

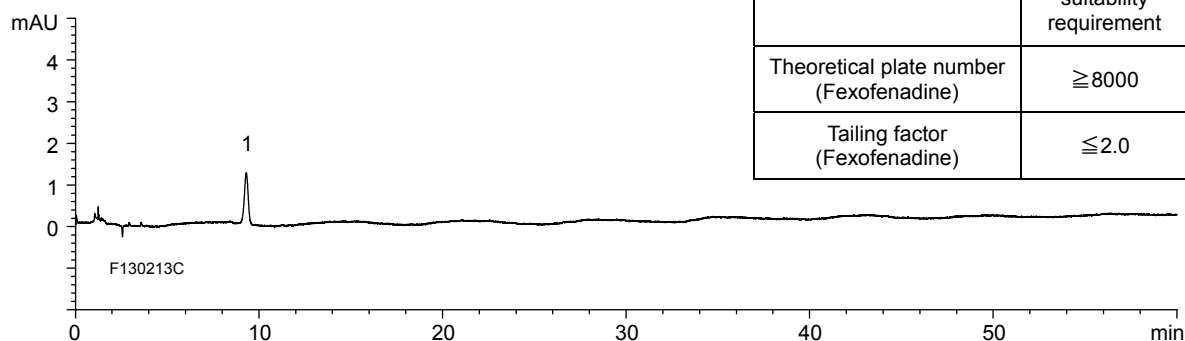
フェキソフェナジン塩酸塩 (日本薬局方記載条件)

Fexofenadine Hydrochloride (The Japanese Pharmacopoeia)

F130218A

A) Standard solution*¹

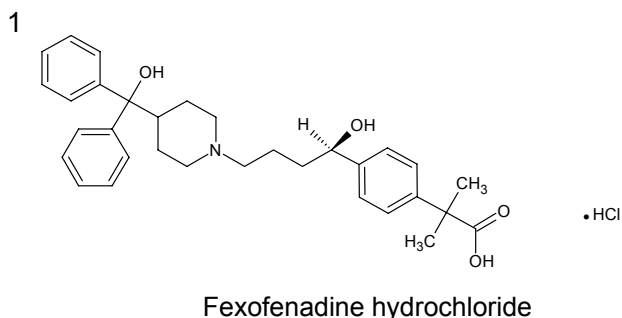
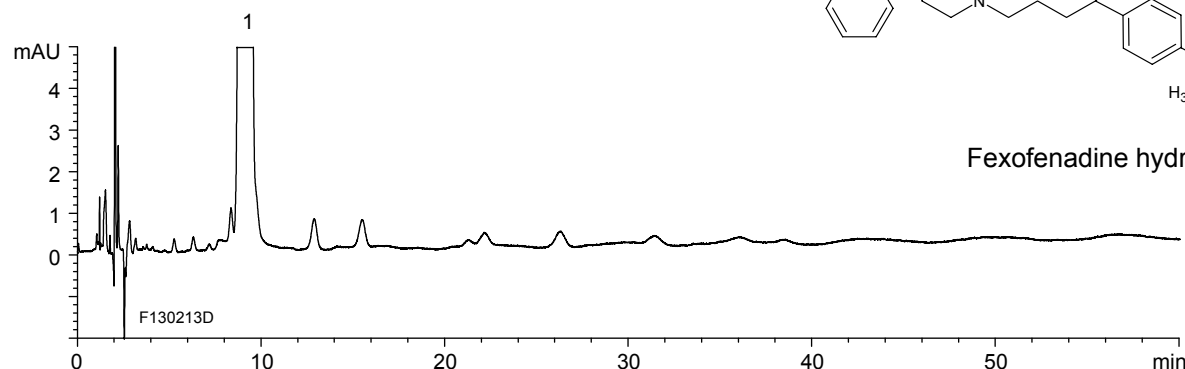
(0.001 mg/mL Fexofenadine hydrochloride)



	System suitability requirement	result
Theoretical plate number (Fexofenadine)	≥ 8000	10100
Tailing factor (Fexofenadine)	≤ 2.0	1.00

B) Sample solution*¹

(1 mg/mL Fexofenadine hydrochloride)



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

Eluent : acetonitrile/buffer*²/triethylamine (350/650/3)
*² Dissolve 7.51 g of NaH₂PO₄ · 2H₂O and 0.96 g of NaClO₄ · H₂O in 1000 mL water, adjust pH 2.0 with H₃PO₄

Flow rate : 2.0 mL/min (adjust the flow rate so that the retention time of fexofenadine is about 9 min)

Temperature : 25°C

Detection : UV at 220 nm

Injection : 20 μL

(The Japanese Pharmacopoeia 16th; Related substances)

*¹ All standard and sample solutions were prepared from Fexofenadine hydrochloride supplied as a reagent for laboratory use.

