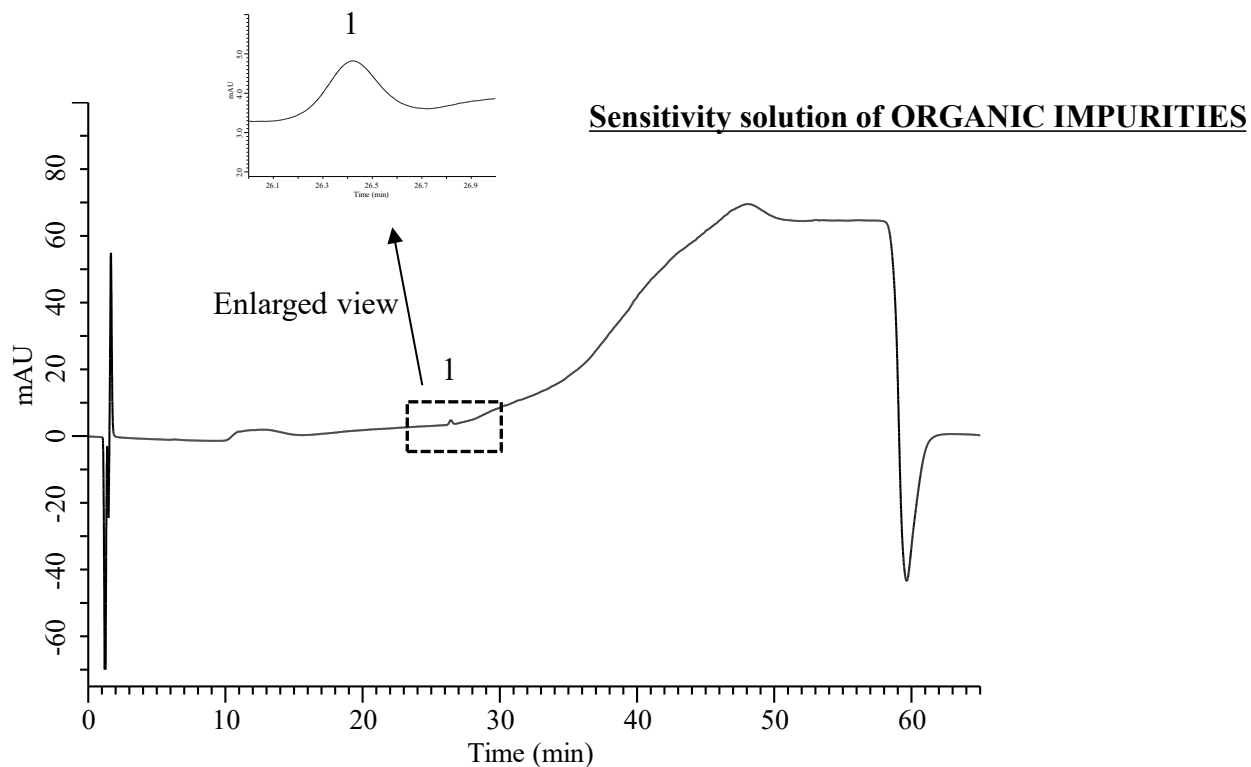


Analysis of Saxagliptin

(Under the Condition of the draft for USP, Saxagliptin and Metformin Hydrochloride Extended-Release 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 = 90/10/0.1, v/v/v
 B) CH₃OH/H₂O/TFA = 10/90/0.1, v/v/v

Analyte:
 1. Saxagliptin 0.5 μ g/mL

Signal-to-noise ratio : 18.2 (\geq 10)

Time (min)	A (vol %)	B (vol %)
0	0	100
5	0	100
25	20	80
45	70	30
55	70	30
56	0	100
65	0	100

Flow Rate : 0.6 mL/min
Col. Temp. : 40 °C
Detection : UV 215 nm
Injection Vol. : 20 μ L
Sample : Standard