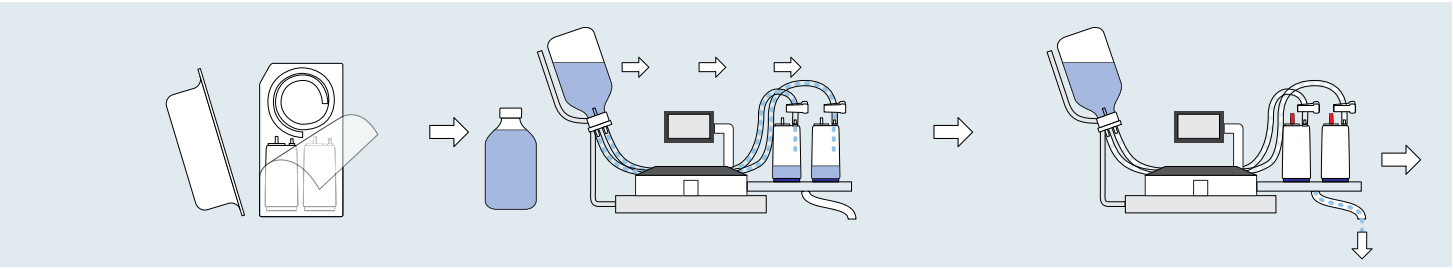
skan

Sterility testing

10 steps

10 steps to your success



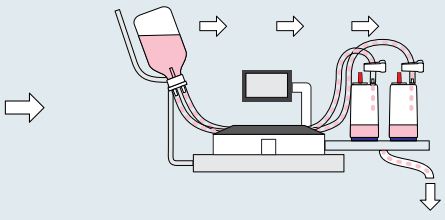
1st testing step: pre-wetting

1: Quality control

According to the current Good Manufacturing Practice (cGMP), aseptic and aseptic-toxic pharmaceutical products require validated process procedures and sterility testing. These tests should be carried out in a defined clean room environment, which corresponds to the current production environment. Sterility testing confirms a successful sterile aseptic processing procedure and releases the batches.

2: State of the art

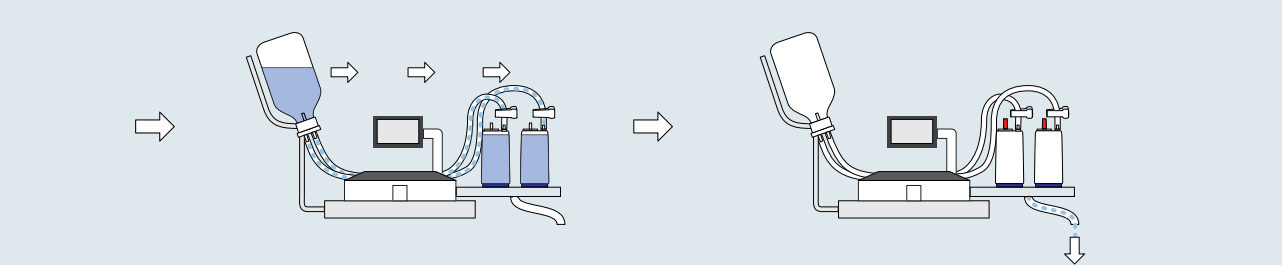
Isolators have been standard for sterility testing and aseptic production for over 20 years. Isolators for sterility testing offer the highest level of safety for the test procedures and the products. The isolators can be placed in any environment, from unclassified rooms to EM GMP class D (ISO 8) rooms. With an air velocity of 0.45m/s, the working chamber meets the required product protection with EU GMP Class A (ISO 5) according to EN ISO 14644-1.



2nd testing step: filtration

3: Connect with our experience

Choosing the right isolator for your specific requirements is no easy task. That is why the world-renowned sterility test isolators from SKAN are available in various configurations with a variety of options. Experts with many years of experience are ready to assist you in making the right decision. Together with you, they determine which configurations meet your requirements. This includes analysing which transfer systems are needed, whether the size of the chamber fits the number of tests to be performed and whether an airlock or other transfer solution is required.



