



Crystal[®] PX Filling Lines **Production Equipment for AT-Closed Vials[®]**

Filling process

The **Crystal[®] PX** family is designed to meet large scale pharmaceutical filling with capacities ranging from 100 vials/min (4 filling nozzles) up to 180 vials/min¹ (8 filling nozzles). Typical batch size may reach 80,000 vials on a single shift basis.

Fully compliant with cGMP requirements, the **Crystal[®] PX** filling lines are able to easily process all sizes of ready-to-fill **AT-Closed Vials[®]**, from 1ml up to 50 ml, thanks to minimized quick and tool-less format change.

In Process Control (IPC) and Process Analytical Technology (PAT) are part of the design, ensuring proper and effective filling, closing and capping. Batch reports and audit trails are automatically generated.

As a multi-purpose platform, the **Crystal[®] PX** is suitable for filling freeze dried products. Moreover, thanks to its original design, the **Crystal[®] PX** family also fits the highest requirements of aseptic-toxic filling.

After vial loading by a robotic unpacking system the full process is made of the following steps:

1. **Filling**
Filling performed by specially designed needles that pierce the stoppers and dispense the liquid inside the vials.
2. **Laser re-sealing**
The puncture trace is re-sealed by a laser shot on the stopper surface.
3. **Capping:**
Simple snap-fit of a plastic cap, inside the barrier.



Products filled on **Crystal[®] PX** filling lines:

- Liquid parenterals;
- Lyophilized parenterals;
- Powder parenterals (under development);
- Aseptic, Aseptic-toxic and Bio-hazard.



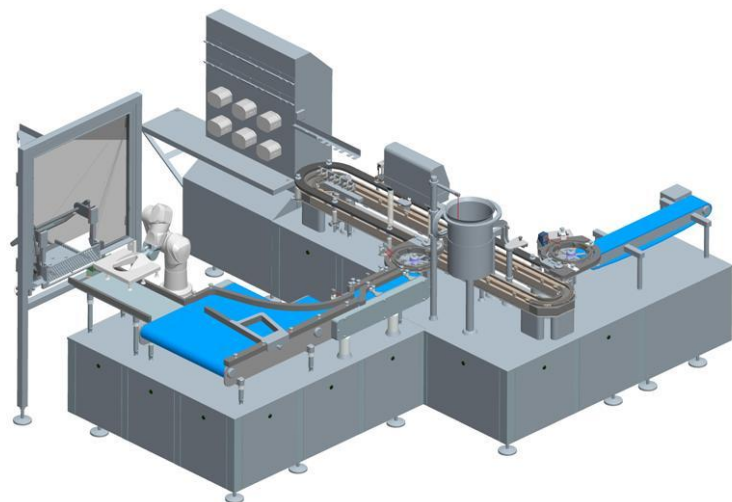
¹ 1ml and 2ml vials

Key facts

Production Crystal[®] PX Filling Lines	
Applications	Aseptic filling of liquid and freeze-dried parenterals. All types of products (including cytotoxics and biohazard).
Output (2 ml vials)	Up to 180 vials/minute (10.800 vials/hour).
Filling volume	0.1 ml to 50 ml + overflow.
Filling accuracy (peristaltic pump)	Typically 1%, depends on filling pump selected.
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 (liquid filling)	m ² : 12 - 16 ft ² : 130 - 172
Utilities	Electricity only. No water, no compressed air.
Materials	AISI 316L inside the barrier and all product contact parts.

Containment systems

- Safety barrier for installation in a clean room;
- CVFS² with glove access into the filling area, for installation in ISO8 surrounding;
- Isolator or closed RABS containment, allowing washing and decontamination, for highly potent and biohazard products;
- Combination of Isolator and CVFS containment.



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.

² "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".