

SX-310-PP

Compact machine for automatic infeed, filling, and closing of injection vials.

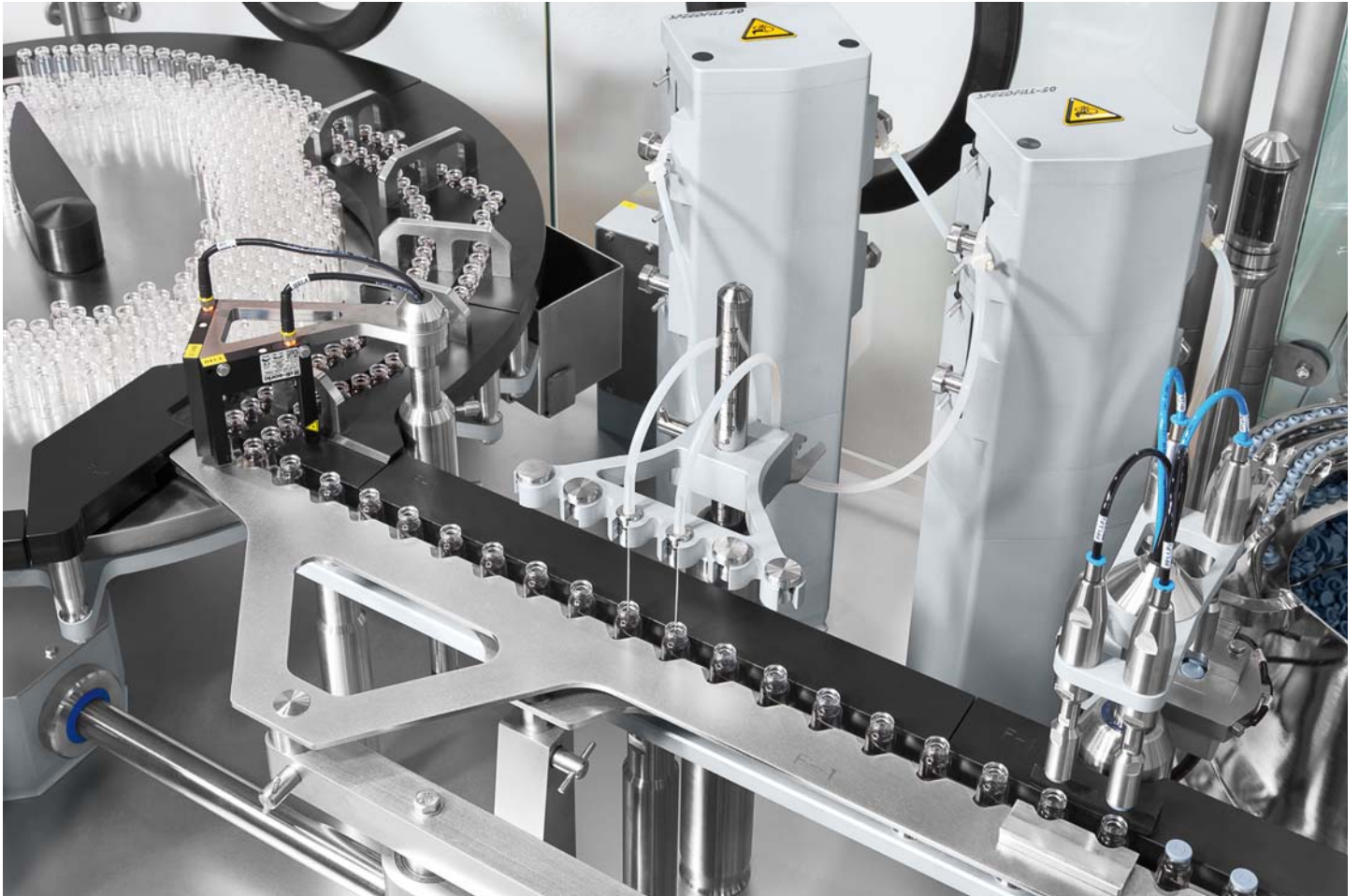
Filling from 0.1 ÷ 250 ml / Filling system 100% weight control / Output up to 7,200 uph / Conforms with cGMP - US FDA



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Compact machine for automatic infeed, filling, and closing of injection vials.



Dosing through valveless rotary piston pumps, made of stainless steel or ceramic.

