



**PROTOCOL  
FOR  
FACTORY ACCEPTANCE TEST  
OF  
STERILIZATION & DRYING TUNNEL**

|                       |                     |
|-----------------------|---------------------|
| <b>LOCATION</b>       | <b>AMPOULE LINE</b> |
| <b>SUPERSEDES No.</b> | <b>NIL</b>          |



**PROTOCOL FOR FACTORY ACCEPTANCE TEST OF STERILIZATION & DRYING TUNNEL**

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**1.0 APPROVAL:**

**INITIATED BY:**

| DESIGNATION                              | NAME | SIGNATURE | DATE |
|--|------|-----------|------|
| OFFICER/EXECUTIVE<br>(QUALITY ASSURANCE) |      |           |      |

**REVIEWED BY:**

| DESIGNATION               | NAME | SIGNATURE | DATE |
|---------------------------|------|-----------|------|
| HEAD<br>(USER DEPARTMENT) |      |           |      |
| HEAD<br>(ENGINEERING )    |      |           |      |

**APPROVED BY:**

| DESIGNATION                 | NAME | SIGNATURE | DATE |
|-----------------------------|------|-----------|------|
| HEAD<br>(QUALITY ASSURANCE) |      |           |      |



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**2.0 PURPOSE:**

- To ensure that the sterilization & Drying tunnel manufactured by M/s Truking Technology Limited (China) .....rforming as per agreed performance specification at manufacturer's site.

**3.0 SYSTEM OVERVIEW:**

- The Sterilization & De-Pyrogenating Tunnel is used for sterilization and De-Pyrogenation of Glass Ampoules of various Sizes, enabling the integration of the process of Liquid Injection Automatic Filling under Aseptic Conditions in which all activities are performed under class 100 area.
- The De-Pyrogenating Tunnel is a complete Automatic control system with the basic unit mounted on stainless steel stand. In this Tunnel, the ampoules are transported by Stainless Steel Wire Loop Conveyor through PRE HEATING ZONE, HEATING ZONE, COOLING ZONES under Non-Turbulent class 100 Air.
- The useful belt width for carrying the Ampoule is 600 mm. The air damper plate is adjusted for Ampoule.
- The Sterile receptacles are then unloaded directly into the sterile area. This process eliminates intermediate Material Handling and the potential for product contamination during those steps no longer exist.



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**4.0 EQUIPMENT COMPONENTS / BOUGHT OUTS:**

| Verification criteria |  |   |        |         |
|-----------------------|--|---|--------|---------|
| S.No.                 | Component  | Expectation   | Actual | Remarks |
| 1.                    | Machine  | Tunnel for Ampoule sterilization with effective conveyor width of 600 mm.   |        |         |
| 2.                    | Make   | Truking ( China)  |        |         |
| 3.                    | Machine Dimensions   | 4310 x 1700 x 2410 mm   |        |         |
| 4.                    | Capacity   | <ul style="list-style-type: none"><li>• 600 pcs/min for 1 ml ampoule</li><li>• 480 pcs/min for 2 ml ampoule</li><li>• 470 pcs/min for 3 ml ampoule</li><li>• 430 pcs/min for 5 ml ampoule</li><li>• 300 pcs/min for 10 ml ampoule</li></ul> |        |         |
| 5.                    | Power capacity   | 72.1 kw   |        |         |
| 6.                    | Machine mounting   | On sturdy SS 304 molded angles welded & grinded surface & fully cladded with SS sheets.   |        |         |
| 7.                    | Machine Installation   | Installation of machine should be suitable as per the drawing. Compare the instillation parameters with respect to room, pendant, drain, exhaust etc.   |        |         |
| 8.                    | Effective width of conveying belt                                | <ul style="list-style-type: none"><li>• MOC- SS 316 L</li><li>• Width -600 mm</li></ul>   |        |         |
| 9.                    | <b>Pre-Filter (Coarse efficiency filter in Pre heating zone)</b> |   |        |         |



