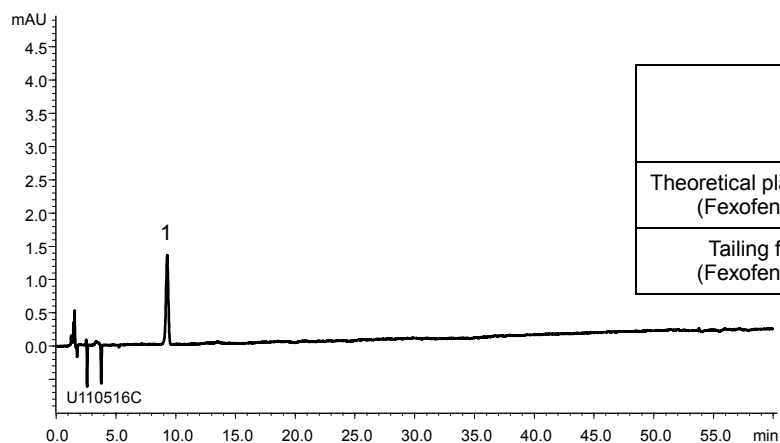


フェキソフェナジン塩酸塩
Fexofenadine Hydrochloride

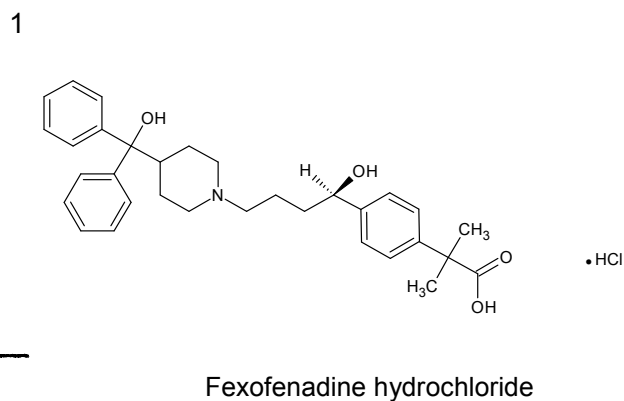
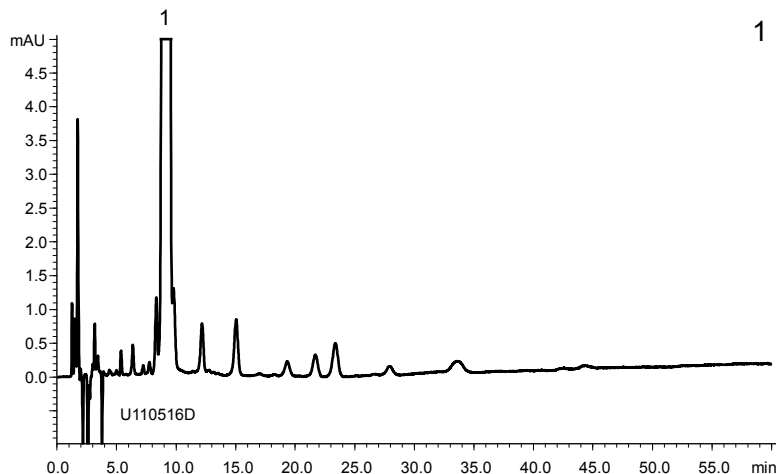
U110518A

A) Standard solution
(0.001 mg/mL Fexofenadine hydrochloride)



	System suitability requirement	result
Theoretical plate number (Fexofenadine)	≥ 8000	11400
Tailing factor (Fexofenadine)	≤ 2.0	0.96

B) Sample solution
(1 mg/mL Fexofenadine hydrochloride)



Column : YMC-CSpack Ph (5 μ m, 12 nm)
250 X 4.6 mm I.D.

Eluent : acetonitrile/buffer*/triethylamine (350/650/3)
*Dissolve 7.51 g of $\text{NaH}_2\text{PO}_4 \cdot 2\text{H}_2\text{O}$ and 0.96 g of $\text{NaClO}_4 \cdot \text{H}_2\text{O}$ in 1000 mL water, adjust pH 2.0 with H_3PO_4 .

