FACTORY ACCEPTANCE TEST FOR DISPENSING, SIEVING & BLENDING ISOLATOR	
Department: Quality Assurance	**FAT No.:**
Title: Factory Acceptance Test for Dispensing, Sieving & Blending Isolator	**Effective Date:**
Supersedes: Nil	**Review Date:**

FACTORY

ACCEPTANCE TEST

FOR

DISPENSING, SIEVING & BLENDING

ISOLATOR

Vendor:

	Title	Name	Signature	Date
Prepared by	**Project Engineer**			
Reviewed by	**Quality Engineer**			
Approved by	**Quality Manager**			

Client Formulations Approvals:

Title	Name	Signature	Date
Quality Assurance			
Project Engineer			
Project Consultant			

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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 Client site. 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 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 Pass/Fail or Yes/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				
Component List				
Instrument list				
Utility list				
DQ				
FDS				
GA diagram of Control Panel				
IGA diagram of Control Panel				
Power wiring diagram				
Control Wiring Diagram				
Terminal wiring diagram				

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Material Chart			-	
Operation Manual of dispensing isolator, sifter, blender			-	
Manual for bought-out components:	AS PER Material Chart			

Comments

Tested By: (VENDOR) Date	Approved By (CLIENT) Date

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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, and check these against the required specification.

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

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

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.	

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Comments

Tested By: (VENDOR) Date	Approved By (CLIENT) Date

3.2 Fittings Check:

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

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.

Instruments

Tag	PART	Location	Available (Yes / No)
	Differential Pressure Indicator	Service plenum	
	Differential Pressure Transmitter	Service plenum	
	Differential Pressure Indicator	Service plenum	
	Differential Pressure Transmitter	Service plenum	
	Differential Pressure Indicator	Service plenum	
	Filter & Regulator	Service plenum	
	Audio Alarm	Service plenum	
	Regulator & Gauge	Service plenum	

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Air Handling Unit

Tag	PART	Location	Available (Yes / No)
	Supply HEPA Filter	Sieving Chamber	
	Blower	Dispensing Chamber	
	Exhaust HEPA Filter	Dispensing Chamber	
	Pre- filter	LHS of chamber	
	Pre- filter	At inlet of Exhaust valve	

Electrical

TAG	PART	Location	Available (Yes / No)
	VFD	Master Control Panel	
	VFD	Master Control Panel	
	MCP	Non-hazardous Area	
	LOP	LOP	
	Indicators	LOP	
	Push Buttons + 1 hand switch	LOP	
	Potentiometer	LOP	
	Lights	Sieving Chamber	
	Lights	Dispensing Chamber	
	Electrical socket	Rear side of chamber	

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Mechanical

	PART	DESCRIPTION	MATERIAL	Accepted Yes / No
	Glove Ports with gloves	Oval Type, Delrin Material, Size:- 250 x 200	Sleeves of Hypalon and Cuffs of Nitrile	
	Glove Ports with gloves	Oval Type, Delrin Material, Size:- 250 x 200	Gloves Hypalon	
	Gas Cylinders	Gas Cylinder 50 KG.	-	
	Gas Cylinders	Gas Cylinder 50 Kg	-	
	Ball Valve	Manual Ball Valve, Flange Connection Size:- 25 NB	SS 316	
	Ball Valve	Manual Ball Valve, with TC Connection Size:- 1'' OD	SS 316	
	Needle Valve	Manual Needle Valve with Flange Connection Size:- 25 NB	SS 316	
	12" Vibro Sifter	To sieve actives and lactose into bin	SS 316	
	Vibratory Motor	0.25 HP, Good earth Make	---	
	Spring	Chrome plated 6 no.	---	
	Spray Nozzle Gun with Flexible Hose Pipe	Water Saver Gun with ½" bsp Hose connector, Capacity 300 Ltr/ hr, Pressure :- ½ kg/ cm^2,	SS 304	
	Rapid Transfer Port active	6" dia non-rotate	SS 316	
	Rapid Transfer Port Passive	6" dia non-rotate	SS 316	

