

Aseptic TECHNOLOGIES

SAFER & EASIER aseptic filling



Crystal[®] Closed Vial Technology

■ ■ ■ *Production Crystal[®] Cx Filling Line*



Enables ***Safer & Easier*** aseptic filling operations.

Designed to fill medium size batches in ready-to-fill polymer vials.

Liquid and lyophilized products.

With a nominal capacity up to **75** Closed Vials/min.

Philosophy and process

The **Crystal[®]** technology is based on the concept that the polymer vials are provided clean (molded in ISO5 clean room), already closed (stopper in place and secured) and sterile (gamma-irradiated), i.e. **ready-to-fill**.

The Production **Crystal[®] Cx** Filling Line has been developed to meet medium scale pharmaceutical filling with a filling capacity going up to 4,500 vials/hour. Typical batch size reaches 25,000 to 30,000 vials on a single shift basis.

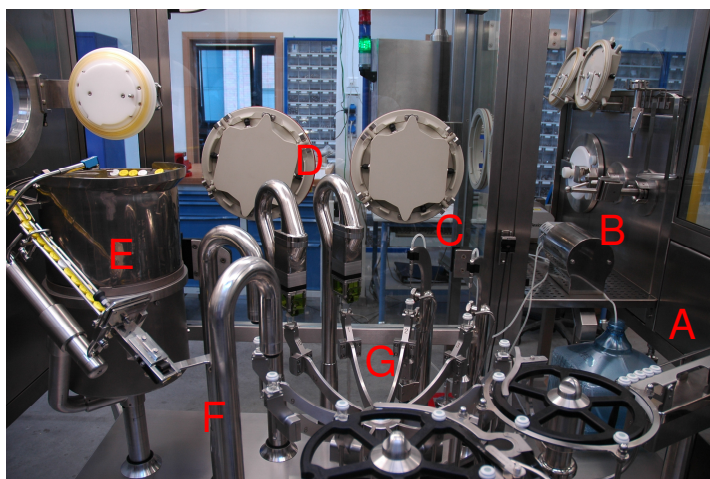
Fully compliant with cGMP requirements, the Production **Crystal[®] Cx** Filling Line is able to process all ready-to-fill **Crystal[®]** Closed Vials (from 1 to 50 ml). The line can be single format or multiformat, according to client requirements.

The complete filling process is made of the following steps:

1. **Vial loading:**
the Closed Vials are introduced into the barrier thanks to a semi-automatic unpacking system which prevents contamination.
2. **Filling:**
the Closed Vials are filled by a specially designed needle that pierces the stopper and dispenses the liquid inside.
3. **Reclosing:**
the puncture trace is re-sealed by a laser shot on the stopper surface.
4. **Capping:**
the Closed Vials are capped inside the barrier, by simple snap-fit of a plastic cap.

Filling, laser re-sealing and capping are performed on a rotary main wheel.

- A. vial supply
- B. Pumps
- C. Filling stations
- D. Laser resealing stations
- E. Cap vibrating bowl
- F. Capping stations
- G: rotary main wheel



Quick facts

Production Crystal[®] Cx Filling Line	
Applications	Aseptic filling of liquid and freeze-dried parenterals.
Output (2ml vials)	Up to 75 vials/min (up to 3 filling heads).
Filling volume	0.1 ml to 50 ml + overflow.
Filling accuracy	+/- 1% (+/-10 µl for small volumes below 1 ml).
Dimensions (L x W x H, in mm)	4500 x 2000 x 2850 (without e-beam option, with CVFS).
Utilities	Electricity, no water, no compressed air.
Materials	AISI 316L inside the barrier and all product contact parts.

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

Versions

Upon your project specifications, the Production **Crystal[®] Cx** Filling Line can be provided in various versions:

- **Containment**
 - Equipped with a safety barrier, to prevent operator presence in the filling area during operations;
 - In a CVFS¹ with glove access into the filling area.

- **Material entry systems**
 - Vials through laminar airflow opening of boxes;
 - Vials through laminar airflow opening of boxes followed by e-beam surface sterilization;
 - Caps, liquid and other materials through RTP (Rapid Transfer Port);
 - Vials and caps through a VHP (Vaporized Hydrogen Peroxide) airlock.

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”.

Overview of *Crystal*[®] line range

	<i>Crystal</i> [®] M1 Filling Station	<i>Crystal</i> [®] L1 Robot Line	<i>Crystal</i> [®] Cx Filling Line	<i>Crystal</i> [®] PX Filling Line	<i>Crystal</i> [®] Pxx Filling Line
Max. output (1ml)	180 v/h	600 v/h.	4.500 v/h	9.000 v/h	36.000 v/h
Applications	Aseptic filling	Aseptic filling, Aseptic-toxic, Biohazard	Aseptic filling	Aseptic filling, Aseptic-toxic, Biohazard	Aseptic filling
Freeze drying	YES	YES	YES	YES	-
Filling volume	0.1 ml to 50 ml + overfill.	0.1 ml to 50 ml + overfill.	0.1 ml to 50 ml + overfill.	0.1 ml to 50 ml + overfill.	0.1 ml to 50 ml + overfill.
Containment	ISO-5 in ISO-8 or isolator	ISO-5 in ISO-8 or isolator	ISO-5 in ISO-8	ISO-5 in ISO-8 or isolator	ISO-5 in ISO-8
Typical footprint	1 m ²	1,5 m ²	9 m ²	16 m ²	44 m ²
Utilities	Electricity, no water, no compres. air	Electricity, no water, no compres. air	Electricity, no water, no compres. air	Electricity, no water, no compres. air	Electricity, compres. air, no water.

Overview of *Crystal*[®] vial range



<i>CVFL</i> [®] Vials	1 ml	2 ml	6 ml	10 ml	20 ml	50 ml
Height (in mm., with /without cap)	33.1/34.1	33.1/34.1	39.3/40.3	49.8/50.8	61.2/62.2	84.9/85.9
Stopper upper diameter (in mm.)	8	9	9	9	9	9
External vial diameter (in mm.)	18.3	22.3	25	25	30	36
Maximum volume filled (in ml.)	1.35	2.25	7.6	11.7	21.8	52.1
Freeze-drying	Yes, every Closed Vial format can be lyophilized*					
Oxygen-depleted	Yes, every Closed Vial format can be delivered with very low O ₂ content*					
Light-sensitive	Yes, every Closed Vial format is available with amber body					
Colored caps	Caps and rings are available in different colors for differentiation					

* Protective packaging against permeability required as for all semi-permeable containers

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