

FACTORY ACCEPTANCE TEST

Title: FAT-200219-TM01-Hold_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 1 of 23

1.1 Equipment Phase - States

1.1.1 Acceptance Criteria

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

1. The test step executes the described step action.
2. If a restarting step is listed, the test step restarts at the indicated restarting step.
3. The step does not continue until the transition criteria are met.
4. 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 Section 9.4 (Protocol Deviation Resolution).

1.1.2 Test Traceability

This test section verifies the equipment phase functionality required 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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 2 of 23

1.1.3 EP-TM01-Hold-Tank-Pressure-Test

1.1.3.1 Running

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
10	Acquire required equipment	Required equipment acquired	20	10		
20	Set EM-TM01-Hold-Nitrogen target to Pressurize	EM-TM01-Hold-Nitrogen state is Pressurize	30	20		
30	No action	PI-TM01-001 PV \geq parameter Pressure Setpoint	40	20		
40	Set EM-TM01-Hold-Nitrogen target to Hold	EM-TM01-Hold-Nitrogen state is Hold	50	20		
50	Set Stabilization timer preset to parameter Stabilization Time Start Stabilization timer	Stabilization timer is done	60	20		
60	Record PI-TM01-001 PV as Initial Pressure Set Hold timer preset to parameter Hold Time Start Hold timer	Hold timer is done	70	20		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 3 of 23

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
70	Record Final Pressure as PI-TM01-001 PV Calculate Pressure Decay: (Pressure Decay) = (Initial Pressure) – (Final Pressure)	Always true	80	20		
80	Set EM-TM01-Hold-Nitrogen to Close	EM-TM01-Hold-Nitrogen is Close	90	80		
90	No action	Pressure Decay ≤ parameter Decay Threshold	100	90		
		Pressure Decay > parameter Decay Threshold	110			
100	Set Pressure Test Result to “Pass”	Always true	120	100		
110	Set Pressure Test Result to “Fail” Operator prompt: “Pressure test failed. Repeat pressure test or advance?”	Prompt response: “Repeat”	10	110		
		Prompt response: “Advance”	120			
120	Set EM-TM01-Hold-Nitrogen to Vent	EM-TM01-Hold-Nitrogen is Vent	130	120		
130	Set EM-TM01-Hold-Nitrogen to Idle	EM-TM01-Hold-Nitrogen is Idle	140	130		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 4 of 23

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
140	Release required equipment	Required equipment released	Complete	130		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 5 of 23

1.1.4 EP-TM01-Hold-Tank-Purge

1.1.4.1 Running

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
10	Acquire required equipment	Required equipment acquired	20	10		
20	Set EM-TM01-Hold-Nitrogen target to Pressurize	EM-TM01-Hold-Nitrogen state is Pressurize	30	20		
30	No action	PI-TM01-001 PV \geq parameter Pressure Setpoint	40	30		
40	Set EM-TM01-Hold-Nitrogen target to Vent	EM-TM01-Hold-Nitrogen state is Vent	50	40		
50	Increment Cycle Counter up by 1	Cycle Counter $<$ parameter Purge Cycles	20	50		
		Cycle Counter \geq parameter Purge Cycles	60			
60	Set EM-TM01-Hold-Nitrogen target to Close	EM-TM01-Hold-Nitrogen state is Close AND Reinitialize Cycle Counter to zero	70	60		
70	Release required equipment	Required equipment released	Complete	60		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 6 of 23

1.1.4.2 Stopping

Step	Step Action	Transition Criteria	Next Step	Pass/Fail	Initial/Date
610	Acquire required equipment	Required equipment acquired	620		
620	Set EM-TM01-Hold-Nitrogen target to Idle	EM-TM01-Hold-Nitrogen state is Idle AND Reinitialize Cycle Counter to zero	630		
630	Release required equipment	Required equipment released	Complete		

1.1.4.3 Aborting

Step	Step Action	Transition Criteria	Next Step	Pass/Fail	Initial/Date
710	Acquire required equipment	Required equipment acquired	720		
720	Set EM-TM01-Hold-Nitrogen target to Idle	EM-TM01-Hold-Nitrogen state is Idle AND Reinitialize Cycle Counter to zero	730		
730	Release required equipment	Required equipment released	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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 7 of 23

