User Requirement Specification (URS)

For BFS capping machine

Document Code:

☞This document is under control and unalterable.

Revision History:

Change from previous version	Date

Prepared By	Technical Department Project Department Quality Assurance		12/18/2023
Project manager	Eng. Khaje h		12/18/2023
QA Manager	Dr. Keshavarz		12/18/2023
Production Manager	Dr. Yousefy		12/18/2023
Technical Manager	Eng. Mohammadshahi	M.SHAHI 23 DEC 2023	12/18/2023
Responsible Pharmacist	Dr. Torabi		12/18/2023

1. Table of contents

2. Purpose and Scope

This document defines the User Requirement Specification (URS) for BFS Capping machine to be installed in Sina Darou Pharmaceutical Company. This document clearly defines the user requirements to ensure compliance of the system with current Good Manufacturing Practices (cGMP) and all applicable regulations.

Scope of this specification will describe the requirements for the design, manufacturing, FAT, supply, inspection, delivery, installation, commissioning, SAT, documentation, and qualification activities of BFS Capping for production department.

3. Responsibility

The Supplier of the system is required to adhere to the content of this document; any deviations proposed must be clearly identified and justified by the Supplier

4. Overview

The BFS Capping machine is required to close the spike caps on BFS bottles in the following way Module fitted with pincers in the capping station, able in permitting to the cap not to drill the BFS bottle top. This process should be fully automated. The BFS Capping machine is located in Grade D Clean rooms on the ground floor of the production building.

5. Operational Requirements

performance specification

The BFS Capping machine shall be capable of performing the following functions within pre-determined specifications, in a controlled, safe, reproducible and consistent way:

5.1 Sort the spike caps to fit on the bottles

5.2 After sorting and placing the caps on the bottles, Screw spike caps closures on the BFS bottle

5.3 The spike caps are loaded manually into the machine tank

Design specification

5.4 Desired speed: Max 120 products/minute

5.5 All components of the BFS Capping machine shall be designed to allow easy access for operation, cleaning, inspection, calibration and maintenance to GMP requirements. Blind areas and unreachable areas for cleaning are not allowed.

5.6 All outer surfaces shall be smooth, easily cleaned and wiped. Un-cleanable areas shall be sealed.

5.7 The BFS bottle and Spike cap specifications

Product	Diameter (mm)	Height (mm)
5 ml BFS bottle	20.5	50.5
10 ml BFS bottle	20.5	71.5
Spike cap	According to the sample dimensions	

5.8 All products, clean compressed air contact parts or equipment process metal parts shall be AISI 304L stainless steel, and non-metal parts shall be FDA approved material.

5.9 All components and parts that are used in the machine must be long term corrosion free.

5.10 Automatic Continuous Motion Capping with one rotary closing turret.

5.11 The use of materials that generate particles within the restricted area is not allowed.

5.12 Module fitted with pincers in the capping station, able in permitting to the cap not to drill the BFS bottle top.

5.13 Bottles should be transferred by one conveyor belt that its motorization should have inclusive inverter for the speed adjustment executed from display.

5.14 The cans should be transported through the tank for sorting operations and then sorted by the appropriate process

5.15 Quick size changeover with minimum adjustments or replacement of parts.

5.16 Star wheel or any mechanism should be considered for the bottle transfer from the infeed area to the capping turret

5.17 Mean time between failures (MTBF) of at least 365 days, based on regular 2-shift operation. Mean time to Repair (MTTR) of less than half day

5.18 Construction of all the machine parts shall enable easy removal and exchange (maintenance access).

5.19 Machine should stop after three consecutive errors.

5.20 All materials shall meet applicable regulatory requirements, and shall be traceable back to the material certificates.

5.21 Equipment must be fabricated following all Good Engineering Practices. The vendor's Quality System must follow applicable national standards

5.22 A detailed specification shall be provided in response to this URS. This may be combined with the quotation or provided separately

5.23 All metallic non-media contact surfaces and frame shall be constructed of AISI 304 Grade Stainless Steel or better with external surface matt finish.

5.24 The size, weight, space requirement, reliability and efficiency, accuracy and energy and other utilities consumptions should be defined by supplier and approved by customer in early unit design phase.

5.25 The 2D preview design must be delivered by the vendor before production and begin construction after approval.

5.26 Vendor shall provide information about the cleaning procedure for the machine.

5.27 Functional design and technical specification should contain the following:

5.27.1 Equipment descriptions and its functions

5.27.2 Equipment operation steps

5.27.3 List of failure indications

5.27.4 List of input/outputs and its functions

5.28 The equipment shall be easily accessible for cleaning the non-product contact part at maintenance side of the equipment.