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**Verification criteria**

| S.No.  | Component               | Expectation   | Actual | Remarks |
|--|-------------------------|---|--------|---------|
|  | Make                    | Camfill farr  |        |         |
|  | Model                   | TK-GLQ-Camfil-CN  |        |         |
|  | Particle retention size | 5 micron  |        |         |
|  | Dimensions (in mm)      | 620 X 495 X 46  |        |         |
|  | Class                   | G-4   |        |         |
| <b>LAMINAR FLOW FAN IN PREHEATING ZONE</b>                   |                         |   |        |         |
|  | Brand                   | Popula  |        |         |
|  | Qty.                    | one set of TK-YDF-2.8A-F-R90 double-sided inlet air centrifugal fan |        |         |
|  | Power                   | 1.1 KW  |        |         |
|  | RPM                     | 1400r/min   |        |         |
|  | Exhaust Volume          | 3300-5200m <sup>3</sup> /h  |        |         |
|  | Total pressure          | 380-460pa.  |        |         |
| <b>Pre-Filter (Coarse efficiency filter in cooling zone)</b> |                         |   |        |         |
|  | Make :                  | camfill farr  |        |         |
|  | Model                   | TK-GLQ-Camfil-CN  |        |         |
|  | Particle retention size | 5 micron  |        |         |
|  | Dimensions (in mm)      | 620 X 495 X 46 mm   |        |         |
|  | Class                   | G-4   |        |         |



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| <b>Verification criteria</b> |   |   |               |                |
|------------------------------|---|---|---------------|----------------|
| <b>S.No.</b>                 | <b>Component</b>                        | <b>Expectation</b>  | <b>Actual</b> | <b>Remarks</b> |
|                              | <b>LAMINAR FLOW FAN IN COOLING ZONE</b> |   |               |                |
|                              | Brand                                   | Popula  |               |                |
|                              | Qty.                                    | one set of TK-YDF-2.8A-F-R90 double-sided inlet air centrifugal fan |               |                |
|                              | Power                                   | 1.1 KW  |               |                |
|                              | RPM                                     | 1400r/min   |               |                |
|                              | Exhaust Volume                          | 3300-5200m <sup>3</sup> /h  |               |                |
|                              | Total pressure                          | 380-460pa.  |               |                |
| 10.                          | <b>HEPA (Pre heating Zone)</b>          |   |               |                |
|                              | Make                                    | Camfil brand  |               |                |
|                              | Air Velocity                            | More than 0.45 m/sec  |               |                |
|                              | Particle retention size                 | 0.3 micron  |               |                |
|                              | Efficiency                              | 99.997 %  |               |                |
|                              | Class                                   | H14   |               |                |
|                              | Dimensions (in mm)                      | 610 X 610 X 150 mm  |               |                |
|                              | Maximum Temperature                     | 100 °C  |               |                |
|                              | <b>HEPA (Heating zone)</b>              |   |               |                |
|                              | Make                                    | Camfil brand  |               |                |
|                              | Air Velocity                            | More than 0.60 m/sec  |               |                |
|                              | Particle retention size                 | 0.3 micron  |               |                |



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| Verification criteria                   |                         |   |        |         |
|---|-------------------------|---|--------|---------|
| S.No.                                   | Component               | Expectation   | Actual | Remarks |
|   | Efficiency              | 99.997 %  |        |         |
|   | Class                   | H13   |        |         |
|   | Dimensions (in mm)      | 610 X 457 X 150 mm                                      |        |         |
|   | Maximum Temperature     | 400 °C  |        |         |
| <b>LAMINAR FLOW FAN IN HEATING ZONE</b> |                         |   |        |         |
|   | Brand                   | Popula  |        |         |
|   | Qty.                    | one set of KSZ620/60-12-40-00 Clockwise centrifugal fan |        |         |
|   | Power                   | 1.5 KW  |        |         |
|   | RPM                     | 2840r/min   |        |         |
|   | Exhaust Volume          | 2500m <sup>3</sup> /h                                   |        |         |
|   | Total pressure          | 500-525pa.  |        |         |
| <b>HEPA (Cooling zone)</b>              |                         |   |        |         |
|   | Make                    | Camfil brand  |        |         |
|   | Air Velocity            | More than 0.45 m/sec                                    |        |         |
|   | Particle retention size | 0.3 micron  |        |         |
|   | Efficiency              | 99.997 %  |        |         |
|   | Class                   | H14   |        |         |
|   | Dimensions (in mm)      | 762 X 762 X 150   |        |         |
|   | Maximum Temperature     | 100 °C  |        |         |





