

**FACTORY ACCEPTANCE TEST**  
**FOR**  
**COMPOUNDING AND FILTRATION ISOLATOR**  
**DOCUMENT No.: FTIL-RASTAGENE-21-FAT-VD-001**

**SUBMITTED TO**

**M/s. RASTAGENE BIOPHARMACEUTICALS CO.**

**SUBMITTED BY**



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**M/s. RASTAGENE BIOPHARMACEUTICALS CO.**

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**1. PRE-FAT APPROVAL**

<b>M/s. FABTECH TECHNOLOGIES INTERNATIONAL LTD.</b>					
	<b>Name</b>	<b>Department</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>
Prepared by					
Checked by					
Approved by					

<b>M/s. RASTAGENE BIOPHARMACEUTICALS CO.</b>					
	<b>Name</b>	<b>Department</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>
Reviewed by					
Reviewed by					
Approved by					

**2. REVISION HISTORY**

<b>SR. NO.</b>	<b>REVISION</b>	<b>DATE</b>	<b>REVISION SUMMARY</b>

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### 3. SYSTEM INFORMATION

<b>EQUIPMENT</b>	COMPOUNDING AND FILTRATION ISOLATOR
<b>MANUFACTURER</b>	M/s. FABTECH TECHNOLOGIES INTERNATIONAL LTD.
<b>CUSTOMER</b>	M/s. RASTAGENE BIOPHARMACEUTICALS CO.
<b>SERIAL NO.</b>	FTIL/21/66
<b>MODEL NO.</b>	C&F-ISO
<b>SITE</b>	IRAN

### 4. INTRODUCTION

#### 4.1 WE ARE LIFE ENGINEERS

We are an engineering solutions company working as an essential piece of massive life sciences ecosystem. By bringing together our customers, partners, industry leaders, regulators and governments we effect greater impact and bring our mission to life.

Our purpose is reflected through our strategy, approach and objectives. We consciously evaluate our performance through a broader lens for creating value – economic benefits to our customers, environmental benefits for a greener planet and social benefits to people everywhere.

#### 4.2 LET'S SAVE LIVES TOGETHER

Our start-to-finish engineering solutions help you accelerate growth and optimize costs. With every project we take on, irrespective of size, complexity, or geography, we commit resources, people, know-how and technology to deliver a successful outcome.

Our purpose is deeply rooted in our belief that all lives have equal value. Together with our customers and partners, we're building pharmaceutical and biotech capability, so everyone, wherever they are in the world has the same access to affordable life-saving medicines.

### 5. COPYRIGHT

These documents were drawn up for the aforementioned customer. Without written approval, these documents must not in any way be reproduced, transmitted, sent, stored in a data processing system or translated to another language, neither in whole nor in part

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## 6. OBJECTIVE

Factory acceptance test is a comprehensive document providing all the details required for design and operational point of view. It thus ensures that proposed design of the equipment is suitable for its intended purpose & provides documented evidence that quality is built into the design of the equipment.

This documentation will define the responsibilities, acceptance criteria, basis of design, technical specifications, list of major bought out parts, utility requirements, safety and c-GMP features.

Kindly note, this text has been prepared by **M/s. Fabtech Technologies International Limited**. The contents include detailed information & No part of it can be changed without our written approval.

## 7. SUMMARY

Fabtech Technologies International Ltd. has received an order for the manufacture and supplies of **Compounding and Filtration Isolator** to **M/s. Rastagene Biopharmaceuticals Co** Vide their Purchase Order.

FAT will enable to analyze **Compounding and Filtration Isolator** fitment it is assembled and trial point of view all accessories are matching with reference Approved drawing.

The team from **M/s. Fabtech Technologies International Limited, M/s. Rastagene Biopharmaceuticals Co** will jointly ensure execution, review and approval of protocol.

## 8. VALIDATION

Factory Acceptance Test (FAT), undergo complete checkup of **Compounding and Filtration Isolator** from document verification through DQ, fitment through assembly and trial through utility mentioned in compliance with Approved GA drawing & P&ID.

