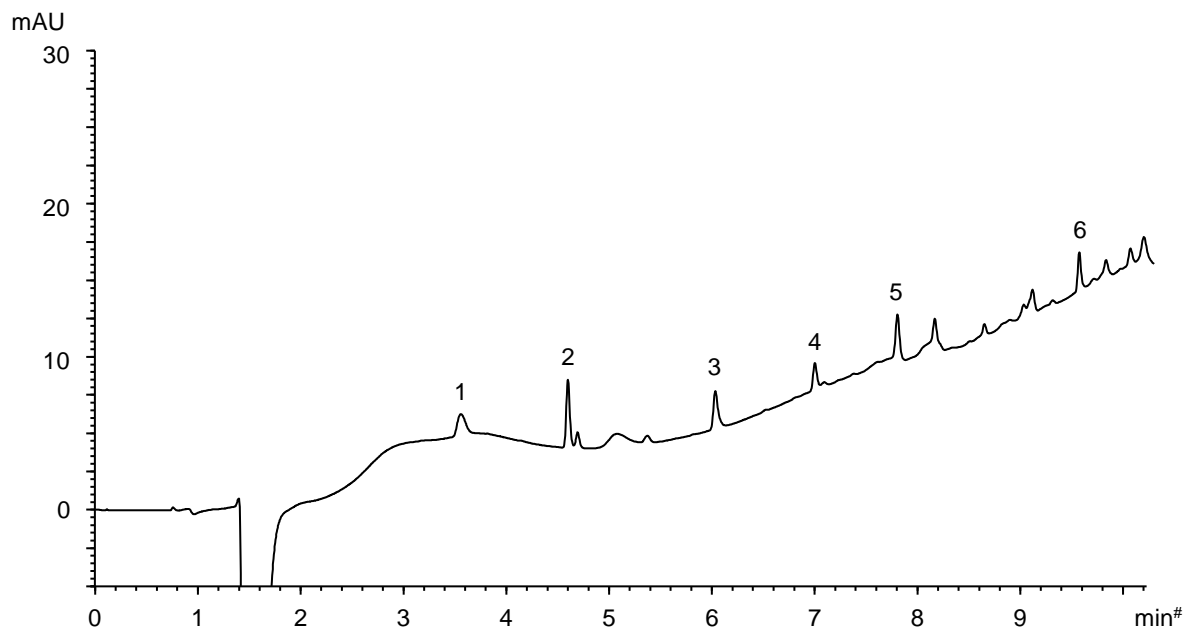
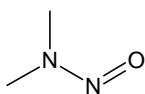


ニトロソアミン類
Nitrosamines

AB210322B

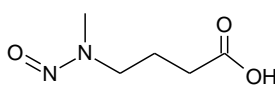


1.



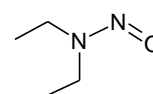
N-Nitrosodimethylamine
(NDMA)

2.



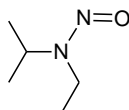
N-Nitroso-*N*-methyl-4-aminobutyric acid
(NMBA)

3.



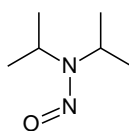
N-Nitrosodiethylamine
(NDEA)

4.



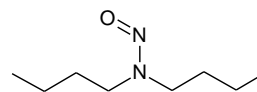
N-Nitrosoisopropylethylamine
(NIPEA)

5.



N-Nitrosodiisopropylamine
(NDIPA)

6.



