FACTORY

ACCEPTANCE TEST

FOR

SAMPLING AND CLEANING STATION

FAT FOR SAMPLING & CLEANING STATION

INDEX

FAT FOR SAMPLING & CLEANING STATION

1.0 INTRODUCTION:

The objective of this Factory Acceptance Test is to verify that the equipment has been built & engineered according to the design specification and, as a result, the equipment is approved for Shipping to the .....handover will be following completion of a successful site acceptance test.

This document will be completed as follows:

- All people who enter data into this report will complete the section of this FAT titled 'FAT Personnel'. See Appendices. A, B, C, D, E, F.
- Any corrections in handwriting will be made by deleting with a single pen stroke; the correction will be initialled and dated.
- Entries shall be made in this document using a ballpoint pen or suitable indelible ink in black only.
- Compliance will be indicated by a written YES or NO in the relevant boxes provided. 'Ticks' and 'crosses' must not be used.
- Correction fluid is not allowed.
- Each section will be signed and dated by the tester/s when it is complete.
- Any non-compliance identified during the execution of the test protocols must be documented in a Deviation report. These report sheets must be attached to the appropriate appendix of this protocol. The report will describe the deviation in detail and, whenever possible, identifying the cause.

2.0 ENGINEERING DOCUMENTATION VERIFICATION:

The objective of this test is to verify that the engineering documentation specified in the order specifications is at the Factory and is present and complete.

Procedure

Review the documentation package of the equipment. Documentation must be present, properly numbered, approved where necessary and containing the necessary information.

In the event that there is an unacceptable or unobtainable document complete a deviation report.

Acceptance Criteria

The review should confirm that all relevant information pertaining to the system is present and complete.

In some cases approval to handover may be given in the absence of documentation providing the review forms are acted upon and that the documentation is available before the client's IQ.

Document Expected	Reference Number	Revision	Approval Date	Available Yes/No
Purchase Order	.....			
G A Drawing	.....			
Canopy Drawing	.....			
Utility list	Doc No. ...../ Utility list			
DQ	Doc No. ...../ DQ			
FDS	Doc No. ...../ FDS			
Material Chart	Doc No. ...../ Material Chart.		-	
Electrical drawing	.....			
Manual				
Operation Manual	Doc No. ...../ IMOI		-	
Manual for bought out components:	As per Material Chart			

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Comments

Tested By:		**Approved By:**	
Date		**Date**	

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3.0 MECHANICAL HARDWARE CHECKS:

3.1 Devices finishes checks

Drawing/Document No.	Revision No.	Title
.....	.....	General Arrangement

Procedure

Take a copy of the GA drawing detailed above.

Write on the on the GA drawing the finishes found using the RA meter against the required specification.

Mark with a yellow 'highlighter' pen the finishes that are verified.

Mark with a red 'highlighter' pen on the drawing any corrections.

Attach the marked-up drawing labelled as ‘FAT Mechanical Hardware Check’ to this FAT as an appendix.

Detail any items in non-compliance in a deviation report and attach as an appendix.

Acceptance Criteria

1. All items identified on drawing.
2. Materials of Construction (MOC): Confirmed by Certificate of Conformity from fabricator.
3. Finish specification is confirmed by RA meter.

Acceptance Criteria	Complies Yes/No
Items identified on the GA drawing.	
MOC identified on the GA drawing.	
Certificates of Conformity located in VTOP.	
RA meter finish specification and required specification marked on the drawing.	

Comments

Tested By:		**Approved By**	
Date		**Date**	

3.2 Fittings Check:

Drawing/Document No.	Revision No.	Initial/Date	Title
			GA Schematic
			FDS

Procedure:

Compare the installed fittings with those specified on the GA and the Component List provided as per Test Sheet.

Mark with a yellow 'highlighter' pen on the drawing the details which are verified.

Mark with a red pen on the drawing any corrections.

Attach the Marked-Up drawing and component list labelled as 'FAT Fittings Check' to this FAT as an appendix E.

Detail any items in non-compliance in a deviation report and attach as an appendix.

Acceptance Criteria
Items identified and correctly fitted.

