

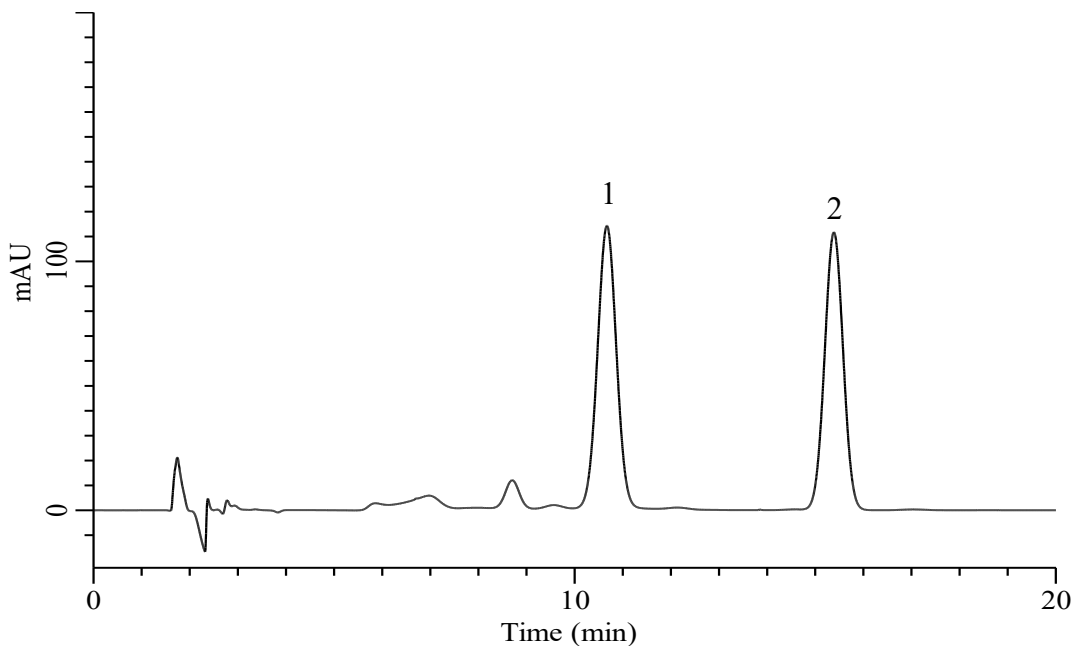
InertSearch™ for LC

Inertsil® Applications

Analysis of Tacrolimus and Heptyl *p*-hydrobenzoate

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

Data No. LB873-1138



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 *p*-hydroxybenzoate 0.1 mg/mL

Tailing factor of Tacrolimus : 1.01 (≤ 1.5)
RSD of the peak response ratio of 1 to 2
(%)(n=6) : 0.10 (≤ 1.0)