FACTORY ACCEPTANCE TEST (FAT)

Title:

FAT for Custom Designed and Manufactured Parts Washer Rack/Sub Rack for Getinge GEW 131313 Parts Washer Machine

Department:

TEG R&D department

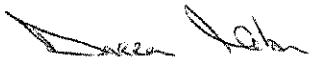
Location:

Forest Park, Mullingar, Co. Westmeath, Ireland

DOCUMENT NO: FAT-03-23205

REVISION NO: 00

DOCUMENT APPROVALS

Written by:			
Name	**Function**	**Signature**	**Date** (dd mmm yyyy)
Darren Nolan	TEG Quality		14 Apr 2025
Approved by:			
Name	**Function**	**Signature**	**Date** (dd mmm yyyy)
	TEG Design		
BENJAMIN CARTER	TFS Process Engineering		14 Apr ~~2024~~ 2025 (1)

NOTE: N/A ANY UNUSED ROWS OR CELLS

(1) Corrected Date. BC 14 Apr 2025

TABLE OF CONTENTS

1. OBJECTIVE

The objective of this Factory Acceptance Test (FAT) protocol is to confirm and document, through appropriate checks and testing, that the equipment (may also be referred to as Rack or Sub Rack) as defined in Table 1 are built in accordance with the applicable specifications and Good Engineering Practice (GEP)/Good Manufacturing Practices (GMP).

Table 1:

TE Number	Equipment Name	Quantity Ordered
TE51073	Sub Rack 8-01	1
TE51075	Sub Rack 10-01	1
TE51076	Sub Rack 11-01	1
TE51083	Sub Rack 18-01	1
TE51084	Sub Rack 19-01	1
TE51100	Accessory 10-01	1
TE51101	Accessory 11-01	1
TE51102	Accessory 12-01	1
TE51103	Accessory 13-01	1

The objectives of the FAT are:

- To ensure that the equipment is designed and built in accordance with the requirements of the User Requirements Specification (URS) or Approval Drawing.
- To determine the equipment complies with the relevant requirements of the current GMP (cGMP).
- To provide a record of principal features of the equipment and components as available during FAT.
- To determine that the equipment is ready for shipment to the customer.

2. SCOPE

The execution of this protocol will verify that the equipment is built according to the customers User Requirements and manufacturer's specifications. Execution of this protocol will be documented by completing the test sheets listed within the relevant sections.

3. SYSTEM DESCRIPTION

The TEG testing system involves the use of a simulation wash chamber with filtered mains supplied water and a variable pump set to mimic a typical partswasher wash chamber. The simulation wash chamber is constructed of such a material that the outer chamber walls are transparent. This transparency facilitates the visual verification and operation of the equipment's rotating wash arms, and the spray pattern of the fixed sprayballs.

4. REFERENCES

Table 2:

Document Title	Document Number
TEG Coverage Testing Guidelines	TEG – Testing – 1010 – rev E
TEG Riboflavin Preparation Procedure	TEG – Testing – 1011 – rev A
User Requirement Specifications (URS)	N/A

5. PROTOCOL EXECUTION

The personnel completing the protocol should enter results in the tables provided according to Good Documentation Practices (GDP). Specific information and values should be recorded where indicated in the test method or results column. Dates will be documented in DDMMMYYYY format. Any data entries or boxes intentionally left blank will be marked N/A along with initials & date.

Where a deviation from the specified acceptance criteria is observed, the deviation should be noted, and a Punchlist item raised.

Typographical errors are not considered as deviations and may be handled by the person executing the protocol by adding a "Protocol Generation Error" comment in the comments box of the test results document.

The personnel completing the protocol should enter any comments arising from their findings in the relevant comments box of the test results. Individual comments must be initialled and dated. The reviewers of the completed report may add their own initialled and dated responses to the comments if necessary.

All printouts and other supporting data included must be cross-referenced to the specific confirmation in this protocol, signed and dated, then attached to this protocol.

Any corrections should be made according to Good Documentation Practices.

The following colour conventions should be used when annotating or confirming drawings, sketches, and data:

Drawing marking:

Green: Information verified as correct should be highlighted in green.

Yellow: Information that cannot be verified should be highlighted in yellow (state reason for non-confirmation).

Red/Pink: Information verified as incorrect should be highlighted in red or pink.

Red ink: Comments, amendments, and corrections should be in red ink with initials and date.

Copies of documents used for confirmation should be marked with the FAT protocol title and reference number. The documents must be signed and dated on completion of all checks and attached to this protocol in the appendices section.

6. ABBREVIATIONS

Table 3:

Abbreviation	Definition
AISI	American Iron and Steel Institute
cGMP	Current Good Manufacturing Practice
DIN	Deutsches Institut für Normung eV
EHS	Environmental Health and Safety
ETOP	Engineering Turn Over Package
FAT	Factory Acceptance Test
GMP	Good Manufacturing Practice
GEP	Good Engineering Practice
GDP	Good Documentation Practice
SAT	Site Acceptance Test
SF	Surface Finish
TE	Technical Engineering
TEG	Technical Engineering Group

7. IDENTIFICATION OF PERSONNEL

The table lists the following:

- Individuals who have read and understood this FAT protocol.
- Individuals involved in documentation review.

Company	Department	Print Name	Function in FAT	Signature	Initial	Date
TEG	Quality		Walkdown			
TEG	Documentation		Paperwork			
TEG	Desing		Testing			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Document review by (Customer): _____ Date:

8. TEST INSTRUMENTS AND DEVICES

Instrument Description	Equip Ref	Serial/Model No	Manufacturer	Calibration Date	Calibration Due Date	Documented By (Initial and Date)
UV Torch	N/A	SN:11438	UV Light Technology	N/A	N/A	
Weighing Scale	932	AE76101660	Adam Equipment	19 FEB 2024	18 FEB 2026	
RS Pro JS-10 Weighing Scale	1303	1113679/179	RS	28 FEB 2025	28 FEB 2027	
Pressure Gauge	1239	1606270033	SSI Technologies	12 JUL 2023	11 JUL 2025	
Pressure Gauge	1240	1606270049	SSI Technologies	12 JUL 2023	11 JUL 2025	
Turbine Flow Meter S10T	1236	4016445	Flomec	10 JUL 2023	10 JUL 2026	
Turbine Flow Meter S10T	1237	4016448	Flomec	10 JUL 2023	10 JUL 2026	
Turbine Flow Meter S201	1238	4715819	Flomec	10 JUL 2023	10 JUL 2026	
RA Meter	499	313031101	Mitutoyo	24 OCT 2022	24 OCT 2027	
GOLDD Alloy Analyser	473	40859	Niton UK	03 MAR 2025	03 MAR 2027	

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

9. PREREQUISITES VERIFICATION

9.1. OBJECTIVE:

- Verify that all documentation required for FAT execution is available.
- Verify that all required utilities are available for use.