Components:

Tag	PART	DESCRIPTION	QTY	MAKE	Available Yes/No
	Main Body	10 MIL Clear ,anti-static polyurethane 950 x 950 x 930 mm	1		
	Trash in Sleeve	10 MIL Clear anti-static polyurethane. 200 mm dia. X 150 mm long	1		
	Trash out Sleeve	250 mm dia.x 1500 mm long	1		
	Feed in Sleeve	10 MIL Clear, anti-static polyurethane 200 mm dia. X 1200 mm long	1		
	Left Glove Assembly	Nitrile , 8 MIL Frosty	1		
	Right Glove Assembly	Nitrile , 8 MIL Frosty	1		
	Canister	200 mm dia. Canister Polypropylene with adjustable bend clamps, & O ring	1		
	Zipper Coil Outer Gas proof Zip	200 mm dia. opening anti-static polyurethane coated	1		
	Zipper Coil Inner Dust Proof Zip	8" opening anti-static polyurethane coated	1		

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Tag	PART	DESCRIPTION	QTY	MAKE	Available Yes/No
	U Grip		4 mtr		
	SS Base Plate	SS 316 Base plate 3 mm thick ,0.4 Ra mirror polished	1		
	SS frame	SS 304 frame for attaching the canopy	1		
	Wash gun	**Type -** Water Saver Gun, with Hose connector **Size-** ½" bsp **MOC** - SS 316 **Capacity** 300 Ltr/ Hr, **Pressure :-** ½ kg/ cm^2	1		
	Ball valve 1"	Drain of Sampling and Cleaning Station TC end connection SS316 L	3		
	Wash Media Supply Ball valve 1"	**Type -**Manual Ball Valve, Flange Connection end **Size-** 25 NB, **MOC** - SS 316 Teflon seat	1		
	Compressed Air Supply Needle valve 1"	**Type -**Manual Needle Valve, Flange Connection end **Size-** 25 NB, **MOC** - SS 316 Teflon seat	1		
	Spray Ball IBC Cleaning	SS 316 ,3/8" BSP TC End connections, Model: E20.021.24.Y.AH Mounted on SS 316 Cover Plate to suit the IBC	1		
	Dust Extraction port	Type – 2 ½" TC type MOC- SS 316 With –EU 13 Filter	1		
	RTPA	**Type -** seat Rapid transfer Active Port **Size-** 6" **MOC** - SS 316 Teflon seat	1		

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Tag	PART	DESCRIPTION	QTY	MAKE	Available Yes/No
	Jacking Trolley	Manually operated Hydraulic Jack in SS 304	1		
	Support rod	SS 316 with ring and SS 136 funnel	1		
	Sampling Rod	SS 316 1000 mm long, 2gm sample pockets (3 nos.), 3 sampling slots	1		

Comments

Tested By:		Approved By:	
Date		Date	

3.3 Critical Dimensional Check:

Drawing No.	Revision No.	Initial/Date	Title
			General Arrangement

Procedure

Compare the critical dimensions with those specified on the drawing.

Mark with a yellow 'highlighter' pen on the drawing the details which are verified.

Mark with a red pen on the drawing any corrections.

Attach the marked-up drawing labelled as ‘FAT Critical Dimensions Check’ to this FAT as an appendix.

Detail any items in non-compliance in a deviation report and attach as an appendix.

Acceptance Criteria	Complies Yes/No
All Dimensions under 1000mm +/- 3mm	
All Dimensions over 1000mm +/- 5mm	
Critical hole centres +/- 2mm.	

Comments

Tested By:		Approved By:	
Date		Date	

4.0 HEPA FILTERS INSTALLATION & INTEGRITY TESTING:

Document/Drawing No.	Revision No.	Initial / Date	Title
			FDS
			GA

To ensure that all HEPA filters installed within the system comply with manufacturer's specifications. HEPA filters are not to be installed at FAT; supplier integrity test certificates must be checked.

Procedure

Take a copy of the list of all HEPA filters from the following sheet, and check against the P&ID and the unopened boxes of those filters allocated to be sent to the client's site. Review the certificates for all of the HEPA filter integrity tests from the vendor.

Attach the marked-up drawing and filter list labelled as 'FAT Filter Check' to this FAT as an appendix.

Tag	PART	Acceptance criteria	Pass/Fail
	Exhaust Filter	The certificates for the supplier integrity testing are included in the documentation package and meet acceptance criteria set for filter integrity testing.	

Comments

Tested By:		Approved By	
Date		Date	

5.0 PRESSURE HOLD TEST:

Required		
Calibrated Manometer	6 mm Nylon Pneumatic Tube	Needle Valve
Stop Watch	Isolation Valve	Compressed Air Supply

Procedure:

	Description of Test
1	This test requires the isolator and the room to be in thermal equilibrium with minimal external influences from drafts from open doors and windows.
2	Ensure all valves on service entries are closed and any non-valved service entries are blanked off with suitable blanking plates and gaskets.
3	Ensure all gloves are fitted to the glove ports with no sign of damage to gauntlets. Gloves must not be touched or disturbed during the test.
4	Connect the manometer to the isolator.
5	Connect the compressed air supply to the isolator.
6	Place the thermometer inside the isolator.
7	Open the Isolation valve slowly until a pressure of +250Pa is recorded on the Manometer then close the valve.
8	Allow to stabilise for 5 minutes.
9	For the duration of the test do not allow doors to be opened or closed in the room. The room must not be subjected to pressure and temperature variation.
10	Record in the table the pressure and temperature within the Isolator every minute for a period of 10 minutes.
11	Calculate the pressure decay using the formula below.
12	If the acceptance criteria are not achieved locate the leak and re test.

