

Adventitious Virus Testing

A major concern when using mammalian cell lines for production of a biotechnology product is the risk of viral contamination. Such contamination could have serious clinical consequences; in particular, the administration of the contaminated drug could be detrimental to the patient. Drug contamination can arise through the introduction of adventitious (accidentally introduced) viruses during the manufacturing process. The likely sources of contamination include the use of contaminated cell culture media, a breakdown in GMP allowing operator or other external contamination, or the use of contaminated reagents used in the process, such as a monoclonal antibody affinity chromatography column.¹

These contaminations require the development of suitable analytical techniques to ensure the absence of human and animal adventitious viruses.

What Products Should be Tested?

The absence of adventitious viruses in cell cultures is critical and evidence is required to establish its absence. It is important to recognize that certain hybridomas used for monoclonal antibody production may contain endogenous retroviruses.

- Monoclonal antibodies 3AB4a (75/318/EEC)
- Master cell bank
- End of production cells
- Unprocessed bulk
- Vector supernatant

When Should Testing be Performed?

Continuous monitoring of the production process is necessary to avoid or limit adventitious contamination. The importance of the sourcing and the qualification of all raw materials used in the manufacturing process has become a key area for the biopharmaceutical industry to exclude viral contamination.¹

Your
partner for
critical testing in
microbiology

Study Design

- *In vitro* detection of virus presence by cytopathic effects and/or adsorption of red blood cells to cultured cells, inoculated with test article
- Sub-passages on fresh indicator cells
- Qualitative assay

Assay Duration: Cultivation period of 14 (EP) or 28 days (USP)

Sample Requirement: Dependent on customer supplied product

Regulatory Compliance

- European Pharmacopeia
- ICH Q5A/Q5B
- Center for Biologics Evaluation and Research, FDA, Points to Consider in the Characterization of Cell Lines Used To Produce Biologicals (1993)

Final Report

MicroSafe Services from Millipore can provide each client with the following final reports:

- GLP report that includes all raw data, protocol methods and final result.
- GMP report that includes a certificate of results.

Custom Assays

We understand that no production plant is identical and that every process is unique. Using a combination of practical experience and a scientific approach, we will customize adventitious virus testing methods to meet your specific requirements including scientifically sound data that will be accepted by regulatory authorities around the globe.

Your Partner in Microbiology

MicroSafe Services from Millipore delivers a complete range of critical testing and consultancy services for the development and production of biopharmaceuticals. Leaders in the field of microbiology including *in vitro* virology testing, our staff of accomplished scientists, engineers and microbiologists will help you meet your specific critical testing requirements throughout every phase of drug production. All testing is conducted under GMP and/or GLP certifications as well as our own internal quality system.

SAFETY

RELIABILITY

QUALITY

CUSTOMER RELATIONSHIP

FEEDBACK & SUPPORT

Let Us Be Your Critical Service Provider

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