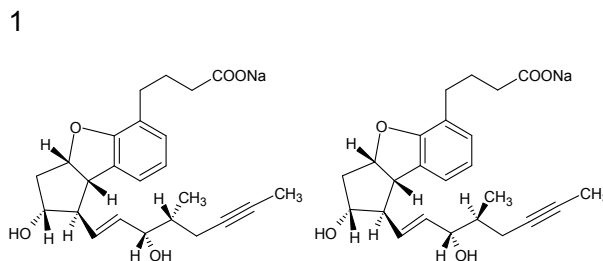


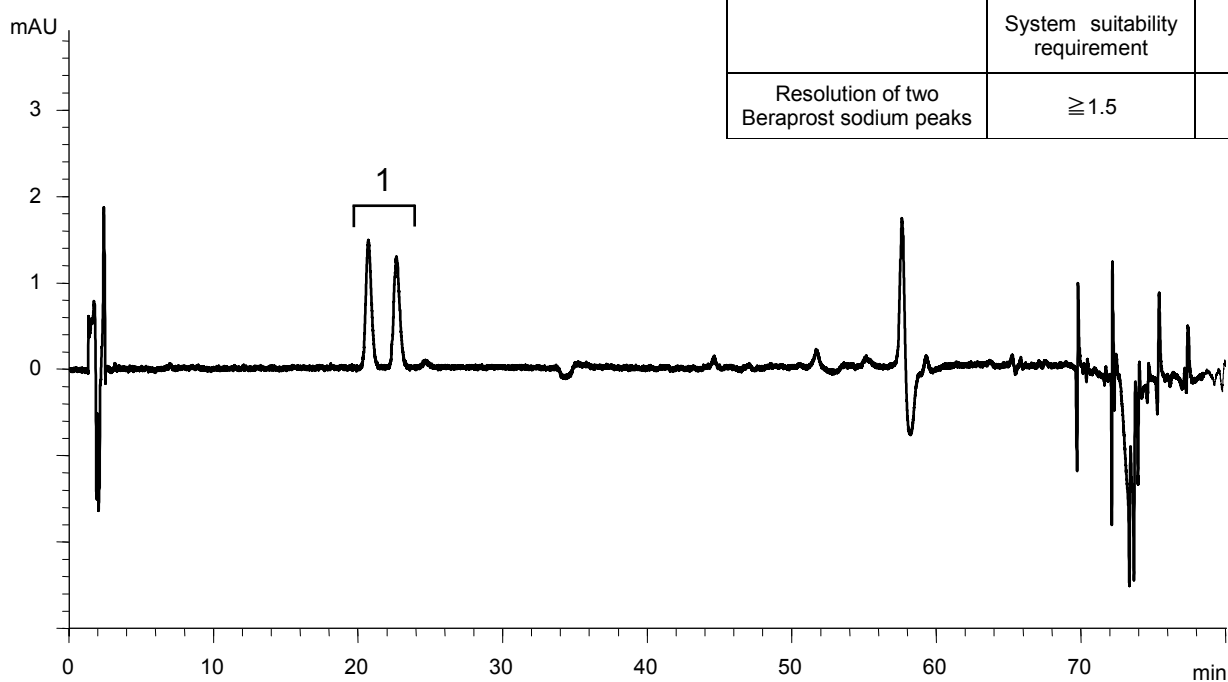
ベラプロストナトリウム（日本薬局方記載条件）
Beraprost sodium (The Japanese pharmacopoeia)

D111129A



Beraprost sodium

System suitability solution*
(0.025 mg/mL Beraprost sodium)



	System suitability requirement	Result
Resolution of two Beraprost sodium peaks	≥ 1.5	2.7

Column : J'sphere ODS-L80 (4 μ m, 8 nm)
250 X 4.0 mmI.D.