9.2. MATERIALS AND EQUIPMENT REQUIRED:

- UV torch of 365nm (does not need to be calibrated)
- Riboflavin
- Balance
- Validation Support Documentation & ETOP

9.3. PROCEDURE:

- Verify that all required documentation listed in the results section is available for execution of the FAT.
- Verify that all required utilities listed in the results section are available for use.
- Verify that all Customer parts to be washed are available for FAT.

9.4. ACCEPTANCE CRITERIA:

- All required documentation is available for execution of the FAT.
- All required utilities listed in the results section are available for use.
- Verify that all Customer parts to be washed are available for FAT.

9.5 RESULTS: DOCUMENTATION VERIFICATION

9.5 Documentation Verification				
TE Number		**Equipment Name**		
TE51073		**Sub Rack 8-01**		
Procedure	**Expected Results**	**ETOP Section**	**Available (Yes/No)**	**Performed By** (Initial and Date)
Verify documents listed are available and record the document section.	Approval Drawing	4		
	General Arrangement Layout	6		
	Component Cut Sheet Drawings	7		
	Bill of Materials	8		
	Component/Material data sheets	9.1 & 9.2		
	Recommended Spare Parts Drawing	18		

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

9.5 RESULTS: DOCUMENTATION VERIFICATION

9.5 Documentation Verification				
TE Number		**Equipment Name**		
TE51075		**Sub Rack 10-01**		
Procedure	**Expected Results**	**ETOP Section**	**Available (Yes/No)**	**Performed By** (Initial and Date)
Verify documents listed are available and record the document section.	Approval Drawing	4		
	General Arrangement Layout	6		
	Component Cut Sheet Drawings	7		
	Bill of Materials	8		
	Component/Material data sheets	9.1 & 9.2		
	Recommended Spare Parts Drawing	18		

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

9.5 RESULTS: DOCUMENTATION VERIFICATION

9.5 Documentation Verification				
TE Number		**Equipment Name**		
TE51076		**Sub Rack 11-01**		
Procedure	**Expected Results**	**ETOP Section**	**Available (Yes/No)**	**Performed By** (Initial and Date)
Verify documents listed are available and record the document section.	Approval Drawing	4		
	General Arrangement Layout	6		
	Component Cut Sheet Drawings	7		
	Bill of Materials	8		
	Component/Material data sheets	9.1 & 9.2		
	Recommended Spare Parts Drawing	18		

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

9.5 RESULTS: DOCUMENTATION VERIFICATION

9.5 Documentation Verification				
TE Number		**Equipment Name**		
TE51083		**Sub Rack 18-01**		
Procedure	**Expected Results**	**ETOP Section**	**Available (Yes/No)**	**Performed By** (Initial and Date)
Verify documents listed are available and record the document section.	Approval Drawing	4		
	General Arrangement Layout	6		
	Component Cut Sheet Drawings	7		
	Bill of Materials	8		
	Component/Material data sheets	9.1 & 9.2		
	Recommended Spare Parts Drawing	18		

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

9.5 RESULTS: DOCUMENTATION VERIFICATION

9.5 Documentation Verification				
TE Number		**Equipment Name**		
TE51084		**Sub Rack 19-01**		
Procedure	**Expected Results**	**ETOP Section**	**Available (Yes/No)**	**Performed By** (Initial and Date)
Verify documents listed are available and record the document section.	Approval Drawing	4		
	General Arrangement Layout	6		
	Component Cut Sheet Drawings	7		
	Bill of Materials	8		
	Component/Material data sheets	9.1 & 9.2		
	Recommended Spare Parts Drawing	18		

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

9.5 RESULTS: DOCUMENTATION VERIFICATION

9.5 Documentation Verification				
TE Number		**Equipment Name**		
TE51100		**Accessory 10-01**		
Procedure	**Expected Results**	**ETOP Section**	**Available (Yes/No)**	**Performed By** (Initial and Date)
Verify documents listed are available and record the document section.	Approval Drawing	4		
	General Arrangement Layout	6		
	Component Cut Sheet Drawings	7		
	Bill of Materials	8		
	Component/Material data sheets	9.1 & 9.2		
	Recommended Spare Parts Drawing	18		

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

9.5 RESULTS: DOCUMENTATION VERIFICATION

9.5 Documentation Verification				
TE Number		**Equipment Name**		
TE51101		**Accessory 11-01**		
Procedure	**Expected Results**	**ETOP Section**	**Available (Yes/No)**	**Performed By** (Initial and Date)
Verify documents listed are available and record the document section.	Approval Drawing	4		
	General Arrangement Layout	6		
	Component Cut Sheet Drawings	7		
	Bill of Materials	8		
	Component/Material data sheets	9.1 & 9.2		
	Recommended Spare Parts Drawing	18		

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

9.5 RESULTS: DOCUMENTATION VERIFICATION

9.5 Documentation Verification				
TE Number		**Equipment Name**		
TE51102		**Accessory 12-01**		
Procedure	**Expected Results**	**ETOP Section**	**Available (Yes/No)**	**Performed By** (Initial and Date)
Verify documents listed are available and record the document section.	Approval Drawing	4		
	General Arrangement Layout	6		
	Component Cut Sheet Drawings	7		
	Bill of Materials	8		
	Component/Material data sheets	9.1 & 9.2		
	Recommended Spare Parts Drawing	18		

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

9.5 RESULTS: DOCUMENTATION VERIFICATION

9.5 Documentation Verification				
TE Number		**Equipment Name**		
TE51103		**Accessory 13-01**		
Procedure	**Expected Results**	**ETOP Section**	**Available (Yes/No)**	**Performed By** (Initial and Date)
Verify documents listed are available and record the document section.	Approval Drawing	4		
	General Arrangement Layout	6		
	Component Cut Sheet Drawings	7		
	Bill of Materials	8		
	Component/Material data sheets	9.1 & 9.2		
	Recommended Spare Parts Drawing	18		

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

9.6. RESULTS: VERIFICATION OF UTILITIES

9.6 Verification of Utilities					
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Confirm supply of water is available and a variable pump set is installed.	Supply of water is available and a variable pump set is installed.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ **Date:**

9.7. RESULTS: VERIFICATION OF CUSTOMER PARTS

9.7 Verification of Customer Parts					
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify all customer parts to be washed are present in accordance with Approval Drawing	Customer Parts to be washed are present in accordance with Approval Drawing			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ **Date:**

10. MECHANICAL VERIFICATION

10.1. OBJECTIVE:

- Verify the outside dimensions of the equipment are in accordance with the specified dimensions of the approval drawing/top level component cut sheet drawing.
- Verify the equipment has been mechanically completed as per component cut sheet drawings, weld maps and borescope videos.

