

anaRIC biologics

Analytical solutions readily delivered

NEW CHEMICAL ENTITIES & GENERICS

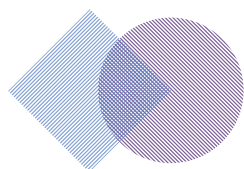


EXPERIENCE

- Drug substance
- Drug product: solids, liquids, injectables
- Complex formulations
 - Low solubility products
 - Microspheres
 - Liposomal products
 - Extended release formulations
 - Combination products in range of strengths
 - API loaded medical devices

ANALYTICAL SOLUTIONS

- Product characterization
- Method development
- Validation & transfer
- Release
- Stability (ICH, in-use, cyclic stress)
- Shelf life prediction (ASAP)
- Forced degradation
- Excipient compatibility
- Consultancy



NEW CHEMICAL ENTITIES & GENERICS

TESTING CAPABILITIES

Chromatography/Electrophoresis

- HPLC & UPLC (UV/DAD/CAD/MS/ELSD/FLD)
- Gas chromatography (GC)
 - liquid & headspace
 - FID & MS
- Capillary electrophoresis (CE)

Physico-chemical testing

- Differential scanning calorimetry (DSC)
- Laser diffraction
- Light obscuration
- Hardness
- Disintegration
- Friability
- XRD

Mass spectrometry

- LC-MS (low/high resolution)
- GC-MS (low resolution)

Karl Fischer

- Volumetric
- Coulometric (with/without VAP)

Spectroscopy

- FT-IR
- UV-VIS

Other

- Water activity
- Appearance

Dissolution

- USP type 1 (baskets)
- USP type 2 (paddles)
- QC (real-time & accelerated)
- Biorelevant

Color, particulate matter, visible particles

- Solubility
- Microbiology (outsourced)
- Endotoxines

Wet chemistry

- Osmolality
- pH
- Density
- Viscosity
- Heavy metals
- Sulfated ash
- Titration