Eluent : A) acetonitrile/methanol/water/acetic acid (33/3/64/0.1)
B) acetonitrile/water/acetic acid (90/10/0.1)
0%B (0-30 min), 0-44%B (30-45 min), 44%B (45-60 min),
44-100%B (60-70 min), 100%B (70-80 min)

Flow rate : 1.2 mL/min (*adjust the flow rate so that the retention time of the second peak of beraprost is about 23 min*)

Temperature : 35°C

Detection : UV at 285 nm

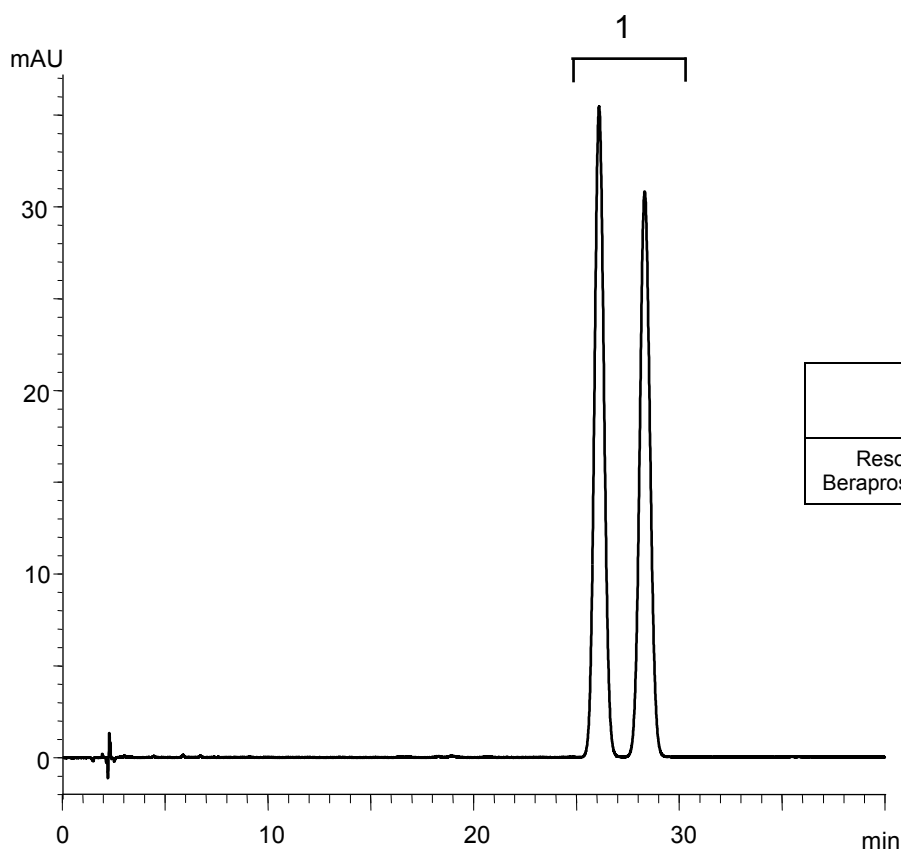
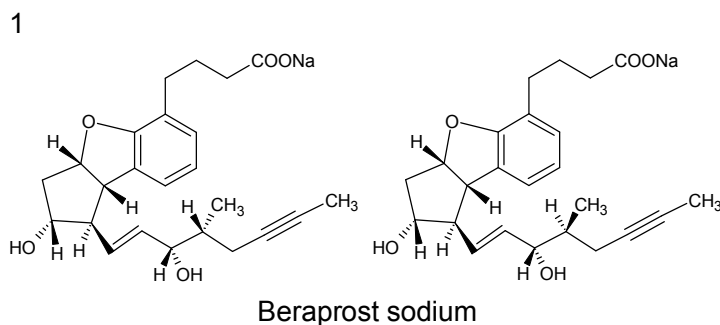
Injection : 15 μ L

(The Japanese Pharmacopoeia 16th; Related substances)

* System suitability solution was prepared from Beraprost sodium supplied as a reagent for laboratory use.

ベラプロストナトリウム（日本薬局方記載条件）
Beraprost sodium (The Japanese Pharmacopoeia)

D111213C



	System suitability requirement	Result
Resolution of two Beraprost sodium peaks	≥ 1.2	2.5

Column : YMC-Pack Pro C18 (5 μ m, 12 nm)
150 X 6.0 mmI.D.

