

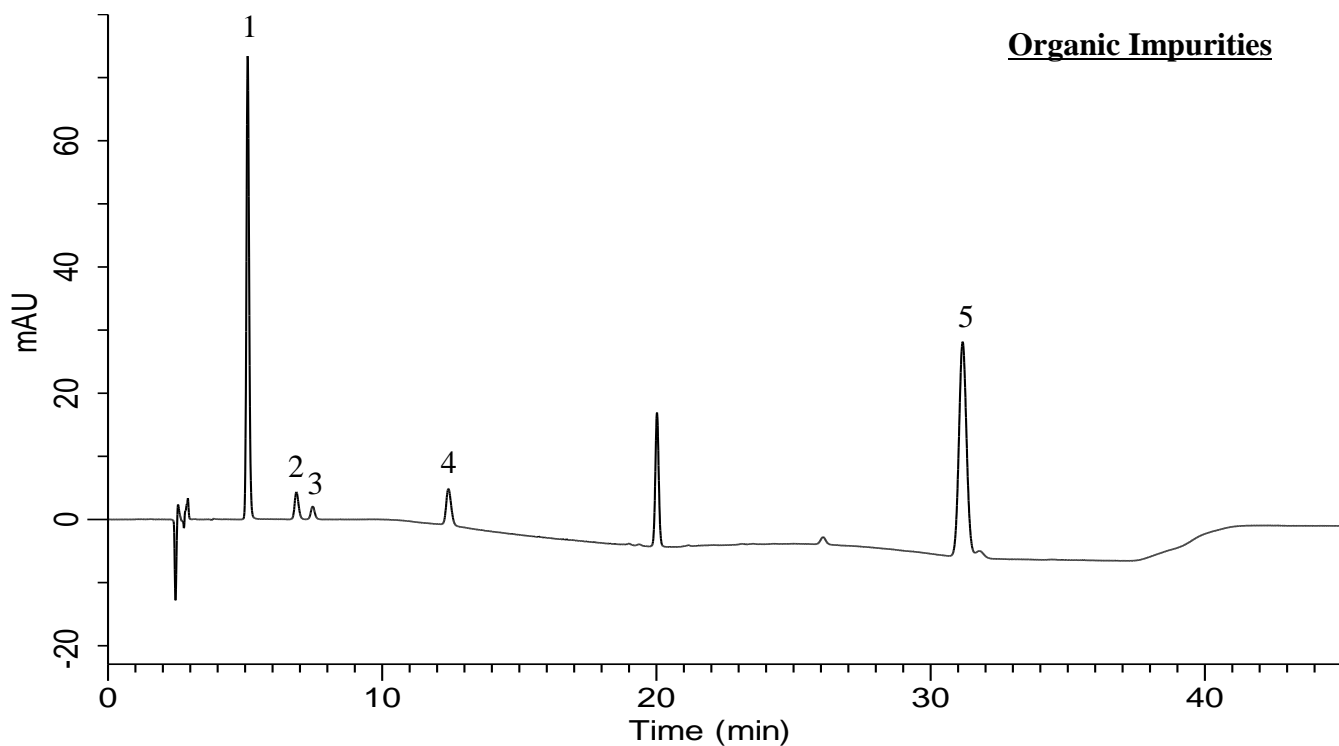
InertSearch™ for LC

Inertsil™ Applications

Analysis of Pregabalin

(Under the Condition of USP41-NF36, Pregabalin)

Data No. LB618-0894



Conditions

Column : Inertsil ODS-3 (5 μm, 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 μL

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)