor No.& its Location)				
Total Cycle Time				
Sterilization Zone Exposure Time				
Result				
Cold Spot (external placed Temp. Sensors)				
Cycle End Date / Time				

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(Quality Assurance)**

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**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

7.11 Heat distribution study for loaded chamber:

Test Instrument Name	
Sensors type & Qty.	
Model No	
Make	
Calibration done Date	
Calibration due Date	
Vial Size	10 ml.

Loaded heat distribution cycle parameter:

Parameters	Set Value	Observed Value		
		1 st Cycle	2 nd Cycle	3 rd Cycle
Cycle Start Date / Time				
Relative Humidity of Area				
No. of external placed Temp. Sensors	12			
No. of In - built Temp. Sensors	05			
Set Point 1 (Heater Bank 1 cut off)	330 ⁰ C			
Set Point 2 (Heater Bank 1 cut off)	332 ⁰ C			
Set Point 3 (Heater Bank 1 cut off)	334 ⁰ C			
Set Point 4 (Heater Bank 1 cut off)	336 ⁰ C			
Set Point 5 (Heater Bank 1 cut off)	338 ⁰ C			
Set Point 6 (Heater Bank 1 cut off)	345 ⁰ C			
Conveyor Start Temp.	310 ⁰ C			
Conveyor Stop Temp.	305 ⁰ C			
Conveyor Belt Speed	120 mm / minute			
Pressure differentials (Drying Zone)	05-15 mm wc			
Pressure differentials (Sterilization)	17-25 mm			



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**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

Parameters	Set Value	Observed Value		
		1 st Cycle	2 nd Cycle	3 rd Cycle
Zone)	wc			
Pressure differentials (Cooling Zone)	05-15 mm wc			
Minimum Avg. Temperature (Sensor No.& its Location)				
Maximum Avg. Temperature(Sensor No.& its Location)				
Total Cycle Time				
Sterilization Zone Exposure Time				
Result				
Cold Spot (external placed Temp. Sensors)				
Cycle End Date / Time				

**Checked By
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Sign/Date:

Verified By

(Quality Assurance)

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(Manager QA)

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**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

7.12 HEAT DISTRIBUTION STUDY FOR LOADED CHAMBER:

Test Instrument Name	
Sensors type & Qty.	
Model No	
Make	
Calibration done Date	
Calibration due Date	
Vial Size	20 ml

Loaded Heat Distribution Cycle Parameter:

Parameters	Set Value	Observed Value		
		1 st Cycle	2 nd Cycle	3 rd Cycle
Cycle Start Date / Time				
Relative Humidity of Area				
No. of external placed Temp. Sensors	12			
No. of In - built Temp. Sensors	05			
Set Point 1 (Heater Bank 1 cut off)	330 ⁰ C			
Set Point 2 (Heater Bank 1 cut off)	332 ⁰ C			
Set Point 3 (Heater Bank 1 cut off)	334 ⁰ C			
Set Point 4 (Heater Bank 1 cut off)	336 ⁰ C			
Set Point 5 (Heater Bank 1 cut off)	338 ⁰ C			
Set Point 6 (Heater Bank 1 cut off)	345 ⁰ C			
Conveyor Start Temp.	310 ⁰ C			



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**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

Parameters	Set Value	Observed Value		
		1 st Cycle	2 nd Cycle	3 rd Cycle
Conveyor Stop Temp.	305 ⁰ C			
Conveyor Belt Speed	110 mm / min			
Pressure differentials (Drying Zone)	05-15 mm wc			
Pressure differentials (Sterilization Zone)	17-25 mm wc			
Pressure differentials (Cooling Zone)	05-15 mm wc			
Minimum Avg. Temperature (Sensor No.& its Location)				
Maximum Avg. Temperature(Sensor No.& its Location)				
Total Cycle Time				
Sterilization Zone Exposure Time				
Result				
Cold Spot (external placed Temp. Sensors)				
Cycle End Date / Time				

**Checked By
(Production)
Sign/Date:**

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(Quality Assurance)
Sign/Date:**

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FOR
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PROTOCOL No.:

7.13 Heat penetration study for loaded chamber:

Test Instrument Name	
Sensors type & Qty.	
Model No	
Make	
Calibration done Date	
Calibration due Date	
Vial Size	5 ml.

