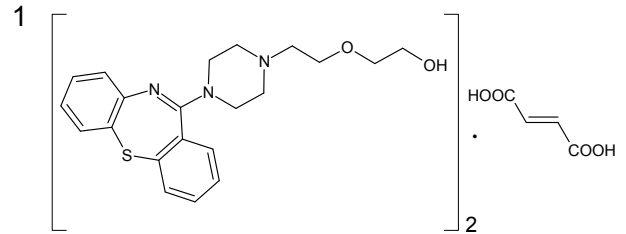


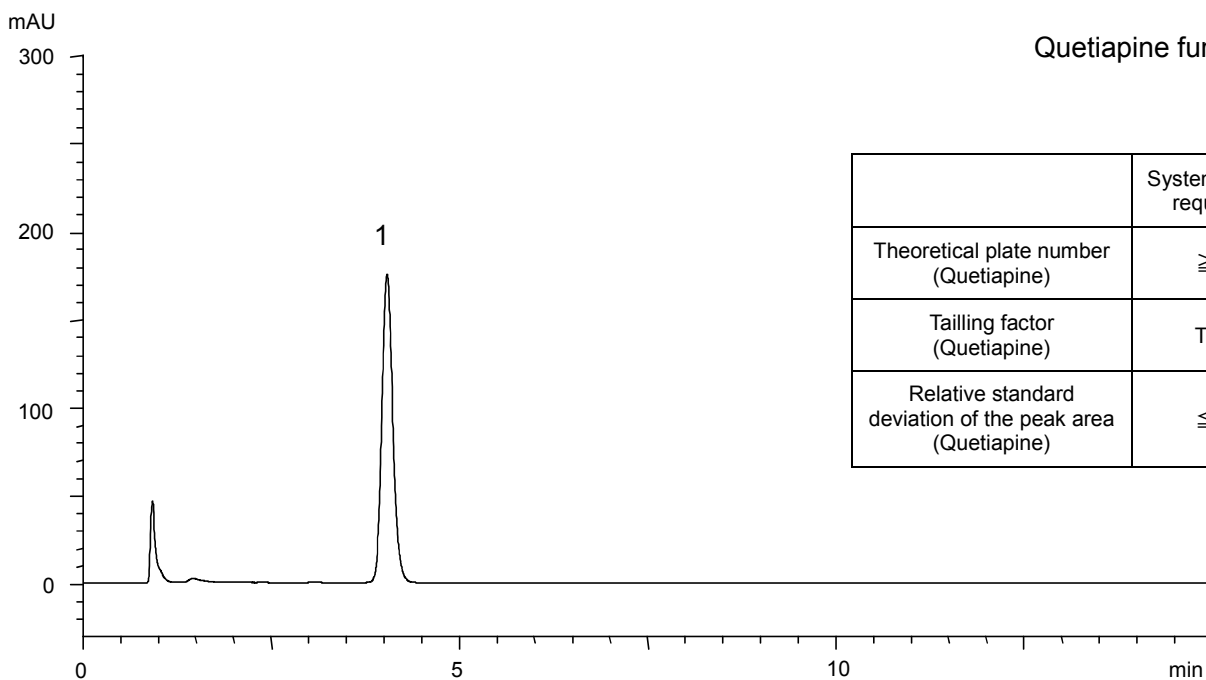
クエチアピソフマル酸塩錠  
Quetiapine fumarate fine tablets

P130808D

Dissolution: Standard solution\*<sup>1</sup>  
(0.016 mg/mL Quetiapine fumarate)



Quetiapine fumarate



	System suitability requirement	Result
Theoretical plate number (Quetiapine)	$\geq 1400$	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  $\mu$ m, 20 nm)  
75 X 4.6 mm I.D.  
Eluent : methanol/acetonitrile/(NH<sub>4</sub>)<sub>2</sub>HPO<sub>4</sub> aq \*<sup>2</sup> (54/7/39)  
\*<sup>2</sup> Dissolve 3.3 g of (NH<sub>4</sub>)<sub>2</sub>HPO<sub>4</sub> 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  $\mu$ L

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

\*<sup>1</sup> Standard solution was prepared from Quetiapine fumarate supplied as a reagent for laboratory use.