PERFORMANCE QUALIFICATION PROTOCOL FOR STERILIZING & DEPYROGENATING TUNNEL

EQUIPMENT ID. No.	
LOCATION	**Ampoule Washing and De-Pyrogenation Tunnel**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR STERILIZING & DEPYROGENATING TUNNEL	PROTOCOL No.:

PROTOCOL CONTENTS

S.No.	Title	Page No.
1.0	Protocol 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	Reason for Qualification	8
8.0	Site of Study	8
9.0	Frequency of Qualification	8
10.0	Pre Qualification Requirements	8
11.0	Tests & Checks	9
12.0	Checklist of all Tests & Checks	21
13.0	References	22
14.0	Documents to be Attached	22
15.0	Non Compliance	22
16.0	Deviation From Pre–Defined Specification, If Any	22
17.0	Change Control, If Any	22
18.0	Abbreviations	23

 PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR STERILIZING & DEPYROGENATING TUNNEL	PROTOCOL No.:

1.0 PROTOCOL APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

The objective of this protocol 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 Protocol covers all aspects of Performance Qualification for the Sterilizing and Depyrogenating Tunnel **(Make – Truking Technologies Ltd.)** installed in the Ampoule Washing & Depyrogenating tunnel of …….
- This Protocol will define the methods and documentation used to qualify the Sterilizing and Depyrogenating tunnel for PQ.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation, Approval Compilation of the Performance Qualification. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Analytical Support (Microbiological Testing / Analysis)
External Qualification Agency (if Applicable)	• Performance of qualification activity as per protocol
Engineering	• Reviewing of qualification protocol for correctness, completeness and technical excellence • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

5.0 EQUIPMENT DETAILS:

Equipment Name	Sterilizing and De-pyrogenating Tunnel
Equipment ID.	……
Manufacturer's Name	Truking Technologies Ltd.
Supplier's Name	Truking Technologies Ltd.
Model	…….
Location of Installation	Ampoule Washing and Depyrogenating Tunnel

6.0 SYSTEM DESCRIPTION:

The Unit:

- The **Truking** Sterilization & De-Pyrogenating Tunnel is used for sterilization and De-Pyrogenation of Glass Ampoules of various Sizes, enabling the integration of the process of Liquid Injection Automatic Filling under Aseptic Conditions in which all activities are performed under grade A or class 100 area.
- The Ampoules are washed and reloaded on the tunnel, with the help of wire loop conveyor, enter in to the Preheating zone where Ampoules get dried up and passes to sterilizing zone where Ampoules are heated to more than 300°C for not less than 3 minutes or equivalent time to make it depyrogenation.
- The height of receptacles must not exceed 100 mm. The useful belt width for carrying the Ampoules is 600 mm. The air damper plate is adjusted for Ampoules.
- The Sterile receptacles are then unloaded directly into the sterile area. This process eliminates intermediate Material Handling and the potential for product contamination during those steps no longer exist.

➢ **PREHEATING ZONE:**

- In the feed area, the air taken from the room is pre filtered and aspirated by a blower through HEPA filter. The Laminar flow of air is sent vertically down on to the containers.
- As the containers reach near the sterilizing zone, they are preheated up to 80°C by the Hot Air Bleeding out of the Sterilizing Zone. This air along with water vapour is picked up underneath of the conveyor belt by the extract blower and ejected to outside.
- The Conveyor system is controlled by the container accumulation at in-feed and the set temperature point for "Conveyor Start".

➢ **HEATING ZONE:**

- The dried containers are moved over to the sterilizing zone. The Sterilizing Zone mainly comprises of resistance heating elements, HEPA Filter and Temperature Sensing Devices. Hot filtered air at more than 300°C is re-circulated in this zone which sweeps the containers from top to bottom. The equal pressure drop across the filters enables in creating an extremely even distribution of air circulation. This uniformity distributed hot air sterilizes and de-pyrogenates the containers by heating the containers at more than 300°C for more than 03 minutes.
- Due to the over pressure in the sterilizing zone (normal air quantity passing into the area through heater terminals and Hot air turbine shaft) small amount of air flows to the Preheating & cooling zones thus allowing adequate exchange of air.