Fabtech Technologies International Ltd. assures **M/s. Rastagene Biopharmaceuticals Co** that the machine is manufactured and tested as per URS and PO.

Fabtech Technologies International Ltd. assures **M/s. Rastagene Biopharmaceuticals Co** by undergoing the above said document verification in DQ. Approved GA Drawing, Electrical

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Drawing, fitment and trial through this Factory Acceptance Test (FAT), will ensure **M/s. Rastagene Biopharmaceuticals Co** that they are being given what they have offered in Offer Specification (OS) & Purchase Order (PO).

## 9. RESPONSIBILITIES

Specific requirements regarding testing of this equipment are:

### 9.1 MANUFACTURER'S

- Preparation of the FAT protocol.
- Release the FAT protocol to **M/s. Rastagene Biopharmaceuticals Co** for Approval, Acceptance & Execution.

### 9.2 CLIENT'S

- Supervising and reporting all FAT checks with respect to the **Compounding and Filtration Isolator**.
- Approval of the Protocol prior to commencement of the work.
- Final completed report approval.

### 9.3 PREREQUISITE

Following documents are required for execution of the FAT protocol: -

<b>DOCUMENTS</b>	<b>REFERENCE NO</b>	<b>REMARKS YES / NO</b>
G.A Drawing	FTIL-DRI-RBC-2021-05(R5)	
Electrical Drawing	FTIL-DRI-ED-2021-00	
P & ID Drawing	FTIL-DRI-P&ID-2021-00	

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## 10. DOCUMENTATION PRACTICES

The Factory Acceptance Test is to verify that the equipment has been built, engineered and installed according to the design specification and as a result approve the equipment for handover to the client and shipping to site.

This document will be completed as follows:

- Entries shall be made in this document using a ballpoint pen or suitable indelible ink in blue only.
- All people who enter data into this report will complete the section of this FAT titled "signature log".
- Compliance will be indicated by a tick mark in the relevant boxes provided for YES or No.
- Each section will be signed and dated by the tester/s when it is complete

## 11. SCOPE

Successful completion of the FAT will allow the shipment procedure to commence and will provide a higher degree of assurance that the system will operate in the manufacturing environment as intended. Thus, the objectives of FAT can be enumerated as follows:

- To ensure the client gets what is specified and paid for.
- To begin execution process of validation plans.
- Assembly of documents as a standard package to demonstrate that the product is suitable for the given application.

The Factory Acceptance Test process verifies that:

- The equipment operates as specified in the /DQ.
- Electrical rating will be as per requirements.
- The build quality is acceptable.
- The equipment includes the instrument and components as specified in the respective list.
- The equipment meets the requirement of the Approved drawing.
- The equipment has been constructed according to the design specification(DQ)

The documentation specified in the PO & DQ has been provided.



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## 12. SYSTEM DESCRIPTION

Based on the application and containment requirement, **Compounding Isolator** is designed to work under negative pressure inside of **Compounding chamber** with respect to atmosphere and **Filtration Isolator** is designed to work under positive pressure inside of **Filtration Chamber** with respect to atmosphere.

Fabtech Isolator utilizes physical and aerodynamic means to create improved levels of separations between inside and outside of a defined volume. Physical separation means include both rigid and flexible barriers.