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	Hecht Continuous Liner Head	400 mm Dia	SS 316	
	Weighing Balance	Client scope	--	
	Weighing Display	Client scope	--	
	Blender	15 Lit Blender Drive with mechanical seal	SS 316	
	Blender Motor	**Type** –Break type motor **Rating** – 2Hp, 3Ph, 415 V,50Hz **Make** – HMM/ crompton	---	
	Gear Box	**Ratio** – 64 : 1 **No** – W110 UFC, P90 B5 **Make** -Bonfiglioli	--	
	Seal	**Type** –Single cartage **Size**- 60 dia **Make** – Hi-Fab	---	
	Bin	15 Lit Bin	SS 316	
	Cable Grommets	Standard	--	
	Jacking Trolley	Hydraulic lifting, manual operation	SS 304	
	Disc rotary valve	4 way 3 position	--	

Comments

Tested By: (VENDOR)	Approved By (CLIENT)
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: (VENDOR) Date	Approved By (CLIENT) Date

4.0 CRITICAL INSTRUMENT LIST & CALIBRATION:

Drawing/Document No.	Revision No.	Title.
		P & ID

Verification that all-critical instruments are installed, calibrated to a traceable national standard and within their calibration time frame.

Procedure

For all instruments defined as critical, document below the information requested for each of the identified instruments.

Ensure the instrument has been properly tagged / labelled with Calibration date, Calibration due date, identification of the person who performed the calibration and a unique instrumentation identification number.

Verify that the calibration records / certificates are attached.

From following instrument list, mark in yellow where the instruments are in compliance and red where they are not.

Attach the Marked-Up instrument list labelled as 'FAT Instrument Check' to this FAT as an appendix.

Acceptance Criteria	Complies Yes/No
All critical instruments are calibrated and a tag / label attached stating the calibration date.	
The calibration records are filed in the documentation package for all critical instruments including a calibration due date, identification of the person who performed the test and a unique instrument identification number.	

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Tag	PART	Acceptance	Certificate Attached (Yes / No)
	Differential Pressure Indicator	Dwyer Make Magnehelic Pressure Gauge Range: - 0 pa to 250 pa Pressure Conduit 6mm Push On Contact Configuration, with BC logo	
	Differential Pressure Transmitter	Magnasense DPT NON FLP Out Put:- 4-20 mA	
	Differential Pressure Indicator	Dwyer Make Magnehelic Pressure Gauge Range: - 0 pa to 500 pa Pressure Conduit 6mm Push On Contact Configuration, with BC logo	
	Differential Pressure Transmitter	Magnasense DPT NON FLP Out Put:- 4-20 mA	
	Differential Pressure Indicator	Dwyer Make Magnehelic Pressure Gauge Range: - 0 pa to 250 pa Pressure Conduit 6mm Push On Contact Configuration with BC logo	
	Filter Regulator	Festo make Catalogue No…….	

Comments

Tested By: (VENDOR) Date	Approved By (CLIENT) Date

5.0 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 and filter integrity test shall be performed during SAT.

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		
	Supply Filter		
	Supply Filter		
	Supply Filter		
	Exhaust Filter		
	F6 Prefilter		
	F6 exhaust filter		

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6.0 ELECTRICAL & INSTRUMENT HARDWARE CHECKS

Drawing No.	Revision No.	Initial / Date	Title.
			Electrical Schematic Drawings

Procedure

Compare the installed components with those specified on the drawings- (Sheet 2 of 8)

Check the wiring identification is as shown on the drawings.

Carry out a wiring tug test.

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

Mark with a red pen on the drawing any corrections.

Date sign and attach the Marked-Up drawing labelled as ‘FAT Electrical 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

Test	Observation	Acceptance Criteria	Complies Yes/No
1.	Identification of Components	Components identified as per drawings	
2.	Component Layout	Components arrangement as per drawings	
3.	Identification of wiring	Wiring identified as per drawing	
4.	Component Description	Components installed are as detailed on drawings	
5.	Component Rating Check	Component Rating - fuses; MCB’s Overloads are as drawings.	
6.	Wiring Tug Test	Wires pass tug test.	

