Crystal® PURE M1

The first isolated aseptic filling unit

- Dedicated to small batches
- Designed for novel therapies
- Combines novel isolator technology and AT-Closed Vial® filling

ASEPTIC TECHNOLOGIES

Crystal® PURE M1

The first plug-and-play isolated aseptic filling unit

Result of over 10 years of Aseptic Technologies' experience in setting-up the cGMP aseptic filling process for novel therapies and deep knowledge of user's requirements, *Crystal*® Pure M1 is a complete fill & finish solution, neatly combining the AT-Closed Vial® Technology and a new generation of isolator by SKAN.

Crystal® Pure M1 ensures full cGMP compliance, smooth validation and overall cost of goods reduction for small and extra-small batches.

Main features

Ergonomic

arrangement and integration of each element of the unit was performed in tight collaboration with our users with a goal to design an intuitive and ergonomic process

Plug-and-play

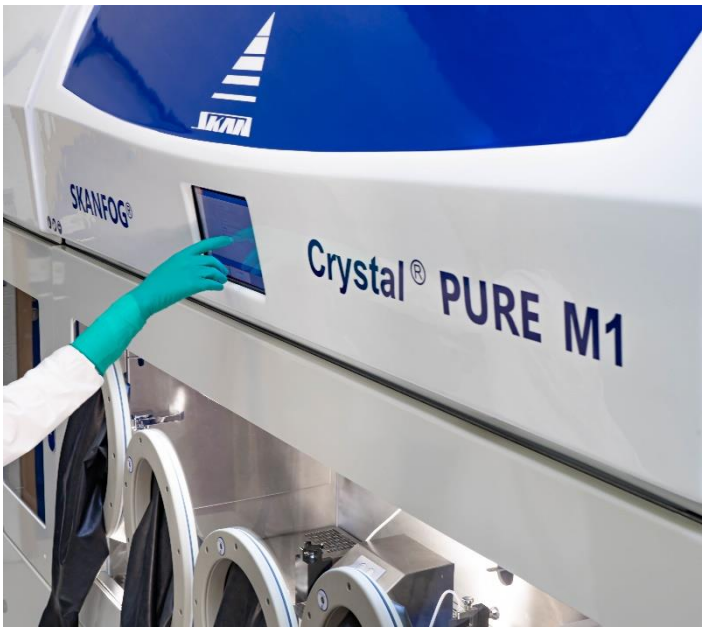
installation in Grade C (or Grade D, depending on the regulation), no HVAC connection is possible

Fast

automated decontamination cycles (<30 min) by H_2O_2 and continuous material transfer for continuous operation

Timesaving

pre-engineering of the work flow and validation package



Small batch operation

A manual filling station operating with AT-Closed Vial® is integrated in the main chamber of the *Crystal*® M1 Pure. Overall operation, as for every AT-Closed Vial® Technology filling line, consists of filling the vials through the stopper by piercing it with a special needle, restoring the closure integrity with a laser shot and capping with a snap-fit capsule. All the necessary elements are ergonomically embedded in the working area of isolator:

- a filling unit and its stainless-steel peristaltic pump with an integrated weighting cell, allowing effortless dose calibration;
- a laser sealing unit with an integrated power meter to allow laser calibration while starting the batch;
- a capping tool to snap-fit caps onto each vial.

The operator is continuously informed of the main process parameters thanks to a large screen mounted on the back wall of the working area. Control buttons inside the chamber allow to perform the main interactions with the system during production while keeping hands in the gloves.

A batch report is generated by the equipment at the end of the batch and can be downloaded in .pdf format.

Isolator design

The main chamber and left rapid decontamination airlock for material entry of *Crystal*® M1 Pure work under positive pressure up to 60 Pa and are decontaminated by direct injection of micro-nebulized H_2O_2 droplets (SKANFOG Cloud™ system).

The inlet air is taken from the room, and the exhaust air can be rejected directly to the room thanks to NANOX™ catalyser breaking the H_2O_2. Therefore, the installation can be stand-alone, with no connection to the outside of the room.

The material continuous exit is performed through the mouse-hole of the LAF located on the right of the main chamber.

Attention to detail

AT-Port™ System
The bulk product is kept outside the isolator, saving space. The aseptic connection ensures minimal dead volume.

No connection to the HVAC system needed
The exhaust air can be rejected directly to the room, thanks to the use of a SKAN NANOX® catalyst breaking the H_2O_2

Space saving design
The compact design allows the bringing-in through standard doorways and elevators.