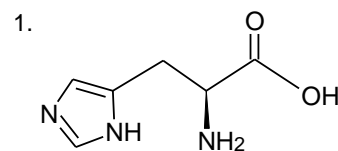
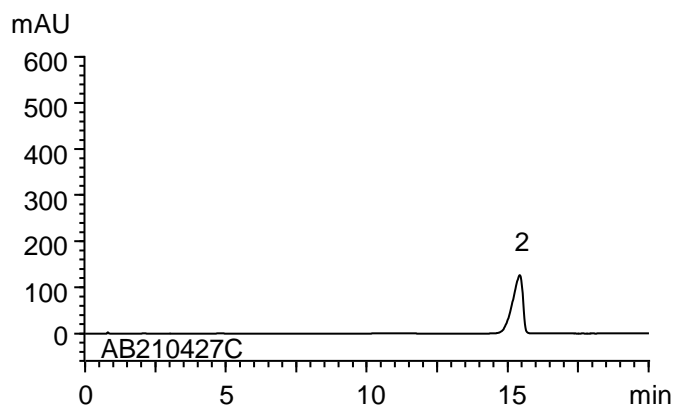
N-Nitrosodibutylamine
(NDBA)

Column	: YMC-Triart C18 (1.9 μ m, 12 nm) 100 X 2.0 mm I.D.
Eluent	: A) water/formic acid (100/0.1) B) methanol/formic acid (100/0.05) 0-95%B (0-10 min)
Flow rate	: 0.2 mL/min
Temperature	: 40°C
Detection	: UV at 245 nm
Injection	: 40 μ L (10 ng/mL)

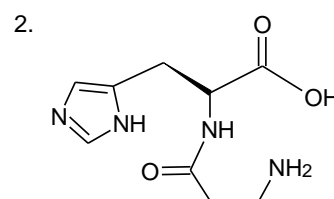
ポラプレジンク (日本薬局方記載条件)
Polaprezinc (The Japanese Pharmacopoeia)

AB210510A

(A) Standard solution*2 (0.2 mg/mL L-Carnosine)

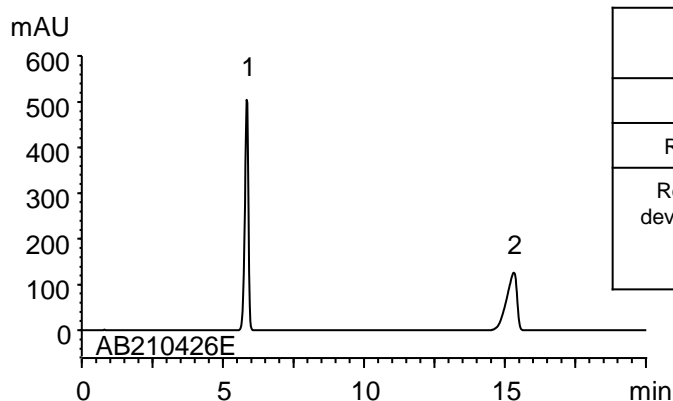


L-Histidine



L-Carnosine

(B) System performance test solution*2
(0.25 mg/mL L-Histidine, 0.2 mg/mL L-Carnosine)



	System suitability requirement	Result
Elution order	1, 2	1, 2
Resolution (1,2)	≥ 12	19
Relative standard deviation of the peak area (n=6) (L-Carnosine)	$\leq 1.0\%$	0.2%

Column : YMC-Triart C18 (5 μm , 12 nm)
150 X 4.6 mm I.D.

Eluent : phosphate buffer (pH 3.5)*1 containing 2.22 g/L sodium 1-octanesulfonate /acetonitrile (90/10)

*1 Dissolve 1.4 g of KH_2PO_4 in 1000 mL of water, adjust pH 3.5 with 1% H_3PO_4 .

Flow rate : 1.35 mL/min (adjust the flow rate so that the retention time of L-Carnosine is about 15 min)

Temperature : 45°C

Detection : UV at 210 nm

Injection : 10 μL

(The Japanese Pharmacopoeia 17th 2nd supplement; Assay (1) Polaprezinc)

*2 All system performance test and standard solutions were prepared from L-Carnosine supplied as a reagent for laboratory use.

