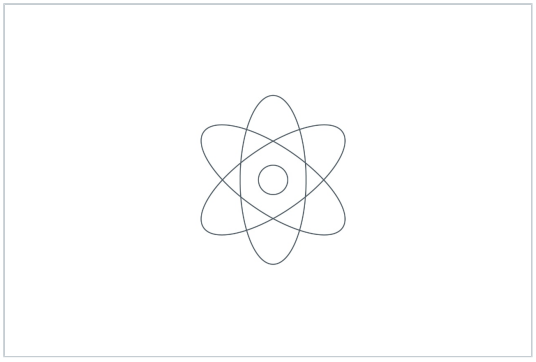
Waters™

Application Note

Test Application Note Page Heightened Characterization of AAVs by SEC-MALS with XBridge™ Premier GTx BEH™ SEC 450 Å 2.5 µm Columns

A. Esquivel



Abstract

Gene therapy (GTx) products comprised of adeno-associated viral vectors (AAVs)

require detailed characterization to ensure their safety and efficacy. In this application note, we evaluate the utility of XBridge Premier GTx BEH SEC 450 Å 2.5 µm columns for size exclusion chromatography coupled with multiangle light scattering (SEC-MALS) and the biophysical analysis of AAVs. High throughput size variant analysis is made possible by a combination of new column hardware manufactured with hydrophilic MaxPeak High Performance Surfaces (h-HPS) and high efficiency packed beds consisting of 2.5 µm diol bonded 450 Å BEH particles. These SEC columns exhibit enhanced sensitivity for low volume samples, low MALS noise and little to no particle shedding. Accurate molar mass and size measurements are thus facilitated for sample components. This SEC-MALS technique can generate detailed information about process and product related impurities that is critical to process development decisions and the preparation of comprehensive regulatory submissions.

Benefits

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Introduction

Experimental

Results and Discussion

Conclusion

References

1.

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