OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR STERILIZING & DEPYROGENATING TUNNEL

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

CONTENTS

S.No.	TITLE	PAGE No.
1.0	Protocol Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Equipment Details	6
6.0	System Description	6
7.0	Pre-Qualification Requirements	7-8
8.0	Critical Variables to be Met	9
9.0	References	16
10.0	Documents to be Attached	16
11.0	Deviation from Pre-Defined Specification, If Any	17
12.0	Change Control, If Any	17
13.0	Review (Inclusive of follow up action, If Any)	17
14.0	Conclusion	18
15.0	Recommendation	18
16.0	Abbreviations	19
17.0	Protocol Post Approval	20

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

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)			

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- Truking Technologies)** installed in the Ampoule 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	Truking Technologies Limited
Model	……..
Supplier's Name	Truking 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.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 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.	SOP for Operation & Cleaning of Ampoule Sterilizing and De-pyrogenating.				
4.	SOP for Preventive Maintenance of Ampoule Sterilizing and De-pyrogenating.				

Checked By
(Production)
Sign/Date: ……

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

Inference:

……

……

……

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

7.2 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

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

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Operational Checks for Safety Feature :

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

Component	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Verify the conveyor movement without any jerk.	The conveyor should move smoothly without any noise.		
Differential pressure abnormal between filling room and washing room	gives alarm		
Differential pressure abnormal in preheating zone	gives alarm		
Differential pressure abnormal in heating zone	gives alarm		
Differential pressure abnormal in cooling zone	gives alarm		
Fan overload in preheating zone	gives alarm		
Fan1 overload in heating zone	gives alarm		
Fan2 overload in heating zone	gives alarm		
Fan3 overload in heating zone	gives alarm		
Fan1 overload in cooling zone	gives alarm		
Fan2 overload in cooling zone	gives alarm		
Exhaust motor overload	gives alarm		
Temperature too low for heater from set value	gives alarm		
Dehumidify motor overload	gives alarm		
Ampoule conveying motor overload	gives alarm		
Ampoules cramming in the outlet	gives alarm		
Temperature too high in preheating zone	gives alarm		
Temperature 1 too high in heating zone	gives alarm		
Temperature 2 too high in heating zone	gives alarm		
Temperature 3 too high in heating zone	gives alarm		
Temperature too high for air make up port	gives alarm		
Temperature1 too high in cooling zone	gives alarm		
Temperature 1 too high in cooling zone	gives alarm		
Temperature 2 too high in cooling zone	gives alarm		

Component	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Temperature too high in the outlet of heater 1	gives alarm		
Temperature too high in the outlet of heater 2	gives alarm		
Temperature too high in the outlet of heater 3	gives alarm		

Checked By
(Engineering)
Sign/Date: ……

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

Inference:

……

……

……

……

……

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

8.2 Operational Checks in Auto Operation:

Test	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
The difference pressure between preheating zone and the washing room	5-10 Pa		
The differential pressure between up and down of HEPA filter in preheating zone	100-300 Pa		
The difference pressure between heating zone and the washing room	6-12 Pa		
The differential pressure between up and down of high temperature HEPA filter 1 in heating zone	150-350 Pa		
The differential pressure between up and down of high temperature HEPA filter 2 in heating zone	150-350 Pa		
The differential pressure between up and down of high temperature HEPA filter 3 in heating zone	150-350 Pa		
The differential pressure between up and down of high temperature HEPA filter 1 in cooling zone	80-250 Pa		
The differential pressure between up and down of high temperature HEPA filter 2 in cooling zone	80-250 Pa		
The difference pressure between cooling zone and the washing room	5-10 Pa		
The difference pressure between washing room and filling room	15-30 Pa		
Temperature of sterilization and drying zone	The Temperature can increase to the set point.		
Testing Port	There should be port for air speed check and PAO test		
Whole machine interlocking	Lack of ampoule, mesh belt stops, and mesh belt runs once there are ampoules.		

