charles river

Drug Product Release

The Biologics Testing Solutions group at Charles River provides release testing services for bulk drug substances and clinical and marketed products in the European Union (EU), United States (US) and other regulatory-distinct markets, Charles River Biologics Testing Solutions can act as a single site for your global release testing.

Services and Experience

To ensure that your biopharmaceuticals, pharmaceuticals and medical devices are produced according to the strict requirements of Good Manufacturing Practice (GMP) and that the release testing packages are carefully designed to demonstrate that compliance, we provide a full range of product release support, from addressing biosafety concerns and analyzing potency using suitable bioassays, to determining purity and other biochemical characteristics. Our commitment to providing rapid turnaround times for all testing helps minimize the period between production and release. We offer assays in compliance with European Pharmacopoeia (EP) and US Pharmacopeia (USP) monographs, as well as new assay development and validation. JP assays are available upon request.

The Biologics Group at Charles River is a highly experienced team, committed to successful long-term relationships with our product release clients. We have gained valuable experience over the past 10 years generating data in support of more than 1,000 batches of various protein products. We work closely with operational staff offering flexibility to meet your manufacturing schedules.

EU Release

All marketed products or investigational medicinal products (IMPs) manufactured outside the EU require re-testing at an EU-based facility. Charles River can provide this service through our local European facilities. Testing programs may include differing combinations of microbial testing, biochemical analysis, purity, safety and potency testing, as required by the client for market entry.

Release Requirements

- Identity
- Potency
- Purity and impurities
- Physicochemical properties
- Presentation attributes
- Sterility

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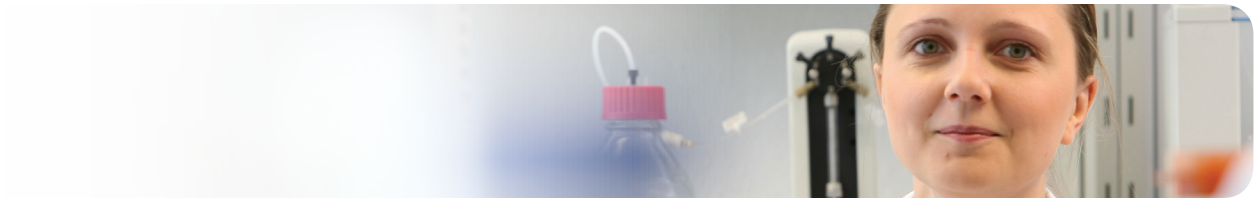

Technology Transfer

Controlled management of technology transfer is key to efficiently establishing an effective lot release program at a contract research organization (CRO). Charles River achieves this management by initiating discussions with clients regarding their methods at the earliest stages and undertaking careful study of how the process is actually conducted. This methodology allows us to transfer and establish client methods at our facility in the shortest timeline, and to maintain control of these methods throughout the life of the product. Our experience with technology transfer, our focus on communication and our rigorous generation of documentation and study performance enables us to support you in the most effective and timely manner possible.

Typical Release Testing Package

- pH determination
- Visual assessment
- Determination of volume in syringes and vials
- Osmolality determination
- LAL test for bacterial endotoxins or *in vivo* pyrogen testing
- Monocyte activation test
- Determination of excipient levels
- Protein concentration
- SDS-PAGE with western blot
- Isoform analysis (IEF, C-IEF)
- Size-exclusion HPLC of proteins
- Cation-exchange HPLC of proteins
- Reverse-phase (RP) HPLC of proteins
- Cell based potency assays
- *In vivo* potency and stability testing
- Sterility and other microbiology tests
- General safety/abnormal toxicity
- Residual DNA/host protein

Biochemical Analysis

Typically, a release testing program is comprised of key quality-indicating assays determined during earlier characterization studies. Utilizing a range of techniques, these assays cover areas such as identity, purity and impurity, physicochemical properties and dose form-specific tests.

Potency

Potency is a crucial release specification for biopharmaceuticals. Physical techniques, typically used to determine whether proteins have folded correctly, cannot be easily applied to final product for regulatory compliance purposes. Therefore, bioassays are frequently used as a suitable alternative method to measure activity and potency. Bioassays may be either *in vitro* or *in vivo*. *In vivo* bioassays measure appropriate clinical end points after dosing with the product, while *in vitro* bioassays detect a quantifiable end point after the product is added to an appropriate cell line. The bioassay staff at Charles River can develop or transfer and validate *in vitro* and *in vivo* potency assays as required.

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