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| Verification criteria |  |   |        |         |
|-----------------------|--|---|--------|---------|
| S.No.                 | Component  | Expectation   | Actual | Remarks |
| 11.                   | Chamber of Pre heating, Cooling, pipe line, Inner wall of tunnel, Electric Heating pipe & Appearance parts | MOC : SS304   |        |         |
| 12.                   | VFD  | <b>Brand</b> : Schneider<br><b>Model</b> :<br>ATV12HU15M2(1.5kw<br>ATV12H037M2(0.37kw |        |         |
| 13.                   | PLC  | <b>Brand</b> : Siemens<br><b>Model</b> : CPU226CN                                     |        |         |
| 14.                   | MMI  | <b>Brand</b> : Siemens<br><b>Model</b> : IPC677C                                      |        |         |
| 15.                   | <b>TEMPERATURE SENSORS :</b>   |   |        |         |
| 16.                   | Pre Heating  | <b>Brand</b> : Tianmu<br><b>Model</b> :<br>KSZ620/43(B)-13-45                         |        |         |
|                       | Sterilization area in high temperature zone  | <b>Brand</b> : Tianmu<br><b>Model</b> : GAWRN2-138-370                                |        |         |
|                       | Air make up port in high temperature zone  | <b>Brand</b> : JUMO<br><b>Model</b> : 901050/10-402-80-618/000                        |        |         |
|                       | In the outlet of heating seat of high temperature zone   | <b>Brand</b> : Tianmu<br><b>Model</b> : GAWRN2-138-270                                |        |         |
|                       | Temperature in the outlet of cooling zone  | <b>Brand</b> : Tianmu<br><b>Model</b> : GAWRN2-138-370                                |        |         |
| 17.                   | <b>PRESSURE TRANSMITTER :</b>  |   |        |         |
|                       | Check the differential pressure between preheating   | <b>Brand</b> : Ashcroft<br><b>Model</b> :CX8MB242<br>60PA                             |        |         |



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**Verification criteria**

| S.No.      | Component  | Expectation                                       | Actual | Remarks |
|------------|--|---|--------|---------|
|            | zone, high temperature zone and cooling zone and washing room, the differential pressure between washing room and filling room |   |        |         |
| <b>18.</b> | <b>DIFFERENTIAL PRESSURE GAUGE :</b>   |   |        |         |
|            | Differential pressure between up and down of the filter in Preheating zone   | <b>Brand:</b> Duwei<br><b>Model :</b> D2000-500Pa |        |         |
|            | Differential pressure between preheating zone and washing Room   | <b>Brand:</b> Duwei<br><b>Model :</b> D2000-60Pa  |        |         |
|            | Differential pressure between up and down of the filter in high temperature zone   | <b>Brand:</b> Duwei<br><b>Model :</b> D2000-500Pa |        |         |
|            | Differential pressure between high temperature zone& washing room  | <b>Brand:</b> Duwei<br><b>Model :</b> D2000-500Pa |        |         |
|            | Differential pressure between up and down of the filter in cooling zone  | <b>Brand:</b> Duwei<br><b>Model :</b> D2000-500Pa |        |         |
|            | Differential pressure between cooling zone & washing room  | <b>Brand:</b> Duwei<br><b>Model :</b> D2000-60Pa  |        |         |



