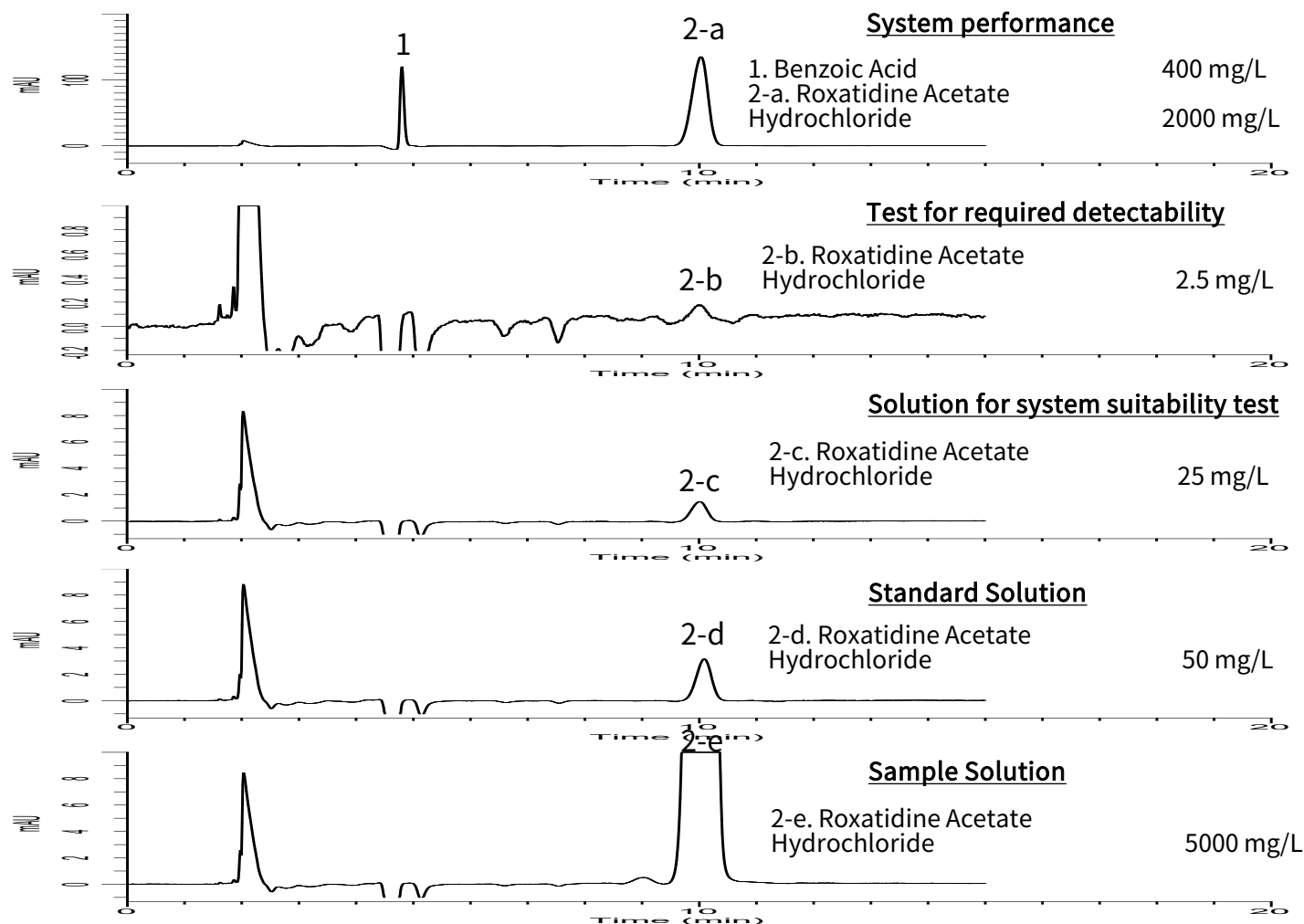


Analysis of Roxatidine Acetate Hydrochloride

(Under the Condition of the Japanese Pharmacopoeia 17th edition, (3) Related Substances)

Data No. LB501-0894



Conditions

System : GL7700 HPLC system
Column : InertSustain Cyano (5 μ m, 250 x 4.0 mm I.D.)
Column Cat. No. : 5020-89270
Eluent : A) *n*-Hexane
 B) C₂H₅OH
 C) Triethylamine
 D) CH₃COOH
 A/B/C/D = 384/16/2/1, v/v/v/v
Flow Rate : 2.05 mL/min
Col. Temp. : 35 °C
Detection : UV 274 nm (PD7752 PDA Detector)
Injection Vol. : 10 μ L
Sample : Standard

Analyte:

1. Benzoic Acid
 2-a. Roxatidine Acetate Hydrochloride

Resolution (1, 2-a) : 15.8 (≥ 10)
 The peak area ratio of 2-b to 2-c (%) : (7 $\leq$) 11.8 (≤ 13)
 RSD of the 2-d area (%) (n = 6) : 0.38 (≤ 1.0)