Separation Solutions to Accelerate Next Generation Gene Therapy Development

The therapeutics you are working on are cutting edge, complex and ultimately life-changing. Waters is here to help partner with you from bench to clinic through these challenges.

COMMON ANALYTICAL QUESTIONS IN GENE THERAPY DEVELOPMENT AND HOW TO OVERCOME THEM

How do I get the most information out of my precious sample?

Confidence in Your Analytical Results:

- **Reduce Sample Loss:**
  Don't lose your precious sample conditioning columns to compensate for non-specific adsorption losses; use columns with inert surfaces
- **Improve Sensitivity and Reproducibility:**
  Increase the value and reliability of your analytical data by limiting uncontrolled sample losses with inert surfaces

How do I jump start my method development?

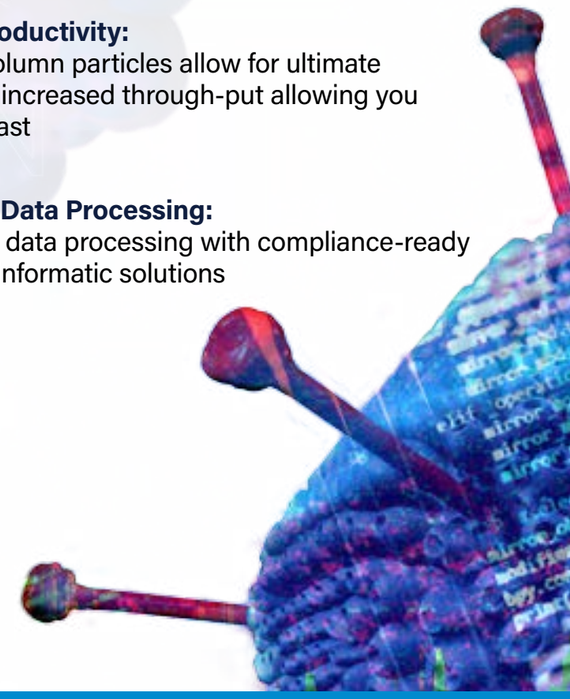
Method Development Made Easy:

- **Utilize Scalable Column Particles:**
  Have confidence in developing robust platform methods from Discovery, Development through Quality Control with scalable column particles
- **Refer to our Application Library:**
  Alleviate the guess-work with our comprehensive list of application notes providing simple method development (see reverse-side for applications)
- **Talk to an Expert:**
  Speak with live technical support experts to help expedite trouble-shooting avoiding time lost in development

How do I get data faster under tight timeline pressures?

Need for speed:

- **Increase Productivity:**
  Sub-2 µm column particles allow for ultimate efficiency & increased through-put allowing you to get data fast
- **Automated Data Processing:**
  Save time in data processing with compliance-ready end-to-end informatic solutions



For more information on Waters solutions for Cell & Gene Therapy visit: waters.com/waters_connect, waters.com/CGT and waters.com/MaxPeakColumns

COLUMNS AND CONSUMABLES

Waters
THE SCIENCE OF WHAT'S POSSIBLE.™

ADENO-ASSOCIATED VIRUS:

CQA	Structure & Size: Aggregation	Purity: Intact Capsid Protein	Purity: Empty/Full Capsid	Desalting AAV	Sequence Variants: Peptide Mapping
LC Technique	SEC	Reversed-Phase	AEX	SEC	Reversed-Phase
Chemistry Solution	XBridge™ BEH™ 450 Å SEC 3.5 µm	ACQUITY™ Premier Protein BEH C4 300 Å 1.7 µm IonHance™ DFA	Protein-Pak Hi Res Q 5 µm	ACQUITY BEH 200 Å SEC 1.7 µm	ACQUITY Premier Peptide BEH C18 300Å 1.7 µm RapiGest™ SF Surfactant
Ordering Info	p/n 176003599 (includes column and BEH 450A SEC Protein Mix Standard)	p/n 186010327 Column p/n 186009201 IonHance DFA	p/n 186004931	p/n 186008471	p/n 186009494 Column p/n 186008090 RapiGest SF
Applications	SEC Analysis of AAV Using 450A Diol-Bonded BEH Column & FLR Detection	Optimizing AAV Capsid Protein Analysis Using UPLC and UPLC-MS	AEX for Determining Empty/Full Capsid Content in AAV	Optimized Reversed-Phase LC/MS Methods for Intact Protein Analysis & Peptide Mapping of AAV Proteins	

LIPID NANOPARTICLES:

CQA	Lipid Discovery & Characterization	Routine Analysis
LC Technique	Reversed-Phase	Reversed-Phase
Chemistry Solution	ACQUITY Premier CSH™ C18 1.7 µm	ACQUITY Premier CSH Pheny-Hexyl 1.7 µm
Ordering Info	p/n 186009461	p/n 186009474
Applications	Rapid Analysis of Lipid Nanoparticle Components using BioAccord LC-MS System	Lipid Nanoparticle Compositional Analysis Using Charged Surface Hybrid Phenyl-Hexyl Separation With Evaporative Light Scattering Detection

ADENOVIRUS:

CQA	Purity: Intact Viral Proteins
LC Technique	Reversed-Phase
Chemistry Solution	BioResolve™ RP mAb Polyphenyl 450 Å 2.7 um IonHance DFA
Ordering Info	p/n 186008946 Column p/n 186009201 IonHance DFA
Applications	Analysis of Adenoviral Vector Proteins by RPLC, Native Fluorescence and Online MS

OLIGONUCLEOTIDES:

CQA	Identity: Purity, Impurities	
LC Technique	Ion-Pairing Reversed-Phase	HILIC
Chemistry Solution	ACQUITY Premier Oligonucleotide BEH C18 130 Å 1.7 µm ACQUITY Premier Peptide BEH C18 300 Å 1.7 µm	ACQUITY Premier BEH Amide 130 Å 1.7 µm
Ordering Info	p/n 186009485 p/n 186009495	p/n 186009504
Applications	Best Practices for Oligonucleotide Analysis Using IPRP- Columns & Chemistries	HILIC as an Alternative Separation Mode for Intact Mass Confirmation of Oligonucleotides on the BioAccord System

mRNA:

CQA	Modifications: 5′ Capping Efficiency	Identity: Oligo Mapping	Identity: Integrity
LC Technique	Ion-Pairing Reversed-Phase	Ion-Pairing Reversed-Phase	AEX
Chemistry Solution	ACQUITY Premier Oligonucleotide BEH C18 130 Å 1.7 µm	ACQUITY Premier Peptide BEH C18 300 Å 1.7 µm	Protein-Pak Hi Res Q 5 µm
Ordering Info	p/n 186009484	p/n 186009495	p/n 186004931
Applications	Rapid Analysis of Synthetic mRNA Cap Structure Using Ion-Pairing RPLC with the BioAccord LC-MS System	Synthetic mRNA Oligo-Mapping Using Ion-Pairing Liquid Chromatography and Mass Spectrometry	Methods for the Anion Exchange Chromatographic Analysis of mRNAs

PLASMID/DNA:

CQA	Impurities: Supercoiled, Linear or Open Circular	Identity: Size
LC Technique	AEX	AEX
Chemistry Solution	Protein-Pak Hi Res Q 5 µm	Protein-Pak Hi Res Q 5 µm
Ordering Info	p/n 186004931	p/n 186004931
Applications	Plasmid Isoform Separation and Quantification by Anion-Exchange Chromatography (AEX)	Separation and Size Assessment of dsDNA Fragments by Anion-Exchange Chromatography (AEX)

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