## 13. BASIC EQUIPMENT

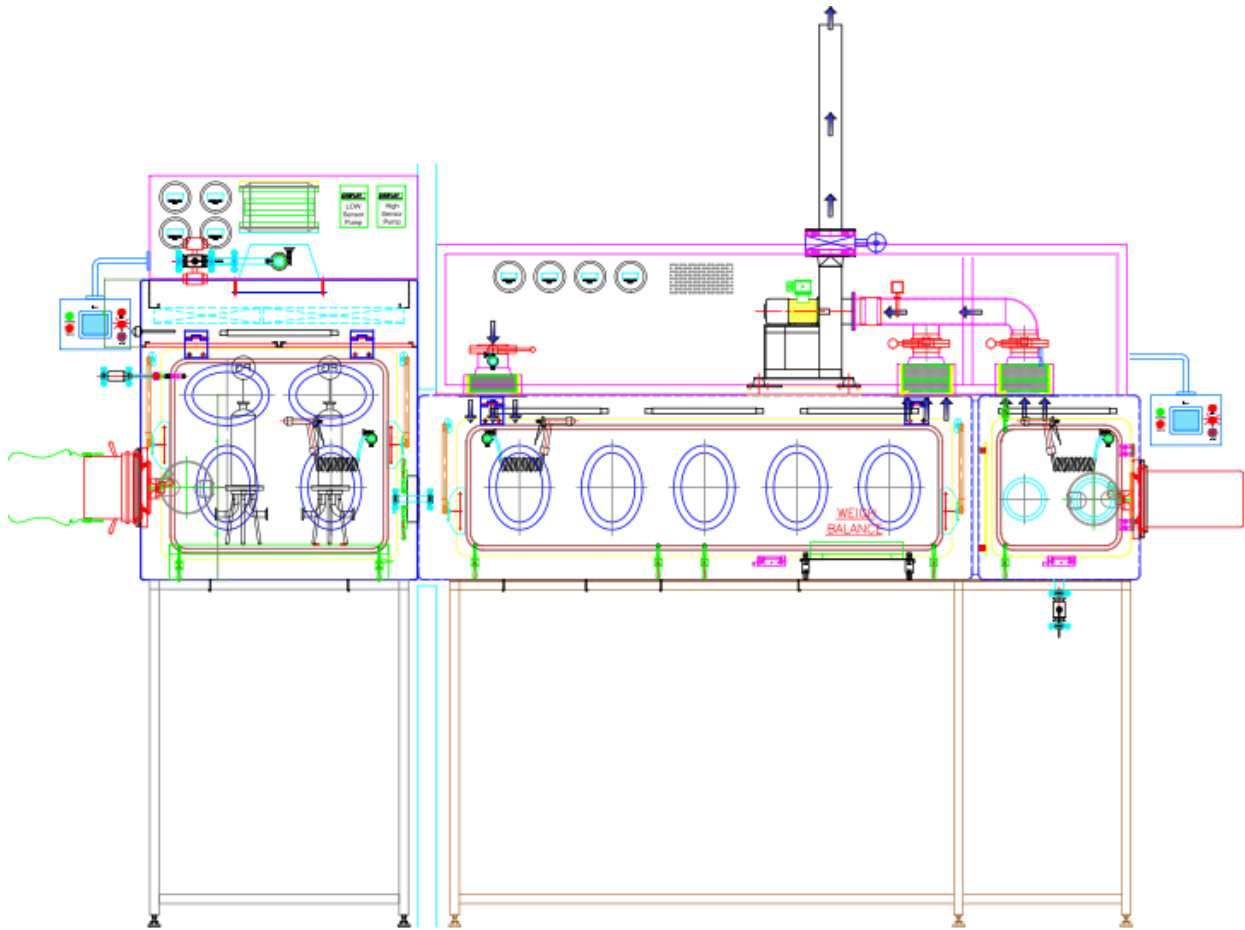
**Compounding Isolator** is designed to offer containment for **Compounding** operation. The control system for isolator will effect containment and also monitor, control and alarm pressure inside the isolator. The unit will run at negative pressure with turbulent air flow in the compounding working chamber. In the case of a containment breach, the unit will alarm.

**Filtration Isolator** is designed to offer containment for **Filtration** operation. The control system for isolator will effect containment and also monitor, control and alarm pressure inside the isolator. The unit will run at positive pressure with unidirectional air flow in the filtration working chamber.

The products to be handled are designated with an OEL level 5 (0.1-1 µg/m<sup>3</sup> on an 8 hrs.) operation. Proposed isolation systems are designed to work under negative pressure for inside of compounding chamber and for filtration chamber work under positive pressure inside of filtration chamber with respect to ambient and conforms leak test **class 3** as per leak test classified in ISO 10648 – 2 standards.