➢ **COOLING ZONES:**

- In this area (arrangement are similar to that of Preheating Zone) the containers are subjected to laminar flow of HEPA filtered air taken from the room. The air flow is profiled in such a way that the Glass Ampoule Temperature as the Ampoule exit the sterilizing zone would be transitioned at a nearly linear rate. This zone is long enough to significantly reduce the temperature range between the 300°C – 25°C resulting in reduced breakages.
- The exhaust blower below the conveyor belt extracts heated air and ejects outside.
- Stabilizing zone is similar to the Preheating zone and is used as a transition area separating the critical area between filling and washing area. This is achieved by controlling the air volume exhausted by adjusting the damper provided.
- At the tunnel out feed, the glass container/Ampoules are bulk-feed into the in feed turn table of the downstream machine. Proximity switches provided on in feed and out feed control conveyer movement with reference to container accumulation and loading.

USE:

1. To Sterilize and De-pyrogenating Various Sized Glass Ampoules which shall be transferred to the Aseptic Area for Aseptic Filling of the Drug Product.

7.0 REASON FOR QUALIFICATION:

Qualification will be performing in case of:

- New facility.
- Periodically.

- Change in Location
- Replacement of major component.
- Major modification in the existing

8.0 SITE OF STUDY:

Ampoule Washing & Depyrogenating.

9.0 FREQUENCY OF QUALIFICATION:

- Once in year ± 30 Days.
- After any major breakdown or after major modification.
- After Change of Location.

10.0 PRE – QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Calibration of all critical instruments which are used for verifying the performance such as Anemometer, Photometer, Particle Counter & Duly Calibrated Data Logger with temperature sensors.
- Preparation of SOP for Operation & Cleaning of Sterilizing & De-Pyrogenation Tunnel.
- Preparation of SOP for Preventive Maintenance Sterilizing & De-Pyrogenation Tunnel.
- Verify all the persons involved in the execution of Qualification trained in all aspects of the qualification activity.

- **Pre & Post Calibration of Temperature Sensors:**
  - Pre & Post calibration shall be carried out before starting and after completion of qualification activity.
  - Pre & Post calibration shall be done by External party.

11.0 TESTS AND CHECKS:

11.1 AIR VELOCITY MEASUREMENT:

- **Objective:**

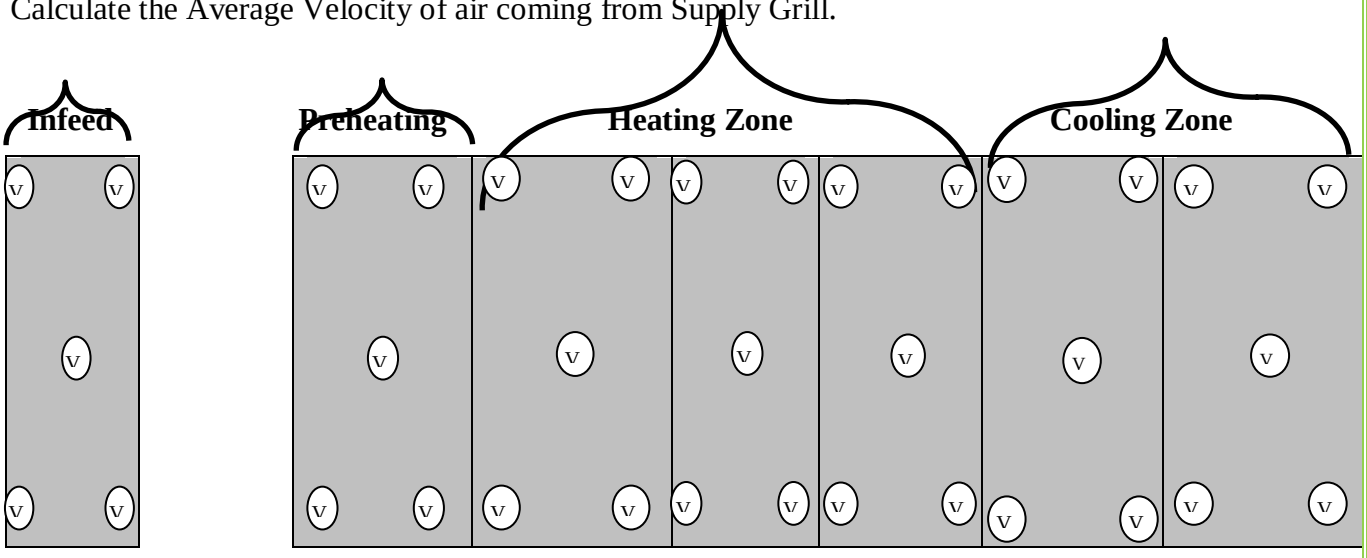
  To demonstrate that the system is capable of delivering Air Velocities as per the requirement and to maintain continuous Linearity under the HEPA filter.

