INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR STERILIZING & DEPYROGENATING TUNNEL

EQUIPMENT ID. No.	
LOCATION	**Vial Washing and Depyrogenation**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR STERILIZING & DEPYROGENATING TUNNEL	PROTOCOL No.:

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PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM 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 (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Sterilizing and Depyrogenation Tunnel.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to qualification of Sterilizing and Depyrogenation Tunnel to be installed in the Vial Washing and Depyrogenation Tunnel.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Sterilizing and Depyrogenation Tunnel.

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 cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity. • Post Approval of Qualification Protocol after Execution.
Production	• Review & Pre Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of Protocol cum Report. • Co-ordination, Execution and technical support in Sterilizing and De-Pyrogenation Tunnel Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Qualification Protocol cum Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Sterilizing and De-pyrogenating Tunnel
Equipment ID.	
Manufacturer's Name	
Model	cGMP Model
Supplier's Name	
Location of Installation	Vial Washing and Depyrogenation Tunnel

6.0 SYSTEM DESCRIPTION:

The Unit

The Sterilizing and Depyrogenation Tunnel is a complete Automatic control System with the basic unit mounted on stainless steel stand. The Equipment comprises of four zones, drying, sterilizing, cooling and stabilizing zones. The Depyrogenation and sterilization is achieved under class 100 with a positive pressure gradient. The Equipment is designed to achieve complete sterility and a 3 log reduction in Endotoxin content. The Equipment is connected to a PLC, this model is used for sterilizing of free standing vial, the height of receptacles must not exceed 100 nm, and the useful belt width for carrying the vial is 300 nm.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Piping and instrumentation diagram (P & ID).
- Electrical circuits diagram.
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction of components.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.

7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.

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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Grouting and Mounting	Should be properly grouted and mounted.		
Leveling	Should be properly balanced and leveled.		
Edges of parts	Metal parts should be properly grind without any sharp edges.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Vial Washing and De-Pyrogenation Tunnel		
Room Condition	Temp NMT 22±2 ^{o}C		
Illumination	NLT 300 Lux		
Working space around the Equipment	Should be sufficient for easy Operation, Cleaning, and Maintenance.		

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8.2 Technical Specification Checks:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Unit & Electrical Control Panel	AISI 304		
Drying and Cooling Zone System	The Drying and Cooling System shall have 3 Phase Blower.		
Sterilizing Zone Drive System	The Sterilizing Zone Drive System shall have of 3 Phase Motor coupled with blower through belt drive; the speed of the motor is varied using AC variable frequency drive.		
Exhaust Blower	It shall have 3 phase motor directly coupled to impeller of blower. The cooling zone exhaust blowers shall have 3 Phase Motors directly coupled to impellers of blowers.		
Transport Arrangement	The conveyor will carries the vials through three zones of the tunnel, this conveyor shall be driven by an AC induction motor by chain and sprocket drive. The Speed of the conveyor motor is varied using variable frequency drive (VFD).		
Process Oriented Description • Drying Zone • Sterilizing Zone • Cooling Zone	• In this zone, Positive pressure shall be maintained with respect to vial washing area. • In this zone, required temperature for sterilization and depyrogenation shall be maintained throughout the cycle. • In this zone, required temperature for cooling of vials shall be maintained throughout the cycle.		
Drying and Cooling Zone Drive System Specifications			
Blower	Make : Fabtech		

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Critical Variables	Acceptance Criteria		Observation		Observed By (Engineering) Sign/Date
Discharge	2750 m^3/hr				
Capacity	0.75 kw				
Static Pressure	25 mm				
Qty.	01 No.				
Motor	Make : Green Valley				
Capacity	0.375 kW				
RPM	1440				
Qty.	01 No.				
Sterilizing Zone Drive System Specifications					
Blower	Make : Fabtech				
Discharge	3500 m^3/hr				
Impeller MOC	S.S 316				
Qty.	25 mm				
Qty.	01 No.				
Motor	Make : Bharat Bijlee				
Capacity	1.5 kW				
RPM	1415				
Drive	Belt Pulley				
Qty.	01 No.				
Drive	Make : Allen Bradley				
Capacity	1.5 kW				
Type	3-Φ in3- Φ out				
Qty.	1 No.				
Exhaust Blowers	**Vapour Exhaust**	**Cooling Zone Exhaust**			
Blower	Make : Fabtech	Make : Fabtech			
Casing MOC	MS Powder Coated	MS Powder Coated			

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR STERILIZING & DEPYROGENATING TUNNEL	PROTOCOL No.:

Critical Variables	Acceptance Criteria		Observation		Observed By (Engineering) Sign/Date
Qty.	01 No.	02 No.			
Motor	Make : Bharat Bijlee	Make : Bharat Bijlee			
Capacity	0.75 KW	0.75 KW			
RPM	1405	1405			
Transport Arrangement					
Motor	Make : Bharat Bijlee				
Capacity	0.75 KW				
RPM	925				
Mounting Type	Foot				
Gear Box	Make : Greaves				
Type	Foot wid				
Reduction ratio	70:01				
Drive	Make : Allen Bradley				
Capacity	0.375 KW				
Type	1-Φ in3- Φ out				
Qty.	01				
Drive	Make : Allen Bradley				
Drying Zone Specifications					
Dimension of the drying Zone (in mm)	Length	Width	Height		
	710	710	700		
Air Discharged Approx.	670 m^3/ hr				
Material of Construction	SS304				
Sterilization Zone Specifications					
Dimension of the Sterilization Zone (in mm)	Length	Width	Height		
	1490	910	1200		
Air Discharged Approx.	1415 m^3/ hr				