//// The equipment we present is a compact filling and closing machine for automatic processing of cylindrical vials in glass, plastic, or metal, for liquid, semisolid, and powder products, in sterile areas or clean room.

Suitable for RTU vials (ready-to-use) as well as for vials supplied in bulk.

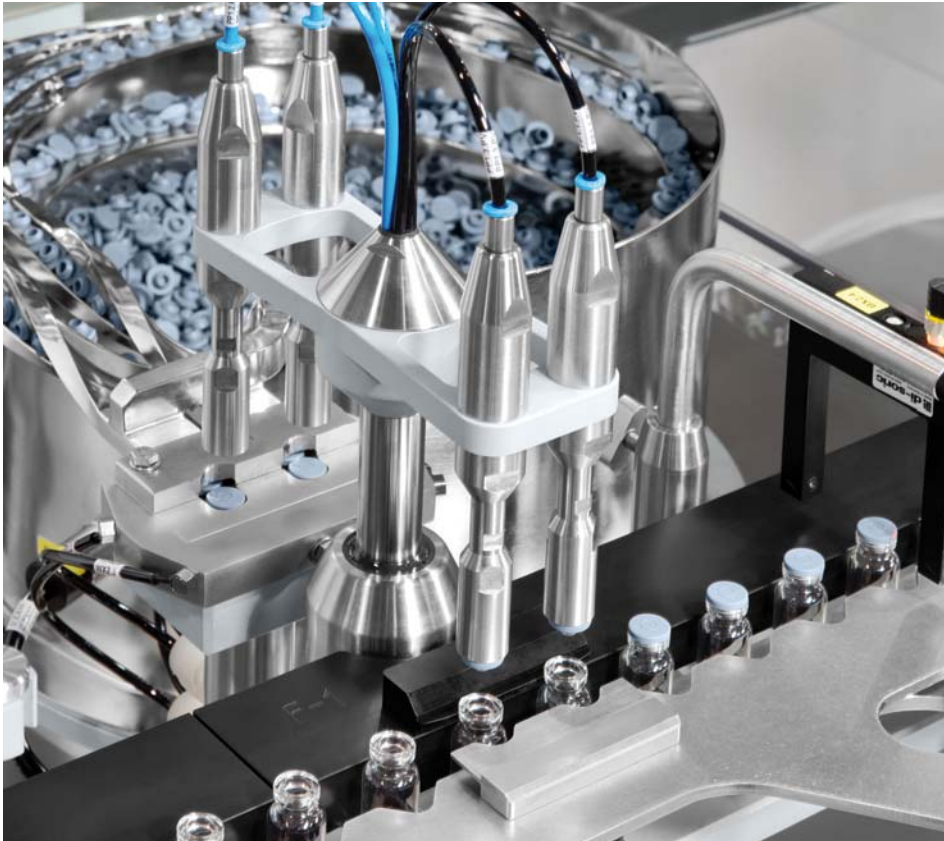
The design has been made in compliance with the regulations of cGMP and US FDA, and in special accordance with the pharmaceutical, biotech, cosmetic, chemical and similar industries.

Output up to 7,200 uph.

The filling station can be equipped with valveless rotary piston pumps, made of stainless steel or ceramic, or with SpeedFill[®] peristaltic pumps for liquid products, and with vacuum-pressure fill guns for powders.

When using CIP / SIP construction elements, it is not necessary to remove the product contact parts for their cleaning or sterilization.

All dosing recipes can be saved and, therefore, can be later retrieved from the control panel. Production parameters, such as dosing volume or the kinematics of the filling system, are saved in the PLC. New recipes can be quickly and easily created.



The pick & place station handles rubbers stoppers by vacuum.



The closing station is equipped with a tangential rolling head, characterized by a minimum generation of particles during the closing process.



Dosing control of 100% of processed vials is done by means of electronic weighing scales.

Dosing volumes from 0.1 to 250 ml for liquids, and from 2 to 1,500 mg for powders.

The pick & place station places the rubber stoppers onto the vials fully or partially, depending on the type of the stopper (injection or lyophilization). The stoppers are handled by vacuum.



