

**OPERATIONAL QUALIFICATION PROTOCOL
CIP SKID
XYZ PHARMA-BIOTECH COMPANY
USA**

Attachment #6 Operator Interface

Verify that the OIT screen and sub-screens are as expected. Note: Document any failing results.

Panel View			
<p><u>Setup Screen:</u> The screen below will appear after pressing F2 (SETUP) button on the Main Menu.</p> <div style="text-align: center; padding: 20px;"> <pre style="font-family: monospace; font-size: 1.2em;"> F1 ENTER TEMP SET POINT [###] F2 ENTER PRESS SET POINT [###] [F3] [F4] ALM SP MAIN </pre> </div>			
Function	Expected Results	Pass/Fail	Initials/Date
This screen displays the setpoint screen. Users can review and change the operating setpoints.	This screen appears when accessed. Information on screen is correct.	Pass/Fail	
Press the F3 and F4 function key.	Screen switches to the correct screen when the function keys are pressed.	Pass/Fail	
Press F1 and F2 to change setpoints.	Popup screen appears allowing operators to change setpoints. Setpoints are changed.	Pass/Fail	

Comments: _____

Acceptance Criteria: The actual results are the same as the expected results or explained.

Meets Acceptance Criteria? () Yes () No

Reviewed by: _____

Date: _____

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Verify that the OIT screen and sub-screens are as expected. Note: Document any failing results.

Panel View			
<p><u>Alarm Setpoint Screen:</u> The screen below will appear after pressing F3 (ALM SP) button on the Setup Screen.</p> <div style="text-align: center; padding: 10px;"> <pre style="font-family: monospace; font-size: 1.2em;"> F1 Lo Press [###] Dev Alm SP F2 Lo Temp [###] Dev Alm SP F3 Tank [###] [F4 Lo Alm SP Back] </pre> </div>			
Function	Expected Results	Pass/Fail	Initials/Date
This screen displays the alarm setpoint screen. Users can review and change the alarm setpoints.	This screen appears when accessed. Information on screen is correct.	Pass/Fail	
Press the F4 function key.	Screen switches to the correct screen when the function key is pressed.	Pass/Fail	
Press F1, F2, and F3 to change setpoints.	Popup screen appears allowing operators to change setpoints. Setpoints are changed.	Pass/Fail	

Comments: _____

Acceptance Criteria: The actual results are the same as the expected results or explained.

Meets Acceptance Criteria? () Yes () No

Reviewed by: _____

Date: _____

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Verify that the OIT screen and sub-screens are as expected. Note: Document any failing results.

Panel View									
<p><u>Auto / Manual Toggle Screen:</u> The screen below will appear after pressing F3 (A/M) button on the Main Menu.</p> <div style="text-align: center; margin: 10px 0;"> <table style="border: 2px solid black; width: 80%; margin: 0 auto;"> <tr> <td style="border: 1px solid black; padding: 5px; font-family: monospace; font-size: 1.2em;">F1 Auto/Man</td> <td style="border: 1px solid black; padding: 5px; font-family: monospace; font-size: 1.2em;">Auto</td> </tr> <tr> <td style="border: 1px solid black; padding: 5px; font-family: monospace; font-size: 1.2em;">F2 Ent Drv Spd%</td> <td style="border: 1px solid black; padding: 5px; font-family: monospace; font-size: 1.2em;">###</td> </tr> <tr> <td style="border: 1px solid black; padding: 5px; font-family: monospace; font-size: 1.2em;">F3 STOP</td> <td style="border: 1px solid black; padding: 5px; font-family: monospace; font-size: 1.2em;">F4 Main</td> </tr> </table> </div>				F1 Auto/Man	Auto	F2 Ent Drv Spd%	###	F3 STOP	F4 Main
F1 Auto/Man	Auto								
F2 Ent Drv Spd%	###								
F3 STOP	F4 Main								
Function	Expected Results	Pass/Fail	Initials/Date						
This screen displays the automatic / manual toggle screen. Users can start and stop the pump and change the pump status between automatic and manual.	This screen appears when accessed. Information on screen is correct.	Pass/Fail							
Press the F4 function key.	Screen switches to the correct screen when the function key is pressed.	Pass/Fail							
Press F1 to toggle between automatic and manual modes.	Equipment toggles between automatic and manual modes.	Pass/Fail							
When in manual mode press F2 to change setpoints.	Popup screen appears allowing operators to change setpoints. Setpoint is changed.	Pass/Fail							
While the pump is running press F3.	The pump stops.	Pass/Fail							

