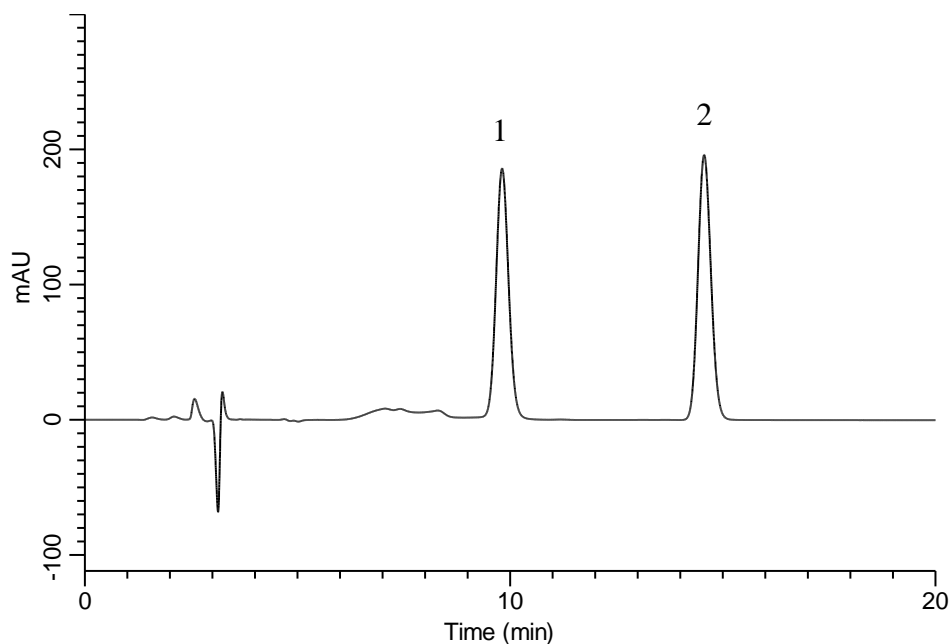


Analysis of Tacrolimus

(Under the Condition of the Japanese Pharmacopoeia, Tacrolimus Capsules)



Conditions

System : GL7700 HPLC system
Column : Inertsil ODS-2
 (5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-01124
Eluent : A) THF
 B) 2-Propanol
 C) H₂O
 A/B = 2/2/5, v/v/v
Flow Rate : 0.55 mL/min
Col. Temp. : 50 °C
Detection : UV 220 nm (UV7750 UV Detector)
Injection Vol. : 10 μ L
Sample : Standard

Analyte:

1. Tacrolimus	500 mg/L
2. <i>p</i> -Hydroxybenzoic acid heptyl ester	150 mg/L

Resolution (1, 2)	: 8.61 (\geq 6)
Theoretical plates (1)	: 5,288 (\geq 3,000)
Tailing factor (1)	: 1.08 (\leq 1.5)
RSD of the peak area ratio of 1 to 2 (%) (n=5)	: 0.16 (\leq 1.0)