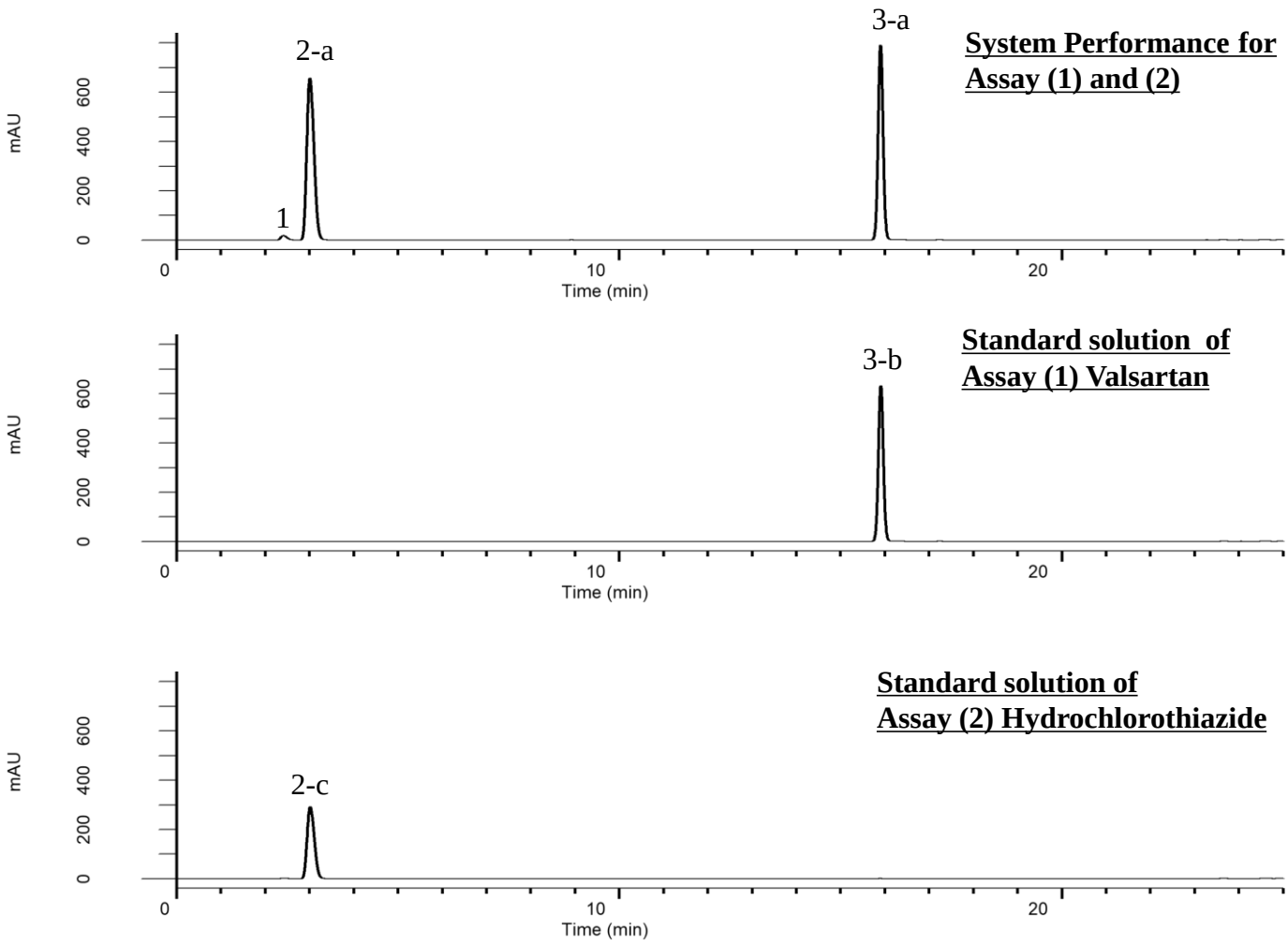
Analysis of Valsartan and Hydrochlorothiazide

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



Conditions

System	:	GL7700 HPLC system
Column	:	InertSustain C18 (5 μm, 125 x 3.0 mm I.D.)
Column Cat. No.	:	5020-07327
Eluent	:	A) $H_2O/CH_3CN/TFA$ = 900/100/1, v/v/v B) $H_2O/CH_3CN/TFA$ = 100/900/1, v/v/v A/B = 90/10 – (25 min) – 10/90, v/v
Flow rate	:	0.6 mL/min
Col. Temp.	:	25 ℃
Detection	:	UV 271 nm (UV7750 UV Detector)
Injection Vol.	:	10 μL
Sample	:	Standard

Analyte:

1. 4-Amino-6-chlorobenzene-1,3-disulfonamide 0.25 mg/L
2. Hydrochlorothiazide 62.5 mg/L (2-a) or 31.25 mg/L (2-c)
3. Valsartan 400 mg/L

Resolution (1, 2-a) : 2.10 (≧ 1.5)
RSD of the peak area of 3-b (%)(n=6) : 0.18 (≦ 1.0)
RSD of the peak area of 2-c (%)(n=6) : 0.11 (≦ 1.0)