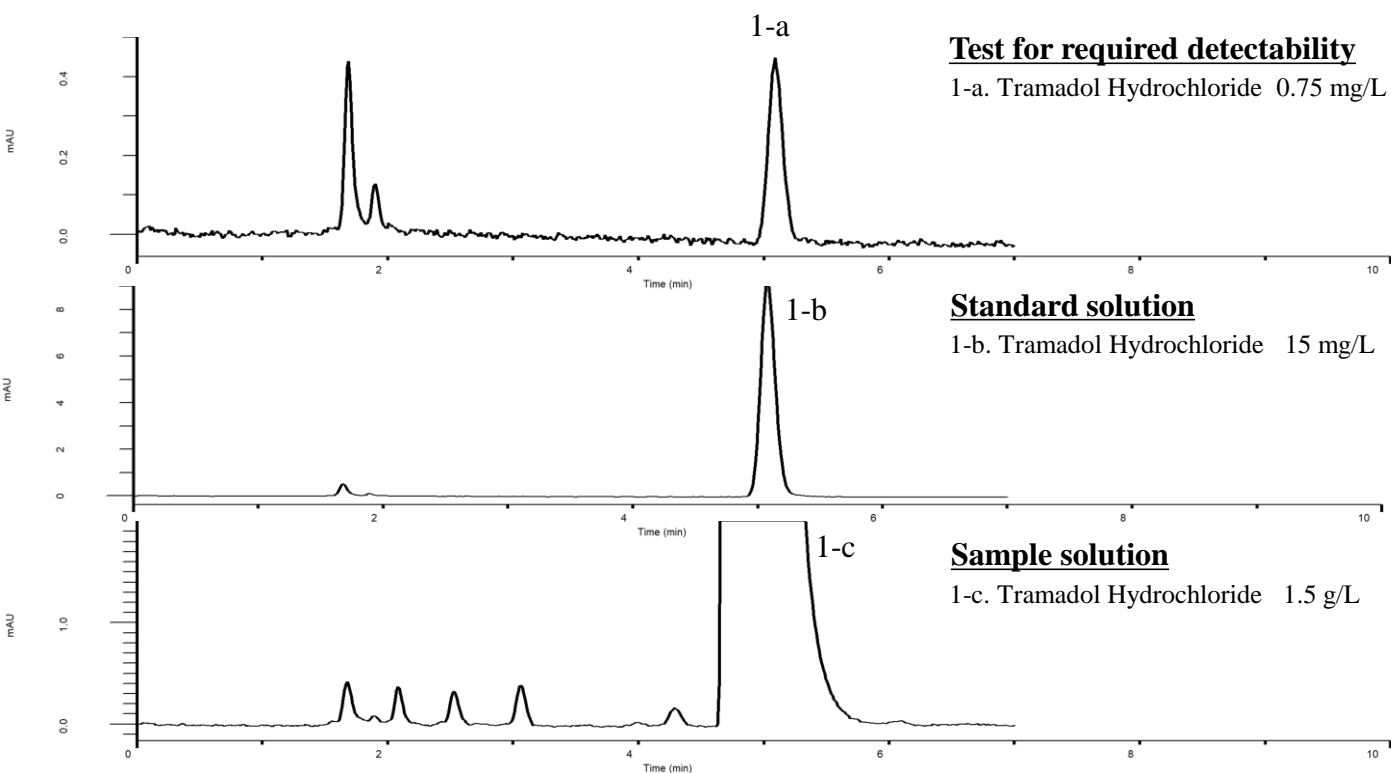


Analysis of Tramadol Hydrochloride

(Under the Condition of the draft for the Japanese Pharmacopoeia)



Conditions

System : GL7700 HPLC system
Column : InertSustain C8
 (5 μ m, 250 x 4.0 mm I.D.)
Column Cat. No. : 5020-16021
Eluent : A) CH₃CN
 B) 0.2 % TFA in H₂O
 A/B = 59/141, v/v
Flow Rate : 1.125 mL/min
Col. Temp. : 25 °C
Detection : UV 270 nm (PD7752 PDA Detector)
Injection Vol. : 20 μ L
Sample : Standard

Analyte:

1. Tramadol Hydrochloride

The peak area ratio of 1-a to 1-b (%) : (3.5 \leq) 4.93 (\leq 6.5)
 Theoretical plate number (1-b) : 8,617 (\geq 5,000)
 RSD of the peak area (%) (n=6) : 0.18 (\leq 2.0)
 Tailing factor (n=6) : 1.13 (\leq 1.5)