



PHARMA DEVILS

**INSTALLATION QUALIFICATION PROTOCOL CUM
REPORT FOR STERILIZING & DEPYROGENATING
TUNNEL**

PROTOCOL No.:

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
STERILIZING & DEPYROGENATING
TUNNEL**

EQUIPMENT ID. No.	
LOCATION	Ampoule Washing and Depyrogenation area
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



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1.0 PROTOCOL 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)			



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2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Sterilizing and Depyrogenation Tunnel for
- 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 De-Pyrogenation Tunnel (**Make:**) to be installed in the Ampoule Washing and De-Pyrogenation Tunnel of
- 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 De-Pyrogenation Tunnel.



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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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Sterilizing and De-pyrogenating Tunnel
Equipment ID.
Manufacturer's Name	Truiking Technologies Limited
Model
Supplier's Name	Truiking Technologies Limited
Location of Installation	Ampoule 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 three zones, Pre-heating, Heating, and cooling zones. The de-pyrogenation 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 Ampoule, the height of receptacles must not exceed 100 mm, the useful belt width for carrying the Ampoule is 600 mm.



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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.



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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	Ampoule Washing and De-Pyrogenation Tunnel		
Illumination	NLT 300 Lux		
Working space around the Equipment	Should be sufficient for easy Operation, Cleaning, and Maintenance.		

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

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8.2 Technical Specification Checks:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Over All Dimension	4310 x1700 x2410 mm		
Preheating and Cooling Zone System	The Preheating 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 Ampoules 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).		
Isolation system for different zones	Isolating preheating zone and heating zone, heating zone and cooling zone, cooling zone and filling room,		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Validation interface	Reserved validation interface <ul style="list-style-type: none">PAO interface (Inlet -05,Outlet -05)Interface of heating zone.		
Preheating Zone:			
Blower	Make : Popula		
Model	TK-YDF-2.8A-F-R90		
Discharge	3300-5200 m ³ /hr		
Speed	1400 r/min		
Pressure	380-460 Pa		
Qty.	01 No.		
Motor			
Capacity	1.1 kW		
RPM	2800 r/min		
Qty.	01 No.		
Drive	Make : Schneider		
Sr. No.	1528410546		
Capacity	1.5 kW		
Power	2HP, 200-240 V		
Qty.	01 No.		
Heating Zone Specifications			
Blower	Make : Popula		
Model	KSZ620/60-12-40-00		
Discharge	2500 m ³ /hr		
Speed	2840 r/min		
Pressure	500-525 Pa		
Qty.	03 No.		
Motor			
Capacity	1.5 kW		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Qty.	03 No.		
Drive	Make : Schneider		
Sr. No.	1412218012,1528410564,15284 10553		
Capacity	1.5 kW		
Power	2HP, 200-240 V		
Qty.	3 No.		
Cooling Zone:			
Blower	Make : Popula		
Model	TK-YDF-2.8A-F-R90		
Discharge	3300-5200 m ³ /hr		
Speed	1400 r/min		
Pressure	380-460 Pa		
Qty.	02 No.		
Motor			
Capacity	0.11 kW		
Qty.	02 No.		
Drive	Make : Schneider		
Sr. No.	1517924099	1528440535	
Capacity	2.2 kW	1.5 kW	
Power	3HP,200- 240V	2HP, 200-240V	
Qty.	1 No.	1 No.	
Exhaust Blowers			
Blower	Make : Popula		
Model	TK-DF-304-1.3A-F-R180		
Capacity	0.18 KW		
RPM	2800 r/min		



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Volume	300m ³ /h		
Total pressure	290-390 Pa		
Temperature	80-150°C		
Qty.	01 No.		
Conveyor Belt			
Motor			
Capacity	0.37 KW		
Sr. No.	1324004106		
Power	½ HP		
Qty.	01		
Ultrasonic cleaning			
Motor			
Capacity	1.2 KW		
Air consumption	2 m ³ /hr		
Purified water consumption	3T/time		
Specifications			
Filters	Preheat ing Zone	Heating Zone	Cooling
Coarse efficiency filter	Make : Camfill	Auto filter 1706	Make : Camfill
Particle retention size	5 micron	-----	5 micron
Dimensions	620 X 495X 46 mm	-----	620 X 495 X 46mm
Qty.	01 Nos.	03 Nos.	01 Nos.
HEPA			



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Critical Variables		Acceptance Criteria			Observation			Observed By (Engineering) Sign/Date
Make	Make : Camfill	Make : Camfill	Make : Camfill					
Particle retention size	0.3 micron	0.3 micron	0.3 micron					
Separation Efficiency	99.997 %	99.997 %	99.997 %					
Class	H14	H13	H14					
Dimensions (in mm)	610 X 610 X 150	610 X 457 X 150	762 X 762 X 150					
Air Velocity 200 mm below HEPA	More than 0.45 m/sec	More than 0.60 m/sec	More than 0.45 m/sec					
Qty.	01 No.	02 Nos.	02 Nos.					
Control and Instrumentation								
Ammeter	0-75 A							
Voltmeter	0-450 V							
Variable Frequency Drive (VFD)								
Make	Schneider							
Model	ATV12 HU15M2(1.5kw) ATV12 H037M2(3.7kw)							
Programmable Logic Controller (PLC)								
Make	Siemens							
Model	CPU226CN							
Human Machine Interface (HMI)								
Make	Siemens							



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Model	IPC677C		
Screen	12 inch		
Power	220 V		
Qty.	01 No.		

