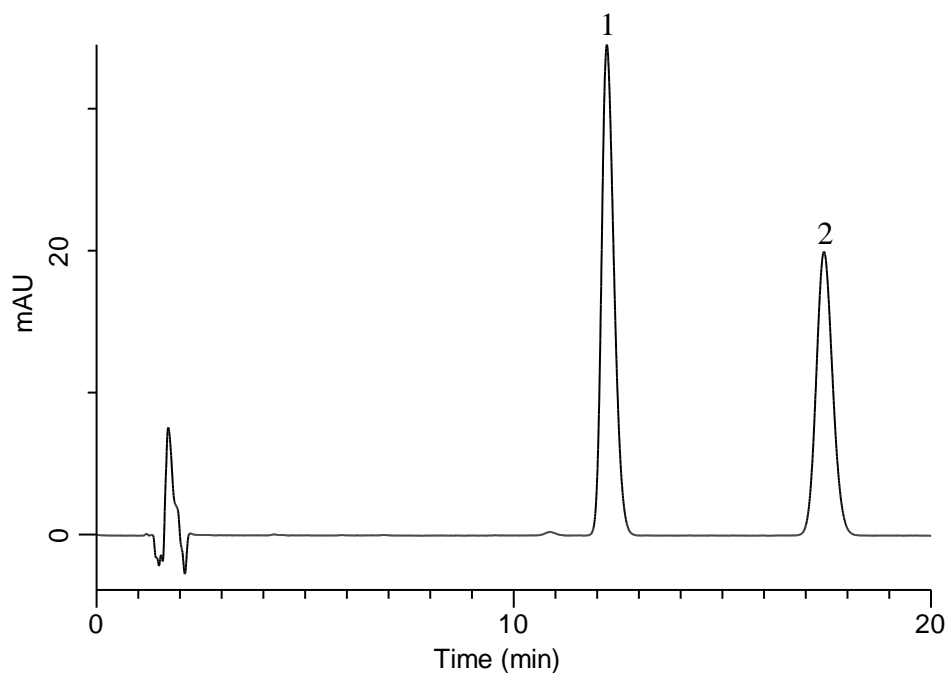


Analysis of Epalrestat

(Under the Condition of the Japanese Pharmacopoeia)



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) 0.05 mol/L KH₂PO₄ in H₂O
 (pH 6.5, 0.05 mol/L Na₂HPO₄ in H₂O)
 A/B = 1/2, v/v
Flow Rate : 1.0 mL/min
Col. Temp. : 25 °C
Detection : UV 280 nm (GL-7452 PDA Detector)
Injection Vol. : 3 μ L
Sample : Standard

Analyte:

1. Epalrestat 200 mg/L
 2. *p*-Hydroxybenzoic acid *n*-propyl ester 200 mg/L

Resolution (1, 2) : 8.31 (\geq 2.0)
 RSD of the peak
 area ratio of
 1 to 2 (%) (n=6) : 0.20 (\leq 1.0)