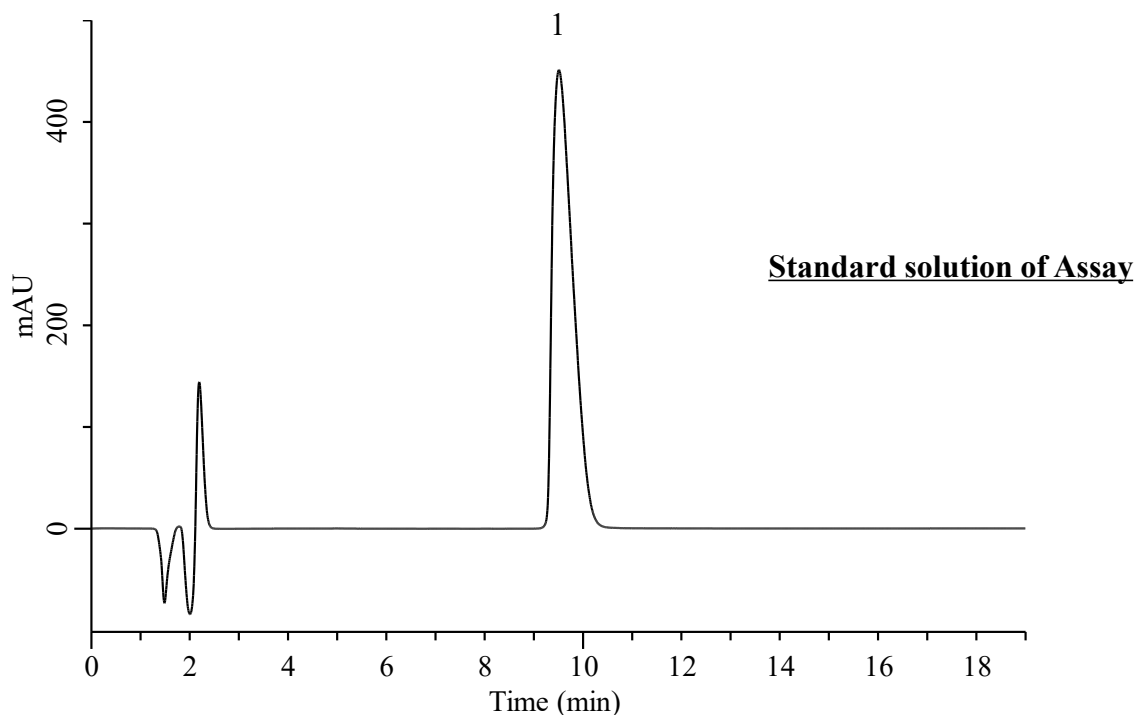


Analysis of Saxagliptin

(Under the Condition of the draft for USP, Saxagliptin and Metformin Hydrochloride Extended-Release Tablets)



Conditions

System : Chromaster HPLC system (HITACHI)
Column : InertSustain C18 (GL Sciences Inc.)
 (3.5 μ m, 150 x 3.0 mm I.D.)
Column Cat. No. : 5020-90559
Eluent : A) CH₃CN
 B) H₂O
 C) TFA
 A/B/C=150/850/1, v/v/v
Flow Rate : 0.7 mL/min
Col. Temp. : 35 °C
Detection : UV 215 nm (5430 DAD)
Injection Vol. : 10 μ L
Sample : Standard

Analyte:

1. Saxagliptin 0.5 mg/mL
 Tailing factor : 1.91 (\leq 2.5)
 RSD of the peak area %(n=6) : 0.49 (\leq 1.0)