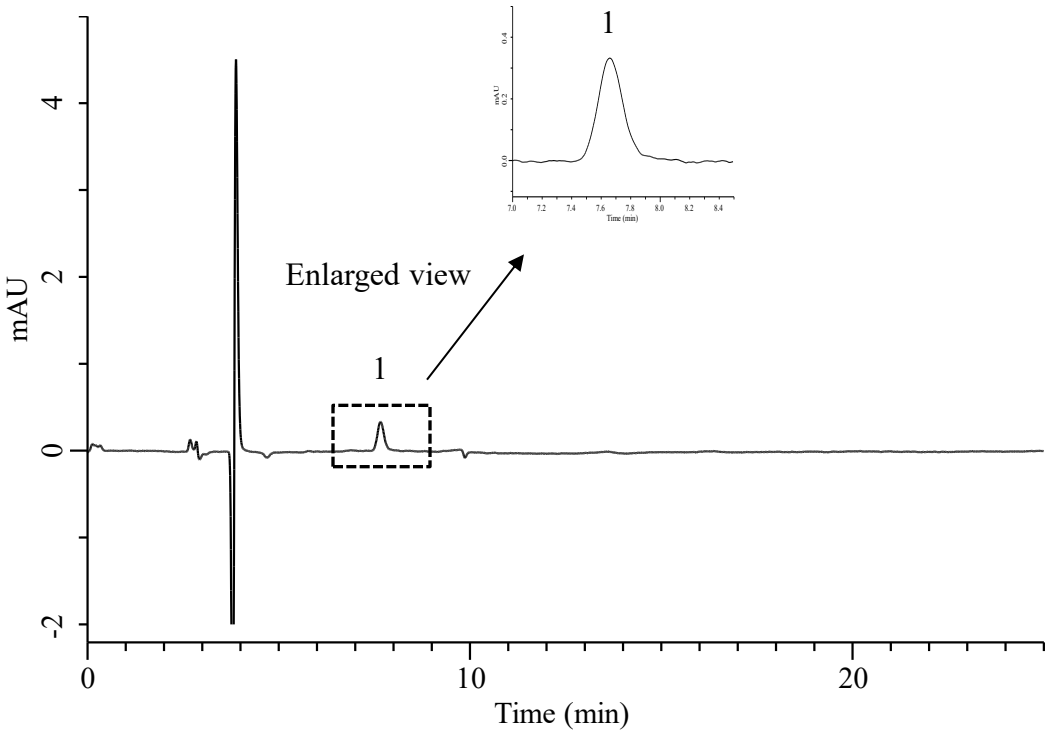
Analysis of Metformin hydrochloride

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

Sensitivity solution of ORGANIC IMPURITIES



Conditions

System	:	Chromaster HPLC system (HITACHI)
Column	:	Inertsil WP300 C18 (GL Sciences Inc.) (10 μ m, 300 x 3.9 mm I.D.)
Column Cat. No.	:	5020-90660
Gurd Column	:	Guard Column Inertsil WP300 C18 (10 μ m, 20 x 3.9 mm I.D.)
Column Cat. No.	:	5020-
Eluent	:	A) CH_3CN B) Buffer* A/B=10/90, v/v
Flow Rate	:	1.0 mL/min
Col. Temp.	:	30 ℃
Detection	:	UV 218 nm (5430 DAD)
Injection Vol.	:	10 μ L
Sample	:	Standard

Analyte:

1. Metformin hydrochloride 0.15 mg/mL

Signal-to-noise ratio : 20.0 (≧ 10)

*: 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.