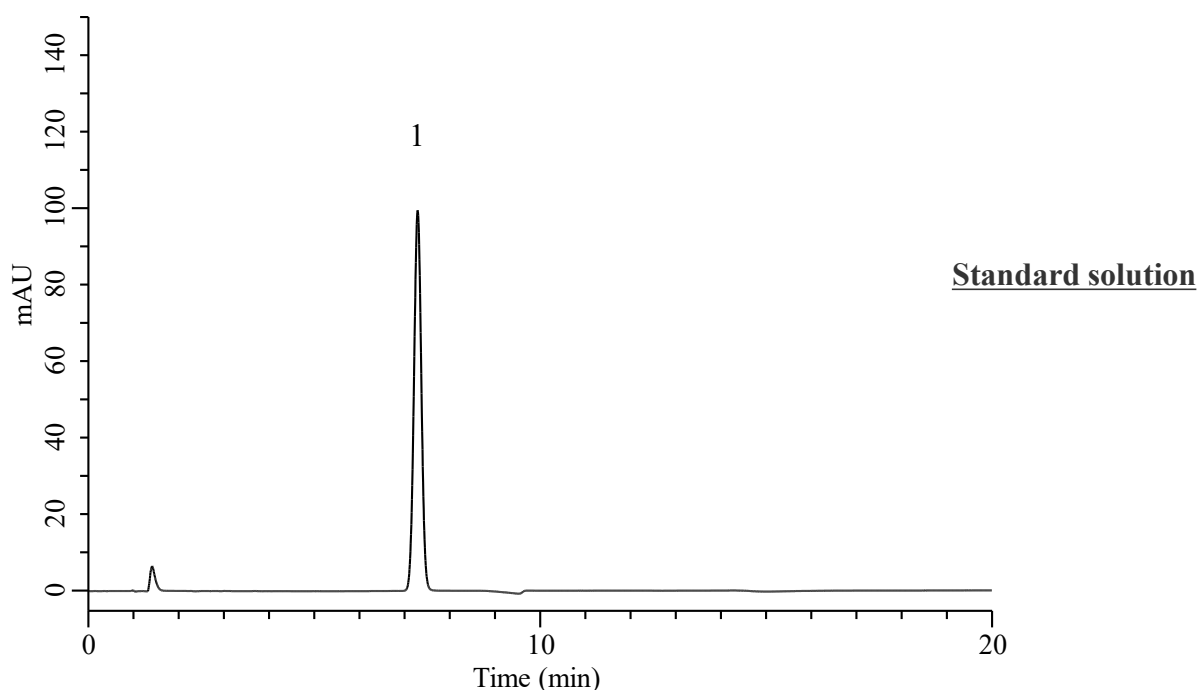


Analysis of Metformin hydrochloride

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



Conditions

System : Primaide (HITACHI)
Column : Inertsil ODS-3 (GL Sciences Inc.)
 (5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-01731
Eluent : Solution*
Flow Rate : 1.5 mL/min
Col. Temp. : 40 °C
Detection : UV 232 nm (Primaide 1435 DAD)
Injection Vol. : 10 μ L
Sample : Standard in CH₃OH/H₂O=50/50, v/v

Analyte:

1. Metformin hydrochloride 50 μ g/mL

Tailing factor : (0.8 $\leq$) 1.02 ($\leq$ 1.8)

RSD of
the peak area (%) (n=6) : 0.38 ($\leq$ 1.0)

* : 1.2 g/L of sodium chloride, 0.87 g/L of sodium 1-pentanesulfonate, anhydrous, 0.5 mL/L of triethylamine in water. Adjust with Solution** to a pH of 3.5.

** : Dilute 10 mL of phosphoric acid with water to 100mL.