

Date:12/19/2023

URS for

سینا دارو
Sina Darou

Version:01

5ml and 10ml Eye Drop bottle labeling machine

User Requirement Specification (URS)

For 5ml and 10ml Eye Drop bottle labeling machine

Document Code:

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Revision History:

| Change from previous version | Date |
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|------------------------|---|--|------------|
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1. Table of contents

| | |
|---|----|
| 1.Table of contents..... | 3 |
| 2.Purpose and Scope..... | 4 |
| 3.Responsibility..... | 4 |
| 4.Overview..... | 4 |
| 5.Operational Requirements..... | 4 |
| Mechanical design | 4 |
| Process Control..... | 5 |
| Electrical requirement | 5 |
| 6.Environment..... | 7 |
| 7.Constraints..... | 7 |
| 7.1 Milestones and Timelines | 7 |
| 7.2 Compatibility and Support | 7 |
| 7.3 Availability/Maintenance | 8 |
| 7.4 Access Level | 8 |
| 8. Lifecycle..... | 8 |
| 8.1 Testing..... | 8 |
| 8.2 Delivery/ Documentation..... | 9 |
| 8.3 Support and training | 9 |
| 9. References..... | 9 |
| 10.Definitions, Acronyms and Abbreviations..... | 9 |
| 11. Document Distribution..... | 10 |
| 12.Attachment | 11 |

2. Purpose and Scope

This document defines the User Requirement Specification (URS) for 5ml and 10ml Eye Drop bottle labeling 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 labeling 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 labeling of 5ml 10ml plastic eye drop bottles with a Speed of 220 Bottles/Min which will be installed in a CNC class on the ground floor of SinaDarou new production building

5. Operational Requirements

Mechanical design

- 5.1 The speed of machine must be adjustable up to 220 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 insert the batch number on the labels automatically.
- 5.3 The machine must have Hot Stamp Printer which provides to print code/letter onto the label.
- 5.4 the label must be completely attached to the body of the bottle after leaving the machine.
- 5.5 The label roll should be easily replaceable.
- 5.6 The machine must have the ability to change the batch number easily.
- 5.7 The machine should work with the speed of 220 bottles/ min without any waste.
- 5.8 The machine should be able to work normally with different label materials available in SinaDarou.
- 5.9 The machine must have high Labeling Accuracy and without any harm to the bottles.

- 5.10 The machine must be fully automatic.
- 5.11 All components of the BFS labling 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.
- 5.12 The dimension of bottles will be attached to this document.
- 5.13 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.
- 5.14 All components should be replaceable and capable of disassembling.
- 5.15 The inlet and Outlet of labeling machine must be connected and synchronized with a Conveyor. the bottles move vertically on the conveyor belts.
- 5.16 All components must have a valid certificate
 - 5.16.1 Compressed air, vacuum connections and other utility equipment will be approved by SINA DAROU Company.
- 5.17 The vendor must provide recommended spare parts list with the machine.
- 5.18 All spare parts machine needed for 2 years should be send by vendor
- 5.19 The system must have the minimum machine downtime and equipment failure.
- 5.20 changing label rolls and replaceable components(e.g. ribbon) must be done as fast as possible
- 5.21 The machine should have minimum friction and also without particles and abrasion.
- 5.22 The vendor must provide a guarantee for devices such as motor, gearbox and main components for 3 years.
- 5.23 Vendor must provide after-sale services for 10 years.
- 5.24 The machine must have low noise.
- 5.25 The compressed air pressure must be between 4 to 8 bar.
- 5.26 The machine covers must be made of Stainless Steel and should be properly polished

Process Control

- 5.27 Power supply: 220 V , 50 HZ + Ground
- 5.28 Control voltage 24 V DC
- 5.29 All electrical equipment, including PLC, HMI must be of prominent European brands.
- 5.30 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.
- 5.31 Emergency-stop button has to be provided in various zones
- 5.32 The machine shall have a sensor to detect missing label and ribbon.
- 5.33 The machine should have a label sensor at the outlet to detect non-adhesive labels and reject defective products.
- 5.34 All Technical documents including electrical drawings must be provided.

Electrical requirement

Control system

- 5.35 All parts have to be grounded.
 - 5.36 In the control-cabinet at least 30% of spare place has to be left over.
 - 5.37 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.
 - 5.38 Allowed temperature of the components within the control-cabinet from +5°C to 35°C (EN 60204) has to be ensured.
 - 5.39 All wires have to be numbered on both sides, external from connector block inside the control cabinet.
 - 5.40 All data lines have to be shielded.
 - 5.41 Free access to the connectors and devices in the control-cabinet.
 - 5.42 Separate laying of the data line and the line for the power supply.
 - 5.43 Control voltage 24 V DC
 - 5.44 Two power connections should be provided, one for UPS and another for direct power connection with emergency power.
 - 5.45 The labeling 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.
- 5.46 Drive: Protection class: at least IP54
 - 5.47 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

- 5.48 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%.
- 5.49 All drives will be switched on directly (without delta-wyes).

