User Requirement Specification (URS)

For Conveyor system for BFS line

Document Code:

☞**This document is under control and unalterable.**

Revision History:

Change from previous version	Date

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1. Table of content

2. Purpose and Scope

This document defines the User Requirement Specification (URS) for the Conveyor of BFS 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.

The scope of this specification is to describe the requirements for the design, manufacturing, FAT, supply, inspection, delivery, installation, commissioning, SAT, documentation, and qualification activities Conveyor of BFS Machine production department.

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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 Conveyor of BFS Machine is required to convey 5 or 10 CC bottle on the first floor to the ground floor which is taking the bottle at the filling machine (First floor) and deliver it to the unscrambler machine (ground floor). This process should be fully automatic which its speed depends on the filling machine (filling machine is 120 per/minute). The filling machine is located in Grade C Clean room on the first floor of the production at the new building and unscrambler machine is located in Grade D on the ground floor.

The Conveyor of BFS machine is located in Grade D Clean rooms on the first and ground floor of the production building

This machine is used for:

Convey eyedrop bottles

5. Operational Requirements

Mechanical design

5.1 The conveyor should pick up the BFS bottle from the output of the filling machine on the first floor and deliver it to the infeed of unscrambler machine on the ground floor.

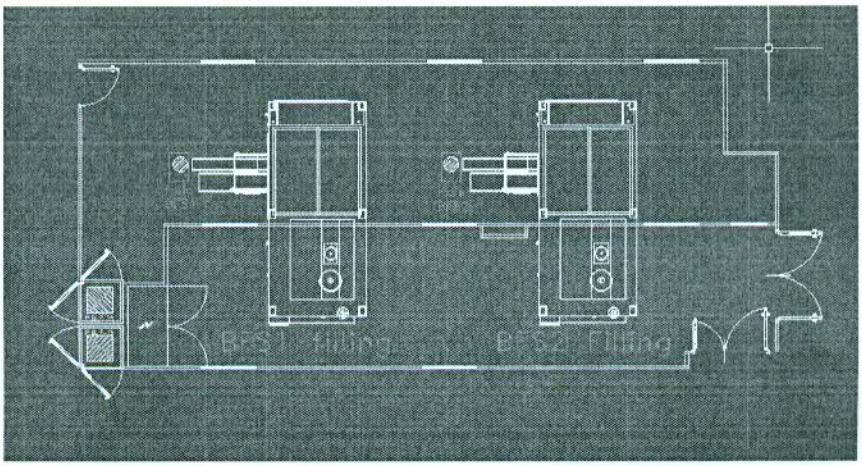
5.2 The machine should work automatically without any damage to the BFS bottle and with high accuracy.

5.3 The machine should work with 5cc or 10cc BFS bottle and must have the ability to change over 5cc to 10cc and contrariwise.

5.4 Dimension of eye drop bottle will be attached in the URS document.

5.5 The dimension of the machine must be approved by Sina Darou Company.

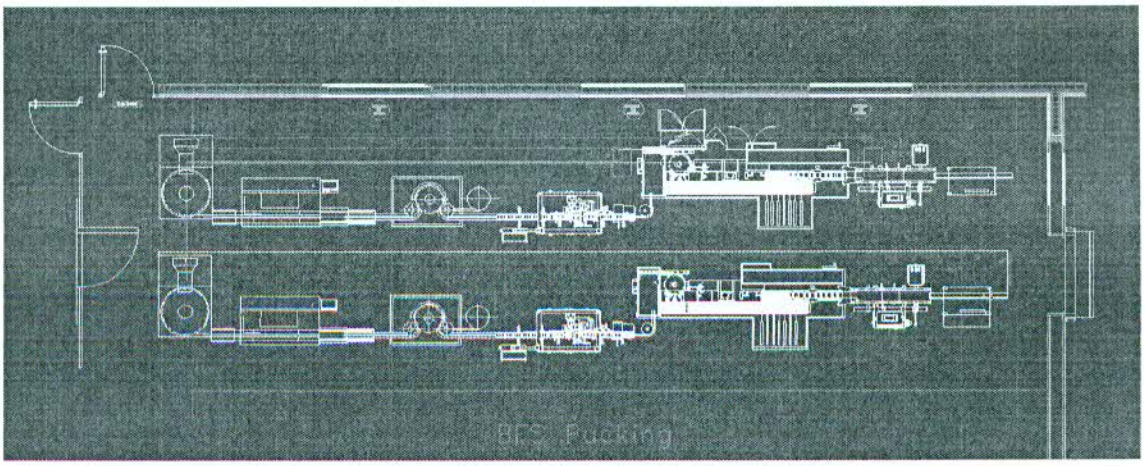
5.6 Location of Filling machine and Hole of conveyor on the first floor are shown in the drawing:



