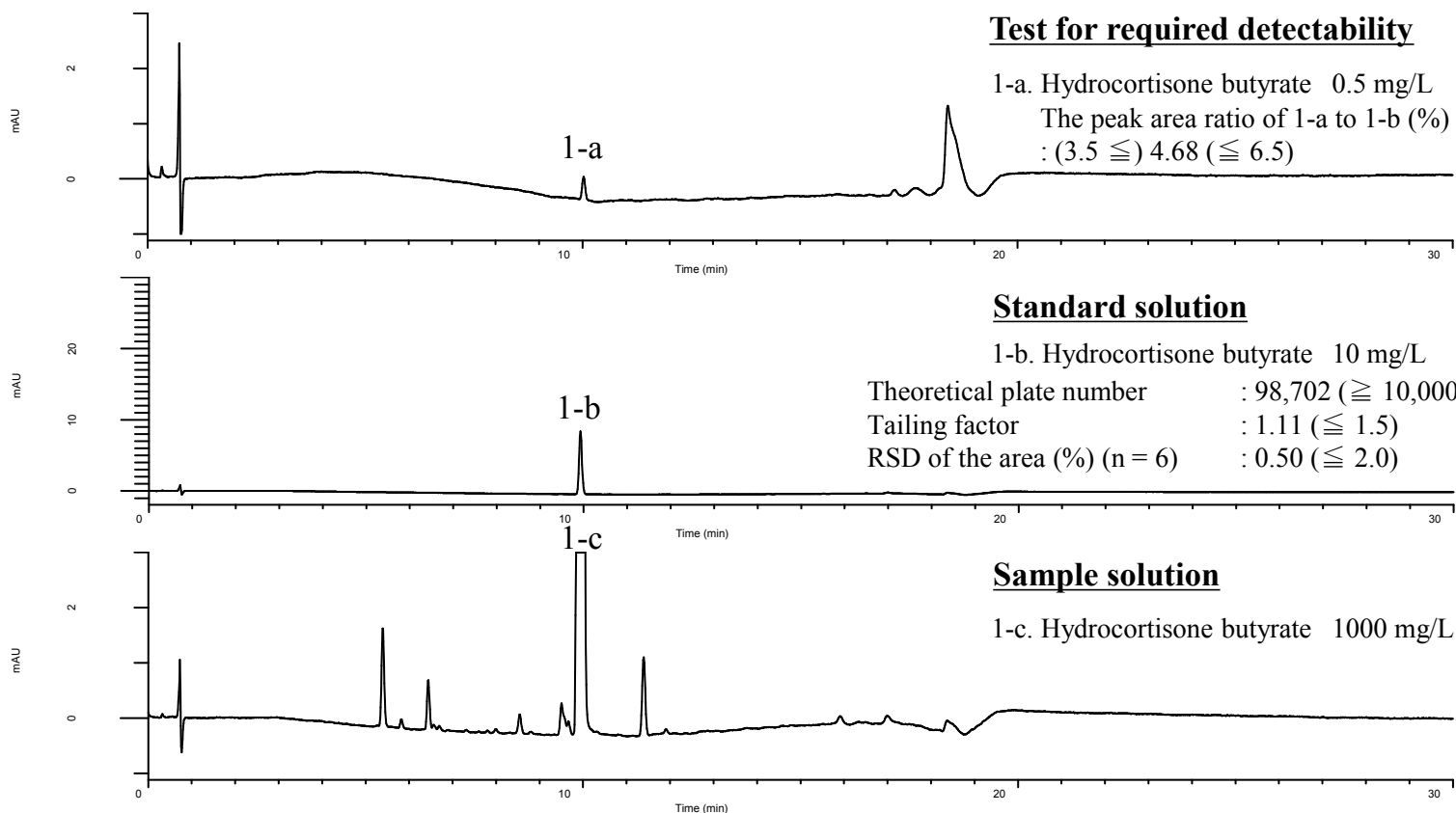


Analysis of Hydrocortisone butyrate

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

Data No. LB446-0894



Test for required detectability

1-a. Hydrocortisone butyrate 0.5 mg/L
 The peak area ratio of 1-a to 1-b (%)
 : (3.5 ≤) 4.68 (≤ 6.5)

Standard solution

1-b. Hydrocortisone butyrate 10 mg/L
 Theoretical plate number : 98,702 (≥ 10,000)
 Tailing factor : 1.11 (≤ 1.5)
 RSD of the area (%) (n = 6) : 0.50 (≤ 2.0)

Sample solution

1-c. Hydrocortisone butyrate 1000 mg/L

Conditions

System : GL7700 HPLC system
Column : Inertsil ODS-3 HP
 (3 μm, 100 x 4.6 mm I.D.)
Column Cat. No. : 5020-14017
Eluent : A) CH₃CN
 B) Buffer*

Analyte:

1. Hydrocortisone butyrate

Pressure: 16 - 23 MPa

Time(min)	A (vol %)	B (vol %)
0.0	20	80
12.5	65	35
15.5	65	35
16.5	20	80
30.0	20	80

Flow Rate : 2.0 mL/min
Col. Temp. : 25 °C
Detection : UV 254 nm (PD7752 PDA Detector)
Injection Vol. : 5 μL
Sample : Standard

*Dissolve 1 g of potassium dihydrogen phosphate in 1000 mL of water.
 adjusted to pH 5.5 with potassium hydroxide TS.