- 5.50 The system has to be designed and built in accordance to the Low Voltage Directive (LVD) 73/23/EEC
Protection against overload is required.
- 5.51 Protection against short circuit is required.
- 5.52 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.
- 5.53 Voltage test according to EN 60204 and VDE 0100 T610.
- 5.54 Residual voltage test according to EN 60204.
- 5.55 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.
- 5.56 0-voltage connections of the devices with low voltage outlet have to be established.
An emergency-stop has to be at every dangerous place.
- 5.57 Safety devices cannot be circumvented on an easy basis or be disabled.
- 5.58 Safety devices operate directly in the circuit.
- 5.59 The line must be adjustable.
- 5.60 One emergency stop must be available for operating personnel.
- 5.61 Simple calibration, recalibration, maintenance or replacing measurement devices must be possible. The length of the cable required for replacing and calibrating the sensor should be considered next to the instrument

6. Environment

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

7 Constraints

7.1 Milestones and Timelines

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

7.2 Compatibility and Support

Eye Drop labeling 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
- 9.2 PICS

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

Date:12/19/2023

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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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URS for

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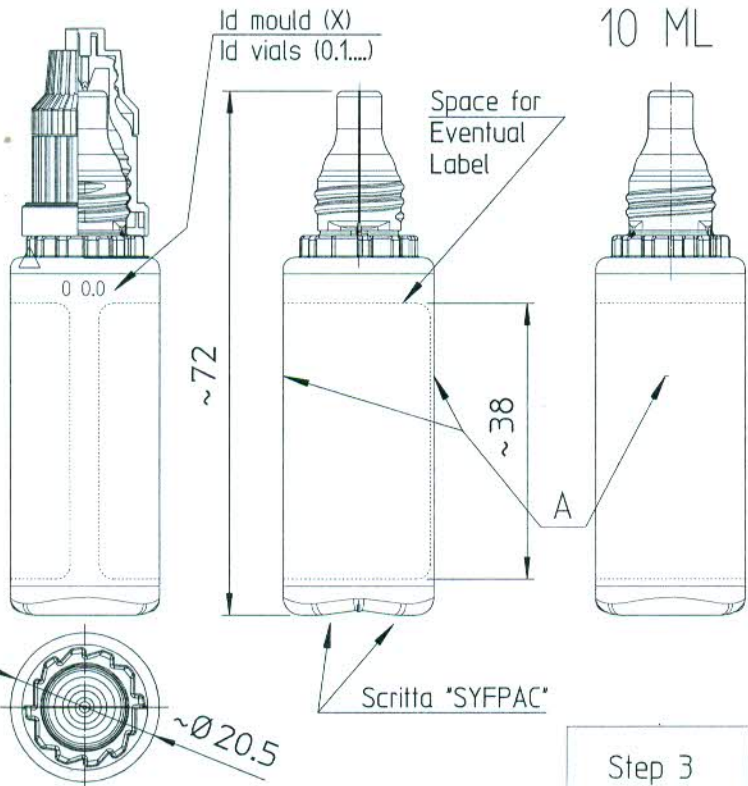
Version:01

5ml and 10ml Eye Drop bottle labeling machine

Sino Darou

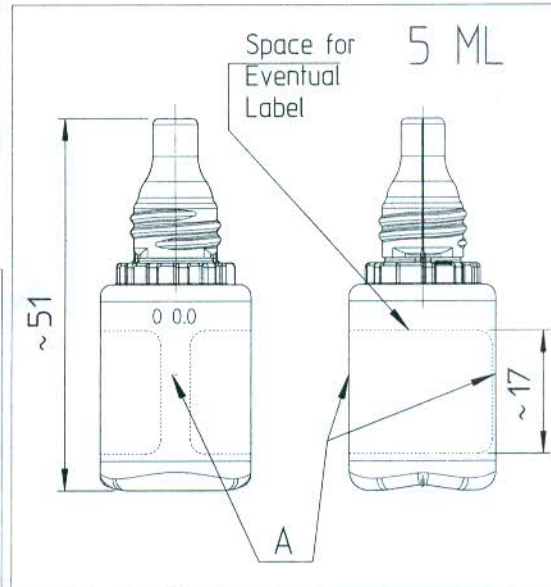
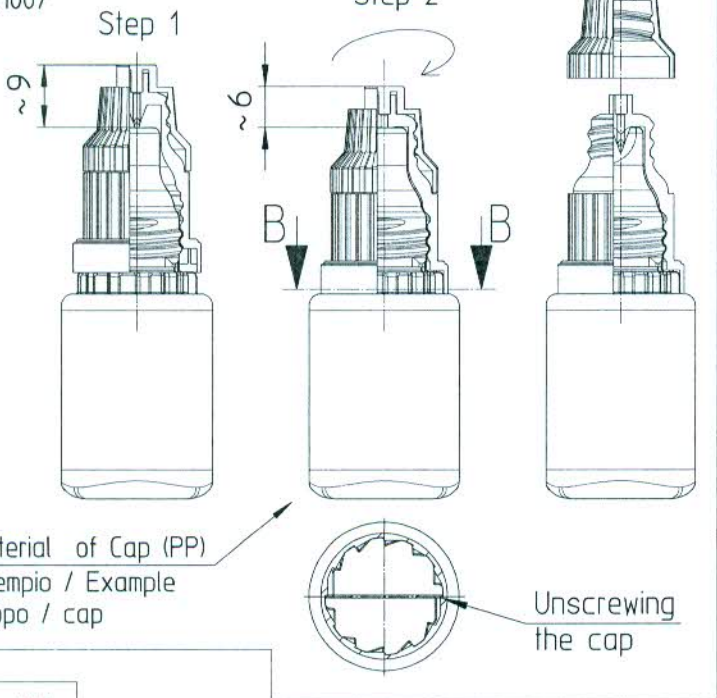
12. Attachment

° 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.

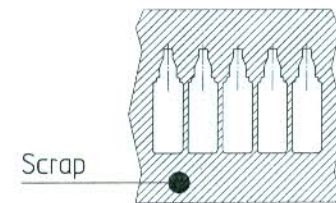


10 ML Attachment 1- dimension of bottles

Esempio / Example
 Multidose Calibrated Drop
 95031007



Example Blister one Parison mould



Scrap

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 % |

| | | | | | |
|------------------------------------|-------------|--|-----------------------------|----------------------|-------------------------------------|
| Notes 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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BREVETTO
ANGELA
 Arzignano (VI)

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