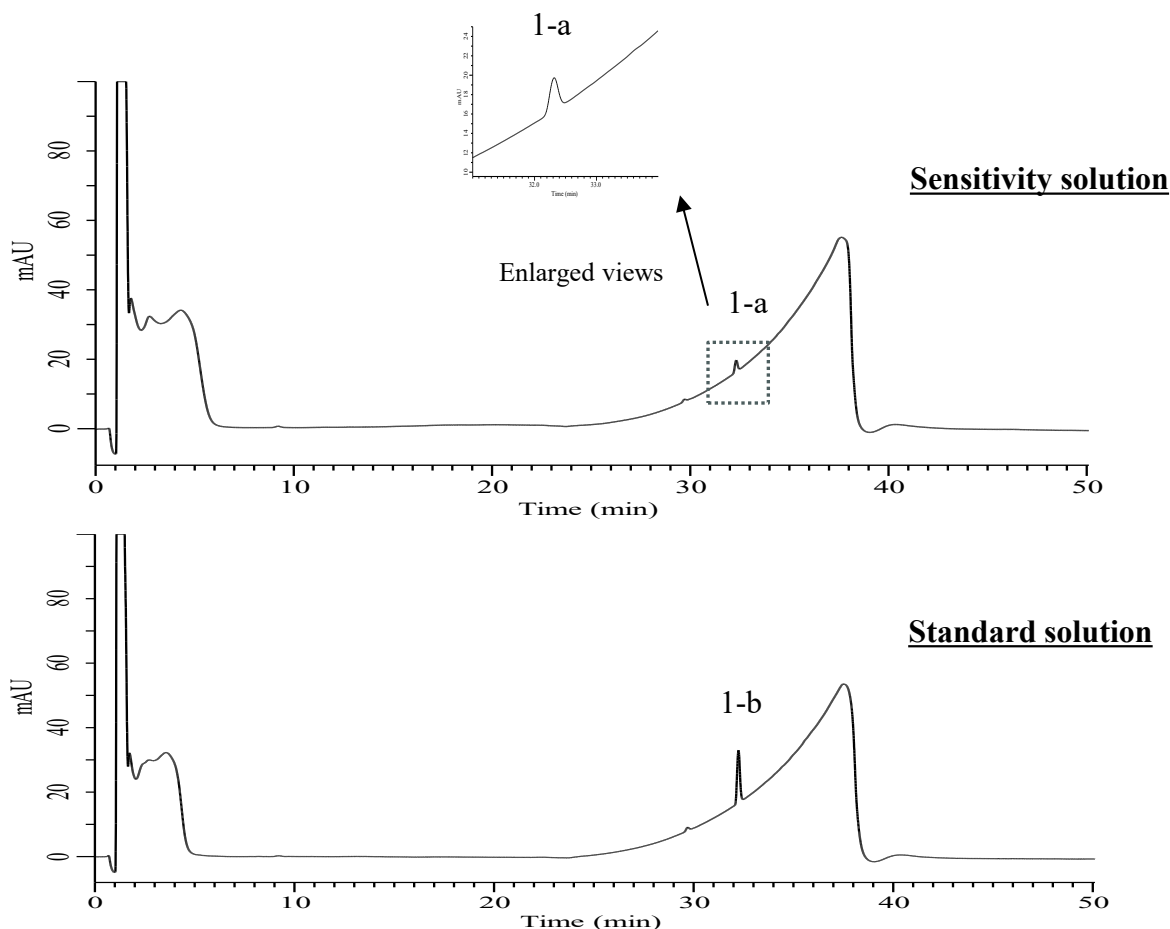


Analysis of Azithromycin

(Based on the Condition of USP NF 2025 Issue 2 Mar, Azithromycin Tablets,
ORGANIC IMPURITIES)



Conditions

System : Chromaster PLUS (HITACHI)
Column : Inertsil Hybrid-C18 (GL Sciences Inc.)
(3.5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-76042
Eluent : A) CH₃CN/CH₃OH/ammonium hydroxide
= 1800/200/1.2,v/v/v
B) H₂O/ammonium hydroxide
= 2000/1.2,v/v

Analyte:

1-a. Azithromycin 0.004 mg/mL
1-b. Azithromycin 0.02 mg/mL

Time (min)	A (vol %)	B (vol %)
0.0	46	54
20.0	46	54
35.0	90	10
35.1	46	54
50.1	46	54

Signal-to-noise ratio (1-a) : 77.3 (≥ 10)

RSD of the peak area(%)(n=6) (1-b) : 0.49 (≤ 2.0)

Flow Rate : 1.2 mL/min
Col. Temp. : 50 $^{\circ}$ C
Detection : UV 210 nm (Chromaster 5430 DAD)
Injection Vol. : 100 μ L
Sample : Standard