FACTORY ACCEPTANCE TEST

FOR

IPQC ISOLATOR

FAT FOR IPQC ISOLATOR

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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. 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 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 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				
GA diagram of Control Panel				
IGA diagram of Control Panel				
Power wiring diagram				
Control Wiring Diagram				
Terminal wiring diagram				
Material Chart List				
Manual				
Operation Manual of BC				
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

Write on the on a copy of 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

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	Complies Yes/No
Items Identified Fitted.	

Instruments

Tag	PART	DESCRIPTION	LOCATION	QTY.	Available (Yes/No)
	Differential Pressure Indicator	Dwyer Make Magnehelic Pressure Gauge Range: 0 Pa to 250 Pa, Pressure Conduit 6mm Push On Contact Configuration, SPCO 1.0A with BC logo	LOP	1	
	Differential Pressure Transmitter	Magnasense DPT NON FLP Output:- 4-20 mA	LOP	1	
	Differential Pressure Indicator	Dwyer Make Magnehelic Pressure Gauge Range: 0 Pa to 500 Pa, Pressure Conduit 6mm Push On Contact Configuration, SPCO 1.0A with BC logo	LOP	1	
	Differential Pressure Transmitter	Magnasense DPT Non-FLP Output:- 4-20 mA	LOP	1	
	Differential Pressure Indicator	Dwyer Make Magnehelic Pressure Gauge Range: 0 Pa to +250 Pa, Pressure Conduit 6mm Push On Contact Configuration, SPCO 1.0A with BC logo	LOP	1	
	Audio Visual Alarm	Audio Visual Alarm for indication	LOP	1	

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Air Handling Unit

Tag	PART	DESCRIPTION	LOCATION	QTY	Available (Yes/No)
	Supply Filter	Grade:- EU13 Filter Casing Size:- 92 mm o.d x 149 mm lg with S S 316 Locking Nut Size:-1" bsp 1" bsp parallel male thread x 35 mm long. Efficiency: - 99.997%, Normal Capacity: -5 L/ sec Integral efficiency against DOP challenge. Pressure Drop: Initial- minimum 160 pa	Main Chamber	4	
	Pre Filter	Grade EU-6	Main Chamber	1	
	Fan	Centrifugal Backward type Curve type Fan Casing: - MOC C.S. Impeller MOC :- Aluminium, 100 cfm, 70mm W G Static Pressure to suit motor 0.5 HP x 2800 rpm foot cum flange mounting.	Main Chamber	1	
	Exhaust Filter	Exhaust Hepa Filter Double with DOP 250 mm x 430 mm long. Made of PVC Casing. Connection:- 2" & 1.5" BSP Male & Female thread x 33 mm long, Efficiency:- 99.997%, Grade:- EU-13, Pressure Drop:- Initial-minimum 400 pa	Main Chamber	1	
	Pre Filter	Grade EU-6	Main Chamber	1	

Electrical

TAG No	PART	Fitting Acceptance criteria	Available (Yes / No)
VFD 101	VFD	0.5 HP x 2800 rpm Input: 460 V AC, 3 Phase	
MCP 101	MCP	Powder Coated panel includes contactors, Relays, M.C.B s,	
LOP 101	LOP	SS 304	
XI 101 to 105	Indicators	Indication Lamps 220 V AC , 22.5 dia Cut out size,	
HS 101 to 105	Push Buttons	Standard 4 x buttons, 1 x switch	
XL 101 & 102	Lights	Non FLP 500 Lux	

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Mechanical

Tag	PART	DESCRIPTION	QTY	Available Yes / No
	Glove Ports with gloves	Oval Type, Delrin Material, Size:- 250 x 200	05	
	Cylinders	Gas Cylinder 50 Kg.	04	
	Ball Valve	Manual Ball Valve, Flange Connection Size:- 25 NB	1	
	Ball Valve	Manual Ball Valve, TC Connection Size:- 1'' OD	1	
	Needle Valve	Manual Needle Valve Flange Connection Size:- 25 NB	1	
	Rapid Transfer Port Active	Rapid transfer Port Active 6" rotate	1	
	Spray Nozzle Gun with Flexible Hose Pipe	Cris	1	
	WIRE Grommets	Standard	8	
	Weighing Balance	Client Scope	1	
	Weighing Display	Client Scope	1	
	IR Moisture Balance	Client Scope	1	
	Friability Test	Client Scope	1	
	Hardness Tester	Client Scope	1	
	Dimension Tester	Client Scope	1	

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Comments

Tested By:		Approved By	
Date		Date	

3.3 Critical Dimensional Check

Drawing No.	Revision No.	Initial / Date	Title.

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.	

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Comments

Tested By:		Approved By	
Date		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.

Complete the following list and attach the calibration certificates to this protocol.

