

Date:12/19/2023

URS for

سينادا/9  
Sina Darou

Version:01

5ml and 10ml Eye Drop bottle packaging machine

## User Requirement Specification (URS)

For 5ml and 10ml Eye Drop bottle packaging machine

*Automatic*

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## 2. Purpose and Scope

This document defines the User Requirement Specification (URS) for 5ml and 10ml Eye Drop bottle packaging 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 is to describe the requirements for the design, manufacturing, FAT, supply, inspection, delivery, installation, commissioning, SAT, documentation, and qualification activities of 5ml and 10ml Eye Drop bottle packaging machine 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

This labeling machine is suitable for automatic packaging of 5ml 10ml plastic eye drop bottles with a Speed of 120 Bottles/Min which will be installed in a CNC class on the ground floor of SinaDarou's new production building

## 5. Operational Requirements

### **Mechanical design**

- 5.1 The speed of machine must be adjustable up to 120 bottle per/min.
- 5.2 The machine shall be designed to have the ability of easy changeover 5cc to 10cc and conversely
- 5.2 The machine must have high Accuracy in operation and without any waste
- 5.3 The machine must be fully automatic.
- 5.4 All components of the BFS packaging 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.
- 5.5 The dimension of bottles will be attached to this document.(find attachment 1)
- 5.6 The metal component material must be made of Stainless Steel 304L for non-metal materials, it should comply with the standards of the Food and Drug Administration.
- 5.7 All components should be replaceable and capable of disassembling.
- 5.8 The eyedrops bottles must be transferred with a Conveyor belt.
- 5.9 The packaging machine must have a leaflet folding machine that transfer leaflets into

- carton boxes automatically without any waste in the same speed.
- 5.10 The leaflet machine must have a leaflet feed source with a capacity of at least 1500 leaflet papers.
- 5.11 The machine must have a carton (can) feed source with a capacity of 600 cartons.
- 5.12 All components must have a valid certificate
- 5.13 Compressed air, vacuum connections and other utility equipment will be approved by SINA DAROU Company.
- 5.14 The vendor must provide recommended spare parts list with the machine.
- 5.15 All spare parts machine needed for 2 years should be send by vendor
- 5.16 The system must have the minimum machine downtime and equipment failure.
- 5.17 The machine should have minimum friction and also without particles and abrasion.
- 5.18 The vendor must provide a guarantee for devices such as motor, gearbox and main components for 3 years.
- 5.19 Vendor must provide after-sale services for 10 years.
- 5.20 The machine must have low noise.
- 5.21 The compressed air pressure must be between 4 to 8 bar.
- 5.22 The machine covers must be made of Stainless Steel and should be properly polished

### ***Process Control***

- 5.23 Power supply: 220 V , 50 HZ + Ground
- 5.24 Control voltage 24 V DC
- 5.25 The machine speed must be adjustable.
- 5.26 All electrical equipment, including PLC, HMI must be of prominent European brands.
- 5.27 The machine must have an Alarm list in the Control Panel and a Help menu in the Alarm list to troubleshoot and solve the problem.
- 5.28 Emergency-stop button has to be provided in various zones
- 5.29 All Technical documents including electrical drawings must be provided.

### ***Electrical requirement***

#### Control system

- 5.30 All parts have to be grounded.
- 5.31 In the control-cabinet at least 30% of spare place has to be left over.
- 5.32 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.
- 5.33 Allowed temperature of the components within the control-cabinet from +5°C to 35°C (EN 60204) has to be ensured.
- 5.34 All wires have to be numbered on both sides, external from connector block inside the control cabinet.
- 5.35 All data lines have to be shielded.



- 5.36 Free access to the connectors and devices in the control-cabinet.
- 5.37 Separate laying of the data line and the line for the power supply.
- 5.38 Control voltage 24 V DC
- 5.39 Two power connections should be provided, one for UPS and another for direct power connection with emergency power.
- 5.40 The packaging machine should be able to work with downstream and upstream machines simultaneously.
- It should be mentioned that Sorter, packaging, labeling and other machines will be connected together automatically and must work as a complete line.
- 5.41 Drive: Protection class: at least IP54
- 5.42 Industrial PC for process control and data acquisition.
- The controller has to be connected to a UPS-system. In case of power supply failure of the machine has to stop in a safe condition. The needed UPS-capacity for this step has to be specified, backup time at least 1h.
- Emergency-stop buttons has to be provided in all dangerous zones
- Protection class: at least IP 54 according to DIN 40065
- 5.43 System / equipment suitable for nominal voltage 400 V (three phases) according to DIN IEC 38.
- System / equipment suitable for rated frequency 50 Hz  $\pm$  10%.
- 5.44 All drives will be switched on directly (without delta-wyes).
- 5.45 The system has to be designed and built in accordance to the Low Voltage Directive (LVD) 73/23/EEC
- 5.46 Protection against overload is required.
- 5.47 Protection against short circuit is required.
- 5.48 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.
- 5.49 Voltage test according to EN 60204 and VDE 0100 T610.
- 5.50 Residual voltage test according to EN 60204.
- 5.51 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.
- 5.52 0-voltage connections of the devices with low voltage outlet have to be established.
- An emergency-stop has to be at every dangerous place.
- 5.53 Safety devices cannot be circumvented on an easy basis or be disabled.
- 5.54 Safety devices operate directly in the circuit.
- 5.55 One emergency stop must be available for operating personnel.
- 5.56 Simple calibration, recalibration, maintenance or replacing measurement devices(sensor and transformer) must be possible. The length of the cable required for replacing and calibrating the sensor should be considered next to the instrument. The line must be