5.29 Vendor shall provide recommended spare parts list.

5.30 All construction material should have test certificates.

5.31 Bottles discharge function, at the end of the cycle, adjustable from the operator panel

5.32 A spare parts delivery guarantee of at least 10 years is required.

5.33 Mean time between failures (MTBF) of at least 365 days, based on regular 2-shift operation. Mean time to Repair (MTTR) of less than half day

5.34 The transport system must not cause damages on the products.

5.35 Minimal friction of the containers during transport

5.36 Vendor shall prepare FAT protocol and it should be approved by Sina Darou.

5.37 The FAT can only start once all the requested documents have been delivered by the vendor.

5.38 The FAT includes checking the mechanical / electrical components, as well as testing the functionality at the manufacturer's site. Minimum scope of FAT

5.38.1 Check of the mechanical and electrical components.

5.38.2 Test of system functions

5.38.3 Performance test

5.38.4 Test of alarms

5.38.5 Check of the system documentation

5.39 Original test results from the FAT shall be included in the documentation package, supplied with the equipment. A FAT report shall be generated by the vendor.

5.40 FAT shall be considered passed if the performances, to be guaranteed, are achieved.

Control Requirements

5.41 Install the ON / OFF switch on the operator panel on the line

5.42 All parameters are stored and controlled by PPC

5.43 The system shall provide with the following operation modes:

5.43.1 Manual mode

5.43.2 Automatic mode

5.43.3 Inching mode

5.44 Insert the sensor to detect empty hopper spike caps of the machine and give alarms, if it is empty.

5.45 incomplete bottles with missing closure should be rejected Automatically, Bottles should be deviated onto a dedicated area, parallel to the discharge conveyor, without machine stop.

5.46 Good Item counter at discharge on display.

5.47 Working hours counter of the machine.

5.48 Compressed air switch with machine stop at low level detection.

5.49 All sensors, controllers, PLC and indicators must be calibrated. Original calibration certificate must be submitted by the vendor.

5.50 3 colors Advisory Lights (5 functions):

5.50.1 Steady Red = The machine is stopped.

5.50.2 Steady Orange = The machine is under a minimum load.

5.50.3 Flashing Orange = Pre-alarm minimum load.

5.50.4 Steady Green = Machine is running.

5.50.5 Flashing Green = Machine is in automatic restart mode.

5.51 Automatic restart for machine operating in line. The Display shows "Downstream Machine is Stopped" and the restart takes place as soon as the normal working conditions restored

5.52 Alerting and failure: As a minimum following alarm messages must be configured and displayed:

5.52.1 Power failure

5.52.2 Protection switch failure

5.52.3 Emergency button actuated

5.52.4 Compressed air pressure drop

5.52.5 PLC failure

5.52.6 Activate the overload sensor

5.52.7 Program aborted

5.52.8 Program run time error

5.52.9 Sensor status not valid

5.52.10 Spike caps tank level low

5.53 Alerts and alarm functions should be specified and cover all system ability to comply with all set points and adjustable parameters.

5.54 Equipment and component standards of the supplier may be used, with respect of local market. All components and materials have to be listed and approved by the customer.

5.55 All parts have to be grounded.

5.56 In the control-cabinet at least 30% of spare place has to be left over.

5.57 The control-cabinet has to be designed so that the part for the power supply and the part for the controller devices are kept separate.

5.58 Allowed temperature of the components within the control-cabinet from +5°C to 35°C (EN 60204) has to be ensured.

5.59 All wires have to be numbered on both sides, external from connector block inside the control cabinet.

5.60 All data lines have to be shielded.

5.61 Free access to the connectors and devices in the control-cabinet.

5.62 Separate laying of the data line and the line for the power supply.

5.63 Control voltage 24 V DC

5.64 Two supply connections have to be foreseen, one for UPS and one for direct power connection with emergency power.

5.65 The control cabinets are either integrated in the equipment or above on the suspended ceiling in the technical area

5.66 The system must unify upstream and downstream machines to work simultaneously Pre-set maximum and minimum values in the parameter setting to prevent user settings over the range

5.67 Equipment failure can be analyzed by failure analysis system comes with equipment diagnostic functions

5.68 Suppliers can archive remote diagnosis through the network for the production line

5.69 Drive: Protection class must be at least IP54

Safety Requirements

1.1 The Capping quickly stopped with Emergency Stop (E-Stop) button on the operator panel.

1.2 Electrical power and instrumentation wiring shall be designed, fabricated, and installed in accordance with the latest version of the National Electrical Code (NEC) or its local equivalent, to minimize the exposure of operators and other personnel to electrical shock hazards.