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

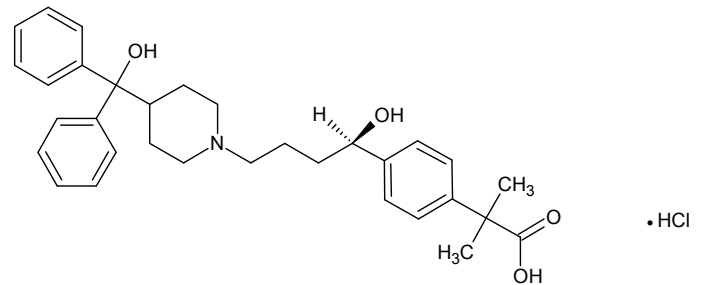
Injection : 20 μ L

(The Japanese Pharmacopoeia 16th; Related substances)

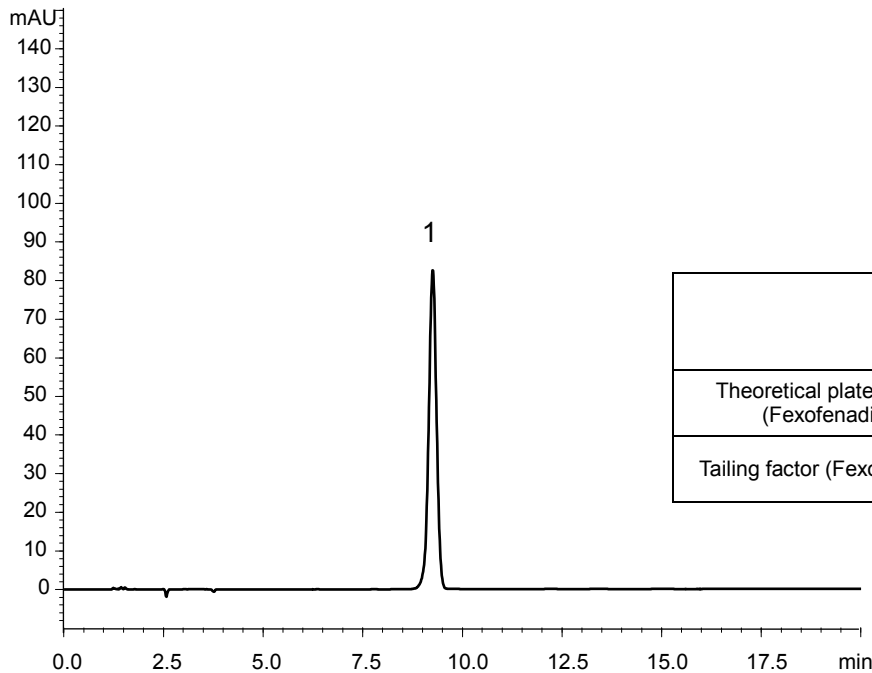
フェキソフェナジン塩酸塩
Fexofenadine Hydrochloride

U110516B

1



Fexofenadine hydrochloride



	System suitability requirement	result
Theoretical plate number (Fexofenadine)	≥ 8000	11100
Tailing factor (Fexofenadine)	≤ 2.0	0.98

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

Eluent : acetonitrile/buffer*/triethylamine (350/650/3)
*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

