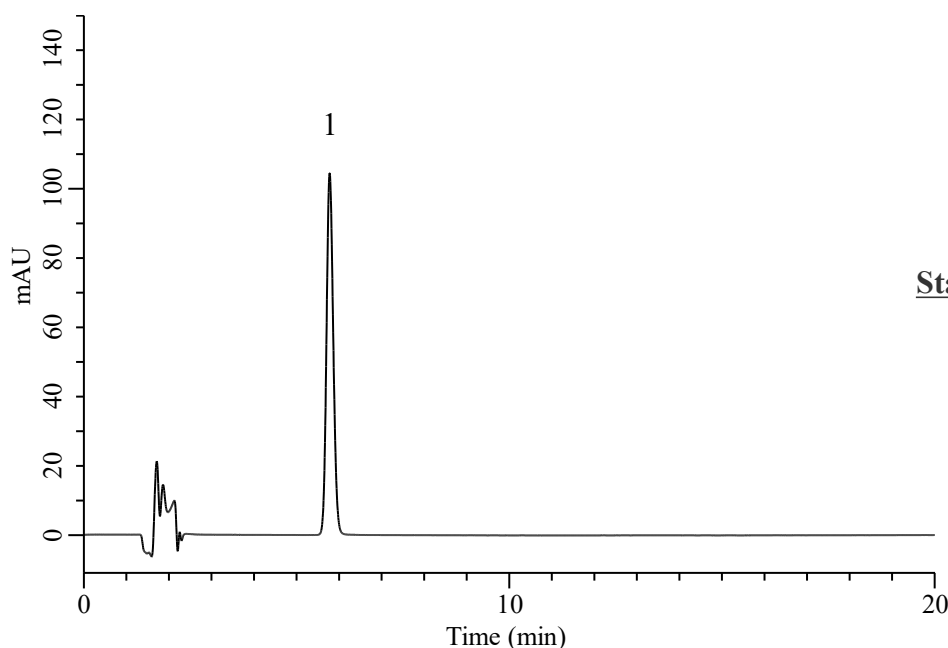


Analysis of Linagliptin

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

(Under the Condition of draft for USP PF52(3), Linagliptin and Metformin Hydrochloride Tablets, ASSAY 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 : 1.0 mL/min
Col. Temp. : 35 °C
Detection : UV 294 nm (Chromaster 5430 DAD)
Injection Vol. : 20 μ L
Sample : Standard in CH₃OH/H₂O = 50/50, v/v

Analyte:

1. Linagliptin 25 μ g/mL

Tailing factor : (0.8 $\leq$) 1.14 ($\leq$ 1.8)

RSD of
the peak area (%)(n=6) : 0.07 ($\leq$ 1.0)

*: 0.5 mL/L of TFA in water