

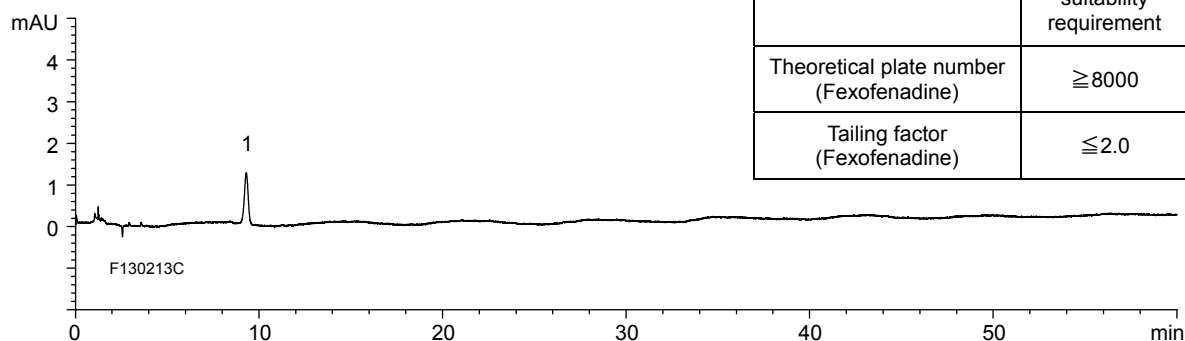
フェキソフェナジン塩酸塩 (日本薬局方記載条件)

Fexofenadine Hydrochloride (The Japanese Pharmacopoeia)

F130218A

A) Standard solution\*<sup>1</sup>

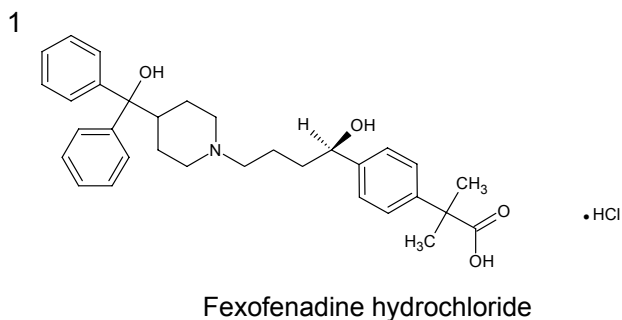
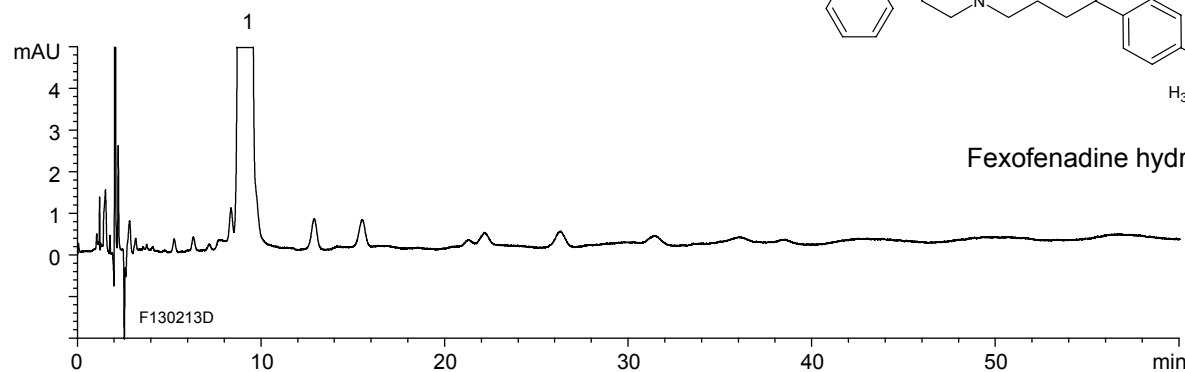
(0.001 mg/mL Fexofenadine hydrochloride)



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

B) Sample solution\*<sup>1</sup>

(1 mg/mL Fexofenadine hydrochloride)



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

Eluent : acetonitrile/buffer\*<sup>2</sup>/triethylamine (350/650/3)  
\*<sup>2</sup> Dissolve 7.51 g of NaH<sub>2</sub>PO<sub>4</sub> · 2H<sub>2</sub>O and 0.96 g of NaClO<sub>4</sub> · H<sub>2</sub>O in 1000 mL water, adjust pH 2.0 with H<sub>3</sub>PO<sub>4</sub>

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)

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