BioReliance®

Pharma & Biopharma Manufacturing & Testing Services

MilliporeSigma

Comprehensive Lot Release Testing

Every lot of biological therapeutic product produced, both for clinical and licensed biologics, requires a series of tests on both unprocessed and purified bulk harvest material that should be separate from final container testing. We offer a comprehensive range of services and assays aimed at ensuring the quality and purity of unprocessed and purified bulk harvest materials used in the production of biologics for the biopharmaceutical industry.

A comprehensive, high-quality testing program

Our bulk harvest lot release testing services are cGMP compliant and are in compliance with quality assurance and regulatory guidelines. We offer the full spectrum of lot release testing, including adventitious agents, identity, purity, potency, concentration, residuals and excipients, moisture and sterility.

With a reputation for trusted innovation, we have developed several industry-defining initiatives and continually evaluate emerging technologies. We employ the latest techniques such as digital PCR and Next Generation Sequencing (NGS).

- cGMP lot release testing assures the highest quality results
- Industry-leading quality systems and turnaround times
- Proactive communication to maximize manufacturing time lines
- Flexibility with multiple facilities
- Real time status tracking and report access via the iNet online client project management system
- Scientific and regulatory experts

	Raw Materials	Unprocessed Bulk Harvest	Purified Bulk (Drug Substance)	Final Filled Product (Drug Product)
Sterility tests	●	●	●	●
Mycoplasma tests (culture and PCR-based)	●	●	●	●
Analytical assays (e.g., HPLC, pH, SDS-PAGE, etc.)	●	●	●	●
LAL assay for endotoxin	●	●	●	●
9CFR and CHMP/CVMP/EP testing for bovine or porcine-derived materials	●			
Bioburden assay		●	●	●
In vitro assays for the detection of viral contaminants		●		
In vivo test for the presence of viral contaminants		●		
Transmission electron microscopy (TEM)		●		
Molecular biology (e.g., PCR, RT-PCR, Q-PCR) tests for detection of viral contamination	●	●		
Next Generation Sequencing for detecting unknown viruses	●	●	●	●
Test for manufacturing process impurities (e.g., residual protein A)			●	
Residual host cell DNA testing			●	
Residual host cell protein testing			●	
Rabbit pyrogen test				●

Contact your account manager to discuss your lot release testing needs.

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