- **Equipment/Instrument Used:**

  Digital Anemometer

- **Method Applied:**

  Ensure that the Sterilization & Depyrogenating Tunnel blower is switch **"ON"** at least 30 minutes prior to the start of the observations. Measure the Air Velocity 6 inches below the grill, at 5 locations of each filters (Four Corners and Center shown in fig.) with the Digital Anemometer and record. Calculate the Average Velocity of air coming from Supply Grill.



Sampling Locations

- **Acceptance Criteria:**
  - Average velocity across the HEPA filter should be within the range as per design.

S.No.	Zone	Average Velocity
1.	Infeed Zone, Preheating Zone & Cooling Zone	90-110 feet/min.
2.	Hot Zone	120-150 feet/min.

- **Result Recording:**

  Measure the Air Velocity at Five Locations (Four Corners and Center) of each HEPA Filters & calculate the Average Velocity of Filter and record the results in the Performance Qualification Report.

- **Evaluation of Result:**

  If velocity is not within the specified limit, check the Motor Blower Assembly and Differential Pressure across the each HEPA Filters for any Abnormal Condition. If the Minimum Velocity is not achievable, Filters should be changed, irrespective to other test complying with the acceptance criteria.

11.2 FILTER INTEGRITY TEST FOR HEPA :

- **Objective:**

  To check the Integrity of the each HEPA Filters installed in the Sterilization & Depyrogenating tunnel.

- **Equipment/Instruments Used:**
  - Calibrated Aerosol Generator
  - Calibrated Aerosol Photometer.

- **Method Applied:**
  - Before starting the test start the Depyrogenating Tunnel before one hour.
  - Check PAO solution level aerosol photometer tank.
  - Connect the compressed air to aerosol photometer.
  - Orient the supply tube of aerosol toward the riser and orient the PU (for downstream concentration) tube on opening of supply aerosol tube–than check the upstream concentration 100 % above the HEPA through port.
  - Keep the aerosol supply tube near the riser grill.
  - Scan the supply grill (HEPA grill) for checking filter integrity test, Adjust the concentration of aerosol above HEPA 100 %.

- **Acceptance Criteria:**

  During Scanning, leakage penetration should not be more than 0.01%.

- **Result Recording:**

  Record the results in the Performance Qualification Report.

- **Evaluation of Result:**

  Results, complying with the Acceptance Criteria, shall establish the Integrity of each HEPA Filters suitable for clean area. If any leakage is observed from side of HEPA filter, it has to be rectified through adjustment and application of Food Grade Silicon Sealant.

11.3 NON - VIABLE PARTICLE COUNT TEST:

- **Objective:**

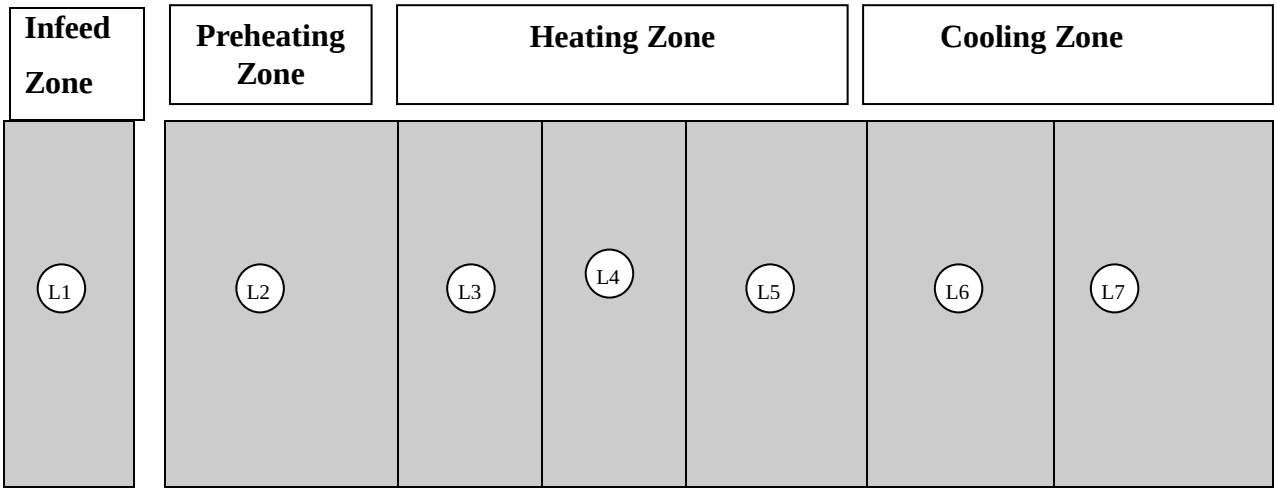
  To establish that critical locations of Sterilization & Depyrogenating Tunnel meet the requirement for desired cleanliness.