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7.0 EQUIPMENT CONTROL FUNCTIONS AND INTERLOCKS VERIFICATION

Objective - To verify that the equipment controls and interlocks function as specified in the PLC FDS

Procedure - Run the machine. By operating verify and check whether the controls and interlocks are in place by simulating the conditions. Any discrepancies to be noted on the review form and on the Deviation Report.
Acceptance Criteria - The Controls and interlocks should function as per following,

FULL TEST METHOD + A/C

S. No	Interlock	TEST Procedure	Acceptance criteria	Pass/Fail
1.	Blower Motor Trip	124 P & 128 contact (VFD relay) change to "NO" from NC	Blower running indication displayed on LOP Blower Trip indication illuminates.	
2.	Filter Blocked Alarm	Block filter Manually	Filter blocked indicator will be indicated on LOP. Once the Filter has been changed the indicator will be turned off on the LOP.	
3.	Containment Breached	1. Remove glove from Glove port. 2. Open Valve which is fitted to machine **Remedy Fact** The alarm condition has been rectified	The RED light indicating Containment Breach on LOP is ON & audible alarm sounds. Isolator Healthy Green Light on LOP goes "OFF" The system will revert to run mode.	
4.	Sifter will not Start	Isolator not in Healthy state (Pressure not between -80 Pa to -120 Pa)	After pressing Start button, Sifter will not start.	

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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 a calibrated 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 retest.

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		

Calculation

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

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 ^{0}K

T2 = Final Temp in ^{0}K

Acceptance Criteria

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Isolator Type	Acceptance Criteria	Pass / Fail
	Hourly leakage rate < 2.5 X 10^{-3}	

Comments

Tested By: (VENDOR)	Approved By (CLIENT)
Date	Date

8.0 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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9.0 COMMISSIONING CHECKS

9.1 Power-Up Checks

Required		
Continuity Tester		

Test	Procedure	Acceptance Criteria	Complies Yes/No
1.	Check that all metallic parts of the Isolator are earth bonded	There is good continuity between the Main Earth Boss on the Isolator to the various bolt-on metallic parts of the Isolator, i.e. 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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Earth Continuity Test.

Required		
Multi-meter		

Test	Procedure	Acceptance Criteria	Complies Yes/No
1.	Check continuity leg Chamber, Service plenum, Filter box area, Blower box area.	Continuity Shall be achieved. (≤ 1 Ω)	

Comments

Tested By: (VENDOR) Date	Approved By (CLIENT) Date

Fuse / MCB Check Results Table

Fuse/MCB Tag No	Rating	Complies Yes/No
	6 Amp, 3 PH	
	6 Amp, 2 PH	
	6 Amp, 2 PH	
	6 Amp, 2 PH	
Fuse	1 Amp	

Acceptance Criteria

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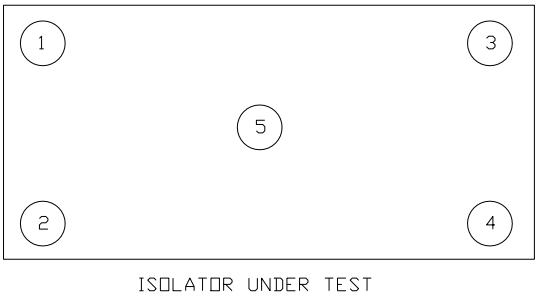
Acceptance Criteria: Fuse not damaged and is rated as shown on Drawing

Comments

Tested By: (VENDOR)	Approved By (CLIENT)
Date	Date

9.2 Lighting Level Check

Required		
Lux Meter		

Test	Procedure	Acceptance Criteria	Complies Yes/No
1.	Ensure that power is available to the Control Panel	Power available.	
2.	Observe the lights inside the unit.	Switch on/Lights on - all tubes in light fittings are illuminated.. Switch off/Lights off.	
3.	Using the Lux meter, check the lighting level in the upper chamber of the isolator at 5 points within the isolator, record the results in  ISOLATOR UNDER TEST the table below. Ensure test locations are not obstructed or shaded from light source. Calculate the average illumination level from the readings taken.	Minimum Illumination level: 500 Lux.	

