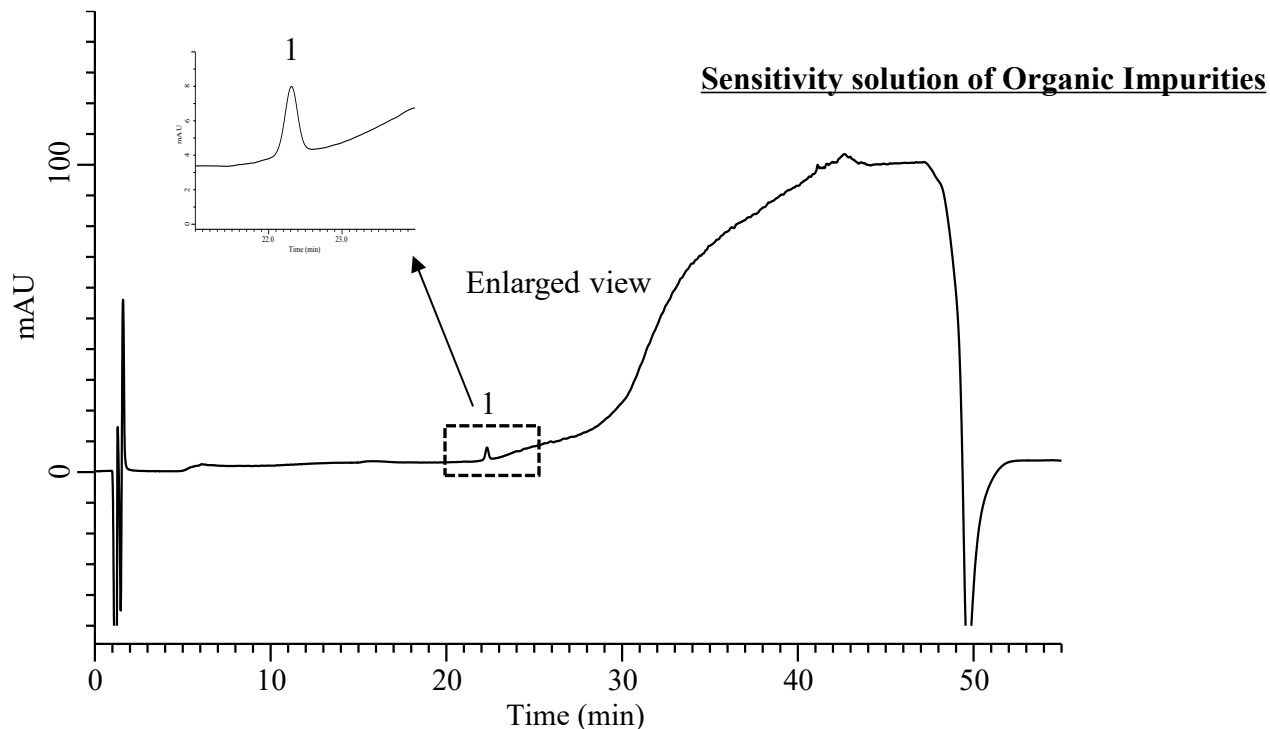


Analysis of Saxagliptin

(Under the Condition of the draft for USP, Saxagliptin Tablets)



Conditions

System : Chromaster HPLC system (HITACHI)
Column : InertSustain C18 (GL Sciences Inc.)
 (HP 3.5 μ m, 150 x 3.0 mm I.D.)
Column Cat. No. : 5020-90751
Eluent : A) CH₃OH/H₂O/TFA = 90/10/0.08, v/v/v
 B) CH₃OH/H₂O/TFA = 10/90/0.08, v/v/v

Analyte:
 1. Saxagliptin 0.5 μ g/mL

| Time (min) | A (vol %) | B (vol %) |
|------------|-----------|-----------|
| 0 | 0 | 100 |
| 20 | 20 | 80 |
| 40 | 100 | 0 |
| 45 | 100 | 0 |
| 46 | 0 | 100 |
| 55 | 0 | 100 |

Signal-to-noise ratio : 36.6 (\geq 10)

Flow Rate : 0.6 mL/min
Autosampler : 5 °C
Col. Temp. : 40 °C
Detection : UV 215 nm (5430 DAD)
Injection Vol. : 60 μ L
Sample : Standard