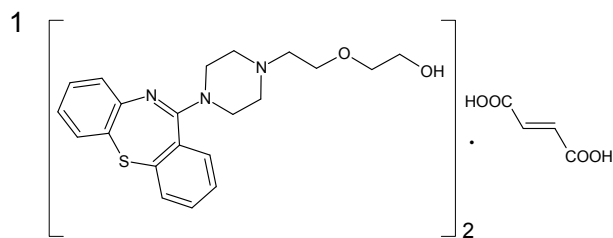


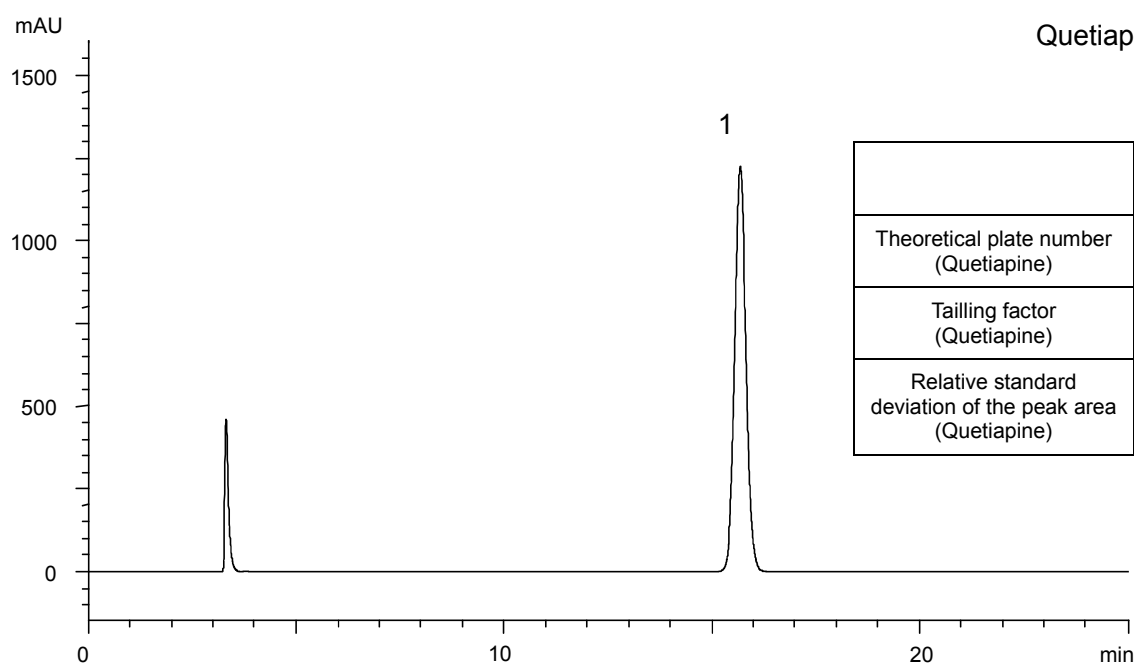
クエチアピソフマル酸塩細粒 (日本薬局方記載条件)

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.