adjustable

## 6. Environment

- a. Moisture, water, dust and direct sunlight should be avoided.
- b. Relative humidity: 10% to 70% (no condensation).
- c. Avoid direct sunlight over the machine, also avoid water splatters.
- d. Keep area free of vibration, and free of gaseous chemicals.
- e. The machine must comply with the environment requirements and must not cause any harm to environment.

## 7. Constraints

### 7.1 Milestones and Timelines

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

### 7.2 Compatibility and Support

Eye Drop packaging machine should comply with cGMP CFR parts 11, 21, 210, 211, 600, 610 and EU guide toGMP.

The machine must comply with the Safety Directive. The Machine must have the ability to work with 5-10cc bottles.

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

### 7.3 Availability/Maintenance

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

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

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

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



### 7.4 Access Level

Different access levels for users:

- 7.4.1 operator,
- 7.4.2 supervisor,
- 7.4.3 administrator,
- 7.4.4 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 site.

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

### 8.2 Delivery/ Documentation

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

- 7.4.5 Installation drawing,
- 7.4.6 P&ID,
- 7.4.7 Electrical wiring diagram,
- 7.4.8 As Built drawing,
- 7.4.9 Operating Manual
- 7.4.10 Maintenance Instructions
- 7.4.11 Safety Instructions
- 7.4.12 Comprehensive recommended spares parts list.
- 7.4.13 FAT Protocol
- 7.4.14 SAT Protocol
- 7.4.15 Design qualification
- 7.4.16 Installation qualification documents
- 7.4.17 Operational qualification documents
- 7.4.18 Performance qualification
- 7.4.19 Calibration certificates
- 7.4.20 Alarm list
- 7.4.21 Component list
- 7.4.22 Parts List / Mechanical and Electrical
- 7.4.23 Troubleshooting list
- 7.4.24 Changeover size process description and manual

### 8.3 Support and training

List of training option with technical support should be available.

## 9. References

- 9.1 CFR11, 21, 210, 211, 600 & 610



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## 10. 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

## 11. 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

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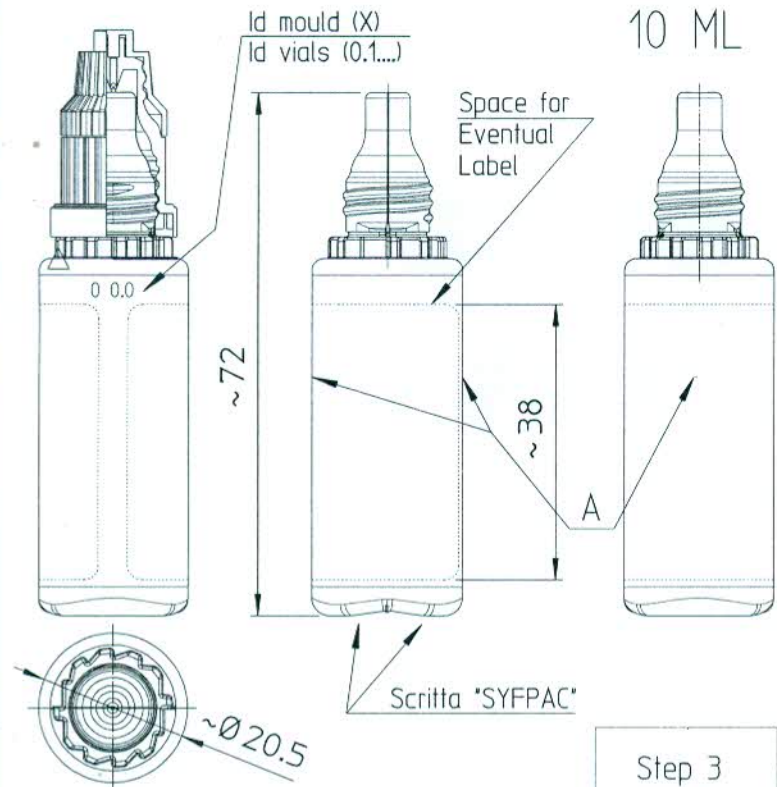
5ml and 10ml Eye Drop bottle packaging machine

