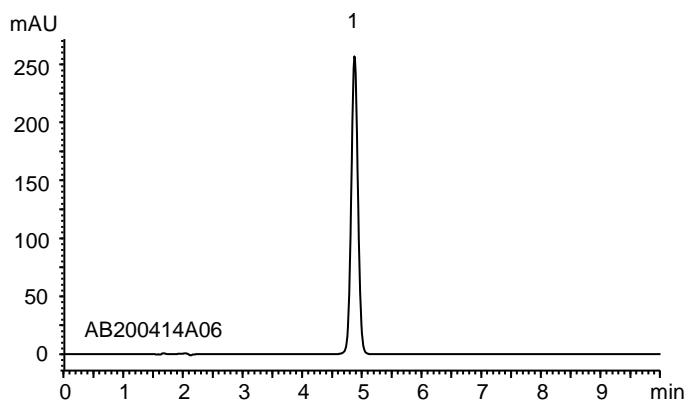


エソメプラゾールマグネシウム (米国薬局方記載条件)
Esomeprazole Magnesium (The United States Pharmacopeia)

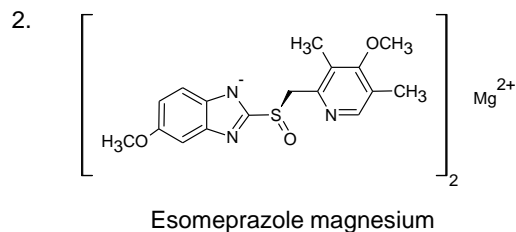
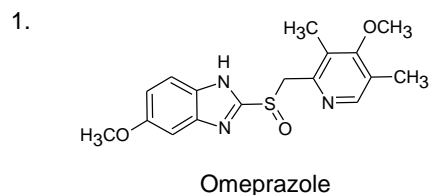
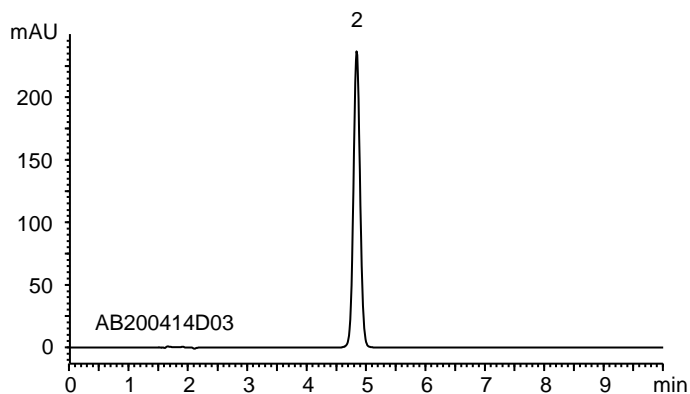
AB200829A

(A) Standard solution*1
(0.05 mg/mL Omeprazole)



	System suitability requirement	Result
Theoretical plate number (Omeprazole)	≥ 2000	9400
Relative standard deviation of the peak area (n=6) (Omeprazole)	$\leq 2.0\%$	0.36%

(B) Sample solution*1
(0.05 mg/mL Esomeprazole magnesium)



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

Eluent : phosphate buffer (pH 7.6)*2/acetonitrile (13/7)

*2 Dissolve 4.472 g of $\text{Na}_2\text{HPO}_4 \cdot 2\text{H}_2\text{O}$ and 0.725 g of NaH_2PO_4 in 1000 mL water, dilute 250 mL of this solution with water to 1000 mL and adjust pH 7.6 with H_3PO_4

