

DESIGN QUALIFICATION

FOR

AUTOMATIC TWO HEAD INJECTABLE

LIQUID FILLING MACHINE

DOCUMENT No.: FTIL- RASTAGENE -20-DQ-VD-002

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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 TWO HEAD INJECTABLE LIQUID FILLING 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 Two Head Injectable Liquid Filling Machine with Rotary Disc Type Rubber Stoppering Unit** 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 Two Head Injectable Liquid Filling Machine with Rotary Disc Type Rubber Stoppering Unit** which will be used for fill liquid in vials and insert rubber plugging.

The system boundary is defined as including the **Automatic Isolator Compatible Two Head Injectable Liquid Filling Machine with Rotary Disc Type Rubber Stoppering Unit**, 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.

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3.0 REFERENCES

User requirement specification (URS) given by customer.

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 Two Head Injectable Liquid Filling Machine with Rotary Disc Type Rubber Stoppering Unit** is in the filling Room of the Injectable Facility with restricted access. The **Automatic Isolator Compatible Two Head Injectable Liquid Filling Machine with Rotary Disc Type Rubber Stoppering Unit** is located such that it can be attended easily for routine operations, monitoring, and sampling and maintenance functions.

The **Automatic Isolator Compatible Two Head Injectable Liquid Filling Machine with Rotary Disc Type Rubber Stoppering Unit** is designed to fill sterile liquid Injectable with different volume in different sizes of Vial and rubber stoppered the same as well pressing of the Rubber Stoppered Vial.

The speed of the machine is 40 vials per minute depending upon the size/shape of the Vials.

The **Automatic Isolator Compatible Two Head Injectable Liquid Filling Machine with Rotary Disc Type Rubber Stoppering Unit** works on volumetric Filling principle giving guarantee of high volumetric accuracy with minimal spillage.

Two inlet nozzles connected to the filling vessel via silicone tubing. Outlet of Peristaltic Pump connected to filling nozzle via silicon tube. Peristaltic Pump are suck the liquid from vessel and pump out into empty vial via nozzle. Nozzle will include pre and post nitrogen facility.

As soon as empty vial comes near to filling station, motion star wheel will stop the vial and start filling. As soon as filling cycle completes, motion star wheel will release the filled vial and transport conveyor for rubber stoppering process.

Now filled vial pick-up by intermittent motion star wheel and bring the filled vial at rubber stoppering station. Rubber stoppering unit is rotary disc type (half and full bunging). Roller will firmly stoppering rubber on vial in motion. Once this cycle complete, vial comes on the conveyor again to release. And collected in out feed turn table.

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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.	INFEEED GUIDE	DELRIN
6.	NOZZLE STAND	DELRIN
7.	ALL COVERS	S.S.316L WITH SILICON SHEET FOR WASHING COMPATIBLE
8.	TURN TABLE PLATE	DELRIN
9.	CHANGE PARTS	DELRIN
10.	SYRINGES	SS 316 L
11.	BOWL	SS 316 L
12.	CHUTE	SS 316 L
13.	NEEDLES	SS 316 L
14.	CONVEYOR	DELRIN
15.	DRAINAGE PIPES	SS 304
16.	BUFFER TANK 3 LITER	SS 316L

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6.2 ELECTRICAL SPECIFICATION

SR. NO.	ITEM NAME	MAKE	MODEL NO
1.	IN FEED TURN TABLE GEARBOX	BONFIGLIOLI	W-63 UFC1 100 P71 B5B3
2.	IN FEED TURN TABLE MOTOR	BONFIGLIOLI	BE 71B 4 230/400-50 IPSS CLF B5 BIS
3.	OUTFEED TURN TABLE MOTOR	BONFIGLIOLI	W-63 UFC1 100 P71 B5B3
4.	OUTFEED TURN TABLE GEARBOX	BONFIGLIOLI	BE 71B 4 230/400-50 IPSS CLF B5 BIS
5.	CONVEYOR MOTOR	ROTOMAQ	120W R15 FHP GEAR MOTOR
6.	SERVO	SIEMENS	V90 SERIES
7.	PERISTALTIC PUMP	WATSON MARLOW	313D PUMPHEAD, 3 ROLLERS 1.6MM WT TUBING
8.	AC DRIVE	SIEMENS	6SL3210-5BB13-7UV V20 0.37 KW
9.	PLC	SIEMENS	S7 1200
10.	HMI	SIEMENS	TP - 900 COMFORT
11.	MCB	SIEMENS	
12.	PNEUMATIC PISTON	SMC	CQ2A20-10DM , CQ2A50-50DZ
13.	PNEUMATIC 5/2 VALVE	SMC	SY7120-SL-02
14.	NITROGEN FLUSHING VALVE	SMC	VX20AAXB
15.	VACUUM PUMP	BECKER	VT 4.10-G008220(G008220)
16.	DOOR PROXY	SICK	

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17.	PHOTOELECTRIC SENSOR	SICK	1052444
18.	FIBER OPTIC SENSOR	SICK	
19.	AIR PRESSURE TRANSMITTER	KELLER	0 TO 10 BAR
20.	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	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 FILLER STAR WHEEL

PARAMETER	DESCRIPTION
FILLER STAR WHEEL	TO STOP THE VIAL ON CONVEYOR FOR FILLING PROCESS

7.9 FILLING HEAD

PARAMETER	DESCRIPTION
FILLING HEAD	Drive mechanism to drive syringes

7.10 MAIN DRIVE

PARAMETER	DESCRIPTION
MAIN DRIVE	To drive the syringes and star wheel

7.11 RUBBER STOPPER HOPPER & CHUTE

PARAMETER	DESCRIPTION
Rubber Stopper Hopper & Chute	To load bulk rubber stopper & transfer chute

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7.12 SENSOR

PARAMETER	DESCRIPTION
Sensor – 1	No Vial – No Fill
Proxy - 1	Door Interlock
Sensor – 2	No rubber Stopper – Machine Stop
Sensor – 3	Out Feed Vial Jam – Machine Stop

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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.	Vial Jam	Machine Stop
6.	No rubber stopper	Machine Stop
7.	Low Air	Machine Stop
8.	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