



Isolated Fill & Finish for small cGMP batches

The spectra M1 is an isolated fill & finish unit, dedicated to small cGMP batches.



SKAN Group

As a member of SKAN, we combined our 20-year expertise and SKAN's state-of-the-art isolator technology to bring you this integrated isolated Filling System.

Combining state-of-the-art technologies

SKAN's most advanced technology, the spectra isolator, is CFR 21 Part 11 compliant and includes features such as the integrated SKAN nanox catalyst and skanfog to help optimize processes and guarantee fast and safe cycle times.

With the AT-Closed Vial® technology and the M1 Filling Station, the spectra M1 is designed to improve your small-batch production efficiency with the highest sterility conditions.

Think one step ahead

SKAN isolators are the perfect solution for your aseptic processes, combining increased levels of contamination control and quick ROI, thanks to SKAN's most advanced technologies, and reduced operational and facilities costs.

Perfecting your small batch processing

The spectra M1 is used for aseptic filling of injectable drugs. Perfect for small production, it presents the following characteristics:

- Up to 150 AT-Closed Vial® per hour
- 0,1 ml to 50 ml filling
- High filling accuracy
- Single-use materials for product contact parts
- Tool-less format change
- CFR 21 PART 11 compliant (spectra)
- Suitable for Grade C/D production environment
- Integrated automated skanfog decontamination system
- Integrated SKAN nanox catalyst for H₂O₂ particules breakdown
- AT-Port™ for liquid transfer through the isolator wall



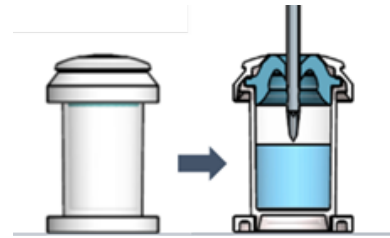
Enabling

Quick, safe and easy fill & finish

The spectra M1 is an easy-to-use manual filling equipment integrated within an isolator. In just three steps, you can fill the AT-Closed Vial®.

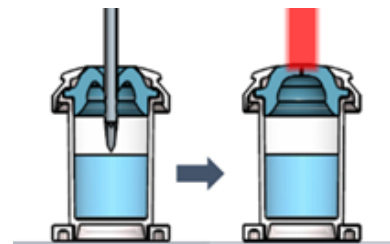
1. Filling

- The ready-to-fill AT-Closed Vial® is manually placed on its supporting base.
- Piercing of the stopper is accurately achieved by simple action on the lever. Filling is performed using a peristaltic pump.



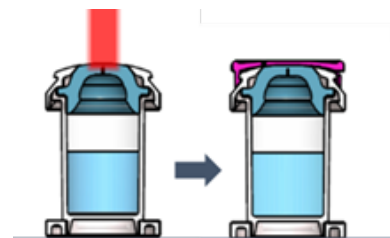
2. Laser re-sealing

- The vial is manually transferred into the laser safety cabinet. The laser control unit is activated via the embedded remote.
- The puncture trace is re-sealed by a 1 second laser shot on the stopper surface.



3. Capping

- Performed by simple snap-fit of a plastic cap.
- Facilitated by the use of the AT-EasyCap™.



Presenting the best of both worlds

The spectra M1 is composed of the best Aseptic Technologies Filling Station for small batches and SKAN's most advanced isolator technology. It ensures safe and aseptic fill & finish operations.

With its integrated elements and optional features, the spectra helps speed up your process operations and therefore overall efficiency. Combined with the M1 Filling Station and the AT-Closed Vial®, the spectra M1 ensures the safety and sterility of your operations.



Our quality engagements

Validation Master Plan

A full Validation Master Plan with all tests related to the AT-Closed Vial® technology is supplied.

Aseptic Technologies certifications

- ISO 9001:2015: Quality management systems
- ISO 15378:2017: Primary packaging materials for medicinal products

Aseptic Technologies Rue Camille Hubert 7-9
5032 Gembloux, Belgium
+32 81 409 410, info@aseptictech.com

SKAN AG Kreuzstrasse 5
4123 Allschwil, Switzerland
+41 61 485 44 44, info@skan.ch

SKAN Stein AG Industriestrasse 3
4332 Stein, Switzerland
+41 62 885 03 00, info.stein@skan.ch

SKAN Deutschland GmbH Nickrischer Straße 2
02827 Görlitz/Hagenwerder, Germany
+49 358 223 789 0, de.info@de.skan.ch

SKAN US, Inc. 7409 ACC Blvd., Suite 200
Raleigh, NC 27617, USA
+1 919 354 6380, us.sales@us.skan.ch

SKAN Japan 5194-61 Katsuren-Haebaru Uruma-shi
Okinawa 沖縄県 904-2311, Japan 日本
+81 98 934 9922, jpskan@skan.ch