- **Equipment / Instrument Used:**

  Non- Viable Particle Counter

- **Method Applied:**
  - Start the Sterilizing and Depyrogenating tunnel as per respective SOP.
  - Ensure that the blower of the Sterilization & Depyrogenating Tunnel is running and Heater is not in "ON" condition.
  - Place the Probe of Non – Viable particle counter at the locations described below observes the readings.

S.No	Zone Name	No. of Location For Non – Viable Particle Count
1.	Infeed Zone	01 Nos.
2.	Preheating Zone	01 Nos.
3.	Heating Zone	03 Nos.
4	Cooling Zone	02 Nos.



Sampling Locations

- **Acceptance Criteria:**

Grade	Maximum number of permitted particles per cubic meter equal to or above.	
	≥ 0.5 µm Particle	≥ 5 µm Particle
A	3520	20

- **Result Recording:**
  Measure the Non – Viable Particle Count at mentioned Locations & record the results in the Performance Qualification Report.

- **Evaluation of Result:**
  In case the particulate count does not meet the requirement, investigation shall be carried out and proper action shall be taken. Non – Viable Particle Count shall be taken again after rectification.

11.4 CONVEYOR SPEED VERIFICATION:

- **Objective:**

  The objective of this test is to show that the conveyor speed of Sterilizing & Depyrogenation Tunnel is within designed values.

- **Equipment Required:**

  - Stop watch
  - Measuring Scale

- **Procedure :**

  Mark the conveyor belt with permanent marker where half of the mark is on the conveyor belt and rest half on the support guard of the conveyor belt. Set the conveyor speed on the PLC as per validated speed and start the conveyor. Simultaneously start the stopwatch. Allow the conveyor to run exactly 1 min. then stop the conveyor. Measure the distance traveled using a calibrated measuring scale.

  - Following formulas shall be used for Calculation of Conveyor Belt Speed & Sterilization:

$$\textbf{Belt Speed in mm} = \frac{(\text{Ampoule Diameter})^2 \text{ X cos } 30 \text{ X Washing M/C Out put}}{\text{Tunnel Conveyor Width}}$$

$$\textbf{Conveyor Belt Speed} = \frac{\text{Travel Distance}}{\text{Time}}$$

- **Acceptance Criteria:**

  The conveyor speed in PLC of sterilizing & Depyrogenation Tunnel and the observed reading should not vary $\pm$ 2%.

