

OPERATIONAL QUALIFICATION

Equipment Name: Sterilizing and depyrogenating tunnel.

Equipment No.: EQI/XX/XXX/01

Protocol Reference No.

Report No.:

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1.0 PROTOCOL APPROVAL:

Signing of this approval page of Protocol indicates agreement with the operational qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following authorities.

FUNCTION	NAME	DEPARTMENT	SIGNATURE	DATE
PREPARED BY		QUALITY ASSURANCE		
REVIEWED BY		ENGINEERING		
REVIEWED BY		PRODUCTION		
APPROVED BY		QUALITY ASSURANCE		

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2.0	OVERVIEW:
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2.1	OBJECTIVE:
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The objective of developing and executing this protocol is to collect sufficient data pertaining to the Sterilizing and depyrogenating tunnel and define the qualification requirements and acceptance criteria for the machine.

The objective of the operational qualification is to prove that each operation proceeds as per design specification and the tolerances prescribed there in the document.

2.2	PURPOSE:
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The purpose of this protocol is to establish documentary evidence to ensure that the installed Sterilizing and depyrogenating tunnel will operate reproducibly and consistently within its full dynamic range of operation according to manufacturer's specifications and to demonstrate that the control panel and other manual operation of Sterilizing and depyrogenating tunnel provides the proper functionality as specified in the design qualification.

2.3	SCOPE:
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The Scope of this protocol is limited to the operational qualification of Sterilizing and depyrogenating tunnel in XYZ Pharmaceuticals.

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Sterilizing and depyrogenating tunnel and define the qualification requirements and acceptance criteria for the machine.

This protocol shall define the test procedures, documentation, references and acceptance criteria to establish that the Sterilizing and depyrogenating tunnel operates and performs as intended in accordance with the design qualification.

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2.4

RESPONSIBILITY:

The following shall be responsible;

Quality assurance officer/Executive – For Preparation of Protocol /Execution

Projects / Engineering Head – For execution

Production Head – For execution support

Quality Assurance Head – For adequacy and final approval

2.5

EXECUTION TEAM:

The satisfactory operation of the Sterilizing and depyrogenating tunnel shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Sterilizing and depyrogenating tunnel is operational and is satisfactorily working.

Execution team is responsible for the execution of operation of Sterilizing and depyrogenating tunnel. All executors involved with this protocol shall sign within the prescribed format given below:

DEPARTMENT	DESIGNATION	NAME	SIGNATURE	DATE
PROJECTS/ENGINEERING				
PRODUCTION				
QUALITY ASSURANCE				

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3.0	ACCEPTANCE CRITERIA:
3.1	The equipment shall be operational as per its specified operating instructions.
3.2	All SOPs for the equipment shall be verified and checked.
3.3	Training is important to all the concerned personnel.
3.4	All material of constructions of the contact parts to be checked as per the specifications.
3.5	All the functionality of equipment components to be checked.
3.6	All the safety features of the equipment shall be verified and utilities shall be available near the equipment.
3.7	The validity of the calibration of tests instruments shall be checked and all the required calibration of the components of the equipment shall be performed.

4.0	REVALIDATION CRITERIA:
	The machine has to be revalidated if
	<ul style="list-style-type: none"> • There are any major changes, which affect the performance of the equipment. • After major breakdown maintenance is carried out. • As per revalidation date and schedule

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5.0	OPERATIONAL QUALIFICATION PROCEDURE :
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5.1	Equipment description
Equipment Name	: Sterilizing and depyrogenating tunnel (10R)
Supplier / Manufacturer	: Filtra Teknopak Cleanroom Systems Ltd.
Overall Dimension (LXW)	: 1525(W) x 2340(H) x 3960(L) mm
Out put	: Out put 240 moulded & 300 Tubular 10 ml per minute
Model	: V – 900 – H2 C3
Service it offers	: Sterilizing and depyrogenating of vials
Location	: XYZ

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5.2	INSTRUCTION FOR FILLING THE CHECKLIST
5.2.1	In case of the compliance of the test use the word 'Complies' otherwise use 'Does not comply' to indicate non-compliance.
5.2.2	For identification of the components of the equipment and utilities use the word "yes" to show its presence and use 'No' to indicate the absence of the identity
5.2.3	Give the detailed information in the summary and conclusion part of the Operational Qualification report.
5.2.4	Whichever column is blank or not used 'NA' shall be used.