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**14. SCHEMATIC DIAGRAM**



**FRONT VIEW**

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## 15. SYSTEM VERIFICATION

### 15.1 PHYSICAL VERIFICATION

METHOD	DESCRIPTION	ACCEPTANCE CRITERIA	OBSERVATION
Internal Surface finish Verification	Check internal surface of machine	-Mirror finish -Curved corner	Yes <input type="checkbox"/> No <input type="checkbox"/>
External Surface finish Verification	Check outer surface of machine	-Matt finish -Curved corner	Yes <input type="checkbox"/> No <input type="checkbox"/>
Document Verification	Verification of Wiring diagram	-As per wiring diagram attached in Documentation file.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Document Verification	Verification of Input / Output connection	-As per Input/ Output List are Mention in PLC FDS.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Document Verification	Verification of MOC certificate	Verification of MOC Contact and Non-Contact parts as per test certificate.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Machine Dimension	Verification with machine	As per attached GA drawing in Documentation file.	Yes <input type="checkbox"/> No <input type="checkbox"/>

Checked By: \_\_\_\_\_

Reviewed By: \_\_\_\_\_

(Sign & Date)

(Sign & Date)

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## 15.2 COMPONENTS VERIFICATION

<b>GLOVE PORT</b>	
Make	Shyam enterprises
Type	Food Grade elliptical type
MOC	Delrin
Size	195 x 295 mm (Inner diameter)
Quantity	13 No's.
Location	Front and back side of the compounding chamber and front side of the filtration chamber.
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	
<b>GLOVES</b>	
Make	Piercan/Honeywell
Size	8"x32"Length
Material	Y (CSM-Chlorosulfonated Polyethylene)
Quantity	13 No's.
Location	Front and back side of the compounding chamber and front side of the filtration chamber.
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	
<b>GLOVE PORT</b>	
Make	Shyam enterprises
Type	Food Grade elliptical type
MOC	Delrin
Size	150 mm (Inner diameter)
Quantity	02 No's.
Location	Front side of the pass box
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

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<b>GLOVES</b>	
Make	Piercan/Honeywell
Size	6"x32"Length
Material	Y (CSM-Chlorosulfonated Polyethylene)
Quantity	02 No's.
Location	Front side of the pass box.
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	
<b>LIGHT</b>	
Make	Banner
Model No.	WLS27CWY-1130DSQ, WLS27CW850DSQ, WLS27CW570DSQ
Type	LED
Quantity	05 No's.
Location	Inside the compounding chamber and filtration chamber and pass box
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	
<b>BALL VALVE</b>	
Make	Aira
MOC	SS 316
Serial No.	H:160222001, H:160222005, H:160222008, H:160222015, H:081221014, H:090222014, H:090222004
Size	Diameter 1"
Quantity	07 No's.
Location	Back side of the compounding chamber and filtration chamber and pass box and out let of the catch pot
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	
<b>DIAPHRAGM VALVE</b>	
Make	Pal Pharma Tech
MOC	SS316
Serial No.	1014, 1028, 1029, 1056, 1083, 1095,
Size	Diameter 1"
Quantity	06 No's.
Location	Connection of drain line
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>

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Remarks			
<b>SPONGE GASKET</b>			
Make	JMT Rubber		
Size	20x25 mm		
Type	Food Grade		
MOC	Silicone		
Location	At intermediate door		
Verification	Yes <input type="checkbox"/>	No	<input type="checkbox"/>
Remarks			
<b>INFLATABLE GASKET</b>			
Make	Vijay Rubber		
MOC	Silicone		
Quantity	04 No's.		
Location	Front and back doors of the compounding chamber and filtration chamber		
Verification	Yes <input type="checkbox"/>	No	<input type="checkbox"/>
Remarks			
<b>GAS SPRING CYLINDER</b>			
Make	Superlift		
Model No.	F1:500 N		
Quantity	02 No's.		
Location	Front side of the compounding chamber		
Verification	Yes <input type="checkbox"/>	No	<input type="checkbox"/>
Remarks			
<b>GAS SPRING CYLINDER</b>			
Make	Stabilus		
Model No.	Lift 500 N		
Quantity	02 No's.		
Location	Front side of the filtration chamber		
Verification	Yes <input type="checkbox"/>	No	<input type="checkbox"/>
Remarks			