Comments: _____

Acceptance Criteria: The actual results are the same as the expected results or explained.

Meets Acceptance Criteria? () Yes () No

Reviewed by: _____ Date: _____

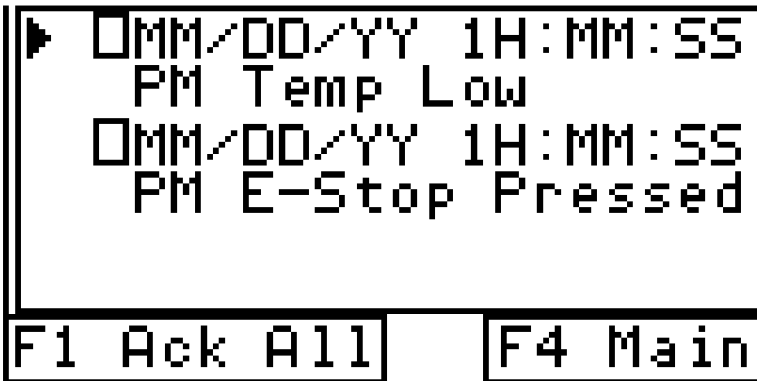
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Verify that the OIT screen and sub-screens are as expected. Note: Document any failing results.

Panel View

Alarm History Screen: The screen below will appear after pressing F4 (ALARM) button on the Main Menu.



Function	Expected Results	Pass/Fail	Initials/Date
This screen displays the alarm history screen. Users can review the alarm history from this screen.	This screen appears when accessed. Information on screen is correct.	Pass/Fail	
Press the F4 function key.	Screen switches to the correct screen when the function key is pressed.	Pass/Fail	
Press F1 while there are active alarms.	The alarms are acknowledged.	Pass/Fail	

Comments: _____

Acceptance Criteria: The actual results are the same as the expected results or explained.

Meets Acceptance Criteria? () Yes () No

Reviewed by: _____ Date: _____

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Verify that the OIT screen and sub-screens are as expected. Note: Document any failing results.

Panel View			
<p><u>Alarm Pop-up Banner:</u> The screen below will appear after an alarm is received.</p> <div style="border: 2px solid black; padding: 10px; text-align: center; margin: 10px auto; width: fit-content;"> <p style="font-size: 24px; margin: 0;">ALARM</p> <p style="font-size: 24px; margin: 5px 0 0 0;">Temp Low</p> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="border: 1px solid black; padding: 5px; text-align: center;"> <p style="font-size: 18px; margin: 0;">F1</p> <p style="font-size: 18px; margin: 0;">Clear</p> </div> <div style="border: 1px solid black; padding: 5px; text-align: center;"> <p style="font-size: 18px; margin: 0;">F4</p> <p style="font-size: 18px; margin: 0;">Ack</p> </div> </div> </div>			
Function	Expected Results	Pass/Fail	Initials/Date
This screen displays the alarm popup banner indicating an alarm has been received.	This screen appears when an alarm is received. Information on screen is correct.	Pass/Fail	
Press the F4 function key.	The alarm is acknowledged. Siren stops sounding.	Pass/Fail	
Press the F1 function key.	The alarm banner disappears.	Pass/Fail	

Comments: _____

Acceptance Criteria: The actual results are the same as the expected results or explained.