Flow rate : 1.0 mL/min

Temperature : 25°C

Detection : UV at 280 nm

Injection : 20 μ L

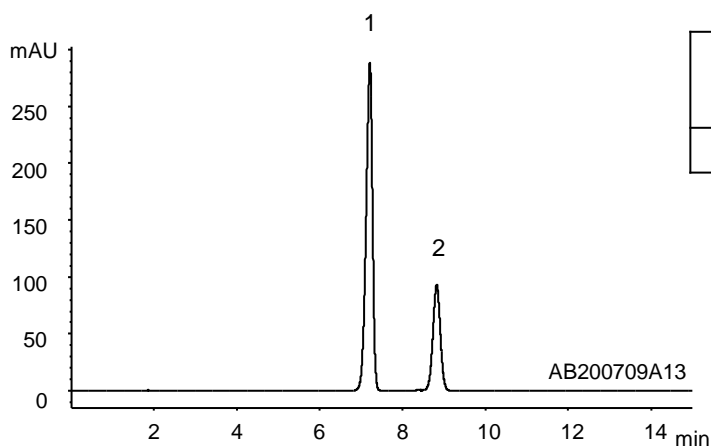
(The United States Pharmacopeia 42th; ASSAY)

*1 All standard and sample solutions were prepared from Omeprazole and Esomeprazole magnesium supplied as a reagent for laboratory use.

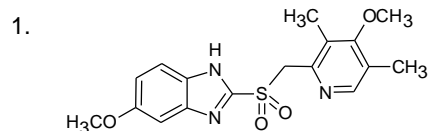
エソメプラゾールマグネシウム (米国薬局方記載条件)
Esomeprazole Magnesium (The United States Pharmacopeia)

AB200830A

(A) System suitability solution*1
(0.04 mg/mL Omeprazole related compound A, 0.04 mg/mL Omeprazole)

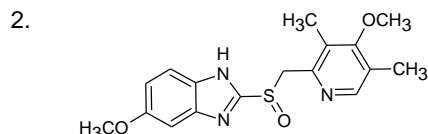
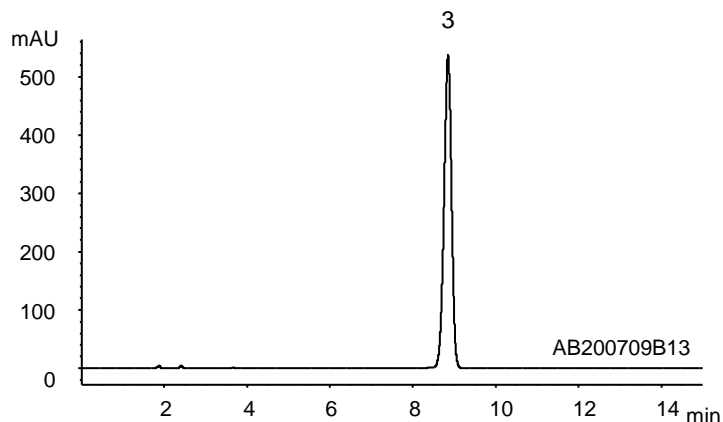


	System suitability requirement	Result
Resolution (1, 2)	≥ 3.0	5.4

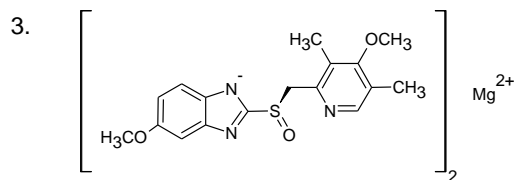


Omeprazole related compound A
(Omeprazole sulfone)

(B) Sample solution*1
(0.16 mg/mL Esomeprazole magnesium)



Omeprazole



Esomeprazole magnesium

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

Eluent : phosphate buffer (pH 7.6)*2/acetonitrile (29/11)

*2Dissolve 4.472 g of Na₂HPO₄·2H₂O and 0.725 g of NaH₂PO₄ in 1000 mL water, dilute 250 mL of this solution with water to 1000 mL and adjust pH 7.6 with H₃PO₄

Flow rate : 1.0 mL/min

Temperature : 45°C

Detection : UV at 280 nm

Injection : 50 μL

(The United States Pharmacopeia 42th; ORGANIC IMPURITIES)

*1All system suitability and sample solutions were prepared from Omeprazole related compound A, Omeprazole and Esomeprazole magnesium supplied as a reagent for laboratory use.