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5.3 VERIFICATION OF FUNCTIONAL CHECKS:

TESTS	ACCEPTANCE CRITERIA	OBSERVATIONS	VERIFIED BY (SIGN)	DATE
1. Switch on the machine.	The machine should be operational			
2. Check machine parameter (availability of Purified water and Compressed air) in manual mode	The machine should be operational in manual mode			
3. Check Load empty bottle at infeed.	Smoothly loading of bottles in infeed			
4. Start Auto Cycle and Check. Smooth loading washing and unloading of bottles.	The machine should be operational in Auto mode with respect to Smooth loading washing and unloading of bottles			
5. Check Functioning of operating parameters while washing trial.	All the operating parameter such as water pressure, air pressure should be with in given limit			
6. check Functioning of safety parameter.	All the interlocking system should functioning			
7. Check the leakage in gearbox, mechanical variator and Geneva Mechanism.	No leakages in gear box, mechanical variator and Geneva mechanism should be operational			

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8. Check vibration / noise less operation of machine drive unit.	vibration / noise less during operation			
9. Check Variable speed of Machine at minimum and maximum speed	The machine should run smoothly.			

TESTS	ACCEPTANCE CRITERIA	OBSERVATIONS	VERIFIED BY (SIGN)	DATE
10. Check operating of pumps	Water Pumps should be functioning during operational			

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5.4 VERIFICATION OF KEY FUNCTIONALITY OF CONTROL PANEL:

OPERATING PANEL : PLC- OPERATED MMI

MAKE : Messung

Sr. No.	Test Particulars	Specified Function	Observations	Checked By
01.	Switch on the main switch.	a) Power supply to the control panel should activate. b) Phase indicators R, Y, B should glow with live status of three phases. c) DPM's should display the current values of voltage and current on voltmeter and Ammeter.		
02.	Switch ON the VSS.	Line voltage for all three phases should be measured on the Voltmeter.		
03.	Switch ON the ASS	Line current for all three phases should be measured on the Ammeter.		
04.	Switch ON the MCB 'CF2'.	24 VAC control supply should be connect to the system.		

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Sr. No.	Test Particulars	Specified Function	Observations	Checked By
05.	Push the Push button 'Control Start'.	System control should be ON. a) Green Light should glow indicating Control on. b) The LED's on Relay output module should glow c) The LED's on Logic timer should glow. d) The LED's on PLC should glow e) K0 Contactor should On f) Exhaust fan should On g) 24 V DC power supply should On h) Panel view should displays Main menu		
06.	Press Enter button on the System setup shown in the Mainmenu.	Screen should show Date, Time, Autostart time and Process Off date.		
07.	Press F5 button from system setup.	It should go to Mainmenu.		

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S. No.	Test Particulars	Specified Function	Observations	Checked By
08.	Press Enter button on the Parameters shown in the Mainmenu screen.	<p>It should go to Parameter Program screen # 1 and it should shows the batch number, the employee number, print interval and excess temperature.</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; padding: 5px; margin: 5px;">Main menu</div> <div style="border: 1px solid black; padding: 5px; margin: 5px;">Accept F4</div> </div> <div style="margin: 10px 0 10px 40px;"> <div style="border: 1px solid black; padding: 5px; display: inline-block;">Pg.Dn F5</div> </div>		
09.	Press Pg.Dn F5 from Parameter program screen # 1.	<p>It should go to Parameter program screen # 2 .it should show vial type programming in ml.</p> <p>Vial type 0 <input type="checkbox"/> ml <input type="checkbox"/> F6 Vial type 1 <input type="checkbox"/> ml <input type="checkbox"/> F7 Vial type 2 <input type="checkbox"/> ml <input type="checkbox"/> F8 Vial type 3 <input type="checkbox"/> ml <input type="checkbox"/> F9</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; padding: 5px; margin: 5px;">Main menu F1</div> <div style="border: 1px solid black; padding: 5px; margin: 5px;">Pg.up F3</div> </div> <div style="margin: 10px 0 10px 40px;"> <div style="border: 1px solid black; padding: 5px; display: inline-block;">Pg.Dn F5</div> </div>		

