KEMWELL
Keeping You Competitive

# ANALYTICAL DEVELOPMENT

Kemwell offers analytical services, analytical method development and method validation services for mammalian cell culture based products to support your clinical and commercial product needs. Our efficient and strong Analytical Development team is unified into R&D services.

Kemwell provides Development approach covers all aspects for intended use of the method (stability indicating, process development support, limits of detection/ quantitation, etc.)

Extent of method validation studies are based on the stage of the product development and comply with the industry guidelines

The analytical team in support of QC establishes reference standards based on regulatory requirements thorough characterization and comparability establishment. The reference standards are then stored under cGMP conditions.

## KEY EQUIPMENT LIST

- Lab-scale lyophilizer
- HPLC and UPLC systems
- Capillary electrophoresis
- Micro-plate reader (UV-Vis, Absorbance, Fluorescence)
- Spectrophotometer

## Analytical method development and optimization for various assays including:

| Process related impurities & identity | Protein related impurities and variants | Invitro Bioassays | Miscellaneous |
|---|---|---|---|
| • CHO HCP quantification -ELISA<br>• Residual DNA determination<br>• Q-PCR & Pico-Green method<br>• Protein A contaminant qualification by ELISA<br>• Mycoplasma by RT-PCR<br>• BET test<br>• Kinetic chromogenic lysate assay<br>• Gel clot assay<br>• Identity<br>• Peptide mapping<br>• Immuno blotting<br>• Electrophoretic techniques | • Charged variant by CEX & cIEF<br>• Size related impurities by SEC, SDS-PAGE (NR) & CE-SDS (NR)<br>• Degraded protein by-SDS-PAGE, CE-SDS (NR)<br>• Oxidised and reduced impurities by RP-HPLC<br>• IgG purity- quantification of free heavy chain and light chain, non-glycosylated IgG, Intact IgG and other fragmented species by Capillary Electrophoresis<br>• Isoform variants by IEF, CZE and IEF with western blotting<br>• Glycan profiling by Capillary Electrophoresis and UPLC | • Cell proliferation assays<br>• Anti-proliferation assays<br>• CDC Complement Dependent Cytotoxicity) assays<br>• Cell based cAMP release assay<br>• Binding assays<br>• Reporter gene assay | • Compendial methods for parenteral i.e. Sterlity, Endotoxin, Visible and sub-visible particulate matter, Degree of coloration and opalescence<br>• Content assays by absorbance, Colorimetric and HPLC based methods<br>• Raw material analysis including moisture content, melting point, refractive index, FTIR and various identity and assay methods |

Biacore, MS, biophysical characterization tests are outsourced to a partner and managed by Kemwell

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