

AT-Closed Vial® Technology

The AT-Closed Vial® Technology for aseptic fill & finish is based on the concept of the ready-to-fill Closed Vial, whereby polymer vials are provided:

- clean (molded and closed in ISO 5 clean room);
- already closed (stopper in place and secured);
- sterilized (gamma-irradiated).



Materials

Materials selected for the product contact parts meet USP and EP requirements for pharmaceutical primary container:

- COC (Cyclic Olefin Copolymer) for vial body;
- TPE (Thermo Plastic Elastomer) for stopper.

Application

- Biologicals;
- Personalized therapies;
- Cryopreserved products.

Advantages

- Minimized contamination risks;
- Unbreakable and user-friendly;
- 100% Container Closure Integrity.

AT-Closed Vial®	1 ml	2 ml	6 ml	10 ml	20 ml	50 ml
Height (in mm, +1mm if capped)	33.10	33.10	39.30	49.80	61.20	84.90
External vial diameter (in mm)	18.30	22.30	25.00	25.00	30.00	36.00
Maximum volume filled (in ml)	1.35	2.25	7.60	11.70	21.80	52.10
Cryogenic storage	can be cryopreserved while keeping Container Closure Integrity					
Colored caps	are available in different colors for product differentiation					

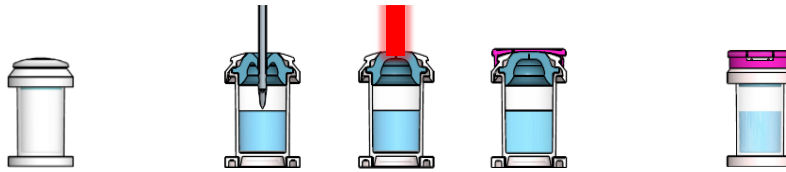
Crystal® Filling Lines



Process

The overall filling process of the ready-to-fill AT-Closed Vials® is made of very few steps:

- Filling: the stopper is pierced by a specially designed needle dispensing the product inside the container;
- Closing: the puncture trace is re-sealed by a laser shot on the stopper;
- Capping: simple snap-fit of plastic cap, inside the barrier.



Ready-to-fill AT-Closed Vial®

3 process steps: filling, laser re-sealing, capping

Filled AT-Closed Vial®

Scaling-up

Straightforward scaling-up: identical processing, tools and disposables are used at all capacity levels.

Validation

To support the approval of your drug products, complete Validation Master Plan (VMP) is provided with every Crystal® Filling Line.

	Manual Crystal® M1 Filling Station, Crystal® Pure M1	Robotized Crystal® L1 Robot Line,	High speed Crystal® PX Filling Line
Max output	180 u/h	600 u/h	6.000-10.800 u/h
Containment	M1: BSC or Isolator (not in scope), Pure M1: isolated equipment	RABS or Isolator	RABS or Isolator
Typical footprint	1,5 m ² or 16 ft ² Pure M1: 3,4 m ² or 37 ft ²	1,5 m ² or 16 ft ²	12-18 m ² or 130-195 ft ²
Closing IPC	100%	100%	100%