

DESIGN QUALIFICATION

FOR

AUTOMATIC EXTERNAL VIAL WASHING

AND DRYING MACHINE

DOCUMENT No.: FTIL- RASTAGENE -20-DQ-VD-001



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1 APPROVAL SHEET

M/s. FABTECH TECHNOLOGIES INTERNATIONAL LTD.

	Name	Department	Designation	Signature	Date
Prepared by					
Checked by					
Approved by					

M/s. RASTAGENE BIOPHARMACEUTICALS CO.

	Name	Department	Designation	Signature	Date
Reviewed by					
Reviewed by					
Approved by					

REVISION HISTORY

SR. NO.	REVISION	DATE	REVISION SUMMARY

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2 SYSTEM INFORMATION

EQUIPMENT	AUTOMATIC EXTERNAL VIAL WASHING AND DRYING MACHINE
MANUFACTURER	FABTECH TECHNOLOGIES INTERNATIONAL LTD.
CUSTOMER	M/s. RASTAGENE BIOPHARMACEUTICALS CO
SITE	IRAN

1.0 OBJECTIVE

This document summarizes the Design Qualification of **Automatic Isolator Compatible External Vial Washing & Drying Machine** that will be installed at the Customer. The purpose of the Design Qualification (DQ) is to provide the specifications and operation requirements of the equipment based on which it is designed. It is used to specify the requirements for the Installation Qualification of the equipment.

2.0 SCOPE

This DQ is applicable to **Automatic Isolator Compatible External Vial Washing & Drying Machine** which will be used for fill liquid in vials and insert rubber plugging.

The system boundary is defined as including the **Automatic Isolator Compatible External Vial Washing & Drying Machine**, it will define the responsibilities, acceptance criteria, basis of design, technical specifications and list of major bought out parts, utility requirements, safety & cGMP features and documentation requirements.

3.0 REFERENCES

User requirement specification (URS) given by customer.

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4.0 RESPONSIBILITIES

4.1 CLIENT'S

- For providing complete technical specifications for design along with Purchase Order.
- To qualify equipment along with manufacturer.

4.2 MANUFACTURER'S

- To manufacture and supply the equipment incorporating all the specifications as per purchase order and user requirement specification (URS).
- 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.
 - Machine overview
 - Equipment orientation with layout
 - Specification of the sub-components/ bought out items, their make, model, quantity.
 - And backup records/brochures.
 - Details of Utilities.
 - Identification of components for calibration.
 - Material of construction of all components.
 - Brief process description.
 - Safety features and alarms.
 - Pre-installation requirements.

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5.0 SYSTEM DESCRIPTION

The Automatic Isolator Compatible External Vial Washing & Drying Machine is designed to wash outside surfaces round shaped Vials according to the washing cycle provided to you.

In Rotary design is such that separation is maintained between feeding zone and discharge zone of the cleaned containers. All the mechanical drives are separated and isolated from the washing zone. Approved materials only are used for construction, together with a careful choice of components, thereby taking into consideration all aspects of sanitation and consequence complying with the pharmaceutical G.M.P. requirements.

After Capping Machine sealed vial goes for external wash.

Operation will be done by using star wheel (3 Nos)

After completing the washing of the vials, the washed vials will be collected by the Tray at outfeed.

WASHING SEQUENCE

- 1) IN FEED OF VIAL
- 2) WFI WASH
- 3) HOT WATER WASH
- 4) AIR WASH
- 5) HOT AIR WASH
- 6) VACCUM WASH
- 7) OUT FEED OF VIALS
- 8) TRAY COLLECTION

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6.0 HARDWARE SPECIFICATION

Note: The identifiers/ Tag numbers for the major components will be listed during the qualification of the equipment.

6.1 MECHANICAL HARDWARE SPECIFICATION

SR. NO.	ITEM NAME	MOC
1.	MACHINE FRAME STRUCTURE	S.S.304 PIPE (50 X 50)
2.	MACHINE TOP PLATE	SS 316 L (20 MM THICKNESS)
3.	DOOR SET	S.S.304
4.	STAR WHEEL	DELRIN
5.	INFEED GUIDE	DELRIN
6.	NOZZLE STAND	DELRIN
7.	ALL COVERS	S.S.316L WITH SILICON SHEET FOR WASHING COMPATIBLE
8.	CHANGE PARTS	DELRIN
9.	NEEDLES	SS 316 L
10.	CONVEYOR	DELRIN
11.	DRAINAGE PIPES	SS 304
12.	TANK	SS 304

