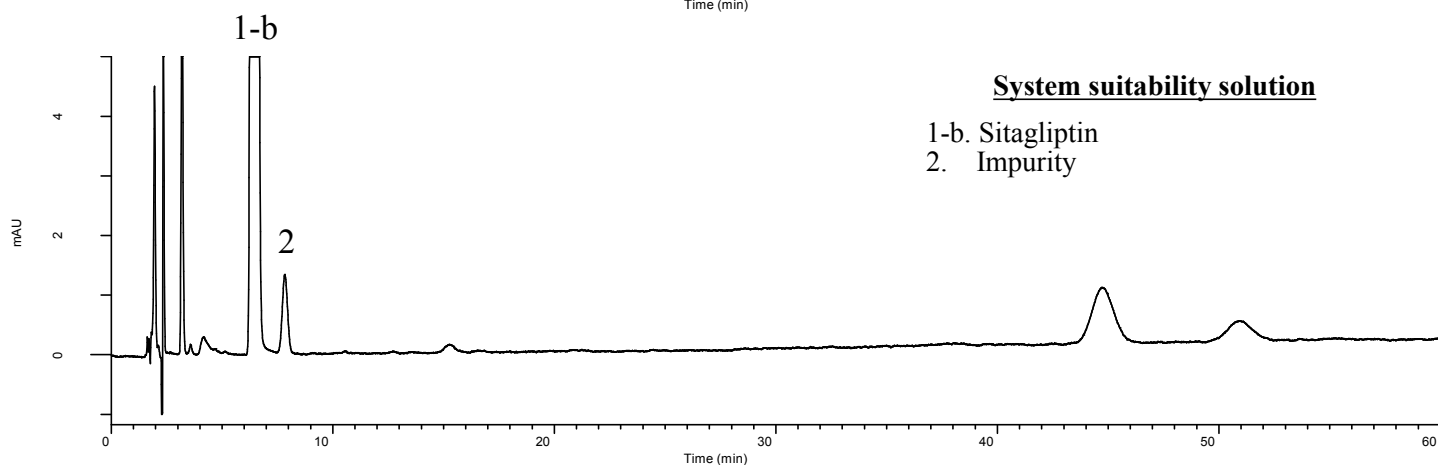
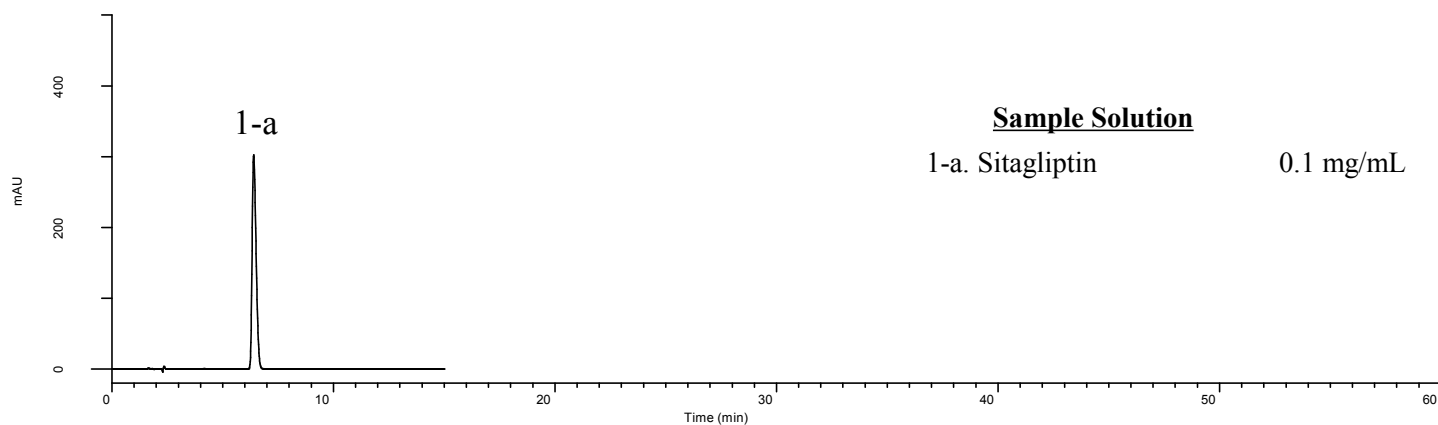


Analysis of Sitagliptin

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

Data No. LB508-0894



Conditions

System : GL7700 HPLC system
Column : InertSustain Cyano
(5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-89276
Eluent : A) Buffer*
B) CH₃CN
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 μ L
Sample : Standard

*Dissolve 1.36 g of KH₂PO₄ 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.