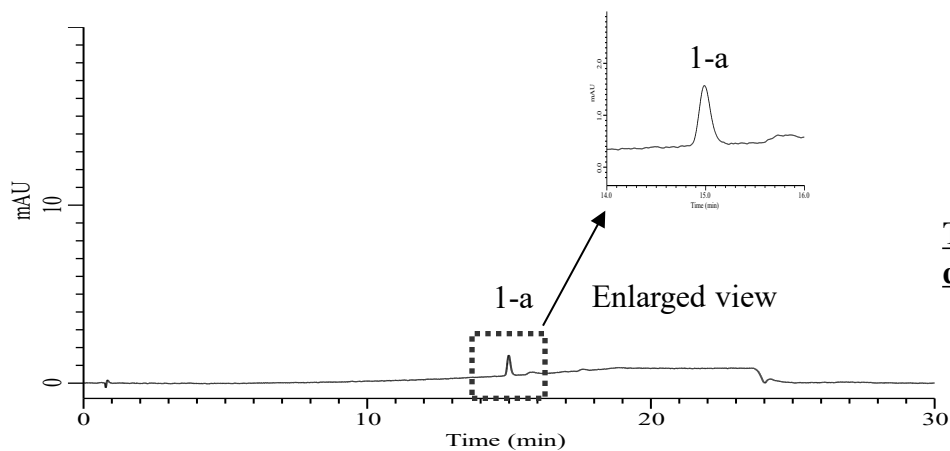
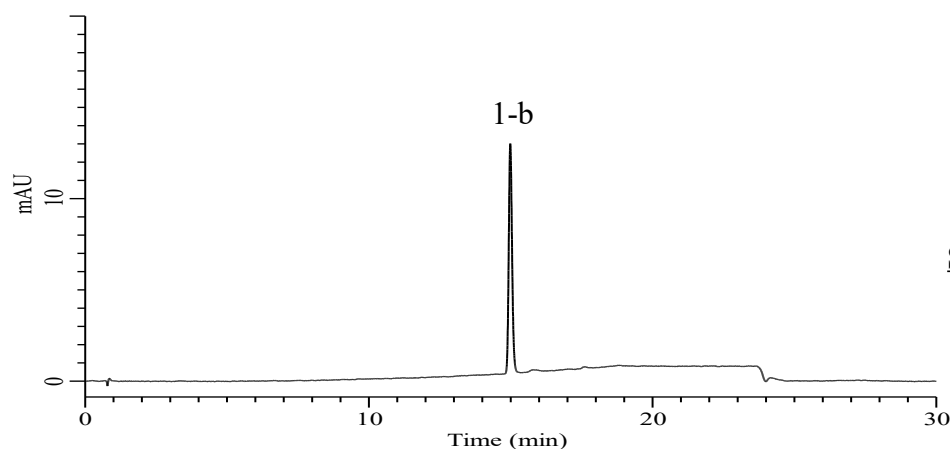


Analysis of Risperidone

(Under the Condition of Japanese Pharmacopoeia 19th, Risperidone, Related substances)



Test for required detectability solution



Standard solution

Conditions

System : Chromaster PLUS (HITACHI)
Column : Inertsil ODS-3 HP(GL Sciences Inc.)
 (3 μ m, 100 x 4.6 mm I.D.)
Column Cat. No. : 5020-14017
Eluent : A) CH₃OH
 B) 65mM CH₃COONH₄ in H₂O

Time (min)	A (vol %)	B (vol %)
0	30	70
2	30	70
17	70	30
22	70	30
30	30	70

Flow Rate : 1.5 mL/min
Col. Temp. : 30 °C
Detection : UV 260 nm (Chromaster 5420 UV-VIS)
Injection Vol. : 10 μ L
Sample : Standard in CH₃OH

Analyte:

1-a. Risperidone 2 μ g/mL
 1-b. Risperidone 20 μ g/mL

Test for required detectability (1-a)(%) : (7 \leq) 9.3% (\leq 13)

Theoretical plates number (1-b) : 80577 (\geq 10000)

Tailing factor (1-b) : 1.18 (\leq 2.0)

RSD of the peak area (%) (1-b)(n=6) : 0.44 (\leq 2.0)