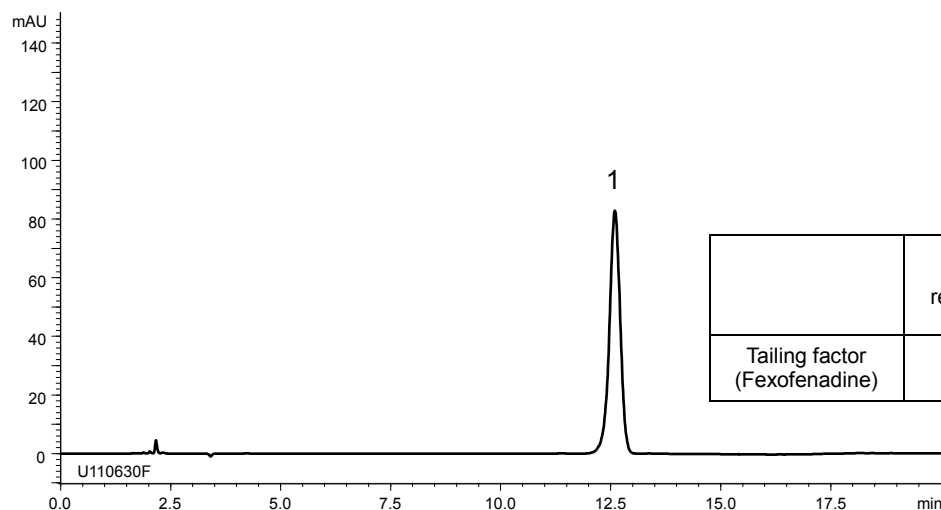
Injection : 20 μL (0.06 mg/mL)

(The Japanese Pharmacopoeia 16th; Assay)

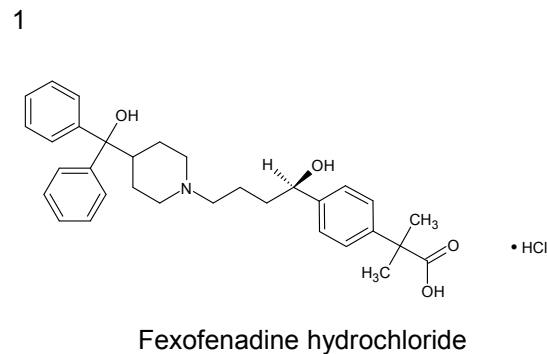
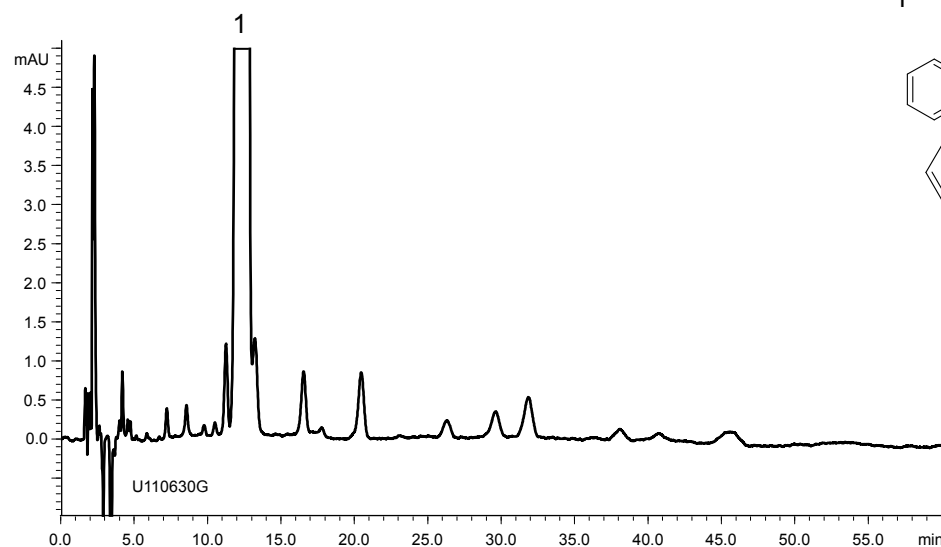
フェキソフェナジン塩酸塩
Fexofenadine Hydrochloride

U110702C

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



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



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

Eluent : acetonitrile/buffer*/triethylamine (350/650/3)
*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°C

