DESIGN QUALIFICATION

FOR

WEIGHING, DISPENSING & COMPOUNDING ISOLATOR

DOCUMENT NO. - FTIL/RASTAGEN/DQ/VD/001

Fabtech®
Technologies International Ltd
Life Engineering™

M/s. RASTAGEN BIOPHARMACEUTICALS CO, IRAN

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1. SYSTEM INFORMATION

EQUIPMENT	WEIGHING, DISPENSING & COMPOUNDING ISOLATOR
MANUFACTURER	M/s. FABTECH TECHNOLOGIES INTERNATIONAL LTD
CUSTOMER	M/s. RASTAGEN BIOPHARMACEUTICALS CO, IRAN.
SERIAL NO.	FTIL/20/046
YEAR	2020-21
SITE	IRAN

2. INTRODUCTION AND PURPOSE OF DOCUMENTS

- 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.
- 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.

- **Design Qualification (DQ)** is carried out to analyze that the design and documentation for the equipment meets the **M/s RASTAGEN BIOPHARMACEUTICALS CO.** Requirements and design intentions of product, process, safety, regulatory bodies and GMP obligations. This document is prepared as per technical specification /URS from **M/s. RASTAGEN BIOPHARMACEUTICALS CO.**
- Based on the application and containment requirement, This Isolator is designed to work under Negative pressure with respect to atmosphere.
- Fabtech's 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. Aerodynamic means include air flow with filtration. System is designed to operate under a negative pressure with between – **80 Pa to - 100 Pa**. With engineered air supply & control by client.

3. BASIC EQUIPMENT

Isolator is designed to offer containment for **WEIGHING, DISPENSING & COMPOUNDING ISOLATOR** 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 working chamber. In the case of a containment breach, the unit will alarm and provide glove 'in rush' protection until rectified.

The products to be handled are designated with an OEL level 5 (<1 µG/ M3 TWA) operation. Proposed isolation systems are designed to work under negative pressure with

respect to ambient and conforms leak test class 3 as per leak test classified in ISO 10648 – 2 standards.

4. COPYRIGHT

5. OBJECTIVE

This document summarizes the Design Qualification of **WEIGHING, DISPENSING & COMPOUNDING ISOLATOR** that will be installed at the **M/s. RASTAGEN BIOPHARMACEUTICALS CO.**

The purpose of the Design Qualification (DQ) is to provide the specifications and operation requirements of the equipment on the basis of which it is designed, engineered and supplied as per cGMP guidelines. It is used to specify the requirements for the Installation Qualification of the equipment.

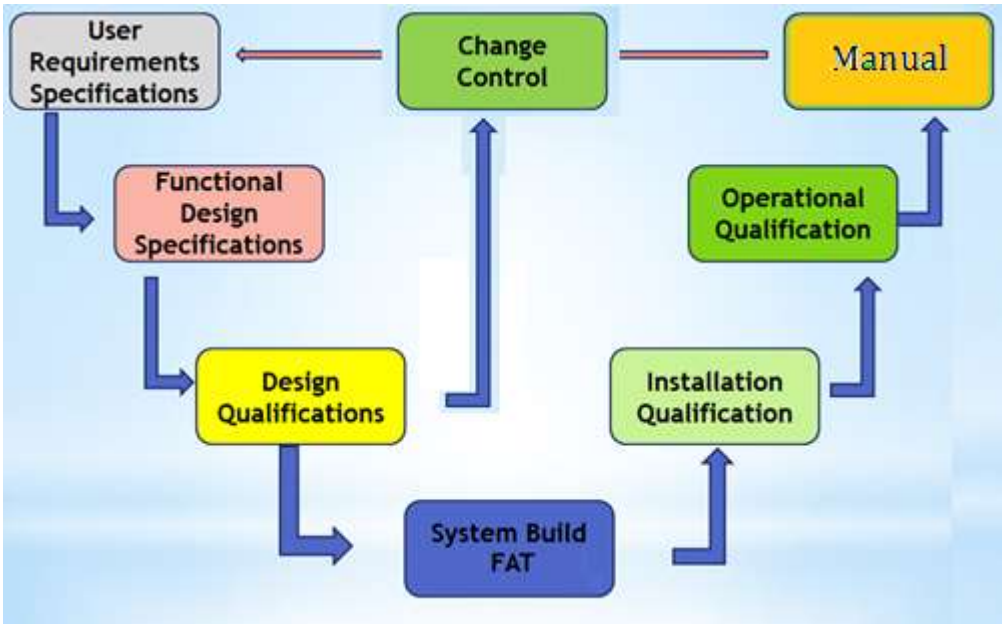
The Qualification Documents are intended to help you to perform machine qualification or re-qualification completely and correctly, and to document this in such a way that the qualification steps are transparent and understandable to inspectors in the event of a review.