Eluent : methanol/water/acetic acid (60/40/0.1)

Flow rate : 1.2 mL/min (*adjust the flow rate so that the retention time of the second peak of beraprost is about 27 min*)

Temperature : 40°C

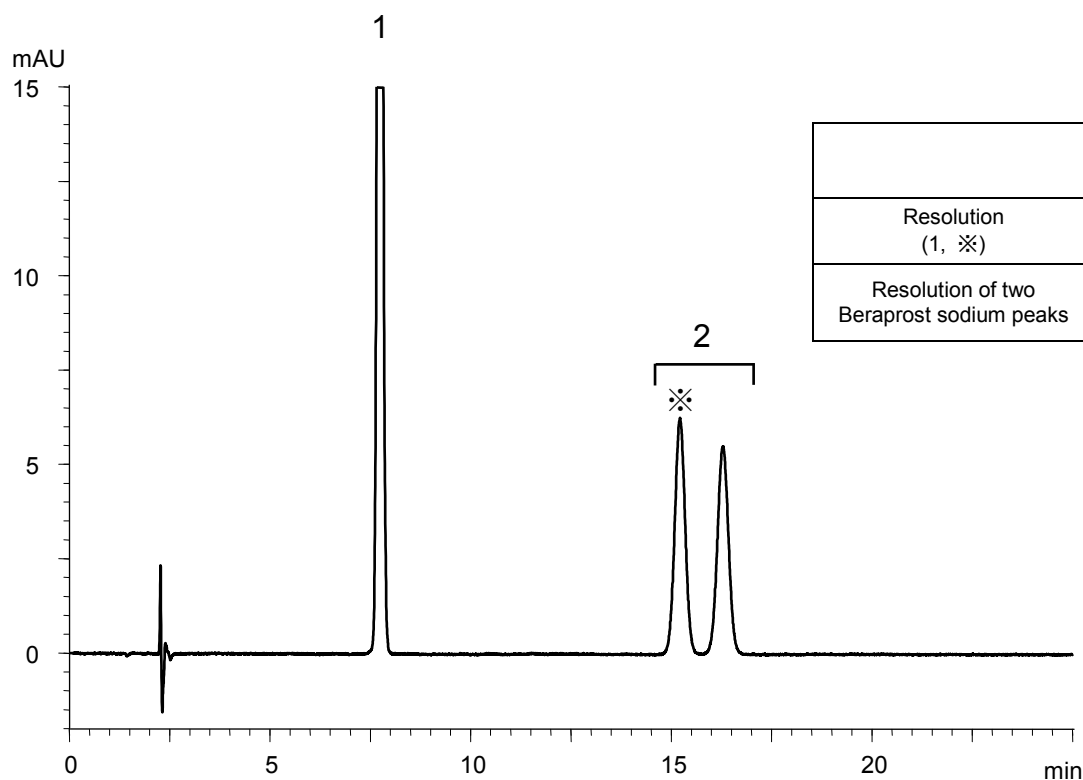
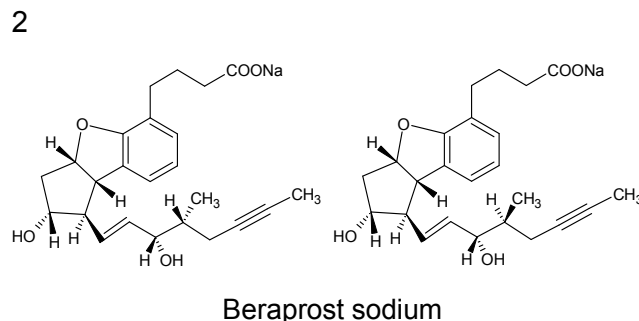
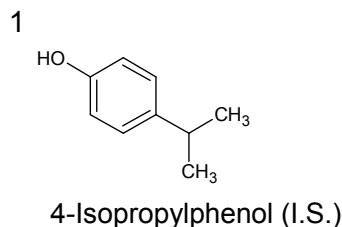
Detection : UV at 285 nm

Injection : 15 μ L (0.5 mg/mL)

(Modified conditions of The Japanese Pharmacopoeia 16th; Isomer ratio)

ベラプロストナトリウム錠 (日本薬局方記載条件)
Beraprost sodium tablets (The Japanese Pharmacopoeia)

D111209B



	System suitability requirement	Result
Resolution (1, ※)	≥ 11	21.5
Resolution of two Beraprost sodium peaks	≥ 1.5	2.2

Column : YMC-Pack Pro C18 (5 μ m, 12 nm)
150 X 6.0 mm I.D.

