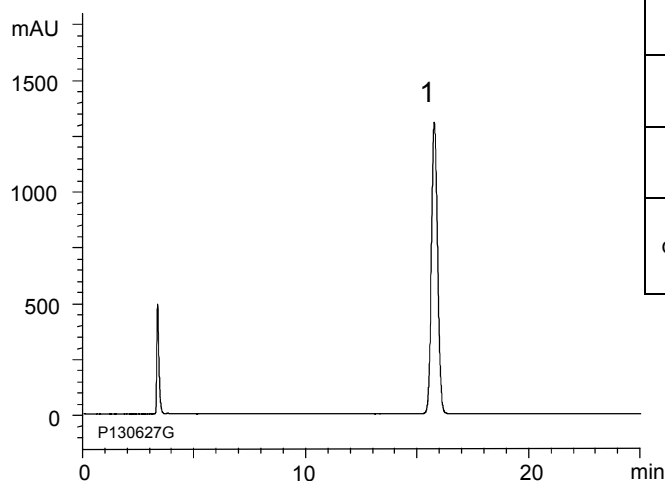


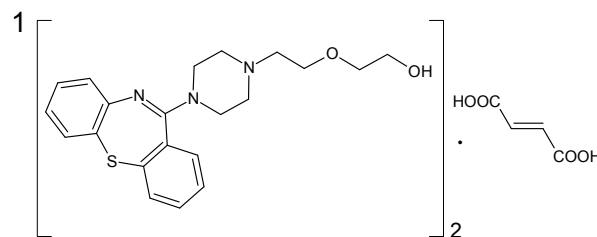
クエチアピソフマル酸塩錠 (日本薬局方記載条件)
Quetiapine fumarate tablets (The Japanese Pharmacopoeia)

P130703B

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

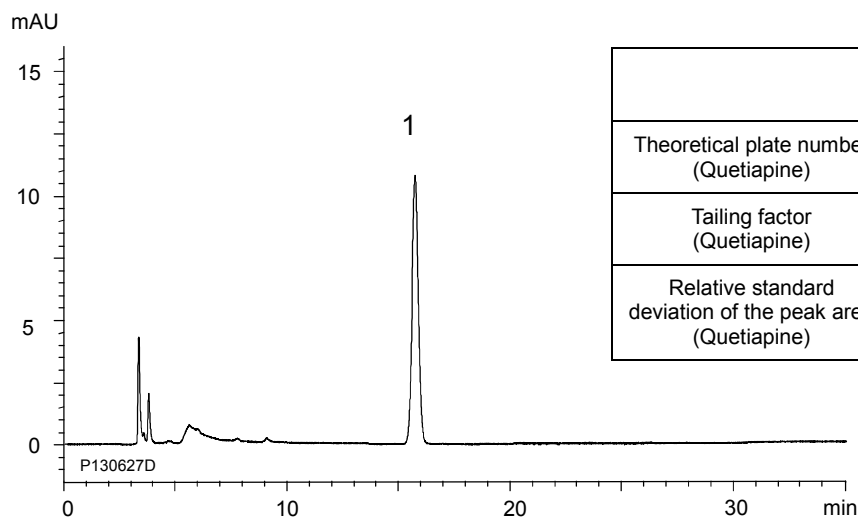


	System suitability requirement	Result
Theoretical plate number (Quetiapine)	≥ 7000	15900
Tailing factor (Quetiapine)	$Tf \leq 1.5$	1.07
Relative standard deviation of the peak area (Quetiapine)	$\leq 1.0\%$	0.15%



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/ $(NH_4)_2HPO_4$ aq *2 (54/7/39)
*2 Dissolve 3.3 g of $(NH_4)_2HPO_4$ 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.