Mitigate Risk from Start to Finish with a Robust Microbiological QC Strategy

Microbiological quality control (QC) is an important aspect of the pharmaceutical manufacturing process

Microbial contamination of pharmaceutical products poses serious risks for product integrity and safety, and manufacturers must implement robust QC procedures both in-process and as part of final release testing. Sartorius offers a range of smart solutions to overcome the challenges of microbiological QC.

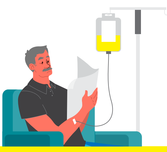
In-Process QC Solutions

Microbial Enumeration

The ability to detect and quantify microorganisms in liquid samples is important for any QC laboratory. Membrane filtration is an established method of choice for liquid testing as it provides reliable and reproducible results.

Microsart® @filters are ready-to use sterile filter units that combine a funnel, filter base, and gridded membrane filter in a single unit. @media dishes are pre-filled with different types of agar medium, sterile-packaged, and ready to use. Together, they enable a touch-free membrane transfer that reduces the risks of secondary contamination.

Microbial Contamination



Advanced therapy medicinal products (ATMPs) used in cell-based therapies often have a very short shelf-life, and for compendial QC release, must be tested for sterility from bacteria, fungi, and mycoplasma. The short shelf-life poses challenges for traditional testing methods that require 14 days for bacteria and fungi, and 28 days for mycoplasma.

Micosart® ATMP real-time PCR kits are a rapid alternative to traditional methods, providing accurate results in three hours. ATMP Bacteria enables rapid detection of contamination by more than 95% of all known bacterial species; ATMP Fungi detects almost all fungal species in cell culture, and ATMP Mycoplasma enables early detection of mycoplasma contamination. Kits contain highly specific TaqMan® probes to reduce the risk of false positives.

Ensure validated quality test results are in compliance with international standards:

- Micosart® ATMP Bacteria validation is based on EP 5.1.6 and USP <1223>
- Micosart® ATMP Fungi validation is based on EP 5.1.6, EP 2.6.27, and USP <1223>
- Micosart® ATMP Mycoplasma validation is based on EP 2.6.7, and EP 2.6.21 and gases

Final Release QC Solutions

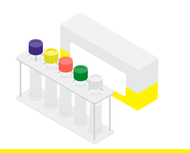
Sterility Testing

Every lot of product requires final release testing to ensure it is free of contamination. Sterility testing involves transferring sample into a filtration unit, which is filled with culture media and used for filter incubation. Visible turbidity is indicative of contamination.

The Sterisart® universal pump enables sample and media transfer into a closed loop system for sterility testing based on the membrane filter method. It is suitable for cleanrooms, clean benches, or isolators.

Mycoplasma

Mycoplasma contamination is often not associated with observable changes, and easily passes undetected. As such, alternative methods are employed to detect mycoplasma DNA. Early detection is critical to ensure sufficient time to react, and avoid significant losses, and real-time PCR dramatically reduces time-to-results.



Micosart® ATMP Mycoplasma real-time PCR kits enable rapid detection of mycoplasma contamination.

Air Monitoring

Environmental monitoring is important in production environments for sterile pharmaceutical products. A facility's contamination control strategy should include continuous air contamination monitoring to determine the air quality of the manufacturing environment.

The MD8 Airscan® and portable AirPort MD8 monitors provide continuous, active air monitoring with gelatin membrane filters to retain even the smallest airborne microorganisms.

It is imperative that microbiological QC testing is accurate and timely, to ensure patient safety and prevent delays in product release. Sartorius smart solutions are designed for efficiency and ease-of use, and ensure safety and compliance in sampling, detection, and microbiological quantification processes.