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**Verification criteria**

| S.No.      | Component  | Expectation   | Actual | Remarks |
|------------|--|---|--------|---------|
|            | Differential pressure between chamber of preheating zone and washing room                  | <b>Brand:</b> Duwei<br><b>Model :</b> D2300-250Pa   |        |         |
|            | Differential pressure between chamber of heating zone and washing room                     | <b>Brand:</b> Duwei<br><b>Model :</b> D2300-250Pa   |        |         |
|            | Differential pressure between chamber of cooling zone and washing room                     | <b>Brand:</b> Duwei<br><b>Model :</b> D2300-250Pa   |        |         |
|            | Differential pressure between chamber of dehumidify and exhaust pipeline and washing room  | <b>Brand:</b> Duwei<br><b>Model :</b> D2300-1KPa  |        |         |
|            | Differential pressure between chamber of exhaust pipeline of cooling zone and washing room | <b>Brand:</b> Duwei<br><b>Model :</b> D2300-1KPa  |        |         |
| <b>19.</b> | <b>Safety Features</b>   | <ul style="list-style-type: none"><li>• Emergency Stop</li><li>• Independent Emergency Heater Cut Off facility upon high temperature.</li><li>• Blowers not ON/ Tripped – Heater gets OFF.</li><li>• Different password levels (At least Three) in PLC for recipe setting and operation</li></ul> |        |         |



**PROTOCOL FOR FACTORY ACCEPTANCE TEST OF STERILIZATION & DRYING TUNNEL**

**5.0 TESTS & CHECKS:**

**5.1 HEAT DISTRIBUTION STUDY:**

**A) OBJECTIVE:**

- To ensure that the Sterilization & Depyrogenation Tunnel when operated with Empty Chamber is capable of producing the Temperature Profiles as per the temperature set points set in the PLC of the equipment.
- To ensure that the Temperature Distribution is uniform throughout the Sterilization & Depyrogenation Period of different size of ampoules i.e. 1 ml, 2 ml, 3 ml & 5 ml.
- Single Run shall be performed to qualify the measurement of the Temperature throughout the Chamber by 12 Temperature Sensors during the Sterilization and Depyrogenation Cycle.

**B) PROCEDURE**

- Suspend the probe in the chamber in different position in such a way that probes don't touch any metallic surface.
- Connect the probes to suitable data logger, which can scan and print the actual temperature observed at different locations with respect to time.
- Operate the Sterilizing & Depyrogenating Tunnel .Also start the data logger to record the actual temperatures with respect to time.
- After completion of Sterilization Cycle "Switch OFF" the data logger.
- Collect printout from the printer of Sterilizing & Depyrogenating Tunnel.
- Download the data from the data logger in the computer for the data analysis and printing enclosed the printout obtained from the data logger.
- Following formulas shall be used for Calculation of Conveyor Belt Speed & Sterilization:

$$\text{Belt Speed in mm} = \frac{(\text{Ampoule Diameter})^2 \times \cos 30 \times \text{Washing M/C Out put}}{\text{Tunnel Conveyor Width}}$$

$$\text{Sterilization hold time} = \frac{\text{Length of sterilization Zone}}{\text{Conveyor Belt Speed}}$$

**C) ACCEPTANCE CRITERIA:**

A Minimum Exposure Time of Total 03 minutes should be achieved at Depyrogenation temperature of 300 °C & above.

**D) OBSERVATIONS AND RESULTS:**

- Record the temperature in Annexure: I



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**ANNEXURE: I**

|  |                  |                       |      |
|--|------------------|-----------------------|------|
| <b>Name of Cycle</b>                               |                  | <b>Ampoule Size</b>   | 1 ml |
| <b>Equipment Name</b>                              |                  | <b>Equipment Make</b> |      |
| <b>Equipment Make</b>                              |                  |                       |      |
| <b>Set Parameters:</b>                             |                  |                       |      |
| <b>Parameters</b>                                  | <b>Set Value</b> | <b>Observed Value</b> |      |
| <b>Cycle Start Date / Time</b>                     |                  |                       |      |
| <b>Relative Humidity of Area</b>                   |                  |                       |      |
| <b>No. Of In-built Temperature Sensors</b>         |                  |                       |      |
| <b>Conveyor Start Temp.</b>                        |                  |                       |      |
| <b>Conveyor Stop Temp.</b>                         |                  |                       |      |
| <b>Conveyor Belt Speed</b>                         |                  |                       |      |
| <b>Pressure differentials (Drying Zone)</b>        |                  |                       |      |
| <b>Pressure differentials (Sterilization Zone)</b> |                  |                       |      |
| <b>Pressure differentials (Cooling Zone)</b>       |                  |                       |      |
| <b>Minimum Temperature</b>                         |                  |                       |      |
| <b>Maximum Temperature</b>                         |                  |                       |      |
| <b>Total Cycle Time</b>                            |                  |                       |      |
| <b>Sterilization Zone Exposure Time</b>            |                  |                       |      |
| <b>Result</b>                                      |                  |                       |      |
| <b>Cold Spot</b>                                   |                  |                       |      |
| <b>Cycle End Date / Time</b>                       |                  |                       |      |





