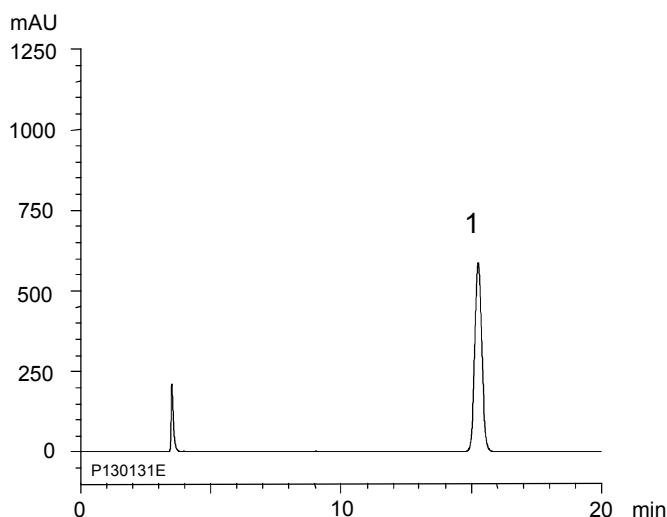


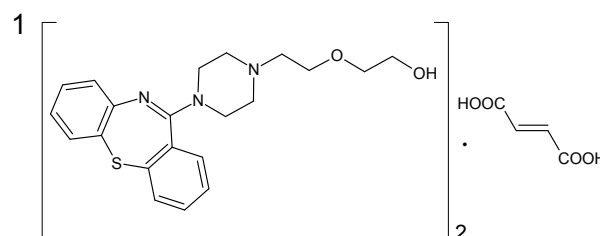
クエチアピソフマル酸塩 (日本薬局方記載条件)
 Quetiapine fumarate (The Japanese Pharmacopoeia)

P130703A

A) Assay: Standard solution*1
 (0.08 mg/mL Quetiapine fumarate)

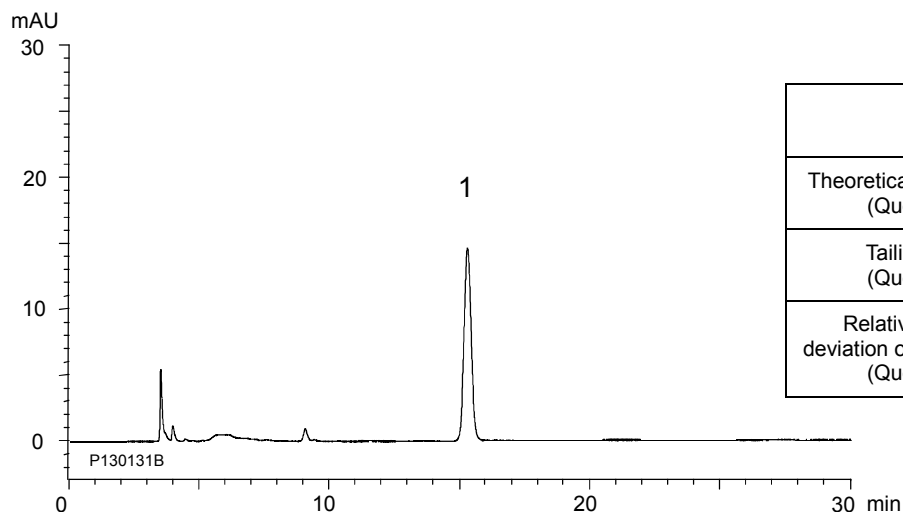


	System suitability requirement	Result
Theoretical plate number (Quetiapine)	≥ 6000	15400
Tailing factor (Quetiapine)	$Tf \leq 2.0$	1.07
Relative standard deviation of the peak area (Quetiapine)	$\leq 1.0\%$	0.05%



Quetiapine fumarate

B) Related substances i: Standard solution*1
 (0.002 mg/mL Quetiapine fumarate)



	System suitability requirement	Result
Theoretical plate number (Quetiapine)	≥ 6000	15400
Tailing factor (Quetiapine)	$Tf \leq 2.0$	1.06
Relative standard deviation of the peak area (Quetiapine)	$\leq 2.0\%$	0.13%

Column : YMCbasic (5 μ m, 20 nm)
 250 X 4.6 mmI.D.
 Eluent : phosphate buffer (pH 6.5)*2/methanol/acetonitrile (39/54/7)
 *2 Dissolve 2.6 g of $(NH_4)_2HPO_4$ in 1000 mL of water, adjust pH 6.5 with H_3PO_4
 Flow rate : 0.85 mL/min (adjust the flow rate so that the retention time of quetiapine is about 15 min)
 Temperature : 25°C
 Detection : UV at 230 nm
 Injection : 50 μ L

