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Publication Spotlight

Pfizer's icIEF Method Optimizes AAV Characterization

For Gene Therapy Development

Pfizer published a peer-reviewed study entitled *Development of an icIEF Assay for Monitoring AAV Capsid Proteins and Application to Gene Therapy Products* in the journal of Molecular Therapy.

The study described the development of an imaged cIEF (icIEF) platform method on the **Maurice**™ system for charge heterogeneity analysis of AAV capsid proteins, which in turn provided critical insights into post-translational modifications (PTMs) and associated decrease in potency as a stability indicating assay.

> While a quantitative peptide map or MAM, as in the data we presented, is a powerful tool to monitor capsid deamidation, a more rapid and suitably GMP-compliant method benefits routine product testing.
>
> — **Xiaoping He *et al.*,** 2023

Importantly, the study also drew comparisons between the results obtained from icIEF, RP-HPLC, and a multi-attribute method (MAM) using high-resolution LC-MS, demonstrating the suitability of GMP compliant icIEF method for routine product testing.

The study demonstrated multiple uses of Maurice icIEF for AAV product characterization, from differentiating between serotypes to deducing potential impacts on potency based on capsid stability.

Highlights of the study:

- ✓ The development of an icIEF platform method for resolving AAV capsid proteins (VP1, VP2, and VP3) and other charges species linked to PTMs
- ✓ Fractionation and analysis of different charged species with RP-HPLC MS, and subsequent isoelectric point (pI) verification with icIEF
- ✓ The introduction of point-mutations in AAVs to induce and measure deamidation
- ✓ Forced degradation of AAVs and charge assessment to confirm that icIEF is stability-indicating, validating the results against RP-HPLC and MAM
- ✓ Correlation of AAV stability with transduction efficiency (relative potency)

The **study in the paper** used RP-HPLC for AAV charge isoform fractionation, but we now offer that capability too with our new **MauriceFlex**™ system!

Read the full paper

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