6. CARRYING OUT QUALIFICATION AND DOCUMENTATION

The process of machine qualification must be undertaken in parallel with the development of the machine. Proceed as follows.

- You will find a detailed description of the machine and its assemblies as well as detailed instructions for correctly and safely carrying out individual operations on the machine.
- Read the Qualification Documents in detail.
- Make sure the complete machine documentation is available. You will need it during qualification.
- Draw up a qualification plan. Fabtech has already established a qualification plan for you. Please read the qualification plan and add to it if necessary.
- Now successively perform the Design Qualification, Installation Qualification, Operational Qualification tests.
- Document the tests, following the rules described inside each test document.
- Archive the Qualification Documents in a controlled location.

7. INFORMATION FLOW & FEEDBACK PROCESS



8. SCOPE

- This Design Qualification is limited to **M/s. RASTAGEN BIOPHARMACEUTICALS CO.** and will also cover responsibilities like acceptance criteria and technical specifications. This qualification document is part of a validation activity for the **WEIGHING, DISPENSING & COMPOUNDING ISOLATOR.**
- Qualification of support utilities is not within the scope of the qualification document. The equipment shall operate under dust free environment and conditions as per the cGMP requirements.

9. REFERENCE

- As per Approved GA Drawing.
- Customer PO.
- URS

10. RESPONSIBILITIES

CUSTOMER: M/s. RASTAGEN BIOPHARMACUTICALS CO.

- For providing complete User requirement specifications for design along with Purchase Order.
- Approval of DQ.

MANUFACTURER'S: M/s. FABTECH TECHNOLOGIES INTERNATIONAL LTD.

- To manufacture and supply the equipment incorporating all the specifications as per User requirement specifications.
- To assist client for successful installation & commissioning at the site.
- To design, engineer and provide the complete technical details of the equipment pertaining to its design qualification viz.
- Specification of the sub-components/ bought out items, their make, model, quantity.
- Details of Utilities.
- Identification of components.
- Material of construction of components.
- Safety features and alarms.
- Pre-installation requirements.

11. ATTACHMENTS

- DQ test sheets, detailing the objective, method and acceptance criteria for each of the above qualification tests are as attached below and must be completed

12. DOCUMENTATION SPECIFICATION

DOCUMENTS	REFERENCE NO
GA Drawing	FTIL-DRI-RBC-2021-05-(R4)
P & ID Drawing	FTIL-P&ID-RBC- 2021-05-(R0)
Electrical Wiring Diagram	FTIL-ED-RBC-2021-05-(R0)

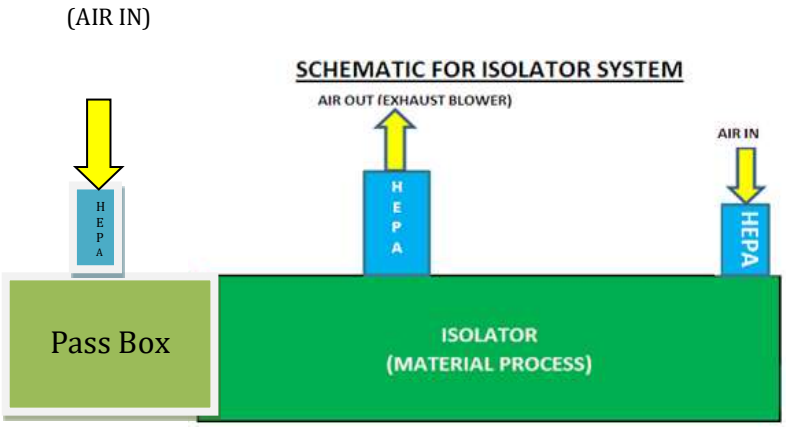
13. cGMP REQUIREMENT SPECIFICATION

cGMP Requirement	Design Criteria	Acceptance Criteria
1) MOC	MOC of Main chamber Should be SS316L. And the MOC of the non-contact Parts should be SS304.	MOC of Main Chamber– SS316L And MOC of Non-Contact Parts –SS304
2) Finish	External : Matt Finish (≤ 0.6 µm) Internal: Mirror Finish (≤ 0.4 µm)	Finish should be as per Technical details requirement.
3) Gaskets	Sponge Gaskets and Inflatable Gasket Are used.	Sponge Gaskets and Inflatable Gasket Are used. Food grade gaskets should be non-shredding, process Compatible, washable and easily Accessible.
4) Exposed Threaded Fasteners	Dome Bolts and nuts are to be used In All wetted area.	No exposed threaded Fasteners.
5) Crevices / corners (for contact surface areas)	Radius of curvature of 12.5 mm to facilitate cleaning and sterilization Operations.	No crevices. Round corners. Smooth Surfaces.