フェキソフェナジン塩酸塩 (日本薬局方記載条件)

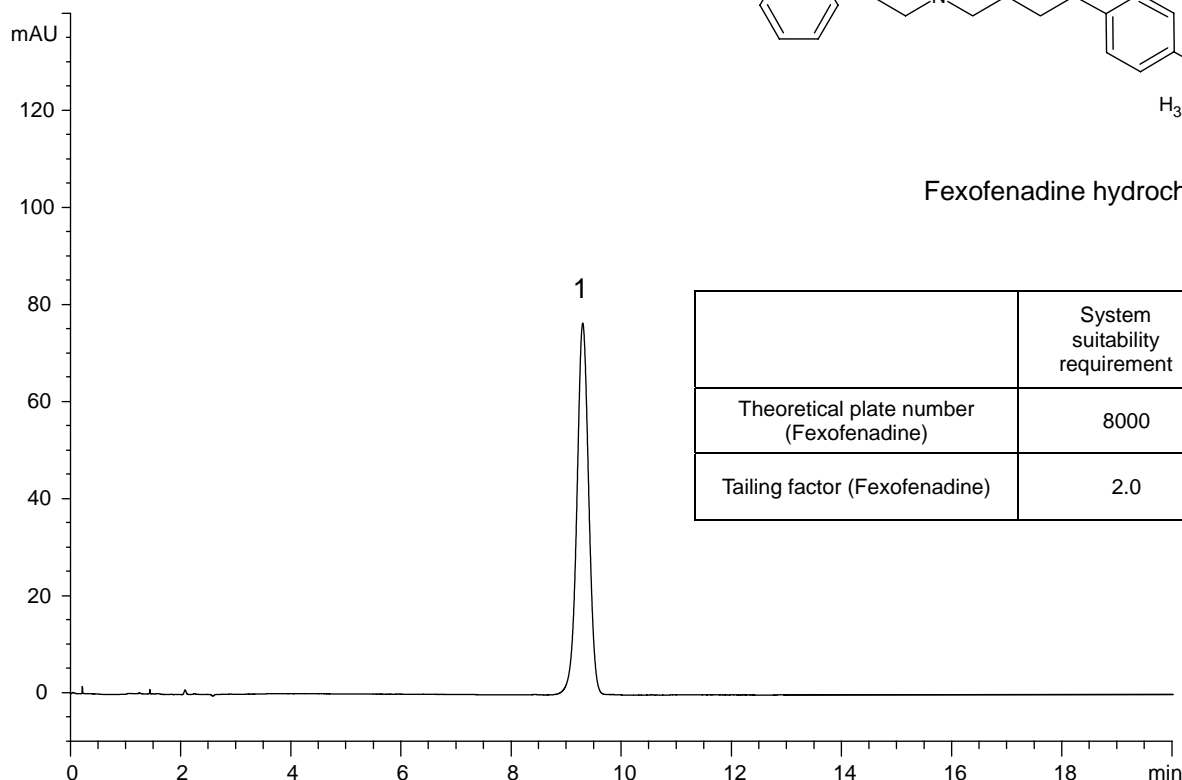
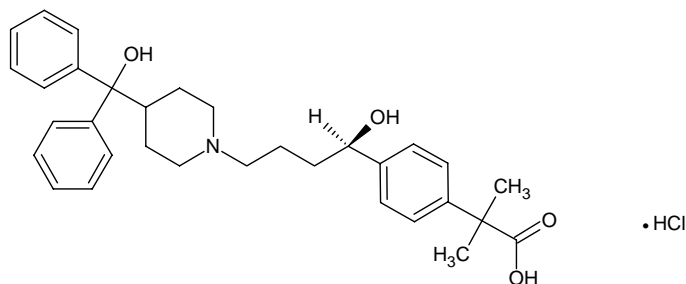
Fexofenadine Hydrochloride (The Japanese Pharmacopoeia)

F130213B

Standard solution*¹

(0.06 mg/mL Fexofenadine hydrochloride)

1



	System suitability requirement	result
Theoretical plate number (Fexofenadine)	8000	9500
Tailing factor (Fexofenadine)	2.0	0.98

Column : YMC-Triart Phenyl (5 μ m, 12 nm)
250 X 4.6 mmI.D.

