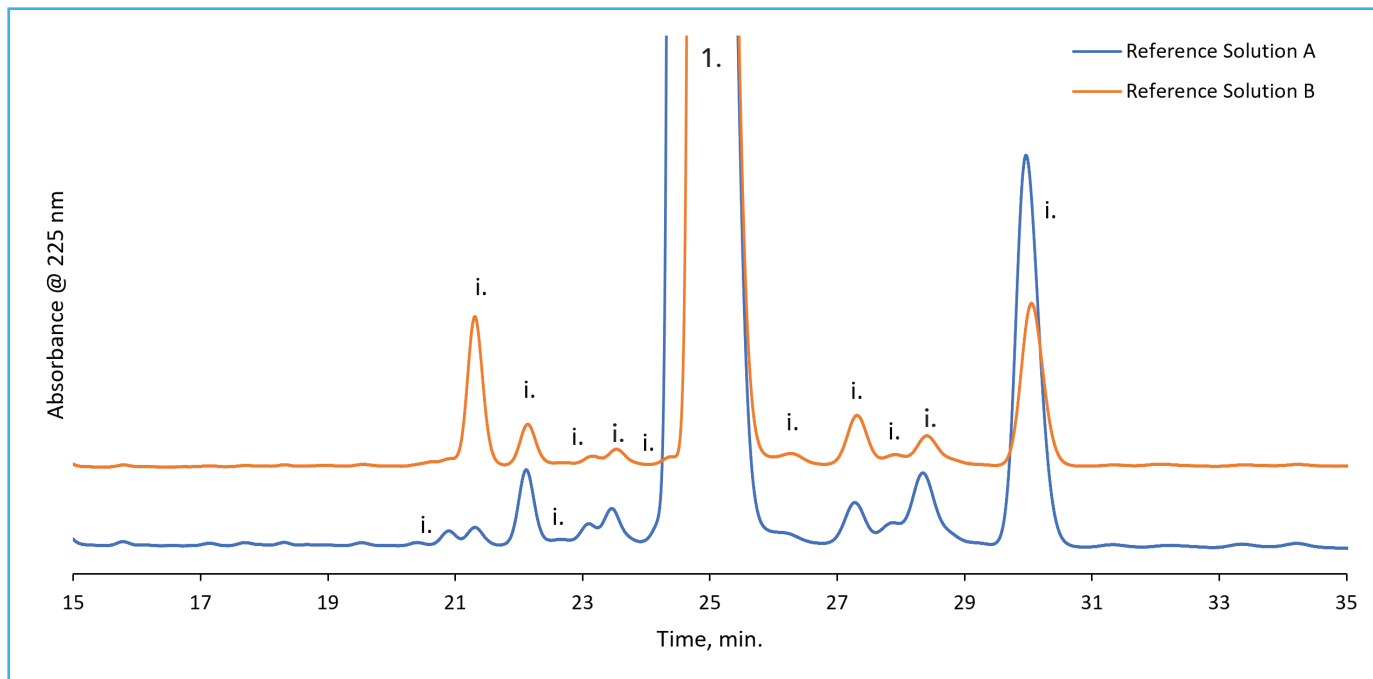




Daptomycin and Related Impurities

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TEST CONDITIONS:

Column 1: HALO 160 Å PCS-C18, 2.7 µm, 2.1 x 150 mm

Column 2: HALO 160 Å PCS-C18, 2.7 µm, 2.1 x 50 mm

-Columns 1/2 are coupled together

Part Number 1: 92112-717

Part Number 2: 92112-417

Mobile Phase A: ACN/ Solution A (30:70)

Mobile Phase B: Solution A/ ACN (30:70)

Solution A: dissolve 2.75 g potassium dihydrogen phosphate in 1000 mL water, adjust to pH 2.5 w/ phos. acid

Isocratic: 9 %B

Flow Rate: 0.15 mL/min.

Pressure: 185 bar

Temperature: 39 °C

Injection Volume: 3 µL

Detection: PDA, 225 nm

Sample Solvent: 35/65 ACN/ Water

LC System: Shimadzu Nexera X2

PEAK IDENTITIES

1. Daptomycin
- i:impurity

Daptomycin, a cyclic lipopeptide antibiotic, is analyzed by HPLC/UV using a 160 Å positive charge surface (PCS) stationary phase according to the EP 37.3 draft method. Degradation studies are performed by incubating two samples, reference solutions A and B, for 48 hours at 80 °C. Reference solution A is dissolved in the sample solution, while reference solution B is treated with sodium hydroxide, neutralized with mobile phase A, and diluted with the sample solvent. Columns are coupled to maximize chromatographic resolution.