Eluent : methanol/water/acetic acid (65/35/0.1)

Flow rate : 1.2 mL/min (adjust the flow rate so that the retention time of the first peak of beraprost is about 15 min)

Temperature : 40°C

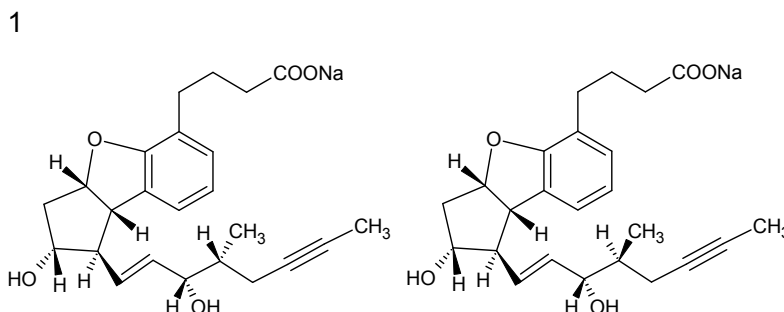
Detection : UV at 285 nm

Injection : 20 μ L (0.05 mg/mL)

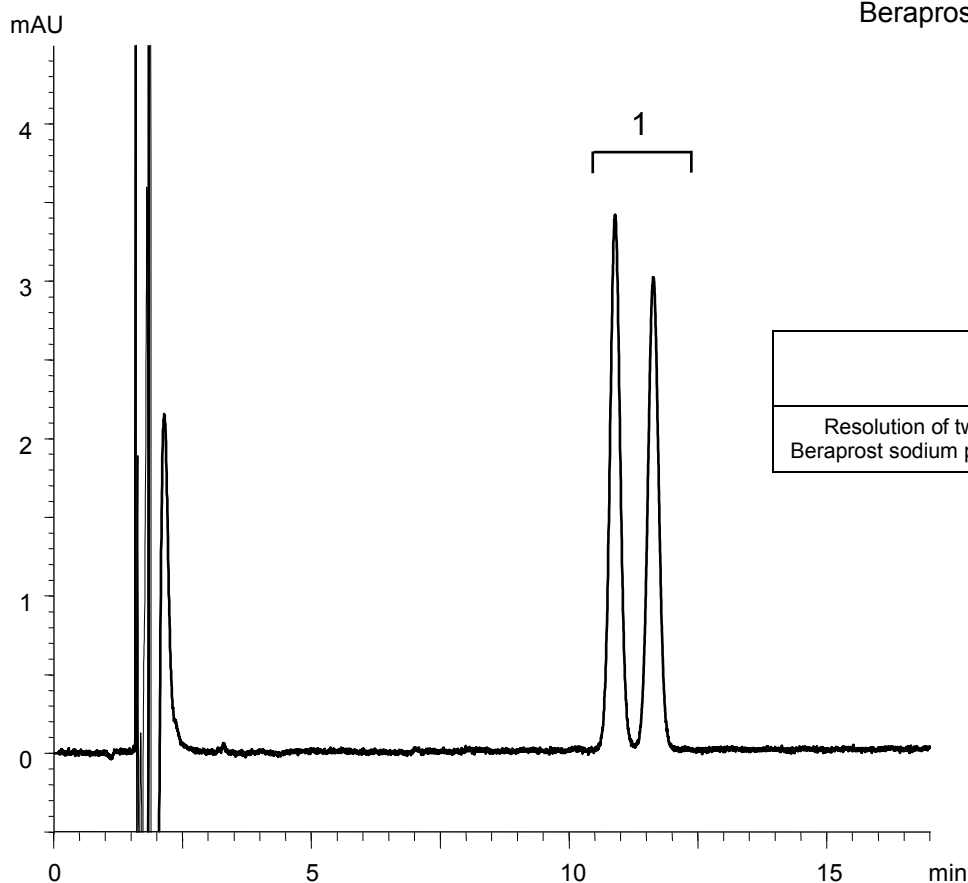
(Modified conditions of The Japanese Pharmacopoeia 16th; Assay)

ベラプロストナトリウム錠 (日本薬局方記載条件)
Beraprost sodium tablets (The Japanese Pharmacopoeia)

D111208D



Beraprost sodium



	System suitability requirement	Result
Resolution of two Beraprost sodium peaks	≥ 1.2	1.9

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

Eluent : methanol/water/acetic acid (65/35/0.1)

Flow rate : 1.0 mL/min (adjust the flow rate so that the retention time of the first peak of beraprost is about 10 min)

Temperature : 40°C

Detection : UV at 285 nm

Injection : 200 μ L (0.002 mg/mL)

(Modified conditions of The Japanese Pharmacopoeia 16th; Dissolution)