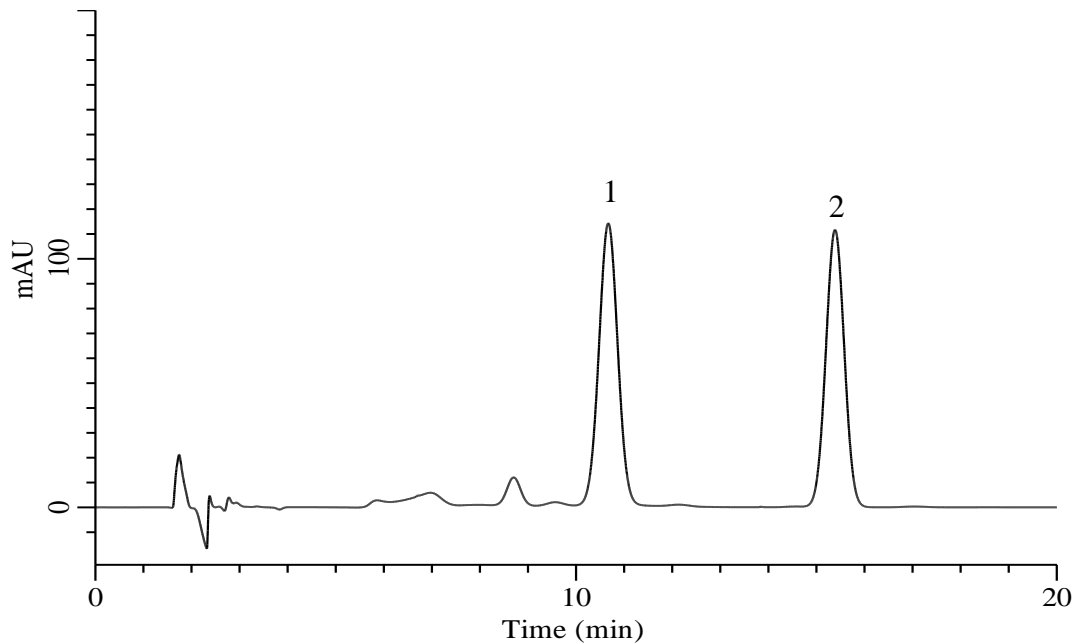


Analysis of Tacrolimus and Heptyl *p*-hydrobenzoate

(Under the Condition of draft for USP, Tacrolimus Extended-Release Capsules)



Conditions

System : Primaide HPLC system (HITACHI)
Column : InertSustain AQ-C18 (GL Sciences Inc.)
 (5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-89730
Eluent : A) THF
 B) 2-Propanol
 C) 100mL/L H₃PO₄ in H₂O
 D) H₂O
 A/B/C/D = 20/20/0.5/50, v/v/v/v
Flow Rate : 0.8 mL/min
Col. Temp. : 50 °C
Detection : UV 220 nm
Injection Vol. : 20 μ L
Sample : Standard

Analyte:

1. Tacrolimus	0.33 mg/mL
2. Heptyl <i>p</i> -hydroxybenzoate	0.1 mg/mL
Tailing factor of Tacrolimus	: 1.01 (\leq 1.5)
RSD of the peak response ratio of 1 to 2 (%)(n=6)	: 0.10 (\leq 1.0)