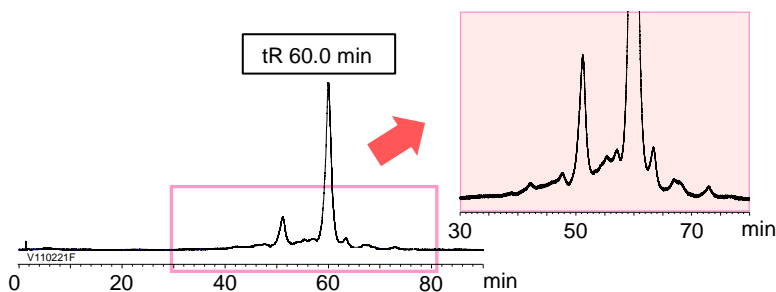


Analysis of Monoclonal Antibody (MAb) Pharmaceuticals Using Non-Porous Type Ion Exchange Columns

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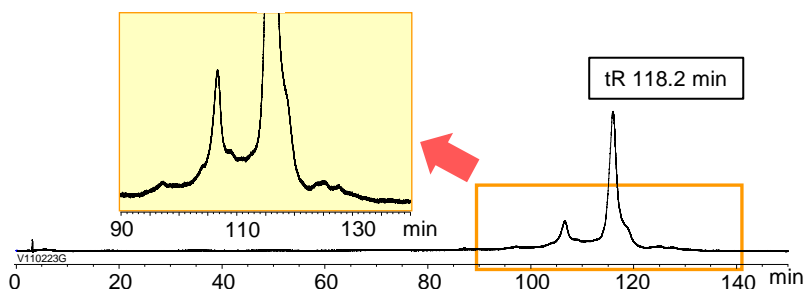
【MAb Analysis on Non-Porous Type Cation Exchange Columns】

BioPro IEX SF 5 μm, 100 X 4.6 mmI.D.



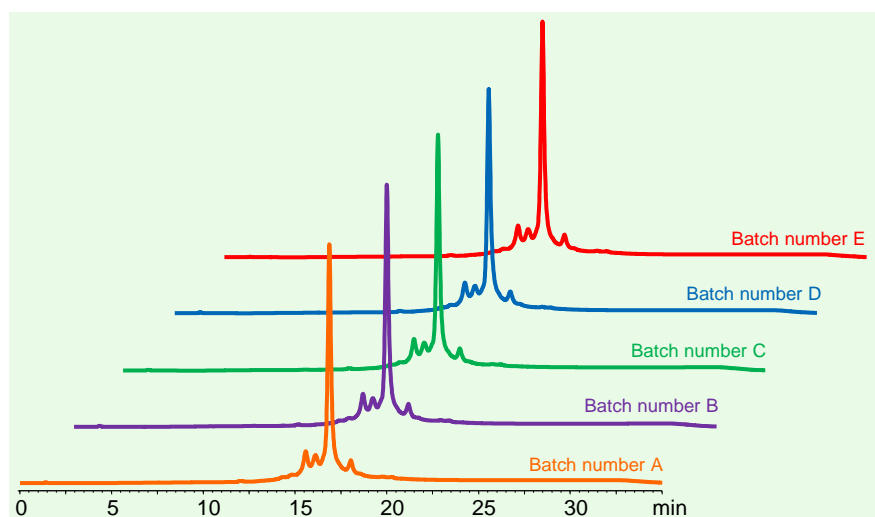
Eluent	: A) 20 mM MES-NaOH (pH 5.6) B) 20 mM MES-NaOH (pH 5.6) containing 0.2 M NaCl
Initial gradient conc.	: 35%B (70 mM NaCl)
Gradient slope	: 0.25%B/min (0.5 mM NaCl)
Flow rate	: 0.5 mL/min for 100 X 4.6 mmI.D., 0.378 mL/min for 250 X 4.0 mmI.D.
Temperature	: 30°C
Detection	: UV at 280 nm
Sample	: Humanized monoclonal IgG 1
Injection	: 10 μL

Competitor WCX column 10 μm, 250 X 4.0 mmI.D.



The separation of MAb is compared on SCX (BioPro IEX SF) and WCX (competitor's) under the same gradient condition at pH 5.6. BioPro IEX SF column provides the higher resolution of MAb in shorter analysis time than the competitor column.

【Excellent Batch-to-Batch Reproducibility – Ideal for QC of MAb】



Column	: BioPro IEX SF 5 μm, 100 X 4.6 mmI.D.
Eluent	: A) 20 mM NaH ₂ PO ₄ -Na ₂ HPO ₄ (pH 6.5) B) 20 mM NaH ₂ PO ₄ -Na ₂ HPO ₄ (pH 6.5) containing 0.2 M NaCl
Flow rate	: 0.5 mL/min
Temperature	: 25°C
Detection	: UV at 215 nm
Injection	: 10 μL
Sample	: monoclonal antibody (IgG1)

BioPro IEX SF column exhibits excellent batch-to-batch reproducibility on MAb analysis, and even on resolution of peaks for small charge variants. All the gel batches are inspected by various quality control tests including HPLC analysis of MAb, and must pass rigorous criteria before release. BioPro IEX columns are the best choice for the quality control of MAb and other biopharmaceuticals.