DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR STERILIZING & DEPYROGENATING TUNNEL

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR STERILIZING & DEPYROGENATING TUNNEL

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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)			

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2.0 OBJECTIVE:

- To prepare the Design Qualification document on basis of URS 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: Fabtech Technologies International Pvt. Ltd.)** for ……
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & IDs 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	• Preparation, Review and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification reviewed by. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Production	• Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification.
Engineering	• 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. ➢ 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 four zones, Drying, Sterilizing, and stabilizing 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 vial , the height of receptacles must not exceed 100 mm, the useful belt width for carrying the vial is 30 mm.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared …….. The manufacturer of equipment ensures complies with User Requirement Specification.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS / PRODUCT PARAMETERS:

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: 2.0 HP Voltage: 415 V, 3 Phase ,50 Hz	GMP Requirement
Room Condition	Temperature should be 22 ± 2^0 C and RH should be NMT 55 % required.	Equipment Documents

7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

Critical Variables	Acceptance Criteria
Main unit comprising of S.S 304.	AISI 304
Conveyor Belt, Drying Zone , Sterilizing Zone & Cooling Zone	AISI304
Sensors	To sense, measure and transducer temperature and regulatory indication & interlock function.
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).

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Critical Variables	Acceptance Criteria
Process Oriented Description • Drying Zone	• In this zone, Positive pressure shall be maintained with respect to vial washing area.
• Sterilizing Zone	• In this zone, required temperature for sterilization and depyrogenation shall be maintained throughout the cycle.
• Stabilizing Zone	• In this zone temperature starts to stabilize downwards so that no cracking in vials produce by rapid Heat and Cooling.
• Cooling Zone	• In this zone, required temperature for cooling of vials shall be maintained throughout the cycle.
System Specifications	
Drying Zone:	
Blower	Make : Fabtech
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.

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Critical Variables	Acceptance Criteria	
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
Qty.	01 No.	02 No.
Motor	Make : Bharat Bijlee	Make : Bharat Bijlee
Capacity	0.75 KW	0.75 KW
RPM	1405	1405
Drive	Direct Coupled	Direct Coupled
Qty.	01 No.	02 Nos.
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	
Drying Zone Specifications		
Length of the drying zone	710 mm	
Air Discharged Approx.	670 m^3/ hr	

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Critical Variables	Acceptance Criteria		
Material of Construction	SS304		
Air Velocity 200 mm below HEPA	0.45 ± 0.1 m/s		
Sterilization Zone Specifications			
Length of the Sterilization Zone	1490 mm		
Air Discharged Approx.	1415 m^3/ hr		
Material of Construction	SS304		
Air Velocity 200 mm below HEPA	0.45 ± 0.1 m/s		
Minimum Endotoxin reduction	3 log		
Maximum Adjustable Temperature	350^0 C		
Temperature Variation in the zone	± 5.0^0 C		
Cooling Zone Specifications			
Length of the Cooling Zone	1380 mm		
Air Discharged Approx.	1440 m^3/ hr		
Material of Construction	SS304		
Air Velocity 200 mm below HEPA	0.45 ± 0.1 m/s		
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
Dimensions (in mm)	610 X 610 X 100	460 X 610 X 150	610 X 610 X 100

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Critical Variables	Acceptance Criteria		
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		
Human Machine Interface (HMI)			
Make	Allen Bradley		
Model	Touch Screen 550		
Qty.	01 No.		

7.4 MATERIAL OF CONSTRUCTION:

S. No.	Parts Name	Material of Construction
1.	Conveyor Belt	SS304
2.	Exhaust Blower	MS Powder Coated
3.	Sterilizing Zone Blower	SS316
4.	Drying Zone	SS304
5.	Sterilizing Zone	SS304
6.	Cooling Zone	SS304
7.	Electrical Panel	SS304
8.	Stabilizing Zone	SS304

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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 sterilizing chamber falls below set value.	Safety Requirement
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.	Safety Requirement

7.5.1 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.

7.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Sterilizing 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

Reference: (1) Specifications and Requirements as specified in P.O. and URS.

(2) Operating and service manual for Depyrogenation Tunnel.

8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- 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:

URS	:	User requirement specification
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

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			