10.2. MATERIALS AND EQUIPMENT REQUIRED:

- Measuring tape (Measuring tape does not need to be calibrated).
- Customer Components to be washed.

10.3. PROCEDURE:

- A copy of the approval drawing and top-level component cut sheet drawing are used to record the design requirements.
- As information on the drawings is verified as correct on the equipment, it should be marked on the drawing with a highlighter.
- Complete the result section by noting Pass or Fail for each test requirement.
- If a detail cannot be checked, the reason must be recorded on the plan and/or in the comment section of the test.
- Review the weld documentation, surface finish, and boroscope videos for documentation completion and compliance.
- The controlled and marked up drawings are attached to this executed protocol.

10.4. ACCEPTANCE CRITERIA:

- The measured dimensions are according to the specification.
- The equipment is mechanically complete and conforms to component cut sheet drawings.
- Welding and surface finish documentation conforms to specifications outlined in approval drawings.
- The equipment design is compatible with the customer’s components.

10.5 RESULTS: MECHANICAL ASSEMBLY

10.5 Mechanical Assembly					
TE Number		**Equipment Name**			
TE51073		**Sub Rack 8-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Measure the overall dimensions of the equipment and compare them to those detailed on the approval drawing/ top level component cut sheet drawing.	Measured dimensions conform to the dimensions detailed on the approval/top level component cut sheet drawing.			
2.	Verify presence of all components.	All the components are present as per components list/as annotated on the approval drawing.			
3.	Verify equipment conforms to component cut sheet drawing	Component cut sheet drawings reflects machine as built condition			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

10.5 RESULTS: MECHANICAL ASSEMBLY

10.5 Mechanical Assembly					
TE Number		**Equipment Name**			
TE51075		**Sub Rack 10-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Measure the overall dimensions of the equipment and compare them to those detailed on the approval drawing/ top level component cut sheet drawing.	Measured dimensions conform to the dimensions detailed on the approval/top level component cut sheet drawing.			
2.	Verify presence of all components.	All the components are present as per components list/as annotated on the approval drawing.			
3.	Verify equipment conforms to component cut sheet drawing	Component cut sheet drawings reflects machine as built condition			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

10.5 RESULTS: MECHANICAL ASSEMBLY

10.5 Mechanical Assembly					
TE Number		**Equipment Name**			
TE51076		**Sub Rack 11-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Measure the overall dimensions of the equipment and compare them to those detailed on the approval drawing/ top level component cut sheet drawing.	Measured dimensions conform to the dimensions detailed on the approval/top level component cut sheet drawing.			
2.	Verify presence of all components.	All the components are present as per components list/as annotated on the approval drawing.			
3.	Verify equipment conforms to component cut sheet drawing	Component cut sheet drawings reflects machine as built condition			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

10.5 RESULTS: MECHANICAL ASSEMBLY

10.5 Mechanical Assembly					
TE Number		**Equipment Name**			
TE51083		**Sub Rack 18-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Measure the overall dimensions of the equipment and compare them to those detailed on the approval drawing/ top level component cut sheet drawing.	Measured dimensions conform to the dimensions detailed on the approval/top level component cut sheet drawing.			
2.	Verify presence of all components.	All the components are present as per components list/as annotated on the approval drawing.			
3.	Verify equipment conforms to component cut sheet drawing	Component cut sheet drawings reflects machine as built condition			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

10.5 RESULTS: MECHANICAL ASSEMBLY

10.5 Mechanical Assembly					
TE Number		**Equipment Name**			
TE51084		**Sub Rack 19-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Measure the overall dimensions of the equipment and compare them to those detailed on the approval drawing/ top level component cut sheet drawing.	Measured dimensions conform to the dimensions detailed on the approval/top level component cut sheet drawing.			
2.	Verify presence of all components.	All the components are present as per components list/as annotated on the approval drawing.			
3.	Verify equipment conforms to component cut sheet drawing	Component cut sheet drawings reflects machine as built condition			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

10.5 RESULTS: MECHANICAL ASSEMBLY

10.5 Mechanical Assembly					
TE Number		**Equipment Name**			
TE51100		**Accessory 10-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Measure the overall dimensions of the equipment and compare them to those detailed on the approval drawing/ top level component cut sheet drawing.	Measured dimensions conform to the dimensions detailed on the approval/top level component cut sheet drawing.			
2.	Verify presence of all components.	All the components are present as per components list/as annotated on the approval drawing.			
3.	Verify equipment conforms to component cut sheet drawing	Component cut sheet drawings reflects machine as built condition			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

10.5 RESULTS: MECHANICAL ASSEMBLY

10.5 Mechanical Assembly					
TE Number		**Equipment Name**			
TE51101		**Accessory 11-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Measure the overall dimensions of the equipment and compare them to those detailed on the approval drawing/ top level component cut sheet drawing.	Measured dimensions conform to the dimensions detailed on the approval/top level component cut sheet drawing.			
2.	Verify presence of all components.	All the components are present as per components list/as annotated on the approval drawing.			
3.	Verify equipment conforms to component cut sheet drawing	Component cut sheet drawings reflects machine as built condition			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

10.5 RESULTS: MECHANICAL ASSEMBLY

10.5 Mechanical Assembly					
TE Number		**Equipment Name**			
TE51102		**Accessory 12-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Measure the overall dimensions of the equipment and compare them to those detailed on the approval drawing/ top level component cut sheet drawing.	Measured dimensions conform to the dimensions detailed on the approval/top level component cut sheet drawing.			
2.	Verify presence of all components.	All the components are present as per components list/as annotated on the approval drawing.			
3.	Verify equipment conforms to component cut sheet drawing	Component cut sheet drawings reflects machine as built condition			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

10.5 RESULTS: MECHANICAL ASSEMBLY

10.5 Mechanical Assembly					
TE Number		**Equipment Name**			
TE51103		**Accessory 13-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Measure the overall dimensions of the equipment and compare them to those detailed on the approval drawing/ top level component cut sheet drawing.	Measured dimensions conform to the dimensions detailed on the approval/top level component cut sheet drawing.			
2.	Verify presence of all components.	All the components are present as per components list/as annotated on the approval drawing.			
3.	Verify equipment conforms to component cut sheet drawing	Component cut sheet drawings reflects machine as built condition			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

10.6 RESULTS: MECHANICAL WALKDOWN

10.6 Mechanical Walkdown					
TE Number		**Equipment Name**			
TE51073		**Sub Rack 8-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Visually inspect the equipment for sharp edges.	Equipment has no sharp edges.			
2.	Visually inspect all external welds.	All welds are continuous, free from cracks and crevices and are easily cleanable.			
3.	Any covered welds must be boroscoped.	Covered welds have been boroscoped.			
4.	Dead legs in pipe work shall not exceed L/D < 2.	Dead legs in pipe work are less than L/D < 2.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

