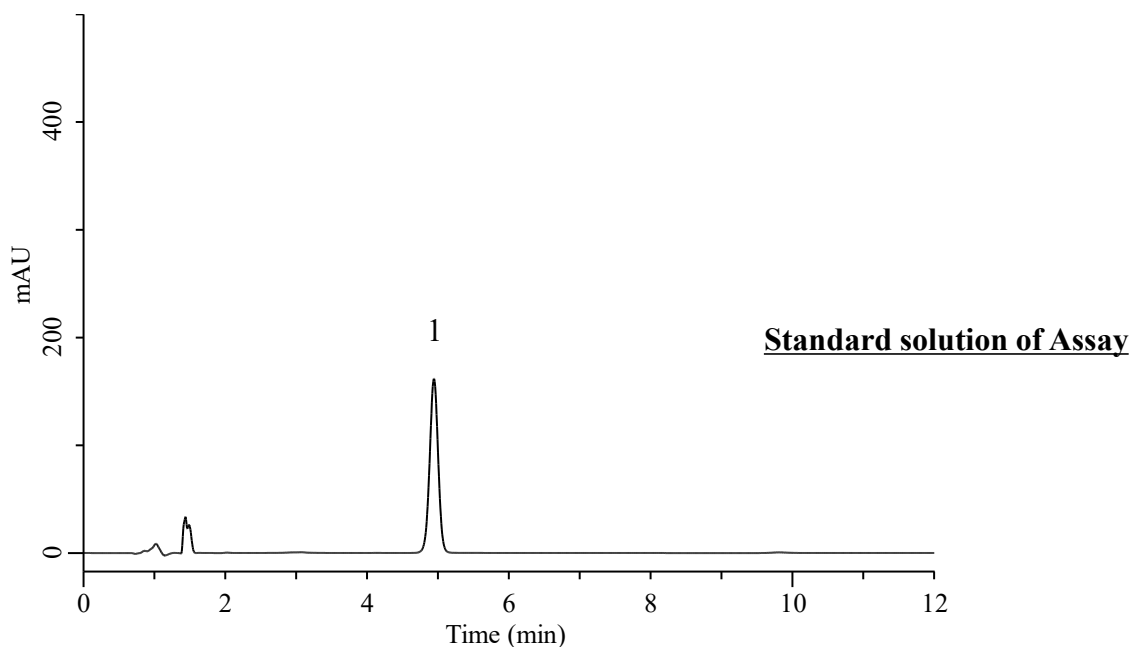


## Analysis of Itraconazole

(Under the Condition of USP-NF 2021 Issue 2, Itraconazole Capsules, ASSAY)



### Conditions

**System** : Primaide (HITACHI)  
**Column** : InertSustain C18 (GL Sciences Inc.)  
                   (HP 3  $\mu$ m, 150 x 4.6 mm I.D.)  
**Column Cat. No.** : 5020-14425  
**Eluent** : A) CH<sub>3</sub>CN/THF = 90/10 ,v/v  
               B) Buffer\*  
               A/B = 55/45 ,v/v  
**Flow Rate** : 1.5 mL/min  
**Col. Temp.** : 30 °C  
**Detection** : UV 225 nm (Primaide 1435 DAD)  
**Injection Vol.** : 10  $\mu$ L  
**Sample** : Standard in CH<sub>3</sub>OH/THF = 50/50, v/v

### Analyte:

1. Itraconazole                      0.1 mg/mL

Tailing factor : 0.99 ( $\leq$  2.0)

RSD of the peak area (%)(n=6) : 0.54 ( $\leq$  2.0)

\*: 5.8 g/L of monobasic ammonium phosphate in water. Adjust with phosphoric acid to a pH of 2.0.