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S. No.	Test Particulars	Specified Function	Observations	Checked By
10.	Press Pg.up F3 from the Parameter program screen # 2.	It should go to Parameter program screen # 1.		
11.	Press Pg.Dn F5 from the Parameter Program screen # 2. Mainmenu	It should show Parameter program screen # 3. <div style="border: 1px solid black; padding: 5px; margin: 5px 0;">Programming of set speed for conveyor belt.</div> <p>Conveyor Belt Speed <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Mm /min 0 1 2 3 vial type</p> <div style="display: flex; justify-content: space-around; margin: 5px 0;"> <div style="border: 1px solid black; padding: 2px 10px;">Main menu F1</div> <div style="border: 1px solid black; padding: 2px 10px;">Pg.up F3</div> </div> <div style="border: 1px solid black; padding: 2px 10px; margin: 5px auto; width: 100px;">Pg.Dn F5</div>		
12.	Press Pg.Dn F5 from the Parameter Program screen # 3.	It should show Parameter program screen # 4 <div style="border: 1px solid black; padding: 2px 10px; margin: 5px auto; width: 100px;">Vial type 0</div> <p>Set temperature for heater bank 1 2 3 4 5 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 6 7 3 fine series <input type="text"/> <input type="text"/> <input type="text"/> Conveyor start Blowers Off <input type="text"/> <input type="text"/></p> <div style="display: flex; justify-content: space-around; margin: 5px 0;"> <div style="border: 1px solid black; padding: 2px 10px;">Mainmenu F1</div> <div style="border: 1px solid black; padding: 2px 10px;">Pg.up F3</div> </div> <div style="border: 1px solid black; padding: 2px 10px; margin: 5px auto; width: 100px;">Pg.Dn F5</div>		

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S. No.	Test Particulars	Specified Function	Observations	Checked By																														
13.	Press Pg.Dn F5 from the Parameter Program screen # 4.	<p>It should show Parameter program screen # 5</p> <p style="text-align: center;">Vial type 1</p> <p>Set temperature for heater bank</p> <table style="width: 100%; border: none;"> <tr> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> </tr> <tr> <td style="text-align: center;">1</td> <td style="text-align: center;">2</td> <td style="text-align: center;">3</td> <td style="text-align: center;">4</td> <td style="text-align: center;">5</td> </tr> <tr> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td colspan="3"></td> </tr> <tr> <td style="text-align: center;">6</td> <td style="text-align: center;">7</td> <td colspan="3" style="text-align: right;">3 fine series</td> </tr> <tr> <td colspan="2">Conveyor start</td> <td colspan="3" style="text-align: right;">Blowers</td> </tr> <tr> <td>Off</td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td colspan="3" style="text-align: right;"> <input style="width: 20px; height: 15px;" type="checkbox"/> </td> </tr> </table> <p>Main menu F1 Pg.up F3</p> <p>Pg.Dn F5</p>						1	2	3	4	5						6	7	3 fine series			Conveyor start		Blowers			Off		<input style="width: 20px; height: 15px;" type="checkbox"/>				
1	2	3	4	5																														
6	7	3 fine series																																
Conveyor start		Blowers																																
Off		<input style="width: 20px; height: 15px;" type="checkbox"/>																																
14.	Press Pg.Dn F5 from the Parameter Program screen # 5.	<p>It should show Parameter program screen # 6</p> <p style="text-align: center;">Vial type 2</p> <p>Set temperature for heater bank</p> <table style="width: 100%; border: none;"> <tr> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> </tr> <tr> <td style="text-align: center;">1</td> <td style="text-align: center;">2</td> <td style="text-align: center;">3</td> <td style="text-align: center;">4</td> <td style="text-align: center;">5</td> </tr> <tr> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td colspan="3"></td> </tr> <tr> <td style="text-align: center;">6</td> <td style="text-align: center;">7</td> <td colspan="3" style="text-align: right;">3 fine series</td> </tr> <tr> <td colspan="2">Conveyor start</td> <td colspan="3" style="text-align: right;">Blowers</td> </tr> <tr> <td>Off</td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td colspan="3" style="text-align: right;"> <input style="width: 20px; height: 15px;" type="checkbox"/> </td> </tr> </table> <p>Main menu F1 Pg.up F3</p> <p>Pg.Dn F5</p>						1	2	3	4	5						6	7	3 fine series			Conveyor start		Blowers			Off		<input style="width: 20px; height: 15px;" type="checkbox"/>				
1	2	3	4	5																														
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S. No.	Test Particulars	Specified Function	Observations	Checked By
19.	Move cursor on to the Auto mode and press Enter button.	<p>It should has been entered in to Auto Mode screen</p> <div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; padding: 5px;">Process Status</div> <div style="border: 1px solid black; padding: 5px;">Blowers Status</div> </div> <p style="text-align: center;">Start Process Shut down Pro Stop Process</p> <div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; padding: 5px;">Main Menu F1</div> <div style="border: 1px solid black; padding: 5px;">Page Up F2</div> </div> <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: 100px;">Select Vial - F3</div>		
20.	Press F3 key from the Auto mode screen.	<p>It should have been show set the vial type to be used in auto mode.</p> <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: 100px;">Process</div>		
21.	Pressing F4 from the setting of vial type to be in Auto mode.	It should be entered into Auto mode.		
22.	Move cursor on to the Start Process in the Auto mode screen and press Enter button.	Process should be start in the Auto mode.		
23.	Move cursor on to the Shut Down Pro. in the Auto mode screen and press Enter button.	Process should be shut down.		

