SARTORIUS

Simplifying Progress

Microbiological Quality Control Throughout the Biopharma Production Process

Process Development

Bioburden Control

USP <61>, <62> & <1231>
Quantify microbial contamination with touch-free membrane transfer to agar.

Regulation-compliant methods for monitoring your bioproduction process for bacterial contamination.

Microbial Enumeration Tests
USP <61> | <62> | <1231>

Pharmaceutical Bioburden Testing

The following paper provides an overview on bioburden and microbial contamination testing, including a discussion of common procedures and newer, more rapid methods.

DOI: 10.1002/9780470054581.eib655

Microsart®@filter and Microsart®@media system
Membrane filtration is the method-of-choice for detecting and quantifying microorganisms in liquid culture.

Microbiological Quality Control
Sartorius offers easy-to-use, smart solutions for your pharmaceutical QC process, including sampling, detecting, and counting microorganisms.

Upstream

Mycoplasma Detection

USP <63> | EP 2.6.7
Test for mycoplasma contamination in your bioreactor. Get your answer within 3 hrs (not 28 days).

Use our fully compliant qPCR-based test to detect even weak mycoplasma contamination, easily, rapidly, and reliably.

USP <61> | <62> | <1231>

A PCR Mycoplasma Detection Method

The following paper discusses a rapid method for detecting mycoplasma contamination. This method reduces the testing time by 2 weeks, and shows comparable sensitivity to the current agar-based detection methods.

DOI: 10.1002/9780470054581.eib655

Microsart® Mycoplasma qPCR detection kits
Mycoplasma qPCR detection assays offer gold standard performance for your pharmaceutical QC processes..

Downstream

Microbial Air Monitoring

USP <1116>
EU GMP Annex 1
Monitor your clean-room environment for 8 hours non-stop.

Air sampling with active devices is a commonly-used method for environmental monitoring

USP <1116> | EU GMP Annex 1

Assessment of the MD8 Microbiological Air Sampler

The gelatine filters used in our MD8 Air Sampler recovered monodispersed aerosols with 99.9995% efficiency. The flexible hose design makes the MD8 suitable for microbial monitoring in laminar flow hoods and isolators.

DOI: 10.1111/j.1365-2672.1996.tb03252.x

Gelatine Membrane Filters (GMF)
Gelatine filter disposables (membrane and holder) for use with the MD8 are individually packed, pre-sterilized, and ready-to-use.

MD8 Airscan®
Rule out false negative results with the MD8 Airscan®. The MD8 provides non-stop, active air monitoring over at least 8 hours with a single gelatine membrane. The USP-approved filter retains the smallest airborne microorganisms, and allows monitoring of viability.

Fill + Finish

Sterility Testing

USP <71> | EP 2.6.1
Sample your product aseptically to ensure sterility.

Get proof-of-sterility before batch-release with regulation-compliant sterility testing.

USP <71> | EP 2.6.1

Sterility Testing in Antibody Production

Maintaining sterility between a perfusion bioreactor and the capture step is critical. Read this study to see a good solution.

DOI: 10.1002/bit.26069

Sterisart® Family Consumables
Ensure aseptic transfer of liquids with Sterisart® Septum technology. Your sample remains safely protected against contamination due to the septum's sterile barrier, while also minimizing the risk of puncture injuries during sample injection due to the simple piercing mechanism.

Sterisart® Universal Pumps
Our peristaltic pump can be used in clean rooms, integrated into clean benches, or installed countersunk in the working surface of isolators. The pump is available as an upgraded version with display and user software.