



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

PROTOCOL No.:

**DESIGN QUALIFICATION
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FOR
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TUNNEL**

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 prepare the Design Qualification document on basis of Party Document and information given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of Sterilizing and Depyrogenation Tunnel (**Make: TruKing Technology Limited**) for
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.



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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 and Approval of the Protocol cum Report.• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Co-ordination with Production and Engineering to carryout Design Qualification.
Production	<ul style="list-style-type: none">• Review of the Protocol cum Report.• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.
Engineering	<ul style="list-style-type: none">• Review of the Protocol cum Report.• Assist in the Preparation of the Protocol cum Report.• To co-ordinate and support the Activity.• To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e.<ul style="list-style-type: none">➤ GA Drawing➤ Specification of the sub-components/ bought out items, their Make, Model, Quantity and backup records / brochures.➤ Details of utilities.➤ Identification of components for calibration.➤ Material of construction of all components.➤ Brief Process Description.➤ Safety Features and Alarms.



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5.0 BRIEF EQUIPMENT DESCRIPTION:

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.

6.0 EQUIPMENT:

Equipment Specifications are based on Process Requirement and Design Requirement at The manufacturer of equipment ensures complies with Process Requirement and Design Requirement Specification.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 EQUIPMENT:

Critical variables	Acceptance criteria	Reference
Application: The Sterilizing & Depyrogenation tunnel is used for glass container sterilization and de-pyrogenation purpose.	Sterilizing and De-pyrogenation tunnel should meet the requirement for Sterile Dosage Forms.	Process Requirement
Working: Working of Sterilizing and Depyrogenation Tunnel	The Sterilizing and Depyrogenation Tunnel should be able to perform Sterilization and De-pyrogenation of glass container.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement



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7.2 UTILITIY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Power for Electric Drive: Power: 72 kw Voltage: 400 V, 3 Phase, 50Hz	GMP Requirement
Softener water	Pressure: More than 0.2 MPa Flow: 0.2T/h	Equipment Documents
Wet air	Exhaust volume:300 m ³ /h	Equipment Documents
Compressed air	Pressure: More than 0.3MPa Flow: 0.2T/h	Equipment Documents

7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

Critical Variables	Acceptance Criteria
Temperature Variation in the empty zone	$\pm 5.0^0$ C
Temperature Variation in the loaded zone	$\pm 7.5^0$ C
Capacity	<ul style="list-style-type: none">• 600 pcs/minute for 1 ml Ampoule• 480 pcs/minute for 2 ml Ampoule• 470 pcs/minute for 3 ml Ampoule• 430 pcs/minute for 5 ml Ampoule
Power capacity	72.1 kw
Ampoule breakage rate	Less than 0.01%
Over All Dimension	4310 x1700 x2410 mm
Preheating and Cooling Zone System	The Preheating and Cooling System shall have 3 Phase Blower.
Heating Zone Drive System	The Heating 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.



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Critical Variables	Acceptance Criteria
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,
Validation interface	Reserved validation interface <ul style="list-style-type: none">• PAO interface• Interface of heating zone.
System Specifications	
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



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Critical Variables		Acceptance Criteria	
Qty.		03 No.	
Motor			
Capacity		1.5 kW	
Qty.		03 No.	
Drive		Make : Schneider	
Sr. No.		1412218012,1528410564,1528410553	
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, 200-240 V	2HP, 200-240 V
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	
Volume		300m ³ /h	



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Critical Variables		Acceptance Criteria	
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		
Sterilization Zone Specifications			
Minimum Endotoxin reduction	3 log		
Heat Penetration	FH _≥ 1365		
Filters	Preheating Zone	Sterilization (Air make up filter)	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.	02 Nos.	02 Nos.
HEPA			
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
Maximum Temperature	100 ⁰ C	400 ⁰ C	100 ⁰ C



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Critical Variables		Acceptance Criteria	
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.	03 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		
Model	6AV7890-0HB00-0AB0		
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		



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Critical Variables	Acceptance Criteria
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
DIFFERENTIAL PRESSURE GAUGE :	
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
Differential pressure between chamber of	Brand: Duwei



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Critical Variables	Acceptance Criteria
cooling zone and washing room	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

7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of Construction
1.	Frame	Non-stainless steel imported paint preheating 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



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7.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
Joints	Welding of joints without any welding burrs.	Safety Requirement
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.	Safety Requirement
Leveling and Balancing	Equipment should be Properly balanced & leveled.	Safety Requirement
Temperature Control	Air Temperature should be maintained within set limit, if goes out above limit, the heater supply will cut off.	Safety Requirement
Intake and Exhaust Blower	Both blowers shall not be switched off unless the temperature in the heating chamber falls below set value.	Safety Requirement
Password Protection of Operation	Three Level of Password Protection	Safety Requirement
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.	Safety Requirement



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7.6 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.

7.7 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Heating and Depyrogenation Tunnel	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feedback from market (customers already using the equipment).	Process Requirement

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



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8.0 DOCUMENTS TO BE ATTACHED:

- Approved Design and Specifications.
- Purchase Order Copy.
- Any other relevant documents.

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

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATIONS:

QA	:	Quality Assurance
PO	:	Purchase Order
Kg	:	Kilogram
Hr	:	Hour
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
P & ID	:	Piping and Instrumentation Diagram
HP	:	Horse Power
HEPA	:	High Efficiency Particulate Air
HMI	:	Human Machine Interface
PLC	:	Programmable Logic Control
KW	:	Kilo Watt
RPM	:	Revolution Per Minute



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13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			