LOADED HEAT PENETRATION CYCLE PARAMETER:

Parameters	Set Value	Observed Value		
		1 st Cycle	2 nd Cycle	3 rd Cycle
Cycle Start Date / Time				
Relative Humidity of Area				
No. of external placed Temp. Sensors	12			
No. of In - built Temp. Sensors	05			
Set Point 1 (Heater Bank 1 cut off)	330 ⁰ C			
Set Point 2 (Heater Bank 1 cut off)	332 ⁰ C			
Set Point 3 (Heater Bank 1 cut off)	334 ⁰ C			
Set Point 4 (Heater Bank 1 cut off)	336 ⁰ C			
Set Point 5 (Heater Bank 1 cut off)	338 ⁰ C			
Set Point 6 (Heater Bank 1 cut off)	345 ⁰ C			
Conveyor Start Temp.	310 ⁰ C			
Conveyor Stop Temp.	305 ⁰ C			
Conveyor Belt Speed	120 mm / min			



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**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

Parameters	Set Value	Observed Value		
		1 st Cycle	2 nd Cycle	3 rd Cycle
Pressure differentials (Drying Zone)	05-15 mm wc			
Pressure differentials (Sterilization Zone)	17-25 mm wc			
Pressure differentials (Cooling Zone)	05-15 mm wc			
Minimum Avg. Temperature (Sensor No.& its Location)				
Maximum Avg. Temperature(Sensor No.& its Location)				
Total Cycle Time				
Sterilization Zone Exposure Time				
Result				
Cold Spot (external placed Temp. Sensors)				
Cycle End Date / Time				

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(Quality Assurance)
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Sign/Date:**



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**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

7.14 F_H Calculation & Endotoxin Test Report:

Probe No.	De-pyrogenating Temperature		Duration of Depyrogenating Temp. (300°C & Above)		F _H Value	Reduction of Endotoxin	Remarks
	Max	Min	From	To			

Acceptance Criteria:

Reduction of Endotoxin NLT 3 log

**Checked By
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Sign/Date:

**Verified By
(Quality Assurance)**

Sign/Date:

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**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

7.15 HEAT PENETRATION STUDY FOR LOADED CHAMBER:

Test Instrument Name	
Sensors type & Qty.	
Model No	
Make	
Calibration done Date	
Calibration due Date	
Vial Size	10 ml.

Loaded heat penetration cycle parameter:

Parameters	Set Value	Observed Value		
		1 st Cycle	2 nd Cycle	3 rd Cycle
Cycle Start Date / Time				
Relative Humidity of Area				
No. of external placed Temp. Sensors	12			
No. of In - built Temp. Sensors	05			
Set Point 1 (Heater Bank 1 cut off)	330 ⁰ C			
Set Point 2 (Heater Bank 1 cut off)	332 ⁰ C			
Set Point 3 (Heater Bank 1 cut off)	334 ⁰ C			
Set Point 4 (Heater Bank 1 cut off)	336 ⁰ C			
Set Point 5 (Heater Bank 1 cut off)	338 ⁰ C			
Set Point 6 (Heater Bank 1 cut off)	345 ⁰ C			
Conveyor Start Temp.	310 ⁰ C			
Conveyor Stop Temp.	305 ⁰ C			
Conveyor Belt Speed	120 mm / min			
Pressure differentials (Drying Zone)	05-15 mm wc			
Pressure differentials (Sterilization Zone)	17-25 mm wc			
Pressure differentials (Cooling Zone)	05-15 mm wc			



PHARMA DEVILS

**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

Parameters	Set Value	Observed Value		
		1 st Cycle	2 nd Cycle	3 rd Cycle
Minimum Avg. Temperature (Sensor No.& its Location)				
Maximum Avg. Temperature(Sensor No.& its Location)				
Total Cycle Time				
Sterilization Zone Exposure Time				
Result				
Cold Spot (external placed Temp. Sensors)				
Cycle End Date / Time				