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, SPCO 1.0A with BC logo	
	Differential Pressure Transmitter	Magnasense DPT Non-FLP Output:- 4-20 mA	
	Differential Pressure Indicator	Dwyer Make Magnehelic Pressure Gauge Range: 0 Pa to 500 Pa, Pressure Conduit 6mm Push On Contact Configuration, SPCO 1.0A with BC logo	
	Differential Pressure Indicator	Dwyer Make Magnehelic Pressure Gauge Range: 0 Pa to +250 Pa, Pressure Conduit 6mm Push On Contact Configuration, SPCO 1.0A with BC logo	
Comments			

Tested By:		Approved By:	
Date		Date	

5.0 HEPA FILTERS INSTALLATION & INTEGRITY TESTING:

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

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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		
	Supply Filter		
	Supply Filter		
	Exhaust Filter		

Comments			
Tested By:		Approved By	
Date		Date	

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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.

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.	

Comments

Tested By:		Approved By	
Date		Date	

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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,

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 Fault** 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.	

Comments

Tested By:		Approved By	
Date		Date	

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8.0 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.

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	

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9.0 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	

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10.0 COMMISSIONING CHECKS:

10.1 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

Tested By:		Approved By	
Date		Date	

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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:		Approved By	
Date		Date	

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Fuse / MCB Check Results Table

Fuse/MCB Tag No	Rating	Complies Yes/No
MCB-1	**6 Amp, 3 PH**	
MCB-2	**6 Amp, 2 PH**	
MCB-3	**6 Amp, 2 PH**	
MCB-4	**6 Amp, 2 PH**	
Fuse	**1 Amp**	

Acceptance Criteria

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

Comments

Tested By:		Approved By	
Date		Date	

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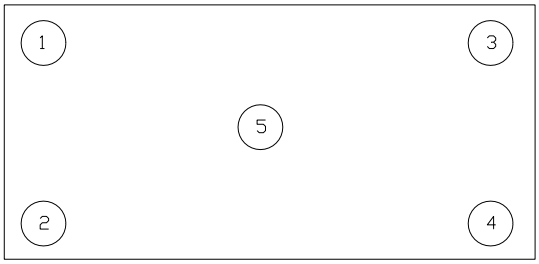
10.2 Lighting Level Check:

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 chamber of the isolator at 5 points within the isolator, record in the results table below. Ensure test locations are not obstructed or shaded from  ISOLATOR UNDER TEST 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							

Comments

Tested By:		Approved By	
Date		Date	

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10.3 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 impeller	
3	Fan 'STOP' initiated	Fan stops	

Comments

Tested By:		Approved By	
Date		Date	

10.4 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 and 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: 20 Air Changes per hour

Volume Into Chamber	Chamber Volume	No. of Air Changes	Pass / Fail
M^3/Hr	0.099 M^3	P/hr	
Comments			

Tested By:		Approved By	
Date		Date	

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10.5 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 ± 20 Pa	

Comments

Tested By:		Approved By	
Date		Date	

10.6 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.

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

Comments

Tested By:		Approved By	
Date		Date	

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10.7 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-m/sec	
2			> 0.3 m/sec	
3			> 0.3-m/sec	
4			> 0.3 m/sec	
5			> 0.3-m/sec	
6			> 0.3 m/sec	

Comments

Tested By:		Approved By	
Date		Date	

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10.8 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
		≤ 80db at 1m	

Comments

Tested By:		Approved By	
Date		Date	

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11.0 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 API or Tablets is brought in sealed canister, which having RTP Passive, 6”.
3. Tablets are weighed on weighing platform.
4. The Moisture analysis, weigh checking, friability testing of API is carried out inside the chamber through glove port.
5. The Chamber accommodates moisture analyser, friability tester and micro balance.
6. 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 has a ball valve recessed in the isolator which is connected to drain to the ‘Kill Tank’.
7. The chamber can be wiped or hand sprayed with decontamination solution.

Acceptance Criteria	Complies Yes/No
Equipments Operated as per Operation	
Comments	

Tested By:		Approved By	
Date		Date	

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12.0 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 off 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	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:		Approved By	
Date		Date	

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13.0 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			
Stop Watch			

Comments

Tested By:		Approved By	
Date		Date	

14.0 POST APPROVAL:

Completion of the FAT, including satisfactory resolution of any 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.

Agreed criteria	Agreement YES / NO
1. Approval for shipment	
2. Machine is approved for shipment after correction of all Deviations 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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15.0 APPENDIX A - FACTORY ACCEPTANCE TEST (FAT) PERSONNEL:

Print Name	Signature	Date	Company

16.0 APPENDIX B - CALIBRATION CERTIFICATES REGISTER:

Number	Description	Attached Yes/No

Comments

Tested By:		Approved By	
Date		Date	

17.0 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.

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18.0 APPENDIX D - FAT DEVIATION REGISTER:

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

19.0 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:

FAT FOR IPQC ISOLATOR

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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20.0 APPENDIX F - ATTACHMENTS REGISTER:

Description	Number/Revision

Comments

Tested By:		Approved By	
Date		Date	