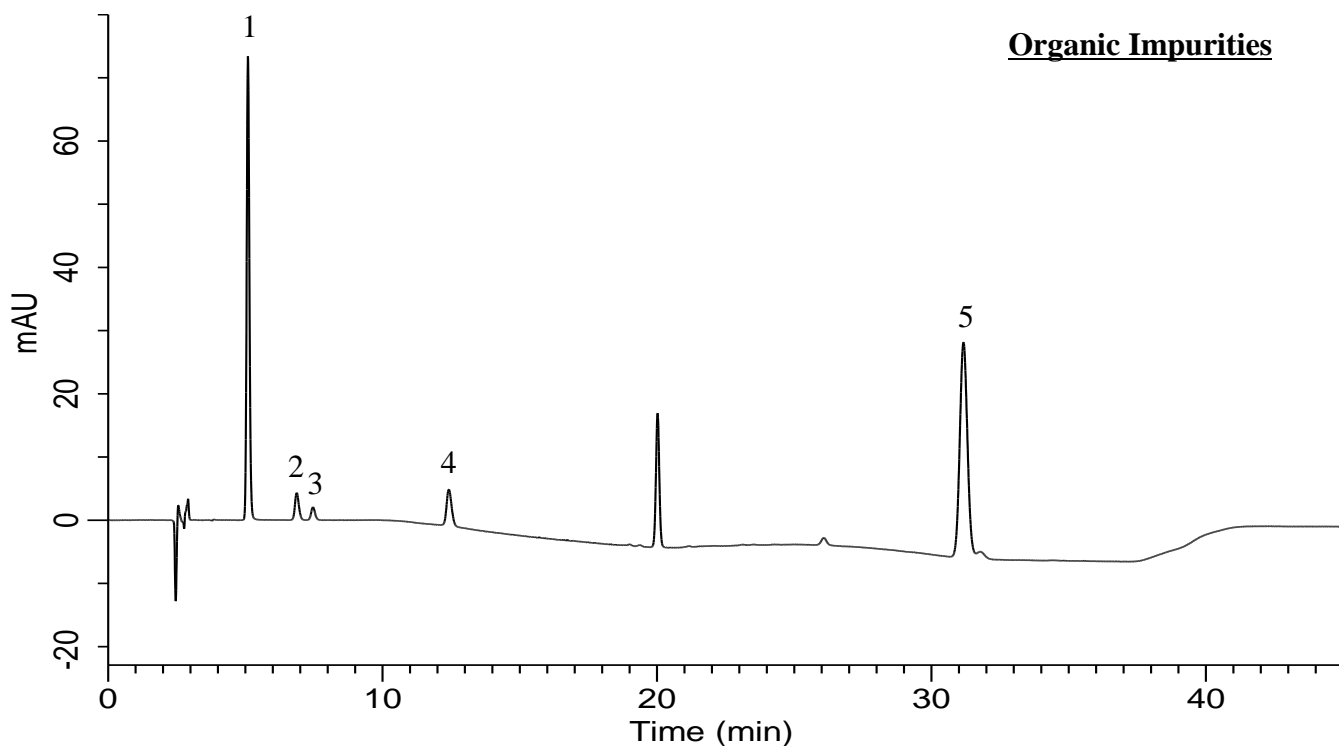


Analysis of Pregabalin

(Under the Condition of USP41-NF36, Pregabalin)



Conditions

Column : Inertsil ODS-3 (5 μ m, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-01732
Eluent : A) CH₃OH/Buffer* = 20/80
 B) CH₃OH/CH₃CN = 10/90

Time(min)	Solution A(%)	Solution B(%)
0	98	2
5	98	2
16	20	80
33	20	80
34	98	2
45	98	2

Flow rate : 1.0 mL/min
Col. Temp. : 35 °C
Detection : UV 210 nm (UV7750 UV Detector)
Injection Vol. : 20 μ L
Sample : Standard

* 0.04 M dibasic ammonium phosphate.
 Adjust with phosphoric acid to a pH of 6.5.

Analyte:

- | | |
|---|---------|
| 1. Mandelic acid | 10 mg/L |
| 2. 3-Isobutylglutaric acid | |
| 3. Pregabalin | 50 mg/L |
| 4. 3-(2-Amino-2-oxoethyl)-5-methylhexanoic acid | |
| 5. 4-Isobutylpyrrolidin-2-one | 50 mg/L |

RSD of the peak area of 1 (%) (n=6) : 0.08(<5)

RSD of the peak area of 3 (%) (n=6) : 0.68(<5)

RSD of the peak area of 5 (%) (n=6) : 0.16(<5)