

Crystal[®] Vials



The first Ready-to-fill vial provided clean, sterile and already closed.

Enables Safer and Easier aseptic filling operations.

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

The product contact materials of the vial are: COC (Cyclo-Olefin Co-polymer) for the body and a proprietary TPE (Thermo Plastic Elastomer) for the stopper, both meeting Authority requirements for pharmaceutical primary container.

Technical specifications:



CVFL [®] 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 product differentiation					

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

** M1 standard solution for freeze drying is not adapted for 1 ml vials

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

Crystal[®] Filling Lines



The overall filling process of the ready-to-fill **Crystal[®]** vials is made of very few steps:

1. *Vial loading*: the sterile Closed Vials are introduced into the barrier in a way that prevents contamination.
2. *Filling*: the Closed Vials are filled by a specially designed needle that pierces the stopper and dispenses the liquid inside the vial.
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 snap-fitting of a plastic cap.

Technical specifications:

	Crystal[®] M1 Filling Station	Crystal[®] L1 Robot Line	Crystal[®] CX Filling Line	Crystal[®] PX Filling Line	Crystal[®] Pxx Filling Line
Max. output (1ml)	180 v/h	600 v/h.	100 v/min	200 v/min	600 v/min
Applications	Aseptic filling, Aseptic-toxic, Biohazard	Aseptic filling, Aseptic-toxic, Biohazard	Aseptic filling, Aseptic-toxic, Biohazard	Aseptic filling, Aseptic-toxic, Biohazard	Aseptic filling
Freeze dried	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	CVFS* or isolator	CVFS* or isolator	CVFS* or isolator	CVFS* or isolator	CVFS*
Typical footprint	1 m ²	1,5 m ²	10 m ²	12-16 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.

* CVFS is a secured barrier system guaranteeing an uncompromised ISO 5 environment in ISO8 surrounding

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