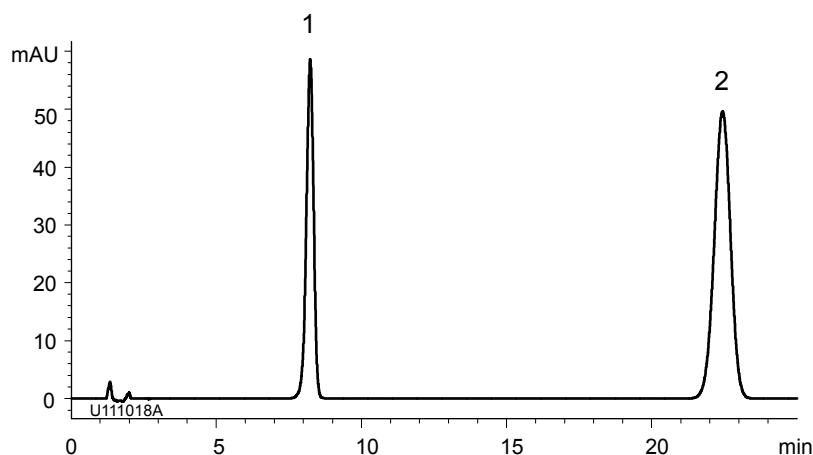


オメプラゾール
Omeprazole

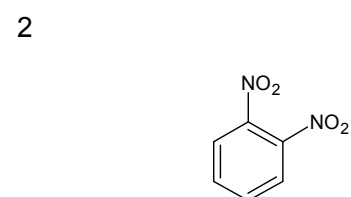
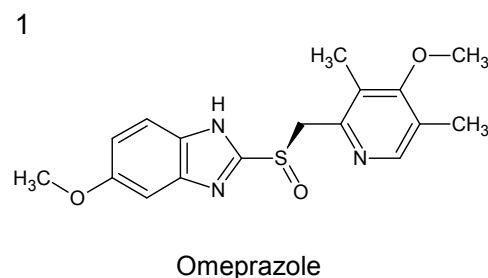
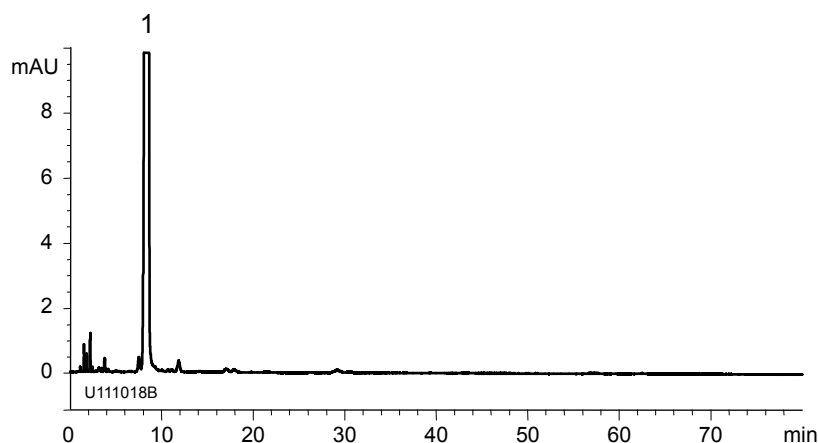
U111029A

A) System performance (0.1 mg/mL Omeprazole, 0.25 mg/mL 1,2-Dinitrobenzene)



	System suitability requirement	result
Resolution (1, 2)	≥ 10	19.1

B) Sample solution (1.0 mg/mL Omeprazole)



1,2-Dinitrobenzene (I.S.)

Column : YMC-Triart C8 (5 μ m, 12 nm)
150 X 4.6 mmI.D.

