FASTFACTS

# Simplifying AAV protein analytics with Maurice

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## SIMPLIFYING AAV PROTEIN ANALYTICS WITH MAURICE

In recent years, the pharmaceutical industry has seen a great increase in biotherapeutics, and companies have begun to leverage newer therapeutic modalities, including viruses and nanoparticles. Adeno-associated viral (AAV) vectors in particular have emerged as an attractive gene therapy delivery tool. However, they are also complex, and challenging to manufacture – the process is long and costly, and hard to scale. These challenges require manufacturers to carefully design and implement tests and control strategies to address the various attributes of their viral product. ProteinSimple, a Bio-Techne brand, have built on and evolved existing viral vector analytical techniques to provide faster, better analysis of AAV products through products like the Maurice CE-SDS PLUS system for AAV analytics.

## CE-SDS ANALYSIS OF AAV PROTEIN PURITY

AAV protein purity is a critical quality attribute that Maurice can address. At a run time of only 35 minutes per sample, with up to 48 samples per batch, Maurice CE-SDS provides a rapid approach to gathering data from AAV samples. It is reproducible, with a relative standard deviation (RSD) of typically under 10%. Maurice provides a widely accepted platform for biopharmaceutical purity analysis, and is also easy to use, making it suitable for a broad range of users in applications ranging from research and development to quality control (QC).

SDS-PAGE has traditionally been used for viral vector identity and purity analysis but is now a dated technique which presents several challenges. In contrast, Maurice CE-SDS can provide clearer results while using only a few microliters of sample **(Figure 1)**.

## ICIEF ANALYSIS OF AAV CHARGE HETEROGENEITY

Maurice also provides the gold standard platform for charge heterogeneity analysis of biopharmaceuticals, using imaged capillary isoelectric focusing (icIEF) to characterize AAV charge variants. AAV protein charge heterogeneity information is crucial to understanding changes to individual viral proteins. Unlike ion exchange chromatography, iCIEF is a fast and high-throughput technique, at a run time of under 15 minutes per sample, with the ability to analyze up to 96 samples per batch. Maurice also provides detection flexibility, as it uses 280 nanometer light to provide absorbance data, but is also equipped with both native fluorescence and optional blue fluorescence (458 nm) in order to leverage multiple detection capabilities for AAV analysis.

For AAV analysis using the icIEF mode of Maurice, two methods were developed to characterize AAV capsid proteins or intact AAV particles. The capsid protein method breaks the capsid into individual proteins using a denatured approach, while the particle characterization method is much gentler, and maintains the AAV particle while providing sufficient solubility for analysis. Both methods can be run in under 12 minutes per sample, using only a few microliters of product **(Figure 2)**. These icIEF methods can be used for AAV stability testing, and for examining empty/full capsids.

## MAURICE: A FULLY INTEGRATED AAV ANALYTICAL SOLUTION

The demand for techniques for AAV protein analytics continues to grow, and Maurice addresses those needs by combining two AAV characterization tools in one instrument: CE-SDS to measure capsid ratio and AAV sample purity, and icIEF to allow both capsid protein and intact capsid analysis. Maurice is a QC-friendly system that is CFR 21-part 11 complaint, with optional Empower integration, and provides a fast, easy-to-use tool to assess a variety of viral vector quality attributes.

**Figure 1.** CE-SDS analysis of AAVs.

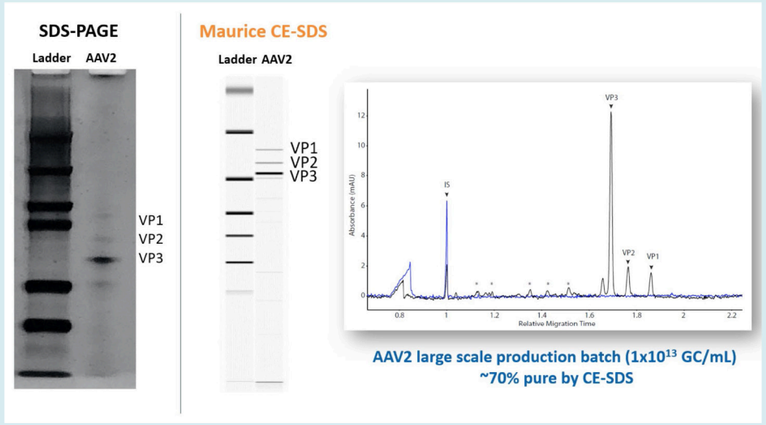
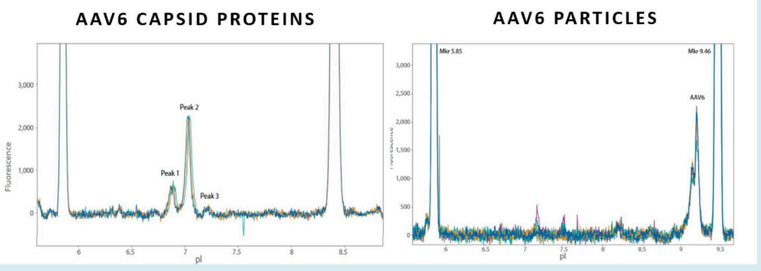



**Figure 2.** iCIEF analysis of AAVs.

| | Capsid Protein Characterization | AAV Particle Characterization |
|---|---|---|
| Method Approach/Goal | Denatured/Break Capsid | Mild/Maintain solubility |
| Run time (per sample) | 12min | 7min |
| Sample Requirement | 2-5uL at 1x $10^{13}$ GC/mL | |
| Detection Method | Absorbance and Native fluorescence | |

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