

**OPERATIONAL QUALIFICATION PROTOCOL
VIAL WASHER
XYZ PHARMA-BIOTECH, INC.
USA**

Attachment #6 Functional Verification

Verify that the equipment/system operations function as indicated.

Procedure	Expected Result	Pass/Fail	Initials/Date
<u>Material Handling</u> Use flip trays and load vials into washer. Wash vials. Remove vials and transfer them onto depyrogenation trays. Repeat test for each vial size.	Vial packs fit into flip trays. Vials fit into vial holders. Vials transfer into depyrogenation trays correctly.	Pass/Fail	
<u>Endotoxin Challenge</u> Add endotoxin in the amount of 1000 to 10,000 EU per vial to 10 vials. Swirl and then dry at 45°C in a vacuum oven for 1 hour or until no visual water is present. Add the spiked vials into a wash load. Wash the vials and then test for endotoxin. Repeat test for each vial size.	Test results in a 3 log reduction in endotoxin for all vial sizes.	Pass/Fail	
<u>Washing Verification</u> Spray vials with riboflavin solution. Verify presence using black light. Load vials into washer run wash cycle. Inspect vials with black light. Repeat test for each vial size.	Test results in visual absence of riboflavin for all vial sizes.	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 Alarms, Safeties and Interlocks

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

Procedure	Expected Result	Pass/Fail	Initials/Date
<u>Water Ready Interlock</u> When the tanks are filling or have not charged with air, press the vial washer start button.	Vial washer does not run.	Pass/Fail	
<u>Air Pressure Fault</u> While running a wash cycle, the equipment loses air pressure.	The yellow purge / fault button is blinks indicating a valid cycle did not complete. Pressing button places the equipment into standby.	Pass/Fail	
<u>Emergency Stop</u> While operating the equipment press the E-Stop button.	All valves revert to safe state. System relieves air pressure. 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: _____

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Attachment #8 Sequence of Operation

Verify the sequence of operation.

Sequence	Procedure	Expected Results	Pass/Fail	Initials/Date
Power Up and System Operation				
1	Ensure that the machine is connected to a 120VAC power supply.	Machine is connected to a 120VAC power supply.	Pass/Fail	
2	Verify air is connected and on.	Air pressure is on.	Pass/Fail	
3	Connect RODI and WFI water lines. Open valves.	Lines are connected and valves are open.	Pass/Fail	
4	Turn the main power switch to the "on" position.	Equipment powers up.	Pass/Fail	
Normal Wash Sequence				
5	Verify unit is in standby mode.	Both pushbutton lights extinguished. No water in either tank.	Pass/Fail	
6	Operator initiates fill/prime sequence by pressing green button.	Green button blinks while fill/prime sequence proceeds.	Pass/Fail	
		Unit begins to fill tanks by opening water valves.	Pass/Fail	
		Level indicators reach fill level set point fill valves and vent valve close.	Pass/Fail	
		Air to tanks valve opens.	Pass/Fail	
		Pressure switch makes indicating sufficient air pressure.	Pass/Fail	
		WFI and RODI to washer valves open completing fill prime seq.	Pass/Fail	

Comments: _____

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

Meets Acceptance Criteria? () Yes () No

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Attachment #8 Sequence of Operation

Verify the sequence of operation.

Sequence	Procedure	Expected Results	Pass/Fail	Initials/Date
Power Up and System Operation				
7	Observe lights.	Green button illuminates solid indicating unit ready for washer to start.	Pass/Fail	
8	Using flip trays load vials into vial washer, close lid.	Vials are loaded and lid is closed.	Pass/Fail	
9	Operator places vial washer hand switch to run.	Hand switch in run.	Pass/Fail	
10	Operator initiates washer cycle by pressing start button on washer for 1-2 seconds.	Washer automatically runs a washing cycle.	Pass/Fail	
11	Remove vials, and observe control skid.	Control skid repeats the filling and ready sequences to allow another wash.	Pass/Fail	

Comments: _____

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

Meets Acceptance Criteria? () Yes () No

Reviewed by: _____

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Attachment #8 Sequence of Operation

Verify the sequence of operation.

Sequence	Procedure	Expected Results	Pass/Fail	Initials/Date
Purge Sequence at End of Batch				
12	Operator loads last tray of vials and initiates purge to empty skid tanks of water by pressing and holding yellow purge button for 3 seconds until purge button illuminates solidly. Operator presses vial wash button for 1-2 seconds.	Washer completes wash of last tray. Unit skips fill portion of fill/prime cycle and indicates ready by illuminating green button solidly.	Pass/Fail	
13	Operator removes vials and closes lid.	Vials are removed and lid is closed.	Pass/Fail	
14	Operator initiates washer cycle by pressing start button for 1-2 seconds.	Cycle runs without refilling tanks with water.	Pass/Fail	
15	Operator continues to purge unit by running washer cycles each time green button illuminates solidly.	Tank levels fall below 0 %. Operator continues to run washer cycles until 30 seconds of run time elapse at which time skid will enter standby as indicated by both lights extinguishing.	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: _____