Eluent : phosphate buffer (pH 7.6)* / acetonitrile (29/11)
*Dissolve 2.83 g of $\text{Na}_2\text{HPO}_4 \cdot 12\text{H}_2\text{O}$ and 0.21 g of $\text{NaH}_2\text{PO}_4 \cdot 2\text{H}_2\text{O}$ in 1000 mL water, adjust pH 7.6 with H_3PO_4 (1 \rightarrow 100)

Flow rate : 1.25 mL/min (adjust the flow rate so that the retention time of omeprazole is about 8 min)

Temperature : 25°C

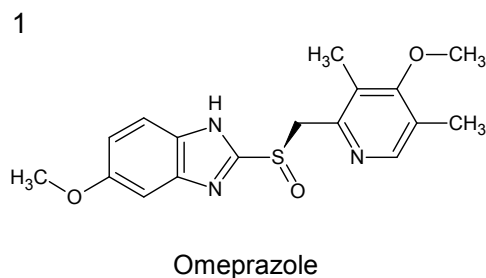
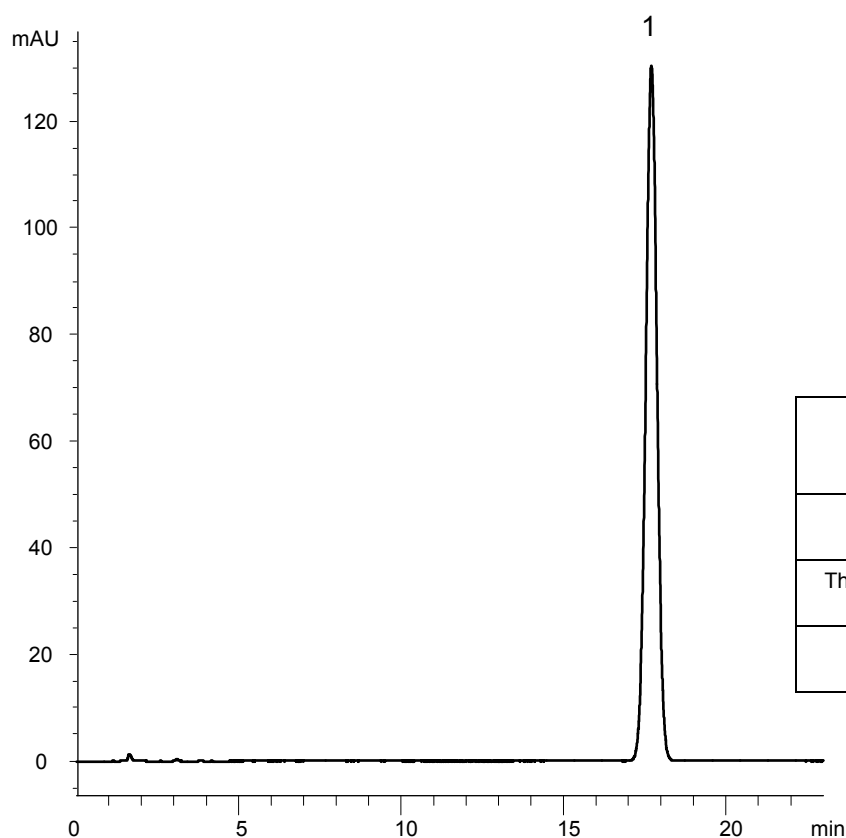
Detection : UV at 280 nm

Injection : 10 μ L

(The Japanese Pharmacopoeia 16th; Related substances)

オメプラゾール
Omeprazole

U111102D



	System suitability requirement	result
Capacity factor (Omeprazole)	≥ 6.0	9.9
Theoretical plate number (Omeprazole)	≥ 3000	12200
Tailing factor (Omeprazole)	≤ 1.5	1.00

Column : YMC-Triart C8 (5 μ m, 12 nm)
150 X 4.6 mmI.D.

Eluent : phosphate buffer (pH 7.6)* / acetonitrile (3/1)
*Dissolve 2.83 g of $\text{Na}_2\text{HPO}_4 \cdot 12\text{H}_2\text{O}$ and 0.21 g of $\text{NaH}_2\text{PO}_4 \cdot 2\text{H}_2\text{O}$ in 1000 mL water, adjust pH 7.6 with H_3PO_4 (1 \rightarrow 100)

Flow rate : 0.8 mL/min

Temperature : 25°C

Detection : UV at 280 nm

Injection : 20 μ L (0.1 mg/mL)

(The United States Pharmacopeia 34th; Assay)