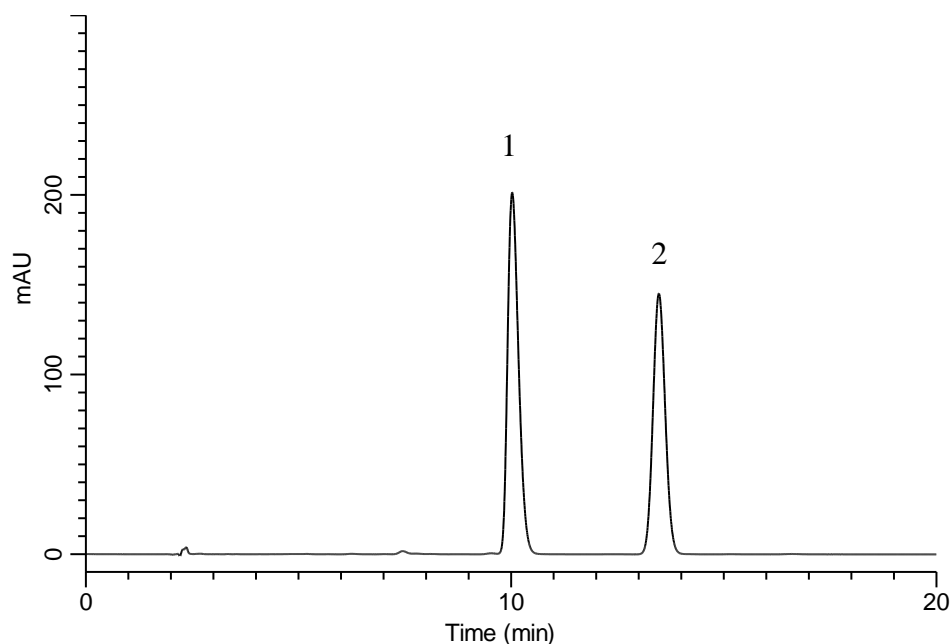


## Analysis of Pramlukast hydrate (Under the Condition of Japanese Pharmacopoeia)



### Conditions

**System** : GL-7400 HPLC system  
**Column** : InertSustain C8  
 (5 $\mu$ m, 150 x 6.0 mm I.D.)  
**Column Cat. No.** : 5020-16057  
**Eluent** : A) CH<sub>3</sub>CN  
 B) CH<sub>3</sub>OH  
 C) 20 mM KH<sub>2</sub>PO<sub>4</sub>  
 A/B/C = 5/1/5, v/v/v  
**Flow Rate** : 1.2 mL/min  
**Col. Temp.** : 25 °C  
**Detection** : UV 260 nm (GL-7452 PDA Detector)  
**Injection Vol.** : 4  $\mu$ L  
**Sample** : Standard

### Analyte:

1. Pramlukast hydrate 200 mg/L  
 2. *p*-Hydroxybenzoic acid *iso*-amyl ester 200 mg/L

Resolution (1, 2) : 6.9 ( $\geq 3$ )  
 RSD of the peak  
 area ratio of  
 1 to 2 (%) (n=6) : 0.06 ( $\leq 1.0$ )