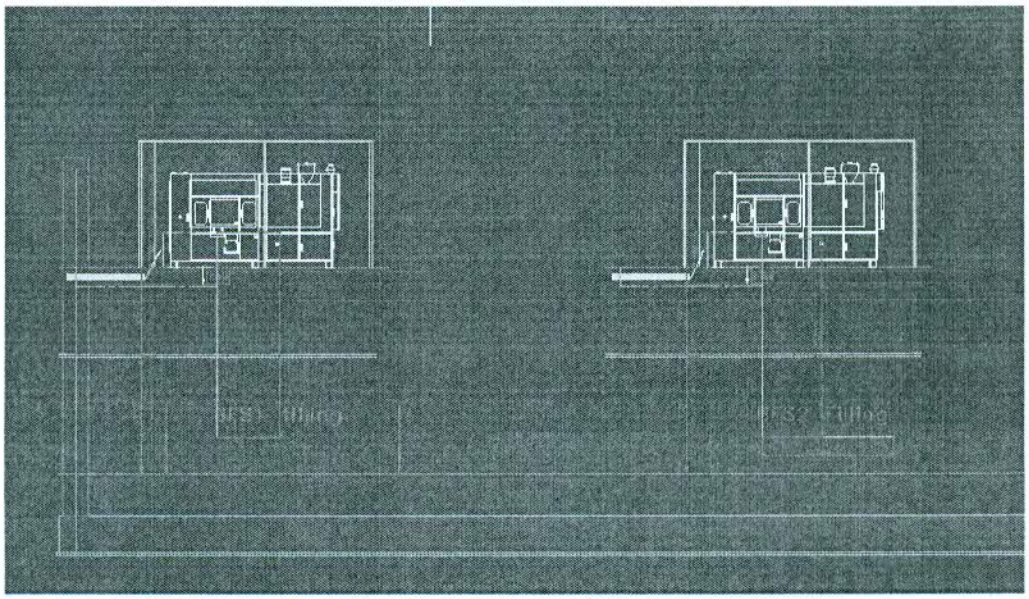
5.7 The BFS conveyor belt must pass through the Hole of the BFS Filling line as indicated in the above drawing.

5.8 The hole Dimension of the BFS filling line is 400mm and 600mm as indicated in the above drawing.

5.9 Drawing of conveyor and cartooning machines are shown in the below drawing:



5.1 The conveyor must pass through the hole and the technical area from the top of the ground floor and deliver the products to the unscrambler and capping line as indicated in the below picture.



5.2 The conveyor input should be linked with the filling machine as shown in the above picture

5.3 The machine should work without any particles.

5.4 The conveyor should deliver the BFS bottles to unscrambler machine.

5.5 The filling machine is located in Grade B Clean room on the first floor and it is so important to maintain a positive Air pressure and the conveyor machine must have a cabinet or airlock on the first floor.

5.6 The vendor must provide a guarantee for main components of this machine for 3 years

5.7 Vendor must provide after-sale services for 10 years

5.8 The vendor must provide spare parts for 2 years.

5.9 The machine must have minimum vibration.

5.10 The machine must have completely automatic operation.

5.11 the bottles must not have any damage during transferring process to the unscrambler machine.

Material / General

5.12 All material-contact parts must be Stainless Steel ~~316L~~ 304 and the other non-contact partcould be Stainless Steel 304 and should be properly polished Ra ≤1.2 µm

Material Certificates

5.13 Certificates for all stainless-steel components and materials in direct or non-direct contact with the product should be available and signed by the vendor. All materials of construction should have certificates that must be sent by the vendor.

5.14 Welding Quality – Orbital welds must be passivized (mirror) with a suitable product that re-establishes the material surface intact state with no discoloration at the site of the weld.

Capacity

5.15 The machine should be able to work at a speed of 120 bottles per minute. The speed should be adjustable.

6. Control System and Required Components

6.1 All components and materials have to be listed and approved by the customer.

6.2 All parts have to be grounded.

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

6.4 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.

