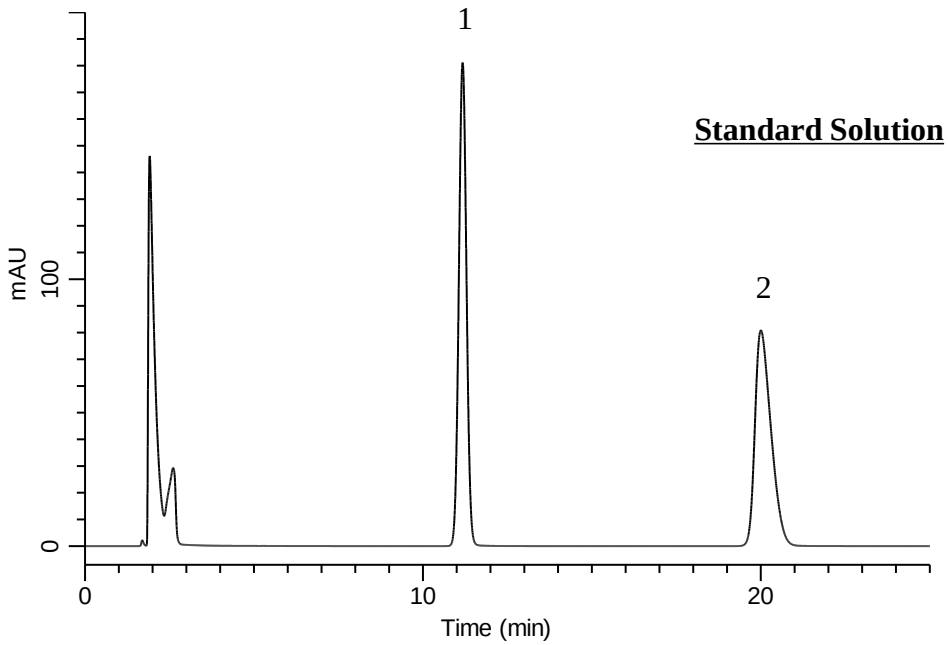
Analysis of Rebamipide

(Under the Condition of the Japanese Pharmacopoeia, Rebamipide Tablets)



Conditions

System : GL7700 HPLC system
Column : InertSustain C18 (5 μm, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-07345
Eluent : A) CH_3CN
B) Buffer*
A/B = 17/83, v/v
Flow Rate : 0.91 mL/min
Col. Temp. : 25 ℃
Detection : UV 254 nm (UV7750 UV Detector)
Injection Vol. : 20 μL
Sample : Standard

*Add 750 mL of water in 300 mL of pH6.2 phosphate buffer**
**Dissolve 9.08 g of potassium dihydrogen phosphate in 1,000 mL of water (Solution A).
Add 1.892 g of disodium hydrogen phosphate in 200 mL of water to 800 mL of SolutionA.

Analyte:

1. Acetanilide	40 μg/L
2. Rebamipide	60 μg/L

Resolution (1, 2) : 13.8 (≧ 8)
RSD of the peak area ratio of 2 to 1 (%)(n=6) : 0.13 (≦ 1.0)