Optional equipment:

- Washing unit and sterilization tunnel for vials supplied in bulk.
- Dosing control of 100% of processed vials through electronic weighing scales.
- Gas flushing before, during or after the filling process.
- Dosing system for CIP / SIP conditions.
- Vacuum-assisted insertion of stoppers to reduce the presence of oxygen in headspace.
- Automatic rejection of defective vials.
- Process data acquisition software in accordance with FDA 21CFR Part 11.
- Particle monitoring and counting.
- Vial output onto a double tray.
- Laminar flow unit / RABs / Isolator unit.
- IQ / OQ validation package.
- Printing / Codification.



Aluminum cap positioning, closing station and rejection of vials with process defects.



Allen Bradley or Siemens PLC.

The closing station is equipped with a servo-driven tangential rolling head, characterized by a minimum generation of particles during the closing process.

Feeding of closures is automatically done through AISI-316L vibrating feeders with electromechanical toolless fixation for easy change of format.

For sterile applications, Dara Pharma provide tailored solutions, such as LAF (Laminar Flow) and RABs (Restricted Access Barrier Systems). The generated vertical flow of sterile air ensures a permanent and reliable expulsion of particles and microorganisms from the working area.

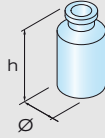
When operating inside an isolator, the sterile area is reduced to the working area of the filling and closing equipment. This allows working in a clean room class D, complying with the regulations of the pharmaceutical industry.

SX-310-PP

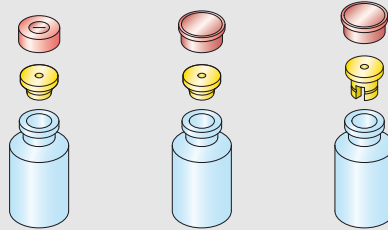
SX-310-PP/S

SX-310-PP/D

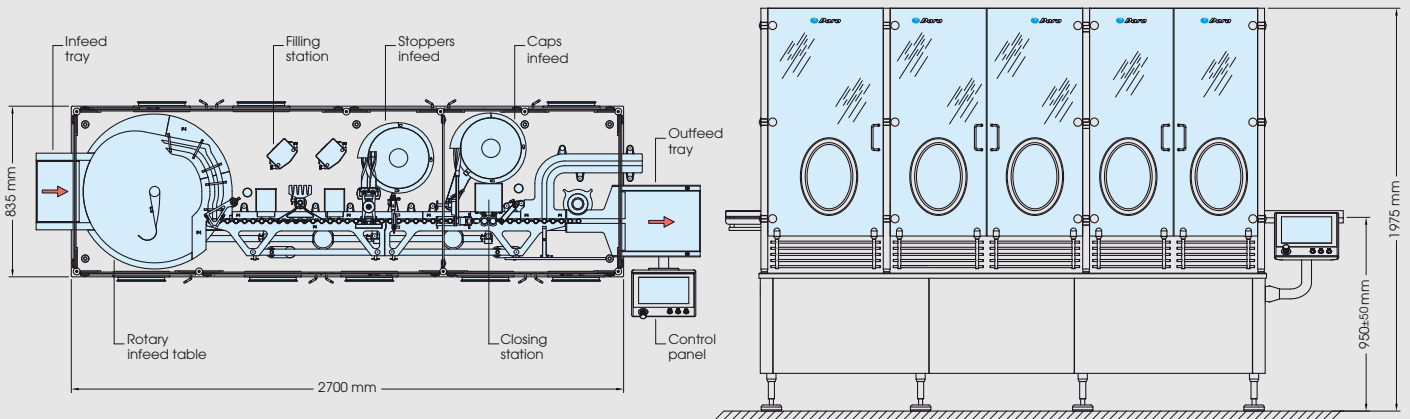
Max. output / uph:	3,600	7,200
Container dimensions:	Ø 65 mm max. h 210 mm max.	Ø 36 mm max. h 75 mm max.
Type of closures:	Rubber stopper + aluminum cap Ø 13/20/30/32 mm	
Dosing range / accuracy:	0.1 ÷ 250 ml / ±0.5% (liquid) / 2 ÷ 1,500 mg / ±0.5 ÷ 2% (powder)	
Electrical supply:	230/400 VAC – 50/60 Hz – 8 kW max.	
Max. weight:	1,380 kg	1,520 kg
Materials:	AISI-304 stainless steel, anodised aluminum, POM and contact parts with product in AISI-316L stainless steel	



Format range:



Dimensions: (*)



(*) SX-310-PP/D version. Other configurations of the machine are possible.

Subject to technical modifications.

Please note that the illustrations may vary from the standard version in some details.

Your official representative: