

## Customer case study

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***“SCIEX capillary electrophoresis is a versatile tool to identify the size heterogeneity of biologics”***



### Project goal

To achieve size heterogeneity and impurity analysis of low molecular weight species of monoclonal antibodies and quantify the glycan occupancy.

### Biggest challenges

- Developing a robust method to separate, identify and quantify the purity and impurity analysis of monoclonal antibodies (mAbs) with baseline resolution
- Quantification of low molecular weight (LMW) impurities with good reproducibility

### The solution

- The PA 800 Plus with PDA detector was used to perform size heterogeneity analysis of mAbs by using the CE-SDS kit. It was the right combination to give the reproducible size distribution analysis data and quantify the impurities. The system was easy to operate and the reproducibility we obtained was commendable. The CE-SDS kit provided ultra-high resolution of mAbs in reduced and non-reduced application. The obtained LOD and LOQ were as per the requirements, with good linearity.
- The 32 Karat software with 21 CFR Part 11 compatibility gave access to instrument operation and seamless data integration and quantification of impurities.

### Outcomes of research

- This study focuses on the optimization of a capillary-based gel electrophoresis method that can be used to support antibody development, including bioprocess optimization, antibody characterization, release and formulation stability assessment.
- The PA 800 Plus and CE-SDS kit helped us to successfully characterize a wide range of monoclonal antibodies.

***“The ruggedness, sensitivity and precision of the instrument has helped us perform method development and qualification.”***

### Organization

National Institute of Biologicals (NIB)  
(Ministry of Health & Family Welfare, Government of India)

### Goal

To perform primary statutory function of quality control of biologicals e.g. recombinant products including therapeutic monoclonal antibodies like trastuzumab and rituximab used in cancer treatment etc. in accordance with provisions of Drugs & Cosmetics Act 1940 and Rule 1945 amended from time to time.

### SCIEX products

- PA 800 Plus pharmaceutical analysis system
- 32 Karat software
- CE-SDS kit