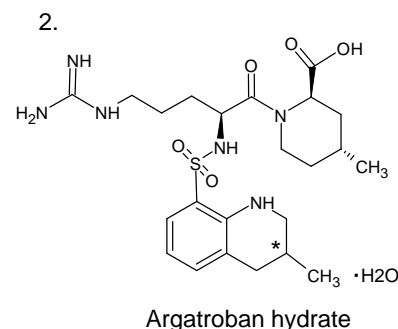
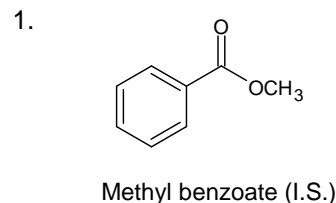
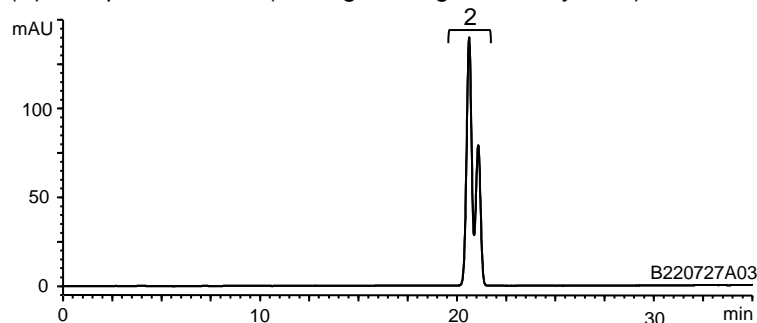


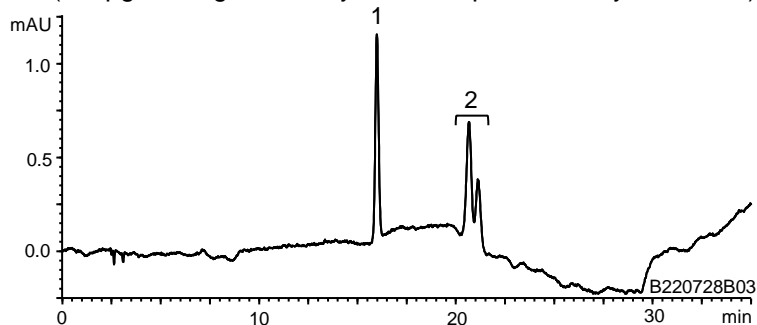
アルガトロバン水和物 (日本薬局方記載条件)
Argatroban Hydrate (The Japanese Pharmacopoeia)

B220824A

(A) Sample solution*1 (0.5 mg/mL Argatroban hydrate)

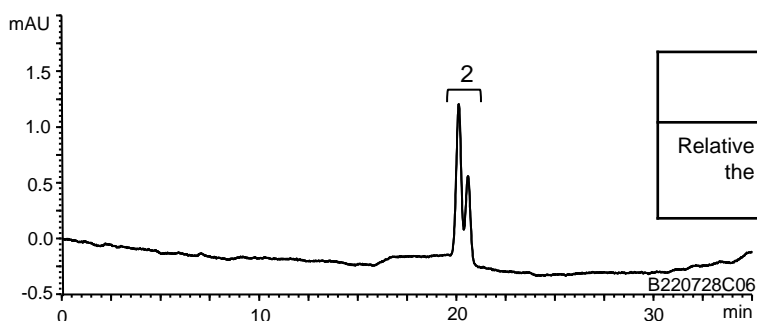


(B) System performance test solution*1
(2.5 µg/mL Argatroban hydrate, 2.5 µL/mL Methyl benzoate)



	System suitability requirement	Result
Elution order	1,2	1,2
Resolution (1,2)	≥ 3	12.0

(C) System suitability solution*1 (5.0 µg/mL Argatroban hydrate)



	System suitability requirement	Result
Relative standard deviation of the peak area (n=6) (Argatroban)	≤ 2.0%	1.62%

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

Eluent : A) buffer (pH 5.0)*2/methanol (50/50)
B) buffer (pH 5.0)*2/methanol (20/80)
0%B (0-5 min), 0-95%B (5-35 min)
*2 To 2.5 mL of acetic acid (100) add water to make 1000 mL, adjust pH 5.0 with ammonia TS.

Flow rate : 1.0 mL/min

Temperature : 45°C

Detection : UV at 254 nm

Injection : 10 µL

(The Japanese Pharmacopoeia 18th; Related substances 1)

*1 Sample solution, system performance test solution and system suitability solution were prepared from Argatroban hydrate supplied as a reagent for laboratory use.