

Viral Safety Testing

For all stages throughout the development, manufacturing and release of your biological product, Eurofins BioPharma Product Testing offers comprehensive, fully cGMP-compliant Viral Safety Services.

Why Choose Eurofins BioPharma Product Testing?

With more than 60 years of combined viral safety experience, our technical staff provides you with the technical advice to ensure that your study design and execution is in compliance with FDA, ICH and EU Guidelines for Viral Safety Evaluation.

In addition to our Virology Services, we provide a seamless transition to any supporting services you may require, such as Microbiology and Molecular and Cell Biology - all fully cGMP compliant.

Viral Safety Services

Eurofins BioPharma Product Testing offers comprehensive Viral Safety Services that are available for:

- Characterization of Cell Banks
- Unprocessed Bulk Testing
- End of Production Cell Testing
- Raw Materials Testing

Facilities and Instrumentation

- Segregated virology and cell-culture laboratories
- HEPA-filtered laboratories maintained at differential pressure for isolation and control
- Validated cleaning disinfection and environmental monitoring programs

Available Viral Assays

All assays performed in-house are fully validated according to ICH Q2:



Adventitious Viruses

- *In Vitro* Assays (multiple cell lines are available for Mouse, Hamster, Rabbit, Bovine, Insect and Human-derived products)
- *In Vivo* Assays*

Specific Viruses

- Bovine Viral Assay (according to 9 CFR 113)
- Porcine Viral Assay (according to 9 CFR 113)
- qPCR Assays

Retrovirus Assays

- XC Assay for Ecotropic Retroviruses
- S+L- Assay for Xenotropic Retroviruses
- Electron Microscopy for Evaluation of Cell Banks and Culture Harvests*
- Co-Cultivation
- PERT

Antibody Production Tests

- Mouse Antibody Production (MAP)*
- Hamster Antibody Production (HAP)*
- Rat Antibody Production (RAP)*

*Tests are subcontracted to an approved vendor.

Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing
Cell Banking Services • Virology Services • Facility & Process Validation
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology
Stability Testing & Storage • Primary & Secondary Package Testing

Flexible Service Models

Fee For Service (FFS)
Full-Time-Equivalent (FTE)
PSS Insourcing Solutions®

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