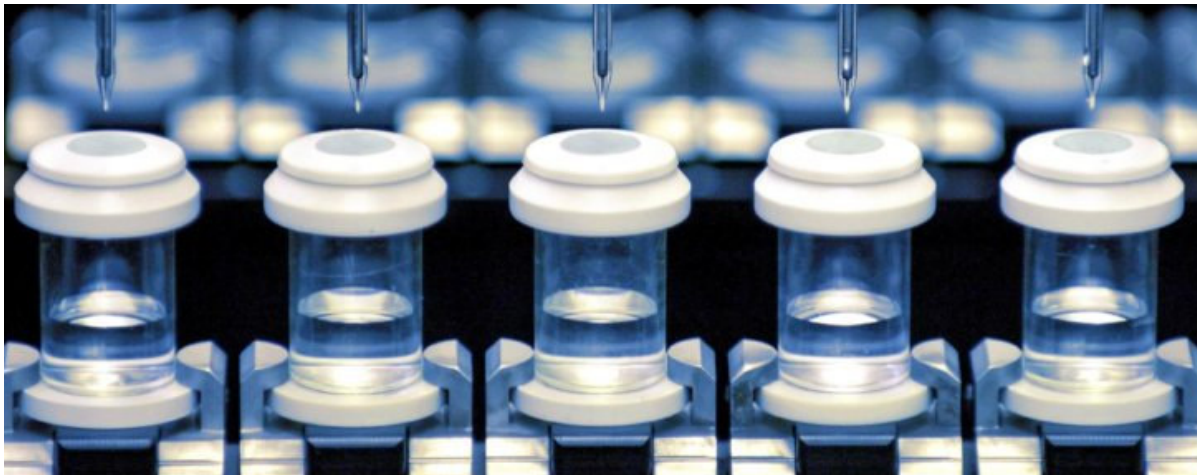


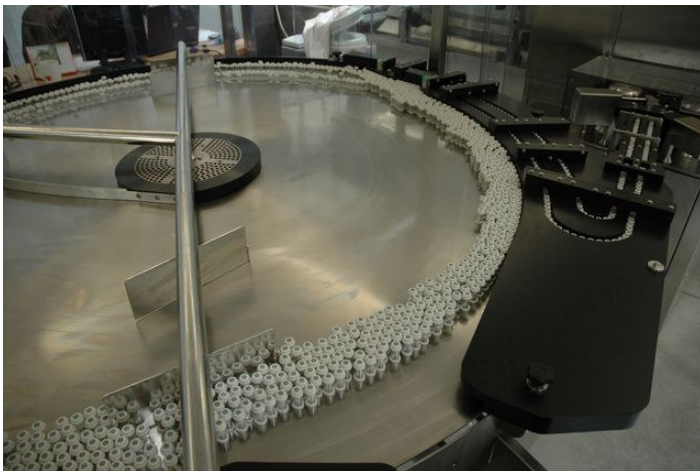


SAFER & EASIER aseptic filling



Crystal[®] Closed Vial Technology

■ ■ ■ **Production Crystal[®] Pxx Filling line**



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

Designed to fill large size batches of liquid products in ready-to-fill polymer vials.

With a nominal capacity up to **600** 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 **Crystal[®] Pxx** family has been developed to meet very large scale pharmaceutical filling with a capacity up to 600 vials/min. Batch size can reach 200,000 vials on a single shift basis.

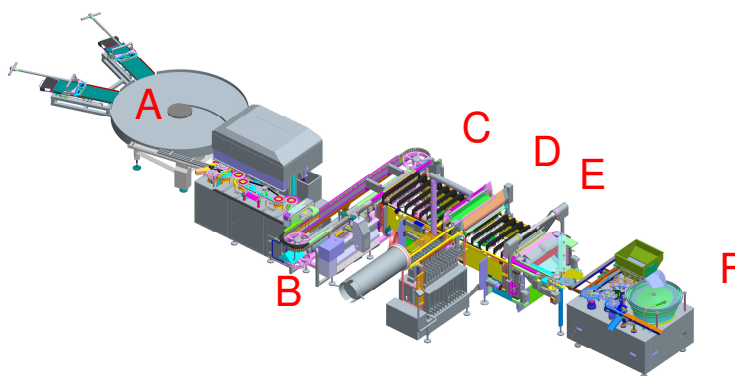
Fully compliant with cGMP requirements, the **Crystal[®] Pxx** is able to process all ready-to-fill **Crystal[®]** Closed Vials (from 1 to 50 ml). These lines are recommended to be monoformat.

The complete 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 the Closed Vials from contamination.
2. *First weighing* :
samples of the Closed Vials are weighed empty before filling.
3. *Filling* :
the Closed Vials are filled by a specially designed needle that pierces the stopper and dispenses the liquid inside.
4. *Reclosing* :
the puncture trace is re-sealed by a laser shot on the stopper surface.
5. *Second weighing* :
the same samples of the Closed Vials are weighed when filled and laser re-sealed.
6. *Capping* :
the Closed Vials are capped inside the barrier, by simple snap-fit of a plastic cap.

Filling and laser re-sealing are performed under multiple head tools on a parallel conveying system.

- A. Vial loading
- B. Weighing 1
- C. Filling stations
- D. Laser resealing stations
- E. Weighing 2
- F. Capping station



Quick facts

Production Crystal[®] Pxx Filling Line	
Applications	Aseptic filling of liquid and freeze-dried parenterals.
Output (2ml vials)	Up to 600 vials/minute (up to 24 filling heads).
Filling volume	0.1 ml to 50 ml + overfill.
Filling accuracy	+/- 1% (+/-10 µl for small volumes below 1 ml).
Dimensions (L x W x H, in mm)	11,000 x 4000 x 3200 (without e-beam option, with CVFS).
Utilities	Electricity and compressed air only, no water.
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[®] Pxx** 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);

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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