eurofins | BioPharma Product Testing



Lot Release Testing

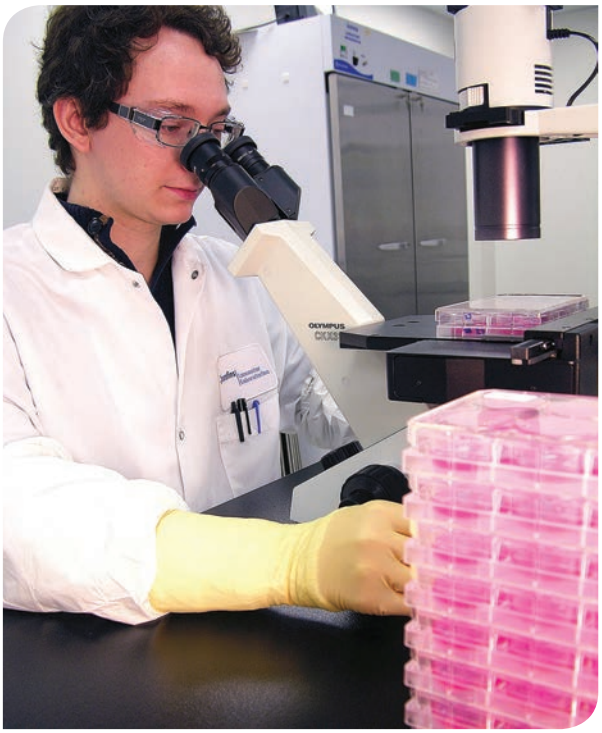
Unprocessed bulk (UPB) is the material collected directly from the bioreactor in which genetically engineered cells grow and produce product. Low levels of adventitious agents such as bacteria, yeast, fungi, molds, mycoplasma and viruses that bypass detection during raw materials testing, may grow to detectable levels under the highly enriching conditions of the bioreactor. At this point in the manufacturing process, it is optimal to test for these adventitious agents and testing of each lot of UPB is a regulatory requirement.

Eurofins BioPharma Product Testing's experienced team offers a streamlined, cGMP approach to lot release testing to ensure product purity in order to move into downstream purification faster and with less risk of contamination.

While we can fully customize our approach to meet any testing needs, our recommended approach consists of a package of testing including, bioburden, mycoplasma testing, in vitro viral screening, and virus specific qPCR assays, all performed in 35 calendar days.

Why Choose Eurofins BioPharma Product Testing?

- Our specialized sample delivery and receipt process ensures seamless communication between our lab and yours and expedites your samples into our laboratory within a few days of receipt.
- We provide test reports within 35 calendar days and can provide interim results upon request.
- Our secure, 24/7 online data portal, LabAccess.com provides timely access to your test results.
- We can issue individual or summary Certificate of Analysis, depending on your needs.
- Our experienced project management and technical teams serve as your single-source solution for all of your cell line and production needs.



Our Recommended Testing

- Bioburden testing
- Mycoplasma Testing (Compendial, Semi Rapid or Rapid)
- *In vitro* viral screening
- Virus specific qPCR

Cell Lines Available for *in vitro* Viral Screening

- Vero
- MRC-5
- CHO K1
- A9
- NIH 3T3
- HeLa
- 324K
- HT1080
- MDCK
- A549
- BHK-21
- MDBK
- Sf9
- Other cell lines upon request

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)
Professional Scientific Services® (PSS)

Global Facilities

Australia, Belgium, Canada, Denmark, France, Germany, India, Ireland, Italy, Japan, Netherlands, New Zealand, Spain, Sweden, Switzerland, UK, US