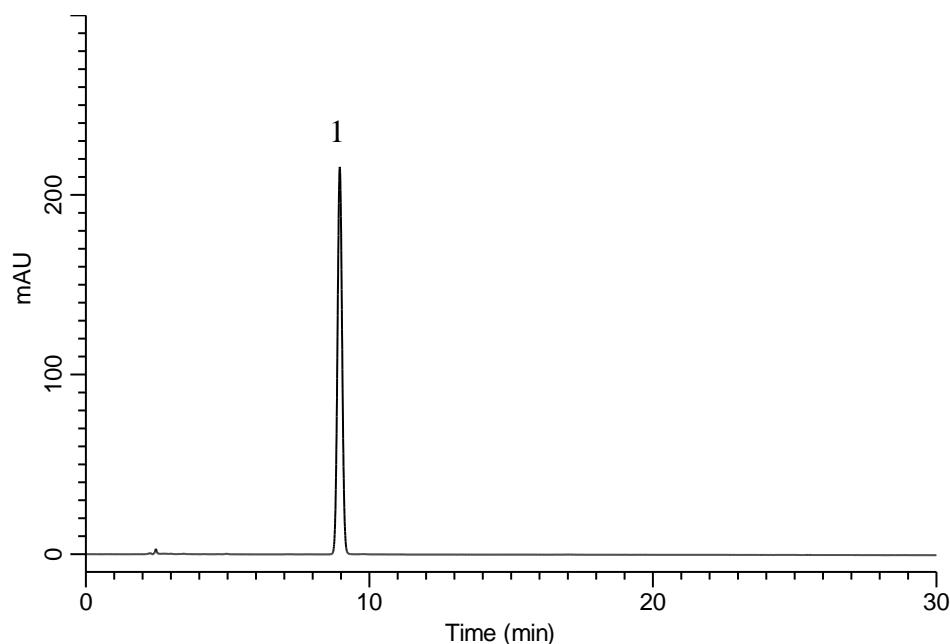


Analysis of Simvastatin

(Under the Condition of the Japanese Pharmacopoeia, Simvastatin Tablets)



Conditions

System : GL-7400 HPLC system
Column : Inertsil WP300 C18
 (5 μ m, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-05846
Eluent : A) CH₃CN
 B) Buffer*
 A/B = 65/35, v/v
Flow Rate : 1.2 mL/min
Col. Temp. : 45 °C
Detection : UV 238 nm (GL-7452 PDA Detector)
Injection Vol. : 10 μ L
Sample : Standard

Analyte:

1. Simvastatin 100 mg/L

 Theoretical plates : 13,936 (\geq 6,000)
 Tailing factor : (0.9 \leq) 1.03 (\leq 1.1)
 RSD of the
 peak area (%) (n=6) : 0.52 (\leq 1.0)

* Dissolve 3.90 g of Sodium dihydrogen phosphate dihydrate in 900 mL of water.
 Adjust pH 4.5 by phosphoric acid.
 Add water to make 1000 mL.