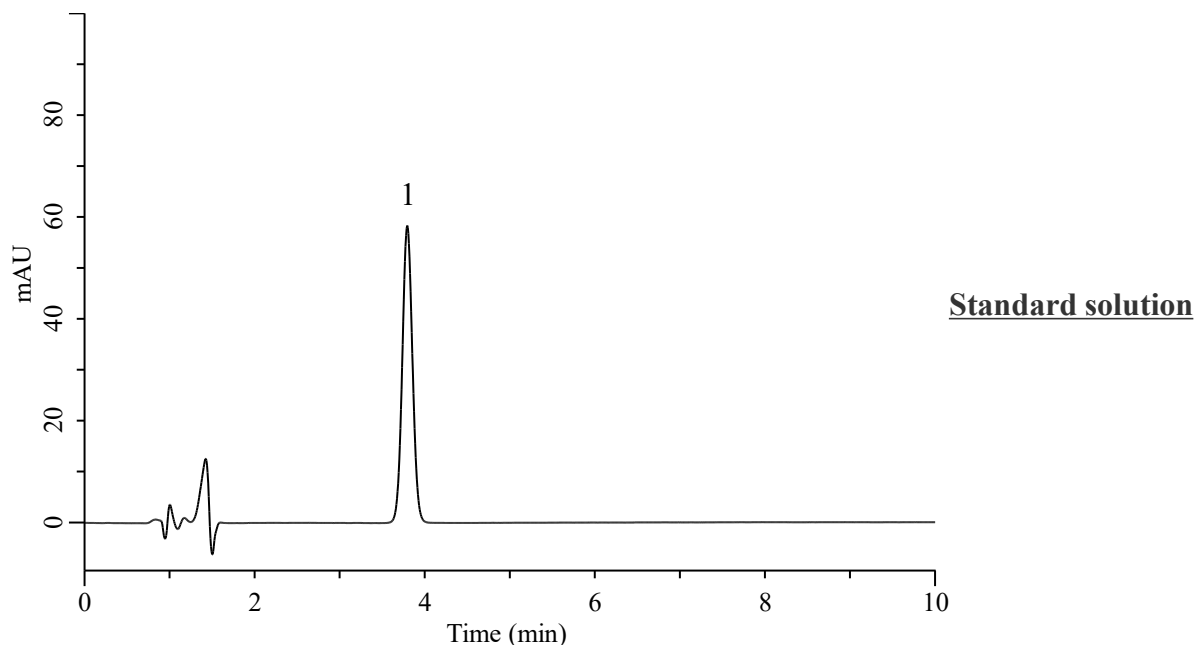


Analysis of Linagliptin

(Under the Condition of draft for USP PF52(3), Linagliptin Tablets, DISSOLUTION)

(Under the Condition of draft for USP PF52(3), Linagliptin and Metformin Hydrochloride Tablets, DISSOLUTION Linagliptin)



Conditions

System : Chromaster PLUS (HITACHI)
Column : Inertsil ODS-3 (GL Sciences Inc.)
 (5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020- 01731
Eluent : CH₃CN/Solution*=25/75, v/v
Flow Rate : 1.5 mL/min
Col. Temp. : 35 °C
Detection : UV 294 nm (Chromaster 5430 DAD)
Injection Vol. : 50 μ L
Sample : Standard

Analyte:
 1. Linagliptin 5.6 μ g/mL

RSD of
 the peak area (%)(n=6) : 0.07 ($\leq$ 2.0)

*: 0.5 mL/L of TFA in water