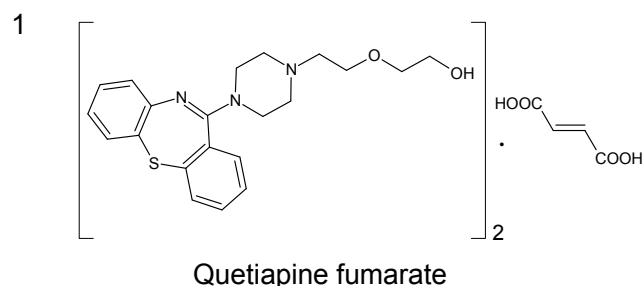
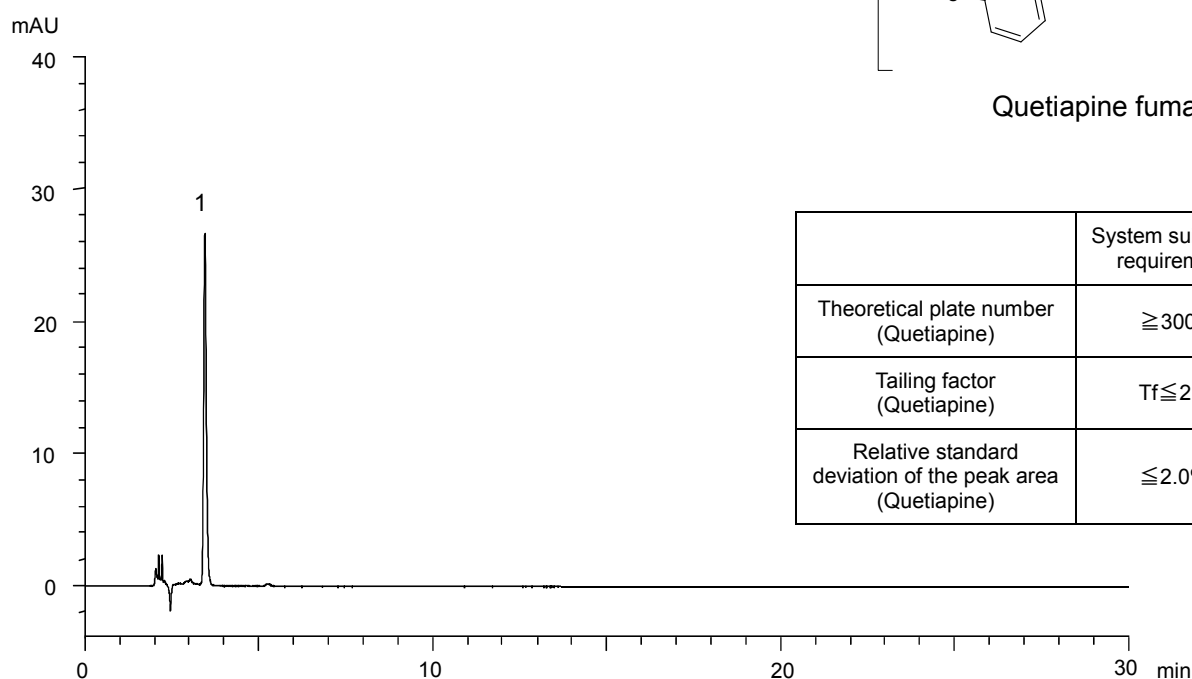
(The Japanese Pharmacopoeia 16th Supplement I ; Assay, Related substances i)

*1 All standard solutions were prepared from Quetiapine fumarate supplied as a reagent for laboratory use.

クエチアピソフマル酸塩 (日本薬局方記載条件)
Quetiapine fumarate (The Japanese Pharmacopoeia)

P130201A

Related substances ii: Standard solution*¹
(0.002 mg/mL Quetiapine fumarate)



	System suitability requirement	Result
Theoretical plate number (Quetiapine)	≥ 3000	10900
Tailing factor (Quetiapine)	$Tf \leq 2.0$	1.24
Relative standard deviation of the peak area (Quetiapine)	$\leq 2.0\%$	0.36%

Column : YMCbasic (5 μ m, 20 nm)
250 X 4.6 mm I.D.

