

# **Filling process**

The Laboratory *Crystal*<sup>®</sup> *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*<sup>®</sup> *L1* Robot Line is able to process all ready-to-fill **AT-Closed Vials**<sup>®</sup> (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 AT-Closed Vials<sup>®</sup> 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 CVFS1



Crystal® L1 in a SKAN PSI-M isolator





<sup>&</sup>lt;sup>1</sup> "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 resealed to preclude the possibility of microbial ingress".

# **Key facts**

Laboratory <i>Crystal</i> ® <i>L1</i> 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: $1190 \times 760 \times 930$ (clean room arrangement). in: $47 \times 30 \times 37$
Utilities	Electricity only. No water, no compressed air.
Materials	AISI 316L for product contact parts.

#### **Versions**

Upon your project specifications, the Laboratory *Crystal*<sup>®</sup> *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<sup>1</sup> for installation in Grade C;
- Isolator allowing washing and decontamination for highly potent and biohazard products.

## Material entry/exit systems

- Mousehole;
- RTP (Rapid Transfer Port);
- H<sub>2</sub>O<sub>2</sub> decontamination airlock.

#### Vial formats

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



Crystal® L1 Robot Line for clean room



#### 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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