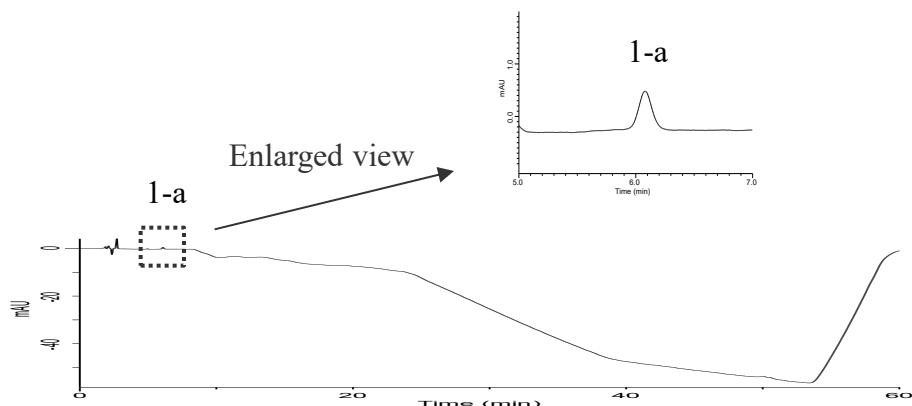
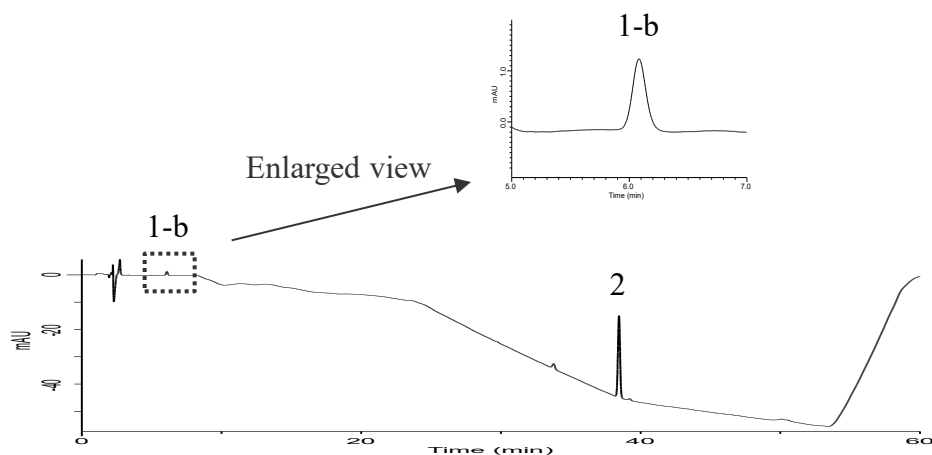


Analysis of Pregabalin

(Under the Condition of draft for USP PF52(4), Pregabalin Capsules, ORGANIC IMPURITIES)



Sensitivity solution



Standard solution

Conditions

System : Primaide (HITACHI)
Column : InertSustainSwift C18 (GL Sciences Inc.)
 (5 μ m, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-88027
Eluent : A) CH_3CN
 B) $\text{CH}_3\text{CN}/\text{Buffer}^*=3/97$, v/v

Time (min)	A (vol %)	B (vol %)
0.0	0	100
20.0	4	96
35.0	20	80
50.0	25	75
55.0	0	100
60.0	0	100

Flow Rate : 1.5 mL/min
Autosampler : 20 $^{\circ}\text{C}$
Col. Temp. : 40 $^{\circ}\text{C}$
Detection : UV 205 nm (Primaide 1410 UV)
Injection Vol. : 50 μL
Sample : Standard

Analyte:

1-a. (S)-Pregabalin 6 $\mu\text{g/mL}$
 1-b. (S)-Pregabalin 12 $\mu\text{g/mL}$
 2. 4-Isobutyl-2-pyrrolidinone 12 $\mu\text{g/mL}$

Signal-to-noise ratio (1-a) : 11.15 (≥ 10)

RSD of
 the peak area(%) (1-b)(n=6) : 0.94 (≤ 10.0)

the peak area(%) (2)(n=6) : 0.11 (≤ 10.0)

* : Dissolve 5.6 g of ammonium phosphate, dibasic in 1000 mL of water. Adjust with phosphoric acid to a pH of 6.5.