

**DESIGN QUALIFICATION**

**FOR**

**AUTOMATIC TWO HEAD ALUMINIUM CAP**

**SEALING MACHINE**

**DOCUMENT No.: FTIL- RASTAGENE -20-DQ-VD-003**

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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

<b>EQUIPMENT</b>	<b>AUTOMATIC TWO HEAD ALUMINIUM CAP SEALING MACHINE</b>
<b>MANUFACTURER</b>	<b>FABTECH TECHNOLOGIES INTERNATIONAL LTD.</b>
<b>CUSTOMER</b>	<b>M/s. RASTAGENE BIOPHARMACEUTICALS CO</b>
<b>SITE</b>	<b>IRAN</b>

### 1.0 OBJECTIVE

This document summarizes the Design Qualification of **Automatic Two Head Aluminium Cap Sealing 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 Two Head Aluminium Cap Sealing Machine** which will be used for fill liquid in vials and insert rubber plugging.

The system boundary is defined as including the **Automatic Two Head Aluminium Cap Sealing 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 Two Head Aluminum Vial Cap Sealing Machine works on the basic principle of to seal the filled & plugged Vials.

The machine is having Two head sealing head for the sealing operation. Also it can handle Vial sizes ranging from 2ml to 100ml. with appropriate Change Parts. Cap sizes of 20mm. (Also 13 mm & 32 mm caps can be accommodated with the appropriate Change Parts).

The speed of the operation is increased / decreased by A.C. Frequency drive. The sealing pressure can be adjusted spring tension. Cap feeding operation is done by the Chute from the vibratory Bowl located & placed properly at lower height at left side of the machine for the proper flow of the caps.

The conveyor transfers the vials into the star plate which is working on indexing principle. Once the vial entered to the star wheel the vial will pick-up the cap from the cap delivery chute and pass to the sealing station. The function of the star wheel to convey the vial from Conveyor to Sealing Station and sealed vial transfers to conveyor.

On completion of the sealing operation star plate transfer the bottles and the conveyor carries the sealed vial to collection tray or pass for further operation.

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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

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

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## 6.2 ELECTRICAL SPECIFICATION

<b>SR. NO.</b>	<b>ITEM NAME</b>	<b>MAKE</b>	<b>MODEL NO</b>
1.	<b>MAIN GEARBOX</b>	<b>BONFIGLIOLI</b>	<b>VF-49 1 14 P71 B5 B3</b>
2.	<b>MAIN MOTOR</b>	<b>BONFIGLIOLI</b>	<b>BE 71B 4 230/400-50 IPSS CLF B5 BIS</b>
3.	<b>CONVEYOR MOTOR</b>	<b>ROTOMAQ</b>	<b>120W R15 FHP GEAR MOTOR</b>
4.	<b>AC DRIVE</b>	<b>SIEMENS</b>	<b>SINAMICS V20</b>
5.	<b>PLC</b>	<b>SIEMENS</b>	<b>S7-200</b>
6.	<b>HMI</b>	<b>SIEMENS</b>	<b>TP - 900</b>
7.	<b>MCB</b>	<b>SIEMENS</b>	
8.	<b>DOOR PROXY</b>	<b>SICK</b>	
9.	<b>PHOTOELECTRIC SENSOR</b>	<b>SICK</b>	
10.	<b>FIBER OPTIC SENSOR</b>	<b>SICK</b>	



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## 7.0 TECHNICAL SPECIFICATIONS

### 7.1 BASIC MACHINE

PARAMETER	DESCRIPTION
BASIC UNIT	MACHINE IS SUITABLE FOR 2ML AND 100ML VIAL

### 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 RUBBER STOPPER AND CHUTE

PARAMETER	DESCRIPTION
CONVEYOR	TO TRANSPORT THE OBJECT

## 7.8 SENSOR

PARAMETER	DESCRIPTION
Sensor - 1	No Vial - No Cap
Proxy - 1	Door Interlock
Sensor - 2	No Cap - Machine Stop
Sensor - 3	Out Feed Vial Jam - Machine Stop
Proxy - 2	In feed Vial Clutch JAM
Proxy - 3	Outfeed Vial Clutch JAM

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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 Cap	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.

<b>PARAMETER</b>	<b>DESCRIPTION</b>
<b>ELECTRICAL POWER SUPPLY</b>	<b>380 V, 3 PHASES, 50HZ 4 CORE, 2.5 SQ MM AND EARTHING</b>
<b>POWER REQUIREMENT</b>	<b>1 kW</b>

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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.

<b>APPROVAL TABLE (CLIENT)</b>				
<b>SIGNS FOR</b>	<b>ROLE</b>	<b>NAME</b>	<b>DATE</b>	<b>SIGNATURE</b>
<b>REVIEWED BY</b>				
<b>APPROVED BY</b>				

**CONCLUSION FOR DESIGN QUALIFICATION:**

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## 11 ABBREVIATION

The following abbreviations are used in this document.

<b>ABBREVIATION</b>	<b>DEFINITIONS</b>
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