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**TOUGHENED GLASS**

Manufacturer	Amafhh Glass
Type	Toughened Glass
Size	12 mm Thickness
Quantity	04 No's.
Location	Front and back side of the compounding Chamber & front side of the filtration chamber and pass box
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

**ROXTEC ROUND SEAL**

Make	Roxtec India Pvt. Ltd.
Type	Roxtec Round Seal RS25 AISI 316/RS00100251023
Quantity	05 No's.
Location	At pass box, compounding and filtration chamber
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

**WATER & COMPRESSED AIR GUN**

Make	Festo
Model No.	LSP-1/4-C
Quantity	03 No's.
Location	In side of the compounding Chamber and filtration chamber and pass box
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

**HEPA FILTER AT INLET FOR COMPOUNDING ISOLATOR**

Make	AAF/Netfil
Efficiency	99.999 (%) down to 0.3 µm
Grade	EU-14
Size	200 x 200 x 65 mm
Quantity	03 No's.
Location	Inside inlet filter housing of the pass box and compounding chambers
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

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**HEPA FILTER AT EXHAUST FOR COMPOUNDING ISOLATOR**

Make	AAF/Netfil
Efficiency	99.999 (%) down to 0.3 µm
Grade	EU-14
Size	200 x 200 x 65 mm
Quantity	02 No's.
Location	Inside exhaust filter housing of the pass box and compounding chambers
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

**PRE FILTER AT EXHAUST FOR COMPOUNDING CHAMBER**

Make	AAF/Netfil
Efficiency	95 (%) down to 5µ
Grade	EU-7
Size	200 x 200 x 50 mm
Quantity	02 No's.
Location	Exhaust side of the chamber
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

**HEPA FILTER AT INLET FOR FILTRATION CHAMBER**

Make	AAF/Netfil
Efficiency	99.999 (%) down to 0.3 µm
Grade	EU-14
Size	1066 mm x 610 mm x 75 mm
Quantity	01 No.
Location	Top side of the filtration chamber
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

**MOTOR FOR COMPOUNDING CHAMBER**

Make	Hindustan Electric Motors
Serial No.	
Voltage	380 V, 50 Hz
HP	0.5
Speed	2880 RPM
Quantity	01 No.



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Location	Inside the service panel		
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Remarks			

**BLOWER FOR COMPOUNDING CHAMBER**

Make	Parth Engineering Works/Equivalent		
Static Pressure	4 Inch		
Job No.			
Capacity	(Fan Capacity:200CFM)		
Quantity	01 No.		
Location	Inside the service panel		
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Remarks			

**VHP VALVE (PNEUMATIC TYPE)**

Make	Aira		
Size	2"		
Serial No.	A-631221017		
MOC	SS 316		
Quantity	01 No.		
Location	At VHP Inlet		
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Remarks			

**VHP VALVE (MANUAL TYPE)**

Make	Aira		
Size	2"		
Serial No.	C03032271		
MOC	SS 316		
Quantity	01 No.		
Location	At VHP Inlet		
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Remarks			

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**PNEUMATICALLY OPERATED ON/OFF VALVE**

Make	Aira
Size	4"
Serial No.	A-501221507
MOC	SS 316
Quantity	01 No.
Location	At exhaust blower for compounding chamber
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

**CATCH POT**

Make	Fabtech
Capacity	50 L
MOC	SS 316 L
Quantity	01 No.
Location	Bottom side of the compounding chamber
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

**SS BOURDON PRESSURE GAUGE**

Make	Alot
Range	0-10.6 kg/cm <sup>2</sup>
Serial No.	01220999
Quantity	01 No.
Location	At catch pot
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

**MANUAL BUTTERFLY VALVE**

Make	Das Engineering
MOC	SS 316
Size	4"
Quantity	05 No's.
Location	At exhaust filter housing of compounding chamber
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

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**RAPID TRANSFER PORT (ALPHA & BETA PORT)**

Make	Das Engineering Works		
Type	Rigid		
Diameter	270 mm		
MOC	SS 316 L		
Quantity	01 No.		
Location	At pass box		
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Remarks			

