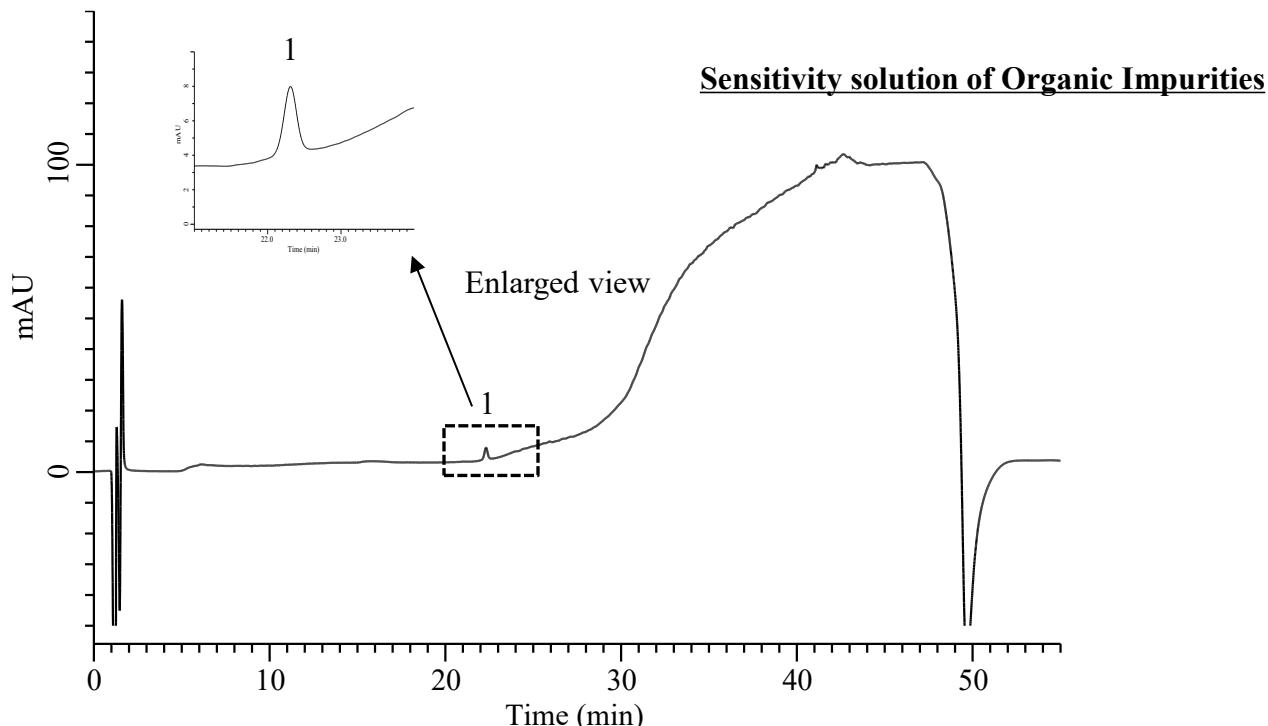


Analysis of Saxagliptin

(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 (≥ 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