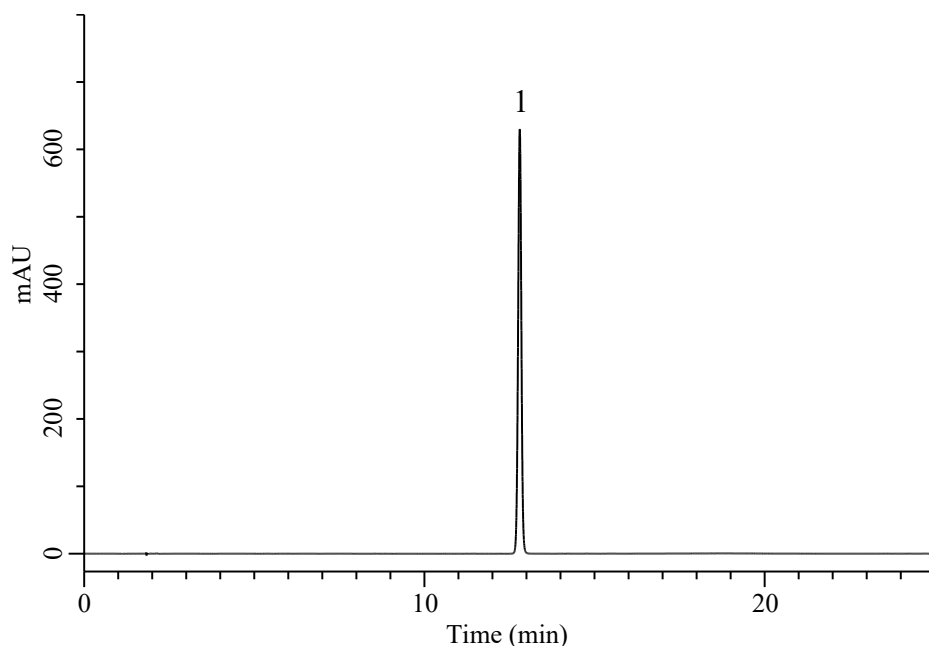


Analysis of Omeprazole

(Under the Condition of USP41-NF36, Omeprazole Delayed-Release Capsules, ASSAY)



Conditions

System : Primaide (HITACHI)
Column : InertSustain C8 (GL Sciences Inc.)
 (5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-16027
Eluent : A) Solution *
 B) CH₃CN/CH₃OH=(85/15,v/v)

Time(min)	A%	B%
0	88	12
20	40	60
21	88	12
25	88	12

Flow Rate : 1.2 mL/min
Col. Temp. : 40 °C
Detection : UV 305 nm (Primaide 1435 DAD)
Injection Vol. : 10 μ L
Sample : Standard in Diluent**

Analyte:

1. Omeprazole 0.2 mg/mL

Theoretical plates number : 88,213 ($\geq 20,000$)

Tailing factor : (0.8 $\leq$) 1.01 (≤ 2)

RSD of the peak area (%)(n=6) : 0.26 (≤ 2.0)

* : Dissolve 6.0 g of glycine in 1500 mL of water, adjust with 50% sodium hydroxide solution to a pH of 9.0, and dilute with water to 2000 mL.

** : Dissolve 7.6 g of sodium borate decahydrate in about 800 mL of water. Add 1.0 g of edetate disodium, and adjust with 50% sodium hydroxide solution to a pH of 11.0 $\pm$ 0.1. Transfer the solution to a 2000-mL volumetric flask, add 400 mL of dehydrated alcohol, and dilute with water to volume.