eurofins | BioPharma Product Testing

Mycoplasma Testing

Mycoplasma contamination events can lead to altered physio-chemical properties of cells, potentially resulting in reduced or altered cellular products and perhaps unsafe biopharmaceuticals. Thus, testing for the presence of mycoplasma contamination in development and manufacturing is a requirement by worldwide regulatory agencies. Guidance for this testing is provided in the United States Pharmacopeia (USP) Chapter <63> Mycoplasma Tests, European Pharmacopoeia (Ph. Eur.) Chapter 2.6.7 Mycoplasmas, and Japanese Pharmacopoeia.

Traditional compendial testing for mycoplasma includes direct culture and indicator cell culture methods. While both of these methods are the gold standard for mycoplasma detection, the timing for results is not conducive for newer autologous cellular therapies. To overcome this, Nucleic Acid Techniques, such as MycoSEQ™ and BIOFIRE® are becoming more accepted.

Eurofins BioPharma Product Testing offers harmonised mycoplasma assays, which comply with regulatory guidelines.

Why Choose Eurofins BioPharma Product Testing?

We provide fully characterised and qualified positive control strains.

We have a formalised analyst training program, including required proficiency assessments using blind samples.

We perform mycoplasmastasis testing to qualify each assay for each test article.

With over 20 years of experience, we offer support for mycoplasma clearance studies, including consultation and study design.

We utilise an optimised proprietary media

Mycoplasma Assays

Eurofins BioPharma Product Testing offers comprehensive mycoplasma services that are available for:

- Testing of master, working and end-of-production cell banks
- Unprocessed bulk harvest
- Cell culture raw materials (e.g., serum, trypsin)
- Final product release
- ATMPS

Available Assays

- Compendial
- MycoSEQ®
- BIOFIRE®
- Mollicute Screening

MycoSEQ™ vs BIOFIRE® Assays

The MycoSEQ™ assay is the current industry standard for rapid detection of mycoplasma contaminations. It is a real-time qPCR assay that detects mycoplasma DNA using a magnetic bead extraction of DNA and Power SYBR® Green dye. This allows for results in 5 calendar days. Results within 3 calendar days is achievable with prioritisation to meet tighter timelines.

The BIOFIRE® assay encompasses the nucleic acid extraction, PCR plating, and analysis within a single cartridge. This reduction in steps decreases the timing of the test from start to finish. This system also targets RNA, of which the half-life is much shorter than that of DNA. By targeting RNA, there is higher probability that any mycoplasma detected is viable, reducing the possibility of false positive results. With the BIOFIRE system, mycoplasma results may be obtained within 3 calendar days. For some extremely tight timelines, 24-hour results can be achieved.

Both MycoSEQ and BIOFIRE assays meet Ph. Eur. 2.6.7 guidelines, as well those set by USP and JP general chapters. Both methods have in silico validations of over 100 mollicute species performed by the vendor. Both method validations performed by the vendors have been confirmed with live-spike recovery studies performed at Eurofins. With the advent of autologous cellular therapies, testing time is valuable, and these assays reduce that testing time to the minimum that is achievable with current technology.

Facilities & Instrumentation

- Limited-access laboratories that are pressure-controlled, HEPA-filtered and operate on independent air handling systems to prevent cross-contamination.
- Separate areas for testing of client test articles and handling of positive control strains, including a unidirectional workflow that ensures handling of test articles prior to manipulating positive controls on each working day.
- Validated cleaning disinfection and environmental monitoring programs.
- Access to our proprietary LabAccess.com system, allowing 24/7 easy access to study information, final reports and actual raw study data.