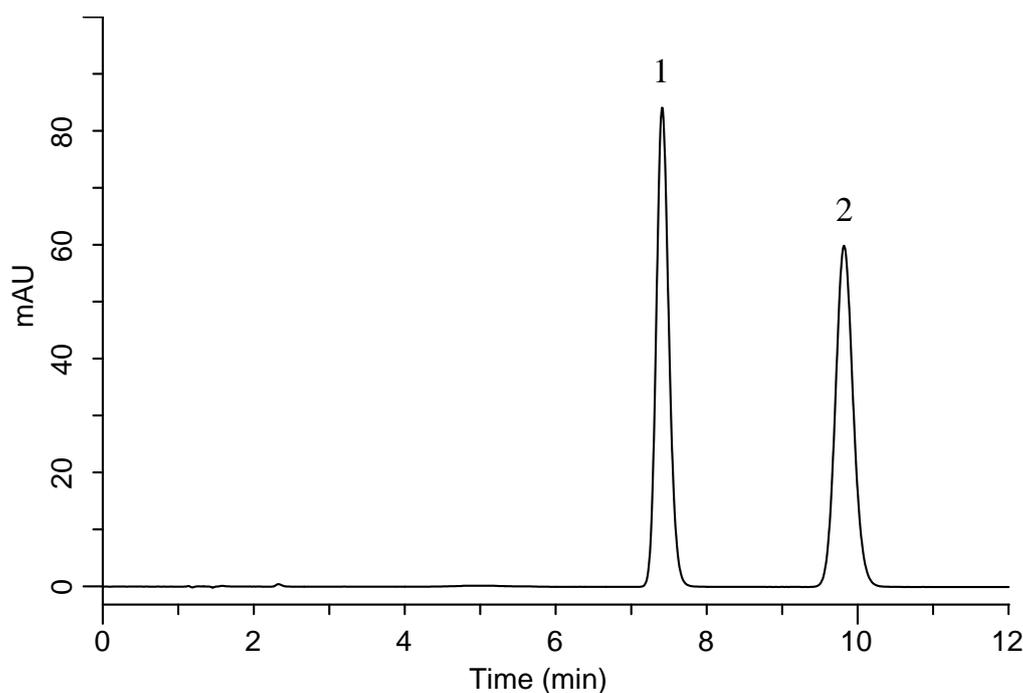


## Analysis of Sivelestat sodium hydrate

(Under the Condition of the Japanese Pharmacopoeia)

Data No. LB111-0919



### Conditions

**System** : GL-7400 HPLC system  
**Column** : InertSustain C18  
(5  $\mu$  m, 150 x 4.6 mm I.D.)  
**Column Cat. No.** : 5020-07345  
**Eluent** : A) CH<sub>3</sub>CN  
B) 5.44 g/L KH<sub>2</sub>PO<sub>4</sub> in H<sub>2</sub>O (pH 3.5, H<sub>3</sub>PO<sub>4</sub>)  
A/B = 4/5, v/v  
**Flow Rate** : 1.0 mL/min  
**Col. Temp.** : 25 °C  
**Detection** : UV 240 nm (GL-7452 PDA Detector)  
**Injection Vol.** : 10  $\mu$  L  
**Sample** : Standard

### Analyte:

1. *p*-Hydroxybenzoic acid *n*-propyl ester  
2. Sivelestat sodium hydrate

Resolution (1, 2) : 6.6 ( $\geq 5$ )  
RSD of the peak  
area ratio of  
2 to 1 (%) (n=6) : 0.44 ( $\leq 1.0$ )