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**5.2 HEAT PENETRATION STUDY:**

**A) OBJECTIVE:**

- To ensure that, heat is sufficiently penetrating into the innermost portion of the Ampoule subjected for sterilization & Depyrogenation to achieve desired temperature i.e. more than 300°C during the sterilization & Depyrogenation cycle.
- Loaded chamber Heat Penetration Studies shall be conducted for single cycle with Temperature Probes for Different ampoule size i.e. 1 ml, 2 ml, 3 ml, & 5 ml ampoules.
- To ensure that, Heat is sufficiently penetrating into the innermost portion of the Ampoule subjected for Sterilization & Depyrogenation to achieve desired Temperature i.e. More Than 300°C using Endotoxin Challenge Test.
- The recovery of Endotoxin Concentration after exposing to Sterilization & Depyrogenation Tunnel should show more than 3 log reduction.
- Single run shall be performed to qualify the measurement of the Temperature throughout the tunnel by 12 Temperature Sensors during the sterilization cycle.

**B) EQUIPMENT REQUIRED:**

- Calibrated Data Logger with 12 Probes.

**C) PROCEDURE:**

- Conduct the study with loaded chamber for single cycle with Calibrated Temperature probes of each Ampoule size..
- Suspend the 12 Temperature Sensors inside the ampoule and put into tunnel for Heat Penetration Study.
- Record the position of the probes in a representative schematic form.
- Insert 9 Endotoxin Ampoules (Marked Ampoules) having 10000 EU each along with the temperature sensors.
- Connect the probes to suitable data logger, which can scan and print the actual temperature observed at different locations with respect to time.
- Operate the Sterilizing & Depyrogenating Tunnel.
- Also start the data logger to record the actual temperatures within the Tunnel with respect to time.
- After completion of sterilization cycle collect printout from tunnel printer.



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- Download the data from the data logger in the computer for the data analysis and printing enclosed the printout obtained from the data logger.
- Seal the exposed Endotoxin Ampoules and wrap the exposed Endotoxin Challenge Ampoules aseptically with sterile Aluminium foil and identify suitably. Send the exposed Endotoxin Challenge Ampoules to microbiology laboratory for testing. Microbiologist shall analyze the exposed Endotoxin Challenge Ampoules and recovery of Endotoxin.
- Calculate the  $F_H$  Value as per following formula :-

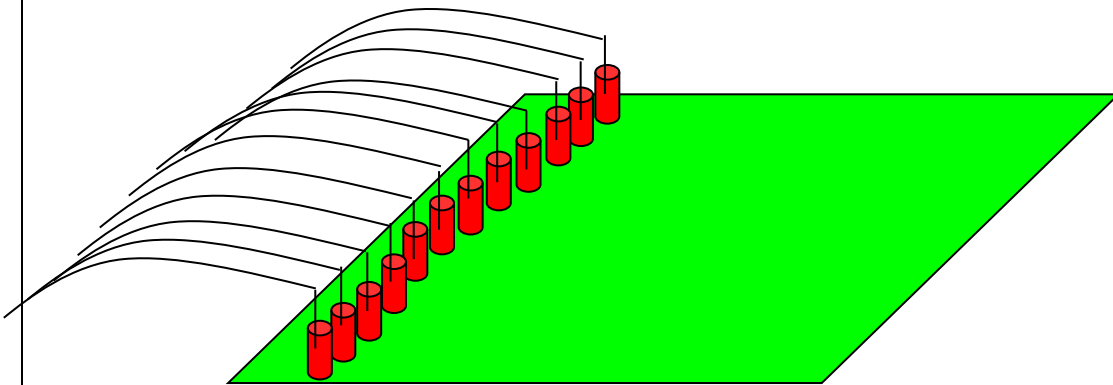
$$F_H = \Delta t \times 10^{(T-300/Z)}$$

