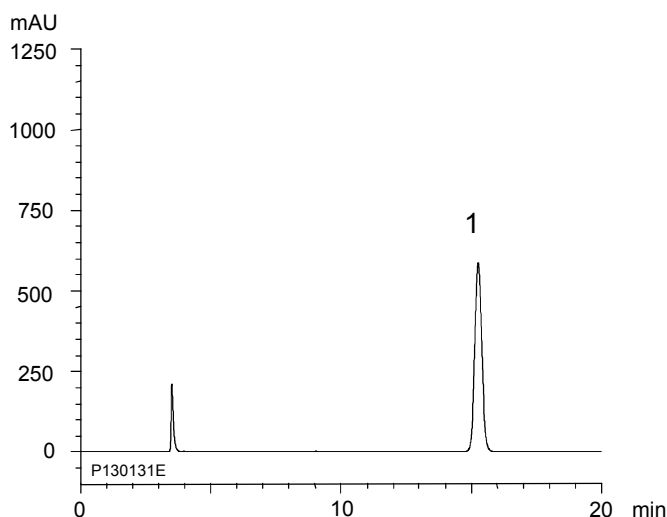


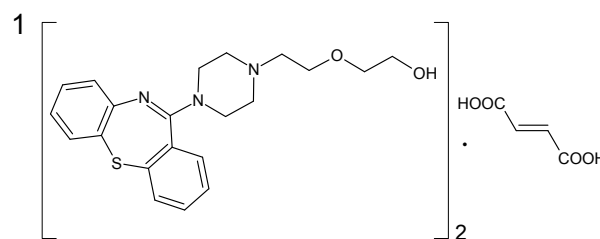
クエチアピソフマル酸塩 (日本薬局方記載条件)
 Quetiapine fumarate (The Japanese Pharmacopoeia)

P130703A

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

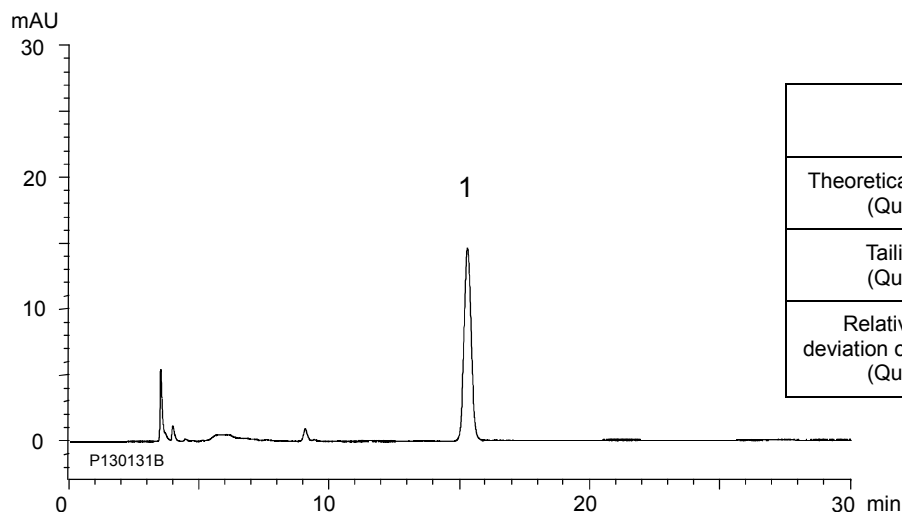


	System suitability requirement	Result
Theoretical plate number (Quetiapine)	≥ 6000	15400
Tailing factor (Quetiapine)	$Tf \leq 2.0$	1.07
Relative standard deviation of the peak area (Quetiapine)	$\leq 1.0\%$	0.05%



Quetiapine fumarate

B) Related substances i: Standard solution*¹
 (0.002 mg/mL Quetiapine fumarate)



	System suitability requirement	Result
Theoretical plate number (Quetiapine)	≥ 6000	15400
Tailing factor (Quetiapine)	$Tf \leq 2.0$	1.06
Relative standard deviation of the peak area (Quetiapine)	$\leq 2.0\%$	0.13%

Column : YMCbasic (5 μ m, 20 nm)
 250 X 4.6 mmI.D.
 Eluent : phosphate buffer (pH 6.5)*²/methanol/acetonitrile (39/54/7)
 *² Dissolve 2.6 g of (NH₄)₂HPO₄ in 1000 mL of water, adjust pH 6.5 with H₃PO₄
 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 i)

*¹ All standard solutions were prepared from Quetiapine fumarate supplied as a reagent for laboratory use.