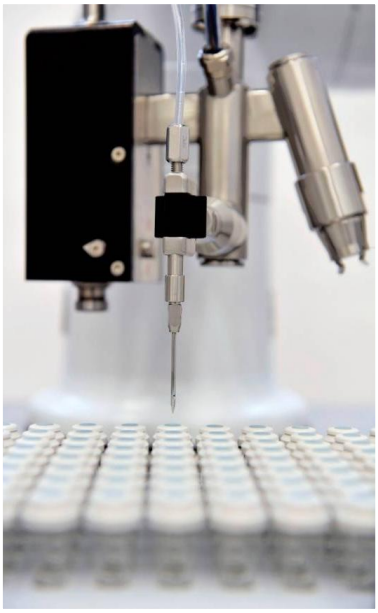
Crystal® L1 Robot Line
Laboratory Equipment for Closed Vials

Filling process

The Laboratory ***Crystal® L1*** Robot Line is designed to meet small scale pharmaceutical filling with a capacity going up to 600 vials/hour. Typical batch size ranges from a few hundred up to 5,000 vials per shift.

Fully compliant with cGMP requirements, the Laboratory ***Crystal® L1*** Robot Line is able to process all ready-to-fill ***Crystal®*** Closed Vials (from 1 to 50 ml) with minimum format change. As an option, glass vials can also be filled and stoppered.

The full process is made of the following steps:



1. ***Filling***
   - Ready-to-fill Closed Vials are organized in racks manually positioned and locked.
   - Filling performed by the robot, by means of a specially designed needle that pierces the stopper and dispenses the liquid inside the vial.
2. ***Laser resealing***
   - The robot re-places the needle on its support, and activates its laser tool.
   - The puncture trace is re-sealed by a laser shot on the stopper surface.
3. ***Capping***
   - Using its third tool, the robot performs capping inside the barrier, by simple snap-fit of a plastic cap.

Crystal® L1 Robot Line in a CVFS[1]

Crystal® L1 in a SKAN PSI-M isolator

[1] "CVFS - Closed Vial Filling System" is defined as "*An aseptic filling system providing an environment achieving uncompromised Class ISO 5 protection that surrounds containers which are delivered closed and sterile inside, are filled through their stoppers and then immediately re-sealed to preclude the possibility of microbial ingress*".

Key facts

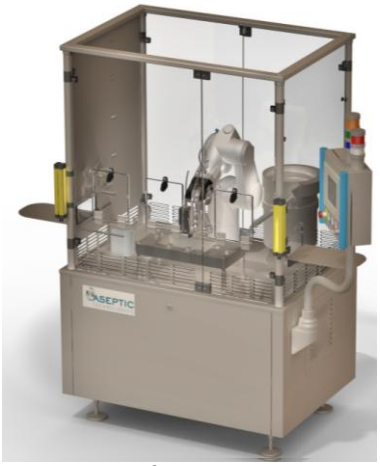
Laboratory ***Crystal*® *L1*** Robot Line	
Applications	Aseptic filling of liquid and freeze-dried parenterals. All types of products (including cytotoxics and biohazard).
Output (1ml vials)	Up to 600 vials/hour.
Filling volume	0.1 ml to 50 ml + overfill.
Filling accuracy	Typically 1%, depends on filling pump selected.
Dimensions (L x W x H)	mm: 1190 x 760 x 930 (clean room arrangement). in: 47 x 30 x 37
Utilities	Electricity only. No water, no compressed air.
Materials	AISI 316L for product contact parts.

Versions

Upon your project specifications, the Laboratory ***Crystal*® *L1*** Robot Line can be provided in various versions:

Containment

- As a sub-system, to be installed in a third party barrier;
- Safety barrier for installation in a clean room;
- CVFS[1] for installation in Grade C;
- Isolator - allowing washing and decontamination – for highly potent and biohazard products.



Crystal*® *L1 Robot Line
for clean room

Material entry/exit systems

- Mousehole;
- RTP (Rapid Transfer Port);
- H_2O_2 decontamination airlock.

Vial formats

- Closed Vials only (1 to 50 ml);
- Closed Vials and classical open vials (glass or polymer).

More information available on www.aseptictech.com

Aseptic Technologies S.A. reserves the right to make any changes to the described equipment and characteristics without notice.

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