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24.	Move cursor on to the Stop Process in the Auto mode screen and press Enter button.	Process should be Stop.		
25.	Press the F2 key.	Should be entered into Auto mode.		
26.	Move cursor on to Semi-Auto mode and press Enter key.	<p>It should be entered in to Semi – Auto mode screen.</p> <p>Date : Time :</p> <p>Start Process Shutdown Pro. Stop Process</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 5px auto;">Process</div> <p>Vial Type :</p> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="border: 1px solid black; padding: 2px;">Blowers Status</div> <div style="border: 1px solid black; padding: 2px;">Main Menu</div> <div style="border: 1px solid black; padding: 2px;">Page up F2</div> <div style="border: 1px solid black; padding: 2px;">Select vial F3</div> <div style="border: 1px solid black; padding: 2px;">Output select</div> </div>		
27.	Press F3 key in the Semi – Auto mode screen.	It should be entered in to set the vial type to be used in Auto mode.		
28.	Press F4 key in the setting of vial type to be used in Auto mode.	It should be change or enter the vial type 1, 2 OR 3.		

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29.	Press F5 key in the Auto mode screen.	It should be entered into semi – Auto mode screen # 2 <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 5px 0;">Process status</div> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 5px 0;"> Process Start LAF Blower Exhaust Blower Sterilization blower Conveyor supply Conveyor Start </div> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 5px 0;">On / Off Status</div>		
30.	Press F1 key in the semi – Auto mode screen # 2	Programmed and output should be kept in Off in semi Auto mode.		
31.	Press F2 key in the Semi – Auto mode screen # 2	Programmed and output should be kept in ON in semi Auto mode		
32.	Press F5 key in the Semi – Auto mode Screen # 2	It should be entered in to Semi – Auto mode screen # 3 Heater Bank 1 Heater Bank 2 Heater Bank 3 Heater Bank 4 Heater Bank 5 Heater Bank 6 Heater Bank 7 <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 5px 0;">ON / OFF Status</div>		
33.	Press F3 key from Semi-Auto mode screen # 3	It should be entered into Semi – Auto mode screen # 2.		

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34.	Move cursor on to Maintenance Mode and press Enter key.	It should be entered into maintenance mode screen # 1 <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px auto; text-align: center;">Process</div> Vial type : Maintenance Mode ON Maintenance Mode OFF <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="border: 1px solid black; padding: 2px;">Main Menu F1</div> <div style="border: 1px solid black; padding: 2px;">Page up F3</div> <div style="border: 1px solid black; padding: 2px;">Page down F5</div> </div>		
35.	Move cursor on to Maintenance Mode ON and press Enter key.	Maintenance Mode screen should show the status Maintenance Mode ON.		
36.	Move cursor on to Maintenance Mode OFF and press Enter key.	Maintenance Mode screen should show the status Maintenance Mode OFF.		
37.	Press F5 key from the Maintenance mode screen # 1	It should be entered into Maintenance mode screen # 2 <div style="border: 1px solid black; width: 100px; height: 20px; margin: 5px auto; text-align: center;">Process</div> Process start Output LAF blower Command / Status Exhaust blower Sterilization blower Conveyor supply Conveyor start		

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38.	Move cursor on to Process start and press F1 key.	a) Command & status should show ON b) Pressure Indicators Should ON c) IP 5 & RL 5 red lights should glow in the Relay output Module. d) Temperature Controller should ON e) Output 15 in the PLC Should glow.		
39.	Move cursor on to Process start and press F2 key.	a) Command & status should show OFF b) Pressure Indicators Should OFF c) IP 5 & RL 5 red lights should Not glow in the Relay output Module. d) Temperature Controller should OFF e) Output 15 in the PLC Should stop glowing.		
40.	Move cursor on to LAF Blower and press F1 key.	a) K 1 Contactor should ON b) Out put 0 in the PLC should glow red light.		
41.	Move cursor on to LAF Blower and press F2 key.	a) K 1 Contactor should OFF b) Out put 0 in the PLC should stop glowing red light.		

