

## Crystal<sup>®</sup> PX Filling Lines

The Crystal<sup>®</sup> PX family is designed to meet large scale pharmaceutical filling with capacities ranging from 100 vials/min (4 filling nozzles) up to 180 vials/min (8 filling nozzles).

Typical batch size may reach 80,000 vials on a single shift basis.



### Process

#### Filling

- Ready-to-fill AT-Closed Vials<sup>®</sup> organized in trays are automatically loaded and transported to the conveyor.
- Filling is performed by means of specially designed needles that pierce the stoppers and dispense the liquid inside the vials.

#### Laser re-sealing

- The filled vials are then automatically transported to the laser sealing zone, where laser heads re-seal the puncture trace on the stoppers surface with 1 second shot.

#### Capping

- The capping is performed inside the barrier, by simple snap-fit of a plastic cap.

### Compliance

Fully compliant with cGMP requirements and CFR 21 Part 11, the Crystal<sup>®</sup> PX filling lines are able to easily process all sizes of ready-to-fill AT-Closed Vials<sup>®</sup>, from 1ml up to 50 ml, thanks to minimized quick and tool-less format change.

# Crystal<sup>®</sup> PX Filling Lines: Specification

Applications	Aseptic filling of liquid parenterals, including cell and gene therapy products
Output (2ml vials)	Up to 180 vials/minute and 10.800 vials/hour.
Filling volume	0.1 ml to 50 ml.
Filling accuracy	Typically, 1% (over 1 ml, for water-like viscosity product).
IPC (In Process Control)	100% filling check by weighing (up to 150 vial/min). 100% capping check.
PAT (Process Analytical Technology)	100% laser re-sealing effectiveness.
Typical footprint	m <sup>2</sup> : 12 - 16 ft <sup>2</sup> : 130 - 172
Utilities	Electricity only. No water, no compressed air.
Product Path	All single-use.
Materials	AISI 316L for product contact parts. Compatible with classical sanitizing agents, H <sub>2</sub> O <sub>2</sub> decontamination.

## Versions

To meet your project specifications, the *Crystal*<sup>®</sup> PX filling lines can be provided in various containments:

- Isolator;
- Closed RABS;
- Safety barrier for installation in a clean room;
- Combination of Isolator and closed RABS containment.

## Validation package

The *Crystal*<sup>®</sup> PX filling lines are delivered with a full Validation Master Plan of the AT-Closed Vial<sup>®</sup>. The table of content is available on our website in the chapter Compliance > Validation > AT-Closed Vial<sup>®</sup> Technology.

