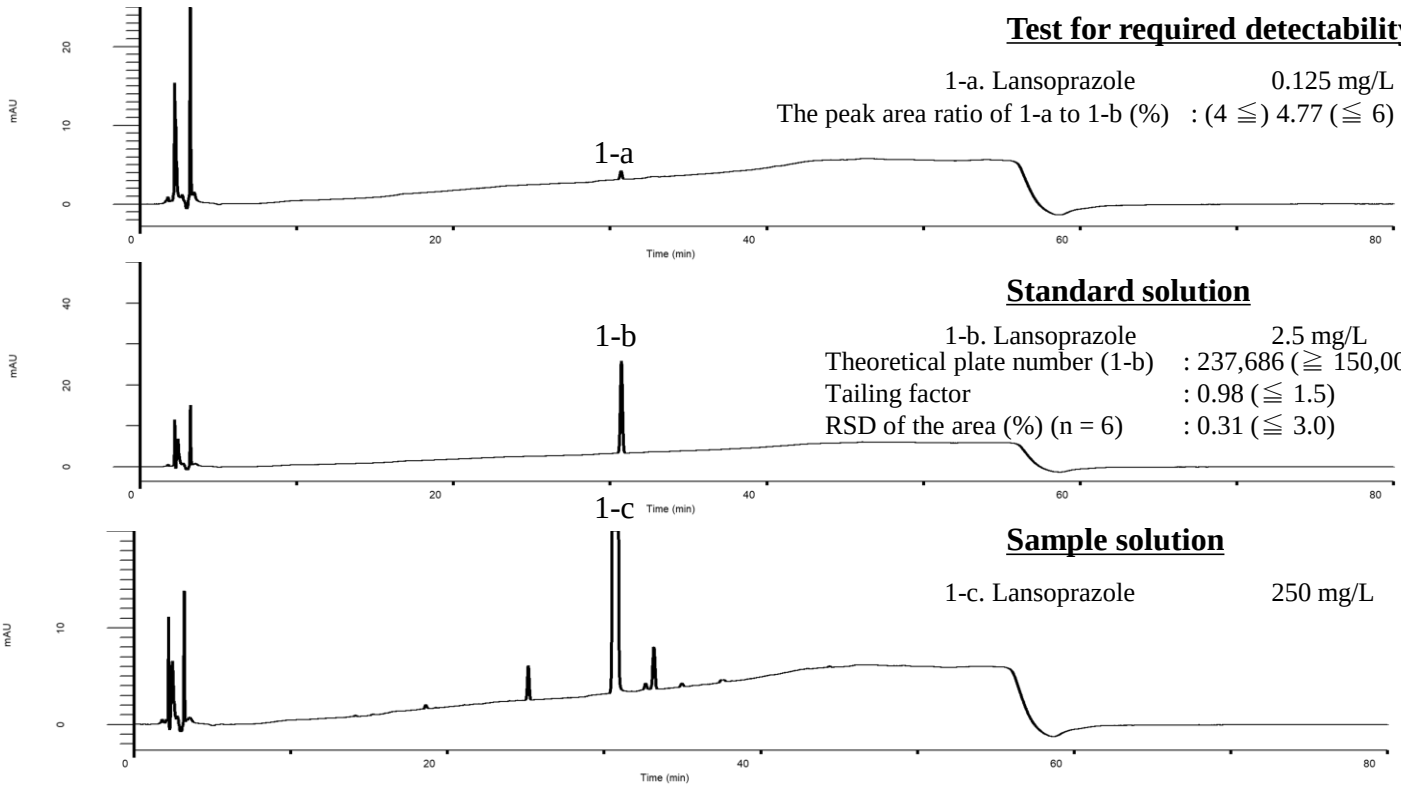
Analysis of Lansoprazole

(Under the Condition of the Japanese Pharmacopoeia)



Test for required detectability

1-a. Lansoprazole 0.125 mg/L
The peak area ratio of 1-a to 1-b (%) : (4 ≦) 4.77 (≦ 6)

Standard solution

1-b. Lansoprazole 2.5 mg/L
Theoretical plate number (1-b) : 237,686 (≧ 150,000)
Tailing factor : 0.98 (≦ 1.5)
RSD of the area (%) (n = 6) : 0.31 (≦ 3.0)

Sample solution

1-c. Lansoprazole 250 mg/L

Conditions

System : GL7700 HPLC system
Column : InertSustain C18
(5 μm, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-07345
Eluent : A) Solution*
B) H_2O

Time(min)	A(vol %)	B(vol %)
0.0	10	90
40.0	80	20
50.0	80	20
51.0	10	90
80.0	10	90

Flow Rate : 0.8 mL/min
Col. Temp. : 25 ℃
Detection : UV 285 nm (PD7752 PDA Detector)
Injection Vol. : 40 μL
Sample : Standard
*A mixture of acetonitrile, water and triethylamine (160:40:1), adjusted to pH 7.0 with phosphoric acid.

Analyte:

1. Lansoprazole