Eluent : acetonitrile/buffer*²/triethylamine (350/650/3)
*² Dissolve 7.51 g of NaH₂PO₄·2H₂O and 0.96 g of NaClO₄·H₂O in 1000 mL water, adjust pH 2.0 with H₃PO₄

Flow rate : 2.0 mL/min (adjust the flow rate so that the retention time of fexofenadine is about 9 min)

Temperature : 25

Detection : UV at 220 nm

Injection : 20 μ L

(The Japanese Pharmacopoeia 16th; Assay)

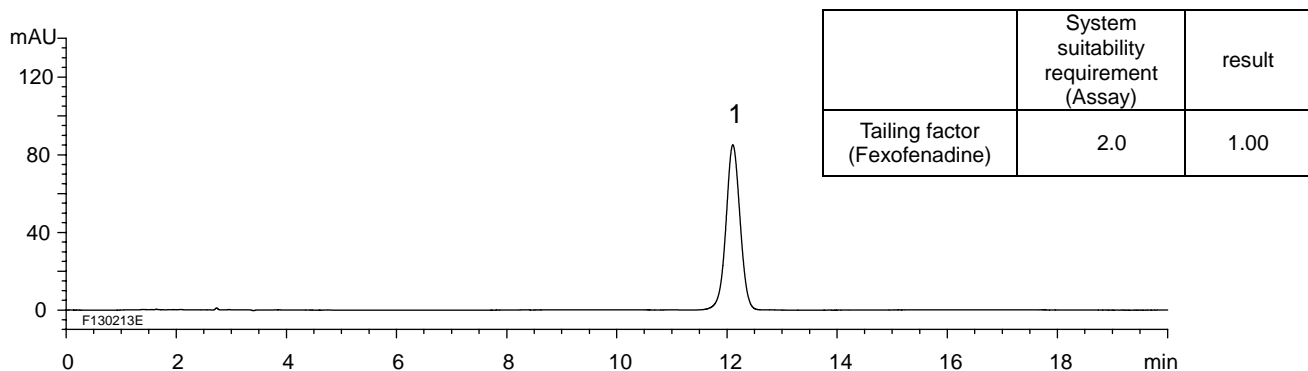
*¹ Standard solution was prepared from Fexofenadine hydrochloride supplied as a reagent for laboratory use.

フェキソフェナジン塩酸塩 (米国薬局方記載条件)

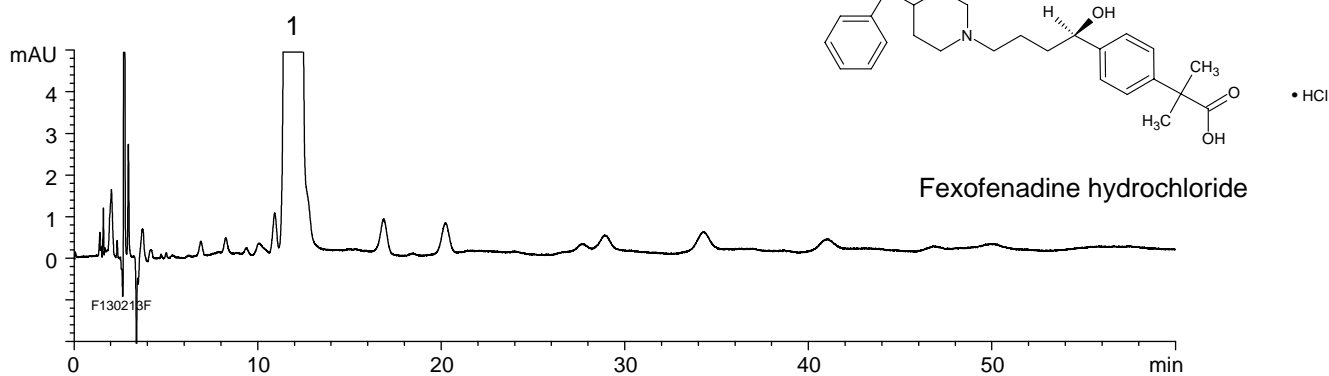
Fexofenadine Hydrochloride (The United States Pharmacopeia)

F130218B

A) Assay preparation*¹ (Assay), Reference solution*¹ (Related compounds)
(0.06 mg/mL Fexofenadine hydrochloride)



B) Test solution*¹ (Related compounds)
(1 mg/mL Fexofenadine hydrochloride)



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

Eluent : acetonitrile/buffer*²/triethylamine (350/650/3)
*² Dissolve 7.51 g of NaH₂PO₄·2H₂O and 0.96 g of NaClO₄·H₂O in 1000 mL water, adjust pH 2.0 with H₃PO₄.