Manual filling line
Operating with AT-Closed Vial®, remaining closed throughout the process, minimizing contamination risks and guaranteeing no product exposure to the residual H_2O_2.

Continuous material entry
Rapid decontamination airlock allows continuous material feeding to the main chamber to save space and to ensure a non-stop operation.

Smart product entry

The bulk product (Drug Substance) is passed through AT-Port™ System, an aseptic liquid alpha-beta connector. This allows to keep it outside of isolator, where it can be homogenized and cooled, if needed.

Batch status tracking and recording

The batch status is tracked and visualized by operator thanks to a LED screen in the back of the main chamber

Innovative decontamination technology

Fast, reproducible and validated decontamination cycle and material transfer with micro-nebulization of H_2O_2 (SKANFOG® Cloud™ technology)

Continuous product exit

Filled vials are moved out of the main chamber through a mouse-hole to the exit LAF, to be exited from the isolator for further processing, continuously.

Easy cleaning

The exterior materials are durable and resistant. The internal part and its equipment are made for efficient H_2O_2 decontamination and the cleaning is validated.

Validation package

- Standard decontamination cycle is provided for the maximum load. Biological Indicators (BI) will be used to determine the Total Kill-Time;
- Validated cleaning of all the chambers and the integrated equipment;
- Microbiological Qualification;
- Validation Master Plan for the AT-Closed Vial® Technology.

Innovative Decontamination

Micro-nebulization method

SKANFOG® decontamination process is a decontamination technology based on the micro-nebulization of hydrogen peroxide (H_2O_2). Nebulized H_2O_2 in moderate concentrations can be used without concern regarding toxicity, corrosion and persistence.

Total kill is achieved faster

By micro-nebulizing H_2O_2 directly in the chamber

The aeration (down to 0.5 ppm) is faster

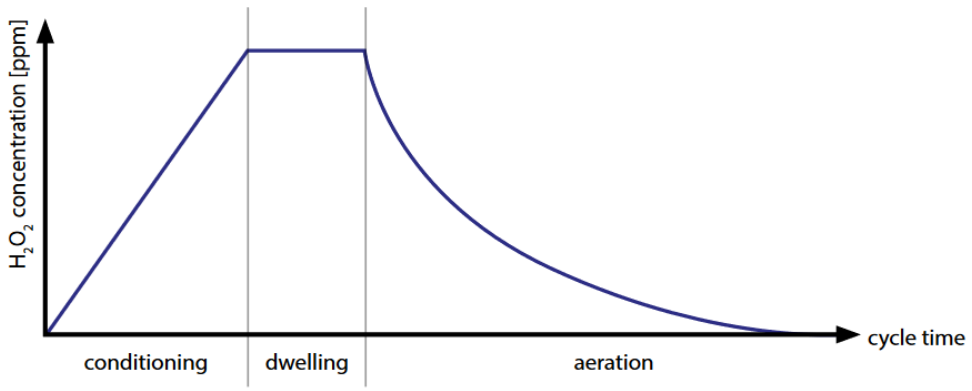
Unlike with Vaporized Hydrogen Peroxide (VHP), the filter is not saturated with H_2O_2

< 30 min

Total decontamination cycle duration with *Crystal*® Pure M1

Fast decontamination

The decontamination process is divided in three phases: In the conditioning phase, the required H_2O_2 amount is micro-nebulized into the containment. A well-defined dwelling time follows and comprehensively ensures that the desired decontamination efficacy is accomplished. In the aeration phase, the decontaminated containment is aerated by means of a catalytic loop.



Specification

Crystal® Pure M1

Applications	Aseptic filling of liquid parenterals, including - Autologous and allogeneic cell therapy; - Gene therapy; - Intermediate Products for Cell and Gene Therapy (viral vectors, plasmid DNA, working and master cell banks…); - Immunotherapies; - Compounding pharmacy; - Individualized or small batch production.
Dimensions	L 3300 x W 982 x H 2272 mm
Weight	ca. 650 kg
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.
H_2O_2 type	2,5 L, 35%
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
Air velocity down flow	0,45 m/s +/- 20%
Exhaust (double filtered)	SKAN FIPA HEPA H14 filtered (independent, no exhaust duct needed)
Filter type to airlock	Intake HEPA H14 plate filter/ Exhaust SKAN FIPA H14 filtered
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
Interfaced	USB
Noise level	Max. 60 db
Light	Min. 800 lx inside the chamber

Aseptic Technologies, member of SKAN Group, is engaged in long-term mutually beneficial partnerships with first class companies that provide us with their respective resources, expertise and products

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