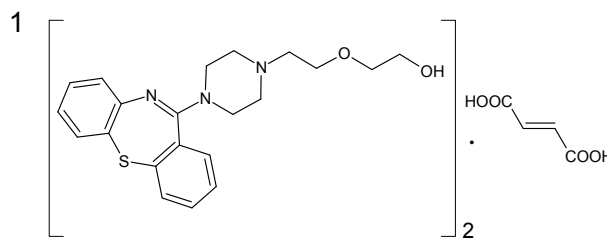


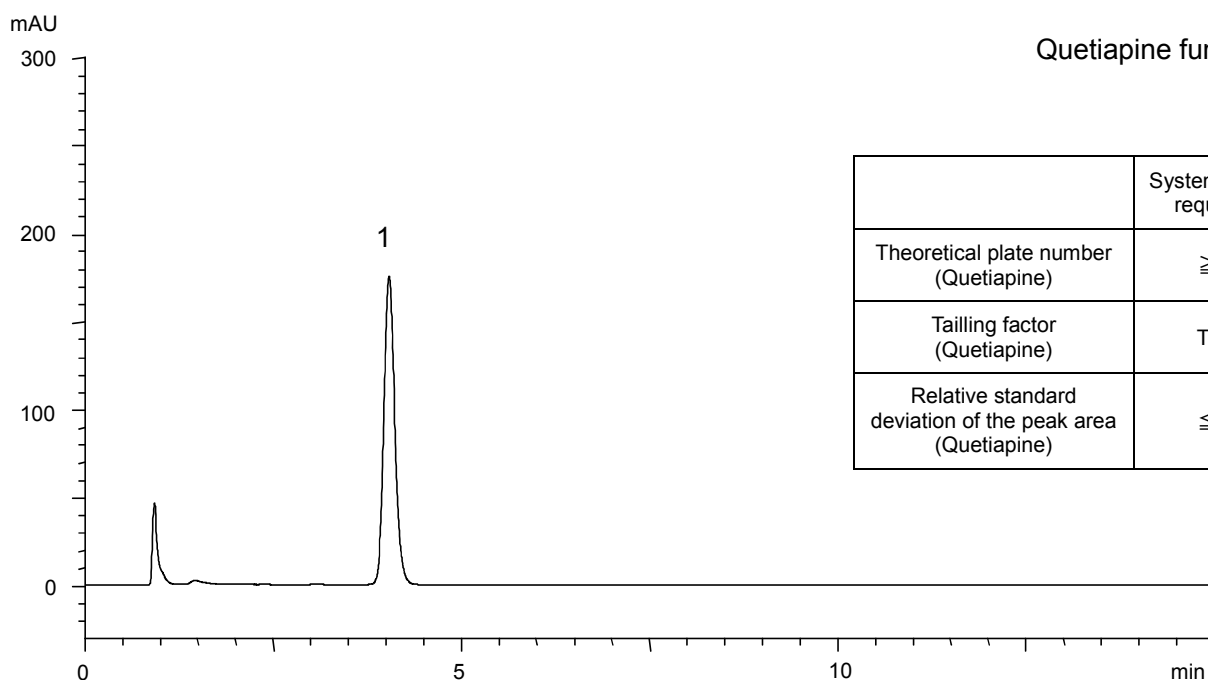
クエチアピソフマル酸塩錠
Quetiapine fumarate fine tablets

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.