Detection : UV at 220 nm

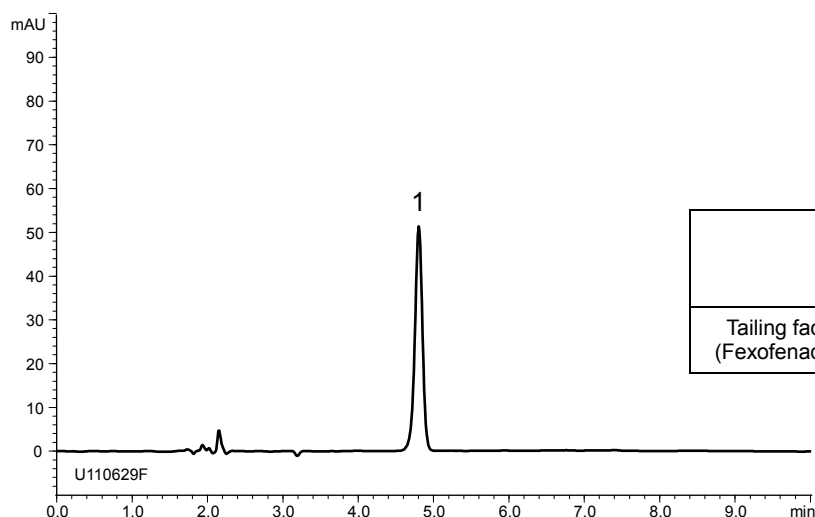
Injection : 20 μL

(The United States Pharmacopeia 34th; Assay, Related compounds)

フェキソフェナジン塩酸塩錠
Fexofenadine Hydrochloride Tablets

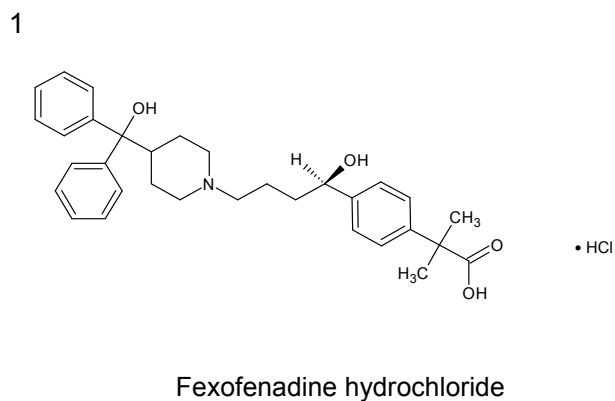
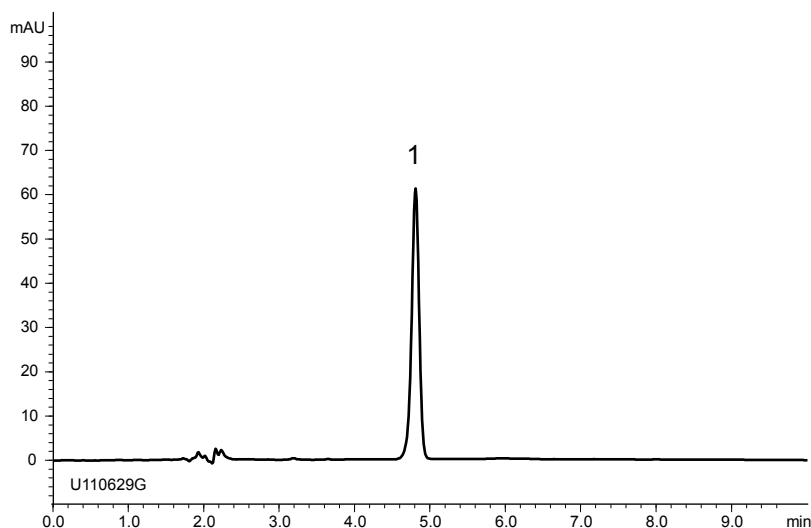
U110702B

A) Standard solution
(0.015 mg/mL Fexofenadine hydrochloride)



	System suitability requirement	result
Tailing factor (Fexofenadine)	≤ 2.0	0.97

B) Sample solution*
(0.018 mg/mL Fexofenadine hydrochloride)



*Sample solution was prepared from Fexofenadine hydrochloride tablets.