3rd testing step: rinsing

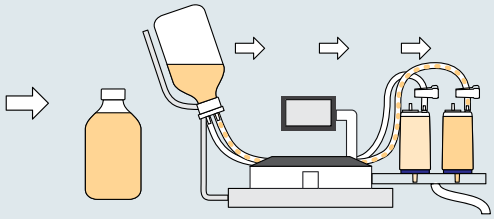
4th testing step: FTM culture media to detect both aerobic and anaerobic bacteria

4: The best technology for you

Manufacturing isolators has been our core competence for more than half a century. Thousands of satisfied customers worldwide trust in our highest quality standards and make us world market leader. SKAN's sterility test isolators combine the best technology for modern decontamination and increase the safety as well as the productivity of your processes. The integrated skanfog® H_2O_2 decontamination technology has already established itself as a standard on the market with its short decontamination time of less than one hour. Increased safety for operators is achieved by the SKAN nanox® catalyst, which neutralises hydrogen peroxide (H_2O_2) within seconds.
In addition, all SKAN sterility test isolators are equipped with modern control panels that record and analyse current information about the running process. This keeps you up-to-date at all times.

5: Choose the right unit for your process

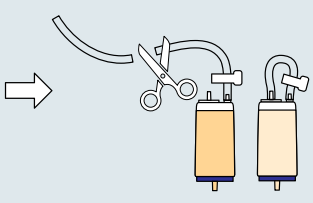
SKAN offers several units and options for a variety of processes and applications. Choose the unit that fits your quality control, research or development process and your required safety level. Various predefined assemblies and options enhance your individual application and provide maximum flexibility.



5th testing step: TSB culture media
to detect mould and yeast

6: Your application defines the configuration

The configuration of your individual sterility test isolator is based on an analysis of your processes and the number of tests you need to perform daily. This will determine which sensors you need, which type of monitoring is possible and which sterility test pump you should prefer to use. In addition, it shows whether you need an airlock now or if it should be retrofitted later. In this way, you can benefit from our predefined options and discuss with us which additional devices, such as scales or incubators, can be usefully integrated. The modular system easily adapts to all your requirements.



6th testing step: closing and
disconnecting canisters

7: We accompany you through the project

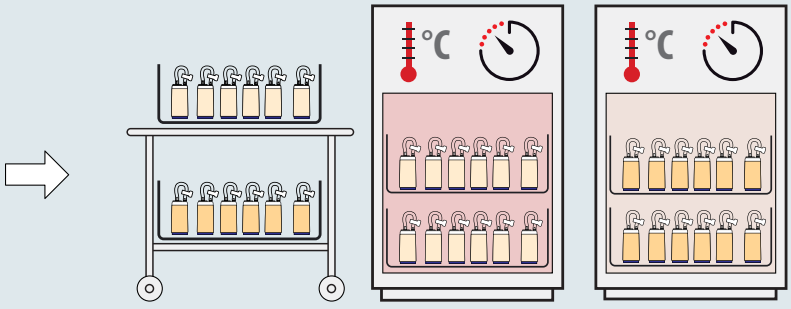
Each project is supervised by an experienced project manager and developed according to a defined quality project plan. This includes Factory Acceptance Test (FAT) at SKAN, our qualification service at the user site and the microbiological qualification package by our experts. Right from the start, you receive comprehensive and GMP-compliant documentation in provided SKAN's proven quality.

8: Benefit from our material studies

For the further development of our systems, we have conducted meaningful studies regarding material suitability and surface decontamination. The results of these studies are used as the foundation for possible new developments as well as the initialization of individual studies in our special laboratories. We would be pleased to submit a proposal for an individual initialisation analysis of your processes and systems.

