Crystal® PURE M1

Dedicated to a small batch, *Crystal*® Pure M1 is a first plug-and-play isolated aseptic filling unit. Combining AT-Closed Vial® technology and last generation isolator from SKAN, it was designed in tight cooperation with users, to offer ergonomic and detail-oriented process.

Process

Material introduction

- The material is introduced through the left rapid decontamination airlock to the main chamber.
- The Drug Substance is introduced directly to the main chamber via the aseptic liquid connector, AT-Port™ System, in order to keep the bulk product outside of the isolator and keep it homogenized and cooled, if needed.

Filling – Laser re-sealing – Capping

- In the main chamber, the ready-to-fill AT-Closed Vial® is first filled through piercing of the stopper with the special needle.
- The puncture trace is then re-sealed by a 1 second laser shot on the stopper surface.
- A snap-fit plastic cap is placed on the vial with a capping tool, protecting the sterility of the stopper.
- Overall batch status is demonstrated live on the integrated screen in the back of the isolator chamber.

Material exit

- The filled vials and other materials can be continuously brought outside of the isolator through the mouse house of the right exit LAF.

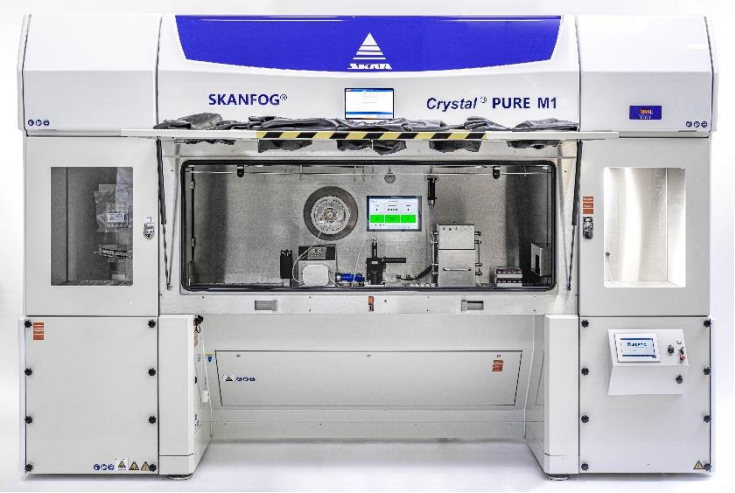
Crystal® PURE M1: Specification

Decontamination with SKANFOG®

Innovative decontamination process SKANFOG®, used in *Crystal*® Pure M1, is based on the micro-nebulization of hydrogen peroxide (H_2O_2).

This technology allows

- achieving of the Total Kill faster, by direct injection of the H_2O_2 in the chamber;
- achieve the aeration down to 0.5 ppm faster;
- short decontamination cycle: < 30 min.



Use of the catalytic converter, breaking the H_2O_2, allows a possibility of air exhaust directly in the room, decreasing installation requirements.

Applications	Aseptic filling of liquid parenterals, including - Autologous and allogeneic cell therapy, gene therapy; - Intermediate products for cell and gene therapy; - Immunotherapies; - Hospital pharmacy preparations; - Individualized or small batch production.
Dimensions	L 3300 x W 982 x H 2272 mm
Weight	ca. 1200 kg
Materials	Body housing: ABS polymer Working chamber: Stainless steel AISI 316L (EN 1.4404) surface roughness ≤ 0.8 µm. Filling equipment: Mostly stainless steel AISI 316L, PEEK.
Operation pressure	+60 Pa
H_2O_2 catalyst	Patented SKAN NANOX®
Bulk connection	Drug Substance is located outside of isolator and passed through an AT-Port™ System
Filling volume	0.1 ml to 50 ml
Filling accuracy	Typically, 1% (over 1 ml, for water-like viscosity product)
Product Path	All single-use
Control system	Embedded control system with 2 touch screen control panels, and 1 screen in the main chamber. Batch report generation.
Utilities	Two independent power inlets 220-240 V, 16 A Compressed air of 6 - 10 bar, 10 Nm3/h, ISO 8573-1: 2010 Class 1.3.1.