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42.	Move cursor on to Exhaust Blower and press F1 key.	a) K 2 Contactor should ON b) Out put 1 in the PLC should glow red light.		
43.	Move cursor on to Exhaust Blower and press F2 key.	a) K 2 Contactor should OFF b) Out put 1 in the PLC should stop glowing red light.		
44.	Move cursor on to Sterilization blower and press F1 key.	a) K 3 Contactor should ON b) Out put 1 in the PLC should glow red light. c) Input 13 in the PLC should glow red light.		
45.	Move cursor on to Sterilization blower and press F2 key.	a) K 3 Contactor should OFF b) Out put 1 in the PLC should not glow red light. c) Input 13 in the PLC should stop glowing red light.		
46.	Move cursor on to Conveyor supply and press F1 key.	a) K 4 Contactor should ON b) Out put 3 in the PLC should glow red light.		
47.	Move cursor on to Conveyor supply and press F2 key.	a) K 4 Contactor should OFF b) Out put 3 in the PLC should stop glowing red light.		
48.	Move cursor on to Conveyor Start and press F1 key.	a) Relay output module IP 1 & RL1 red lights should glow. b) Out put 12 in the PLC should glow red light.		
49.	Move cursor on to Conveyor Start and press F2 key.	a) Relay output module IP 1 & RL1 red lights should OFF. b) Out put 12 in the PLC should stop glowing red light.		

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50.	Press F5 in the Maintenance mode Screen # 2.	<p>It should be entered into Maintenance mode Screen # 3.</p> <div style="border: 1px solid black; padding: 2px; display: inline-block;">Maintenance mode status</div> <p>Heater Bank 1 Output Command / Status Heater Bank 2 Heater Bank 3 ON/OFF Heater Bank 4 Heater Bank 5 Heater Bank 6 Heater Bank 7</p>		
51.	Move cursor on to Heater Bank 1 and press F1 key.	a) K 5 Contactor should ON b) Output 4 in the PLC should glow.		
52.	Move cursor on to Heater Bank 1 and press F2 key.	a) K 5 Contactor should OFF b) Output 4 in the PLC should stop glowing.		
53.	Move cursor on to Heater Bank 2 and press F1 key.	a) K 6 Contactor should ON b) Output 5 in the PLC should glow.		
54.	Move cursor on to Heater Bank 2 and press F2 key.	a) K 6 Contactor should OFF b) Output 5 in the PLC should stop glowing.		
55.	Move cursor on to Heater Bank 3 and press F1 key.	a) K 7 Contactor should ON b) Output 6 in the PLC should glow.		
56.	Move cursor on to Heater Bank 3 and press F2 key.	a) K 7 Contactor should OFF b) Output 6 in the PLC should stop glowing.		
57.	Move cursor on to Heater Bank 4 and press F1 key.	a) K 8 Contactor should ON b) Output 7 in the PLC should glow.		
58.	Move cursor on to Heater Bank 4 and press F2 key.	a) K 8 Contactor should OFF b) Output 7 in the PLC should stop glowing.		

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59.	Move cursor on to Heater Bank 5 and press F1 key.	a) K 9 Contactor should ON b) Output 8 in the PLC should glow.		
60.	Move cursor on to Heater Bank 5 and press F2 key.	a) K 9 Contactor should OFF b) Output 8 in the PLC should stop glowing.		
61.	Move cursor on to Heater Bank 6 and press F1 key.	a) K 10 Contactor should ON b) Output 9 in the PLC should glow.		
62.	Move cursor on to Heater Bank 6 and press F2 key.	a) K 10 Contactor should OFF b) Output 9 in the PLC should Stop glowing.		
63.	Move cursor on to Heater Bank 7 and press F1 key.	a) K 11 Contactor should ON b) Output 10 in the PLC should glow.		
64.	Move cursor on to Heater Bank 7 and press F2 key.	a) K 11 Contactor should OFF b) Output 10 in the PLC should stop glowing.		
65.	Move cursor on to Display and press enter key.	It should be entered into display screen # 1 Date : Time : Process status Vial Type : Moulded / Tubular Process Temperature Sterilization : Drying : Cooling : Stabilizing : Conveyor Speed : Set Speed : <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="border: 1px solid black; padding: 5px; text-align: center;">Main Menu F1</div> <div style="border: 1px solid black; padding: 5px; text-align: center;">Page Down F5</div> </div>		

