OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STERILIZING & DEPYROGENATING TUNNEL

EQUIPMENT ID. No.	
LOCATION	**Vial Washing and De-Pyrogenation**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

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

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PHARMA DEVILS	OPERATIONAL 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 verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Sterilizing and De-Pyrogenating Tunnel and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification of Sterilizing and De-Pyrogenating Tunnel **(Make- Fabtech Technologies)** installed in the Vial Washing and De-Pyrogenation.
- This Protocol will define the methods and documentation used to perform OQ activity the Sterilizing and De-Pyrogenating Tunnel for OQ.
- Successful completion of this Protocol will verify that Sterilizing and De-Pyrogenating Tunnel meet all acceptance criteria and ready for Performance Qualification.

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 operational Qualification protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operation Process. • Post Approval of Operational Qualification Protocol cum Report after Execution
Production	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol. • Execution & Review of operational qualification protocol cum report.
Engineering	• Review of Operational Qualification. • To co-ordinate and support Operational Qualification Activity. • Calibration of Process Instruments. • Post Approval of Operational Qualification Protocol cum Report after Execution

5.0 EQUIPMENT DETAILS:

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

6.0 EQUIPEMENT 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 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, and the useful belt width for carrying the vial is 300 mm**.**

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Draft SOP for Operation and Cleaning of Vial Sterilizing and Depyrogenating.
- Draft SOP for Preventive Maintenance of Vial Sterilizing and Depyrogenating.
- Electrical circuits diagram.
- Technical specification of equipment.

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 OQ Protocol cum report.

7.1.2 Acceptance Criteria:

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

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1.	DQ Protocol cum Report				
2.	IQ Protocol cum Report				
3.	Draft SOP for Operation & Cleaning of Vial Sterilizing and De-pyrogenating.				
4.	Draft SOP for Preventive Maintenance of Vial Sterilizing and De-pyrogenating.				

Checked By
(Production)
Sign/Date: ……

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

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system are in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment / Instruments Name	Equipment/Instrument I.D.	Calibration On	Due On	Observed By Sign/Date

Checked By
(Production)
Sign/Date: ……

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

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.3 Operational Checks for Safety Feature :

Operate the Sterilizing and De-pyrogenating Tunnel as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

Component	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Maximum accumulation at feeding point.	Conveyor should OFF.		
Check all gauge, Temperature sensor and Temperature controller are calibrated and ready for operation.	All calibration should be in the validity period.		
Verify that the oven is under positive pressure at the beginning of the cycle and during the cooling cycle.	The manometer must be ≥1.5 mm W.G with respect to washing area.		
Verify the conveyor movement without any jerk.	The conveyor should move smoothly without any noise.		
Check the functioning of heater elements and blower by observing ammeter readings	Heater must show a deflection of 0 - 70 amps. Blower must show a deflection of 5-6 amps.		
Check direction of drying, cooling zone & exhaust vapor extraction blower.	Direction of blower should be towards discharge chute.		
Check direction of conveyor motor.	Direction of motor should be such that the conveyor should move towards sterile side.		
Heater Safety Switch OFF	'Heater Safety Switch Off' fault should be displayed on the MMI with an alarm.		
Thermostat switch excess temperature	Thermostat switch excess temperature' fault should be displayed on the MMI with an alarm.		
Drying Zone high temperature	'Drying Zone temperature high' fault should be displayed on the MMI with an alarm.		

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Component	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Cooling Zone low temperature	'Cooling zone temperature low' fault should be displayed on the MMI with an alarm.		
Cooling Zone air velocity low	'Cooling zone air velocity low' fault should be displayed on the MMI with an alarm consequently Conveyor belt should be stop.		
Infeed Proximity switch OFF	Infeed proximity switch OFF' fault should be displayed on the MMI with an alarm.		
Out feed Proximity switch OFF	'Out feed proximity switch OFF' fault should be displayed on the MMI with an alarm.		
Motors trip	'Drying zone motor trip' fault should be displayed on the MMI with an alarm.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.4 Operational Checks in Auto Operation:

Component	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Press F1 key on MMI to start the process.	Exhaust blower should be enabled. Heater switch should be enabled. Heater bank (HB 1, 2, 3, 4) should be enabled.		
Set conveyor start temperature.	When conveyor start temp. is reach Conveyor should be start.		
Set conveyor stop temperature.	When conveyor stop temp. is reach Conveyor should be stop .		
Set temp. for heater banks (HB1,2,3,4)	The temperature should be maintain by enabling and disabling of heater banks (HB1,2,3,4)		
Set conveyor speed in mm / mints.	Conveyor should be run as per set value.		
Press F2	Tunnel auto cycle should be started.		
Press F3	Tunnel auto cycle should be stop.		
Login and logout			
To login the system press F2 key and enter the password	The system should goes in login mode.		
To logout press F5 key	The system should come out from login mode		
Operator details			
To enter the operator detail cursor brought to the **Operator Details** and press enter.	The operator detail should be display on screen.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.5 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.6 EMERGENCY OPERATION VERIFICATION:

Item	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
ON/OFF Push button • Press Stop Push Button • Release ON Push Button	Equipment should Stop.		
	Equipment should Start.		
With the Emergency Stop Pressed in, in Try to cause movement of an Operating function	The Equipment will be inoperative.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

9.0 REFERENCES:

The Principle Reference is the following:

- Master Validation Plan.
- Schedule - M - "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2. Good Manufacturing Practices and Inspection.

10.0 DOCUMENTS TO BE ATTACHED:

- Operation and Maintenance Manual.
- Copy of Draft SOP's.
- Any Other Relevant Documents.

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:

No.	:	Number
WHO	:	World Health Organization
cGMP	:	Current Good Manufacturing Practices
QA	:	Quality Assurance
mm	:	Millimetre
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
MOC	:	Material of Construction
NLT	:	Not Less Than
HP	:	Horse Power
KW	:	Kilo Watt
SS	:	Stainless Steel
ID.	:	Identification
Kg	:	Kilo Gram
Ltrs	:	Liters
mm	:	Millimeter
MCB	:	Miniature Circuit Break
MMI	:	Man Machine Interface

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:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			