6.5 The allowed temperature of the components within the control cabinet from +5°C to 35°C (EN 60204) has to be ensured

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

6.7 All data lines have to be shielded.

6.8 Free access to the connectors and devices in the control cabinet.

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

6.10 Control voltage 24 V DC

6.11 The control cabinets are integrated either into the equipment or above the suspended ceiling in the technical area.

6.12 Equipment failure can be analyzed by a failure analysis system that comes with equipment diagnostic functions

6.13 Suppliers can archive remote diagnoses through the network for the production line

6.14 Drive: Protection class: at least IP54

6.15 If needed the customer provides the UPS system and two possibilities are foreseen:

6.15.1 To protect the product's sterility and the data

6.15.2 To keep production running.

6.16 Emergency-stop buttons have to be provided in all dangerous zones

6.17 All drives will be switched on directly (without delta-wyes).

6.18 The system has to be designed and built by the Low Voltage Directive (LVD) 73/23/EEC

6.19 Protection against overload is required.

6.20 Protection against a short circuit is required.

6.21 Cross-sectional areas and connections of the protective conductor according to EN 61010-1. Insulating resistance according to EN 60204-1 and VDE 0100 T610.

6.22 Voltage test according to EN 60204 and VDE 0100 T610.

6.23 Residual voltage test according to EN 60204.

6.24 Every electric circuit, that has to be grounded, has to be connected to one central grounding point. The connection to the 0-potential will be provided on-site.

6.25 Solvable 0-voltage connections of the control low voltage to the grounding system have to be established.

6.26 0-voltage connections of the devices with low voltage outlets have to be established. An emergency stop has to be at every dangerous place.

6.27 Safety devices cannot be circumvented on an easy basis or be disabled.

6.28 Safety devices operate directly in the circuit.

6.29 In case of instrument air failure, a safe mode of operation has to be assured at all times.

6.30 In case of electrical power failure, a safe mode of operation has to be assured at all times.

6.31 In case of electrical power failure, a safe mode of operation has to be assured at all times

6.32 In case of electrical power failure, the requested UPS must buffer and save all relevant process data and must assure a secure and reliable system shut down after a certain period of power failure. Valve positions after pneumatic or electric utility failure according to the PIDs.

6.33 In case of no sufficient utilities, the operation has to stop in a second way.

6.34 Ventilator (control cabinet) failure must be indicated by an alarm. Not included in the control system.

6.35 In the case of the ventilator (control cabinet), the failure process start is interlocked.

6.36 Active processes must not be aborted.

6.37 High temperature in the control cabinet must be indicated by an alarm message and

active processes must not be aborted.

6.38 Motor protection failure must be indicated.

6.39 Line safety switch failure must be indicated.

6.40 As a minimum following alarm and messages must be configured and displayed:

6.40.1 Power failure

6.40.2 Emergency button actuated

6.40.3 Motor safeguard

6.40.4 Run time error valve

6.40.5 PLC failure

6.40.6 Utility failure (Temp. pressure etc.)

6.40.7 Upstream Machine was stop

6.40.8 Downstream Machine was stop

6.40.9 Line Mode Status

6.40.10 Single Mode Status

6.40.11 Actual Speed

6.40.12 Program run time error

6.40.13 Sensor status is not valid

7. ENVIRONMENT:

7.1 The equipment will be installed in class D and shall be compliant with the foresaid

7.2 class.Room temperature: 18 to 24 °C,

7.3 Relative humidity: 45 ± 5%

8. Cleaning

8.1 The equipment must be designed for easy cleaning according to DS/EN 1672-2 and DS/EN 1672-2/AC and hygienic design consideration.

8.2 All parts of the machine must be designed for easy access for cleaning. There mustn't have any place that can't be cleaned.

8.3 All parts of the machine must be designed for an easy visual cleaning inspection.

8.4 The machine should be connected to the existing CIP and SIP units.

9. Calibration

9.1 A calibration certificate from an accredited institute with traceable references for all pressure and calibration devices must be available.

9.2 The pressure, temperature, volume (Scaled measure), RPM, and RPM measuring devicesmust be accessible for calibration.

9.3 It must be possible to remove the pressure, temperature, volume, and RPM measuring devices for calibration.

9.4 Note: All instruments must be mounted in such a way that visual inspection can be performed as part of maintenance and monitoring.