Flow rate : 1.5 mL/min

Temperature : 25

Detection : UV at 220 nm

Injection : 20 μL

(The United States Pharmacopeia 36th; Assay, Related compounds)

*¹ All standard and sample solutions were prepared from Fexofenadine hydrochloride supplied as a reagent for laboratory use.

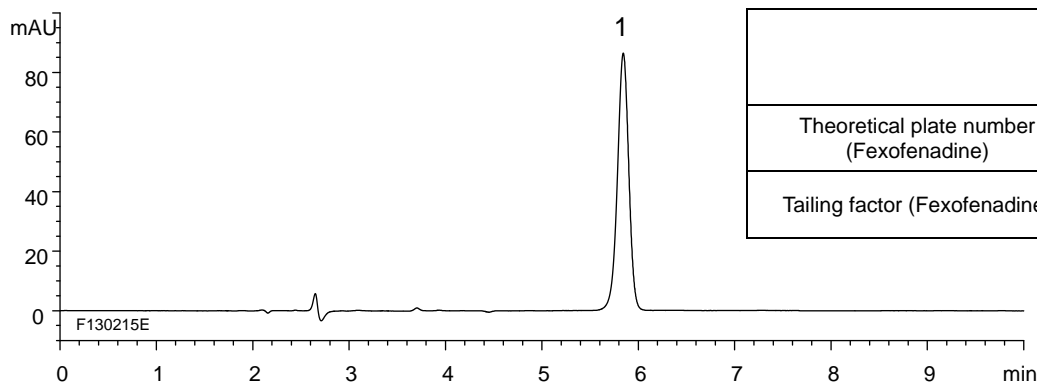
フェキソフェナジン塩酸塩錠 (日本薬局方記載条件)

Fexofenadine Hydrochloride Tablets (The Japanese Pharmacopoeia)

F130218C

A) Standard solution*¹

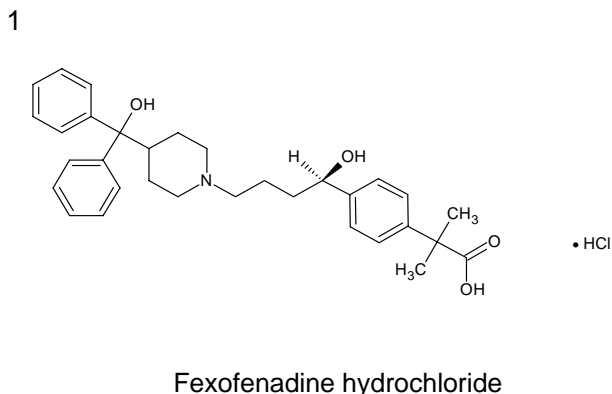
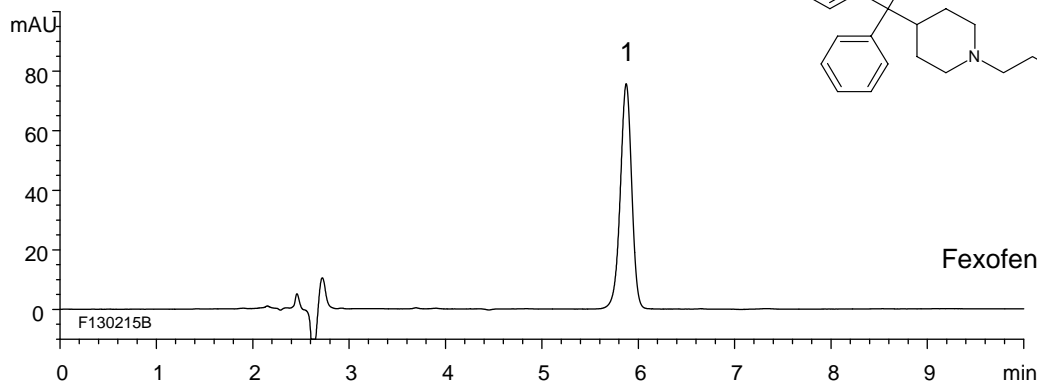
(0.018 mg/mL Fexofenadine hydrochloride)



	System suitability requirement	result
Theoretical plate number (Fexofenadine)	7000	12400
Tailing factor (Fexofenadine)	2.0	0.95

B) Sample solution*²

(0.018 mg/mL Fexofenadine hydrochloride)



Column : YMC-Triart Phenyl (5 μ m, 12 nm)
250 X 4.6 mmI.D.