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

Test	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Temperature guarantee system for heating zone	Conveying belt should stop running when temperature in heating zone is lower than set point		
Ultra-high temperature protection system	Machine should stop heating automatically and gives alarm when temperature in heaters bank exceeds upper limit 465°C		
Protection system for preventing partial areas overheating while the machine stops	Fan should not stop running when the temperature inside the tunnel is higher than 100°C		
Protection system for preventing over heating when fan in trouble	Tunnel should stop heating automatically when the any fan stops because of faults		
Protection system for preventing the air speed of laminar flow too low or fan faults	When rotating speed of laminar flow fan is less than the set standard value, or the fan can not run normally. The heater can not heat.		
Pressure regulation	The pressure of each zone inside tunnel and up and down pressure of filter can be adjusted individually.		
Overload fault for each motor	Fan overload and the main drive motor overload alarm.		
The Temperature of heating zone exceed the upper limit of set value	The temperature of heating zone exceed the set value, the machine should stop (±5°C) automatically and give alarm (±10°C).		
conveyor speed regulation	The conveyor speed should be adjustable from the operator interface.		

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

Test	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Printing interval regulation	The set points and cycle data should be printed by the printer. The printing interval can be settable on PLC.		
Any abnormal sound or vibration	Machine should not make any abnormal sound or vibration during operation		
Running control:	There should be automatic /manual /maintenance mode/ validation mode in which machine can be operated to perform maintenance activity /PAO tests/particle count etc.		
Cooling effect	Adjust the cooling effect by adjusting the speed of conveying belt		
Linkage Control	• When the tunnel temperature doesn't reach the set value, the Washing machine cannot start. • When Ampoules cram for the tunnel, the washing machine stops.		
Operation with different password levels.	1. Operator 2. Craft 3. Supervisor		
The recipe setting	1.Control Temperature (°C) 2.Conveyor starts temp. (°C) 3.Conveyor stop temp. (°C) 4.Conveyor start/restart delay (seconds) 5.Start up delay (seconds) 6.Over shoot temp. (°C) 7.Conveyor speed (mm/min)		

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

Test	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Inputs required start the process of the Tunnel	Product – Alphanumeric 8 digit Batch Number – Alphanumeric 8 digit Run Number – 04 digit		
Operator Level	Operator level should have access to process selection, process start & stop in auto, manual mode, print start & stop, alarm, visualization. It should have access to acknowledge the alarm & reset the process.		
Supervisory Level	Supervisory level should have access to operator level all menu and in addition to that, should have excess to set the process parameter, batch info, recipe preparation & recipe upload		
Administrative Level	Administrative should have access to supervisory level all menu and in addition to that, should have excess to change the password.		

Checked By
(Engineering)
Sign/Date: ……

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

Inference:

……

……

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

8.3 Power Failure Verification:

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

8.4 EMERGENCY OPERATION VERIFICATION:

Item	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
ON/OFF Push button • Press Emergency Stop 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
(Engineering)
Sign/Date: ……

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

Inference:

……

……

……

……

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

9.0 REFERENCES:

The Principle Reference is the following:

- Design Qualification of party document.
- Installation Qualification of party document.
- Operational Qualification of party document.
- Manual of Party Document

10.0 DOCUMENTS TO BE ATTACHED:

- Calibration Certificates.
- Any Other Relevant Documents.

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION IF, ANY:

……

……

……

……

……

……

……

……

……

……

12.0 CHANGE CONTROL, IF ANY:

……

……

……

……

……

……

……

……

……

……

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

……

……

……

……

……

……

……

……

14.0 CONCLUSION:

……

……

……

……

……

……

……

……

……

15.0 RECOMMENDATION:

……

……

……

……

……

……

……

……

……

16.0 ABBREVIATIONS:

No.	:	Number
WHO	:	World Health Organization
cGMP	:	Current Good Manufacturing Practices
QA	:	Quality Assurance
mm	:	Millimetre
MOC	:	Material of Construction
NLT	:	Not Less Than
Temp.	:	Temperature
HP	:	Horse Power
KW	:	Kilo Watt
SS	:	Stainless Steel
ID.	:	Identification
Kg	:	Kilo Gram
Ltrs	:	Liters
mm	:	Millimeter
MCB	:	Miniature Circuit Break
HMI	:	Human Machine Interface
PLC	:	Programmable Logic Control

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)			