**Where**

T= Observed Temp. During sterilization

Z= 46.6°C

t = Time Interval



**Schematic Diagram of Sterilization and Depyrogenation Tunnel with Probe Location**

**D) ACCEPTANCE CRITERIA:**

- Throughout the dwell time, all temperature measured in the chamber should be  $\geq 300^\circ\text{C}$ .
- The recovery of Endotoxin concentration after exposing in Sterilization and Depyrogenation Tunnel should show at least 3 log reduction.
- The Calculated minimum  $F_H$  value should be more than.

**E) OBSERVATIONS AND RESULTS:**

- Record the temperature in ANNEXURE: II





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**ANNEXURE: II**

**Sterilization Cycle Parameter:**

|                       |  |                       |      |
|-----------------------|--|-----------------------|------|
| <b>Name of Cycle</b>  |  | <b>Ampoule Size</b>   | 1 ml |
| <b>Equipment Name</b> |  | <b>Equipment Make</b> |      |
| <b>Equipment Make</b> |  | <b>Speed</b>          |      |

**Set Parameters:**

| <b>Parameters</b>                                  | <b>Set Value</b> | <b>Observed Value</b> |
|--|------------------|-----------------------|
| <b>Washing Done On</b>                             |                  |                       |
| <b>Cycle Start Date / Time</b>                     |                  |                       |
| <b>No. Of In-built Temperature Sensors</b>         |                  |                       |
| <b>Conveyor Start Temp.</b>                        |                  |                       |
| <b>Conveyor Stop Temp.</b>                         |                  |                       |
| <b>Conveyor Belt Speed</b>                         |                  |                       |
| <b>Pressure differentials (Drying Zone)</b>        |                  |                       |
| <b>Pressure differentials (Sterilization Zone)</b> |                  |                       |
| <b>Pressure differentials (Cooling Zone)</b>       |                  |                       |
| <b>Minimum Temperature</b>                         |                  |                       |
| <b>Maximum Temperature</b>                         |                  |                       |
| <b>Sterilization Zone Exposure Time</b>            |                  |                       |
| <b>Total Cycle Time</b>                            |                  |                       |
| <b>Result</b>                                      |                  |                       |
| <b>Cold Spot</b>                                   |                  |                       |
| <b>Cycle End Date / Time</b>                       |                  |                       |



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### F<sub>H</sub> Calculation & Endotoxin Test Report:

| S. No.                     | Probe No. | De-pyrogenating Temperature |         | Duration of De-pyrogenating Temperature (300°C & Above) |    | F <sub>H</sub> Value | Reduction of Endotoxin | Remarks |
|----------------------------|-----------|-----------------------------|---------|---|----|----------------------|------------------------|---------|
|                            |           | Maximum                     | Minimum | From  | To |                      |                        |         |
| <b>Acceptance Criteria</b> |           | →                           |         |   |    | <b>NLT 30 min.</b>   | <b>NLT 3 log</b>       |         |
| 1                          |           |                             |         |   |    |                      |                        |         |
| 2                          |           |                             |         |   |    |                      |                        |         |
| 3                          |           |                             |         |   |    |                      |                        |         |
| 4                          |           |                             |         |   |    |                      |                        |         |
| 5                          |           |                             |         |   |    |                      |                        |         |
| 6                          |           |                             |         |   |    |                      |                        |         |
| 7                          |           |                             |         |   |    |                      |                        |         |
| 8                          |           |                             |         |   |    |                      |                        |         |
| 9                          |           |                             |         |   |    |                      |                        |         |
| 10                         |           |                             |         |   |    |                      |                        |         |
| 11                         |           |                             |         |   |    |                      |                        |         |
| 12                         |           |                             |         |   |    |                      |                        |         |