1.1.5 EP-TM01-Hold-Tank-Rinse

1.1.5.1 Running State

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
10	Acquire required equipment	Required equipment acquired	20	10		
20	No Action	WIP01 Acquisition Request signal received	30	20		
30	Set WIP01 Acquired Status signal	LI-TM01-002 <= TM01-Hold parameter Empty Level	50	30		
		LI-TM01-002 > TM01-Hold parameter Empty Level	40			
40	Operator prompt: "Tank level is above configured empty level. Empty tank to proceed."	Prompt acknowledged AND LI-TM01-002 <= TM01-Hold parameter Empty Level	50	40		
50	Operator prompt: "Acknowledge to confirm the tank is ready to rinse solvent waste to drum."	Prompt acknowledged	60	50		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 8 of 23

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
60	Set EM-TM01-Hold-Nitrogen target to Vent Set EM-TM01-Hold-Receive target to WIP Tank Set EM-TM01-Hold-Transfer target to Stop Set EM-TM01-Hold-WIP target to Close	EM-TM01-Hold-Nitrogen state is Vent AND EM-TM01-Hold-Receive state is WIP Tank AND EM-TM01-Hold-Transfer state is Stop AND EM-TM01-Hold-WIP state is Close	70	60		
70	Set the Ready Status signal	WIP01 Target Flow Path signal = 1	70	60		
80	Set EM-TM01-Hold-Nitrogen target to Vent Set EM-TM01-Hold-Receive target to WIP Tank Set EM-TM01-Hold-Transfer target to WIP Set EM-TM01-Hold-WIP target to Spray Balls	EM-TM01-Hold-Nitrogen state is Vent AND EM-TM01-Hold-Receive state is WIP Tank AND EM-TM01-Hold-Transfer state is WIP AND EM-TM01-Hold-WIP state is Spray Balls	90	80		
90	Set the WIP01 Aligned Flow Path signal to 1	WIP01 Target Flow Path signal = 2	95	80		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 9 of 23

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
95	Set EM-TM01-Hold-Nitrogen target to Vent Set EM-TM01-Hold-Receive target to WIP Tank Set EM-TM01-Hold-Transfer target to WIP Set EM-TM01-Hold-WIP target to Spray Balls & Addition Line	EM-TM01-Hold-Nitrogen state is Vent AND EM-TM01-Hold-Receive state is WIP Tank AND EM-TM01-Hold-Transfer state is WIP AND EM-TM01-Hold-WIP state is Spray Balls & Addition Line	100	95		
100	Set EM-TM01-Hold-Nitrogen target to Vent Set EM-TM01-Hold-Receive target to WIP Tank Set EM-TM01-Hold-Transfer target to WIP Set EM-TM01-Hold-WIP target to Addition Line	EM-TM01-Hold-Nitrogen state is Vent AND EM-TM01-Hold-Receive state is WIP Tank AND EM-TM01-Hold-Transfer state is WIP AND EM-TM01-Hold-WIP state is Addition Line	110	100		
110	Set the WIP01 Aligned Flow Path signal to 2	WIP01 Complete signal received	120	100		
120	Clear WIP01 Aligned Flow Path signal	WIP01 Acquisition Request signal cleared	125	120		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 10 of 23

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
130	Clear WIP01 Acquired Status signal Clear WIP01 Ready Status signal Set EM-TM01-Hold-Nitrogen target to Vent Set EM-TM01-Hold-Receive target to WIP Tank Set EM-TM01-Hold-Transfer target to WIP Set EM-TM01-Hold-WIP target to Drain	EM-TM01-Hold-Nitrogen state is Vent AND EM-TM01-Hold-Receive state is WIP Tank AND EM-TM01-Hold-Transfer state is WIP AND EM-TM01-Hold-WIP state is Drain	140	130		
140	No Action	LI-TM01-002 <= TM01-Hold parameter Empty Level	150	130		
150	Set Drain timer preset to parameter Drain Time Start Drain timer	Drain timer is done	160	130		
160	Set EM-TM01-Hold-Nitrogen target to Control Set EM-TM01-Hold-Receive target to WIP Tank Set EM-TM01-Hold-Transfer target to Stop Set EM-TM01-Hold-WIP target to Close	EM-TM01-Hold-Nitrogen state is Control AND EM-TM01-Hold-Receive state is WIP Tank AND EM-TM01-Hold-Transfer state is Stop AND EM-TM01-Hold-WIP state is Close	170	160		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 11 of 23

