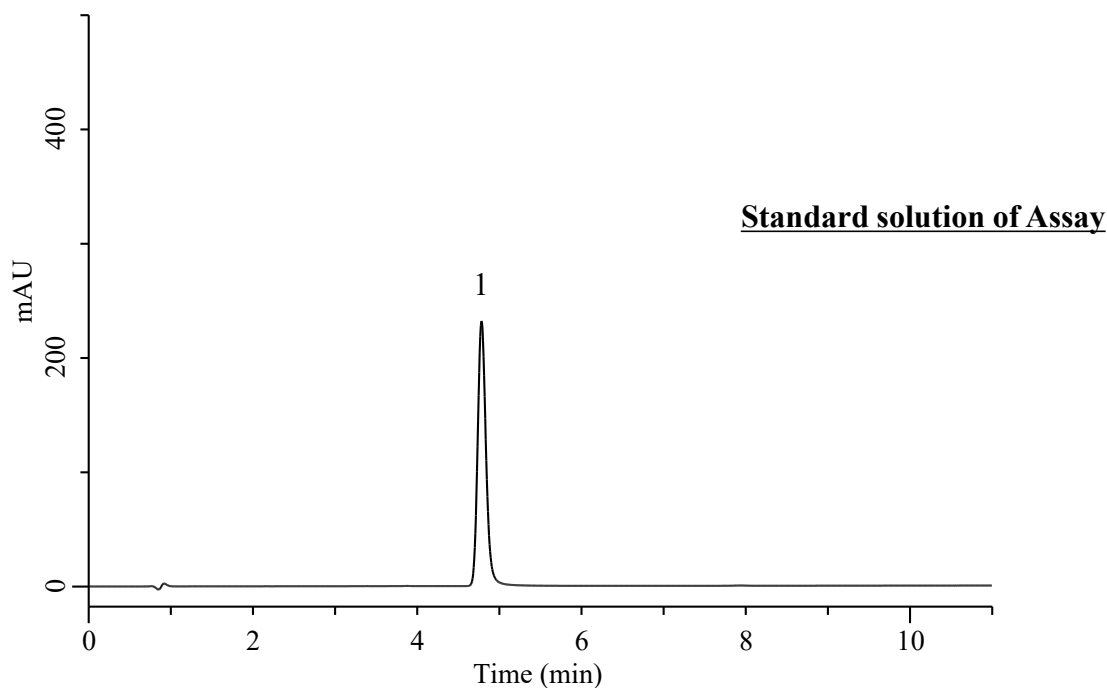


Analysis of Pitavastatin Calcium

(Under the Condition of the draft for USP, Pitavastatin Calcium)



Conditions

System : Primaide HPLC system (HITACHI)
Column : InertCore Plus C18 (GL Sciences Inc.)
 (2.6 μ m, 100 x 4.6 mm I.D.)
Column Cat. No. : 5020-17521
Eluent : A) CH₃CN
 B) Buffer*
 A/B = 35/65, v/v
Flow Rate : 1.0 mL/min
Col. Temp. : 40 °C
Detection : UV 245 nm (1430 DAD)
Injection Vol. : 10 μ L
Sample : Standard

Analyte:

1. Pitavastatin calcium 0.03 mg/mL

Tailing factor : 1.22 (0.8 – 1.8)

RSD of the peak area (%)(n=6) : 0.20 (\leq 0.73)

* : Dissolve 2.0 g of ammonium acetate in 1000 mL of water. Adjust with glacial acetic acid to a pH of 4.2.