### 6.0 OPERATIONAL CONTROL FUNCTION CHECKS :

| S.No. | Operation   | Observation | Remarks |
|-------|---|-------------|---------|
| 1.    | <ul style="list-style-type: none"> <li>Take trial of the machine on the site by operating the machine with 1 ml, 2 ml 3 ml &amp; 5 ml glass ampoule).</li> </ul>  | •           |         |
| 2.    | <ul style="list-style-type: none"> <li>Ampoules are loaded on infeed turntable of washing machine, which will be carried forward to infeed of the tunnel. From here the ampoule enters the tunnel and carried forward by the conveyor.</li> <li>The Ampoule should be carried smoothly through the tunnel to outfeed.</li> <li>The conveyor speed should be adjustable from the operator interface.</li> <li>The heating should be controlled according to the set value on operator interface.</li> <li>The heater bank is being controlled on the temperature of two temperature sensors in the sterilization zone.</li> <li>The set points and cycle data should be</li> </ul> | •           |         |



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| S.No. | Operation  | Observation | Remarks |
|-------|--|-------------|---------|
|       | <p>printed by the printer. The printing interval can be settable on PLC.</p> <ul style="list-style-type: none"><li>• The alarms are being displayed and acknowledged on the MMI.</li><li>• Machine should not make any abnormal sound or vibration during operation</li><li>• MMI &amp; PLC support should be available during Auto operation.</li><li>• There should be manual /maintenance mode/ validation mode in which machine can be operated to perform maintenance activity / PAO tests/particle count etc.</li><li>• Before starting the tunnel the PLC should require to enter the Product, Batch Number by the operator.</li><li>• The data printed by the printer should print the Product, Batch number, recipe before the start of cycle.</li><li>• The printer should also print every stage, alarm with date irrespective of print interval time and temperature of the various zones as well as the conveyor speed at the set print interval.</li></ul> |             |         |
| 3.    | <b>Cooling effect:</b> <ul style="list-style-type: none"><li>• Adjust the cooling effect by adjusting the speed of conveying belt</li></ul>  |             |         |
| 4.    | <b>Linkage Control:</b> <ul style="list-style-type: none"><li>• When the tunnel temperature doesn't reach the set value, the Washing machine cannot start.</li><li>• When Ampoules cram for the tunnel, the washing machine stops</li><li>• When Ampoules cram for the tunnel, the tunnel stops.</li></ul>   |             |         |
| 5.    | <b>Alarm &amp; indication:</b> <ul style="list-style-type: none"><li>• LF fan overload</li><li>• Temperature too high in the outlet of heating zone</li><li>• Temperature doesn't meet the requirement in heating zone</li><li>• The pressure inside the air hood doesn't reach the setting value during working Differential</li></ul>  |             |         |



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## PROTOCOL FOR FACTORY ACCEPTANCE TEST OF STERILIZATION & DRYING TUNNEL

| S.No. | Operation  | Observation | Remarks |
|-------|--|-------------|---------|
|       | pressure of room is abnormal.  |             |         |
| 6.    | <b>Running control:</b><br>During running, touch the button “parameter setting” on the production interface gently 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.    | <b>Endotoxin reduction:</b><br>1000 EU/ML ,at least 3 log reduction  |             |         |
| 8.    | <b>Validation Ports :</b><br>Should be available for giving in PAO smoke before HEPA for all zones   |             |         |
| 9.    | <b>Operational Interlocks :</b> <ul style="list-style-type: none"><li>• Intake and exhaust blowers cannot be switched OFF until the chamber temp is below the set point.</li><li>• Temp falls below set point – Conveyor stops and restarts after the set delay after temperature achieving</li><li>• In feed max accumulation – Washing machine Inadequate in feed – conveyor stops after a delay period</li><li>• Outfeed max accumulation – Conveyor stop immediately and the heater banks get off after a delay time.</li><li>• Any of the blowers OFF – Heater and conveyor gets OFF</li><li>• Out feed Ampoule temperature high – Conveyor stops</li></ul> |             |         |
| 10.   | <ul style="list-style-type: none"><li>• <b>The recipe setting and operation should be with different password levels.</b></li><li>• The following parameters should be settable as a part of recipe.<ul style="list-style-type: none"><li>○ Control Temperature (°C)</li><li>○ Conveyor start temperature (°C)</li><li>○ Conveyor stop temperature (°C)</li><li>○ Conveyor start / restart delay (seconds)</li><li>○ Start up delay (seconds)</li><li>○ Over shoot temperature (°C)</li><li>○ Conveyor speed (mm/min)</li></ul></li><li>• The following inputs should be required to start the process of the Tunnel</li></ul>                                   |             |         |



