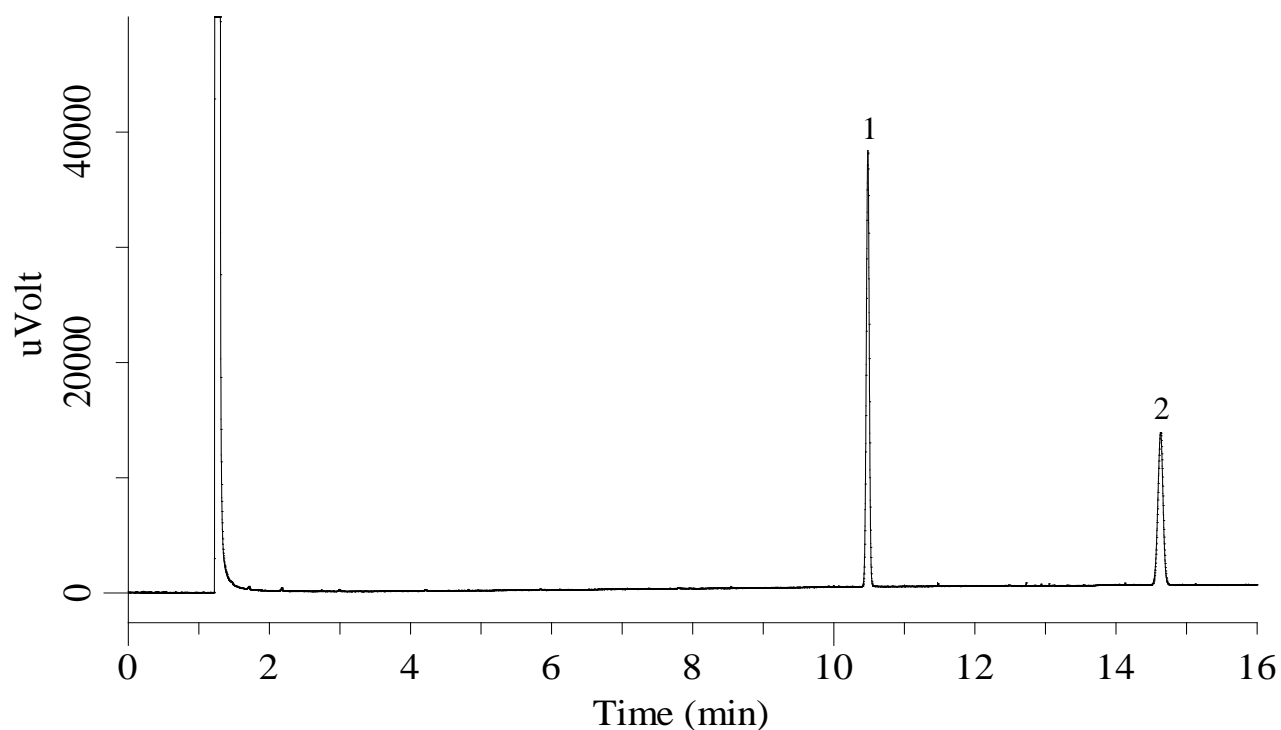


Analysis of Bupivacaine hydrochloride hydrate

(Under the Condition of the Japanese Pharmacopoeia 16)



Conditions

System : GC-FID
Column : InertCap 5
 0.32 mm I.D. x 30 m df = 0.25 μ m
Col. Cat. No. : 1010-18242
Col. Temp. : 180 °C - 5 °C/min - 230 °C(6 min hold)
Carrier Gas : He 120 kPa
Injection : Split flow 30mL/min
 250 °C
Detection : FID Range 10⁰
 250 °C
Sample Size : 1 μ L
Sample : Standard

Analyte

1. Bupivacaine hydrochloride 100 mg/L
 2. Methyl behenate 50 mg/L (I.S.)

Resolution (1, 2) : 39.7 (\geq 20)

RSD of the peak
 area ratio of
 1 to 2 (%) (n=6) : 0.18 (\leq 2.0)