

CoreFocus
Report
No.304

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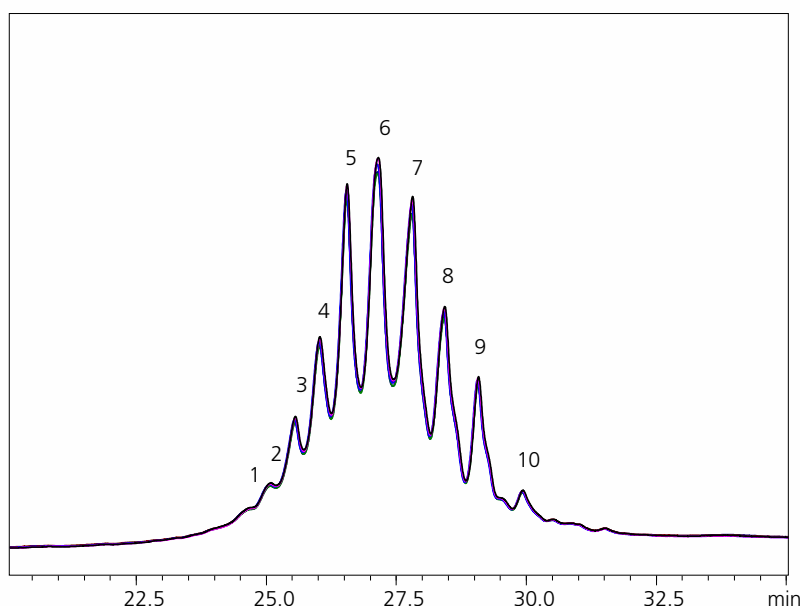
Ion Exchange (IEX)

Shim-pack Series

Shim-pack™ Bio IEX SP-NP

Analysis of Charge Variant of Monoclonal Antibody

Keywords: mAb, Cetuximab bio-similar



Peak No.	Retention time (min)	RSD* (%)
1	24.69	0.046
2	25.08	0.028
3	25.55	0.025
4	26.02	0.022
5	26.54	0.021
6	27.14	0.025
7	27.80	0.023
8	28.42	0.021
9	29.07	0.022
10	29.92	0.017

*Relative Standard Deviation, n=6

Sample.

Cetuximab bio-similar (for research use only)
2.5mg/mL

System : Nexera™ XS inert
Column : Shim-pack Bio IEX SP-NP (100 mm x 4.6 mm I.D., 3 μm), P/N: 227-31005-03
Mobile phase : A) 20 mmol/L MES*1-HEPES*2-Sodium Acetate (pH 5.0)
: B) 20 mmol/L MES-HEPES-Sodium Acetate (pH 10.6)
Time program : 0 %B(0 min) — 100%B (15-20 min) — 0 %B (20.1-30 min)
Flow rate : 0.3 mL/min
Column Temp. : 25 °C
Injection volume : 5 μL(6 times injection)
Detection : UV 280 nm
Vial : TORAST™-H glass vial, P/N: 370-04301-03

*1 MES:2-(N-morpholino)ethanesulfonic acid, *2 HEPES: 4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid

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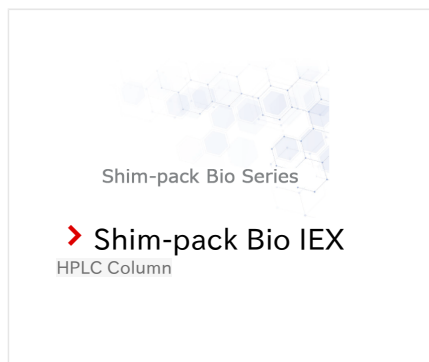
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