1.3 In the event of a power failure, the system shall protect the product against damage by stopping in safe mode automatically. It will require operator intervention to re-start.

6. Electrical and utility requirement

The equipment shall operate with the following services provided at Company

6.1 Electrical Supply

6.1.1 220V, Single Phase, 50Hz

6.1.2 380V, 3 Phase, 50Hz

6.2 Compressed Dry Air

6.2.1 Supplied at 7 bar.

Environment conditions:

6.3 Moisture, water, dust and direct sunlight should be avoided.

6.4 Relative humidity: 10% to 70% (no condensation).

6.5 Avoid direct sunlight over the machine, also avoid water splatters.

7. Constraints

7.1 Milestones and Timelines

The BFS capping machine shall be installed, commissioned and ready for operation till **September 2024**

7.2 Equipment Constraints

7.2.1 Noise generated by the machine shall be below 60dB at 1 meter distance from the machine for all normal operating conditions.

7.3 Compatibility and Support

The supplied Equipment shall comply with all Iranian statutory and regulatory requirements and the stated international standards applicable to the equipment type, operating environment and operating site.

7.4 Availability/Maintenance

7.4.1 The machine is intended to operate continuously, 24 hours per day, 7 days per week.

7.4.2 The machine shall be maintained on a schedule as indicated by the supplier. Supplier should provide (at minimum) the following maintenance instructions:

7.4.2.1 A comprehensive recommended maintenance (regular recommended inspection intervals, wear points, recommended spare parts list)

7.4.2.2 Supplier shall supply 2 (two) copies of Operation, Installation, Maintenance and commissioning manuals in English.

7-5- Access Level

Different access levels for users:

7.5.1 operator,
7.5.2 supervisor,
7.5.3 administrator,
7.5.4 maintenance

8. Lifecycle

8.1 Testing

Factory Acceptance Test (FAT) is performed at the supplier site prior to shipping.Site Acceptance Test (SAT) is performed and approved at the manufacturer s i t e .

8.2 Delivery/ Documentation

Documentation includes:

#	Document title	Format
1	Electrical components lists	
2	Electrical documents lists	
3	Electrical diagrams	
4	Fault finding (troubleshooting	
5	Parts List / Mechanical & Electrical	All documents shall be in the English language and supplied with hard copies and electronic versions (pdf)
6	Tag number must be key to the list.	
7	Component description	
8	Function of component	
9	Supplier parts number	
10	Manuals, Maintenance, Drawings & Descriptions / Mechanical & Electrical	
11	Manufacturer part number	
12	installation, operation, and maintenance instruction	
13	Cleaning SOP and Check list	
14	Calibration certificates of each component	
15	IQ/OQ/PQ protocols	
16	FAT protocols	
17	SAT protocols	
18	Material & test certificate	

8. Support and training

List of training option with technical support should be available.

9. References

As a minimum, these shall include but not limited to the current versions of the following:

9.1 PIC/S Guide line.

9.2 ISPE Baseline Guide Pharmaceutical Engineering Guide

9.3 CE Standards

10. Vendor Responsibilities

10.1 Development: FAT protocols along with schematic drawings followed by SAT protocols review, approval then execution, which complies with cGMP requirements.

10.2 Equipment shall be qualified for design phase, installation phase, operational phase and the performance phase.

10.3 Testing: Commissioning for line will be conducted before SAT

10.4 Delivery:

10.4.1 All supplied document shall be in English (hardcopy and softcopy)

10.4.2 Data to be prepared or converted

10.4.3 Tools: if Applicable

10.4.4 Training courses: Vendor shall provide training for proper operating and usage procedures.

10.5 The supplier is to be aware of the documentation that will be required and is to include but not be limited to

10.5.1 Operating Manual
10.5.2 Maintenance Instructions
10.5.3 Safety Instructions
10.5.4 Layouts drawings
10.5.5 Functional Design Specification
10.5.6 Hardware/Software Design Specification
10.5.7 Installation, current flow, clamp and cable plans
10.5.8 Selected sub-assembly drawings
10.5.9 Configuration setting back-up CD
10.5.10 Comprehensive recommended spares parts list.
10.5.11 FAT Protocol
10.5.12 SAT Protocol
10.5.13 Certificate of control equipment calibration
10.5.14 Alarm List
10.5.15 Part List / Mechanical and Electrical
10.5.16 Component list
10.5.17 DQ.IQ.OQ documents

10.6 Support:

10.6.1.1 Start-up Support: The installation operation activity shall be made by the vendor.

10.6.1.2 Calibration: Local calibration service provided.

10.7 Supplier shall notify user of any improvements available on a regular basis.

10.8 Environmental Health and Safety

10.8.1 The supplier shall meet and abide by the site regulations of the Sina Darou's appointed project management contractor at all times.