10. Protection class: at least IP 54 according to DIN 40065

10.1 System/equipment suitable for nominal voltage 400 V (three phases) according to DIN IEC 38.

10.2 System/equipment suitable for rated frequency 50 Hz ± 10%.

11.Constraints

11.1 Equipment constraints

Noise Generated by the machine shall be below 60dB at a 1-meter distance from the machine for all normal operating conditions

11.2 Milestones and Timelines

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

11.3 Compatibility and Support

The conveyor machine should comply with cGMP CFR, 21 parts 11, 210, 211, 600, 610, and the EU guide to GMP.

It is the responsibility of the supplier to ensure that the equipment complies with all relevant national and international requirements and regulations.

11.4 Availability/Maintenance

11.4.1 1The machine is intended to be operated continuously, 24 hours per day, 7 days per week.

11.4.2 The machine shall be maintained on a schedule as indicated by the supplier.

Suppliershould provide (at minimum) the following maintenance instructions:

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

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

11.5 Access Level

Different access levels for users:

11.5.1 operator,
11.5.2 supervisor,
11.5.3 administrator,
11.5.4 maintenance

12. Lifecycle

12.1 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 site.

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

12.2 Delivery/ Documentation

Supplier should supply the documentation, and the machine test qualifications, including:

12.2.1 Installation drawing,
12.2.2 P&ID,
12.2.3 Electrical wiring diagram,
12.2.4 As Built drawing,
12.2.5 Operating Manual
12.2.6 Maintenance Instructions
12.2.7 Safety Instructions
12.2.8 Comprehensive recommended spares parts list.
12.2.9 FAT Protocol
12.2.10 SAT Protocol
12.2.11 Design qualification
12.2.12 Installation qualification documents
12.2.13 Operational qualification documents
12.2.14 Performance qualification
12.2.15 Calibration certificates
12.2.16 Alarm list
12.2.17 Component list
12.2.18 Parts List / Mechanical and Electrical
12.2.19 Troubleshooting list

12.3 Support and training

List of training option with technical support should be available.

13. References

13.1 CFR11, 21, 210, 211, 600 & 610

13.2 PICS

14 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

15 Document Distribution

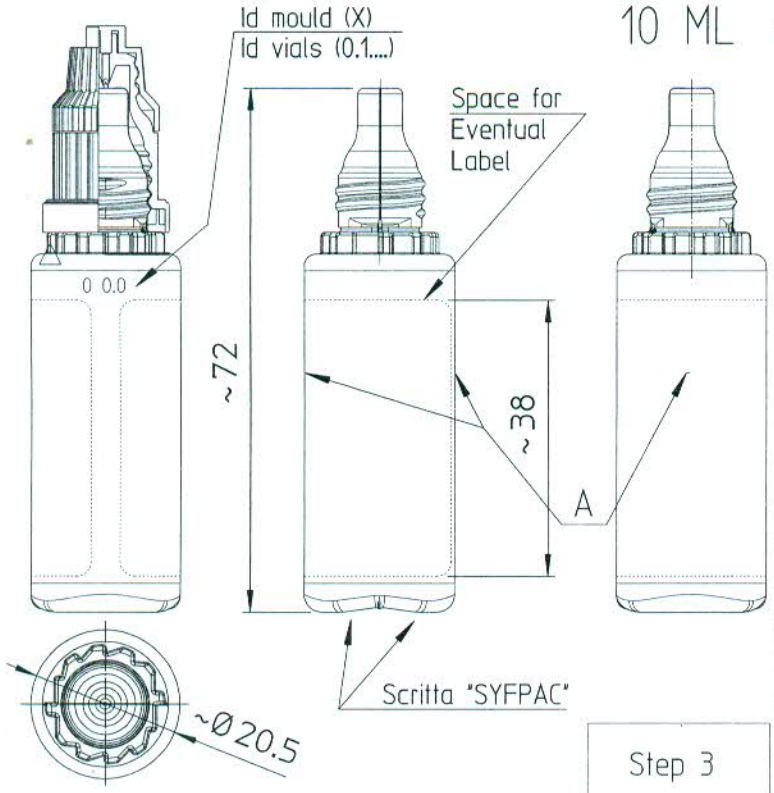
Department	Version
Original version	Project Department
Copy No. 1	QA Department
Copy No. 2	QC Department
Copy No. 3	Technical Department
Copy No. 4	Production Department

