

FACTORY ACCEPTANCE TEST



Title: FAT-200219-TM01-Hold_Attachment08

Parent Document ID: FAT-200219-TM01-Hold

Page 1 of 6

1.1 Equipment Module - States

1.1.1 Acceptance Criteria

For each equipment module state, verify the following are true for each step of the state:

1. The test step executes the described step action.
2. The step does not continue until the transition criteria are met.
3. The test steps proceed as expected without any unexpected stuck conditions.

If all the criteria are met, mark the test step as 'Pass'. If all the criteria are not met, evaluate if the discrepancy requires a deviation resolution as detailed in FAT-200219-TM01-Hold Section 9.4 (Protocol Deviation Resolution).

1.1.2 Test Traceability

This test section verifies the states required by the equipment modules as specified in the following specification sections:

- Document # SPC-200219-SLP_DS, Section 6.2 "Large Solution Prep Hold Tank (TM01-Hold) Unit"

Comments

☐ N/A

Reviewer
Signature

Review
Date

CONFIDENTIAL INFORMATION

Do not distribute outside of Upsher-Smith Laboratories without approval or a confidentiality agreement.
Printed or downloaded documents must be verified against the effective version.

FACTORY ACCEPTANCE TEST

Title: FAT-200219-TM01-Hold_Attachment08

Parent Document ID: FAT-200219-TM01-Hold

Page 2 of 6

1.1.3 EM-TM01-Hold-WIP

1.1.3.1 Idle

Step	Step Action	Transition Criteria	Next Step	Pass / Fail	Initial / Date
0	Command XS-TM01-010A to Close Command XS-TM01-010B to Close Command XS-TM01-021A to Close Command XS-TM01-021B to Close Command XS-TM01-026 to Close Command XS-TM01-035 to Close Command XS-TM01-033 to Close	XS-TM01-010A is Closed AND XS-TM01-010B is Closed AND XS-TM01-021A is Closed AND XS-TM01-021B is Closed AND XS-TM01-026 is Closed AND XS-TM01-035 is Closed AND XS-TM01-033 is Closed	Complete		

1.1.3.2 Close

Step	Step Action	Transition Criteria	Next Step	Pass / Fail	Initial / Date
10	Command XS-TM01-010A to Close Command XS-TM01-010B to Close Command XS-TM01-021A to Close Command XS-TM01-021B to Close Command XS-TM01-026 to Close Command XS-TM01-035 to Close Command XS-TM01-033 to Close	XS-TM01-010A is Closed AND XS-TM01-010B is Closed AND XS-TM01-021A is Closed AND XS-TM01-021B is Closed AND XS-TM01-026 is Closed AND XS-TM01-035 is Closed AND XS-TM01-033 is Closed	Complete		

Comments

☐ N/A

Reviewer
Signature

Review
Date

CONFIDENTIAL INFORMATION

Do not distribute outside of Upsher-Smith Laboratories without approval or a confidentiality agreement.
Printed or downloaded documents must be verified against the effective version.

FACTORY ACCEPTANCE TEST

Title: FAT-200219-TM01-Hold_Attachment08

Parent Document ID: FAT-200219-TM01-Hold

Page 3 of 6

1.1.3.3 Drain

Step	Step Action	Transition Criteria	Next Step	Pass / Fail	Initial / Date
20	Command XS-TM01-010A to Open Command XS-TM01-010B to Open Command XS-TM01-021A to Open Command XS-TM01-021B to Open Command XS-TM01-026 to Open Command XS-TM01-035 to Open Command XS-TM01-033 to Open	XS-TM01-010A is Opened AND XS-TM01-010B is Opened AND XS-TM01-021A is Opened AND XS-TM01-021B is Opened AND XS-TM01-026 is Opened AND XS-TM01-035 is Opened AND XS-TM01-033 is Opened	Complete		

1.1.3.4 Addition Line

Step	Step Action	Transition Criteria	Next Step	Pass / Fail	Initial / Date
30	Command XS-TM01-010A to Close Command XS-TM01-010B to Open Command XS-TM01-021A to Close Command XS-TM01-021B to Close Command XS-TM01-026 to Close Command XS-TM01-035 to Close Command XS-TM01-033 to Close	XS-TM01-010A is Closed AND XS-TM01-010B is Opened AND XS-TM01-021A is Closed AND XS-TM01-021B is Closed AND XS-TM01-026 is Closed AND XS-TM01-035 is Closed AND XS-TM01-033 is Closed	Complete		

Comments

☐ N/A

Reviewer
Signature

Review
Date

CONFIDENTIAL INFORMATION

Do not distribute outside of Upsher-Smith Laboratories without approval or a confidentiality agreement.
Printed or downloaded documents must be verified against the effective version.