10.8.2 The supplier shall meet the latest international standards for EH&S.

11. Definitions, Acronyms and Abbreviations

DQ = Design Qualification
FAT = Factory Acceptance Test
SAT = Site Acceptance Test
USP = United States Pharmacopoeia
HMI = Human-Machine Interface
P&ID = Piping and Instrumentation Diagram
cGMP = Current Good Manufacturing Practice
IQ = Installation Qualification
OQ = Operational Qualification
PICS = Pharmaceutical Inspection Co-operation Scheme
EP= European Pharmacopoeia

FS= Functional Specification
GAMP = Good Automated Manufacturing Practices
HSE = Health, Safety, Environment
IPC = In Process Control
ISO = International Organization for Standardization
PLC = Programmable Logic Controller
URS = User Requirement Specification

12. Document Distribution

Department	Version
Original version	Project Department
Copy No. 1	QA Department
Copy No. 2	QC Department
Copy No. 3	Technical Department
Copy No. 4	Production Department

13. Document Distribution

Department	Version
Original version	Project Department
Copy No. 1	QA Department
Copy No. 2	QC Department
Copy No. 3	Technical Department
Copy No. 4	Production Department

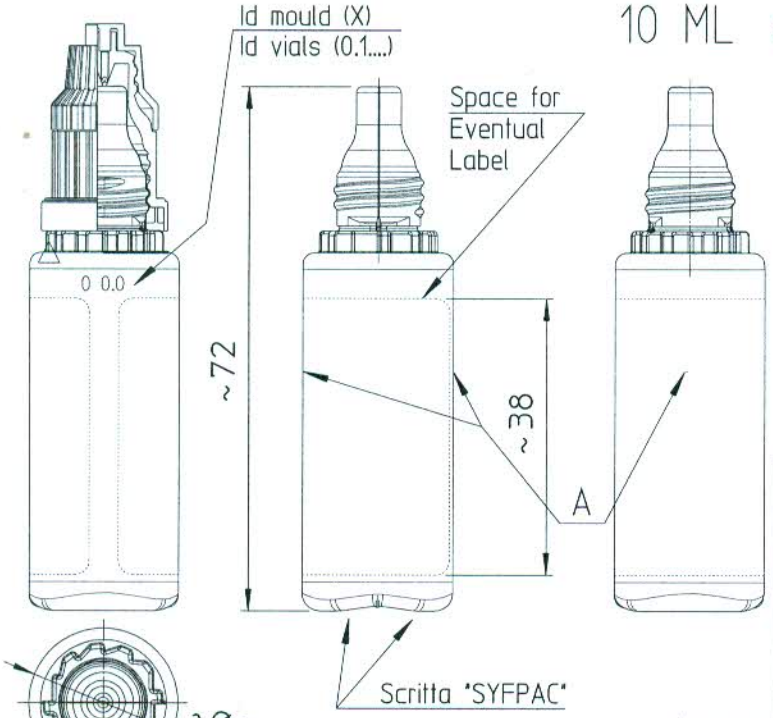
14. Attachments

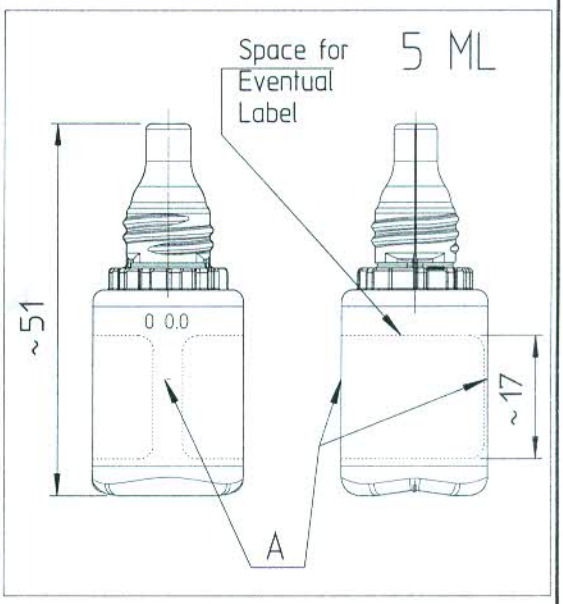
° DATI INDICATIVI CON RISERVA DI MODIFICHE SENZA PREAVVISO

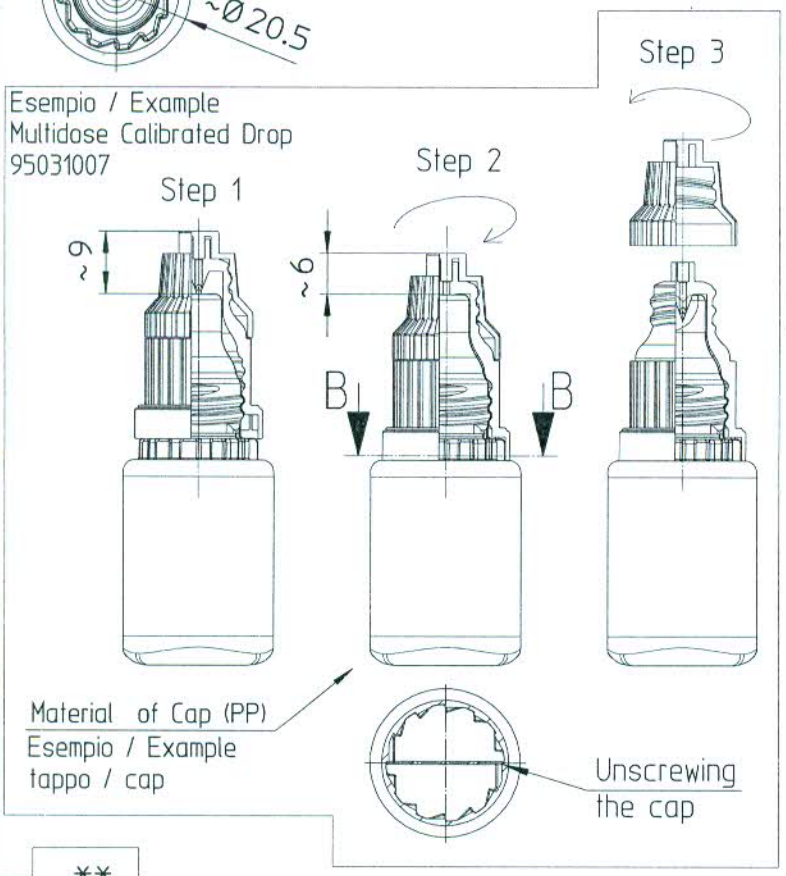
° DATA ARE INDICATIVE AND MAY BE REVISED WITHOUT NOTIFICATION.