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S. No.	Test Particulars	Specified Function	Observations	Checked By
66.	Press F5 key from the Display screen #1	It should be entered into Display screen # 2 Set Process Status Temperature : STERL TEMP : Heater Bank 1 Conv spd mm/min Heater Bank 2 : Vial type Heater Bank 3 : Heater Bank 4 : <input type="text" value="Main"/> Heater Bank 5 : <input type="text" value="Menu"/> Heater Bank 6 : <input type="text" value="F1"/> Heater Bank 7 : Bank 3 series : <input type="text" value="Page"/> Conveyor start : <input type="text" value="Up"/> Blower OFF : <input type="text" value="F4"/> <input type="text" value="Page down"/> <input type="text" value="F5"/>		
67.	Press F5 key from the Display screen # 2	It should be entered in to Display screen # 3 and it should show OUTPUT STATUS LAF blower Output : <input type="text" value="ON"/> Exhaust blower : <input type="text" value="OFF"/> Ster.blower output : <input type="text" value="status"/> Conveyor supply : Conveyor start : Process start : <input type="text" value="Main"/> <input type="text" value="Menu"/> <input type="text" value="F1"/> <input type="text" value="Page"/> <input type="text" value="Up"/> <input type="text" value="F4"/> <input type="text" value="Page"/> <input type="text" value="Down"/> <input type="text" value="F5"/>		

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S. No.	Test Particulars	Specified Function	Observations	Checked By
68.	Press F5 key from the Display screen # 3	<p>It should be entered into Display screen # 4 and it should show</p> <p>OUTPUT STATUS</p> <p>Heater Bank 1 : <input type="checkbox"/> ON Heater Bank 2 : <input type="checkbox"/> / Heater Bank 3 : <input type="checkbox"/> OFF Heater Bank 4 : <input type="checkbox"/> status Heater Bank 5 : <input type="checkbox"/> Heater Bank 6 : <input type="checkbox"/> Heater Bank 7 : <input type="checkbox"/></p> <p>Vial Select Output Output 13 : On / Off Status Output 14 : On / Off Status Vial Type :</p> <p> <input type="checkbox"/> Main Menu F1 <input type="checkbox"/> Page Up F4 <input type="checkbox"/> Page Down F5 </p>		
69.	Press F5 key from the Display screen # 4	<p>It should be entered into Display screen # 5 and it should show</p> <p>INPUT STATUS</p> <p>LAF drying blower Trip: LAF cooling blower 1 Trip : ON LAF cooling blower 2 Trip : / Vapour Extract Blower Trip : OFF Main exhaust blower 1 Trip : S Main exhaust blower 2 Trip : T Sterilization blower 1 Trip : A Sterilization blower 2 Trip : T Sterilization AC drive Trip : U Conveyor motor Trip : S Conveyor AC drive Trip :</p>		

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S. No.	Test Particulars	Specified Function	Observations	Checked By
70.	Press F5 key from the Display screen # 5	<p>It should be entered into Display screen # 6 and it should show</p> <p>INPUT STATUS</p> <p>Sterilization blower ON :Yes/ No Heater safety switch 1 : ON Heater safety switch 2 : / Heater excess temp TS1 : OFF Heater excess Temp TS2 : S Conveyor remote start : T Conveyor supply ON : A Adequate Input PX1-L : T Adequate Input PX1-R : U Excess Out feed PX2 : S 24 V DC control supply :</p>		
71.	Move cursor on to Alarms & press enter key.	<p>It should be enter to Alarm screen # 1</p> <p>Alarm Screen # 1</p> <p>Date : Time :</p> <p>Alarm Status</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; padding: 5px; text-align: center;">Main Menu F1</div> <div style="border: 1px solid black; padding: 5px; text-align: center;">Alarm ACK F2</div> </div> <div style="margin-top: 10px; text-align: center;"> <div style="border: 1px solid black; padding: 5px; display: inline-block;">Proces s status</div> </div>		
72.	Move cursor on to Credit and press enter key.	<p>It should be enter in to Credit screen.</p> <p>CREDIT</p> <p>THEPLCSYSTEM CONCEIVED AND DEVELOPED BY TECHNO ELWECTRIQUE SHOP,3,MINIVILLA, SHREE KRISHNA DHAM, KISAN NAGAR,3,Nr.GARDEN, ROAD NO.22,WAGLE ESTATE, THANE 400604 TEL : 91-22-5801275 PLC :- SLC – 500 + PV 550</p>		