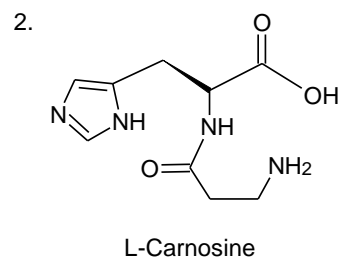
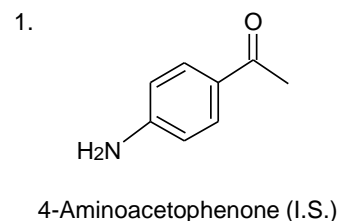
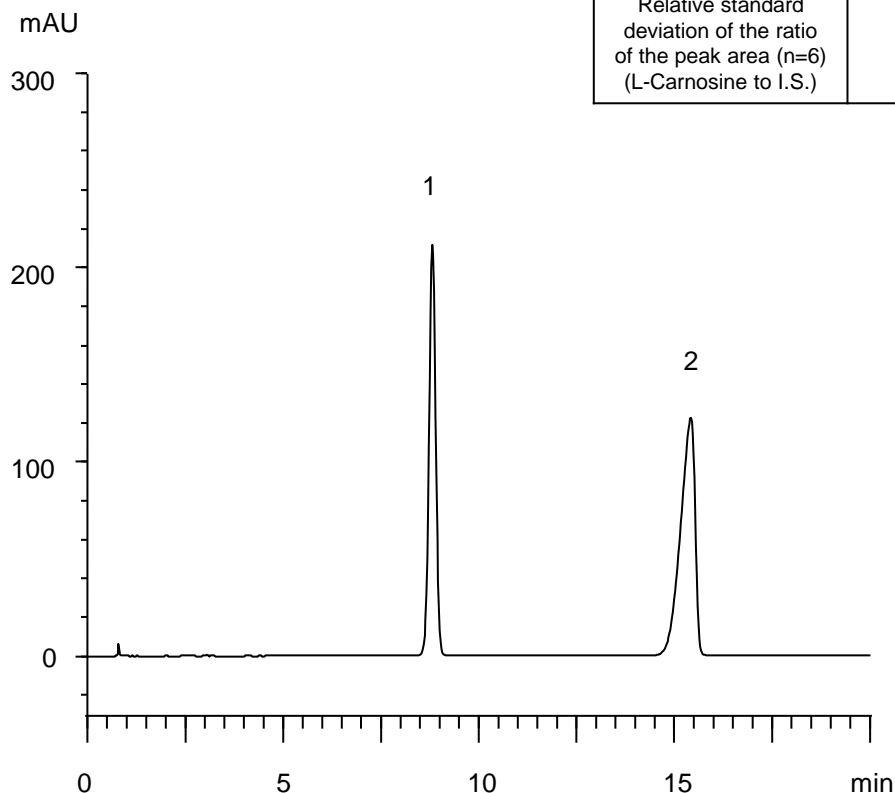
ポラプレジンク顆粒 (日本薬局方記載条件)

Polaprezinc Granules (The Japanese Pharmacopoeia)

AB210427A

Standard solution*2
(0.25 mg/mL 4-Aminoacetophenone,
0.4 mg/mL L-Carnosine)

	System suitability requirement	Result
Elution order	1, 2	1, 2
Resolution (1,2)	≥ 6	12
Relative standard deviation of the ratio of the peak area (n=6) (L-Carnosine to I.S.)	$\leq 1.0\%$	0.1%



Column : YMC-Triart C18 (5 μ m, 12 nm)
150 X 4.6 mm I.D.

Eluent : phosphate buffer (pH 3.5)*1 containing 2.22 g/L sodium 1-octanesulfonate /acetonitrile (90/10)

*1 Dissolve 1.4 g of KH_2PO_4 in 1000 mL of water, adjust pH 3.5 with 1% H_3PO_4 .

