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FACTORY ACCEPTANCE TEST

FOR

FAT GLOVE BOX

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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 approves the equipment for Shipping to ..... site and handover will be following completion of 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 Appendix. 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 appendix of this protocol. The report will describe the deviation in detail and, whenever possible, identifying the cause.

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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	Rev	Approval Date	Available Yes/No
Purchase Order				
G A Drawing				
P & I Drawing				
Utility list				
DQ				
FDS				
Material Chart List				
Manual				
Operation Manual				
Manual for Bought out components:	AS PER Material Chart			

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3.0 MECHANICAL HARDWARE CHECKS:

3.1 Devices finishes checks:

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

Procedure

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 which 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

Items Identified on Drawing.

Materials of Construction (MOC): Confirmed by Certificate of Conformity from Fabricator.

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

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3.2 Fittings Check:

Drawing/Document No.	Revision No.	Initial / Date	Title.
			P&ID Schematic
			FDS

Procedure

Compare the installed fittings with those specified on the P & ID 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 Fitted

Components

Tag	PART	DESCRIPTION	LOCATION	QTY	MAKE	Available Yes/No
	Glove Ports with gloves	**Type** ------- Round Type, **Material** - Delrin **Size:-** ------9	Chamber	4	Bectochem	
	Cylinders	Gas Cylinder 25 Kg.	Gull Wing Doors of main chamber	02	Standard	
	Pneumatic cylinder	Model – CRDSNU-25-40-P-A	Below Y-piece	1	Festo	
	Solenoid valve	Solenoid actuated valve for pneumatic cylinder	Service plenum of tablet press	1	Bectochem Standard	
	Ball Valve	**Type** -Manual Ball Valve, Flange	Supply of wash media	1	Shakti Engineeri	

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Tag	PART	DESCRIPTION	LOCATION	QTY	MAKE	Available Yes/No
		Connection end **Size-** 25 NB, **MOC** - SS 316 Teflon seat			ng	
	Ball Valve	**Type** -Manual Ball Valve, Flange Connection end **Size-** 25 NB, **MOC** - SS 316 Teflon seat	Main Chamber Drain	1	Shakti Engineering	
	Needle Valve	**Type** -Manual Needle Valve, Flange Connection end **Size-** 25 NB, **MOC** - SS 316 Teflon seat	Compressed Air inlet to Main Chamber	1	Shakti Engineering	
	Spray Nozzle Gun with Flexible Hose Pipe	**Type** - Water Saver Gun, with Hose connector **Size-** ½" bsp **MOC** - SS 316 **Capacity** 300 Ltr/ Hr, **Pressure :-** ½ kg/ cm 2,	Main Chamber	1	Cris	
	RTP	RTP 6" Non-Rotate Active	Chamber	1	Bectochem	
	RTP	RTP 6" Non-Rotate Passive	Bag Grommet	1	Bectochem	
	RTP	RTP 6" Non-Rotate Active	Chamber	1	Bectochem	
	RTP	RTP 6" Non-Rotate Passive	Bag Grommet	1	Bectochem	
	Timer	Model – XP5040	Service plenum of tablet press	1	Bectochem Standard	

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Tag	PART	DESCRIPTION	LOCATION	QTY	MAKE	Available Yes/No
	Divertor	Divertor in the Spool Piece entry for the direction change of the Tablet Flow	Y-piece	1	Bectochem	
	Y-Piece	Type – Y type Moc – SS306	Chamber	1	Bectochem	
	Dust Extraction port	Type – 2 ½" TC type MOC- SS 316 With –EU 13 Filter	Chamber	1	Bectochem	
	Socket	For Pneumatic cylinder Utility	Chamber	2	Bectochem	

Comments

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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

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Date		Date	

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4.0 HEPA FILTERS INSTALLATION & INTEGRITY TESTING:

Document/Drawing No.	Revision No.	Initial / Date	Title.
			FDS
			P & ID

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
	Supply Filter	The certificates for the supplier integrity testing are included in the documentation package and meet acceptance criteria set for filter integrity testing.	
	Supply Filter		

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Date		Date	

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5.0 PRESSURE HOLD TEST:

Required		
Calibrated Manometer	6mm 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.

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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

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

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

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 ^{0}K

T2 = Final Temp in ^{0}K

Acceptance Criteria:

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

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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

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7.0 COMMISSIONING CHECKS:

7.1 Power-Up Checks

Required		
Continuity Tester		

Test	Procedure	Acceptance Criteria	Complies Yes/No
1.	Check that all metallic parts of the Isolator are bonded	There is good continuity between the Main Earth Boss on the Isolator to the various bolt on metallic parts of the Isolator ie access covers doors etc.	
2.	Check that all fuses are not defective using the Continuity tester.	Record that all fuses have been checked in the table below.	
3.	Replace all fuses in the correct position	Check all circuit breakers are in the on position.	
4.	Power Supply.	Power supply to the isolator is available.	

Comments

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7.2 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	1					
Passive 2	1					

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8.0 ISOLATOR OPERATIONAL CHECKS:

Document	Number	Rev
Functional Design Specification		

Procedure

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

OPERATION:

1. The glove box with two RTP actives and 4 glove ports has got a 2½" spool piece with TC end.
2. The end of the Metal Detector is docked with this Spool Piece.
3. The Spool Piece is connected through a Diverter to the two Diverting Plates.
4. The diverting plates are connected to the RTP through Flexible Pipes.
5. The material coming from Metal Detector goes through these plates to the RTP.
6. Bag Grommets with RTP passive are docked and material can be collected into the bag
7. Once one of the bag Grommets is near to filling the Diverter is moved to change the flow of Tablets to the other bag Grommet, through the second RTP.
8. Throughout the operation, the dust extraction is to be connected to the glove box and is to be operational.
9. After operation, the interior of the glove box is to be decontaminated by spraying with water.
10. For air circulation 3"Dust extraction port with TC connection provided on Glove box. This is connected to Dust extractor via Exhaust filter.

Acceptance Criteria	Complies Yes/No
Equipments Operated as per Operation	

Comments

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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

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10.0 POST APPROVAL:

Acceptance of the successful 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.

The FAT data for this equipment has been reviewed and found to be acceptable as per acceptance criteria.

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

Customer			
Reviewed By	**Print Name**	**Signature**	

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

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

Print Name	Signature	Date	Company

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12.0 APPENDIX B - CALIBRATION CERTIFICATES REGISTER:

Number	Description	Attached Yes/No

Comments

Tested By:		Approved By	
Date		Date	

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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.

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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.

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14.0 APPENDIX D - FAT DEVIATION REGISTER:

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

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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
Customer				
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
Customer			
Client			

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16.0 APPENDIX F - ATTACHMENTS REGISTER:

Description	Number/Revision

Comments

Tested By:		Approved By	
Date		Date	