10.6 RESULTS: MECHANICAL WALKDOWN

10.6 Mechanical Walkdown					
TE Number		**Equipment Name**			
TE51075		**Sub Rack 10-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Visually inspect the equipment for sharp edges.	Equipment has no sharp edges.			
2.	Visually inspect all external welds.	All welds are continuous, free from cracks and crevices and are easily cleanable.			
3.	Any covered welds must be boroscoped.	Covered welds have been boroscoped.			
4.	Dead legs in pipe work shall not exceed L/D < 2.	Dead legs in pipe work are less than L/D < 2.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

10.6 RESULTS: MECHANICAL WALKDOWN

10.6 Mechanical Walkdown					
TE Number		**Equipment Name**			
TE51076		**Sub Rack 11-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Visually inspect the equipment for sharp edges.	Equipment has no sharp edges.			
2.	Visually inspect all external welds.	All welds are continuous, free from cracks and crevices and are easily cleanable.			
3.	Any covered welds must be boroscoped.	Covered welds have been boroscoped.			
4.	Dead legs in pipe work shall not exceed L/D < 2.	Dead legs in pipe work are less than L/D < 2.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

10.6 RESULTS: MECHANICAL WALKDOWN

10.6 Mechanical Walkdown					
TE Number		**Equipment Name**			
TE51083		**Sub Rack 18-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Visually inspect the equipment for sharp edges.	Equipment has no sharp edges.			
2.	Visually inspect all external welds.	All welds are continuous, free from cracks and crevices and are easily cleanable.			
3.	Any covered welds must be boroscoped.	Covered welds have been boroscoped.			
4.	Dead legs in pipe work shall not exceed L/D < 2.	Dead legs in pipe work are less than L/D < 2.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

10.6 RESULTS: MECHANICAL WALKDOWN

10.6 Mechanical Walkdown					
TE Number		**Equipment Name**			
TE51084		**Sub Rack 19-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Visually inspect the equipment for sharp edges.	Equipment has no sharp edges.			
2.	Visually inspect all external welds.	All welds are continuous, free from cracks and crevices and are easily cleanable.			
3.	Any covered welds must be boroscoped.	Covered welds have been boroscoped.			
4.	Dead legs in pipe work shall not exceed L/D < 2.	Dead legs in pipe work are less than L/D < 2.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

10.6 RESULTS: MECHANICAL WALKDOWN

10.6 Mechanical Walkdown					
TE Number		**Equipment Name**			
TE51100		**Accessory 10-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Visually inspect the equipment for sharp edges.	Equipment has no sharp edges.			
2.	Visually inspect all external welds.	All welds are continuous, free from cracks and crevices and are easily cleanable.			
3.	Any covered welds must be boroscoped.	Covered welds have been boroscoped.			
4.	Dead legs in pipe work shall not exceed L/D < 2.	Dead legs in pipe work are less than L/D < 2.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

10.6 RESULTS: MECHANICAL WALKDOWN

10.6 Mechanical Walkdown					
TE Number		**Equipment Name**			
TE51101		**Accessory 11-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Visually inspect the equipment for sharp edges.	Equipment has no sharp edges.			
2.	Visually inspect all external welds.	All welds are continuous, free from cracks and crevices and are easily cleanable.			
3.	Any covered welds must be boroscoped.	Covered welds have been boroscoped.			
4.	Dead legs in pipe work shall not exceed L/D < 2.	Dead legs in pipe work are less than L/D < 2.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

10.6 RESULTS: MECHANICAL WALKDOWN

10.6 Mechanical Walkdown					
TE Number		**Equipment Name**			
TE51102		**Accessory 12-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Visually inspect the equipment for sharp edges.	Equipment has no sharp edges.			
2.	Visually inspect all external welds.	All welds are continuous, free from cracks and crevices and are easily cleanable.			
3.	Any covered welds must be boroscoped.	Covered welds have been boroscoped.			
4.	Dead legs in pipe work shall not exceed L/D < 2.	Dead legs in pipe work are less than L/D < 2.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

10.6 RESULTS: MECHANICAL WALKDOWN

10.6 Mechanical Walkdown					
TE Number		**Equipment Name**			
TE51103		**Accessory 13-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Visually inspect the equipment for sharp edges.	Equipment has no sharp edges.			
2.	Visually inspect all external welds.	All welds are continuous, free from cracks and crevices and are easily cleanable.			
3.	Any covered welds must be boroscoped.	Covered welds have been boroscoped.			
4.	Dead legs in pipe work shall not exceed L/D < 2.	Dead legs in pipe work are less than L/D < 2.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

11. VERIFICATION OF RECOMMENDED SPARE PARTS DRAWING

11.1. OBJECTIVE:

- To verify the recommended spare parts drawing is present and that the components comply to the specifications mentioned in the material certs/detail sheets.

11.2. MATERIALS AND EQUIPMENT REQUIRED:

- Recommended Spare Parts Drawing

11.3. PROCEDURE:

- Use a copy of the recommended spare parts drawing and each component's material certs/detail sheets to check the specification agreement.
- Walkdown the equipment using the spare parts drawing and confirm all removable parts are listed with correct quantities.
- For each component, check the presence of the material certs/detail sheets in ETOP documentation; if the material certs/detail sheets are missing for any components, record it on the recommended spare parts drawing as well as in the comment section of this test.
- Date, sign and attach the checked recommended spare parts drawing to this executed protocol.

11.4. ACCEPTANCE CRITERIA:

- All the required components are reported on the recommended spare parts drawing.
- The specification of each component complies with those indicated on the recommended spare parts drawing.
- The checked recommended spare parts drawing is attached to this test sheet.

11.5 RESULT: VERIFICATION OF RECOMMENDED SPARE PARTS DRAWING

11.5 Verification of Recommended Spare Parts Drawing					
TE Number		**Equipment Name**			
TE51073		**Sub Rack 8-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify all the required components are reported on the recommended spare parts drawing.	All the required components are reported on the recommended spare parts drawing.			
2.	Verify each component complies with those indicated on the recommended spare parts drawing.	Each component complies with those indicated on the recommended spare parts drawing.			
3.	Attach the checked recommended spare parts drawing to this executed protocol.	The checked recommended spare parts drawing is attached to this executed protocol.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

11.5 RESULT: VERIFICATION OF RECOMMENDED SPARE PARTS DRAWING

11.5 Verification of Recommended Spare Parts Drawing					
TE Number		**Equipment Name**			
TE51075		**Sub Rack 10-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify all the required components are reported on the recommended spare parts drawing.	All the required components are reported on the recommended spare parts drawing.			
2.	Verify each component complies with those indicated on the recommended spare parts drawing.	Each component complies with those indicated on the recommended spare parts drawing.			
3.	Attach the checked recommended spare parts drawing to this executed protocol.	The checked recommended spare parts drawing is attached to this executed protocol.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