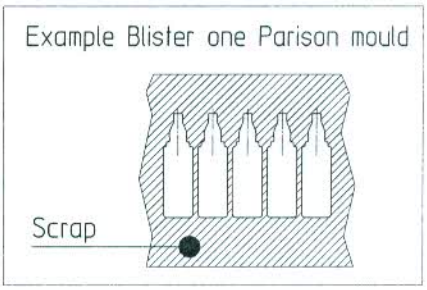
** The capacity mentioned are referred to the vials filled with aqueous solution having density and viscosity very near to water The filled volume tolerance and production are machine related, hence these are not applicable if only mould is purchased, without the machine.

10 ML Attachment 1- dimension of bottles









Controllo spessore
(Punto A)
A = 0.55 ± 0.15

**

Quote indicative Toll. ~ -2%
Approximate dimensions;
subject to shrinkage ~ - 2%

Volume (Teoretical)	** Toll.	** Production	Toll.	Working Range Scrap-Weight ± 15%	Toll. Repeatability	Working range Empty Weight ± 15%	Toll. Repeatability
5 ML	± 5 %	6.560	± 2 %	gr 5.7	± 3 %	gr 1.8	± 3 %
10 ML	± 3.5%	6.400	± 2 %	gr 6.2	± 3 %	gr 2.6	± 3 %

Notes internal technical office	MASER	OPERAZIONE: (SEPARAZIONE IN FIALE SINGOLE A BORDO MACCHINA CON SMATEROZZATRICE)	Model - Modello	Type-Tipo	Material - Materiale
	NO .		SVP 4.20	SYFPAC	PE / (EsBM)

Data Creazione	Disegnato da	Quote mm
25-01-17	Sartori S.	
Data Verifica	Verificato da	
06-07-18	Sartori S.	
Data Rilascio	Rilasciato da	Classe
06-07-18	Sartori S.	
Data Revisione	Revisionato da	Descrizione modifica
06-07-18	Sartori S.	Mod, cod. tappo da 13400498 a 95031007

ID: Part95_RC1aR06 | Data : 30-10-2008

BREVETTI ANGELA
Arzignano (VI)

Descrizione
FIALA STAMPO SCM91703

Description
VIAL MOULD SCM91703

Codice Elemento
10491703

Revisione B1 | Versione 01