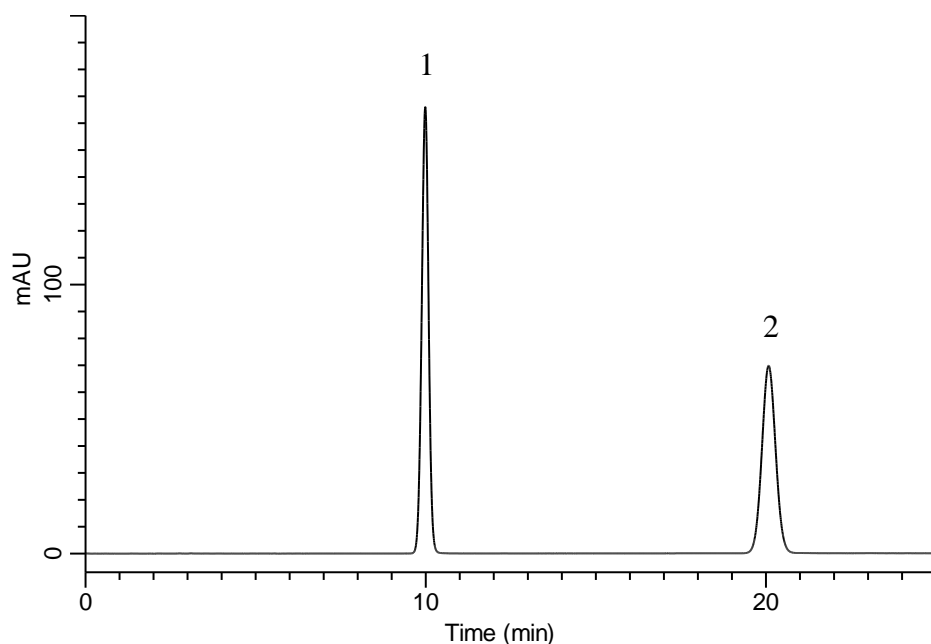


Analysis of Metformin hydrochloride

(Under the Condition of the Japanese Pharmacopoeia,
Metformin hydrochloride Tablets)



Conditions

System : GL-7400 HPLC system
Column : InertSustain C18
 (5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-07345
Eluent : A) CH₃CN
 B) Solution*
 A/B = 38/62, v/v
Flow Rate : 0.77 mL/min
Col. Temp. : 40 °C
Detection : UV 235 nm (GL-7452 PDA Detector)
Injection Vol. : 5 μ L
Sample : Standard

*Dissolve 1 mL of phosphoric acid in 2500 mL of water.
 Dissolve 0.8 g of sodium lauryl sulfate in 620 mL of this solution.

Analyte:

1. Metformin hydrochloride 90 mg/L
 2. *p*-Hydroxybenzoic acid iso-butyl ester 180 mg/L

Resolution (1, 2) : 18.1 (≥ 6)
 RSD of the peak
 area ratio of
 1 to 2 (%) (n=6) : 0.36 (≤ 1.0)