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
170	Set Tank Blowdown timer preset to parameter Tank Blowdown Time Start Tank Blowdown timer	Tank Blowdown timer is done	180	160		
180	Set EM-TM01-Hold-Nitrogen target to Vent Set EM-TM01-Hold-Receive target to WIP Tank Set EM-TM01-Hold-Transfer target to Stop Set EM-TM01-Hold-WIP target to Drain	EM-TM01-Hold-Nitrogen state is Vent AND EM-TM01-Hold-Receive state is WIP Tank AND EM-TM01-Hold-Transfer state is Stop AND EM-TM01-Hold-WIP state is Drain	190	180		
190	Set EM-TM01-Hold-Nitrogen target to Idle Set EM-TM01-Hold-Receive target to Idle Set EM-TM01-Hold-Transfer target to Idle Set EM-TM01-Hold-WIP target to Idle	EM-TM01-Hold-Nitrogen state is Idle AND EM-TM01-Hold-Receive state is Idle AND EM-TM01-Hold-Transfer state is Idle AND EM-TM01-Hold-WIP state is Idle	200	190		
200	Release required equipment	Required equipment released	Complete	190		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 12 of 23

1.1.6 EP-TM01-Hold-Tank-WIP

1.1.6.1 Running

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
10	Acquire required equipment	Required equipment acquired	20	10		
20	No Action	WIP01 Acquisition Request signal received	30	20		
30	Set WIP01 Acquired Status signal	LI-TM01-002 <= TM01-Hold parameter Empty Level	50	30		
		LI-TM01-002 > TM01-Hold parameter Empty Level	40			
40	Operator prompt: "Tank level is above configured empty level. Empty tank to proceed."	Prompt acknowledged AND LI-TM01-002 <= TM01-Hold parameter Empty Level	50	40		
50	Operator prompt: "Acknowledge to confirm the tank is ready to be washed."	Prompt acknowledged	60	50		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 13 of 23

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
60	Set EM-TM01-Hold-Nitrogen target to Vent Set EM-TM01-Hold-Receive target to WIP Tank Set EM-TM01-Hold-Transfer target to Stop Set EM-TM01-Hold-WIP target to Close	EM-TM01-Hold-Nitrogen state is Vent AND EM-TM01-Hold-Receive state is WIP Tank AND EM-TM01-Hold-Transfer state is Stop AND EM-TM01-Hold-WIP state is Close	70	60		
70	Set the Ready Status signal	WIP01 Target Flow Path signal = 1	80	60		
80	Set EM-TM01-Hold-Nitrogen target to Vent Set EM-TM01-Hold-Receive target to WIP Tank Set EM-TM01-Hold-Transfer target to WIP Set EM-TM01-Hold-WIP target to Spray Balls	EM-TM01-Hold-Nitrogen state is Vent AND EM-TM01-Hold-Receive state is WIP Tank AND EM-TM01-Hold-Transfer state is WIP AND EM-TM01-Hold-WIP state is Spray Balls	90	80		
90	Set the WIP01 Aligned Flow Path signal to 1	WIP01 Target Flow Path signal = 2	95	80		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 14 of 23

