Faster and easier charge heterogeneity analysis with ICE (Imaged Capillary Electrophoresis)

Eurofins Biopharma Product Testing

Chemical & Biochemical analysis

Characterization, residual impurities, HPLC, GC, ICP-MS, SAA, ELISA, SDS PAGE

Microbiological tests

Organism identification, sterility testing, bioburden, endotoxin, mycoplasma

Bioassay & biosafety

Potency assay, residual DNA, viral safety and clearance

Cell banking & storage

Preparation of master and working cell banks

Clinical Supply

Batch importation & release, clinical manufacturing, storage and distribution

Biopharmaceutical Critical Quality Attributes

- **Key characteristics are monitored as Critical Quality Attributes (CQAs) throughout bioprocess development**
- **Characteristics also used for setting specifications for stability and release testing**
- **Charge heterogeneity analysis is important in the characterization of monoclonal antibodies and other therapeutic proteins**
- **Charge heterogeneity can be caused by deamination, oxidation, amino acid modification, and post translational modifications**

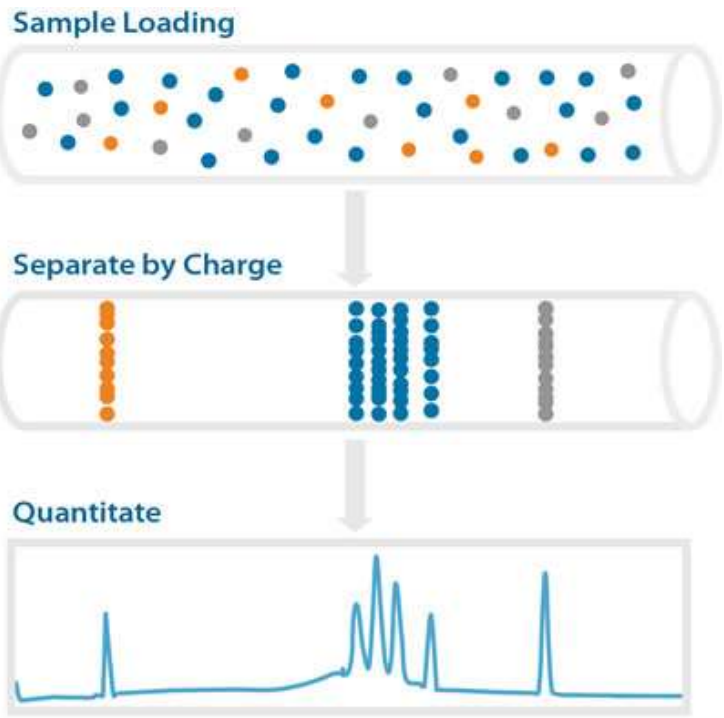
Capillary electrophoresis

- **Characterization charge heterogeneity in proteins : capillary electrophoresis (CE)**
- **This technique is an extension of traditional electrophoresis methods such as SDS-PAGE and Western Blot**
- **Employing a capillary tube and automating the analysis**
- **Species are separated based on their size-to-charge ratio**
- **CQAs such as the isoelectric point (pI) and charge heterogeneity are measured utilizing a form of CE know as cIEF**

ICE Technology

Performs free solution isoelectric focusing in a capillary column and detects focused protein zones using a whole column UV detector.

- **Better resolution than traditional gel IEF**
- **advantage of quantification and automation found in column based separations**
- **Elimination of a mobilization step.**



Source : ProteinSimple, ICE

Provides rapid (10min) and high resolution analysis providing simple and accurate quantitation of protein charge variants

Charge Profile by icIEF