

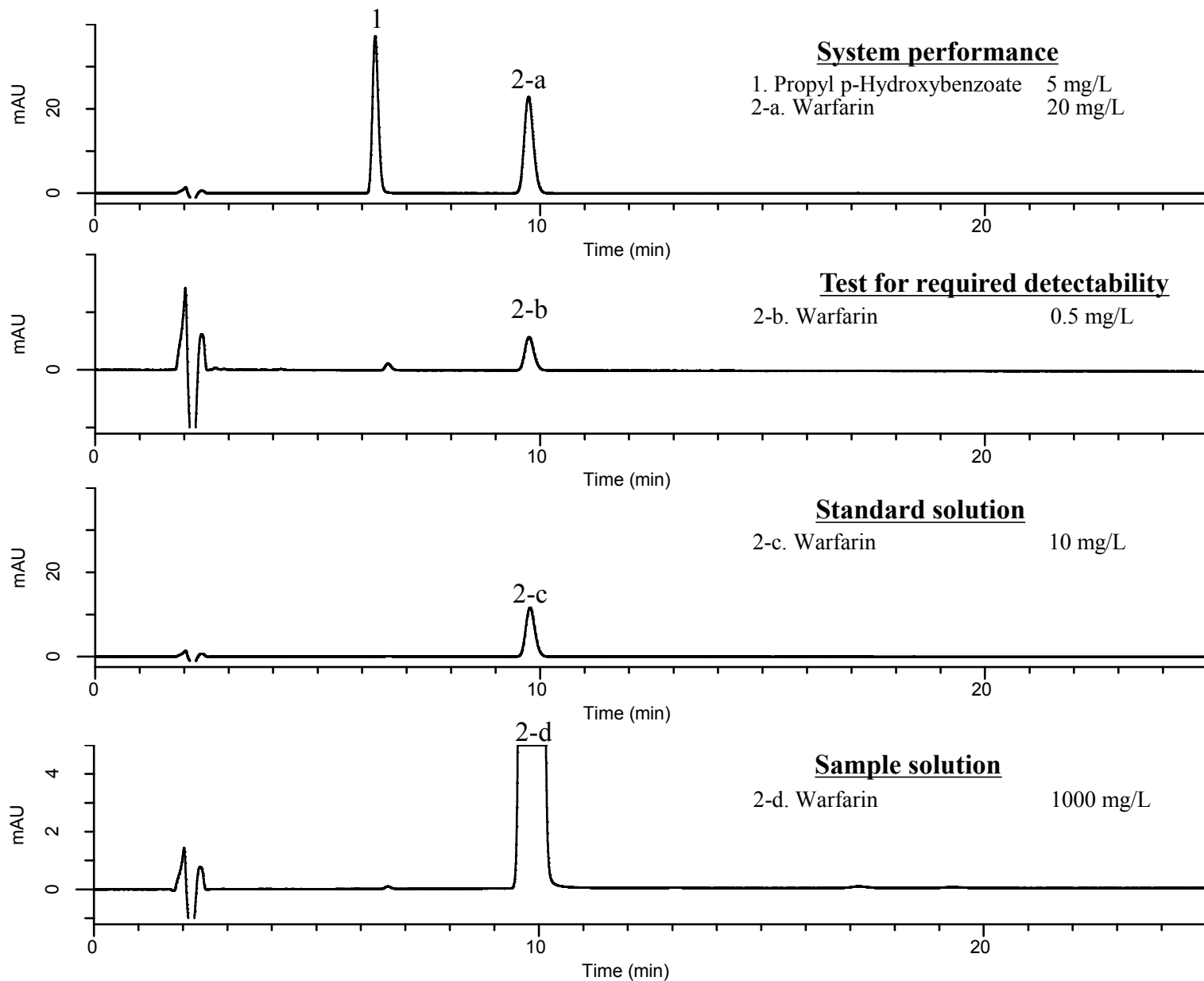
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Analysis of Warfarin Potassium

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

Data No. LB503-0843



System performance

1. Propyl p-Hydroxybenzoate 5 mg/L
2-a. Warfarin 20 mg/L

Test for required detectability

2-b. Warfarin 0.5 mg/L

Standard solution

2-c. Warfarin 10 mg/L

Sample solution

2-d. Warfarin 1000 mg/L

Conditions

System : GL7700 HPLC system
Column : InertSustain Cyano
(5 μ m, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-89277
Eluent : A) CH₃CN
B) H₂O
C) CH₃COOH
A/B/C = 32/68/1, v/v/v
Flow Rate : 1.5 mL/min
Col. Temp. : 40 °C
Detection : UV 260 nm (PD7752 PDA Detector)
Injection Vol. : 20 μ L
Sample : Standard

Analyte:

1. Propyl p-Hydroxybenzoate
2. Warfarin

Resolution (1, 2-a) : 11 (\geq 7.0)
Symmetry factor (2-a) : 1.1 (\leq 1.5)
The peak area ratio of 2-b to 2-c (%) : (3.5 \leq) 5.0 (\leq 6.5)
RSD of the 2-c area (%) (n = 6) : 0.04 (\leq 2.0)