

Analysis of Lansoprazole

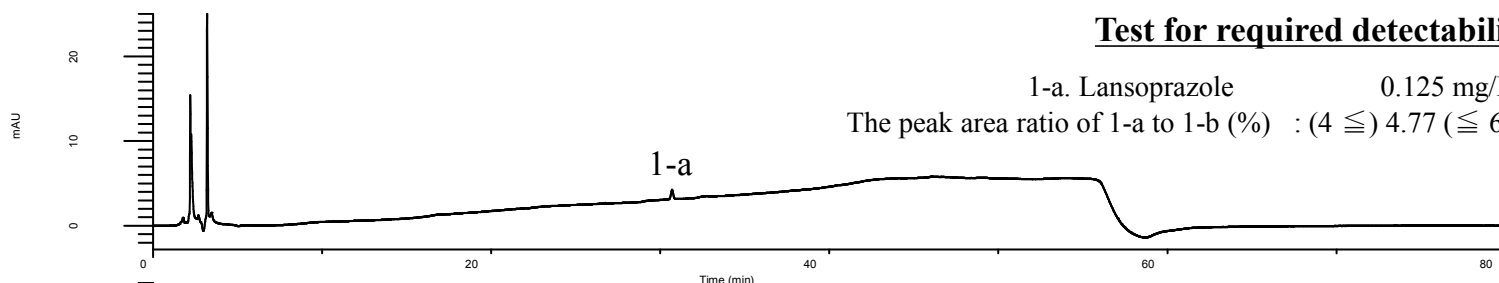
(Under the Condition of the Japanese Pharmacopoeia)

Data No. LB449-0894

Test for required detectability

1-a. Lansoprazole 0.125 mg/L

The peak area ratio of 1-a to 1-b (%) : $(4 \leq) 4.77 (\leq 6)$



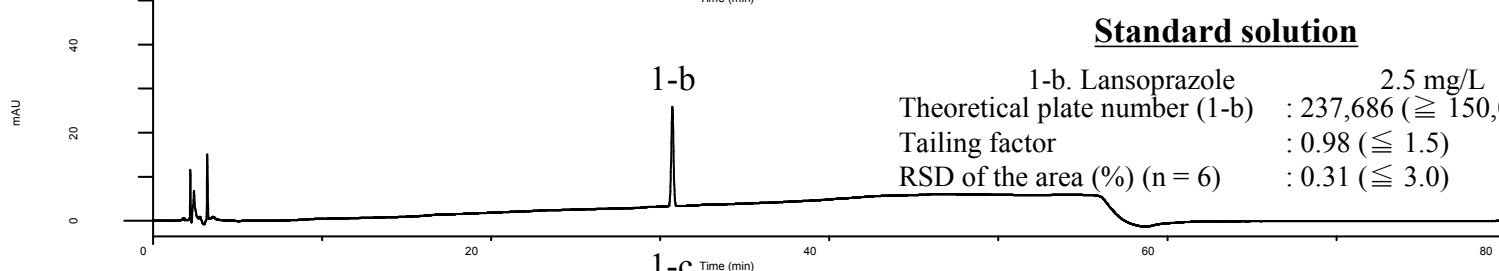
Standard solution

1-b. Lansoprazole 2.5 mg/L

Theoretical plate number (1-b) : $237,686 (\geq 150,000)$

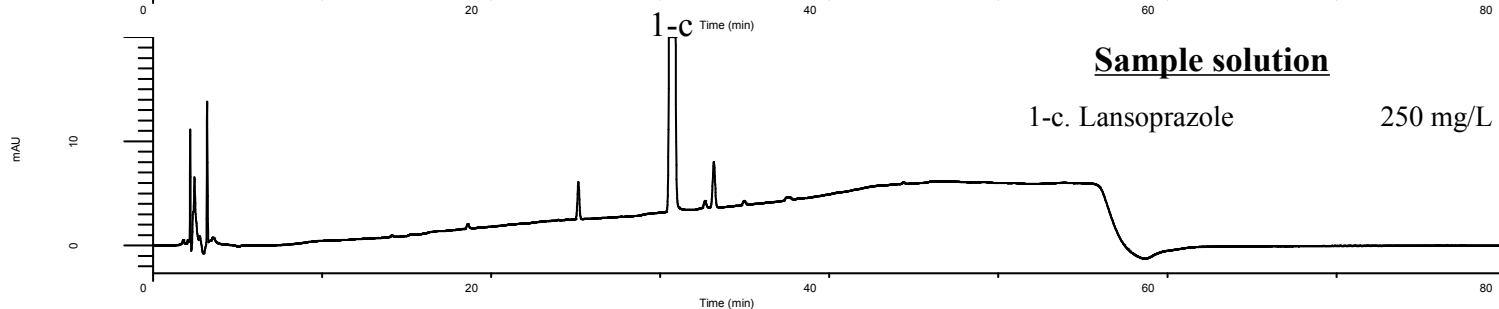
Tailing factor : $0.98 (\leq 1.5)$

RSD of the area (%) (n = 6) : $0.31 (\leq 3.0)$



Sample solution

1-c. Lansoprazole 250 mg/L



Conditions

System : GL7700 HPLC system
Column : InertSustain C18
 (5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-07345
Eluent : A) Solution*
 B) H₂O

Analyte:

1. Lansoprazole

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 °C
Detection : UV 285 nm (PD7752 PDA Detector)
Injection Vol. : 40 μ L
Sample : Standard

*A mixture of acetonitrile, water and triethylamine (160:40:1), adjusted to pH 7.0 with phosphoric acid.