Meets Acceptance Criteria? () Yes () No

Reviewed by: _____

Date: _____

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Attachment #7 Functional Verification

Verify that the equipment/system operations function as indicated.

Procedure					Expected Result	Pass/Fail	Initials/Date
I/O	Input Test Description	Expected Result	Actual Result	Verified by/Date			
I/8	E-Stop is pressed.	LED #1/8 is off					
	E-Stop is not pressed	LED #1/8 is on					
O/0	Steam valve is closed.	LED #4 is off					
	Steam valve is open.	LED #4 is on					
O/1	VFD is not enabled.	LED #5 is off					
	VFD is enabled.	LED #5 is on					
IV1(+)	Pressure transmitter signal	Range 4-20mA					
IV2(+)	Level transmitter signal	Range 4-20mA					
O(+)	Temperature transmitter signal	Range 4-20mA					
Power Up the Equipment. Manually actuate the I/O by either simulating a condition or forcing a condition to activate the output. Verify the system I/O act accordingly.					I/O operates as expected	Pass/Fail	

Comments: _____

Acceptance Criteria: The actual results are the same as the expected results or explained.

Meets Acceptance Criteria? () Yes () No

Reviewed by: _____

Date: _____

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Attachment #7 Functional Verification

Verify that the equipment/system operations function as indicated.

Procedure	Expected Result	Pass/Fail	Initials/Date
Hook up CIP skid. Fill tank full with water. system automatically.	Use control panel and operate the	N/A	N/A
<u>Temperature Heating Verification</u> While the system is operating automatically, verify tank heats water from 20°C to 50°C in 1-1/2 hours.	Starting Temperature: _____ Final Temperature: _____ Time to Reach Temp.: _____	Pass/Fail	
<u>Circulation Verification</u> While the system is operating automatically, verify the pump circulates water while heating. Pump continues to circulate water until low tank level is reached.	Pump runs during heating. When low tank level is reached, pump stops. Low Level Setpoint: _____	Pass/Fail	
<u>Washing Verification</u> Connect system to lyophilizer CIP. Operate the system automatically. Operate lyophilizer CIP cycle. Observe operation.	CIP system automatically circulates and heats water to temperature setpoint. When temperature setpoint is achieved, a message on the OIT is displayed indicating CIP is ready. After pressing continue button, the operator operates the lyophilizer CIP cycle. While the CIP cycle is operating, discharge pressure is maintained. System stops when tank level drops to low tank level setpoint.	Pass/Fail	

Comments: _____

Acceptance Criteria: The actual results are the same as the expected results or explained.

Meets Acceptance Criteria? () Yes () No

Reviewed by: _____

Date: _____

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Attachment #8 Alarms, Safeties and Interlocks

Verify that the alarms, safeties and interlocks function as indicated.

Procedure	Expected Result	Pass/Fail	Initials/Date
<u>Temperature Alarm</u> While operating the equipment, verify the temperature alarm activates if low temperature is received.	Alarm message is received on the OIT when the low temperature alarm setpoint is tripped.	Pass/Fail	
<u>Pressure Alarm</u> While operating the equipment verify the pressure alarm activates if low pressure is received.	Alarm message is received on the OIT when the low pressure alarm setpoint is tripped.	Pass/Fail	
<u>Level Alarm</u> While operating the equipment verify the level alarm activates if low tank level is received.	Alarm message is received on the OIT when the low level alarm setpoint is tripped.	Pass/Fail	
<u>Emergency Stop</u> While operating the equipment press the E-Stop button.	Electrical power is disconnected from the system. The steam valve reverts to a safe state. Unit is placed into standby.	Pass/Fail	

Comments: _____

Acceptance Criteria: The actual results are the same as the expected results or explained.

Meets Acceptance Criteria? () Yes () No

Reviewed by: _____

Date: _____