- **Observations And Results**

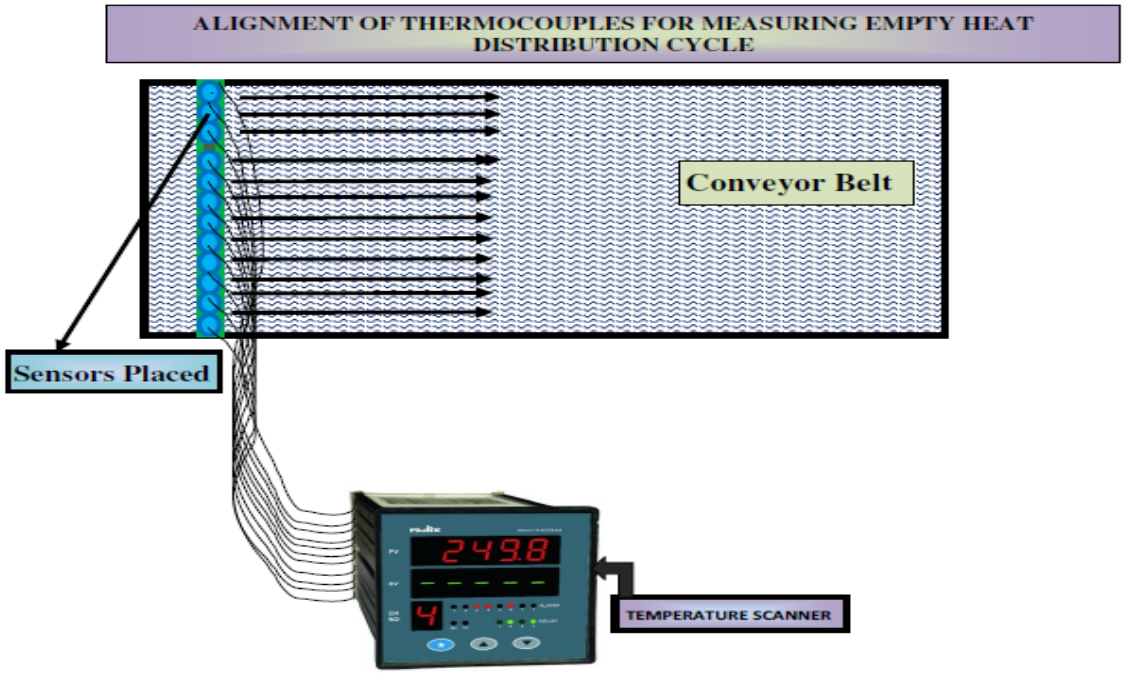
. Record the temperature at various locations in Performance Qualification Report.

11.5 HEAT DISTRIBUTION STUDY FOR EMPTY CHAMBER

- **Objective :**
  - To ensure that the Sterilization & Depyrogenating Tunnel when operated with Empty Chamber is capable of producing the Temperature Profiles as per the temperature set points set in the PLC of the equipment.
  - To ensure that the Temperature Distribution is uniform throughout the Sterilization & Depyrogenating Period.
  - Consecutively three cycles shall be performed to qualify the measurement of the Temperature throughout the Chamber by 12 Temperature Sensors during the Sterilization and Depyrogenating Cycle.

- **Equipment Required:**
  - Calibrated Data Logger with 12 Probes.

Figure-01 Thermocouples Placed Location Diagram for Empty Heat Distribution



- **Procedure :**
  - Heat distribution studies are to be performed in order to determine temperature variation throughout the depyrogenating tunnel especially in the depyrogenation zone in running condition of the conveyor. Simultaneously start the data loggers to scan and record the temperature output from the 12 Thermocouple.
  - Allow to pass all the 12 thermocouples throughout the length of the sterilizing tunnel, into the cooling zone. Record the data throughout the cycle.
  - Set the 12 calibrated thermocouple inside the Preheating zone of the sterilizing tunnel (as per defined location in Figure-01).
  - Thermocouple should not touch the internal walls of the sterilizing zone.
  - Set the parameter of the Thermocouple in the data-logger. Also set the other parameter of the data loggers like
    - Scanning and recording interval time : 30 second
    - Probe numbering : Probe 1 to Probe 12
    - Date : As applicable
    - Data / cycle No. : As applicable
  - Operate the sterilizing tunnel and allow attaining temperature to 320^0C. In the sterilizing zone of the tunnel, keeping the entrance gate of the Preheating zone closed.
  - Start the data loggers to scan and record the temperature output from the 12 Thermocouple.
  - After attainment of the pre-set temperature of the sterilizing tunnel start the tunnel conveyor at a speed of 80 mm/minute and open the entrance gate of the sterilizing.
  - Down load the data recorded from the data loggers to the software and get the hard copy of the data.
  - Run three cycles and record the data.
  - Allow to pass all the thermocouples throughout the length of the sterilizing tunnel, into the cooling zone. Record the data throughout the cycle.

