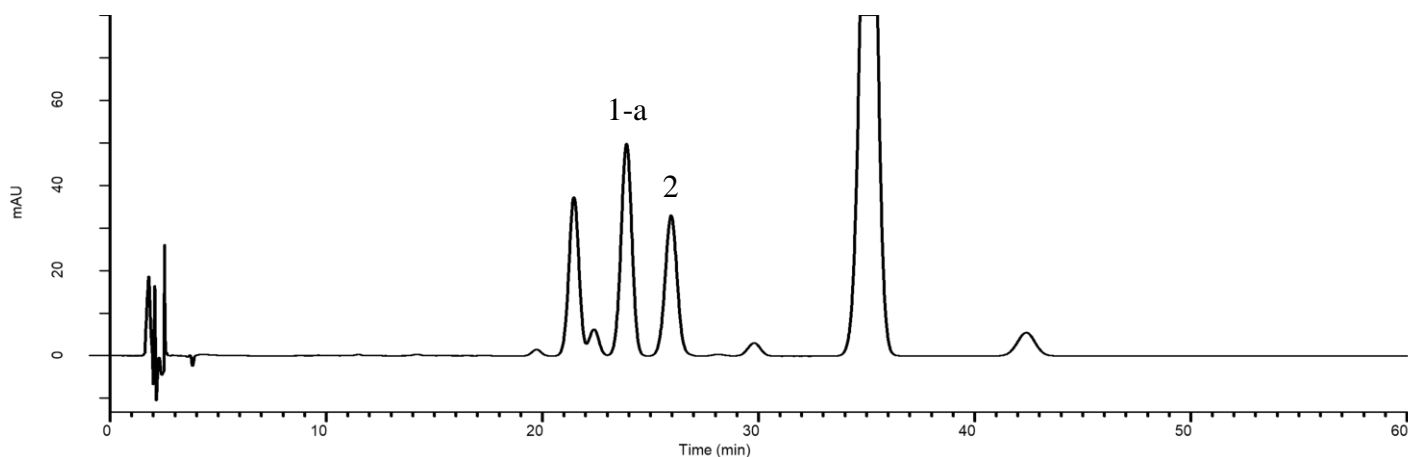


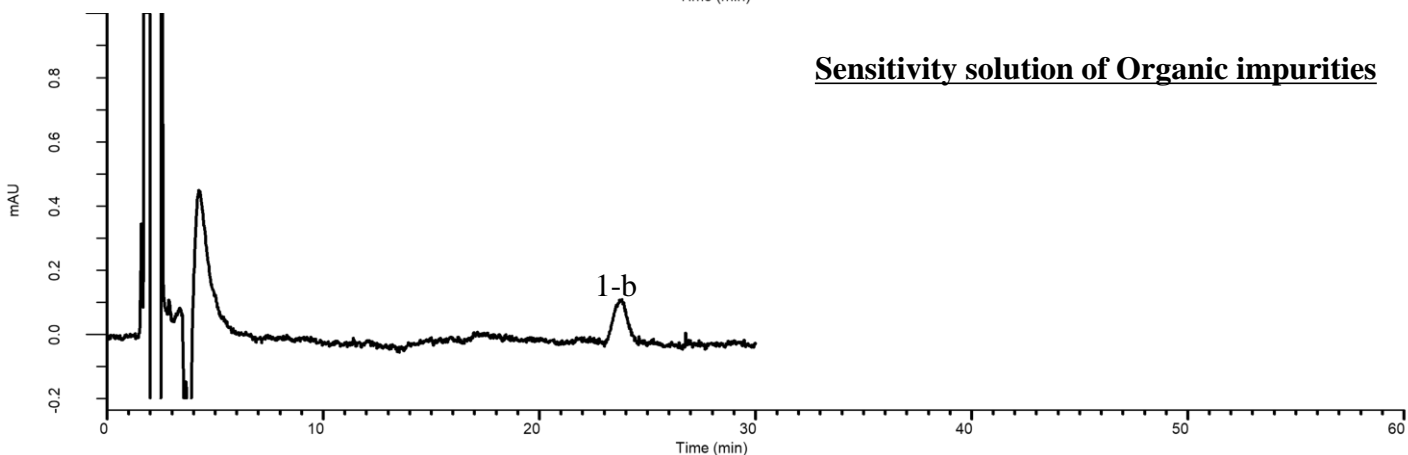
Analysis of Ezetimibe

(Under the Condition of USP41-NF36, Ezetimibe Tablets)

System suitability solution of Organic impurities



Sensitivity solution of Organic impurities



Conditions

System : GL7700 HPLC system
Column : InertSustainSwift C18 (5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-88026
Eluent : CH₃CN/THF/Buffer* = 25/10/65, v/v
Flow rate : 1.0 mL/min
Col. Temp. : 40 °C
Detection : UV 232 nm (PD7752 UV Detector)
Injection Vol. : 30 μ L
Sample : Standard

Analyte:

1. Ezetimibe
unknown(1-a) or 0.1 mg/L(1-b)
2. Unidentified peak 2

Resolution (1-a,2) : 2.08 (> 1.5)
 S/N for 1-b : 14 (> 10)

*6.8 g/L of Potassium dihydrogenphosphate Solution.