Sino Darou

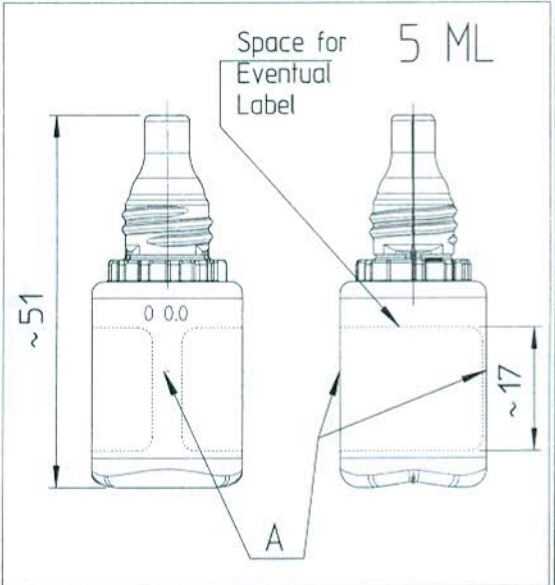
12. Attachments



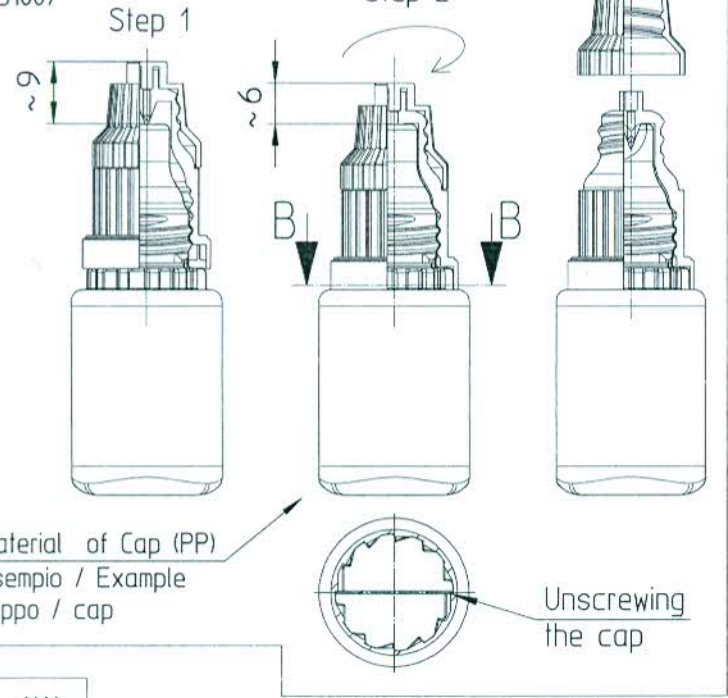
° DATI INDICATIVI CON RISERVA DI MODIFICHE SENZA PREAVVISO  
 ° DATA ARE INDICATIVE AND MAY BE REVISED WITHOUT NOTIFICATION.  
 \*\* The capacity mentioned are referred to the vials filled with aqueous solution having density and viscosity very near to water. The filled volume tolerance and production are machine related, hence these are not applicable if only mould is purchased, without the machine.



10 ML Attachment 1- dimension of bottles



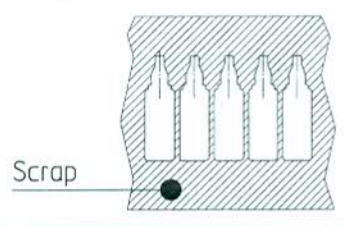
Esempio / Example  
 Multidose Calibrated Drop  
 95031007



Material of Cap (PP)  
 Esempio / Example  
 tappo / cap

Unscrewing  
 the cap

Example Blister one Parison mould



Controllo spessore  
 (Punto A)  
 A = 0.55 ± 0.15

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

Volume (Theoretical)	** 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 %

Noles internal technical office	MASEP NO	OPERAZIONE: (SEPARAZIONE IN FIALE SINGOLE A BORDO MACCHINA CON SMATEROZZATRICE)	Model - Modello SVP 4.20	Type-Tipo SYFPAC	Material-Materiale PE / (EsBM)
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Data Creazione 25-01-17	Disegnata da Sartori S.	Quote mm
Data Verifica 06-07-18	Verificata da Sartori S.	
Data Rilascio 06-07-18	Rilasciato da Sartori S.	Classe
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BREVETTI  
**ANGELA**  
 Arzignano (VI)

Descrizione FIALA STAMPO SCM91703 Description VIAL MOULD SCM91703	Codice Elemento 10491703	Revisione B1	Versione 01
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