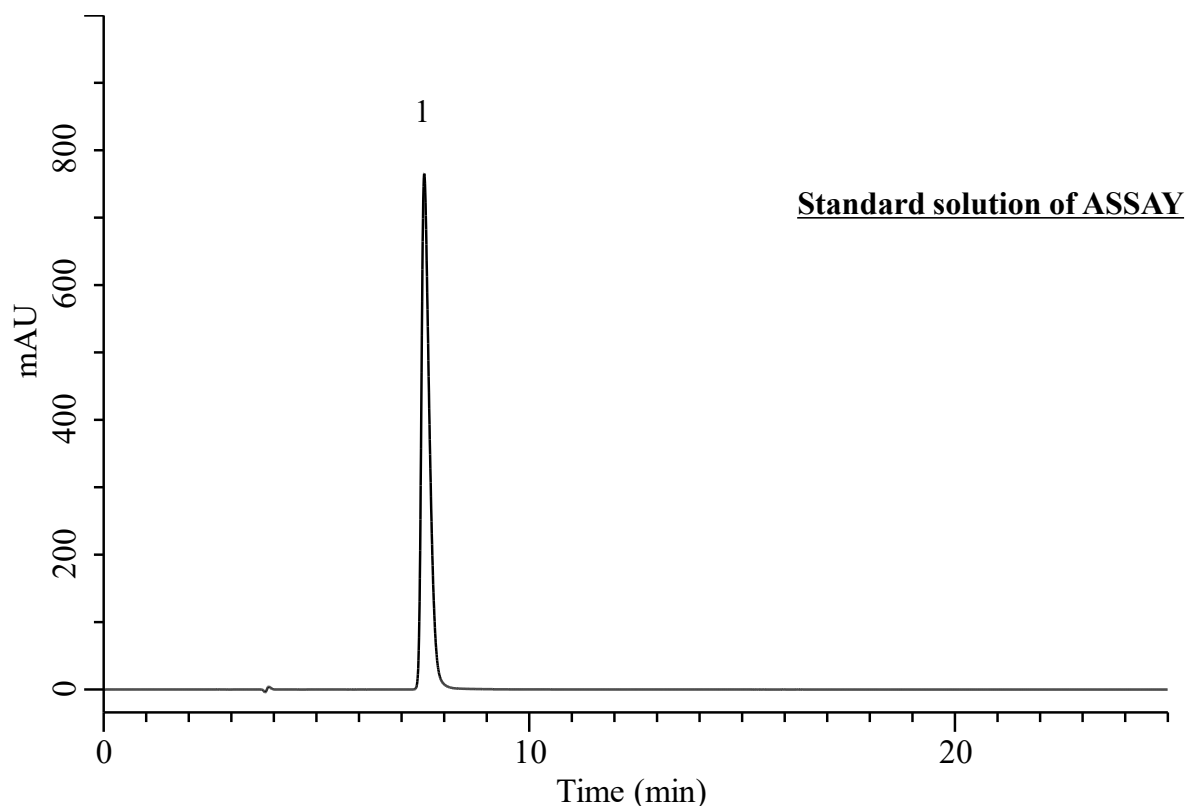


## Analysis of Metformin hydrochloride

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



### Conditions

**System** : Chromaster HPLC system (HITACHI)  
**Column** : Inertsil WP300 C18 (GL Sciences Inc.)  
 (10  $\mu$  m, 300 x 3.9 mm I.D.)  
**Column Cat. No.** : 5020-90660  
**Guard Column** : Guard Column Inertsil WP300 C18  
 (10  $\mu$  m, 20 x 3.9 mm I.D.)  
**Column Cat. No.** : 5020-  
**Eluent** : A) CH<sub>3</sub>CN  
 B) Buffer\*  
 A/B=10/90, v/v  
**Flow Rate** : 1.0 mL/min  
**Col. Temp.** : 30 °C  
**Detection** : UV 218 nm (5430 DAD)  
**Injection Vol.** : 10  $\mu$  L  
**Sample** : Standard

### Analyte:

1. Metformin hydrochloride 0.30 mg/mL

Tailing factor : 1.63 ( $\leq$  2.5)

RSD of the peak area (%) (n=6) : 0.25 ( $\leq$  1.0)

\*: Dissolve 0.5 g of sodium 1-heptanesulfonate and 0.5 g of sodium chloride in 1000 mL of water. Adjust with 0.4% (v/v) phosphoric acid to a pH of 3.85.