11.5 RESULT: VERIFICATION OF RECOMMENDED SPARE PARTS DRAWING

11.5 Verification of Recommended Spare Parts Drawing					
TE Number		**Equipment Name**			
TE51076		**Sub Rack 11-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify all the required components are reported on the recommended spare parts drawing.	All the required components are reported on the recommended spare parts drawing.			
2.	Verify each component complies with those indicated on the recommended spare parts drawing.	Each component complies with those indicated on the recommended spare parts drawing.			
3.	Attach the checked recommended spare parts drawing to this executed protocol.	The checked recommended spare parts drawing is attached to this executed protocol.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

11.5 RESULT: VERIFICATION OF RECOMMENDED SPARE PARTS DRAWING

11.5 Verification of Recommended Spare Parts Drawing					
TE Number		**Equipment Name**			
TE51083		**Sub Rack 18-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify all the required components are reported on the recommended spare parts drawing.	All the required components are reported on the recommended spare parts drawing.			
2.	Verify each component complies with those indicated on the recommended spare parts drawing.	Each component complies with those indicated on the recommended spare parts drawing.			
3.	Attach the checked recommended spare parts drawing to this executed protocol.	The checked recommended spare parts drawing is attached to this executed protocol.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

11.5 RESULT: VERIFICATION OF RECOMMENDED SPARE PARTS DRAWING

11.5 Verification of Recommended Spare Parts Drawing					
TE Number		**Equipment Name**			
TE51084		**Sub Rack 19-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify all the required components are reported on the recommended spare parts drawing.	All the required components are reported on the recommended spare parts drawing.			
2.	Verify each component complies with those indicated on the recommended spare parts drawing.	Each component complies with those indicated on the recommended spare parts drawing.			
3.	Attach the checked recommended spare parts drawing to this executed protocol.	The checked recommended spare parts drawing is attached to this executed protocol.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

11.5 RESULT: VERIFICATION OF RECOMMENDED SPARE PARTS DRAWING

11.5 Verification of Recommended Spare Parts Drawing					
TE Number		**Equipment Name**			
TE51100		**Accessory 10-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify all the required components are reported on the recommended spare parts drawing.	All the required components are reported on the recommended spare parts drawing.			
2.	Verify each component complies with those indicated on the recommended spare parts drawing.	Each component complies with those indicated on the recommended spare parts drawing.			
3.	Attach the checked recommended spare parts drawing to this executed protocol.	The checked recommended spare parts drawing is attached to this executed protocol.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ **Date:**

11.5 RESULT: VERIFICATION OF RECOMMENDED SPARE PARTS DRAWING

11.5 Verification of Recommended Spare Parts Drawing					
TE Number		**Equipment Name**			
TE51101		**Accessory 11-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify all the required components are reported on the recommended spare parts drawing.	All the required components are reported on the recommended spare parts drawing.			
2.	Verify each component complies with those indicated on the recommended spare parts drawing.	Each component complies with those indicated on the recommended spare parts drawing.			
3.	Attach the checked recommended spare parts drawing to this executed protocol.	The checked recommended spare parts drawing is attached to this executed protocol.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ **Date:**

11.5 RESULT: VERIFICATION OF RECOMMENDED SPARE PARTS DRAWING

11.5 Verification of Recommended Spare Parts Drawing					
TE Number		**Equipment Name**			
TE51102		**Accessory 12-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify all the required components are reported on the recommended spare parts drawing.	All the required components are reported on the recommended spare parts drawing.			
2.	Verify each component complies with those indicated on the recommended spare parts drawing.	Each component complies with those indicated on the recommended spare parts drawing.			
3.	Attach the checked recommended spare parts drawing to this executed protocol.	The checked recommended spare parts drawing is attached to this executed protocol.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

11.5 RESULT: VERIFICATION OF RECOMMENDED SPARE PARTS DRAWING

11.5 Verification of Recommended Spare Parts Drawing					
TE Number		**Equipment Name**			
TE51103		**Accessory 13-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify all the required components are reported on the recommended spare parts drawing.	All the required components are reported on the recommended spare parts drawing.			
2.	Verify each component complies with those indicated on the recommended spare parts drawing.	Each component complies with those indicated on the recommended spare parts drawing.			
3.	Attach the checked recommended spare parts drawing to this executed protocol.	The checked recommended spare parts drawing is attached to this executed protocol.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

12. MATERIAL CERTIFICATION VERIFICATION

12.1. OBJECTIVE:

- To verify that material certification has been provided for all materials of construction.

12.2. MATERIALS AND EQUIPMENT REQUIRED:

- ETOP

12.3. PROCEDURE:

- Verify that material certification has been provided for product surfaces.

12.4. ACCEPTANCE CRITERIA:

- All product contact parts have a mimimum AISI 316 (DIN 1.4401) stainless steel.
- Material certificates are available for all stainless steel components.
- Material certificates and detail sheets are available for all plastic components.

12.5 RESULTS: MATERIAL CERTIFICATION VERIFICATION

12.5 Material Certification Verification					
TE Number		**Equipment Name**			
TE51073		**Sub Rack 8-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify metallic surfaces have been constructed from stainless steel and material certification has been provided.	Metallic surfaces have been constructed from stainless steel and material certification has been provided.			
2.	Verify silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.	All silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.			
3.	Verify the material certificates and detail sheets are present and conform to specifications outlined in approval drawings.	The material certificates and detail sheets are present and conform to specifications outlined in approval drawings.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

12.5 RESULTS: MATERIAL CERTIFICATION VERIFICATION

12.5 Material Certification Verification					
TE Number		**Equipment Name**			
TE51075		**Sub Rack 10-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify metallic surfaces have been constructed from stainless steel and material certification has been provided.	Metallic surfaces have been constructed from stainless steel and material certification has been provided.			
2.	Verify silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.	All silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.			
3.	Verify the material certificates and detail sheets are present and conform to specifications outlined in approval drawings.	The material certificates and detail sheets are present and conform to specifications outlined in approval drawings.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

12.5 RESULTS: MATERIAL CERTIFICATION VERIFICATION

12.5 Material Certification Verification					
TE Number		**Equipment Name**			
TE51076		**Sub Rack 11-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify metallic surfaces have been constructed from stainless steel and material certification has been provided.	Metallic surfaces have been constructed from stainless steel and material certification has been provided.			
2.	Verify silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.	All silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.			
3.	Verify the material certificates and detail sheets are present and conform to specifications outlined in approval drawings.	The material certificates and detail sheets are present and conform to specifications outlined in approval drawings.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

