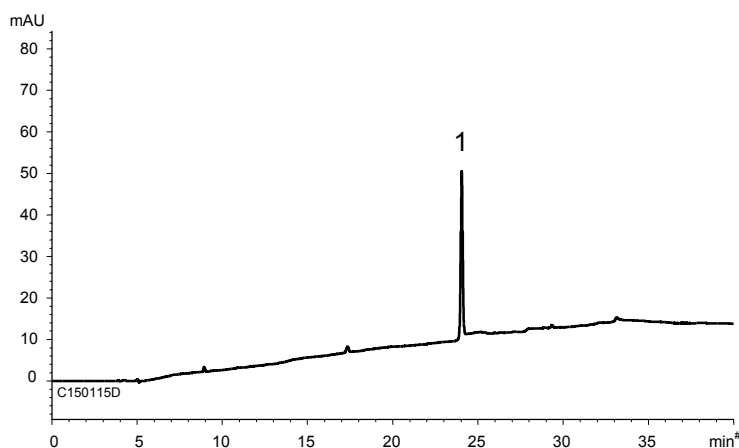


ランソプラゾール腸溶性口腔内崩壊錠（日本薬局方収載原案記載条件）
 Lansoprazole delayed-release orally disintegration tablets
 (The draft for the Japanese Pharmacopoeia)

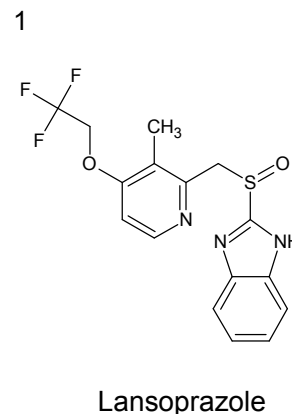
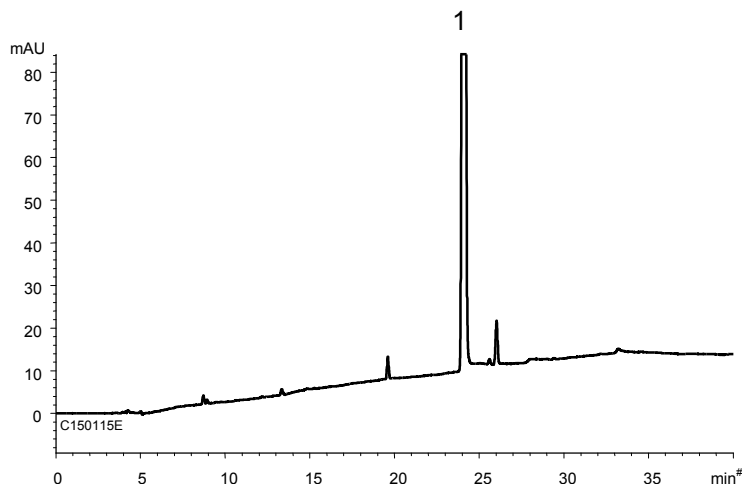
C150304B

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



	System suitability requirement	Result
Theoretical plate number (Lansoprazole)	≥ 150000	201200
Tailing factor (Lansoprazole)	≤ 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 μm , 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 μL

(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