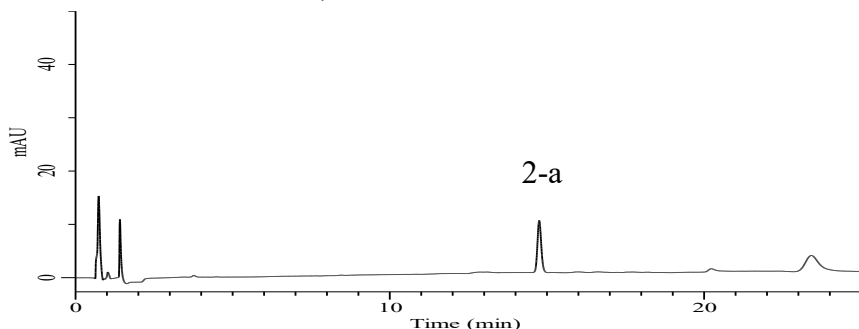


Analysis of Itraconazole

(Under the Condition of the Japanese Pharmacopoeia 18th, Itraconazole, Purity(2)

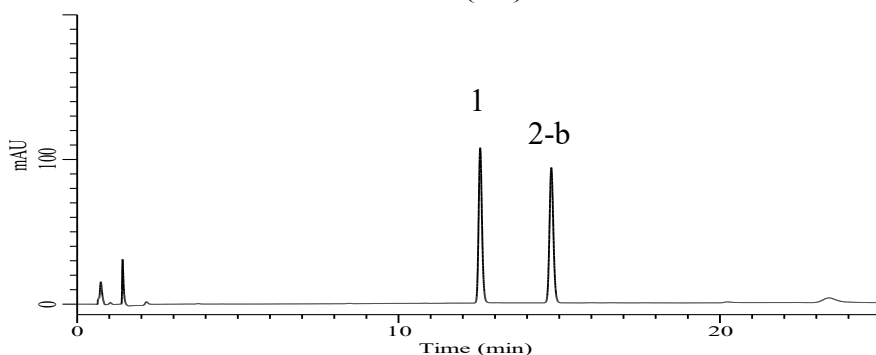
Related substances)



Test for required detectability:

2-a. Itraconazole 5 µg/mL

(Peak area of 2-a) / (Peak area of 2-c)(%)
: (7≧) 10.2 (≦ 13)

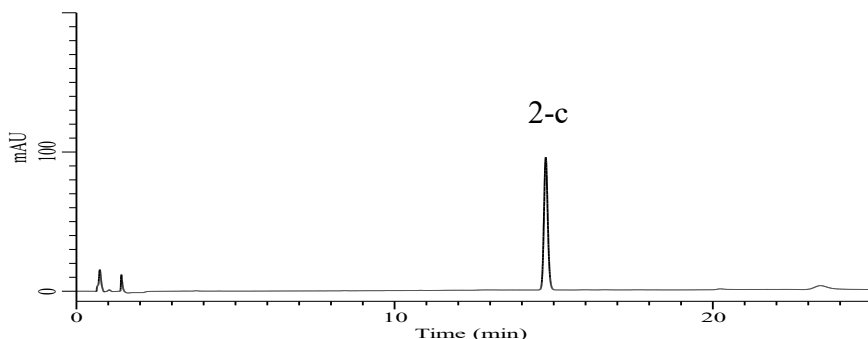


System performance

1. Miconazole 0.05 mg/mL

2-b. Itraconazole 0.05 mg/mL

Resolution (1, 2-b) : 10.9 (≧ 2.0)



System repeatability

2-c. Itraconazole 0.05 mg/mL

RSD of the peak area(%) (n=6)
: 0.69 (≦ 2.0)

Conditions

System : Primaide (HITACHI)
Column : InertSustain C18 (GL Sciences Inc.)
(HP 3 µm, 100 x 4.6 mm I.D.)
Column Cat. No. : 5020-14444
Eluent : A) CH₃CN
B) Solution*

Analyte:

1. Miconazole
2. Itraconazole

Time (min)	A (vol %)	B (vol %)
0.0	20	80
20.0	50	50
25.0	50	50

Flow Rate : 1.5 mL/min
Col. Temp. : 30 °C
Detection : UV 225 nm (Primaide 1410 UV)
Injection Vol. : 10 µL
Sample : Standard in CH₃OH/ THF = 1/1, v/v

* : 27.2 g/L of tetrabutylammonium hydrogen sulfate in water.