12.5 RESULTS: MATERIAL CERTIFICATION VERIFICATION

12.5 Material Certification Verification					
TE Number		**Equipment Name**			
TE51083		**Sub Rack 18-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify metallic surfaces have been constructed from stainless steel and material certification has been provided.	Metallic surfaces have been constructed from stainless steel and material certification has been provided.			
2.	Verify silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.	All silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.			
3.	Verify the material certificates and detail sheets are present and conform to specifications outlined in approval drawings.	The material certificates and detail sheets are present and conform to specifications outlined in approval drawings.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

12.5 RESULTS: MATERIAL CERTIFICATION VERIFICATION

12.5 Material Certification Verification					
TE Number		**Equipment Name**			
TE51084		**Sub Rack 19-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify metallic surfaces have been constructed from stainless steel and material certification has been provided.	Metallic surfaces have been constructed from stainless steel and material certification has been provided.			
2.	Verify silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.	All silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.			
3.	Verify the material certificates and detail sheets are present and conform to specifications outlined in approval drawings.	The material certificates and detail sheets are present and conform to specifications outlined in approval drawings.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

12.5 RESULTS: MATERIAL CERTIFICATION VERIFICATION

12.5 Material Certification Verification					
TE Number		**Equipment Name**			
TE51100		**Accessory 10-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify metallic surfaces have been constructed from stainless steel and material certification has been provided.	Metallic surfaces have been constructed from stainless steel and material certification has been provided.			
2.	Verify silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.	All silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.			
3.	Verify the material certificates and detail sheets are present and conform to specifications outlined in approval drawings.	The material certificates and detail sheets are present and conform to specifications outlined in approval drawings.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

12.5 RESULTS: MATERIAL CERTIFICATION VERIFICATION

12.5 Material Certification Verification					
TE Number		**Equipment Name**			
TE51101		**Accessory 11-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify metallic surfaces have been constructed from stainless steel and material certification has been provided.	Metallic surfaces have been constructed from stainless steel and material certification has been provided.			
2.	Verify silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.	All silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.			
3.	Verify the material certificates and detail sheets are present and conform to specifications outlined in approval drawings.	The material certificates and detail sheets are present and conform to specifications outlined in approval drawings.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

12.5 RESULTS: MATERIAL CERTIFICATION VERIFICATION

12.5 Material Certification Verification					
TE Number		**Equipment Name**			
TE51102		**Accessory 12-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify metallic surfaces have been constructed from stainless steel and material certification has been provided.	Metallic surfaces have been constructed from stainless steel and material certification has been provided.			
2.	Verify silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.	All silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.			
3.	Verify the material certificates and detail sheets are present and conform to specifications outlined in approval drawings.	The material certificates and detail sheets are present and conform to specifications outlined in approval drawings.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

12.5 RESULTS: MATERIAL CERTIFICATION VERIFICATION

12.5 Material Certification Verification					
TE Number		**Equipment Name**			
TE51103		**Accessory 13-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Verify metallic surfaces have been constructed from stainless steel and material certification has been provided.	Metallic surfaces have been constructed from stainless steel and material certification has been provided.			
2.	Verify silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.	All silicone seals and elastomeric components used in machine construction are approved for pharmaceutical use.			
3.	Verify the material certificates and detail sheets are present and conform to specifications outlined in approval drawings.	The material certificates and detail sheets are present and conform to specifications outlined in approval drawings.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer): _____ Date:

13. FIT TESTING

13.1. OBJECTIVE:

- To verify the customer parts supplied for FAT fit on the equipment.

13.2. MATERIALS AND EQUIPMENT REQUIRED:

- Equipment listed in table 1.
- Customer parts supplied for FAT.
- Camera.

13.3. PROCEDURE:

- Load the customer parts onto the equipment, as per the approval drawing.
- Inspect each part when loaded on the equipment to ensure that the part is securely supported for washing and will not dislodge or move during loading.
- Take photo(s) of the equipment with all available customer parts loaded.
- During fit inspection if a part is identified as not securely supported on the equipment record a video highlighting the fit of the part.
- Upload the photo(s)/video to a shared folder for the customer to review during FAT.

13.4. ACCEPTANCE CRITERIA:

- All the supplied components fit on the equipment locations as per the approval drawing.
- The customer parts are securely supported on the equipment.
- The customer part does not dislodge from the equipment during loading.

13.5 RESULT: VERIFICATION OF FIT CHECK

13.5 Verification of Fit Check					
TE Number	**Customer Parts Available (Y/N)**	**Full load / Partial load**	**Photo(s) Taken (Y/N)**	**Video required (Y/N)**	**Verified By** (Initial & Date)

NOTE: N/A ANY UNUSED ROWS OR CELLS

Document review by (Customer):_____ Date:

14. OPERATIONAL TESTING

14.1. OBJECTIVE:

- To verify the equipment loaded with the customer's components performs as intended.
- To verify the Riboflavin spray coverage testing.

14.2. MATERIALS AND EQUIPMENT REQUIRED:

- TEG Test Chamber system.
- Equipment to be tested.
- Customer's components to be tested.
- TEG Coverage Testing Guidelines.
- UV torch.
- Riboflavin.
- Balance.

14.3. PROCEDURE:

- Conduct riboflavin spray coverage testing as per the TEG Coverage Testing Guidelines (refer to riboflavin preparation form in appendix 1).

14.4. ACCEPTANCE CRITERIA:

- All critical part surfaces on the components supplied for FAT testing have met the "very good-excellent" acceptance criteria as per the TEG Coverage Testing Guidelines.
- The orientation of all components on the equipment allows for free drainage (unless Pooling has been highlighted on the approval drawing).
- The equipment is free draining.

14.5 RESULT: VERIFICATION OF PERFORMANCE

14.5 Verification of Performance					
TE Number			**Equipment Name**		
TE51073			**Sub Rack 8-01**		
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Equipment must be self-cleaning (with the aid of washer chamber).	Equipment is self-cleaning (with the aid of washer chamber).			
2.	Equipment piping must be free draining.	Equipment piping is free draining.			
3.	The equipment must not have any areas for puddling or pooling of water.	The equipment has no areas for puddling or pooling of water.			
4.	Provide adequate spacing on the equipment to allow airflow around parts to dry.	There is adequate spacing on the equipment to allow airflow around parts to dry.			
5.	Parts shall be oriented to prevent filling / accumulation of liquid.	Parts are oriented to prevent filling / accumulation of liquid.			
6.	Parts shall be sufficiently secure to prevent movement during washing cycle.	Parts are sufficiently secure to prevent movement during washing cycle.			
7.	Coverage testing will be performed on the equipment load.	Coverage testing has been performed and documented in Appendix 2.			
8.	Spray coverage on parts must be effective, as per the TEG Coverage Testing Guidelines.	Spray and coverage testing is effective.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