The leakage rate is based on the isolator classifications and the acceptance criteria detailed in ISO 10648-2.

Class of Isolator (ISO 10648-2)	Hourly leak Rate (/h)	Percentage Volume Change/Hour (%/h)	Standard Decay Time for a 25 Pa Drop (mins)
2 (with inert gas)	0.0025	Less than 0.25	6
3 (without inert gas)	0.01	Less than 1	1.5

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Time Minutes	Measured Pressure Pa	Measured Temperature ^0C
0		
10		
20		
30		
40		
50		
60		

$$Tf = \frac{60}{t} \frac{((P2 \times T1)-1)}{P1 \times T2}$$

Tf = Leakage rate

t – period of test in Min.

P2 = 100000 + measured Pa at end of test period,

P1 = 100000 + Initial Pa

T1 = Initial Temp. in ^0K

T2 = Final Temp in ^0K

Acceptance Criteria:

Isolator Type	Acceptance Criteria	Pass / Fail
	Hourly leakage Rate Less Than 2.5×10^{-3}	

Comments

Tested By:		**Approved By**	
Date		**Date**	

6.0 CLEANING VERIFICATION (FULL WIP WILL BE DONE AT SAT):

This test function confirms that all internal surfaces can be easily reached and washed and also confirms ease of cleaning external surfaces.

Procedure:

Confirm that all internal and necessary external surfaces can be reached cleaned following the SOP.

Acceptance Criteria	Complies Yes/No
All internal surfaces can be reached easily	
Lighting adequate to perform operations	
All external surfaces can be reached	

Comments

Tested By:		Approved By	
Date		Date	

7.0 RTP OPERATIONAL CHECKS:

Pre Requisites for test
Steri Wipes

Description of Test
Using the passive RTP, Dock to active several times to prove the interlock and ease of use. Ensure that faces are cleaned before docking and no damage is visible on contact surfaces. Record results in tables provided

Acceptance Criteria

Passive port docks to active without excessive force.

Valve opens and closes without excessive force.

Active RTP	No.	Dock	Valve Opens	Valve Closes	De Dock	Complies YES/NO
Passive	1					

Comments

Tested By:		Approved By	
Date		Date	

8.0 ISOLATOR OPERATIONAL CHECKS:

Document	Number	Revision
Functional Design Specification		

Procedure:

Operate the Isolator and confirm that it is in accordance with operational descriptions and specifications below.

OPERATION:

1. The Sampling and Cleaning Station is equipped with
   - Support Structure, Valves for WIP, Spray Ball , RTP Active with base tray
   - Jacking Hoist for docking, lifting the IBC
   - Canopy to provide containment with gas-proof zip, snap tubing for attachment to the structure, Vent Filter, Gloves, Trash out sleeve, Canister to integrate sleeve and trash bag
   - Sampling Rod for sampling purpose, hanger and funnel for sample collection within the canopy.
2. The IBC containing product to be sampled is docked to the base of the station using jacking hoist.
3. A clean sampling rod is transferred to the canopy using feed-in sleeve.
4. The RTP Passive is docked to the RTP Active.
5. The RTP is opened.
6. Using the Sampling Rod, the product is sampled.
7. The sampling rod is withdrawn and the sample collected in the bag through the funnel provided for the purpose inside the canopy.
8. The bag(s) are then sealed and transferred to the trash out bag.
9. The trash out bag is double tied, cut and taken for testing.
10. WIP of the Sampling and Cleaning Station is carried out using the Spray Gun provided in the chamber. The Sampling and Cleaning Station is free draining.
11. The flexible canopy can be wiped or hand sprayed with decontamination solution

Acceptance Criteria	Complies Yes/No
Equipments Operated as per Operation Description above	

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Comments

Tested By:		**Approved By**	
Date		**Date**	

9.0 TEST INSTRUMENTS:

Objective - To identify the equipment and instruments used for testing during the Factory Acceptance Test phase and to verify that they were calibrated.