Eluent : methanol/acetonitrile/ $(NH_4)_2HPO_4$ aq *² (70/9/21)
*² Dissolve 3.3 g of $(NH_4)_2HPO_4$ in 1250 mL of water

Flow rate : 1.4 mL/min (adjust the flow rate so that the retention time of quetiapine is about 3.5 min)

Temperature : 25°C

Detection : UV at 250 nm

Injection : 50 μ L

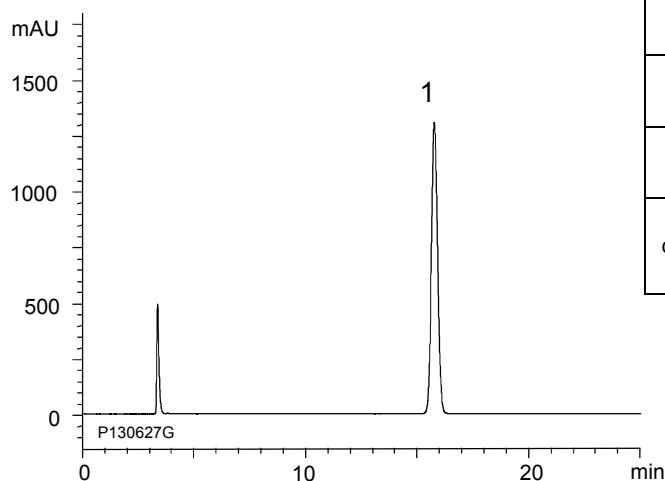
(The Japanese Pharmacopoeia 16th Supplement I ; Related substances ii)

*¹ Standard solution was prepared from Quetiapine fumarate supplied as a reagent for laboratory use.

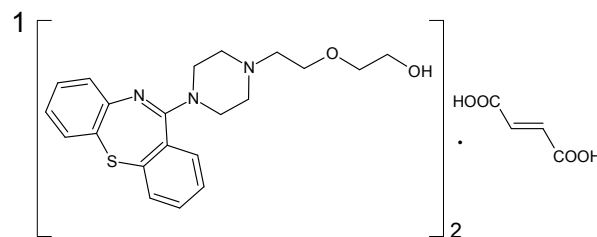
クエチアピソフマル酸塩錠 (日本薬局方記載条件)
 Quetiapine fumarate tablets (The Japanese Pharmacopoeia)

P130703B

A) Assay: Standard solution*¹
 (0.18 mg/mL Quetiapine fumarate)

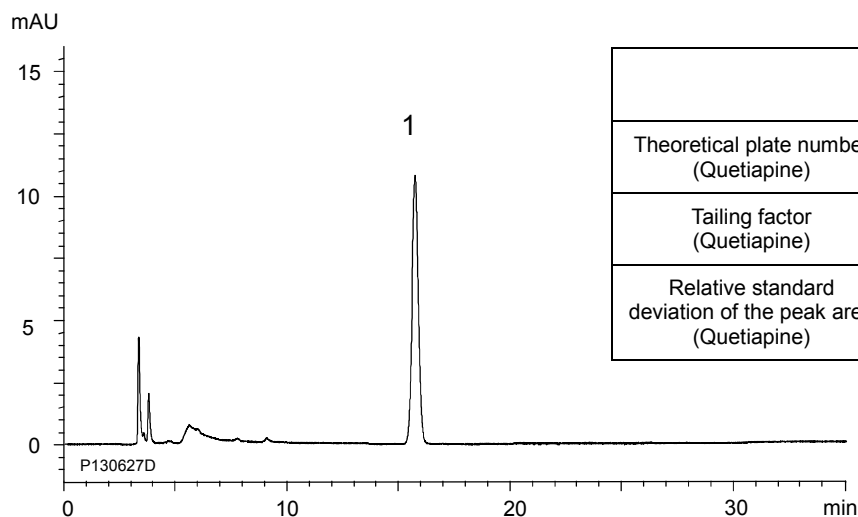


	System suitability requirement	Result
Theoretical plate number (Quetiapine)	≥ 7000	15900
Tailing factor (Quetiapine)	$Tf \leq 1.5$	1.07
Relative standard deviation of the peak area (Quetiapine)	$\leq 1.0\%$	0.15%



Quetiapine fumarate

B) Related substances : Standard solution*¹
 (0.0015 mg/mL Quetiapine fumarate)



	System suitability requirement	Result
Theoretical plate number (Quetiapine)	≥ 7000	15500
Tailing factor (Quetiapine)	$Tf \leq 1.5$	1.05
Relative standard deviation of the peak area (Quetiapine)	$\leq 2.0\%$	0.56%

