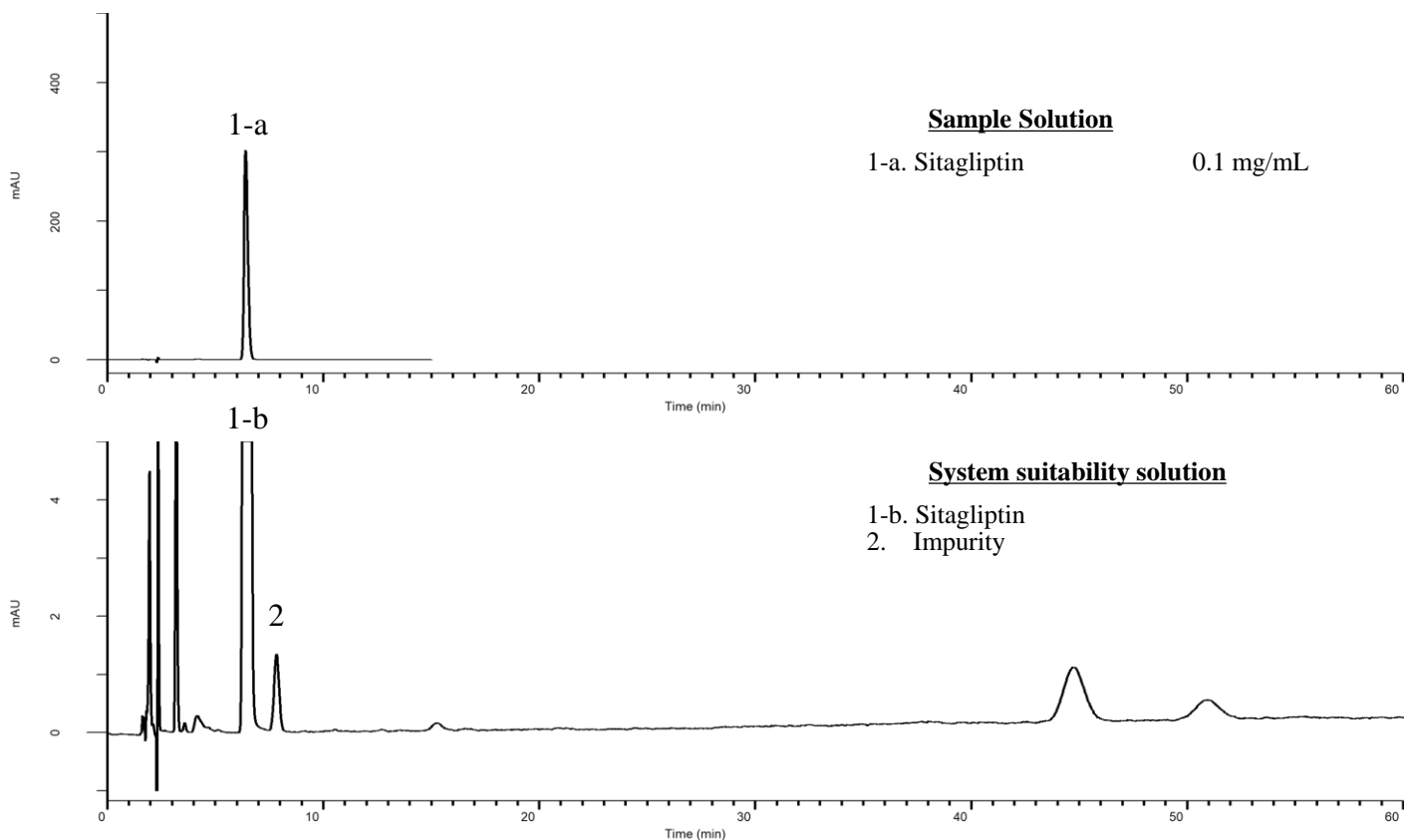


## Analysis of Sitagliptin

(Under the Condition of the draft for the Japanese Pharmacopoeia,  
Sitagliptin Phosphate Hydrate)



### Conditions

**System** : GL7700 HPLC system  
**Column** : InertSustain Cyano  
 (5  $\mu$  m, 150 x 4.6 mm I.D.)  
**Column Cat. No.** : 5020-89276  
**Eluent** : A) Buffer\*  
 B) CH<sub>3</sub>CN  
 A/B = 85/15, v/v  
**Flow Rate** : 1.0 mL/min  
**Col. Temp.** : 30 °C  
**Detection** : UV 205 nm (PD7752 PDA Detector)  
**Injection Vol.** : 20  $\mu$  L  
**Sample** : Standard

\*Dissolve 1.36 g of KH<sub>2</sub>PO<sub>4</sub> in 900 mL of water.  
 Adjust pH 2.0 by phosphoric acid.  
 Add water to make 1,000 mL.

### Analyte:

1. Sitagliptin

Resolution (1-b, 2) : 3.76 ( $\geq$  1.5)

Relative retention time (2 to 1-b) : 1.22 (about 1.2)

### 【NOTE】

When using a brand new column,  
 fully equilibrate with the eluent at 1 mL/min  
 for at least 24 hours prior to the analysis.