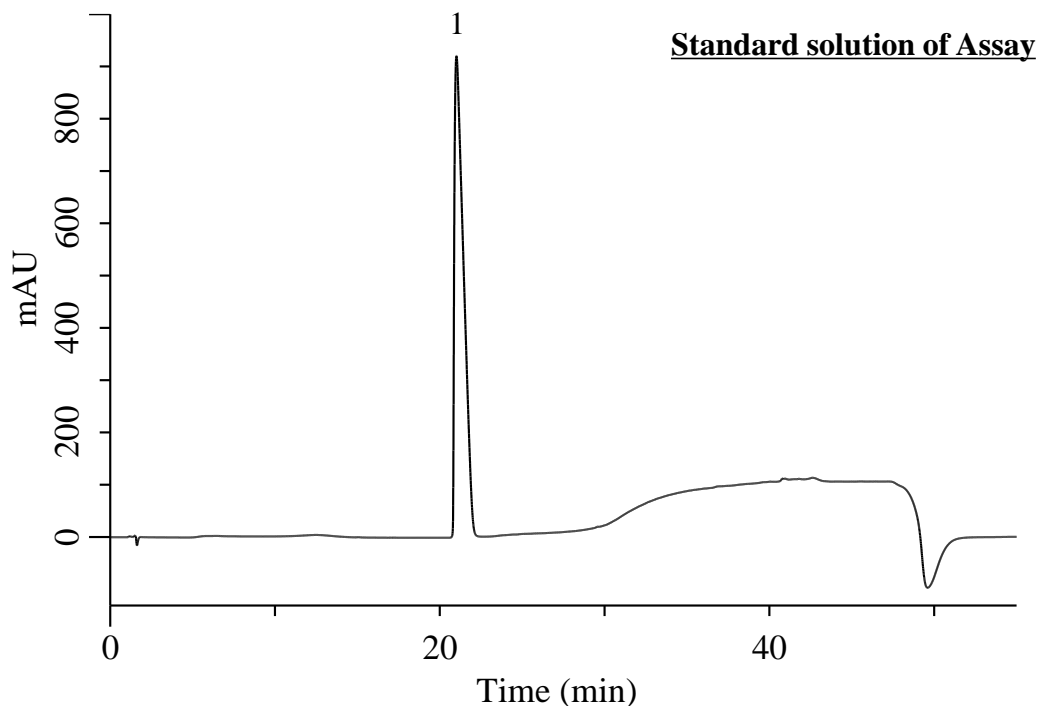


## Analysis of Saxagliptin

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



### 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>OH/H<sub>2</sub>O/TFA = 90/10/0.1, v/v/v  
 B) CH<sub>3</sub>OH/H<sub>2</sub>O/TFA = 10/90/0.1, v/v/v

### Analyte:

1. Saxagliptin 1.0 mg/mL

Tailing factor : 2.8 ( $\leq$  6)

RSD of the peak area (%) (n=6) : 0.442 ( $\leq$  0.73)

Time (min)	A (vol %)	B (vol %)
0	0	100
20	20	80
40	100	0
45	100	0
46	0	100
55	0	100

**Flow Rate** : 0.6 mL/min  
**Col. Temp.** : 40 °C  
**Detection** : UV 215 nm  
**Injection Vol.** : 15  $\mu$  L  
**Sample** : Standard