**RAPID TRANSFER PORT (ALPHA & BETA PORT)**

Make	Das Engineering Works		
Type	Flexible		
Diameter	270 mm		
MOC	SS 316 L		
Quantity	01 No.		
Location	At filtration chamber		
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Remarks			

**AUTO VOLUME CONTROL DAMPER (AVCD) VALVE**

Make	Aira		
Size	8" for supply air duct -02 No's 12" for return air duct -01 No.		
Serial No.	A-1101221196 - 12", A-830516050 & A-831016040 - 8"		
MOC	SS 316		
Quantity	03 No's.		
Location	At return and supply air ducts		
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Remarks			

**SCRUBBER**

Make	Universal air technologies		
Capacity	600 CFM		
Quantity	01 No.		
Location	Service Floor		
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Remarks			

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**COMPONENTS SPECIFICATION FOR SCRUBBER**

**CENTRIFUGAL BLOWER**

Make	Universal Air Technologies		
Serial No.	UAT/600/8		
Speed	2880 RPM		
Capacity	600 CFM		
Quantity	01 No.		
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Remarks			

**DRIVE MOTOR**

Make	Hindustan Electric Motors		
Serial No.			
Voltage/Frequency	380/50Hz		
HP	2.0		
Speed	2870 RPM		
Quantity	01 No.		
Location	Service Floor		
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Remarks			

**MOTOR FOR PUMP**

Make	Hindustan Electric Motors		
Serial No.	20543459,20542677		
HP	1		
Voltage/Frequency	380/50Hz		
Quantity	02 No's.		
Location	Service Floor		
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Remarks			

**RECIRCULATION PUMP - 1 & RECIRCULATION PUMP - 2**

Make	Leakless India Engineering		
Model No.	LCP-20		
Serial No.	1948-21, 1946-22		
Capacity	5 m <sup>3</sup> /hr		
Quantity	02 No's.		
Location	Service Floor		
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Remarks			

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<b>PRESSURE SWITCH</b>	
Make	Danfoss
Quantity	01 No.
Location	Service Floor
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	
<b>PRESSURE GAUGE</b>	
Make	Fiebig
Range	0-2.1 kg/cm <sup>2</sup>
Location	Service Floor
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

**Comments:**

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### 15.3 INSTRUMENTATION COMPONENTS VERIFICATION

<b>DIGITAL PRESSURE GAUGE</b>	
Make	Dwyer
Model No.	DM-2005-LCD
Range	0-500 Pa
Quantity	08 No's.
Location	Front side of the service panel
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	
<b>VFD</b>	
Make	Siemens
Model No.	Sinamics G120 C
Serial No.	XANN02-023999
Quantity	02 Nos.
Location	Inside the control panel
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	
<b>PLC</b>	
Make	Siemens
Model No.	Simatic - S7-1200
Quantity	02 No's.
Location	Inside the Control panel
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	
<b>HMI</b>	
Make	Siemens
Model No.	TP900 Comfort
Serial No.	C-NOJV8352, C-NOK16378
Quantity	02 No's.
Location	At filtration and compounding chamber service panels
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

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**DIFFERENTIAL PRESSURE TRANSMITTER**

Make	Dwyer
Model No.	MSX-W22-PA
Quantity	02 No's.
Location	Inside the service panel
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

**AIR FILTER REGULATOR**

Make	Festo
Model No.	LFR-D-MINI
Quantity	02 No's.
Location	At Pneumatic Panel
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

**PRESSURE SWITCH**

Make	Festo
Model No.	SPAN-P10R-R18M-PN-PN-L1
Quantity	05 No's.
Location	At Pneumatic Panel
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

**MINI REGULATOR**

Make	Festo
Model No.	LR-D-MINI
Quantity	05 No's.
Location	At Pneumatic Panel
Verification	Yes <input type="checkbox"/> No <input type="checkbox"/>
Remarks	

**TEMPERATURE+RH SENSOR**

Make	Radix
Model No.	SC807
Serial No.	421026034 – For compounding
Range	0-100°C/0-100%Rh
Quantity	01 No.
Location	At compounding exhaust ducts