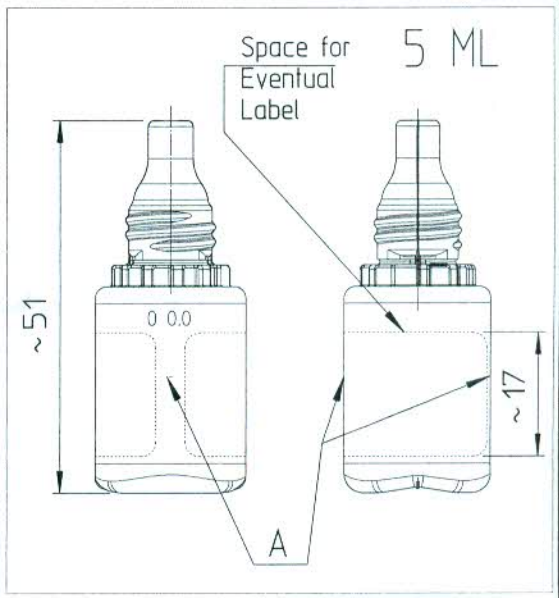
° DATI INDICATIVI CON RISERVA DI MODIFICHE SENZA PREAVVISO

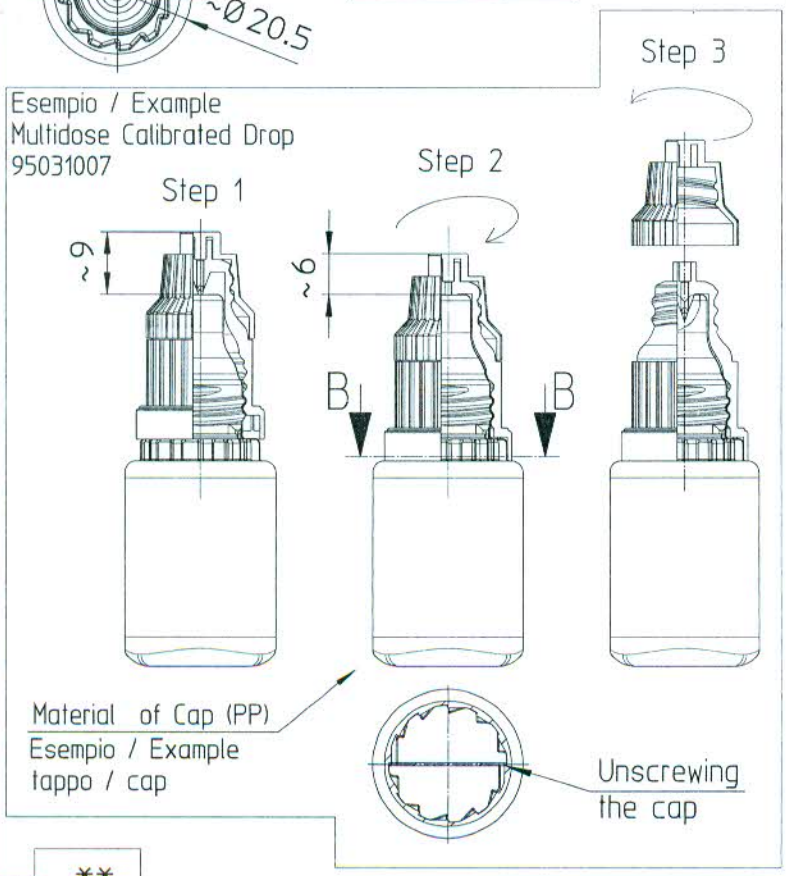
° DATA ARE INDICATIVE AND MAY BE REVISED WITHOUT NOTIFICATION.

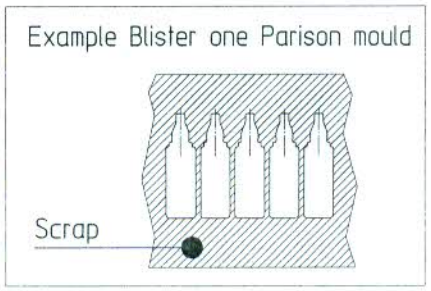
** The capacity mentioned are referred to the vials filled with aqueous solution having density and viscosity very near to water The filled volume tolerance and production are machine related, hence these are not applicable if only mould is purchased, without the machine.

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	MASEP	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_RC1=R06 | Date : 30-10-2008

BREVETTI ANGELA
Arzignano (VI)

Descrizione
FIALA STAMPO SCM91703

Description
VIAL MOULD SCM91703

Codice Elemento: 10491703 | Revisione: B1 | Versione: 01