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
95	Set EM-TM01-Hold-Nitrogen target to Vent Set EM-TM01-Hold-Receive target to WIP Tank Set EM-TM01-Hold-Transfer target to WIP Set EM-TM01-Hold-WIP target to Spray Balls & Addition Line	EM-TM01-Hold-Nitrogen state is Vent AND EM-TM01-Hold-Receive state is WIP Tank AND EM-TM01-Hold-Transfer state is WIP AND EM-TM01-Hold-WIP state is Spray Balls & Addition Line	100	95		
100	Set EM-TM01-Hold-Nitrogen target to Vent Set EM-TM01-Hold-Receive target to WIP Tank Set EM-TM01-Hold-Transfer target to WIP Set EM-TM01-Hold-WIP target to Addition Line	EM-TM01-Hold-Nitrogen state is Vent AND EM-TM01-Hold-Receive state is WIP Tank AND EM-TM01-Hold-Transfer state is WIP AND EM-TM01-Hold-WIP state is Addition Line	110	100		
110	Set the WIP01 Aligned Flow Path signal to 2	WIP01 Target Flow Path signal = 3	115	100		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 15 of 23

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
115	Set EM-TM01-Hold-Nitrogen target to Vent Set EM-TM01-Hold-Receive target to WIP Tank Set EM-TM01-Hold-Transfer target to WIP Set EM-TM01-Hold-WIP target to Addition Line & Vent Line	EM-TM01-Hold-Nitrogen state is Vent AND EM-TM01-Hold-Receive state is WIP Tank AND EM-TM01-Hold-Transfer state is WIP AND EM-TM01-Hold-WIP state is Addition Line & Vent Line	120	115		
120	Set EM-TM01-Hold-Nitrogen target to Vent Set EM-TM01-Hold-Receive target to WIP Tank Set EM-TM01-Hold-Transfer target to WIP Set EM-TM01-Hold-WIP target to Vent Line	EM-TM01-Hold-Nitrogen state is Vent AND EM-TM01-Hold-Receive state is WIP Tank AND EM-TM01-Hold-Transfer state is WIP AND EM-TM01-Hold-WIP state is Vent Line	130	120		
130	Set the WIP01 Aligned Flow Path signal to 3	WIP01 Target Flow Path signal = 1	80	120		
		WIP01 Complete signal received	140			
140	Clear WIP01 Aligned Flow Path signal	WIP01 Acquisition Request signal cleared	150	140		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 16 of 23

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
150	Clear WIP01 Acquired Status signal Clear WIP01 Ready Status signal Set EM-TM01-Hold-Nitrogen target to Vent Set EM-TM01-Hold-Receive target to WIP Tank Set EM-TM01-Hold-Transfer target to WIP Set EM-TM01-Hold-WIP target to Drain	EM-TM01-Hold-Nitrogen state is Vent AND EM-TM01-Hold-Receive state is WIP Tank AND EM-TM01-Hold-Transfer state is WIP AND EM-TM01-Hold-WIP state is Drain	160	150		
160	No Action	LI-TM01-002 <= TM01-Hold parameter Empty Level	170	150		
170	Set Drain timer preset to parameter Drain Time Start Drain timer	Drain timer is done	180	150		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 17 of 23

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
180	Set EM-TM01-Hold-Nitrogen target to Vent Set EM-TM01-Hold-Receive target to WIP Tank Set EM-TM01-Hold-Transfer target to Stop Set EM-TM01-Hold-WIP target to Drain	EM-TM01-Hold-Nitrogen state is Vent AND EM-TM01-Hold-Receive state is WIP Tank AND EM-TM01-Hold-Transfer state is Stop AND EM-TM01-Hold-WIP state is Drain	190	180		
190	Set EM-TM01-Hold-Nitrogen target to Idle Set EM-TM01-Hold-Receive target to Idle Set EM-TM01-Hold-Transfer target to Idle Set EM-TM01-Hold-WIP target to Idle	EM-TM01-Hold-Nitrogen state is Idle AND EM-TM01-Hold-Receive state is Idle AND EM-TM01-Hold-Transfer state is Idle AND EM-TM01-Hold-WIP state is Idle	200	190		
200	Release required equipment	Required equipment released	Complete	190		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 18 of 23

1.1.7 EP-TM01-Hold-Transfer

1.1.7.1 Running

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
10	Acquire required equipment	Required equipment acquired	20	10		
20	Operator prompt: "Acknowledge to initiate the transfer to the destination unit"	Prompt acknowledged	30	20		
30	Set SOL01 Methanol Acquisition Request signal	SOL01 Methanol Acquired signal received	40	30		
40	No Action	SOL01-Methanol Quantity Available \geq parameter Flush Setpoint	60	30		
		SOL01-Methanol Quantity Available < parameter Flush Setpoint	50			
50	Operator prompt: Not enough solvent available.	Prompt acknowledged	40	30		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 19 of 23