Eluent : acetonitrile/buffer*³ (9/16)
*³ Add 15 mL of acetonitrile/triethylamine (1/1) to 1000 mL of acetic acid/water (17/9983), adjust pH 5.25 with H₃PO₄

Flow rate : 1.1 mL/min (adjust the flow rate so that the retention time of fexofenadine is about 6 min)

Temperature : 35

Detection : UV at 220 nm

Injection : 20 μ L

(The Japanese Pharmacopoeia 16th Supplement ; Assay)

*¹ Standard solution was prepared from Fexofenadine hydrochloride supplied as a reagent for laboratory use.

*² Sample solution was prepared from Fexofenadine hydrochloride tablets.

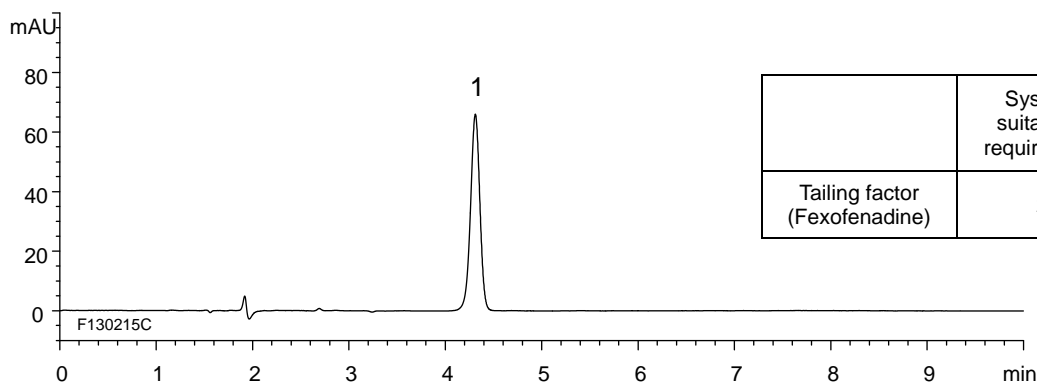
フェキソフェナジン塩酸塩錠 (米国薬局方記載条件)

Fexofenadine Hydrochloride Tablets (The United States Pharmacopeia)

F130218D

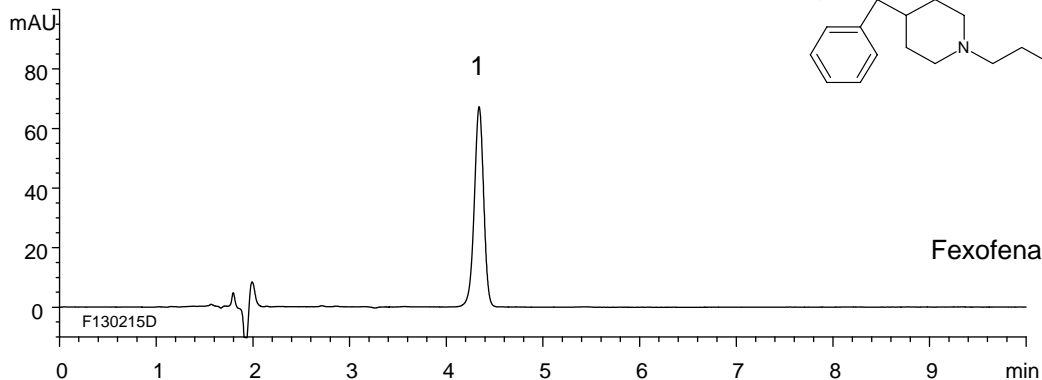
A) Standard solution*¹

(0.015 mg/mL Fexofenadine hydrochloride)

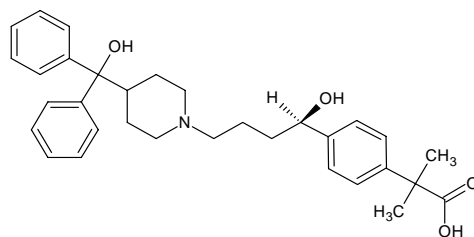


B) Sample solution*²

(0.018 mg/mL Fexofenadine hydrochloride)



1



• HCl

Fexofenadine hydrochloride

Column	: YMC-Triart Phenyl (5 μm, 12 nm) 250 X 4.6 mm I.D.
Eluent	: acetonitrile/buffer* ³ (9/16) <i>*³ Add 15 mL of acetonitrile/triethylamine (1/1) to 1000 mL of acetic acid/water (17/9983), adjust pH 5.25 with H₃PO₄</i>
Flow rate	: 1.5 mL/min
Temperature	: 35
Detection	: UV at 220 nm
Injection	: 20 μL
(The United States Pharmacopeia 36th; Assay)	

*¹ Standard solution was prepared from Fexofenadine hydrochloride supplied as a reagent for laboratory use.

*² Sample solution was prepared from Fexofenadine hydrochloride tablets.