Flow rate : 1.35 mL/min (adjust the flow rate so that the retention time of L-Carnosine is about 15 min)

Temperature : 45°C

Detection : UV at 210 nm

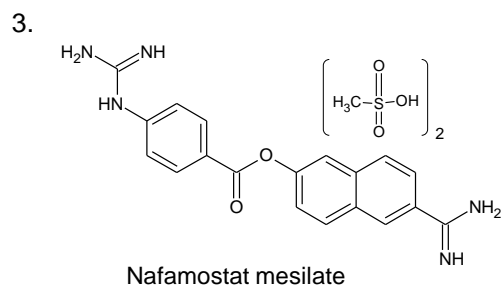
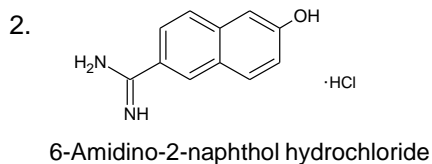
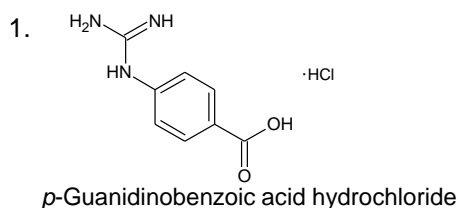
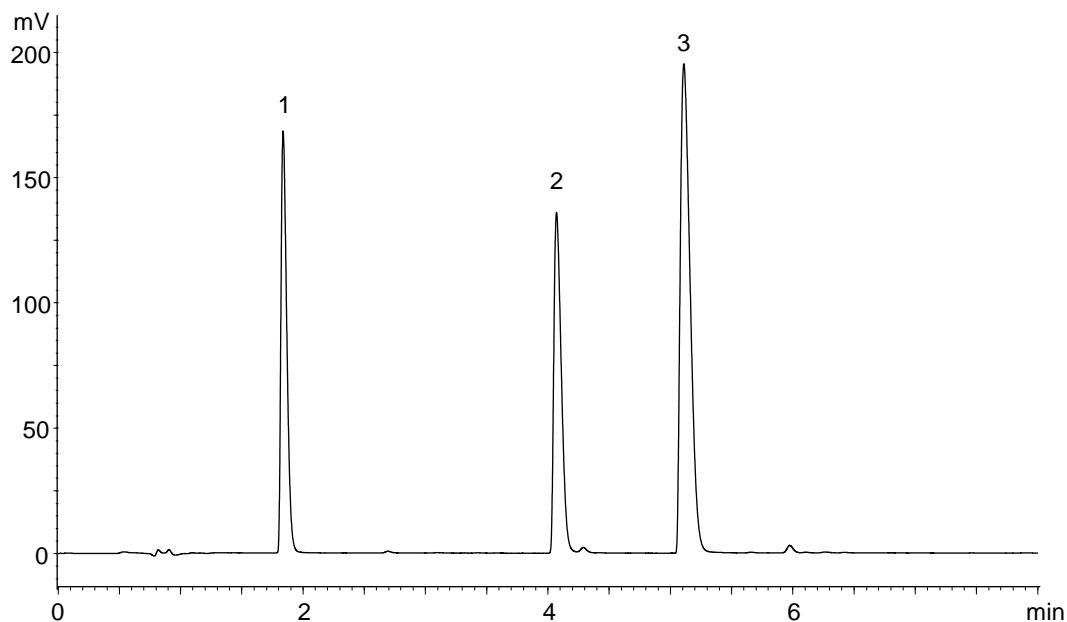
Injection : 5 μ L

(The Japanese Pharmacopoeia 17th 2nd supplement; Assay)

*2 Standard solution was prepared from L-Carnosine supplied as a reagent for laboratory use.

ナファモスタットおよび代謝物
Nafamostat and its metabolites

AA210326A



Column	: YMC-Triart C18 (1.9 μm, 12 nm) 50 X 2.1 mm I.D.
Eluent	: A) water/formic acid (100/0.1) B) methanol/formic acid (100/0.1) 5-35%B (0-6 min), 35%B (6-8 min)
Flow rate	: 0.21 mL/min
Temperature	: 40°C
Detection	: UV at 260 nm
Injection	: 2 μL (0.016 ~ 0.033 mg/mL)