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
60	Set EM-TM01-Hold-Methanol target to Close Set EM-TM01-Hold-Nitrogen target to Pressurize Set EM-TM01-Hold-Transfer target to Transfer	EM-TM01-Hold-Methanol state is Close AND EM-TM01-Hold-Nitrogen state is Pressurize AND EM-TM01-Hold-Transfer state is Transfer	70	60		
70	No action	LI-TM01-002 < TM01-Hold parameter Empty Level	80	60		
80	Set the Delay timer preset to parameter Delay Time Start the Delay timer	Delay timer is done	90	60		
90	Set EM-TM01-Hold-Nitrogen target to Pressurize Set EM-TM01-Hold-Transfer target to Transfer	EM-TM01-Hold-Nitrogen state is Pressurize AND EM-TM01-Hold-Transfer state is Transfer	100	90		
100	Set EM-TM01-Hold-Methanol Charge Setpoint to parameter Flush Setpoint Set EM-TM01-Hold-Methanol target to Control	FQI-TM01-001 is Complete AND EM-TM01-Hold-Methanol state is Control	110	90		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 20 of 23

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
110	Clear the Methanol Request signal Set EM-TM01-Hold-Methanol target to Close Set EM-TM01-Hold-Nitrogen target to Pressurize Set EM-TM01-Hold-Transfer target to Transfer	EM-TM01-Hold-Methanol state is Close AND EM-TM01-Hold-Nitrogen state is Pressurize AND EM-TM01-Hold-Transfer state is Transfer	120	110		
120	Report FQI-TM01-001 quantity as Flush Actual	LI-TM01-002 < TM01-Hold parameter Empty Level	130	110		
130	Set the Blowdown timer preset to parameter Blowdown Time Start the Blowdown timer	Blowdown timer is done	140	110		
140	Set EM-TM01-Hold-Methanol target to Idle Set EM-TM01-Hold-Nitrogen target to Control Set EM-TM01-Hold-Transfer target to Idle	EM-TM01-Hold-Methanol state is Idle AND EM-TM01-Hold-Nitrogen state is Control AND EM-TM01-Hold-Transfer state is Idle	150	140		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 21 of 23

Step	Step Action	Transition Criteria	Next Step	Restart	Pass / Fail	Initial / Date
150	Release required equipment	Required equipment is released	Complete	140		

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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 22 of 23

1.1.7.2 Stopping

Step	Step Action	Transition Criteria	Next Step	Pass/Fail	Initial/Date
610	Acquire required equipment	Required equipment acquired	620		
620	Set EM-TM01-Hold-Methanol target to Reset Set EM-TM01-Hold-Nitrogen target to Control Set EM-TM01-Hold-Transfer target to Idle Clear the Methanol Acquisition signal	EM-TM01-Hold-Methanol state is Reset AND EM-TM01-Hold-Nitrogen state is Control AND EM-TM01-Hold-Transfer state is Idle	630		
630	Set EM-TM01-Hold-Methanol target to Idle	EM-TM01-Hold-Methanol state is Idle	640		
640	Release required equipment	Required equipment released	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_Attachment13

Parent Document ID: FAT-200219-TM01-Hold

Page 23 of 23

1.1.7.3 Aborting

Step	Step Action	Transition Criteria	Next Step	Pass/Fail	Initial/Date
710	Acquire required equipment	Required equipment acquired	720		
720	Set EM-TM01-Hold-Methanol target to Reset Set EM-TM01-Hold-Nitrogen target to Control Set EM-TM01-Hold-Transfer target to Idle Clear the Methanol Acquisition signal	EM-TM01-Hold-Methanol state is Reset AND EM-TM01-Hold-Nitrogen state is Control AND EM-TM01-Hold-Transfer state is Idle	730		
730	Set EM-TM01-Hold-Methanol target to Idle	EM-TM01-Hold-Methanol state is Idle	740		
740	Release required equipment	Required equipment released	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.