

# FACTORY ACCEPTANCE TEST



Title: FAT-200219-TM01-Hold\_Attachment03

Parent Document ID: FAT-200219-TM01-Hold

Page 1 of 5

## 1 FACTORY ACCEPTANCE TEST

### 1.1 Control Module - Key Configuration Parameters

#### 1.1.1 Acceptance Criteria

For each test item, verify the content in the table matches the same values as indicated by the HMI faceplate for the listed control module. If the content matches, mark the test step as 'Pass'. If the content does not match, 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 key configuration parameters required by the control modules as specified in the following specification sections:

- Document # SPC-200219-SLP\_FS, Section 7.2 "Large Solution Prep Hold Tank (TM01-Hold) Unit"
- 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.

1.1.3   Analog Outputs

| No. | CM ID       | Area | Description                         | Label       | Tag         | Pass / Fail | Initial / Date |
|-----|-------------|------|-------------------------------------|-------------|-------------|-------------|----------------|
| 1   | PC-TM01-001 | SLP  | TM01-Hold N2 Pressure Control Valve | PC-TM01-001 | PC_TM01_001 |             |                |

1.1.4   PID Controllers

| No. | CM ID        | Area | Description                         | Label        | Tag          | PV EU | CV EU | Pass / Fail | Initial / Date |
|-----|--------------|------|-------------------------------------|--------------|--------------|-------|-------|-------------|----------------|
| 1   | PIC-TM01-001 | SLP  | TM01-Hold N2 Pressure Control Valve | PIC-TM01-001 | PIC_TM01_001 | psig  | %     |             |                |

Commented [JP1]: Verify PPID graphic in HMI; compare to PID-2005.

Commented [JP2R1]: MC - use PV, CV, SP from GO library and move per image below: 

...

Comments

□ N/A

Reviewer Signature

Review Date

# FACTORY ACCEPTANCE TEST



Title: FAT-200219-TM01-Hold\_Attachment03

Parent Document ID: FAT-200219-TM01-Hold

Page 3 of 5

## 1.2 Equipment Phase - Key Configuration Parameters

### 1.2.1 Acceptance Criteria

For each test item, verify the content in the table matches the same values as indicated by the HMI faceplate for the listed equipment phase. If the content matches, mark the test step as 'Pass'. If the content does not match, evaluate if the discrepancy requires a deviation resolution as detailed in FAT-200219-TM01-Hold Section 9.4 (Protocol Deviation Resolution).

### 1.2.2 Test Traceability

This test section verifies the key configuration parameters required by the equipment phases as specified in the following specification sections:

- Document # SPC-200219-SLP\_FS, Section 7.2 "Large Solution Prep Hold Tank (TM01-Hold) Unit"
- 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\_Attachment03

Parent Document ID: FAT-200219-TM01-Hold

Page 4 of 5

## 1.2.3 Generic Parameters

| No. | EP ID                           | Area | Description                  | Label                 | Tag | Pass / Fail | Initial / Date |
|-----|---------------------------------|------|------------------------------|-----------------------|-----|-------------|----------------|
| 1   | EP-TM01-Hold-Tank-Blanket       | SLP  | TM01-Hold Tank Blanket       | EP-Tank-Blanket       | EP  |             |                |
| 2   | EP-TM01-Hold-Tank-Pressure-Test | SLP  | TM01-Hold Tank Pressure Test | EP-Tank-Pressure-Test | EP  |             |                |
| 3   | EP-TM01-Hold-Tank-Purge         | SLP  | TM01-Hold Tank Purge         | EP-Tank-Purge         | EP  |             |                |
| 4   | EP-TM01-Hold-Tank-Rinse         | SLP  | TM01-Hold Tank Rinse         | EP-Tank-Rinse         | EP  |             |                |
| 5   | EP-TM01-Hold-Tank-WIP           | SLP  | TM01-Hold Tank WIP           | EP-Tank-WIP           | EP  |             |                |
| 6   | EP-TM01-Hold-Transfer           | SLP  | TM01-Hold Transfer           | EP-Transfer           | EP  |             |                |
| 7   | EP-TM01-Hold-Receive            | SLP  | TM01-Hold Receive            | EP-Receive            | EP  |             |                |

## 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\_Attachment03

Parent Document ID: FAT-200219-TM01-Hold

Page 5 of 5

| No. | EP ID                      | Area | Description             | Label            | Tag | Pass / Fail | Initial / Date |
|-----|----------------------------|------|-------------------------|------------------|-----|-------------|----------------|
| 8   | EP-TM01-Hold-Receive-Rinse | SLP  | TM01-Hold Receive Rinse | EP-Receive-Rinse | EP  |             |                |

Comments

☐ N/A

|                       |  |                |  |
|-----------------------|--|----------------|--|
| Reviewer<br>Signature |  | Review<br>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.