clean cells

SOLUTION FOR BIOLOGICS

MYCOPLASMA CONTAMINATION WITH CLEAN CELLS, SECURE YOUR BIOLOGICAL PRODUCTS!

Mycoplasma are small bacteria, without bacterial wall, belonging to the Mollicutes family. Due to their characteristics, they are only detectable by specific assays. These specific assays are implemented at Clean Cells following ISO and GMP grades for more than 15 years.
Clean Cells has the expertise, know-how and technology necessary for the detection of mycoplasma in all types of samples using compendial methods. We have the necessary reference strains to detect mycoplasma for human and veterinary product in a qualified environment.

3 METHODS PROPOSED AT CLEAN CELLS

COMPENDIAL METHODS

DIRECT CULTURE

Volume: 35mL

TAT: 6 weeks
(including QC/QP documentation review)

INDIRECT CULTURE

Volume: 5mL

TAT: 4 weeks
(including QC/QP documentation review)

QPCR METHOD

Volume: 1mL or 5.10E6 cells

TAT: 4 weeks
(including QC/QP documentation review)

TYPE OF SAMPLES:

- Vaccines
- Cell & virus banks
- Recombinant Proteins
- Cell & Gene Therapy Products
- Plasmids
- Media & Reagents

REGULATORY COMPLIANCE WITH:

- European Pharmacopeia 2.6.7
- US Pharmacopeia 63
- FDA: 21CFR610.30 and PTC 1993

3 METHODS PROPOSED AT CLEAN CELLS

COMPENDIAL METHODS

DIRECT CULTURE

The sample is inoculated in liquid and solid media and incubated under microaerobic conditions.

Subcultures are carried out on D3, D7, D14 and D21. All inoculated media are observed periodically for at least 14 days.

A verification of the fertility of the media is performed using positive controls corresponding to at least two species of mycoplasma.
The absence of inhibitory effect of the sample is also checked for each type of sample.

Volume: 35mL

TAT: 6 weeks
(including QC/QP documentation review)

INDICATOR CELL CULTURE METHOD

The sample is co-cultured with Vero indicator cells.

The cells are seeded on a coverslip after at least 7 days of culture and stained with a DNA intercalating agent.

Mycoplasma detection is carried out by fluorescence microscopy as a read-out.

Assay validation is performed in routine using positive and negative controls.

Volume: 5mL

TAT: 4 weeks
(including QC/QP documentation review)

MYCOPLASMA & SPIROPLASMA DETECTION BY QPCR METHOD

qPCR amplification (SYBRGreen technology) is performed after a suitable DNA extraction of the biological product nucleic acids.

The quality of the nucleic acid extracts is checked by spectrophotometry and the efficiency of the extraction is supported by a «control» DNA sequence.

Clean Cells has developed a generic validated method (ICH Q2).
The qPCR reaction is monitored using positive and negative controls. Our consensus assay covers more than 200 mycoplasma strains.

Volume: 1mL or 5.10E6 cells

TAT: 4 weeks
(including QC/QP documentation review)

We can offer a suitability study to check if our generic method is adapted to your matrix. Our validation team can also support **product specific qualification/validation** for mycoplasma detection by qPCR. Different levels of validation, depending your clinical/commercial phases, are proposed and can be discussed during technical exchanges with our experts.

For products of avian origin, we can offered ad hoc validated methods.

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