6) Cleaning	Main Chamber should be cleaned	All Parts are easily accessible for cleaning with purified water and compressed air through Spray gun.
7) OEL	Isolator as per design criteria will Follow OEL Level-5.	Isolator as per design criteria will Follow the limit of <1 µG/ M3 TWA.
8)ACPH	Not Less than 20-40 Air Change per hour (ACPH) for room air ventilation and settable on VFD and operated through console.	Not Less than 20-40 Air Change per hour (ACPH) for room air ventilation and settable on VFD and operated through console.
9)Pressure zoning inside the chamber	The actual reading (measured values by DPT) & the chamber should maintain the desire negative pressure (-80 pa to -100 pa).	The actual reading (measured values by DPT) & the chamber should maintain the desire negative pressure (-80 pa to -100 pa).
10) Leak Test	The Isolator should comply to ISO10648-2 class 3.	The Isolator should comply to ISO10648-2 class 3.

11) Welding	All Stainless steel components are welded using TIG method in Argon atmosphere, then these weld points are grinded and smoothen by surface finish techniques, all inter points are mirror polished and no open welding points will be observed at the product contact area.	All Stainless steel components are welded using TIG method in Argon atmosphere, then these weld points are grinded and smoothen by surface finish techniques, all inter points are mirror polished and no open welding points will be observed at the product contact area.
12) Isolator	Isolator Chamber Air Classification in Class-7. Isolator is Designed to Single Pass System.	ISO Cass-7
13) Temp. & RH	Temperature NMT 25° C, % of RH NMT 55	Actual readings should be maintaining the desire ranges.

14. OPERATING PROCEDURE



- Isolator is design to maintain negative pressure (-40 Pa to -60 Pa) inside the chamber to avoid contamination during operation. Air from room enters into pass box, and chamber through HEPA filters with the help of suction created by exhaust blower. From pass box, air further travels to main chamber through HEPA filter and same exhaust blower will exhaust the air outside the room through HEPA filter. During process ISO-7, class shall be maintained in chamber.
- Material transfer takes place in contained way with the help of Intermediate door. Before material transfer isolator shall give green indication which ensure the required negative pressure is available inside the isolator.
- After completion of process, material discharge in contained way through Pass box at the side of the Chamber.

15. COMPONENTS SPECIFICATION

GLOVE PORT	
Make	Shyam enterprises
Type	Elliptical
MOC	Delrin
Size	200 X 300 mm (Elliptical)
Location	Front side of the Chamber
Quantity	06 No's
GLOVES	
Make	Piercan/Equivalent
Size	8"x32"Length
Material	Hypalon
Location	Front side of the Pass box
Quantity	06 No's
GLOVE PORT	
Make	Shyam enterprises
Type	Round type
MOC	Delrin
Size	Dia. 150 mm
Location	Front side of the pass box

GLOVES	
Make	Piercan
Size	6"x32"Length
Material	Hypalon
Location	Front side of the Passbox
LIGHT	
Make	Banner
Type	N-FLP
Location	Top side of the chamber
Quantity	01 No's.
BALL VALVE	
Make	Aira/Equivalent
MOC	SS 316
Size	Diameter 1"
Location	Back side of the chamber
DIAPHRAGM VALVE	
Make	Aira/Equivalent
MOC	SS 316 L
Size	Diameter 1"
Location	Connection of Drain Line
INFLATABLE GASKET	

Make	Acrosil/Equivalent
MOC	Silicone
Location	Front side of the chamber
GAS SPRING CYLINDER	
Make	Zion/Equivalent
Location	Front side of the chamber
Quantity	02 No's
TOUGHENED GLASS	
Manufacturer	Amafhh Glass Tuff/Equivalent
Type	Toughened Glass
Size	12 mm Thickness
Location	Front side of the chamber and Pass box
Quantity	02 No's
ROXTEC ROUND SEAL	
Make	Roxtec India Pvt. Ltd.
Type	Roxtec Round Seal RS25 AISI 316/RS00100251023
Location	Back side of the chamber
Quantity	02 No's
HEPA FILTER (FOR INLET)	
Make	AAF/Equivalent

Efficiency	Efficiency (%) 99.999 down to 0.3µ
Class	H-14
HEPA FILTER (FOR EXHAUST)	
Make	AAF/Equivalent
Efficiency	Efficiency (%) 99.999 down to 0.3µ
Class	H-14
Location	Top side of the chamber and pass box
MOTOR	
Make	Hindustan
Type	NFLP
Voltage	380 V
HP	0.5 HP
RPM	2880
Location	Inside the service panel
Quantity	01 No.
BLOWER	
Make	Parth Engineering Works/Equivalent
Capacity	(Fan Capacity: 100 CFM)
Location	Inside the service panel
Quantity	01 No.