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S. No.	Test Particulars	Specified Function	Observations	Checked By
73.	Move cursor on to MIMIC and press enter key.	a) It should be entered into MIMIC screen. b) Should show status of all 4 LAF blowers , both the Sterilization blowers and heater banks above the Conveyor belt. c) Conveyor belt should show in the middle section , along with the current speed. d) four – zone temperature should be displayed below the respective zone. e) Vapour extract , main exhaust blower – 1 & 2 should be shown below the conveyor belt. f) Should be with selected vial type with capacity and the container type. g) last and bottom field message should show the message of operation with process status.		

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5.5 VERIFICATION OF SAFETY FEATURE(S) :

S. No.	Safety Feature	Specified Function	Observations	Checked by
01.	Set the Ampere button [Motor rating Amps] of LAF drying blower 0L1 to the minimum Amps.	a) K1 Contactor should OFF. b) Alarm should give audible message as 'One or More Trip inputs – 1to12 ON' Micro switch input fail OR Thermostat input ON OR Sterilization blower OFF		
02.	Set the Ampere button [Motor rating Amps] of LAF cooling blower 1 0L1A to the minimum Amps.	a) K1 Contactor should OFF. b) Alarm should give audible message as 'One or More Trip inputs – 1to12 ON' Micro switch input fail OR Thermostat input ON OR Sterilization blower OFF		
03.	Set the Ampere button [Motor rating Amps] of LAF cooling blower 2 0L1 B to the minimum Amps.	a) K1 Contactor should OFF. b) Alarm should give audible message as 'One or More Trip inputs – 1to12 ON' Micro switch input fail OR Thermostat input ON OR Sterilization blower OFF		

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S. No.	Safety Feature	Specified Function	Observations	Checked by
04.	Set the Ampere button [Motor rating Amps] of Vapour extract blower 0L2 to the minimum Amps.	a) K2 Contactor should OFF. b) Alarm should give audible message as 'One or More Trip inputs – 1to12 ON' Micro switch input fail OR Thermostat input ON OR Sterilization blower		
05.	Set the Ampere button [Motor rating Amps] of Main exhaust blower 1 0L2 A to the minimum Amps.	a) K2 Contactor should OFF. b) Alarm should give audible message as 'One or More Trip inputs – 1to12 ON' Micro switch input fail OR Thermostat input ON		
06.	Set the Ampere button [Motor rating Amps] of Main exhaust blower 2 0L2 B to the minimum Amps.	a) K2 Contactor should OFF. b) Alarm should give audible message as 'One or More Trip inputs – 1to12 ON' Micro switch input fail OR Thermostat input ON OR		

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S. No.	Safety Feature	Specified Function	Observations	Checked by
07	Set the Ampere button [Motor rating Amps] of Sterilization blower 1 OL3 to the minimum Amps.	a)K3 Contactor should OFF. b)Alarm should give audible message as 'One or More Trip inputs – 1to12 ON' Micro switch input fail OR Thermostat input ON OR Sterilization blower		
08.	Set the Ampere button [Motor rating Amps] of Sterilization blower 2 OL3 A to the minimum Amps.	a) K3 Contactor should OFF. b)Alarm should give audible message as 'One or More Trip inputs – 1to12 ON' Micro switch input fail OR Thermostat input ON OR Sterilization blower		
09.	Set the Ampere button [Motor rating Amps] of Conveyor motor OL4 to the minimum Amps.	a) K4 Contactor should OFF. b)Alarm should give audible message as 'One or More Trip inputs – 1to12 ON' Micro switch input fail OR Thermostat input ON OR Sterilization blower		
10.	Press the emergency switch.	Machine should stop.		
11.	Switch OFF the Main electrical supply.	Electrical supply should cut off indicates red, yellow , blue led lights stop glowing.		

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S. No.	Safety Feature	Specified Function	Observations	Checked by
12.	Check for the Earth connection.	The electrical connection should provide with earth connection.		