TEMPERATURE SENSORS :

Pre Heating Zone	Brand : Tianmu Model : KSZ620/43(B)-13-45 Type: K Range: 0-350°C Qty.: 01		
Heating Zone	Brand : Tianmu Model : GAWRN2-138-370 Type: K Range: 0-500°C Qty.: 03		
Air make up port in high temperature zone	Brand : JUMO Model : 901050/10-402-80-618/000 Type: K Range: 0-500°C Qty.: 02		
In the outlet of heating seat of high temperature zone	Brand : Tianmu Model : GAWRN2-138-270 Type: K Range: 0-500°C Qty.: 03		
cooling zone	Brand : Tianmu Model : GAWRN2-138-370 Type: K Range: 0-500°C Qty.: 02		

DIFFERENTIAL PRESSURE TRANSMITTER :

<ul style="list-style-type: none"> • Preheating zone and washing room • High temperature zone and washing room • Cooling zone and washing room • Washing room and filling room 	Brand: Ashcroft Model : CX8MB242 60PA Brand: Ashcroft Model : CX8MB242 60PA		
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DIFFERENTIAL PRESSURE GAUGE :



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Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Differential pressure between up and down of the filter in Preheating zone	Brand: Duwei Model : D2000-500Pa		
Differential pressure between preheating zone and washing Room	Brand: Duwei Model : D2000-60Pa		
Differential pressure between up and down of the filter-1 in high temperature zone	Brand: Duwei Model : D2000-500Pa		
Differential pressure between up and down of the filter-2 in high temperature zone	Brand: Duwei Model : D2000-500Pa		
Differential pressure between up and down of the filter-3 in high temperature zone	Brand: Duwei Model : D2000-500Pa		
Differential pressure between high temperature zone& washing room	Brand: Duwei Model : D2000-60Pa		
Differential pressure between up and down of the filter-1 in cooling zone	Brand: Duwei Model : D2000-500Pa		
Differential pressure between up and down of the filter-2 in cooling zone	Brand: Duwei Model : D2000-500Pa		
Differential pressure between cooling zone & washing room	Brand: Duwei Model : D2000-60Pa		
Differential pressure between chamber of preheating zone and washing room	Brand: Duwei Model : D2300-250Pa		
Differential pressure between chamber of heating zone and washing room	Brand: Duwei Model : D2300-250Pa		



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PROTOCOL No.:

Critical Variables	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Differential pressure between chamber of cooling zone and washing room	Brand: Duwei Model : D2300-250Pa		
Differential pressure between chamber of dehumidify and exhaust pipeline and washing room	Brand: Duwei Model : D2300-1KPa		
Differential pressure between chamber of exhaust pipeline of cooling zone and washing room	Brand: Duwei Model : D2300-1KPa		

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8.3 MOC Verification List:

S.No.	Component	Specification	Observation	Observed by (Engineering) Sign/Date
1.	Frame	Non-stainless steel imported paint drying process		
2.	Chamber of Preheating Zone	SS304		
3.	Chamber of High temperature Zone	SS304		
4.	Chamber of Cooling Zone	SS304		
5.	Electrical Heating pipe	SS304		
6.	Inner wall of tunnel	SS304		
7.	High temperature fan (impeller and housing)	SS304		
8.	Pipe line	SS304		
9.	Conveyor Belt	SS316 L		

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

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(Engineering)**

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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: 72kw Voltage: 400 V, 3 Phase ,50Hz		
Softener water	Pressure: more than 0.2 MPa Flow: 0.2T/h		
Wet air	Exhaust volume:300m ³ /h		
Compressed air	Pressure: more than 0.3MPa Flow: 0.2T/h		

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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	Three Level of Password Protection		
Alarm And Indication	<ul style="list-style-type: none"> • LF fan overload • Temperature too high in the outlet of heating zone • Temperature doesn't meet the requirement in heating zone. • The pressure inside the air hood doesn't reach the setting value during working. • Differential pressure of room is abnormal. 		

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Sign/Date:

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Sign/Date:

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8.6 Interlock Safety:

S.No.	Safety Feature	Triggering Condition
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.
3.	Linkage control	<ul style="list-style-type: none"> • When the tunnel temperature doesn't reach the set value, the washing machine cannot start. • When bottles cram for the tunnel, the washing machine & Tunnel both stops.
4.	Running control	During running, touch the button "parameter setting" on the production interface and set the temperature required by process. Open the mode of daytime start and automatic running of conveying belt. When the temperature reaches the set value, the washing machine starts working and the tunnel also starts working.

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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
HMI	:	Human Machine Interface
PLC	:	Programmable Logic Control
MM	:	millimeter
°C	:	Degree Centigrade



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17.0 PROTOCOL POST 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)			