Location	Recorded Level Lux						Complies Yes/No
	1	2	3	4	5	Average	
Isolator Chamber							

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Comments

Tested By: (VENDOR)	Approved By (CLIENT)
Date	Date

9.3 Fan Rotation Checks

Test Action	Procedure	Accepted Criteria	Complies Yes/No
1	Fan 'START' initiated	Fan / Motor starts	
2	Rotational check on Fan	Fan rotates in direction of Arrow on	
3	Fan 'STOP' initiated	Fan stops	

Comments

Tested By: (VENDOR)	Approved By (CLIENT)
Date	Date

9.4 Air Change Rates

Required		
Vane Anemometer		

Procedure
With the Isolator running, monitor the air velocity entering/or leaving the main chamber using the Vane Anemometer.
From this calculate the volume of air and hence the ACR.
Adjust the fan speed until target ACR's are achieved.
Record readings in table below

Volume into/or out of the Chamber m^3/hr = Velocity (m/s) x Area of Inlet/Outlet m^2 x 3600 sec's

Number of Air Changes = Volume into Chamber m^3/hr/Volume of Chamber m^3

Acceptance Criteria: Minimum 20 Air Changes per hour

Volume Into Chamber	Chamber Volume	No. of Air Changes	Pass / Fail
M^3/Hr	0.71 M^3	P/hr	
Comments			

Tested By: (VENDOR)	Approved By (CLIENT)
Date	Date

9.5 Pressure Running Checks

Procedure

Pressure Gauge Calibration Checks and Air Change Rate Checks must be completed first.

With the Isolator running in Normal Mode, observe the differential pressures between the chamber & room over a period of 60 minutes.

Record the readings in the table below.

Acceptance Criteria

	0 min	15 min	30 min	45 min	60 min	Acceptance Criteria	Complies Yes/No
Main Chamber Pressure						-100 $\pm$ 20 Pa	

Comments

Tested By:	Approved By

(VENDOR)	(CLIENT)
Date	Date

9.6 RTP Operational Checks

Prerequisites for test
Steris 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	Dedock	Complies YES/NO
Passive	1					

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9.7 Glove In-Rush Flow Checks

Required		
Vane Anemometer		

Verification that a glove breech results in continued negative pressure in the main chamber.

Procedure

Activate the Isolator in normal operating condition.

Ensure that the desired pressures within the Isolator are being achieved. (-80 to -120 Pa)

Remove a glove from one of the ports on the main chamber, and observe.

With the Isolator in alarm condition, measure the air velocity through an open glove port. (> -40 Pa)

Acceptance Criteria

Glove Port	Size	Recorded Velocity	Accepted Criteria m/sec	Complies Yes/No
1			0.3-0.7m/sec	
2			0.3-0.7m/sec	
3			0.3-0.7m/sec	
4			0.3-0.7m/sec	
5			0.3-0.7m/sec	
6			0.3-0.7m/sec	
7			0.3-0.7m/sec	
8			0.3-0.7m/sec	
9			0.3-0.7m/sec	

Comments

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9.8 Noise Level Check (at SAT)

Required		
Sound Meter		

Procedure

With the Isolator switched off, record the background noise level in the room. Where the isolator cannot be placed in a suitable room for this test, the test at FAT will be postponed for the SAT.

Record the Background noise level in the results table

Initiate the Isolator in normal running and record the sound level again standing 1 meter away from the isolator.

Acceptance Criteria

Recorded Noise Level Isolator Not Running	Recorded Noise Level Isolator Running	Accepted Criteria	Complies Yes/no
		Less than 80db at 1m	

Comments

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Note: there are no tests for the blender and sifter, these must be added.

