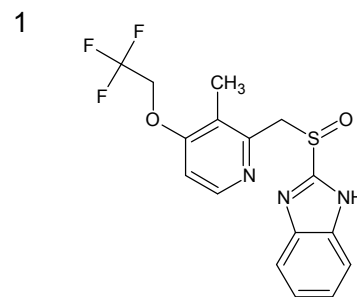
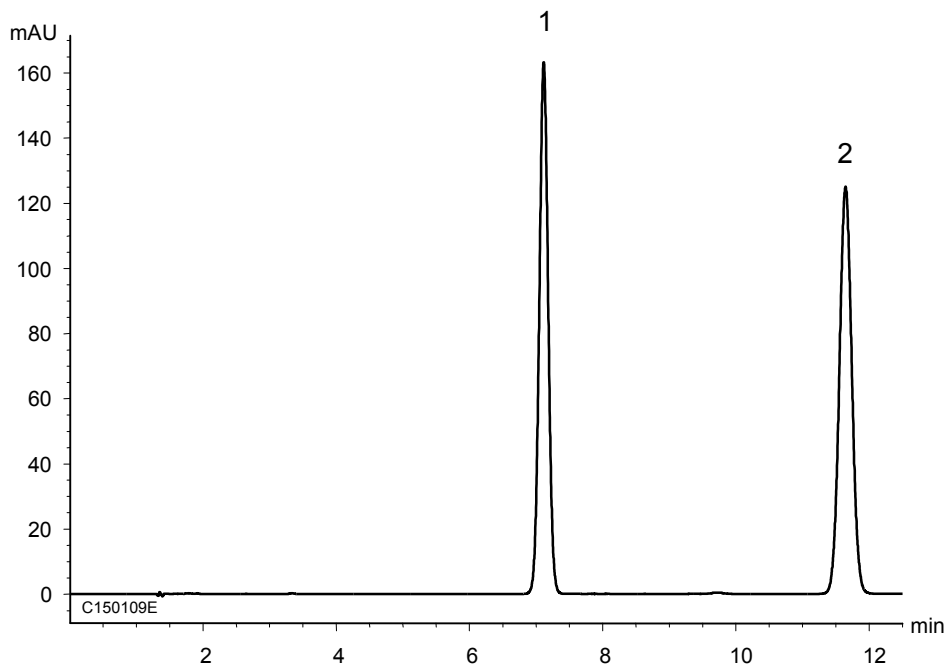


ランソプラゾール（日本薬局方収載原案記載条件）  
Lansoprazole (The draft for the Japanese Pharmacopoeia)

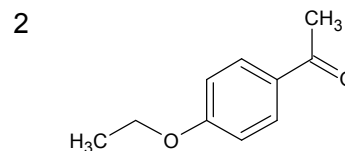
C150109E

	System suitability requirement	Result
Resolution (1, 2)	$\geq 10$	15.5
Relative standard deviation of the peak area ratio of 1 to 2 (n=6)	$\leq 1.0\%$	0.10%

Standard solution\*1  
(0.1 mg/mL Lansoprazole,  
0.05 mg/mL 4'-Ethoxyacetophenone)



Lansoprazole



4'-Ethoxyacetophenone (I.S.)

Column : YMC-Triart C18 (5  $\mu$ m, 12 nm)  
250 X 4.6 mmI.D.  
Eluent : acetonitrile/water/TEA\*2 (40/60/1) adjusted to pH 7.0 with phosphoric acid  
Flow rate : 1.5 mL/min (adjust the flow rate so that the retention time of Lansoprazole is about 7 min)  
Temperature : 25°C  
Detection : UV at 285 nm  
Injection : 10  $\mu$ L  
(The draft for the Japanese Pharmacopoeia; Assay)