11.6 HEAT DISTRIBUTION STUDY FOR LOADED CHAMBER (1ml, 2 ml, 3 ml, 5 ml)

- **Objective :**
    - To ensure that the Sterilization & Depyrogenating Tunnel when operated with Loaded Chamber of 1ml, 2ml, 3ml, 5ml Ampoule is capable of producing the Temperature Profiles as per the temperature set points set in the PLC of the equipment.
    - To ensure that the Temperature Distribution is uniform throughout the Sterilization & Depyrogenating Period.
    - Consecutively three cycles shall be performed to qualify the tunnel, measurement of the Temperature throughout the tunnel by 12 temperature sensors during the loaded runs of 1ml, 2ml, 3ml, 5ml Ampoules.
    - Suspend the probe in the chamber as zigzag position in such a way that probes don't touch any metallic surface or Ampoule. Record the position of the probe in a representative schematic manner.
    - Connect the probes to suitable data logger, which can scan and print the actual temperature observed at different locations with respect to time.
    - On the basis of three consecutively cycles run, Temperature profiling for specified Ampoule size has been developed in-terms of minimum temperature and maximum temperature location can be identified by the running of heat distribution for loaded.
    - Operate the Sterilizing & Depyrogenating Tunnel as per current version of SOP. Also start the data logger to record the actual temperatures with respect to time.
    - After completion of Sterilization Cycle "Switch OFF" the data logger.
    - Download the data from the data logger in the computer for the data analysis and printing enclosed the printout obtained from the data logger.

Acceptance Criteria

- A Minimum Exposure Time at least 03 minutes should be achieved at Depyrogenating temperature of 300 °C & above.

Observations and Results

. Record the temperature at various locations in Performance Qualification Report.

Evaluation of Result

- Any location(s) where the Temperature Sensor is placed, achieving Minimum Sterilization & Depyrogenating Temperature of above 300°C during Sterilization and Depyrogenating Period shall be considered as Cold Spot.

If Depyrogenating temperature (More Than 300°C) is not achieved throughout the cycle, then Temperature Set Points Adjustment, Modifications or Repair shall be performed and the Heat Distribution Studies shall be repeated.

11.7 HEAT PENETRATION STUDY FOR LOADED CHAMBER :

- **Objective**

- To ensure that, heat is sufficiently penetrating into the innermost portion of the Ampoules subjected for sterilization & Depyrogenating to achieve desired temperature i.e. more than 300°C during the sterilization & Depyrogenating cycle for at least three minutes.
- Loaded chamber Heat Penetration Studies shall be conducted for consecutively three cycles with Temperature Probes for 1ml, 2ml, 3ml, 5ml Ampoules.
- To ensure that, Heat is sufficiently penetrating into the innermost portion of the Ampoule subjected for Sterilization & Depyrogenation to achieve desired Temperature for at least three minutes. i.e. More Than 300°C using Endotoxin Challenge Test.
- Endotoxin Challenge Test shall be conducted for in one of the heat penetration cycle which is going for Validation for each size.
- The recovery of Endotoxin Concentration after exposing to Sterilization & Depyrogenating Tunnel should show at least 3 log reduction.
- Three cycle shall be performed to qualify the measurement of the Temperature throughout the tunnel by 12 Temperature Sensors during the sterilization cycle.

Equipment Required

- Calibrated Data Logger with 12 Probes.

Procedure

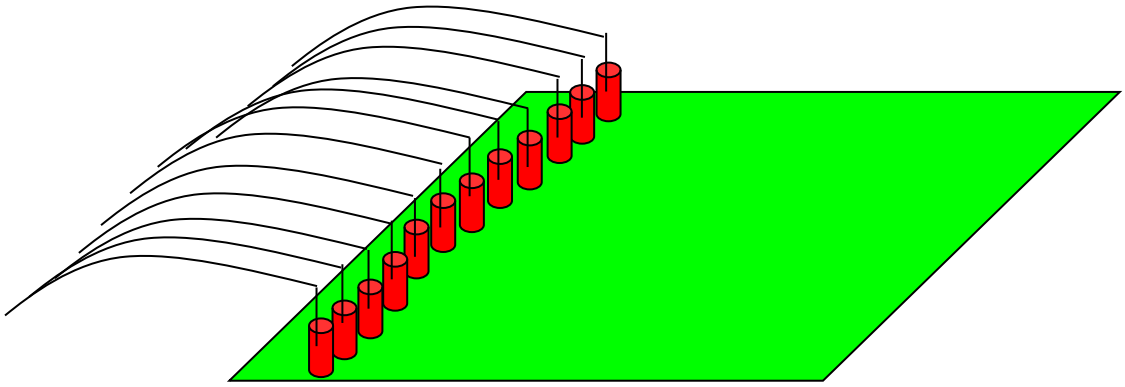
- Conduct the study with loaded chamber for three consecutively cycle with Calibrated Temperature probes of 1ml, 2ml, 3ml, 5ml Ampoule.
- Suspend the minimum 12 Temperature Sensors (including hot & cold locations) inside the Ampoules and put into tunnel for Heat Penetration Study.
- Record the position of the probes in a representative schematic form.
- Insert 12 Endotoxin Ampoules (Marked Ampoules) having 10000 EU each along with the temperature sensors in one cycle of each pack size.
- Connect the probes to suitable data logger, which can scan and print the actual temperature observed at different locations with respect to time.