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Critical Variables	Acceptance Criteria			Observation			Observed By (Engineering) Sign/Date
Material of Construction	SS304						
Minimum Endotoxin reduction	3 log						
Maximum Adjustable Temperature	350^0 C						
Temperature Variation in the zone	± 5.0^0 C						
Cooling Zone Specifications							
Dimension of the Cooling Zone (in mm)	Length 1380	Width 710	Height 700				
Air Discharged Approx.	1440 m^3/ hr						
Material of Construction	SS304						
Filters	**Drying Zone**	**Sterilization**	**Cooling**				
Pre-Filter	Make : Fabtech	------	Make : Fabtech				
Particle retention size	5 micron	------	5 micron				
Separation Efficiency	----	------	----				
Dimensions	640 X 435 X 50 mm	------	640 X 435 X 50 mm				
Qty.	02 Nos.	------	04 Nos.				
Type	Flange	------					
HEPA							
Make	Pharmatek	Pharmatek	Pharmatek				
Particle retention size	0.3 micron	0.3 micron	0.3 micron				
Separation Efficiency	99.997 %	99.997 %	99.997 %				
Class	H13	H13	H13				

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Critical Variables	Acceptance Criteria			Observation			Observed By (Engineering) Sign/Date
Dimensions (in mm)	610 X 610 X 100	460 X 610 X 150	610 X 610 X 100				
Maximum Temperature	80^0 C	400^0 C	80^0 C				
Qty.	01 No.	02 Nos.	02 Nos.				
Control and Instrumentation							
Magnehelic Differential Pressure Gauge	Range 0-25 mm WC-02 Nos.						
Accuracy	± 2 % of FS						
Size	4” dial						
RTD Sensor							
Make	Radix Sensor						
Accuracy Class	B						
Module	PT100						
Max. Temperature	100^0 C						
Qty.	Drying Zone-01 No. & Cooling Zone – 02 Nos.						
Sterilizing Zone							
Make	Radix Sensors						
Accuracy Class	B						
Module	PT100						
Maximum Temperature	400^0 C						
Qty.	02 Nos.						
Thermostat							
Make	Jumo						
Range	0-400^0 C						
Programmable Logic Controller (PLC)							
Make	Allen Bradley						
Model	Micrologix 1200						

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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Human Machine Interface (HMI)			
Make	Allen Bradley		
Model	Touch Screen 550		
Qty.	01 No.		

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8.3 MOC Verification List:

S.No.	Component	Specification	Observation	Observed by (Engineering) Sign/Date
1.	Conveyor Belt	SS 304		
2.	Exhaust Blower	MS Powder Coated		
3.	Sterilizing Zone Blower	SS 316		
4.	Drying Zone	SS 304		
5.	Sterilizing Zone	SS 304		
6.	Cooling Zone	SS 304		
7.	Machine Drive	SS 304		
8.	Electrical Panel	SS 304		
9.	Stabilizing Zone	SS 304		

Note: MOC verification for Stainless steel material is done by the using of Molybdenum Test kit.

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8.4 Utility Verification List:

Parameters	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Electrical Supply	Power for Electric Drive: Power: 2.0 HP Voltage: 415 V, 3 Phase ,50 Hz		
Room Condition	Temperature should be 22 ± 2^0 C and RH should be NMT: 55 % required.		

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8.5 Safety:

Checks	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Joints	Welding of joints without any welding burrs.		
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.		
Leveling and Balancing	Equipment should be Properly balanced & leveled.		
Temperature Control	Air Temperature should be maintained within set limit, if goes out above limit, the heater supply will cut off.		
Intake and Exhaust Blower	Both blowers shall not be switched off unless the temperature in the sterilizing chamber falls below set value.		
Password Protection of Operation	Authorized Operator shall ON the tunnel only by feeding password and appropriate parameters. Set Parameters recipe shall have different password levels.		

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9.5.1 Interlock Safety:

S. No.	Safety Feature	Triggering Condition	Observation	Observed By (Engineering) Sign/Date
1.	Heater ON-OFF action	ON/OFF shall have interlocking with the operation of blowers to safeguard the HEPA Filter.		
2.	Conveyor Belt	Conveyor shall be switched off if adjustable temperature falls below the set value.		

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9.0 REFERENCES:

- Validation Master Plan
- Design Qualification of Sterilizing & De-Pyrogenating Tunnel

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- Calibration certificates.
- Operation and Maintenance Manual.

11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

AC	:	Alternating Current
DQ	:	Design Qualification
IQ	:	Installation Qualification
KW	:	Kilo Watt
MOC	:	Material of Construction
PQ	:	Performance Qualification
RH	:	Relative humidity
SOP	:	Standard Operating Procedure
P & ID	:	Piping & Instrumentation Diagram
NMT	:	Not More Than
NLT	:	Not Less Than
SS	:	Stain less Steel
HEPA	:	High Efficiency Particulate Air
ID	:	Inner Diameter
VFD	:	Variable Frequency Drive
MM	:	millimeter
°C	:	Degree Centigrade

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

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HEAD (QUALITY ASSURANCE)			