FACTORY ACCEPTANCE TEST



Title: FAT-200219-TM01-Hold_Attachment08

Parent Document ID: FAT-200219-TM01-Hold

Page 4 of 6

1.1.3.5 Spray Balls

Step	Step Action	Transition Criteria	Next Step	Pass / Fail	Initial / Date
40	Command XS-TM01-010A to Open Command XS-TM01-010B to Close Command XS-TM01-021A to Close Command XS-TM01-021B to Open Command XS-TM01-026 to Open Command XS-TM01-035 to Close Command XS-TM01-033 to Close	XS-TM01-010A is Opened AND XS-TM01-010B is Closed AND XS-TM01-021A is Closed AND XS-TM01-021B is Opened AND XS-TM01-026 is Opened AND XS-TM01-035 is Closed AND XS-TM01-033 is Closed	41		
41	Set Spray Ball Pulse timer preset to parameter Spray Ball Pulse Time Start Spray Ball Pulse timer	Spray Ball Pulse timer is done	42		
42	Command XS-TM01-026 to Open Command XS-TM01-035 to Close Command XS-TM01-033 to Open	AND XS-TM01-026 is Opened AND XS-TM01-035 is Closed AND XS-TM01-033 is Opened	43		
43	Command XS-TM01-026 to Close Command XS-TM01-035 to Close Command XS-TM01-033 to Open	AND XS-TM01-026 is Closed AND XS-TM01-035 is Closed AND XS-TM01-033 is Opened	44		
44	Set Spray Ball Pulse timer preset to parameter Spray Ball Pulse Time Start Spray Ball Pulse timer	Spray Ball Pulse timer is done	45		
45	Command XS-TM01-026 to Close Command XS-TM01-035 to Open Command XS-TM01-033 to Open	AND XS-TM01-026 is Closed AND XS-TM01-035 is Opened AND XS-TM01-033 is Opened	46		

Comments

□ N/A

Reviewer
Signature

Review
Date

CONFIDENTIAL INFORMATION

Do not distribute outside of Upsher-Smith Laboratories without approval or a confidentiality agreement.
Printed or downloaded documents must be verified against the effective version.

FACTORY ACCEPTANCE TEST

Title: FAT-200219-TM01-Hold_Attachment08

Parent Document ID: FAT-200219-TM01-Hold

Page 5 of 6

Step	Step Action	Transition Criteria	Next Step	Pass / Fail	Initial / Date
46	Command XS-TM01-026 to Close Command XS-TM01-035 to Open Command XS-TM01-033 to Close	AND XS-TM01-026 is Closed AND XS-TM01-035 is Opened AND XS-TM01-033 is Closed	47		
47	Set Spray Ball Pulse timer preset to parameter Spray Ball Pulse Time Start Spray Ball Pulse timer	Spray Ball Pulse timer is done	48		
48	Command XS-TM01-026 to Open Command XS-TM01-035 to Open Command XS-TM01-033 to Close	AND XS-TM01-026 is Opened AND XS-TM01-035 is Opened AND XS-TM01-033 is Closed	40		

Comments

☐ N/A

Reviewer
Signature

Review
Date

CONFIDENTIAL INFORMATION

Do not distribute outside of Upsher-Smith Laboratories without approval or a confidentiality agreement.
Printed or downloaded documents must be verified against the effective version.

FACTORY ACCEPTANCE TEST

Title: FAT-200219-TM01-Hold_Attachment08

Parent Document ID: FAT-200219-TM01-Hold

Page 6 of 6

1.1.3.6 Vent Line

Step	Step Action	Transition Criteria	Next Step	Pass / Fail	Initial / Date
50	Command XS-TM01-010A to Open Command XS-TM01-010B to Close Command XS-TM01-021A to Open Command XS-TM01-021B to Open Command XS-TM01-026 to Close Command XS-TM01-035 to Close Command XS-TM01-033 to Close	XS-TM01-010A is Opened AND XS-TM01-010B is Closed AND XS-TM01-021A is Opened AND XS-TM01-021B is Opened AND XS-TM01-026 is Closed AND XS-TM01-035 is Closed AND XS-TM01-033 is Closed	Complete		

1.1.3.7 Spray Balls & Addition Line

Step	Step Action	Transition Criteria	Next Step	Pass / Fail	Initial / Date
60	Command XS-TM01-010A to Open Command XS-TM01-010B to Open Command XS-TM01-021A to Close Command XS-TM01-021B to Open Command XS-TM01-026 to Open Command XS-TM01-035 to Open Command XS-TM01-033 to Open	XS-TM01-010A is Opened AND XS-TM01-010B is Opened AND XS-TM01-021A is Closed AND XS-TM01-021B is Opened AND XS-TM01-026 is Opened AND XS-TM01-035 is Opened AND XS-TM01-033 is Opened	61		
61	Command XS-TM01-035 to Close Command XS-TM01-033 to Close	XS-TM01-035 is Closed AND XS-TM01-033 is Closed	Complete		

Comments

☐ N/A

Reviewer
Signature

Review
Date

CONFIDENTIAL INFORMATION

Do not distribute outside of Upsher-Smith Laboratories without approval or a confidentiality agreement.
Printed or downloaded documents must be verified against the effective version.