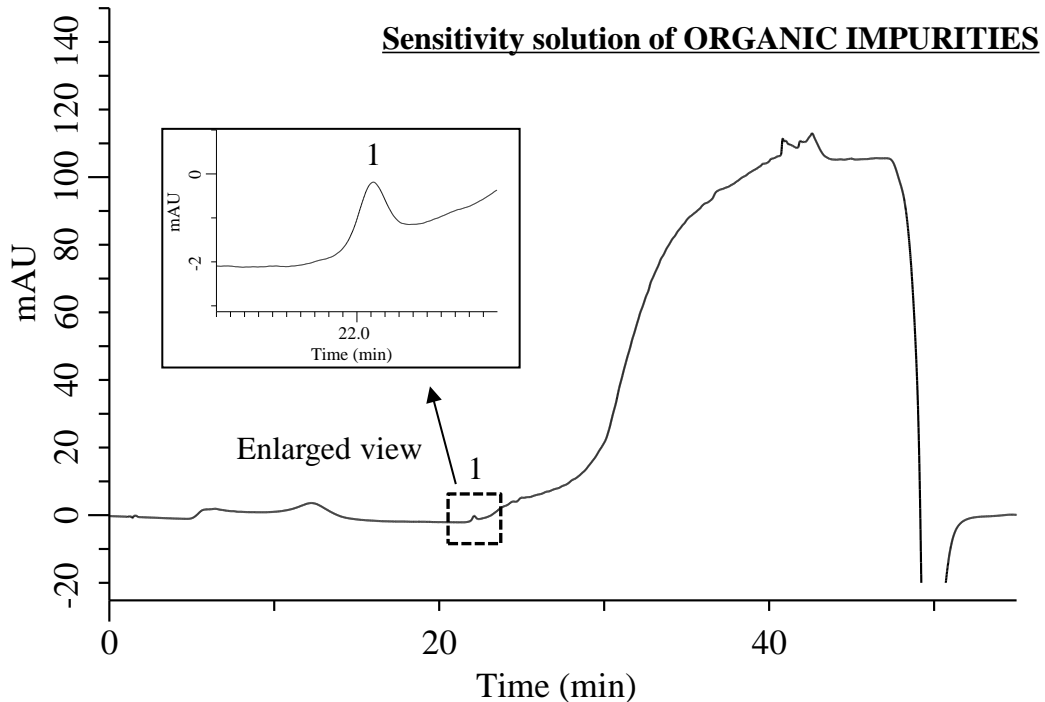


## Analysis of Saxagliptin

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



### Conditions

**System** : Chromaster HPLC system (HITACHI)

**Column** : InertSustain C18 (GL Sciences Inc.)  
(HP 3.5  $\mu$  m, 150 x 3.0 mm I.D.)

**Column Cat. No.** : 5020-90751

**Eluent** : A) CH<sub>3</sub>OH/H<sub>2</sub>O/TFA = 90/10/0.1, v/v/v  
B) CH<sub>3</sub>OH/H<sub>2</sub>O/TFA = 10/90/0.1, v/v/v

**Analyte:**

1. Saxagliptin 0.0005 mg/mL

Signal-to-noise ratio : 24.9 ( $\geq 10$ )

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

**Flow Rate** : 0.6 mL/min

**Col. Temp.** : 40 °C

**Detection** : UV 215 nm

**Injection Vol.** : 15  $\mu$  L

**Sample** : Standard