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| S.No.      | Operation  | Observation | Remarks |
|------------|--|-------------|---------|
|            | <ul style="list-style-type: none"><li>○ Product – Alphanumeric 8 digit</li><li>○ Batch Number – Alphanumeric 8 digit</li><li>○ Run Number – 04 digit</li><li>○ Operator code – Alphanumeric 8 digit</li></ul>  |             |         |
| <b>11.</b> | <p><b>Documents :</b></p> <p>Following document should be available/ will be available with machine.</p> <ul style="list-style-type: none"><li>● MOC certificates of conveyer</li><li>● MOC of Pre- heating, Heating, cooling and stabilizing zone chambers</li><li>● Test certificates of HEPA Filters (Efficiency and integrity)</li><li>● Test certificate of blowers</li><li>● Test certificate of Magnehelic gauges</li><li>● Test certificates of RTDs</li><li>● Test certificate of motors</li><li>● Operating and maintenance manual.</li></ul> <p>As built architectural, electrical and P &amp; ID Drawing</p> |             |         |

**7.0 OBSERVED DEVIATIONS/DISCUSSIONS:**

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**8.0 RECOMMENDATION :**

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**PROTOCOL FOR FACTORY ACCEPTANCE TEST OF STERILIZATION & DRYING TUNNEL**

**9.0 CONCLUSION:**

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| <b>FAT CARRIED OUT BY:</b> | <b>MANUFACTURER:</b>     |
|----------------------------|--------------------------|
| Sign. _____ Date : _____   | Sign. _____ Date : _____ |
| Name : _____               | Name : _____             |
| Sign. _____ Date : _____   | Sign. _____ Date : _____ |
| Name : _____               | Name : _____             |
| Sign. _____ Date : _____   | Sign. _____ Date : _____ |
| Name : _____               | Name : _____             |



**PROTOCOL FOR FACTORY ACCEPTANCE TEST OF STERILIZATION & DRYING TUNNEL**

**10.0 DOCUMENTS:**

- All MOC Certificates, Manual for Bought out items
- Design Qualification protocol.
- Installation Qualification protocol.
- Operational Qualification protocol.
- Schematic Diagram of machine showing Overall Dimensions.
- Instrument list with manufacturer's calibration certificate.
- Electrical unit Diagram.
- P & ID Diagram / G.A Drawing.
- Operating & Service Manual
- Spare Part List.
- Warranty Certificate of machine
- Test Certificate of SS Materials



**PROTOCOL FOR FACTORY ACCEPTANCE TEST OF STERILIZATION & DRYING TUNNEL**

**11.0 ABBREVIATIONS:**

|      |   |   |
|------|---|---|
| cGMP | : | Current Good Manufacturing Practices                |
| ISPE | : | International Society of Pharmaceutical Engineering |
| cGEP | : | Current Good Engineering Practices                  |
| DQ   | : | Design Qualification                                |
| IQ   | : | Installation Qualification                          |
| OQ   | : | Operational Qualification                           |
| MOC  | : | Material of Construction                            |
| SS   | : | Stainless Steel                                     |
| WHO  | : | World Health Organization                           |
| mm   | : | Millimeter  |
| WG   | : | Water Gauge   |
| Hz   | : | Hertz   |
| V    | : | Volt  |
| Cu   | : | Copper  |
| Al   | : | Aluminum  |