Column : YMCbasic (5 μ m, 20 nm)
 250 X 4.6 mmI.D.
 Eluent : methanol/acetonitrile/(NH₄)₂HPO₄ aq *² (54/7/39)
 *² Dissolve 3.3 g of (NH₄)₂HPO₄ in 1250 mL of water
 Flow rate : 0.85 mL/min (adjust the flow rate so that the retention time of quetiapine is about 15 min)
 Temperature : 25°C
 Detection : UV at 230 nm
 Injection : 50 μ L

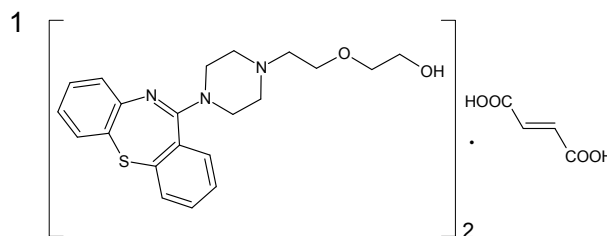
(The Japanese Pharmacopoeia 16th Supplement I ; Assay, Related substances)

*¹ All standard solutions were prepared from Quetiapine fumarate supplied as a reagent for laboratory use.

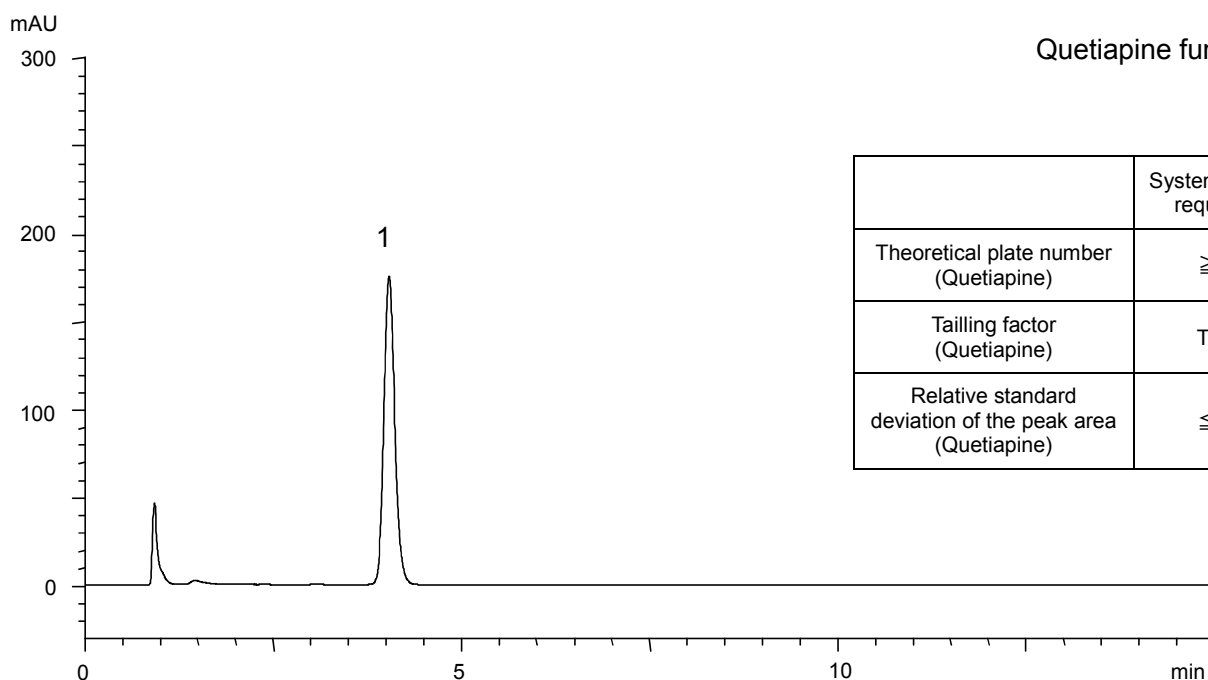
クエチアピソフマル酸塩錠
Quetiapine fumarate fine tablets

P130808D

Dissolution: Standard solution*¹
(0.016 mg/mL Quetiapine fumarate)



Quetiapine fumarate



	System suitability requirement	Result
Theoretical plate number (Quetiapine)	≥ 1400	3800
Tailing factor (Quetiapine)	$Tf \leq 1.5$	1.15
Relative standard deviation of the peak area (Quetiapine)	$\leq 2.0\%$	0.10%

Column : YMCbasic (5 μ m, 20 nm)
75 X 4.6 mm I.D.
Eluent : methanol/acetonitrile/ $(\text{NH}_4)_2\text{HPO}_4$ aq *² (54/7/39)
*² Dissolve 3.3 g of $(\text{NH}_4)_2\text{HPO}_4$ in 1250 mL of water
Flow rate : 1.0 mL/min (adjust the flow rate so that the retention time of quetiapine is about 4 min)
Temperature : 25°C
Detection : UV at 230 nm
Injection : 50 μ L

