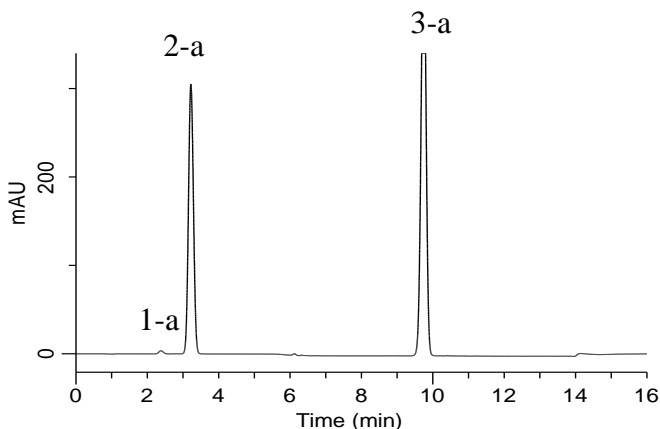


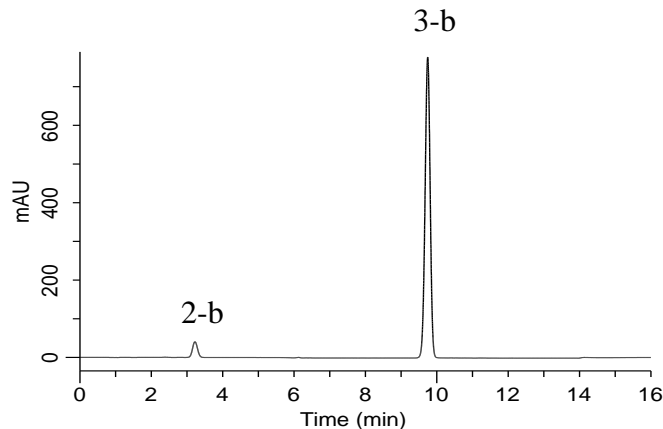
Analysis of Telmisartan and Hydrochlorothiazide

(Under the Condition of USP41-NF36, Telmisartan and Hydrochlorothiazide Tablets)

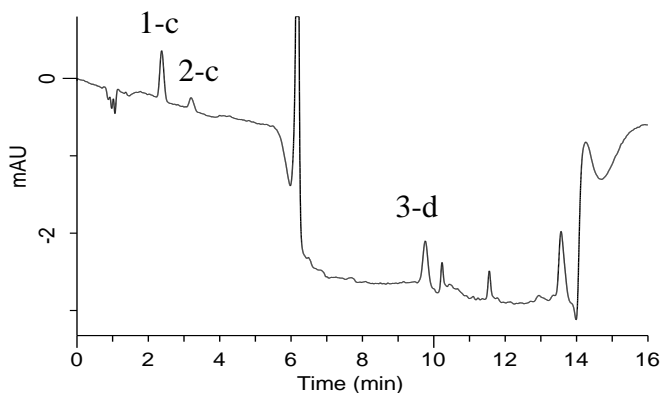
Standard solution A of Assay (UV 270 nm)



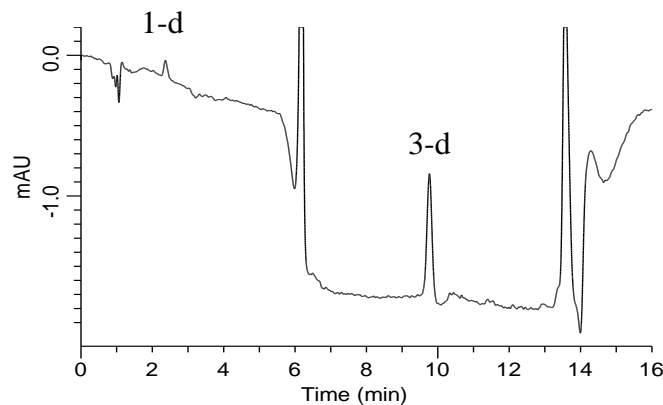
Standard solution A of Assay (UV 298 nm)



Sensitivity solution for Organic impurities (UV 270 nm)



Sensitivity solution for Organic impurities (UV 298 nm)



Conditions

System : GL7700 HPLC system
Column : InertSustain C8 (5 μ m, 125 x 4.0 mm I.D.)
Column Cat. No. : 5020-16853
Eluent : A) CH₃CN /CH₃OH = 50/50 , (v/v)
 B) 2 g/L NH₄H₂PO₄ (pH 3.0, H₃PO₄)

Time(min)	A(vol%)	B(vol%)
0	15	85
3.50	15	85
3.51	55	45
7.70	55	45
7.71	80	20
12.0	80	20
12.1	15	85
15.5	15	85

Flow rate : 1.2 mL/min
Col. Temp. : 40 °C
Detection : UV 270 nm or 298 nm
Injection Vol. : 10 μ L

Analyte:

- 4-Amino-6-chlorobenzene-1,3-disulfonamide
0.5 mg/L (1-a) or 0.1 mg/L (1-c, 1-d)
- Hydrochlorothiazide
100 mg/L (2-a, 2-b) or 0.1 mg/L (2-c, 2-d)
- Telmisartan
320 mg/L (3-a, 3-b) or 0.32 mg/L (3-c, 3-d)

Resolution (1-a, 2-a) : 3.48 (> 2.0)

RSD of the peak area of

2-a (%) (n=6) : 0.14 (< 2.0)

RSD of the peak area of

3-b (%) (n=6) : 0.09 (< 2.0)

S/N for 1-c : 24.3 (> 3.0)

S/N for 2-c : 5.7 (> 3.0)

S/N for 3-d : 29.1 (> 3.0)