



Bovine Virus Testing

Material of ruminant origin (bovine serum) may be an essential ingredient in the culture media of cells used in the production of many medicinal biological products. Bovine Viral Diarrhea Virus (BVDV) is a highly prevalent infection in cattle and its presence in bovine serum cannot be completely avoided.¹

The potential presence of extraneous agents in bovine serum represents a risk to the safety of the biological medicinal product. The testing and removal of BVDV is essential to control the quality and safety of bovine serum used during the manufacture of human biological medicinal products including vaccines and biotech products.¹

What Products Should be Tested?

Biological medicinal products for human and animal use are required to undergo BVDV testing.

- Bovine serum
- Master cell bank
- Vaccines

When Should Testing be Performed?

Testing for BVDV is performed throughout the manufacturing process specifically on serum used during production cell growth and during cell growth prior to a production phase (growth of cell prior to vaccine production). Serum used minimally, such as in the establishment of a master cell bank during cryopreservation or during a developmental phase, is also required to be tested.¹

Your
partner for
critical testing in
microbiology

¹Committee for Proprietary Medicinal Products, *Note for Guidance on the Use of Bovine Serum in the Manufacture of Human Biological Medicinal Products*. CPMP/BWP/1793/02, (European Agency for the Evaluation of Medicinal Products, London, Current).

Study Design

- *In vitro* detection of BVDV by cytopathic effect on indicator cell line susceptible to BVDV infection or by BVDV specific antibodies in IFA (immunofluorescence assay)
- Sub-passages on fresh indicator cells
- Qualitative assay

Assay Duration: 21 days

Sample Requirement: Dependent on customer supplied product

Regulatory Compliance

- 9 CFR
- EMEA/CVMP/743/00
- European Pharmacopeia

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 bovine 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

For more information on our critical support services, please contact Millipore at:

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Lit. No. SDS1704ENEU Rev. - 5/06 06-137 Printed in U.S.A.

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