- Operate the Sterilizing & Depyrogenating Tunnel as per current version SOP.
- Also start the data logger to record the actual temperatures within the Tunnel with respect to time.
- Download the data from the data logger in the computer for the data analysis and printing enclosed the printout obtained from the data logger.
- Seal the exposed Endotoxin Ampoules and wrap the exposed Endotoxin Challenge Ampoules aseptically with sterile Aluminum foil and identify suitably. Send the exposed Endotoxin Challenge Ampoules to microbiology laboratory for testing. Microbiologist shall analyze the exposed Endotoxin Challenge Ampoules and recovery of Endotoxin.
- Calculate the F_H Value as per following formula :-

  $F_H = \Delta t \times 10^{(T-250/Z)}$

  Where

  T= Observed Temp. During sterilization, Z= 46.4°C, t = Time Interval



Schematic Diagram of Sterilization and Depyrogenation Tunnel with Probe Location

Preparation Procedure of Endotoxin Indicator placed Ampoules:

- Take 1,00,000 EU/ml Endotoxin indicator Ampoule.
- Reconstitute the Ampoule in 1 ml of LRW, vortex for 1 min every 10 minutes for 30 minutes.
- Transfer 0.1 ml each into 1ml, 2ml, 3ml, 5ml Ampoules as per cycle. The Ampoules must be identical to the Ampoule used in the sterilizing tunnel.
- Dry the Endotoxin indicator placed inside the Ampoule in a LAF hood overnight. Each Ampoule now contains Endotoxin as 10000 EU/ml.
- One Ampoule per De-Pyrogenation cycle shall be retained as a positive control (Do not pass through sterilizing tunnel). Mark this Ampoule as PPC.

- 12 Endotoxin indicator Ampoules shall be marked as NPC-1, 2, 3, 4, 5, 6, 7, 8,9,10,11 & 12 be placed along with "harness" during heat penetration one cycle of each pack size.
- Record the all Report of the Bacterial Endotoxin challenge test studies.
- After the cycle is complete, carefully collect the Endotoxin indicator Ampoules from sterilizing tunnel and bring all of them to the Microbiology lab. Carry out the Endotoxin test on the De-Pyrogenates Ampoules and check the log reduction.

Acceptance Criteria

- Throughout the dwell time, all temperature measured in the zone should be ≥ 300°C.
- The recovery of Endotoxin concentration after exposing in Sterilization and De-Pyrogenation Tunnel should show at least 3 log reduction.
- The Calculated minimum F_H value should be more than 30 minutes.

Observations and Results

- Record the temperature at various locations in Qualification Report**.**

Evaluation of Result

- If Sterilization Temperature is not achieved throughout the cycle, then Temperature Set Points Adjustment, Modifications or Repair shall be performed and the Heat Penetration Studies shall be repeated.

11.8 DIFFERENTIAL PRESSURE ACROSS HEPA FILTER:

- **Objective:**

  To demonstrate that the air system is capable to maintain Pressure Differential between adjacent zone.
- **Equipment and Instrument:**

  Calibrated Magnehelic Gauge.
- **Procedure:**

  Measure and record the Differential Pressure at three times a day.
- **Acceptance Criteria**

S.No.	Zone	Differential Pressure
1.	Preheating Zone and room	05-10 Pascal
2.	Heating Zone and room	06-12 Pascal
3.	Cooling Zone and room	05-10 Pascal
4.	up and down of HEPA filter in preheating zone	100-300 Pascal
5.	up and down of HEPA filter-1 in heating zone	150-350 Pascal
6.	up and down of HEPA filter-2 in heating zone	150-350 Pascal

7.	up and down of HEPA filter-3 in heating zone	150-350 Pascal
8.	up and down of HEPA filter-1 in cooling zone	80-250 Pascal
9.	up and down of HEPA filter-2 in cooling zone	80-250 Pascal
10.	Washing room and filling room	15-30 Pascal

11.9 AIR FLOW PATTERN TEST

- **Objective:**

  The purpose of airflow direction test and visualization is to confirm that the airflow direction and its uniformity confirm to the design specifications.