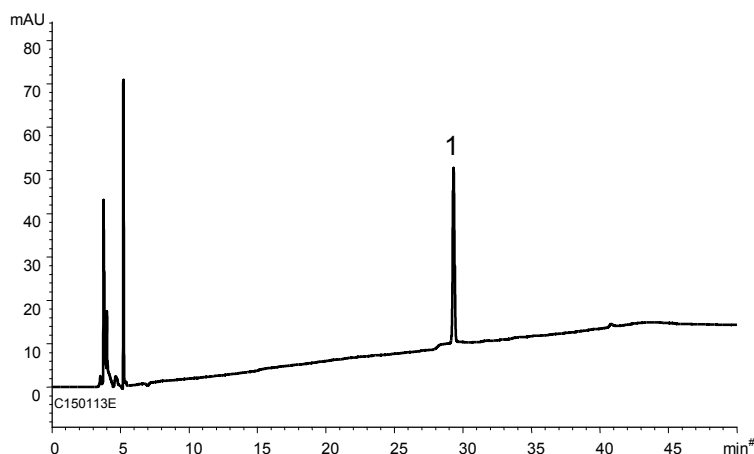
\*1 Standard solution was prepared from Lansoprazole supplied as a reagent for laboratory use.

\*2 triethylamine

ランソプラゾール（日本薬局方収載原案記載条件）  
Lansoprazole (The draft for the Japanese Pharmacopoeia)

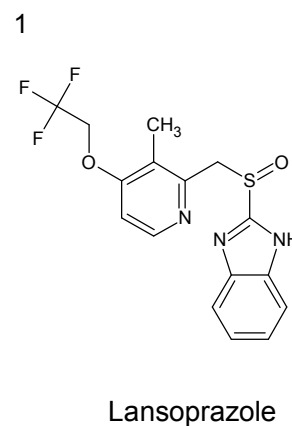
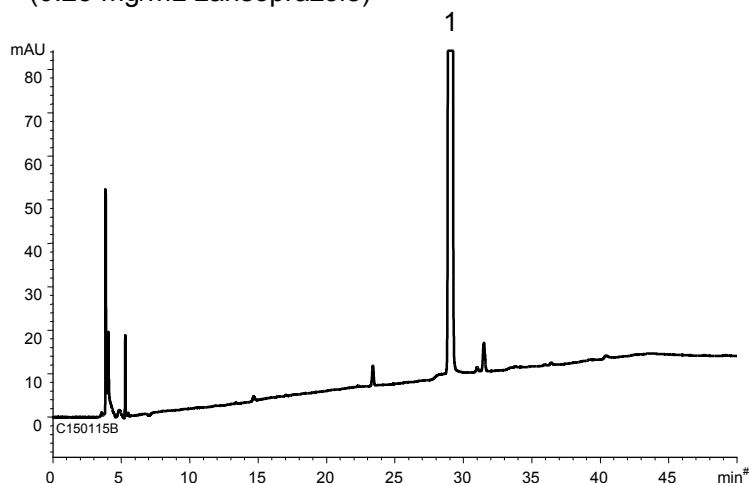
C150304A

(A) Standard solution<sup>\*1</sup>  
(0.0025 mg/mL Lansoprazole)



	System suitability requirement	Result
Theoretical plate number (Lansoprazole)	$\geq 150000$	221000
Tailing factor (Lansoprazole)	$\leq 1.5$	1.03
Relative standard deviation of the peak area (n=6) (Lansoprazole)	$\leq 3.0\%$	0.06%
Peak area ratio of test solution for required detectability (0.125 $\mu\text{g/mL}$ ) to standard solution (Lansoprazole)	4-6%	5.0%

(B) Sample solution<sup>\*1</sup>  
(0.25 mg/mL Lansoprazole)



Column : YMC-Triart C18 (5  $\mu\text{m}$ , 12 nm)  
150 X 4.6 mm I.D.

Eluent : A) water  
B) acetonitrile/water/TEA<sup>\*2</sup> (160/40/1) adjusted to pH 7.0 with phosphoric acid  
10-80%B (0-40 min), 80%B (40-50 min)

Flow rate : 0.65 mL/min (adjust the flow rate so that the retention time of Lansoprazole is about 29 min)

Temperature : 25°C

Detection : UV at 285 nm

Injection : 40  $\mu\text{L}$

(The draft for the Japanese Pharmacopoeia; Related substances)

