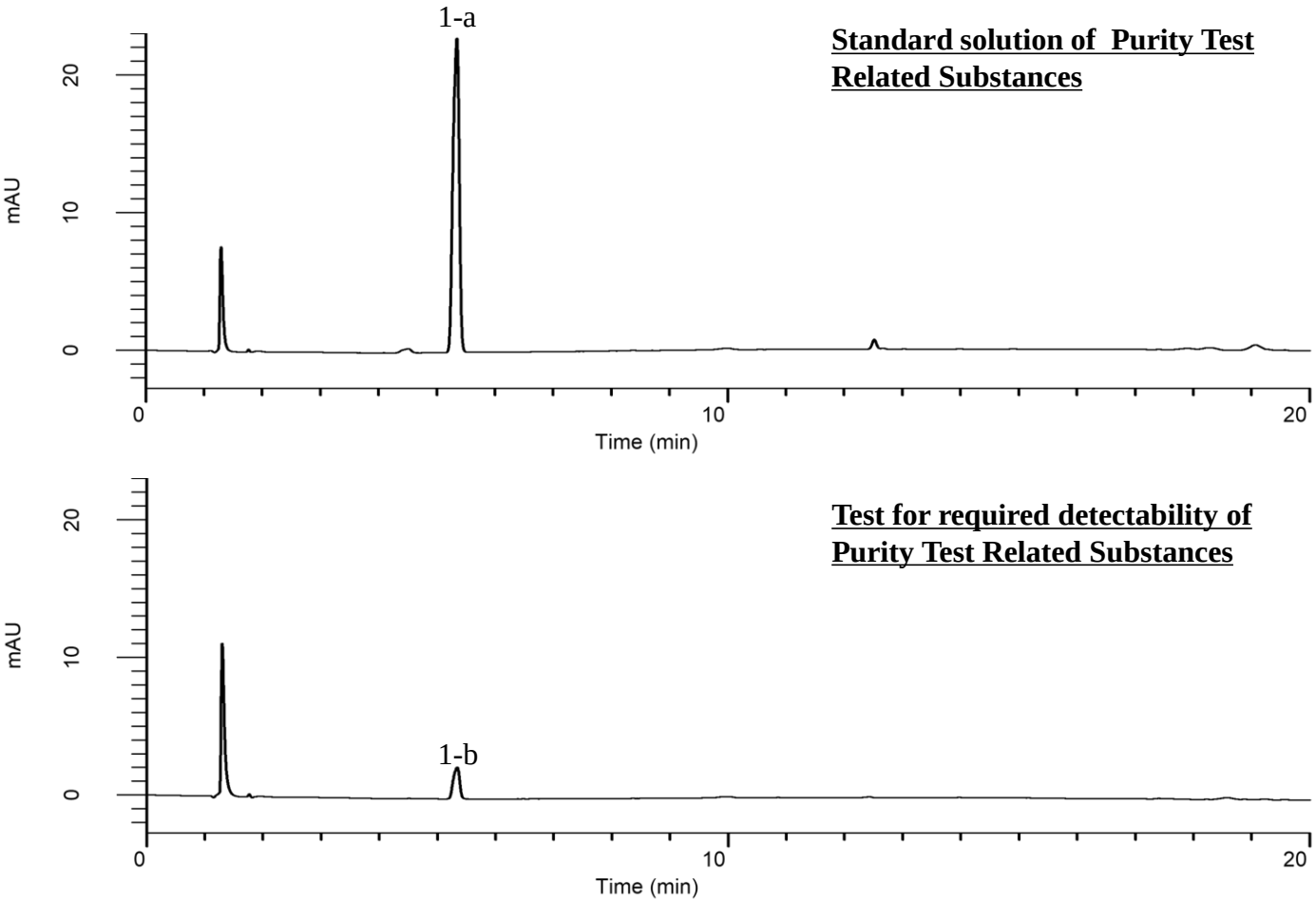
Analysis of Telmisartan and Hydrochlorothiazide

(Under the Condition of the draft for the Japanese Pharmacopoeia, Telmisartan and Hydrochlorothiazide Tablets)



Conditions

System : GL7700 HPLC system
Column : Inertsil C8-3 (3 μm, 150 x 4.0 mm I.D.)
Column Cat. No. : 5020-04835
Eluent : A) CH_3CN
B) 2 g/L $NH_4H_2PO_4$ (pH 3.5, H_3PO_4)

Time(min)	A(vol%)	B(vol%)
0	10	90
8	50	50
12	50	50
18	80	20
20	80	20

Flow rate : 1.0 mL/min
Col. Temp. : 40 ℃
Detection : UV 270 nm (UV7750 UV Detector)
Injection Vol. : 20 μL
Sample : Standard

Analyte:
1. Hydrochlorothiazide
2.5 mg/L (1-a) or 0.25 mg/L (1-b)

The peak area ratio of 1-b to 1-a (%)
: (7 ≦) 9.80 (≦ 13)

Theoretical plates (1-a) : 12,488 (≧ 6,000)
Symmetry factor (1-a) : 0.85 (≦ 2.0)
RSD of the peak
area of 1-a (%)(n=6) : 0.23 (≦ 2.0)