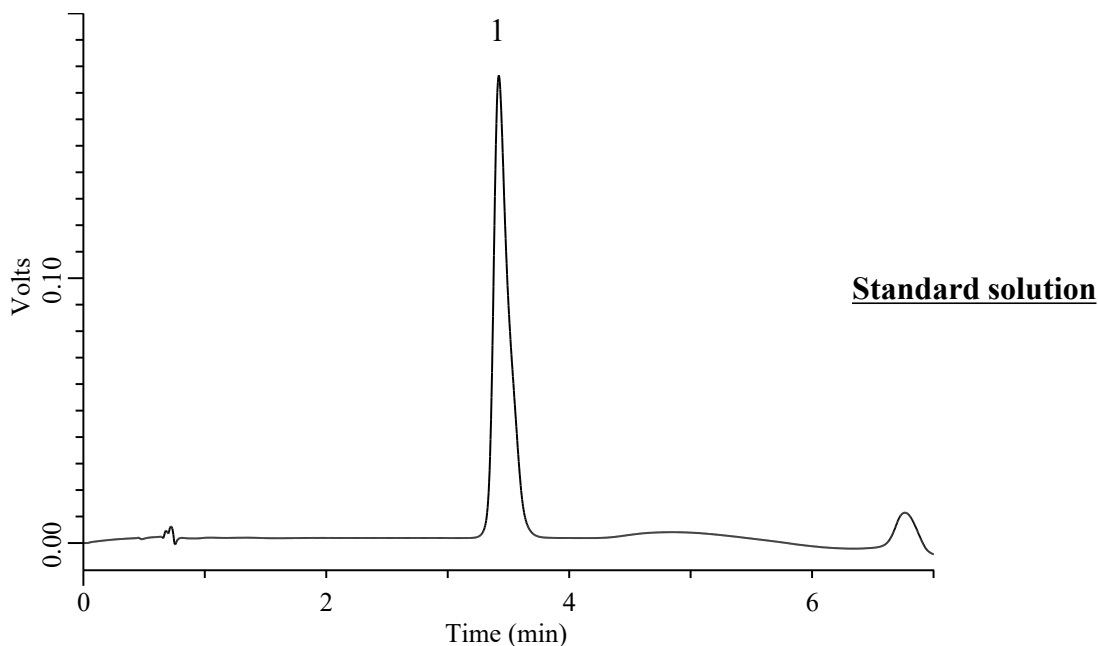


Analysis of Theophylline

(Under the Condition of USP-NF, Theophylline Extended-Release Capsules, Assay)



Conditions

System : Nexera-i HPLC system (Shimadzu)
Column : InertSustainSwift C8 (GL Sciences Inc.)
 (1.9 μ m, 100 x 2.1 mm I.D.)
Column Cat. No. : 5020-88534
Eluent : A) CH₃OH
 B) Buffer*

Time (min)	A (vol %)	B (vol %)
0.0	6.5	93.5
2.5	6.5	93.5
5.0	90.0	10.0
5.1	6.5	93.5
7.0	6.5	93.5

Flow Rate : 0.4 mL/min
Col. Temp. : 40 °C
Detection : UV 270 nm (PDA 210-400nm)
Injection Vol. : 1 μ L
Sample : Standard

Analyte:
 1. Theophylline 0.2 mg/mL

 Tailing factor : 1.57 ($\leq$ 2.0)
 RSD of the peak area (%)(n=6) : 0.22 ($\leq$ 1.0)

*: Transfer 0.77 g of ammonium acetate to a 1-L volumetric flask, and dissolve in 80% of the flask volume of water. Adjust with glacial acetic acid to a pH of 5.4 and dilute with water to volume.