Procedure - List all test or reference instruments used during the Factory Acceptance Test of the system. Include the description, serial number, manufacturer, and calibration for each item, as applicable.
Verify that all such instruments are calibrated.
Document the results in the table below. Any discrepancies to be noted on the review form and on the Deviation Report.

Acceptance Criteria - All instruments used to qualify the system during Factory Acceptance Test shall be listed along with their description, serial number, Certificate number, calibration dates, as applicable.
For each instrument, a copy of the calibration certification is to be included with this protocol or its location referenced.

Instrument	Serial Number	Certificate Number	Available Yes / No
RA meter			
Pressure gauge			
Stop Watch			

Comments

Tested By:		Approved By	
Date		Date	

10.0 POST APPROVAL:

Completion of the FAT, including satisfactory resolution of all discrepancies noted during execution, will be documented below, signed by the person with overall review responsibility for the protocol and by the client's authorised signatories who approved the protocol.

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Agreed criteria	Agreement YES/NO
1. Approval for shipment	
2. Machine is approved for shipment following correction of all Deviations noted during FAT	
3. Machine is not approved & will require repeat FAT following correction of all deviations.	

.....			
Reviewed By	**Print Name**	**Signature**	

Client			
	Print Name	**Signature**	**Date**
Consultant			
Engineering			
Quality Assurance			

11.0 APPENDIX A - FACTORY ACCEPTANCE TEST (FAT) PERSONNEL:

Print Name	Signature	Date	Company

12.0 APPENDIX B - CALIBRATION CERTIFICATES REGISTER:

Number	Description	Attached Yes/No

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Comments

Tested By:		**Approved By**	
Date		**Date**	

13.0 APPENDIX C - DEVIATION REPORTS PROCEDURE:

During FAT testing, a Deviation Report must be raised when there is a failure to meet acceptance criteria.

The aim is to:

- Clearly describe the deviation.
- To document and approve the evaluation of the impact of the deviation.
- To document and approve the corrective action required to resolve it.
- To document the closing out of the deviation with the appropriate approvals.

Procedure

a. If a test step fails to meet test acceptance criteria/method then a Deviation Report must be raised. See Appendix.

b. All Deviation Reports must be logged by completing the Deviation Report Register. See Appendix

c. Each Deviation Report must reference the following identification numbers: -

- Protocol document reference number.
- The applicable test reference number (XX) as defined in the protocol.
- A unique deviation reference number, which comprises the specific test number and a sequential deviation number (YY) for that test in the format XX/YY. Subsequent deviations on the same

d. The person raising the deviation must clearly describe the exact nature of the deviation (why acceptance criteria/method has not been met) using the ‘details of deviation noted’ box provided.

e. The deviation must be fully evaluated and the necessary corrective action formulated and must be pre-approved by Bectochem & the Client. The findings of this evaluation together with details of corrective action required to resolve the deviation should be clearly documented by completing the ‘evaluation of deviation/corrective actions to be taken’ box.

f. Once the proposed corrective action has been pre-approved, the tester will execute the corrective work and verify implementation of corrective action by completing the ‘Results of Corrective Action’ box. The tester will then sign and date the Deviation report.

g. The completed Deviation Report will require approval by the appropriate personnel on the Deviation Report.

h. Completed Deviation Reports must be attached to the Appendix of this FAT protocol.

i. This FAT document cannot be closed off until all deviations have been satisfactorily resolved.

14.0 APPENDIX D - FAT DEVIATION REGISTER:

Deviation Report No.	Brief Description	Date Raised	Date Closed	Checked By

15.0 APPENDIX E - DEVIATION REPORT SHEET:

Deviation No:		**Test Reference:**	
Details Of Deviation Noted:			
Completed By:			**Date:**
Evaluation Of Deviation / Corrective Actions To Be Taken:			
Completed By:		**Date:**	
PRE-APPROVALS - EVALUATION / CORRECTIVE ACTIONS			
The following signatures pre-approve the content of the evaluation and the necessary corrective actions to be taken.			

Function	Pre-Approval Required (Yes / No)	Name (Print)	Signature	Date
.....				
Client				

Results Of Corrective Action:

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Completed By:	**Date:**
APPROVALS - RESULTS OF CORRECTIVE ACTIONS/ DEVIATION CLOSE OUT	
The following signatures approve the results corrective actions taken and the closure of the deviation.	

Approvals	**Name (Print)**	**Signature**	**Date**
.....			
Client			

16.0 APPENDIX F - ATTACHMENTS REGISTER:

Description	Number/Revision

Comments

Tested By:		**Approved By**	
Date		**Date**	