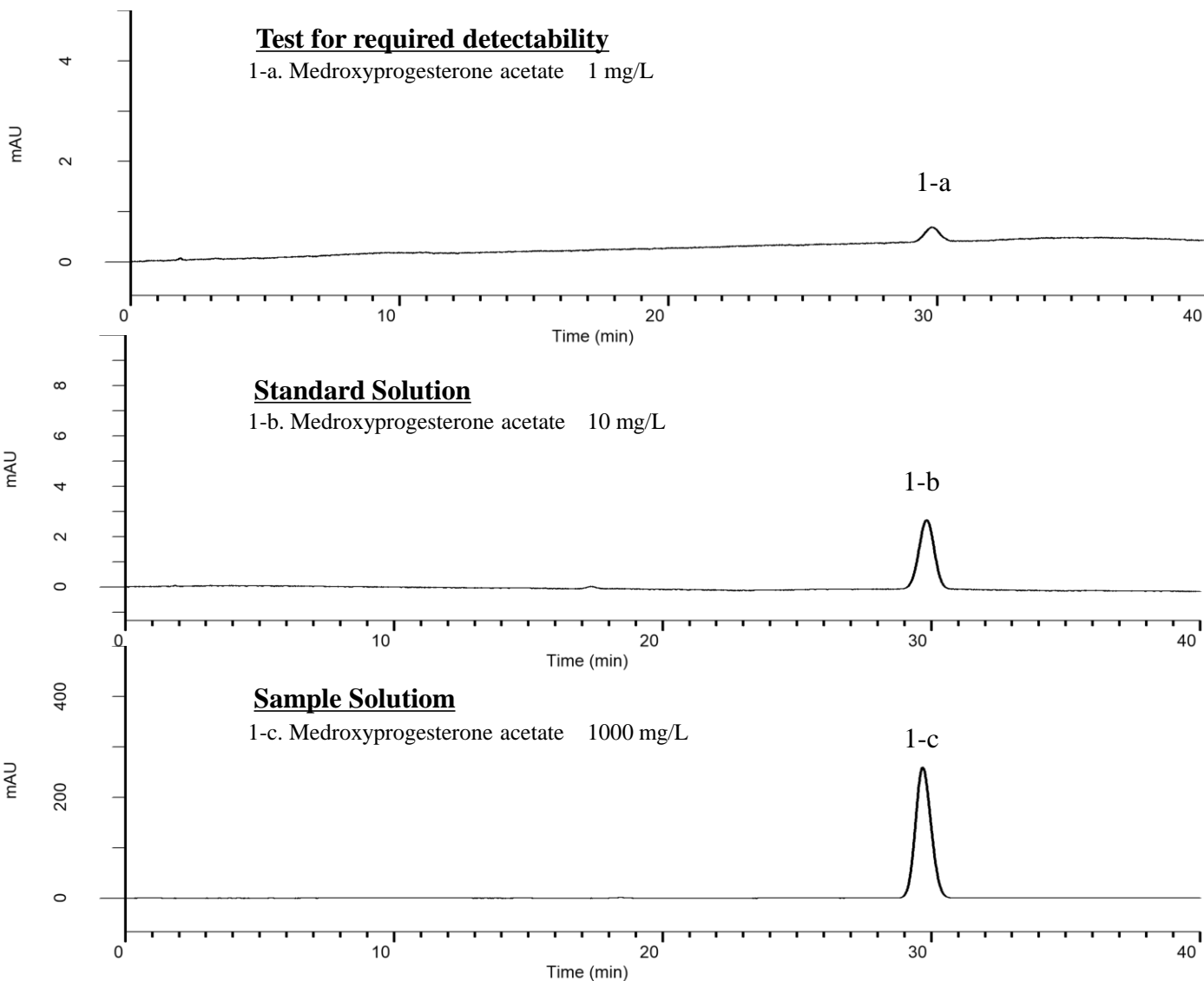


Analysis of Medroxyprogesterone acetate

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



Conditions

System : GL7700 HPLC system
Column : Inertsil WP300 C18
 (5 μ m, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-05846
Eluent : A) CH₃CN
 B) H₂O
 A/B = 40/60, v/v
Flow Rate : 1.7 mL/min
Col. Temp. : 25 °C
Detection : UV 254 nm (PD7752 PDA Detector)
Injection Vol. : 10 μ L
Sample : Standard

Analyte:

1. Medroxyprogesterone acetate

The peak area ratio of 1-a to 1-b : (7 \leq) 9.8 (\leq 13)

Theoretical plate number of 1-b : 12,364 (\geq 5,000)

Tailing factor of 1-b : 0.97 (\leq 2.0)

RSD of the

1-b area (%) (n = 6) : 0.88 (\leq 2.0)