9: Take part in our experience

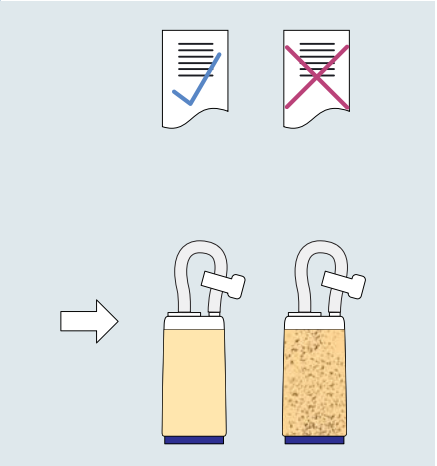
In our SKAN Academy, we have been organizing general and specific training for our customers, agents and of course for our professional organising staff for many years. Benefit from this service and learn more about your systems and facilities.



9th testing step: incubating of canisters

10: Benefit from our worldwide customer service

SKAN offers a worldwide lifecycle partnership with local support for the safe and lasting operation of your systems. Extensive spare parts inventories and the years of experience of our SKAN specialists can be quickly relied upon. Optional, customised service contracts open up a wide range of individual service options.



10th testing step: reading out by visual check and documenting the results


Skan

reddot winner 2021
industrial design

spectra

The spectra isolator is the consistent answer to the requirements of the modern pharmaceutical industry in terms of the highest hygiene standards, high efficiency, automation and digitalisation. Preferred areas of application are sterility testing, quality control and industrial preparations. The integrated SKAN nanox® catalyst and the reduced overall height allow easy integration into almost any room. Sophisticated skanfog® decontamination technology ensures fast cycle times and helps accelerate your process and overall efficiency. Launched in 2019, spectra can be used for both aseptic and aseptic-toxic applications. See product specification and reference list for details.

SARA airlock

The SARA airlock can be attached to either side of the isolator. Depending on the process, the SARA achieves greater flexibility by allowing the material to be independently transferred to the main chamber at any time. Decontamination is completely independent, but interlocked with the isolator.
The airlock offers the possibility of a fast, aseptic transfer of raw products or sterile samples into the working chamber. The SARA provides a clean aseptic environment in accordance with EU Class A requirements and can be retrofitted at any time. Decontamination takes place within a very short time using the proven skanfog® decontamination system. The exhaust air is returned to the room via the SKAN nanox® catalyst.

Description of spectra isolator	spectra
Built-in catalytic converter for exhaust air to room	•
Control system Siemens or Allen Bradley PLC validated acc. to GAMP-5	•
HMI (Human Machine Interface) Zenon or Factory Talk	•
SCADA (Supervisory Control and Data Acquisition) with batch report functionality and optional Ethernet	•
Integrated leak test according to ISO 14644-7	•
Dimensions of the unit (overall) W x H x D	2460x2413x1043 (mm) 96.85x95x41.06 (in)
Dimensions of the working chamber W x H x D [mm]	1894x898x740 (mm) 74.57x35.35x29.13 (in)
Pre-defined integration of sterility testing pump (Merck Millipore or Sartorius) with liquid drain	•
Working chamber with shelves at the back wall	•
Integrated viable and non-viable monitoring	•
H_2O_2 sensors: - TLV operator safety sensor for room - LC (low concentration) and HC (high concentration)	•
Optional temperature control with cooler intake air	•

Description of SARA transfer airlock	SARA airlock
Transfer airlock for left and/or right-side attachment	•
Integrated safe change filter for operator protection	•
Control system and HMI together with isolator	•
Dimensions of the unit (overall) W x H x D	840x2413x1043 (mm) 33.07x95x41.06 (in)
Dimensions of the working chamber W x H x D	788x810x475 (mm) 31.02x31.89x18.70 (in)
Dimensions front door for loading W x H	650x620 (mm) 25.59x24.41 (in)
Dimensions side door for unloading W x H	305x490 (mm) 12.01x19.29 (in)
Construction material: - external: stainless steel AISI 304; Ra 1.20 µm finish - internal: stainless steel AISI 316L; Ra 0.80 µm finish	•
Document packages: - Design for DQ - Qualification for IQ/OQ - Factory acceptance test (FAT)	•
Test document packages: - for cycle development (CD) - for microbiological qualification and validation (MBQ)	•
Manufactured in the EU	•

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

Aseptic Technologies SA Rue Camille Hubert 7-9
5032 Gembloux /Les Isnes, Belgium
+32 81 409 410, info@asepticteh.com

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