14.5 RESULT: VERIFICATION OF PERFORMANCE

14.5 Verification of Performance					
TE Number		**Equipment Name**			
TE51075		**Sub Rack 10-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Equipment must be self-cleaning (with the aid of washer chamber).	Equipment is self-cleaning (with the aid of washer chamber).			
2.	Equipment piping must be free draining.	Equipment piping is free draining.			
3.	The equipment must not have any areas for puddling or pooling of water.	The equipment has no areas for puddling or pooling of water.			
4.	Provide adequate spacing on the equipment to allow airflow around parts to dry.	There is adequate spacing on the equipment to allow airflow around parts to dry.			
5.	Parts shall be oriented to prevent filling / accumulation of liquid.	Parts are oriented to prevent filling / accumulation of liquid.			
6.	Parts shall be sufficiently secure to prevent movement during washing cycle.	Parts are sufficiently secure to prevent movement during washing cycle.			
7.	Coverage testing will be performed on the equipment load.	Coverage testing has been performed and documented in Appendix 2.			
8.	Spray coverage on parts must be effective, as per the TEG Coverage Testing Guidelines.	Spray and coverage testing is effective.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

14.5 RESULT: VERIFICATION OF PERFORMANCE

14.5 Verification of Performance					
TE Number		**Equipment Name**			
TE51076		**Sub Rack 11-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Equipment must be self-cleaning (with the aid of washer chamber).	Equipment is self-cleaning (with the aid of washer chamber).			
2.	Equipment piping must be free draining.	Equipment piping is free draining.			
3.	The equipment must not have any areas for puddling or pooling of water.	The equipment has no areas for puddling or pooling of water.			
4.	Provide adequate spacing on the equipment to allow airflow around parts to dry.	There is adequate spacing on the equipment to allow airflow around parts to dry.			
5.	Parts shall be oriented to prevent filling / accumulation of liquid.	Parts are oriented to prevent filling / accumulation of liquid.			
6.	Parts shall be sufficiently secure to prevent movement during washing cycle.	Parts are sufficiently secure to prevent movement during washing cycle.			
7.	Coverage testing will be performed on the equipment load.	Coverage testing has been performed and documented in Appendix 2.			
8.	Spray coverage on parts must be effective, as per the TEG Coverage Testing Guidelines.	Spray and coverage testing is effective.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

14.5 RESULT: VERIFICATION OF PERFORMANCE

14.5 Verification of Performance					
TE Number		**Equipment Name**			
TE51083		**Sub Rack 18-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Equipment must be self-cleaning (with the aid of washer chamber).	Equipment is self-cleaning (with the aid of washer chamber).			
2.	Equipment piping must be free draining.	Equipment piping is free draining.			
3.	The equipment must not have any areas for puddling or pooling of water.	The equipment has no areas for puddling or pooling of water.			
4.	Provide adequate spacing on the equipment to allow airflow around parts to dry.	There is adequate spacing on the equipment to allow airflow around parts to dry.			
5.	Parts shall be oriented to prevent filling / accumulation of liquid.	Parts are oriented to prevent filling / accumulation of liquid.			
6.	Parts shall be sufficiently secure to prevent movement during washing cycle.	Parts are sufficiently secure to prevent movement during washing cycle.			
7.	Coverage testing will be performed on the equipment load.	Coverage testing has been performed and documented in Appendix 2.			
8.	Spray coverage on parts must be effective, as per the TEG Coverage Testing Guidelines.	Spray and coverage testing is effective.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

14.5 RESULT: VERIFICATION OF PERFORMANCE

14.5 Verification of Performance					
TE Number		**Equipment Name**			
TE51084		**Sub Rack 19-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Equipment must be self-cleaning (with the aid of washer chamber).	Equipment is self-cleaning (with the aid of washer chamber).			
2.	Equipment piping must be free draining.	Equipment piping is free draining.			
3.	The equipment must not have any areas for puddling or pooling of water.	The equipment has no areas for puddling or pooling of water.			
4.	Provide adequate spacing on the equipment to allow airflow around parts to dry.	There is adequate spacing on the equipment to allow airflow around parts to dry.			
5.	Parts shall be oriented to prevent filling / accumulation of liquid.	Parts are oriented to prevent filling / accumulation of liquid.			
6.	Parts shall be sufficiently secure to prevent movement during washing cycle.	Parts are sufficiently secure to prevent movement during washing cycle.			
7.	Coverage testing will be performed on the equipment load.	Coverage testing has been performed and documented in Appendix 2.			
8.	Spray coverage on parts must be effective, as per the TEG Coverage Testing Guidelines.	Spray and coverage testing is effective.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

14.5 RESULT: VERIFICATION OF PERFORMANCE

14.5 Verification of Performance					
TE Number		**Equipment Name**			
TE51100		**Accessory 10-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Equipment must be self-cleaning (with the aid of washer chamber).	Equipment is self-cleaning (with the aid of washer chamber).			
2.	Equipment piping must be free draining.	Equipment piping is free draining.			
3.	The equipment must not have any areas for puddling or pooling of water.	The equipment has no areas for puddling or pooling of water.			
4.	Provide adequate spacing on the equipment to allow airflow around parts to dry.	There is adequate spacing on the equipment to allow airflow around parts to dry.			
5.	Parts shall be oriented to prevent filling / accumulation of liquid.	Parts are oriented to prevent filling / accumulation of liquid.			
6.	Parts shall be sufficiently secure to prevent movement during washing cycle.	Parts are sufficiently secure to prevent movement during washing cycle.			
7.	Coverage testing will be performed on the equipment load.	Coverage testing has been performed and documented in Appendix 2.			
8.	Spray coverage on parts must be effective, as per the TEG Coverage Testing Guidelines.	Spray and coverage testing is effective.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

14.5 RESULT: VERIFICATION OF PERFORMANCE

14.5 Verification of Performance					
TE Number		**Equipment Name**			
TE51101		**Accessory 11-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Equipment must be self-cleaning (with the aid of washer chamber).	Equipment is self-cleaning (with the aid of washer chamber).			
2.	Equipment piping must be free draining.	Equipment piping is free draining.			
3.	The equipment must not have any areas for puddling or pooling of water.	The equipment has no areas for puddling or pooling of water.			
4.	Provide adequate spacing on the equipment to allow airflow around parts to dry.	There is adequate spacing on the equipment to allow airflow around parts to dry.			
5.	Parts shall be oriented to prevent filling / accumulation of liquid.	Parts are oriented to prevent filling / accumulation of liquid.			
6.	Parts shall be sufficiently secure to prevent movement during washing cycle.	Parts are sufficiently secure to prevent movement during washing cycle.			
7.	Coverage testing will be performed on the equipment load.	Coverage testing has been performed and documented in Appendix 2.			
8.	Spray coverage on parts must be effective, as per the TEG Coverage Testing Guidelines.	Spray and coverage testing is effective.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

