Drug Product Release

We’re committed to providing rapid turnaround times for all testing to decrease the time between production and release. Our assays comply with US Pharmacopeia (USP), European Pharmacopoeia (EP), and Japanese Pharmacopoeia (JP) guidance, and we offer assay development and validation.

With over 20 years of experience supporting thousands of products, we have built a solid foundation of scientific excellence, robust quality infrastructure, and wide-ranging expertise to support various proteins. We communicate with clients in real time to resolve challenges in a timely manner to avoid potential delays in the process.

Regulatory Excellence

Our knowledge of regional regulatory requirements helps expedite products to market, shown by the fact that we supported 85% of products approved by the FDA in 2019.

EU Release

All marketed products or investigational medicinal products (IMPs) manufactured outside the EU or a country with an EU Mutual Recognition Agreement require retesting at an EU-based facility. We offer 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 respective regulatory authorities.

Method Development and Phase-Appropriate Validation

Our scientists can develop targeted methods for new analytes to support novel products and meet expected standards of sensitivity, accuracy, and precision. Method qualification establishes the parameters for validation as additional batches of the product become available, and then full GMP method validation is performed to result in the finalized, client-owned method.
Technology Transfer

Where a validated method already exists, and particularly where the method details are linked to regulatory registration, controlled management of technology transfer is key to the efficient establishment of an effective lot release program at a contract research organization. Our team initiates discussions with clients regarding their methods at the earliest stages to ensure a successful transfer within a timely manner. Additionally, regularly scheduled meetings are held to ensure milestones are met and that risk mitigation efforts are embedded in the process every step of the way. This approach allows us to transfer and establish client methods at our facility in the shortest timeline and maintain control of these methods throughout the life of the product. Our experience with technology transfer, focus on communication, and rigorous generation of documentation and study performance enables us to support clients in an effective and timely manner.

Testing Services

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/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 a final product for regulatory compliance purposes. Bioassays, which can be in vitro or in vivo, are frequently used as a suitable alternative method to measure activity and potency. In vivo bioassays measure appropriate clinical endpoints after dosing with the product, while in vitro bioassays detect a quantifiable endpoint after the product is added to an appropriate cell line. Our experienced team of scientists can develop or transfer and validate in vitro and in vivo potency assays as required.

Typical Release Testing Program

<table>
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<tr>
<th>Identity</th>
<th>Potency</th>
<th>Purity and Impurities</th>
<th>Physicochemical Properties</th>
<th>Presentation Attributes</th>
<th>Microbiology</th>
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<tbody>
<tr>
<td>SDS-PAGE with western blot or CE-SDS</td>
<td>Cell-based potency assays</td>
<td>Residual DNA/ host cell protein</td>
<td>pH determination</td>
<td>Visual assessment</td>
<td>Sterility testing</td>
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<td>Isoform analysis (IEF, C-IEF)</td>
<td>in vivo potency</td>
<td>Size-exclusion HPLC of proteins</td>
<td>Osmolality determination</td>
<td>Determination of volume in syringes and vials</td>
<td>Microbiology assays</td>
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<tr>
<td>Protein characterization</td>
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<td>Cation-exchange HPLC of proteins</td>
<td>Determination of excipient levels</td>
<td>LAL/monocyte activation test, in vivo pyrogenicity</td>
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<td>Binding assays</td>
<td>Reverse-phase (RP) HPLC of proteins</td>
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<td>General safety/ abnormal toxicity</td>
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<td></td>
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<td>CE-SDS, C-IEF</td>
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Questions for our scientists?
https://www.criver.com/consult-pi-bi-how-can-we-support-your-program