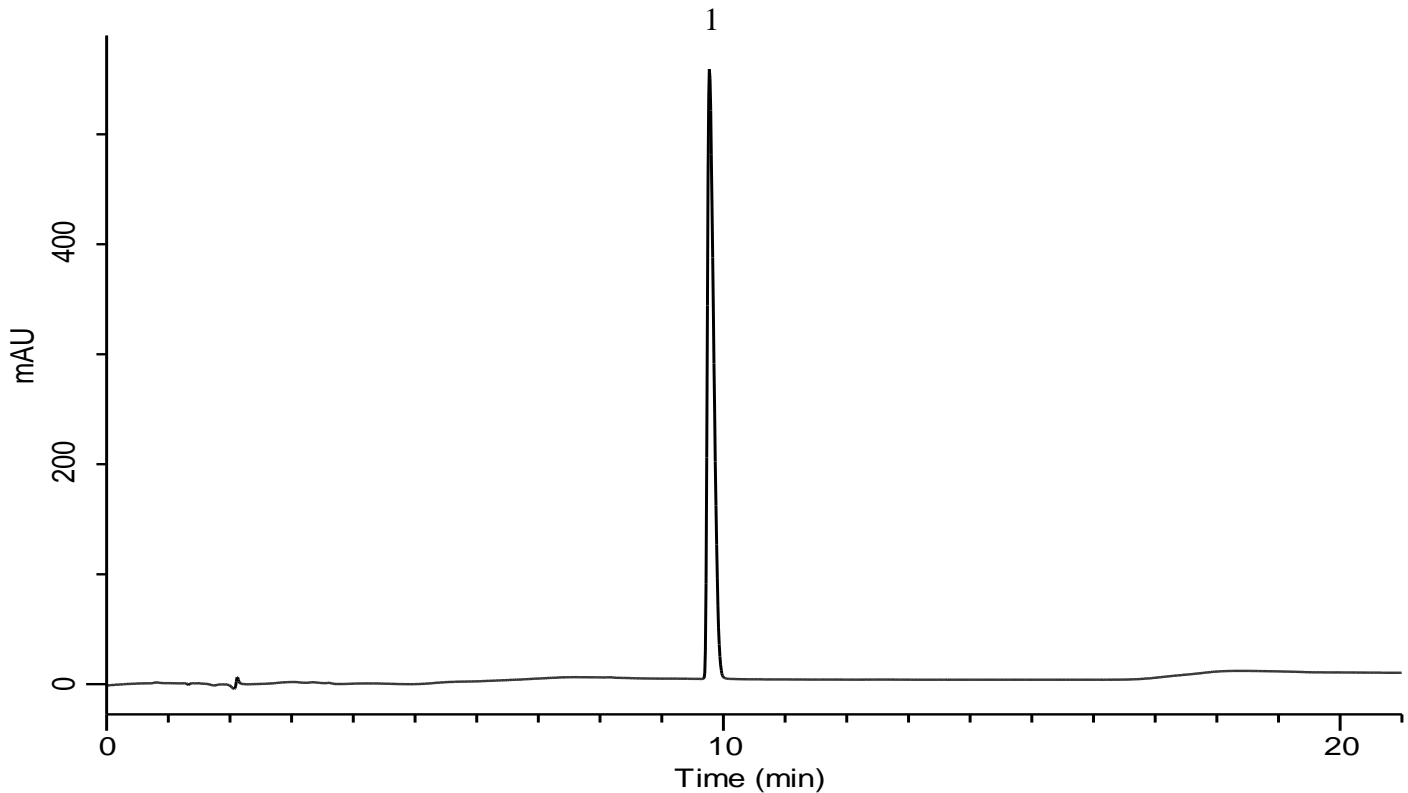


# Analysis of Sitagliptin

(Under the Condition of draft for USP, Sitagliptin and Metformin Hydrochloride Tablets)

## Standard solution of Assay, Procedure 1



### Conditions

**System** : GL7700 HPLC system  
**Column** : InertSustain C18 (3  $\mu$  m HP, 150 x 4.6 mm I.D.)  
**Column Cat. No.** : 5020-14445  
**Eluent** : A) CH<sub>3</sub>CN  
 B) CH<sub>3</sub>CN/Buffer\* = 5/95, v/v

### **Analyte:**

1. Sitagliptin 100 mg/L

Time(min)	A(vol%)	B(vol%)
0	13	87
2	13	87
21	47	53
21.01	13	87
25	13	87

Symmetry factor (1) : 1.78 (< 2.0)

RSD of the peak area of 1 (%) (n=6)

: 0.03 (< 2.0)

**Flow rate** : 1.0 mL/min  
**Col. Temp.** : 40 °C  
**Detection** : UV 205 nm (UV7750 UV Detector)  
**Injection Vol.** : 20  $\mu$  L  
**Sample** : Standard

\* 3.45 g/L of monobasic sodium phosphate (0.025 M). Adjust with phosphoric acid to a pH of 2.5.