10.0 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:

API raw material is supplied in capacity up to max 30 kg drum size. The isolator consists of 2 chambers.

1. Start the system and allow all pressures to reach normal operating conditions. “Isolator healthy” indication illuminated.
2. The Isolator must be in operation. During this process, the entire isolator will be decontaminated.
3. When the drum is inserted into the insertion tube, the HECHT continuous liner is drawn over the drum. Ensure extra liner is pulled with this.
4. This process is stopped mechanically in the glove box.
5. The drum is secured by a pneumatic clamp device and the mechanical stopper is turned.
6. The HECHT continuous liner is held tightly by a tension ring on the drum outside and then cut open on one end.
7. The drum lid is opened.
8. The upper part of the liner is pulled out of drum, opened and the bag containing material is taken inside the chamber.
9. The liner free end is then sealed.
10. The material is then discharged on to the weighing balance..
11. The empty liner of the material is put back in the drum.
12. The liner is pulled out and tied over it.
13. The open end of the liner is folded over the drum on outside.
14. Now secure the drum lid over it.
15. The drum is pulled back out of the insertion tube.

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16. Seal the liner with double tie and cut between the closures.
17. The material is then weighed on the weigh balance (Client Scope).
18. It is then put into the 15 litre Cage Blender. The blended material is then taken out from the Cage Blender into a poly bag.
19. Then the material is discharged into the Vibro sifter -12".
20. The Sieved material coming out from the Vibro sifter is then put through a chute into the IPC bin (75 litres) via a 150 mm dia Non Rotate type RTPA and RTPP (through a tray).
21. WIP of the isolator is carried out using the Spray Gun provided in the chamber by washing down with Purified Water. The isolator is free draining. The waste water drain is with a ball valve recessed in the isolator which is connected to the catch pot.
22. The chamber can be wiped or hand sprayed with decontamination solution.

Acceptance Criteria	Complies Yes/No
Equipments Operated as per Operation	

Comments

Tested By: (VENDOR)	Approved By (CLIENT)
Date	Date

11.0 UTILITIES FAILURE TESTS

Procedure

Start the Isolator in Running Mode and wait till all pressures are within correct operating conditions.

Simulate a power failure by turning of the main incomer switch on the control panel.

Observe the Isolator conditions

After a 1 minute period re instate the power to the system and observe the Isolator status

Acceptance Criteria

Mode	Test Description	Accepted Criteria	Actual	Complies Yes/No
Running Mode	Failure	Isolator In operation Δ P = (-80 to -120 Pa) Green Light "ON" Isolator Turned OFF Δ P ≥ -40 Pa Green light "OFF"		
	Restoration			
Breach Mode	Failure	Isolator In operation Δ P = (-80 to -120 Pa) Green Light "ON" Isolator Turned OFF Δ P ≥ -40 Pa Green light "OFF"		
	Restoration			

Comments

Tested By: (VENDOR) Date	Approved By (CLIENT) Date

12.0 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
Continuity Tester			
Multi-meter			
LUX meter			
RA meter			
Sound level			
Pressure gauge			

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13.0 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. Approved 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.	

Vendor			
Reviewed By	**Print Name**	**Signature**	

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

14.0 APPENDIX A - FACTORY ACCEPTANCE TEST (FAT) PERSONNEL

Print Name	Signature	Date	Company

15.0 APPENDIX B - CALIBRATION CERTIFICATES REGISTER

Number	Description	Attached Yes/No

Comments

Tested By: (VENDOR) Date	Approved By (CLIENT) Date

16.0 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 Vendor & 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.

17.0 APPENDIX D - FAT DEVIATION REGISTER:

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

18.0 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
Vendor				
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
Vendor			
Client			

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19.0 APPENDIX F - ATTACHMENTS REGISTER

Description	Number/Revision

Comments

Tested By: (VENDOR) Date	Approved By (CLIENT) Date