ELECTROMAGNETIC INTERLOCK	
Make	Schemersal
Location	Front side of the chamber and front side of the pass box and inside the pass box and chamber
Quantity	03 Nos.
CATCH POT	
Make	S & S Enterprises/Equivalent
Capacity	50 L
MOC	SS 304
Location	Bottom side of the Pass Box
Quantity	01 No.
SS BOURDON PRESSURE GAUGE	
Make	LA
Range	0-10.6 kg/cm2
Location	Top of Catch Pot
Quantity	01 No.
ANTI VIBRATION PAD	
MOC	Silicone food grade rubber
Location	In side of the chamber
Quantity	01 Nos.
CHAMBER	

Manufacturer	Fabtech
Description	SS Sheet (3 mm Thickness)
MOC	SS 316L
PASS BOX	
Manufacturer	Fabtech
Description	SS Sheet (3 mm Thickness)
MOC	SS 316L
SERVICE PANEL	
Manufacturer	Fabtech
Description	SS Sheet (1.6 mm Thickness)
MOC	SS304
CONTROL PANEL	
Manufacturer	Fabtech
Description	SS Sheet (1.6 mm Thickness)
MOC	SS304
Quantity	01 Nos.
SS STAND	
Manufacturer	Fabtech
Description	SS Square Pipe
MOC	SS 304
Quantity	01 Nos.

16. INSTRUMENTATION COMPONENTS SPECIFICATION

DIGITAL DIFFERENTIAL PRESSURE GAUGE	
Make	Dwyer
Model No.	DM-2000
Range	5.00 " W.C
Location	Front side of the service panel
Quantity	08 No's
VFD	
Make	Siemens
Description	Sinamics G120C PN
Location	Inside the control panel
Quantity	01 No.
PLC	
Make	Siemens
Description	S7 1200
Location	Inside the Control panel
Quantity	01 No.

HMI	
Make	Siemens
Size	9"
Description	TP 900
Location	Front of panel
Quantity	01 No.
DIFFERENTIAL PRESSURE TRANSMITTER	
Make	Dwyer
Model No.	MSII
Range	0-2.0 " W.C.
Accuracy	±0.5% F.S.
Quantity	01 No.
MINI REGULATOR WITH PRESSURE SWITCH	
Make	SMC
Model No.	AR20-F02BG1-B
Location	At Pneumatic Panel
Quantity	01 Nos.

PRESSURE REGULATOR	
Make	SMC
Model No.	IR2020-2GB1
Location	At Pneumatic Panel
Quantity	01 No.
SOLENOID VALVE	
Make	SMC
Model	VO307
Location	Inside the Service Panel
Quantity	02 Nos.
RH+ TEMPERATURE SENSOR	
Make	Radix
Model No.	SC806
Accuracy	±2 % RH/ ±0.5 %
Range	0-100°c/0-100%
Quantity	01 No.

17. MATERIAL CONSTRUCTION

SR.NO	COMPONENTS	SPECIFIED
1.	Main Chamber	SS 316L 3 mm THK Sheet
2.	Pass Box	SS 316L 3 mm THK Sheet
3.	Service Panel	SS 304 1.6 mm THK Sheet
4.	Control Panel	SS 304 1.6 mm THK Sheet
5.	S.S. Stand	SS 304 40mm x 40 mm x 2 mm Sq. Pipe

18. UTILITY SPECIFICATION

SR. NO.	UTILITY	STD SPECIFICATION
1.	Power Supply	380 V/50 HZ/3 PH
2.	Main Cable Size	2.5 mm^2 CU.4 Core
3.	Compressed Air	2-6 Kg/Cm^2

19. 21 CFR COMPLIANCE

The regulation 21 CFR Part 11 "Electronic Records; Electronic Signatures" of the US Regulatory Agency Food and Drug Administration (FDA) was enacted in 1997.