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Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Remarks		
<b>TEMPERATURE+RH SENSOR</b>		
Make	Rotronic	
Model No.	XB32-X2P3IXBC7XX	
Serial No.		
Range	0-150°c/0-100% Rh	
Quantity	01 No.	
Location	At Filtration duct	
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Remarks		
<b>VELOCITY SENSOR</b>		
Make	E+E/Equivalent	
Serial No.		
Quantity	01 No.	
Location	At Filtration chamber	
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Remarks		
<b>ELECTRICAL DOOR LOCK</b>		
Make	Schmersal	
Model No.	AZM 170-11ZRK	
Quantity	04 No's.	
Location	At filtration, compounding and pass box front chamber doors	
Verification	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Remarks		

**Comments:**

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**16. MATERIAL OF CONSTRUCTION CERTIFICATE VERIFICATION**

<b>SR NO.</b>	<b>COMPONENTS</b>	<b>SPECIFIED</b>	<b>REPORT NO.</b>	<b>REMARKS YES/No.</b>
1.	Compounding Chamber	SS 316 L, 3 mm thick sheet		
2.	Filtration Chamber	SS 316 L, 3 mm thick sheet		
3.	Service Panel	SS 304, 1.6 mm thick sheet		

**Comments:**

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(Sign & Date)

Reviewed By: \_\_\_\_\_  
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**17. ELECTRICAL DIAGRAM CHECK**

<b>DOCUMENTS TITLE</b>	<b>DOCUMENT NUMBER</b>	<b>REMARK</b>
Wiring Diagram		

**Comments:**

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## 18. EQUIPMENT DIMENSION VERIFICATION

### Compliance

Deviations in the measured dimensions, if any, should be within acceptable limits.

DRAWING NO :			REV :
SR. NO.	Description	Dimension Observed	Remarks
1.	Overall Dimension		

### Comments:

Checked By: \_\_\_\_\_

(Sign & Date)

Reviewed By: \_\_\_\_\_

(Sign & Date)

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## 19. EQUIPMENT FINISH VERIFICATION

Description of item	Finish required as per DQ protocol.		Finish achieved as per DQ protocol		Observation
	Area	Finish	Area	Finish	
Compounding Chamber	Internal	RA≤0.4µm	Internal		
	External	RA≤0.6µm	External		
Pass box	Internal	RA≤0.4µm	Internal		
	External	RA≤0.6µm	External		
Filtration Chamber	Internal	RA≤0.4µm	Internal		
	External	RA≤0.6µm	External		

Description of item	Visual Inspection		Observation
	Area	Finish	
Compounding Chamber	Internal	Mirror	
	External	Matt	
Pass box	Internal	Mirror	
	External	Matt	
Filtration Chamber	Internal	Mirror	
	External	Matt	

**Comments:**

Checked By: \_\_\_\_\_

Reviewed By: \_\_\_\_\_

(Sign & Date)

(Sign & Date)

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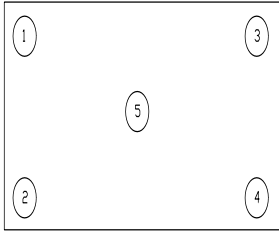
## 20. ILLUMINATION LEVEL CHECK

### VERIFICATION

- To Verify Light Level with Lux Meter.

### COMPLIANCE

- Light Level acceptable as per design norms

Sr. No.	PROCEDURE	ACCEPTANCE CRITERIA	COMPLIES (YES/NO)
1.	Ensure that power is available to the Control Panel	Power available.	Yes <input type="checkbox"/> No <input type="checkbox"/>
2.	Observe the lights inside the unit.	Switch on/Lights on, all tubes in light fittings are illuminated Switches off/Lights off.	Yes <input type="checkbox"/> No <input type="checkbox"/>
3.	<p>Using the Lux meter check the lighting level in the upper chamber (work place) of the isolator at 5 points within the isolator, record in the results table below. Ensure test instrument locations at source side are not obstructed or shaded from light source. Calculate the average illumination level from the readings taken. If light is obstructing while testing, consider height 400 mm from chamber bottom wall.</p>  <p style="text-align: center;">ISOLATOR UNDER TEST</p>	Average illumination value for main Chamber should not be less than 300 Lux.	Yes <input type="checkbox"/> No <input type="checkbox"/>



