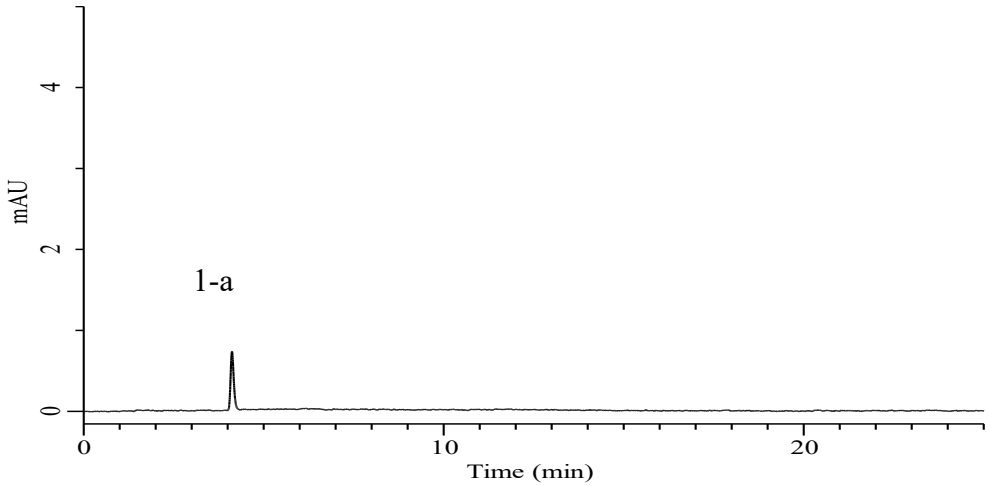
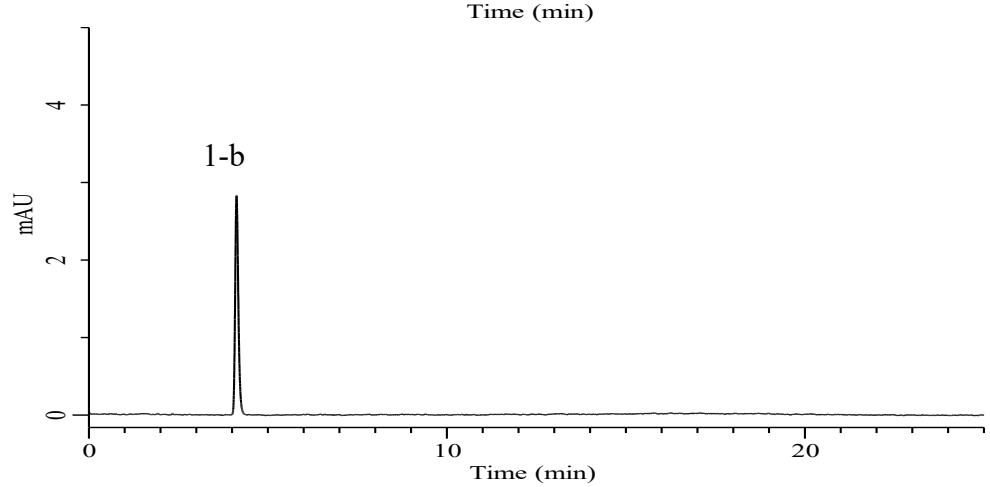
Analysis of Propranolol hydrochloride

(Under the Condition the Japanese Pharmacopoeia 19th, Propranolol Hydrochloride, Purity, Related substances)



Test for required detectability solution



Standard solution

Conditions

System	:	Primaide (HITACHI)
Column	:	InertSustainSwift C18 (GL Sciences Inc.) (5 µm, 250 x 4.6 mm I.D.)
Column Cat. No.	:	5020-88027
Eluent	:	Solution*
Flow Rate	:	1.6 mL/min
Col. Temp.	:	25 ℃
Detection	:	UV 292 nm (Primaide 1410 UV)
Injection Vol.	:	20 µL
Sample	:	Standard in Eluent

Analyte:

1-a. Propranolol hydrochloride	1 µg/mL
1-b. Propranolol hydrochloride	4 µg/mL

Test for required detectability (1-a)(%)	: (17 ≦) 24.9 (≦ 33)
Theoretical plates number (1-b)	: 10555 (≧ 3000)
Tailing factor (1-b)	: 1.28 (≦ 2.0)
RSD of the peak area (%)(1-b)(n=6)	: 0.33 (≦ 2.0)

*: Dissolve 1.6 g of sodium lauryl sulfate and 0.31 g of tetrabutylammonium dihydrogen phosphate in 450 mL of water, add 1 mL of sulfuric acid and 550 mL of CH_3CN, and adjust to pH 3.3 with 2 mol/L sodium hydroxide.