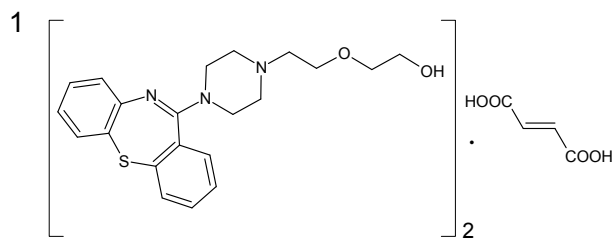
(Modified condition of The Japanese Pharmacopoeia 16th Supplement I ; Dissolution)

*¹ Standard solution was prepared from Quetiapine fumarate supplied as a reagent for laboratory use.

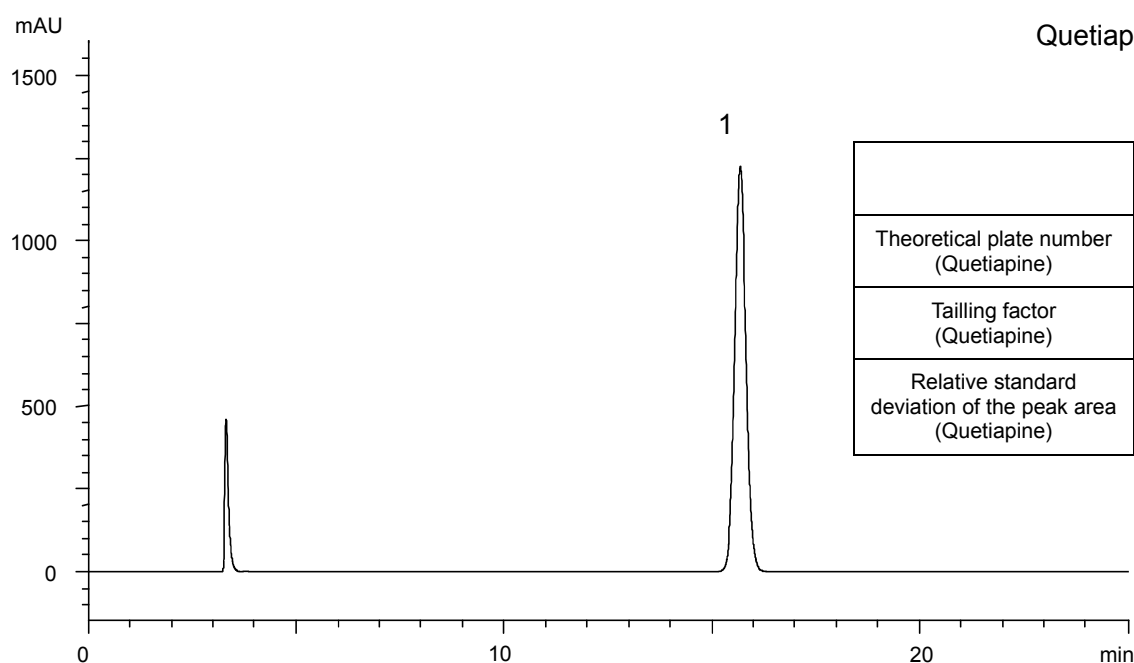
クエチアピン fumarate 細粒 (日本薬局方記載条件)

Quetiapine fumarate fine granules (The Japanese Pharmacopoeia) P130627B

Assay: Standard solution*¹
(0.17 mg/mL Quetiapine fumarate)



Quetiapine fumarate



	System suitability requirement	Result
Theoretical plate number (Quetiapine)	≥ 7000	15900
Tailing factor (Quetiapine)	$Tf \leq 1.5$	1.07
Relative standard deviation of the peak area (Quetiapine)	$\leq 1.0\%$	0.14%

Column : YMCbasic (5 μ m, 20 nm)
250 X 4.6 mm I.D.

Eluent : methanol/acetonitrile/(NH₄)₂HPO₄ aq *² (54/7/39)
*² Dissolve 3.3 g of (NH₄)₂HPO₄ in 1250 mL of water

Flow rate : 0.85 mL/min (adjust the flow rate so that the retention time of quetiapine is about 15 min)

Temperature : 25°C

Detection : UV at 230 nm

Injection : 50 μ L

(The Japanese Pharmacopoeia 16th Supplement I ; Assay)

*¹ Standard solution was prepared from Quetiapine fumarate supplied as a reagent for laboratory use.