21 CFR Part 11 defines the FDA acceptance criteria for the use of electronic records and electronic signatures in place of records in paper form and handwritten signatures on paper. Following parameters considered in our design philosophy.

- Non-Editable Data
- Electronic Signature
- Audit Trail
- Alarm Report
- Offline Printing
- On Line Printing
- Multiuser
- Data Logging

Thus, the equipment manufactured by **M/s. FABTECH TECHNOLOGIES INTERNATIONAL LTD** to supply **M/s. RASTAGEN BIOPHARMACEUTICALS CO.** is in accordance with the above-mentioned 21 CFR Part 11 compliance.

20. SAFETY SPECIFICATION

SAFETY REQUIREMENT	ACCEPTANCE CRITERIA	DESIGN CRITERIA
1) Emergency Stops	Easily accessible location for operator	The Mushroom headed Lockout Emergency Stops are suitably located in **Operating Panel.**
2) Noise Levels	Should not exceed 75 decibels averaged over source operative period at a distance of 1000 mm From the noise source at a height of 1500 mm.	**WEIGHING, DISPENSING & COMPOUNDING ISOLATOR** should be designed so as not to exceed the pre-defined acceptance criteria for noise levels of 75 decibels.
3) Lux Level	Using the Lux meter to check the lighting level in the upper chamber of the isolator at 5 points and make the average of all points to find out the exact illumination level.	Light Level acceptable as per design norms. For CFL Lamp Minimum Illumination level of main chamber will be more than 300 L.
4) Alarms	All Alarms defined in pt. No. 19 above are incorporated.	The Alarms correctly incorporated as per The process flow and inter-linkages.

21. LIST OF CERTIFICATES

SR. NO.	NAME	DOCUMENT
1.	Isolator MOC	Material Test Certificate
2.	Motor Blower	Test Certificate
3.	Gloves	Test Certificate
4.	Glove Port	Test Certificate
5.	Light	Test Certificate
6.	Filters	Test Certificate
7.	RH & Temperature Sensor	Test Certificate
8.	Digital Gauge	Test Certificate
9.	DPT	Test Certificate
10.	Diaphragm Valve	Test Certificate
11.	Gaskets	Test Certificate
12.	VFD	Test Certificate
13.	PLC	Test Certificate
14.	HMI	Test Certificate
15.	Catch pot	Test Certificate
16.	Roxtec Gland	Test Certificate

22. LIST OF DOCUMENTS

M/s. Fabtech Technologies International Ltd will provide following qualification, Documents at the time of below mentioned activity DQ/IQ/OQ, FAT.

SR. NO	TITLE OF DOCUMENT
1.	Design Qualification
2.	Approved GA
3.	Factory Acceptance Test, MOC, Bought Out Test Certificates
4.	As Built GA, Electrical Drawing , P & ID Drawing
5.	Installation, Maintenance & Operating Instruction Manual
6.	Installation Qualification
7.	Operation Qualification

23. TRAINING SERVICE

Fabtech qualified engineers will provide training for operation, assembling, disassembling, safety measures, trouble shooting, cleaning, maintenance, PLC automation and for qualification of isolator.

24. SUMMARY

25. CONCLUSION

26. APPROVAL SHEET

M/s. FABTECH TECHNOLOGIES INTERNATIONAL LTD.				
Name	Department	Designation	Signature	Date

M/s. RASTAGEN BIOPHARMACEUTICALS CO, IRAN				
Name	Department	Designation	Signature	Date

REVISION HISTORY

SR. NO.	REVISION	DATE	REVISION SUMMARY

27. ABBREVIATIONS

ABBREVIATIONS	FULL FORM
FTIL	FABTECH TECHNOLOGIES INTERNATIONAL LTD
Cmp	Current Good Manufacturing Practices
DQ	Design Qualification
FAT	Factory Acceptance test
SAT	Site Acceptance test
GA	General Assembly
HMI	Human Machine Interface
IQ	Installation Qualification
MOC	Material of Construction
MS	Mild Steel
OA	Order Acknowledgement
OQ	Operational Qualification
P&ID	Process & Instrumentation Diagram
PLC	Programmable Logic Controller
PO	Purchase Order
QA	Quality Assurance
QC	Quality Control

RH	Relative Humidity
SOP	Standard Operating Procedure
SS	Stainless Steel
TC	Tri-clover
VFD	Variable Frequency Drive
GEP	Good Engineering practices
AISI	American Iron & Steel Institute
MS	Mild Steel
FLP	Flame Proof
CFM	Cubic Feet Per Minute

28. CUSTOMER SUPPORT CELL

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