14.5 RESULT: VERIFICATION OF PERFORMANCE

14.5 Verification of Performance					
TE Number		**Equipment Name**			
TE51102		**Accessory 12-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Equipment must be self-cleaning (with the aid of washer chamber).	Equipment is self-cleaning (with the aid of washer chamber).			
2.	Equipment piping must be free draining.	Equipment piping is free draining.			
3.	The equipment must not have any areas for puddling or pooling of water.	The equipment has no areas for puddling or pooling of water.			
4.	Provide adequate spacing on the equipment to allow airflow around parts to dry.	There is adequate spacing on the equipment to allow airflow around parts to dry.			
5.	Parts shall be oriented to prevent filling / accumulation of liquid.	Parts are oriented to prevent filling / accumulation of liquid.			
6.	Parts shall be sufficiently secure to prevent movement during washing cycle.	Parts are sufficiently secure to prevent movement during washing cycle.			
7.	Coverage testing will be performed on the equipment load.	Coverage testing has been performed and documented in Appendix 2.			
8.	Spray coverage on parts must be effective, as per the TEG Coverage Testing Guidelines.	Spray and coverage testing is effective.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

14.5 RESULT: VERIFICATION OF PERFORMANCE

14.5 Verification of Performance					
TE Number		**Equipment Name**			
TE51103		**Accessory 13-01**			
Test No.	**Procedure**	**Expected Results**	**Acceptable (PASS/FAIL)**	**Punchlist Item No.**	**Performed By** (Initial and Date)
1.	Equipment must be self-cleaning (with the aid of washer chamber).	Equipment is self-cleaning (with the aid of washer chamber).			
2.	Equipment piping must be free draining.	Equipment piping is free draining.			
3.	The equipment must not have any areas for puddling or pooling of water.	The equipment has no areas for puddling or pooling of water.			
4.	Provide adequate spacing on the equipment to allow airflow around parts to dry.	There is adequate spacing on the equipment to allow airflow around parts to dry.			
5.	Parts shall be oriented to prevent filling / accumulation of liquid.	Parts are oriented to prevent filling / accumulation of liquid.			
6.	Parts shall be sufficiently secure to prevent movement during washing cycle.	Parts are sufficiently secure to prevent movement during washing cycle.			
7.	Coverage testing will be performed on the equipment load.	Coverage testing has been performed and documented in Appendix 2.			
8.	Spray coverage on parts must be effective, as per the TEG Coverage Testing Guidelines.	Spray and coverage testing is effective.			

NOTE: N/A ANY UNUSED ROWS OR CELLS

Comments:

Document review by (Customer):_____ Date:

15. PUNCHLIST/DEVIATIONS

List details of all deviations found during the execution of the protocol (on following page).

Define the level of criticality (category) for each deviation listed.

Deviations can be defined as:

(a) Major: When having an influence on product quality, cGMP or EHS.

(b) Minor: When having no impact on product quality, cGMP or EHS.

Report in the punchlist on the following page the description, references (if any), and person responsible for the completion of the actions agreed for each of the deviations raised during the execution of the FAT.

Additional pages available.

Punchlist Summary

Customer Name:	**PATHEON MANUFACTURING SERVICES LLC**	**Sale Order Number:**	23205

Punchlist Item No:	**Equipment TE Number**	**Description of Punchlist item**	**Major/Minor Deviation**	**Assigned to:** (Customer or TEG dept)	**Resolution Approved** (initial & date)	**Resolution Accepted & Closed** (yes/no)

NOTE: N/A ANY UNUSED ROWS OR CELLS

SEE PUNCHLIST DOCUMENT NO. FOR DETAILS

16. ATTACHMENTS

- Attach applicable documentation and record the applicable test section (and step if applicable), include an attachment description, total number of pages, and initial and date.
- Label attachments clearly.
- If the attachment does not include sequential pagination, indicate on each page of multiple page attachments the document number, attachment number, page number, page count (e.g. Page 2 of 3), initials and date.
- If the attachment includes sequential pagination, the document number, attachment number, initials and date are required on the first and last page.

Sheet __of __

#	Test Section	Attachment Description	# Pages	Initial & Date

NOTE: N/A ANY UNUSED ROWS OR CELLS

Document review by (Customer):_____ Date:

17. FAT SUMMARY AND CONCLUSIONS

The comments below result from a determination of the findings of the FAT protocol execution. These should include whether all of the objectives have been met and a recommendation stating whether the equipment is considered ready for shipment.

Place and date of the FAT: .....

The FAT is:

☐ accepted without remarks
☐ accepted with remarks (see punchlist)
☐ not accepted

Result / actions:

.....

.....

.....

.....

.....

Approval of FAT execution:

Company	Position	Name	Date	Signature
TEG				

18. SHIPPING APPROVAL

The tests and checks detailed in this FAT protocol have been completed and the results documented.

All deviations/Punchlist items have been recorded in the Punchlist section of this document and all the actions agreed.

All deviations/Punchlist items that have been identified are reviewed and deemed acceptable to proceed to the next phase of commissioning/qualification.

All documentation handed over to customer.

The equipment is ready for shipment.

SHIPPING APPROVALS			
Department	**Name**	**Signature**	**Date**
Engineering (TEG)			
Validation			
Quality			

APPENDIX 1

RIBOFLAVIN PREPARATION FORM

Riboflavin Preparation Form			
No.	**Action**	**Result**	**Prepared By** (Initial & Date)
1	Record the date of the preparation of the riboflavin solution	Date:	
2	Record the Manufacturer, Lot Number & Expiry date of the riboflavin	Manufacturer:	
		Lot Number:	
		Expiry Date:	
3	Record Balance ID/Calibration Date/Calibration Expiry	Balance ID:	
		Calibration Date:	
		Calibration Expiry Date:	
4	Record the weight (g) of the riboflavin. Target 0.2g/L (Range 0.18 to 0.22g/L)	Weight:	
5	Record the volume (L) of the water used to prepare the riboflavin solution	Volume:	
6	Record the concentration (g/L) of the solution	Concentration:	
7	Confirm the riboflavin is dissolved and record the time. (*This is the start time of the 48-hour usage period*)	Time:	
8	Record expiry time and date of the riboflavin solution (*maximum usage time duration is 48 hours)*	Date:	
		Time:	

Document review by (Customer): _____Date:

APPENDIX 2

RIBOFLAVIN COVERAGE TEST RECORD SHEET

RIBOFLAVIN COVERAGE TEST RECORD SHEET						
TE Number	**Run Number**	**Water Pressure** (Bar)	**Load** (e.g. full/partial)	**Pass / Fail**	**Performed By** (Initial & Date)	**Verified By** (Initial & Date)

NOTE: N/A ANY UNUSED ROWS OR CELLS

Document review by (Customer):__ Date:

APPENDIX 3

ATTACHMENT PAGE COVER SHEET

ATTACHMENT COVER SHEET

ATTACHMENT DESCRIPTION:

Total Number of pages in Attachment _____(including this page)