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6.2 ELECTRICAL SPECIFICATION

R. NO.	ITEM NAME	MAKE	MODEL NO
1.	STAR WHEEL GEARBOX	BONFIGLIOLI	VF49 F14 P90 B5B3
2.	STAR WHEEL MOTOR	BONFIGLIOLI	BEE90LA4
3.	AC DRIVE	SIEMENS	SINAMICS V20
4.	PLC	SIEMENS	S7-200
5.	HMI	SIEMENS	TP - 900
6.	MCB	SIEMENS	
7.	VACUUM PUMP	BECKER	VT 4.10-G008220(G008220)
8.	DOOR PROXY	SICK	
9.	FIBER OPTIC SENSOR	SICK	
10.	AIR PRESSURE TRANSMITTER	KELLER	0 TO 10 BAR
11.	VACUUM PRESSURE TRANSMITTER	KELLER	-1 TO 0 BAR

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7.0 TECHNICAL SPECIFICATIONS

7.1 BASIC MACHINE

PARAMETER	DESCRIPTION
BASIC UNIT	MACHINE IS SUITABLE FOR 2ML AND 100ML VIAL WITH DIAMETER 24" SCRAMBLER AND UN SCRAMBLER

7.2 CONTAINER SIZE

PARAMETER	DESCRIPTION
ROUND SHAPE	25 MM TO 48 MM (DIAMETER) 45 MM TO 100 MM (HEIGHT)

7.3 CAPACITY / OUTPUT

PARAMETER	DESCRIPTION
MACHINE SPEED	35 to 40 Vials / Min (For 10ML)

7.4 MATERIAL OF CONSTRUCTION

PARAMETER	DESCRIPTION
CONTACT PARTS	SS 316 L
NON-CONTACT PARTS	SS 316L

7.5 OPERATING SYSTEM

PARAMETER	DESCRIPTION
Operating System	2.1.1.1.1.1 HMI

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7.6 OTHER FEATURES

PARAMETER	DESCRIPTION
Gear Box	Make Bonfiglioli gear box with motor for machine
User Friendly	All parts for cleaning are easily removable.
Machine Frame	S.S.304 Pipe Structure

7.7 SLAT CONVEYOR

PARAMETER	DESCRIPTION
CONVEYOR	TO TRANSPORT THE OBJECT

7.8 SENSOR

PARAMETER	DESCRIPTION
Sensor - 1	No Vial - Machine Stop
Proxy - 1	Door Interlock

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8 SAFETY FEATURES

- The equipment shall be provided with safety features as listed below.

SR.NO	FEATURE	SPECIFIED
1.	Emergency Stop	Machine Stop
2.	Motor Overload	Machine Stop
3.	Door Open	Machine Stop
4.	No vial at infeed	Machine Stop
5.	Low Air	Machine Stop
6.	Vial Jam at Outfeed	Machine Stop

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9 UTILITY SPECIFICATIONS

- The electrical specifications where the machine is stored should be within the ranges specified by the hardware manufacturer.

PARAMETER	DESCRIPTION
ELECTRICAL POWER SUPPLY	380 V, 3 PHASES, 50HZ 4 CORE, 4 SQ MM AND EARTHING
POWER REQUIREMENT	4 kW
AIR REQUIREMENT	4 TO 6 KG/CM2 AT 11 CFM

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10 REPORT APPROVAL

This Design Qualification Protocol has been completed, reviewed, and found acceptable. Any deviations found have been reconciled and this system operates and performs properly in accordance with design specifications. This Design Qualification Protocol has been reviewed and approved by the individuals listed below.

APPROVAL TABLE (CLIENT)				
SIGNS FOR	ROLE	NAME	DATE	SIGNATURE
REVIEWED BY				
APPROVED BY				

CONCLUSION FOR DESIGN QUALIFICATION:

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11 ABBREVIATION

The following abbreviations are used in this document.

ABBREVIATION	DEFINITIONS
cGMP	Current Good Manufacturing Practice
GEP	Good Engineering Practices
VFD	Variable Frequency Drive
Hz	Hertz
KW	Kilo Watt
HP	Horsepower
SS	Stainless Steel
RPM	Revolution per minute
MOC	Material of Construction
No	Number
IQ	Installation Qualification Protocol
OQ	Operation Qualification Protocol
FAT	Factory Acceptance Test
MM	Millimeter
ML	Milliliter
PW	Purified Water
WFI	Water for Injection