

APPLICATION OF WATERS UPLC TECHNOLOGY FOR BIOTHERAPEUTIC CHARACTERIZATION

ACQUITY UPLC has proven itself an asset in laboratories around the world, providing the means to transcend the abilities of conventional LC separations. UPLC sets new standards in resolution, sensitivity, and throughput by being the first holistically designed system that maximizes rapid, high-resolution analyses. It has fueled hundreds of peer-reviewed papers; it helps laboratories conserve resources; and it has served the needs of regulatory agencies around the globe. ACQUITY UPLC makes your laboratory simultaneously more sustainable and more efficient.

Manufacturing Consistency for Enhanced Assurance

The ability to perform identical high-quality separations regardless of column lot is critically important to the successful development and commercialization of biotherapeutics. Each batch of Protein-Pak Hi Res IEX material is tested with a relevant mixture of protein standards, helping to ensure consistent column-to-column performance.

Novel IEX Particles Ideal for Biomolecule Characterizations

Protein-Pak Hi Res IEX Columns contain nonporous, pH-tolerant, hydrophilic particles whose surface consists of a multi-layered network of either anion (5 µm) or cation (7 µm) exchange groups. This innovative particle and bonding chemistry produces particles with greater protein loading capacities than those associated with many traditional monodisperse, nonporous resins. These columns, therefore, can resolve complex mixtures of biomolecules in comparatively brief analyses, compared with alternative porous or nonporous IEX columns.

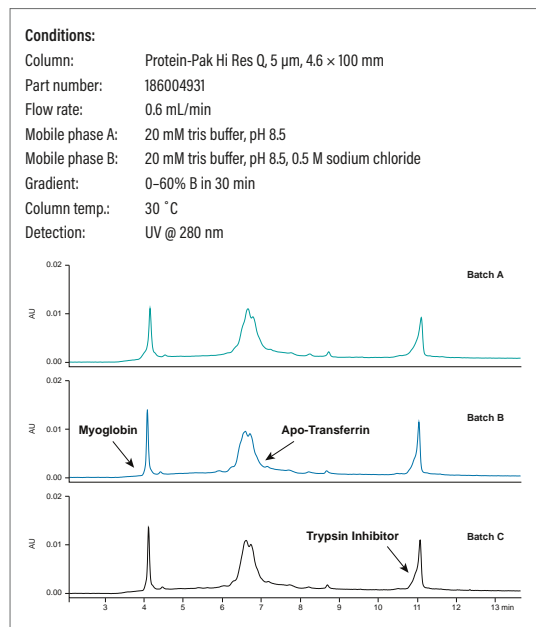
Column	Protein-Pak Hi Res Q	Protein-Pak Hi Res CM	Protein-Pak Hi Res SP
Ion exchange	Strong Anion	Weak Cation	Strong Cation
Functional group	Quaternary ammonium	Carboxymethyl	Sulfopropyl
Matrix	Hydrophilic polymer	Hydrophilic	—
Polymer	Hydrophilic polymer	—	—
Particle size	5 µm	7 µm	7 µm
Pore size	Non porous	Non porous	Non porous
Dimensions	4.6 × 100 mm	4.6 × 100 mm	4.6 × 100 mm
Counter ion	Cl ⁻	Na ⁺	Na ⁺
pH range	3–10	3–10	3–10
Temperature	10–60 °C	10–60 °C	10–60 °C
pK _a	10.5	4.9	2.3
Flow rates	0.3–0.6 mL/min	0.5–1.4 mL/min	0.5–1.4 mL/min
Approximate protein binding capacity, in milligrams/per column	58	33	25
(i.e., BSA for Hi Res Q column, Lysozyme for Hi Res CM and Hi Res SP columns)*			

*For optimal resolution of complex samples, do not exceed 20% of the column's protein binding capacity.



ACQUITY UPLC Technology for biotherapeutic characterization.

Protein-Pak Hi Res IEX Column Batch-to-Batch Reproducibility



Each batch of Protein-Pak Hi Res SP, CM, and Q Column packing material is chromatography-tested using a relevant protein standard mixture to help ensure consistent and predictable performance.