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6.0 HEAT DISTRIBUTION STUDY EMPTY TUNNEL STERILIZER

OBJECTIVE

The objective of the test is to ensure that:

- The tunnel sterilizer when operated empty is capable of producing the uniform temperature profiles, $\pm 10^{\circ}\text{C}$ of the highest temperature set point set in the PLC of the equipment for the first heater bank.
- The temperature distribution is uniform throughout the sterilization period.
- Any location(s) where the temperature sensor is placed, not achieving minimum sterilization and depyrogenation temperature of 300°C during the sterilization period will be considered as cold spot.
- If sterilization temperature (300°C) is not achieved throughout the cycle, the temperature set points, conveyor speed and the zone pressures shall be reviewed and cycle to be repeated.

LOAD DETAILS

- Empty Sterilizer Without Any Load

PROCEDURE

- Record the set parameters for the sterilization cycle to be operated during the test, in the Annexure- 1.
- Placing minimum 16 number of temperature sensors shall carry out heat distribution study of the empty sterilizer without load. Tie temperature sensors firmly to the SS zig in such a way that the tips of the temperature sensors are not touching any of the metallic surfaces.
- The placement of the temperature sensors shall be in equal distance from one another from left to right side of the conveyor belt of the sterilizing tunnel.
- Record the position of the temperature sensors in a representative schematic form in the Annexure- 2.
- Connect the probes to a suitable data logger, which can scan and print the actual temperatures with respect to time.

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- Operate the tunnel sterilizer as per SOP. No. also start the data logger to record the actual temperatures within the sterilization zone with respect to time.

TEMPERATURE SENSOR PLACEMENT IN THE EMPTY TUNNEL STERILIZER

(NOTE: The temperature sensors shall be placed in the predetermined locations with predetermined sensor numbers corresponding to the data logger channels).

SENSOR NUMBER	LOCATION IN THESTERILIZER	SENSOR NUMBER	LOCATION IN THE STERILIZER
1	LEFT SIDE OF CONVEYOR	9	NEXT TO 8
2	NEXT TO 1	10	NEXT TO 9
3	NEXT TO 2	11	NEXT TO 10
4	NEXT TO 3	12	NEXT TO 11
5	NEXT TO 4	13	NEXT TO 12
6	NEXT TO 5	14	NEXT TO 13
7	NEXT TO 6	15	NEXT TO 14
8	NEXT TO 7	16	RIGHT SIDE OF CONVEYOR

JUSTIFICATION FOR THE TEMPERATURE SENSOR LOCATION CHOICE

- Sensor nos. **1 and 16**- the conveyor belt side of the tunnel is most critical area where there may be a possibility of cold spot because the hot air re-circulation ducts are below the conveyor, near by the either conveyor edges.
- Sensor nos. **2 to 15**- to verify the heat distribution across the conveyor belt from left side to right side.

When the sterilization cycle completes:

- Collect strip chart from the multipoint temperature recorder of the tunnel control panel and also enclose the printout of the tunnel sterilizer along with Annexure-3
- Download the data from the data logger into the computer for data analysis and printing.
- Enclose the printouts obtained from the data logger in Annexure-4.

If the heat distribution study results are acceptable perform three consecutive replicate runs to demonstrate cycle and sterilizer reproducibility.

Compile the data generated during the operational qualification test to proceed for Performance Qualification of Equipment.

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Acceptance criteria

- There should be uniform temperature distribution across the conveyor belt during the sterilization hold period.
- The temperature at each temperature sensor should be within the range +/- 10⁰C of the maximum set point of the heater banks (1st heater bank) during the complete sterilization hold period.

Observations and results

Record the observations and results in formats.

Prepare summary report and enclose along with Data logger printouts.

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5.8 VERIFICATION OF COMPONENT (S) TO BE CALIBRATED

Verify that the drafted calibration procedures for different identified components in Sterilizing and depyrogenating tunnel are adequate and appropriate covering the operating range(s). e.g. Pressure gauge, temperature gauge, temperature indicator cum controller etc (As applicable).

COMPONENT / PART TO BE CALIBRATED	SERIAL NO.	EXTERNAL CALIBRATION (ATTACH CERTIFICATE)	VERIFIED BY (SIGN)	DATE

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5.9 DEFICIENCY AND CORRECTIVE ACTION(S) REPORT(S)

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.

Description of deficiency:

Corrective action(s) taken :

Reviewed By:
Date

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6.0 OPERATIONAL QUALIFICATION FINAL REPORT:

6.1 SUMMARY :

6.2 CONCLUSION :

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6.3 FINAL REPORT APPROVAL

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol.

Signature in the block below indicate that all items in this qualification report of Sterilizing and depyrogenating tunnel has been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
		ENGINEERING		
		PRODUCTION		
		QUALITY ASSURANCE		