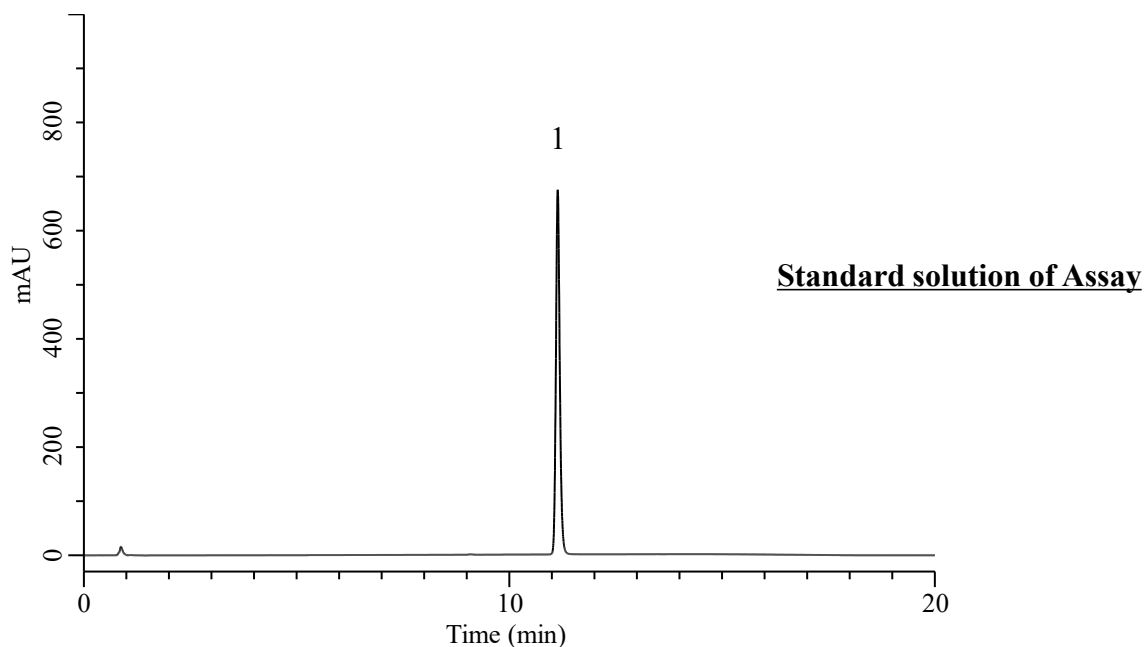


Analysis of Itraconazole

(Under the Condition of USP43-NF38, Itraconazole, ASSAY)



Conditions

System : Primaide (HITACHI)
Column : InertSustainSwift C18 (GL Sciences Inc.)
 (3 μ m, 100 x 4.6 mm I.D.)
Column Cat. No. : 5020-88148
Eluent : A) CH₃CN
 B) Solution*

Time (min)	A (vol %)	B (vol %)
0.0	20	80
12.0	50	50
16.0	20	80
20.0	20	80

Flow Rate : 1.5 mL/min
Col. Temp. : 30 °C
Detection : UV 225 nm (Primaide 1410 UV)
Injection Vol. : 10 μ L
Sample : Standard in 0.4% HCl in CH₃OH

Analyte:

1. Itraconazole 0.3 mg/mL

Tailing factor : 1.17 (≤ 2.0)

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

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