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

Eluent : acetonitrile/buffer* (9/16)
*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 : 1.5 mL/min

Temperature : 35°C

Detection : UV at 220 nm

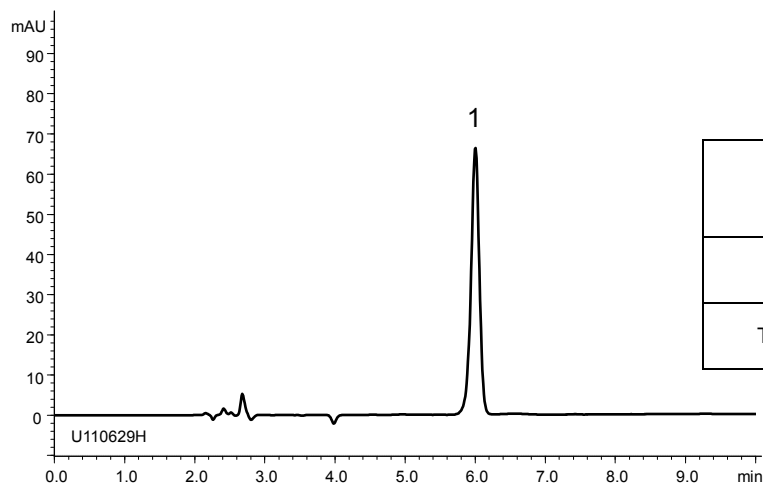
Injection : 20 μL

(The United States Pharmacopeia 34th; Assay)

フェキソフェナジン塩酸塩錠 Fexofenadine Hydrochloride Tablets

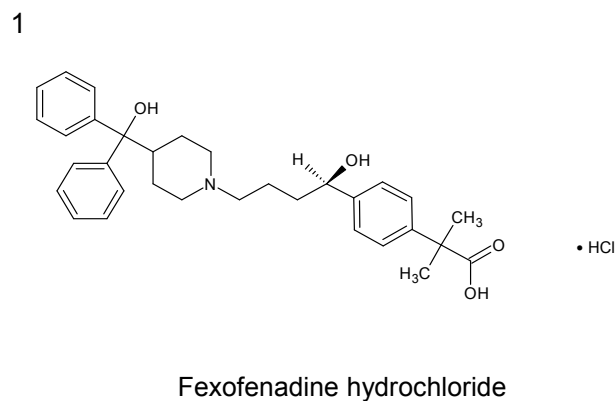
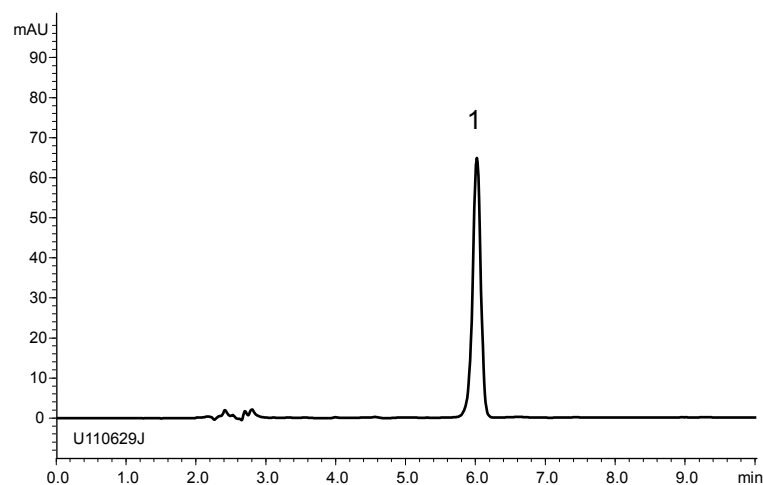
U110702A

A) Standard solution (0.018 mg/mL Fexofenadine hydrochloride)



	System suitability requirement	result
Theoretical plate number (Fexofenadine)	≥ 7000	12600
Tailing factor (Fexofenadine)	≤ 2.0	0.95

B) Sample solution* (0.018 mg/mL Fexofenadine hydrochloride)



*Sample solution was prepared from Fexofenadine hydrochloride tablets.

Column : YMC-CSpack Ph (5 μ m, 12 nm)
250 X 4.6 mm I.D.

Eluent : acetonitrile/buffer* (9/16)
*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 : 1.2 mL/min (adjust the flow rate so that the retention time of fexofenadine is about 6 min)

Temperature : 35°C

Detection : UV at 220 nm

Injection : 20 μ L

(The draft for the Japanese Pharmacopoeia; Assay)