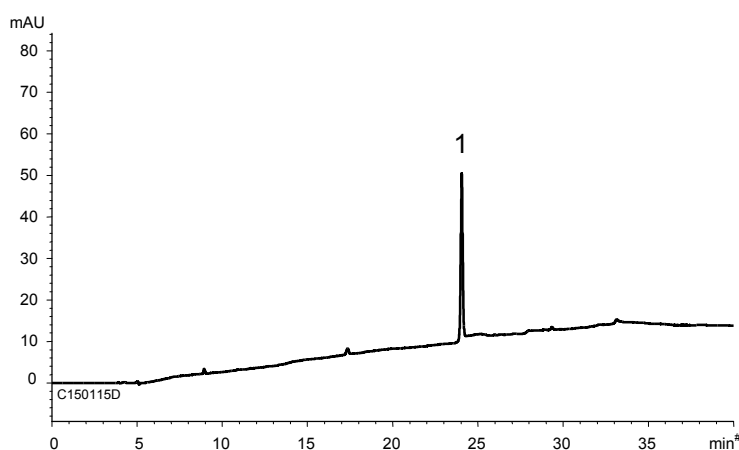
<sup>\*1</sup> All standard and sample solutions were prepared from Lansoprazole supplied as a reagent for laboratory use.

<sup>\*2</sup> triethylamine

ランソプラゾール腸溶性口腔内崩壊錠（日本薬局方収載原案記載条件）  
 Lansoprazole delayed-release orally disintegration tablets  
 (The draft for the Japanese Pharmacopoeia)

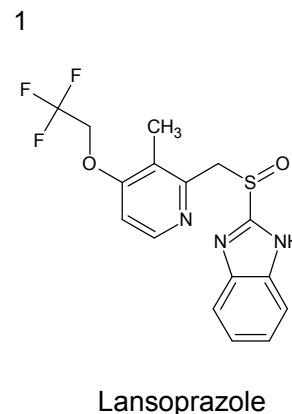
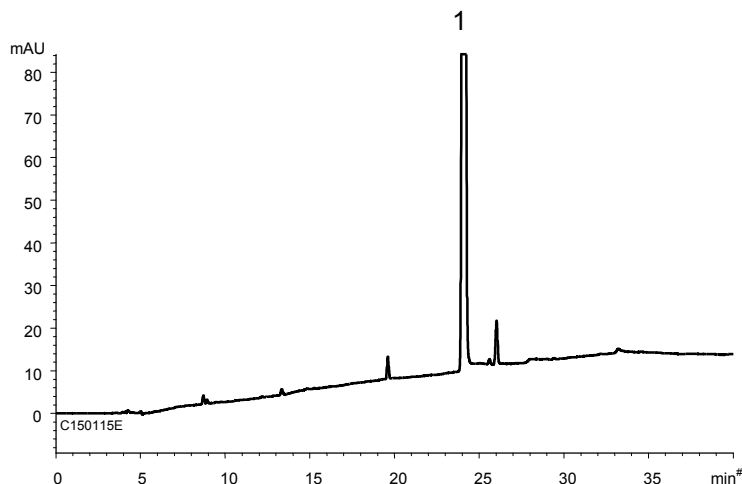
C150304B

(A) Standard solution\*1  
 (0.0025 mg/mL Lansoprazole)



	System suitability requirement	Result
Theoretical plate number (Lansoprazole)	$\geq 150000$	201200
Tailing factor (Lansoprazole)	$\leq 1.5$	1.07
Relative standard deviation of the peak area (n=6) (Lansoprazole)	$\leq 3.0\%$	0.75%
Peak area ratio of test solution for required detectability (0.125 $\mu\text{g/mL}$ ) to standard solution (Lansoprazole)	4-6%	5.4%

(B) Sample solution\*1  
 (0.25 mg/mL Lansoprazole)



Column : YMC-Triart C18 (5  $\mu\text{m}$ , 12 nm)  
 150 X 4.6 mm I.D.  
 Eluent : A) water  
 B) acetonitrile/water/TEA\*2 (160/40/1) adjusted to pH 7.0 with phosphoric acid  
 10-80%B (0-30 min), 80%B (30-40 min)  
 Flow rate : 0.65 mL/min (adjust the flow rate so that the retention time of Lansoprazole is about 24 min)  
 Temperature : 25°C  
 Detection : UV at 285 nm  
 Injection : 40  $\mu\text{L}$

(The draft for the Japanese Pharmacopoeia; Related substances)

\*1 All standard and sample solutions were prepared from Lansoprazole supplied as a reagent for laboratory use.

\*2 triethylamine