**Checked By
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Sign/Date:**

**Verified By
(Quality Assurance)
Sign/Date:**

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**PERFORMANCE QUALIFICATION REPORT
FOR
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PROTOCOL No.:

7.17 HEAT PENETRATION STUDY FOR LOADED CHAMBER:

Test Instrument Name	
Sensors type & Qty.	
Model No	
Make	
Calibration done Date	
Calibration due Date	
Vial Size	20 ml.

LOADED HEAT PENETRATION CYCLE PARAMETER:

Parameters	Set Value	Observed Value		
		1 st Cycle	2 nd Cycle	3 rd Cycle
Cycle Start Date / Time				
Relative Humidity of Area				
No. of external placed Temp. Sensors	12			
No. of In - built Temp. Sensors	05			
Set Point 1 (Heater Bank 1 cut off)	330 ⁰ C			
Set Point 2 (Heater Bank 1 cut off)	332 ⁰ C			
Set Point 3 (Heater Bank 1 cut off)	334 ⁰ C			
Set Point 4 (Heater Bank 1 cut off)	336 ⁰ C			
Set Point 5 (Heater Bank 1 cut off)	338 ⁰ C			
Set Point 6 (Heater Bank 1 cut off)	345 ⁰ C			
Conveyor Start Temp.	310 ⁰ C			
Conveyor Stop Temp.	305 ⁰ C			
Conveyor Belt Speed	120 mm / min			
Pressure differentials (Drying Zone)	05-15 mm wc			
Pressure differentials (Sterilization Zone)	17-25 mm wc			
Pressure differentials (Cooling Zone)	05-15 mm wc			
Minimum Avg. Temperature (Sensor No.& its Location)				



PHARMA DEVILS

**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

Parameters	Set Value	Observed Value		
		1 st Cycle	2 nd Cycle	3 rd Cycle
Maximum Avg. Temperature(Sensor No.& its Location)				
Total Cycle Time				
Sterilization Zone Exposure Time				
Result				
Cold Spot (external placed Temp. Sensors)				
Cycle End Date / Time				

**Checked By
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Sign/Date:

Verified By

(Quality Assurance)

Sign/Date:

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Reviewed By

(Manager QA)

Sign/Date:



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**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

7.18 F_H Calculation & Endotoxin Test Report:

Probe No.	De-pyrogenating Temperature		Duration of De-pyrogenating Temp. (300°C & Above)		F _H Value	Reduction of Endotoxin	Remarks
	Max	Min	From	To			

Acceptance Criteria:
Reduction of Endotoxin NLT 3 log

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:
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Reviewed By
(Manager QA)
Sign/Date:



PHARMA DEVILS

**PERFORMANCE QUALIFICATION REPORT
FOR
STERILIZING & DEPYROGENATING TUNNEL**

PROTOCOL No.:

8.0 DOCUMENTS TO BE ATTACHED:

- Calibration Certificates for Anemometer.
- Calibration Certificates for Airborne particle counter.
- Calibration Certificates for Aerosol Photometer.
- Calibration Certificate of Data logger.
- Calibration Certificate of Sensors.
- Certificate of Analysis for LAL.

9.0 NON COMPLIANCE:

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10.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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11.0 CHANGE CONTROL, IF ANY:

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PHARMA DEVILS

**PERFORMANCE QUALIFICATION REPORT
FOR
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PROTOCOL No.:

15.0 ABBREVIATIONS:

No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure
mm	:	Millimeter
Amp.	:	Ampere
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
FBD	:	Sterilizing & Depyrogenating Tunnel
SOP	:	Standard Operating Procedure
BMR	:	Batch Manufacturing Record



PHARMA DEVILS

**PERFORMANCE QUALIFICATION REPORT
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PROTOCOL No.:

16.0 REPORT POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			