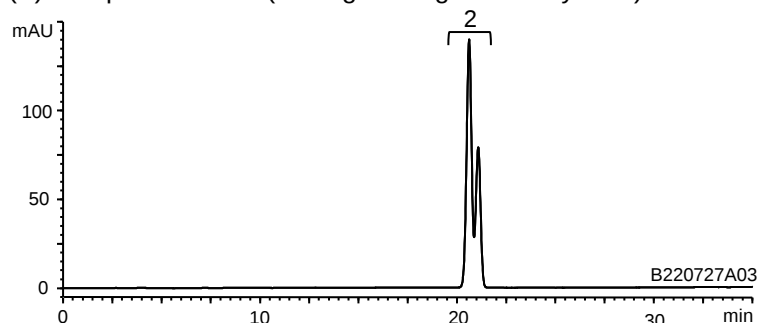


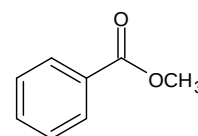
アルガトロバン水和物（日本薬局方記載条件）
Argatroban Hydrate (The Japanese Pharmacopoeia)

B220824A

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

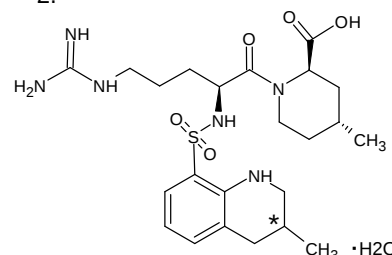


1.



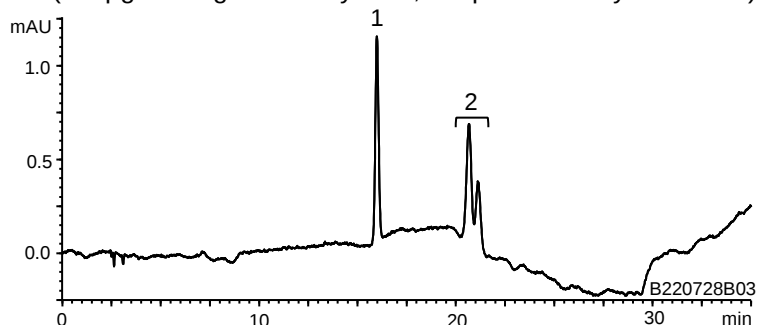
Methyl benzoate (I.S.)

2.



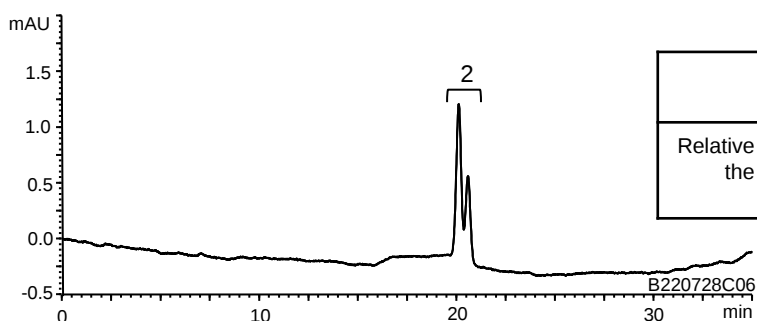
Argatroban hydrate

(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)	$\leq 2.0\%$	1.62%

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

*2To 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)

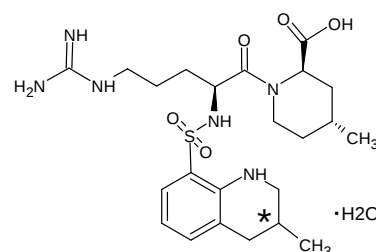
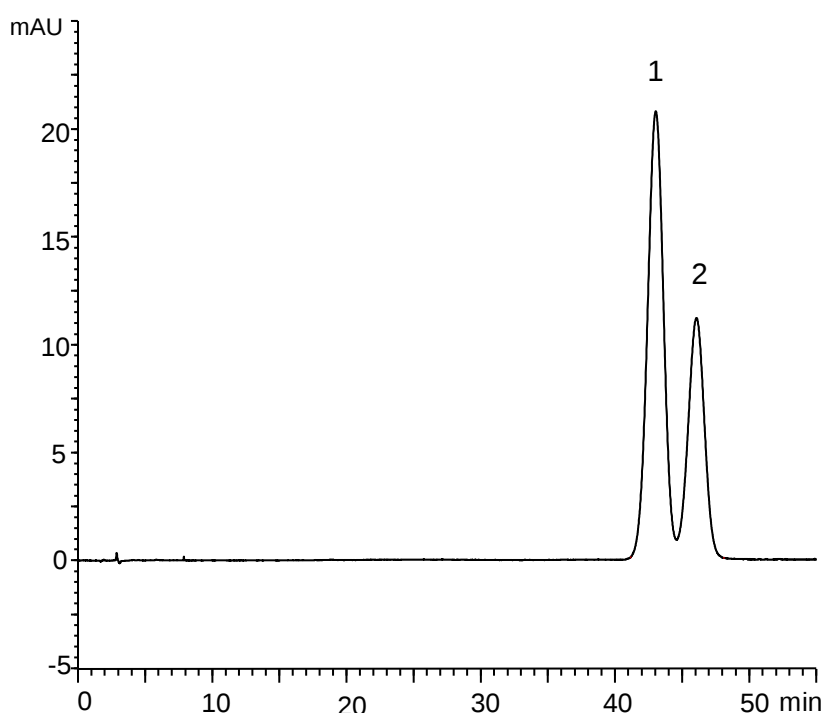
*1 Sample solution, system performance test solution and system suitability solution were prepared from Argatroban hydrate supplied as a reagent for laboratory use.

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

B220927C

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

	System suitability requirement	Result
Resolution (1,2)	≥ 1.2	1.37
Relative standard deviation of the peak area (n=6) (Argatroban)	≤ 2.0	0.28



Argatroban hydrate

Column : YMC-Pack Pro C18 RS (5 μ m, 8 nm)
150 X 6.0 mm I.D.

Eluent : To 500 mL of water add 500 mL of methanol, 13 mL of diluted 40% tetrabutylammonium hydroxide TS (1 $\rightarrow$ 4) and 0.68 mL of phosphoric acid, and adjust the pH to 6.8 with ammonia TS and diluted 28% ammonia solution (1 $\rightarrow$ 20)

Flow rate : 1.3 mL/min
(adjust so that retention time of the peak having the shorter retention time of the two peaks of Argatroban is about 40 min)

Temperature : 40°C

Detection : UV at 254 nm

Injection : 10 μ L

(The Japanese Pharmacopoeia 18th; Isomer ratio)

*1 Sample solution was prepared from Argatroban hydrate supplied as a reagent for laboratory use.