intertek
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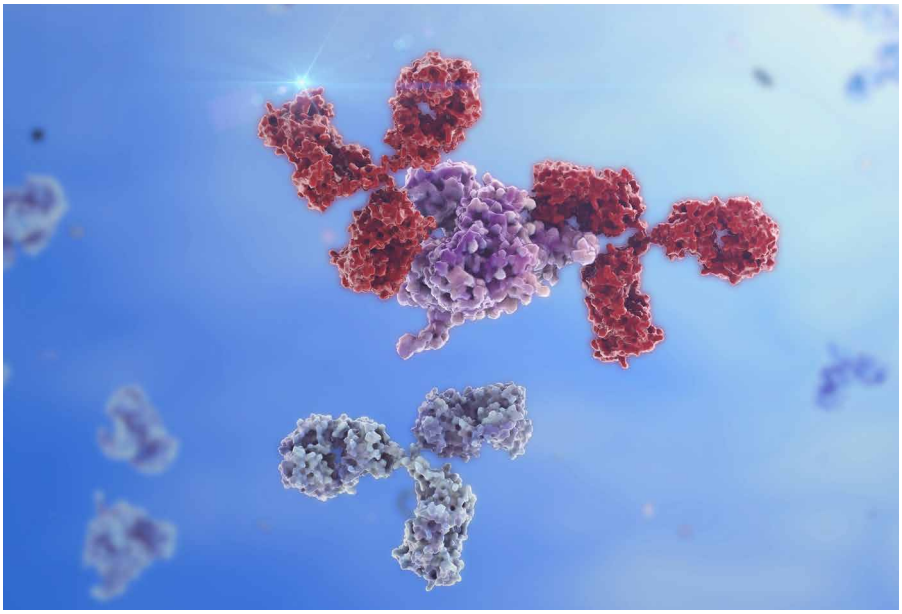
FACT SHEET

BIOPHARMACEUTICAL POTENCY TESTING

DEVELOPMENT SUPPORT SOLUTIONS

Potency testing quantitatively determines the biological activity of a biopharmaceutical. This is a critical quality attribute and measurement of potency plays an essential role in quality control, product release and stability studies.



The method/type of potency test employed is specific to the mechanism of action (MOA) of the biological therapeutic being studied. At Intertek, our potency testing experts offer tailored bioassays for molecules such as biosimilars, peptides, monoclonal antibodies, growth factors, hormones and cytokines. We are experienced in method development, method transfer, method validation and conducting routine potency release testing to GMP standards. Our team are experienced in a wide array of potency assay techniques, including (but not limited to) the following:

Cell-based Assays

Cell-based assays determine the relative potency of a product by comparing the biological response/activity, related to its mode of action, with a control/reference preparation (USP, WHO or in-house reference standard). This allows the product's efficacy and ability to achieve a defined biological effect to be quantified. At Intertek, we apply a wide range of cell-based assay models used to characterize recombinant proteins/ monoclonal antibodies:

- Cell migration assays
- Cell signalling assays
- Cell proliferation/inhibition assays
- Binding and/or competitive assays

Ligand and Receptor Binding Assays

Enzyme Linked Immuno-Sorbent Assays (ELISA) are the most common form of binding assay, allowing direct measurement of the biologic's affinity to its target with, typically, a robust performance.

Flexible, Multiple Assay Approaches

Some products have multiple MOAs, and so multiple assays may be needed to sufficiently demonstrate product efficacy as well as lot-to-lot comparability. A perfect example of a type of product with multiple MOAs would be monoclonal antibodies and/or antibody drug conjugates (ADCs). These molecules are the fastest growing class of biological therapeutic currently on the market. They are complex in nature and sometimes require a new, flexible approach to designing and executing potency assays in order to assess their multiple MOA. Monoclonal antibodies, for example, are often designed to function through direct binding to specific cell surface receptors, as well as providing some form of cytotoxic function. Consequently, we apply a multiple assay approach with selection from an array of cell based assay platforms/models, as well as physico-chemical assays to support product development and quality control.

At Intertek we use our industry knowledge and experience to apply phase-appropriate potency testing to provide a fully validated potency assay that is suitable to test your biological drug substance and/or drug product to ICH Q2 (R2) standards. The advantage to this tailored approach is that it can save time and money by optimising the efficiency of the study design.

Our experts can apply this knowledge to a wide array of applications, including:

- Biopharmaceutical stability testing
- Product release testing
- Optimisation and transfer of assays
- Tracking and trending (establishment and maintenance of assays)
- Candidate selection
- Product characterisation
- Assessment of clinical efficacy
- Reference standard qualification
- Process intermediates characterisation
- Degradation products
- Formulation changes
- Support for production alterations
- Robustness testing/design

FOR MORE INFORMATION

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