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LOCATION	RECORDED LUX LEVEL						COMPLIES (YES/NO)
	1	2	3	4	5	Average	
Compounding Chamber							
Pass box							
Filtration chamber							

**Comments:**

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(Sign & Date)

Reviewed By: \_\_\_\_\_  
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## **21. DIFFERENTIAL PRESSURE ACROSS CHAMBER**

### **➤ PURPOSE**

To check the correct functioning of the machine and machine performance towards maintaining differential pressures across chamber

### **➤ TEST METHOD**

Run the machine by inserting parameters in the HMI for a particular time.

Note down the set values entered in the HMI for indication of alarm

### **➤ ACCEPTANCE**

The actual reading (measured values by HMI) must show in display, & the chamber should maintain the desire negative pressure for Compounding chamber **( - 80 pa to - 100 pa).**

**Comments:**

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## 22. WATER DRAINABILITY TEST

For cleaning verification;

- Put water inside the chamber (where the work is actually going to process)
- Ensure that there is no resistance / obstruction from the test point to drain port.
- Ensure that no water remains inside the chamber.

<b>ACTION</b>	<b>DRAINABILITY (SATISFACTORY/ NOT SATISFACTORY)</b>
Put water inside the chamber	

**Comments:**

Checked By: \_\_\_\_\_

(Sign & Date)

Reviewed By: \_\_\_\_\_

(Sign & Date)

## 23. ACCESSIBILITY TEST OF MACHINE

- Ensure that machine is easy to access through the Glove Port

<b>ACTION</b>	<b>ACCESSIBILITY (SATISFACTORY/ NOT SATISFACTORY)</b>
Put the hands inside the gloves and access the machine	

**Comments:**

Checked By: \_\_\_\_\_

(Sign & Date)

Reviewed By: \_\_\_\_\_

(Sign & Date)

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**24. VERIFICATION OF UTILITY PORTS**

- Ensure that all the utility Ports available according GA drawing & Electrical diagram

<b>ACTION</b>	<b>VERIFICATION OF UTILITY PORTS (SATISFACTORY/ NOT SATISFACTORY)</b>
Verification of utility port according to GA drawing & Electrical diagram	

**Comments:**

Checked By: \_\_\_\_\_  
(Sign & Date)

Reviewed By: \_\_\_\_\_  
(Sign & Date)



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**25. POST-APPROVAL SHEET**

<b>SR. NO.</b>	<b>ACCEPTANCE CRITERIA</b>	<b>REMARKS (YES/NO)</b>
A	Visual Inspection and Fitment check carried out and found satisfactory.	Yes <input type="checkbox"/> No <input type="checkbox"/>
B	MOC & Bought Out Item Verified and found satisfactory.	Yes <input type="checkbox"/> No <input type="checkbox"/>

**Comments:**

**M/s. RASTAGEN BIOPHARMACEUTICALS CO.**

	<b>Name</b>	<b>Department</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>
Reviewed by					
Reviewed by					
Approved by					

<b>Document No.</b>	<b>FTIL-RASTAGENE-21-FAT-VD-001</b>	<b>Revision No.</b>	<b>00</b>
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## 26.ABBREVIATIONS

<b>ABBREVIATIONS</b>	<b>FULL FORM</b>
FTIL	Fabtech Technologies International Ltd
AISI	American Iron & Steel Institute
CFM	Cubic Feet Per Minute
cGMP	Current Good Manufacturing Practices
DQ	Design Qualification
FAT	Factory Acceptance test
FLP	Flame Proof
FS	Full Scale
GA	General Assembly
GEP	Good Engineering Practices
HMI	Human Machine Interface
MCB	Miniature Circuit Breaker
MOC	Material of Construction
NFLP	Non Flame Proof
OQ	Operational Qualification
P&ID	Process & Instrumentation Diagram
PLC	Programmable Logic Controller
RH	Relative Humidity
SAT	Site Acceptance Test
SS	Stainless Steel
VFD	Variable Frequency Drive