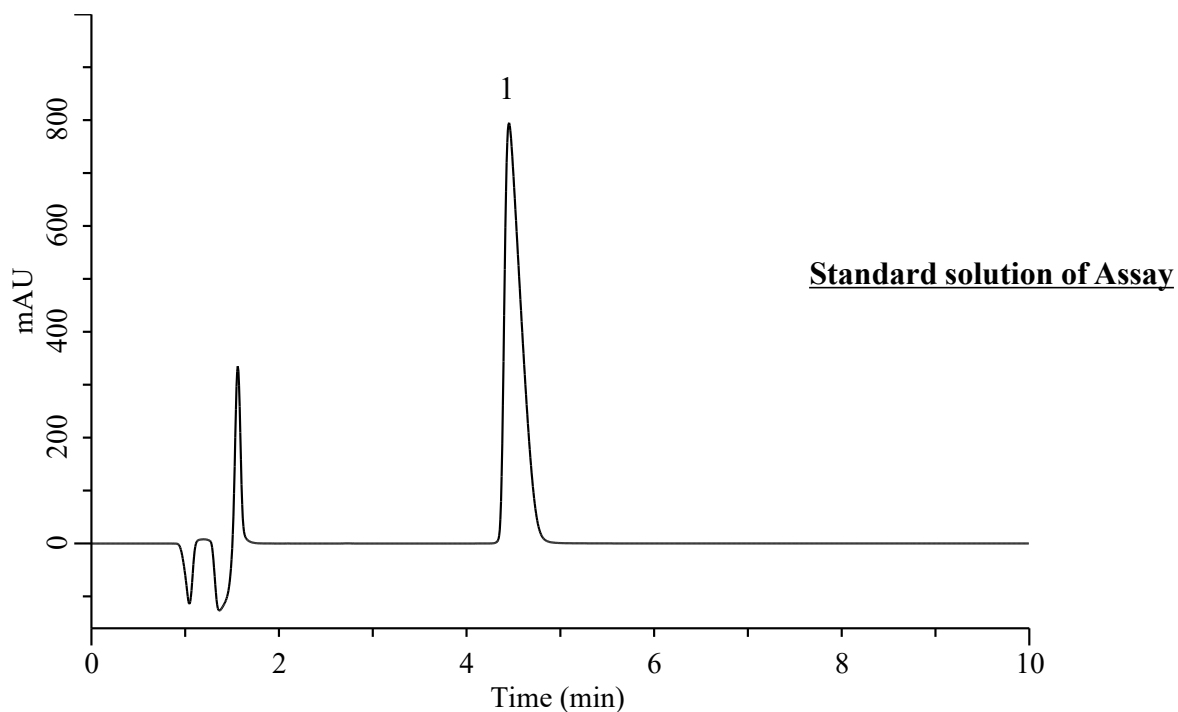


## Analysis of Saxagliptin

(Under the Condition of the draft for USP, Saxagliptin Tablets)



### Conditions

**System** : Chromaster HPLC system (HITACHI)

**Column** : InertSustain C18 (GL Sciences Inc.)  
(HP 3.5  $\mu$  m, 150 x 3.0 mm I.D.)

**Column Cat. No.** : 5020-90751

**Eluent** : A) CH<sub>3</sub>CN  
B) H<sub>2</sub>O  
C) TFA  
A/B/C=180/820/1, v/v/v

**Flow Rate** : 0.6 mL/min

**Col. Temp.** : 40 °C

**Detection** : UV 215 nm (5430 DAD)

**Injection Vol.** : 10  $\mu$  L

**Sample** : Standard

### Analyte:

1. Saxagliptin 0.5 mg/mL

Tailing factor : 2.13 ( $\leq$  2.5)

RSD of the peak area (%) (n=6) : 0.04 ( $\leq$  1.0)