- **Equipment Used:**

  Video Camera & Aerosol Generator by Glycol base /Fogger/WFI or Distilled water

- **Procedure:**

  Generate the aerosol with the help of Generator in the desired area where air flow direction test is being conduct. Then Supply of aerosol generator pipe should be placed typically away from the HEPA filter face in downward position and start the smoke remotely from the source and simultaneously shoot the video.

- **Acceptance Criteria:**

  Airflow direction should be moving in a downward direction and should not travelling Dying and Cooling Zone to Sterilization zone.

12.0 CHECKLIST OF ALL TESTS & CHECKS

S.No.	Name of Test or Check		Acceptance Criteria
1.	Air Velocity Measurement	Infeed Zone, Preheating Zone & Cooling Zone	90-110 feet/min.
		Hot Zone	120-150 feet/min.
2.	HEPA Filter Integrity Test (PAO Test) Report		HEPA filters should not be greater than 0.01% of the upstream PAO Concentration.
3.	Differential Pressure Record	Preheating Zone and room	05-10 Pascal
		Heating Zone and room	06-12 Pascal
		Cooling Zone and room	05-10 Pascal
		up and down of HEPA filter in preheating zone	100-300 Pascal
		up and down of HEPA filter-1 in heating zone	150-350 Pascal
		up and down of HEPA filter-2 in heating zone	150-350 Pascal
		up and down of HEPA filter-3 in heating zone	150-350 Pascal
		up and down of HEPA filter-1 in cooling zone	80-250 Pascal
		up and down of HEPA filter-2 in cooling zone	80-250 Pascal
		washing room and filling room	15-30 Pascal
4.	Non - Viable Particle Count	≥ 0.5 µ Particle	NMT 3520 particles / M^3 of 0.5µ or above at rest/in operation condition should be observed in Grade- A
		≥ 5.0 µ Particle	NMT 20 particles / M^3 Particles of 5.0µ or above at rest /in operation condition should be observed in Grade-A
5.	conveyor speed verification		NMT ± 2% of PLC set value
6.	Air Flow Pattern		Airflow direction should be moving in a downward direction and should not travelling Dying and Cooling Zone to Sterilization
7.	Heat Distribution Study	Empty	A Minimum Exposure Time of 03 minutes should be achieved at Depyrogenating temperature of 300 °C & above.
		Loaded	
8.	Heat Penetration Study Loaded Chamber		**1.** All temperature measured in the zone should be ≥300°C. **2.** The recovery of Endotoxin concentration after exposing in Sterilization and De-Pyrogenation Tunnel should show at least 3 log reduction. **3.** The Calculated minimum F_H value should be more than 30

S.No.	Name of Test or Check	Acceptance Criteria
		minutes.

13.0 REFERENCES:

The Principle References are as following:

- Master Validation Plan.
- SOP No. for "Operation & Cleaning of Sterilization & Depyrogenating tunnel".
- Health Technical Memorandum 2010, Part-3 Validation and Verification.

14.0 DOCUMENTS TO BE ATTACHED:.

- Raw data.
- Pre & Post calibration report of Data logger with sensor.
- Calibration certificates of test instruments.
- Any other relevant document.

15.0 NON COMPLIANCE:

All the Non-compliances of procedure, specifications, and sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an

  Impact on operation as well as on performance of the machine & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.

- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

18.0 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
mm	:	Millimetre
Amp.	:	Ampere
LRW	:	LAL Reagent Water
PPC	:	Product Positive Control
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
Kg	:	Kilogram
MOC	:	Material of Construction
NLT	:	Not Less Than
HP	:	Horse Power
KW	:	Kilo watt
SS	:	Stainless Steel
ID.	:	Identification
mm	:	Millimeter