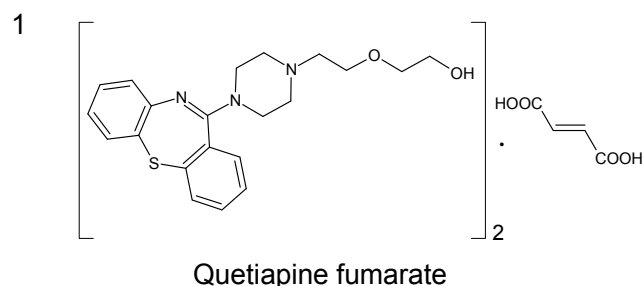
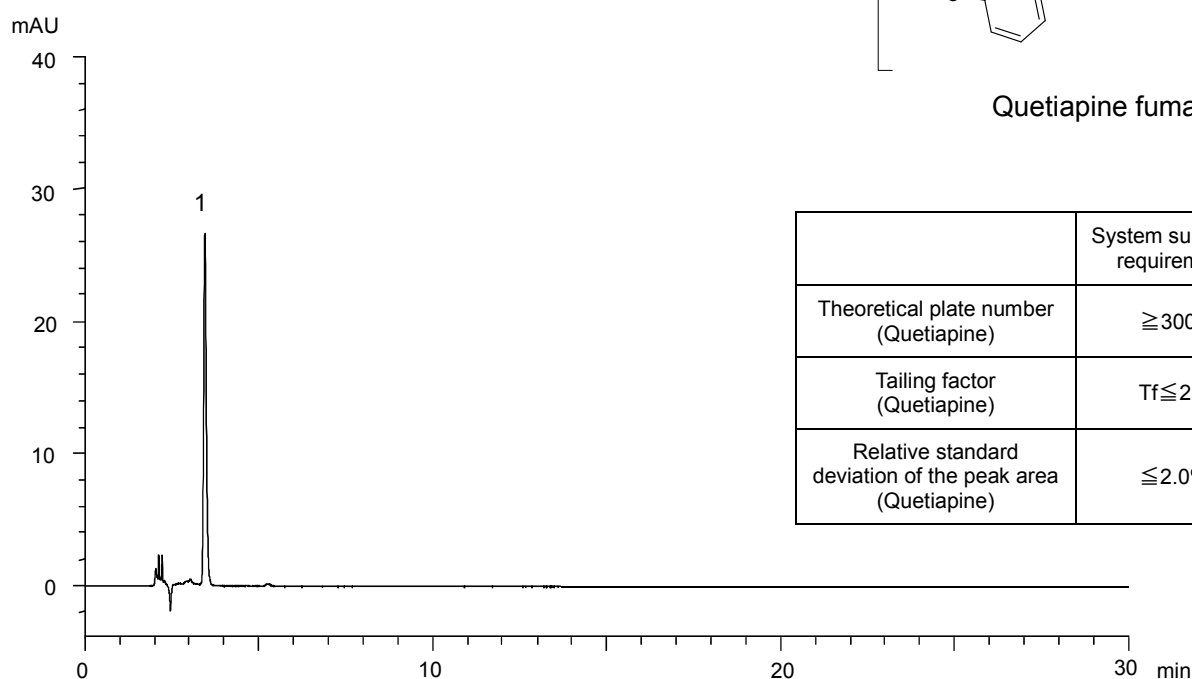


クエチアピソフマル酸塩 (日本薬局方記載条件)
Quetiapine fumarate (The Japanese Pharmacopoeia)

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.