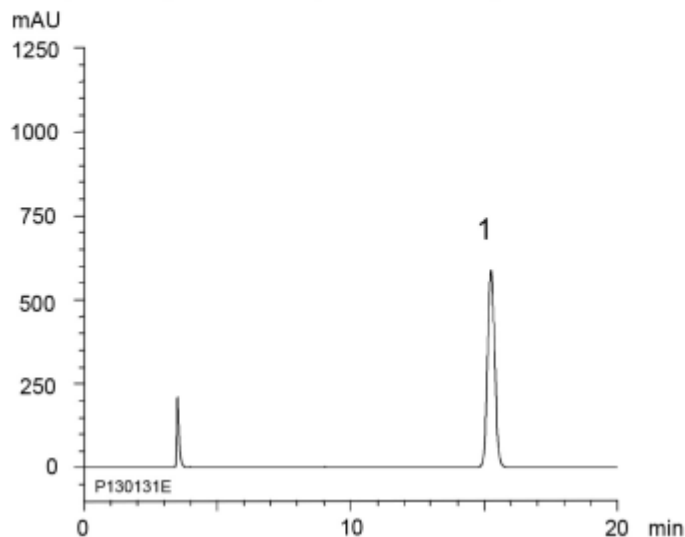
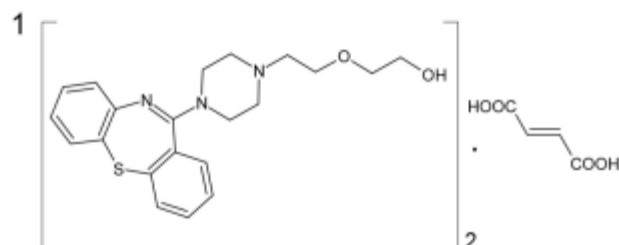


A) Assay: Standard solution\*<sup>1</sup>  
(0.08 mg/mL Quetiapine fumarate)

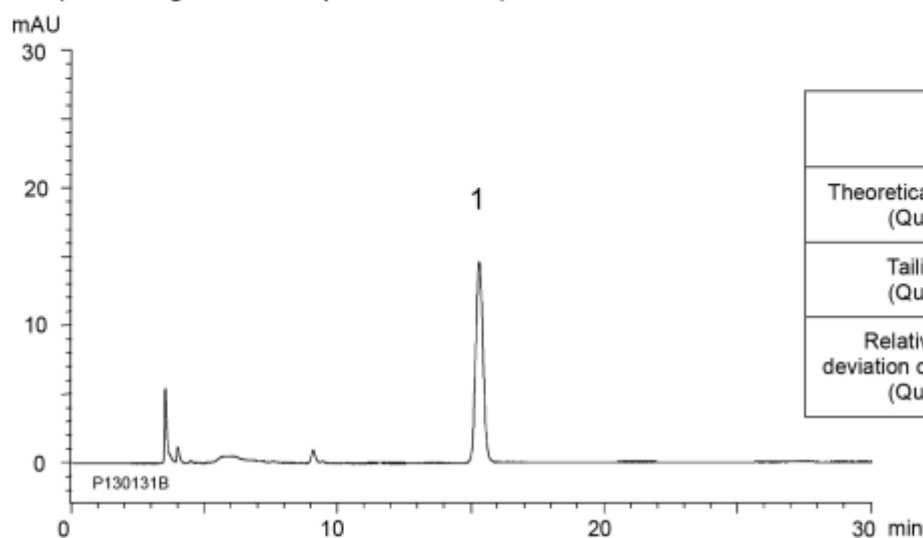


	System suitability requirement	Result
Theoretical plate number (Quetiapine)	$\geq 6000$	15400
Tailing factor (Quetiapine)	$Tf \leq 2.0$	1.07
Relative standard deviation of the peak area (Quetiapine)	$\leq 1.0\%$	0.05%



Quetiapine fumarate

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



	System suitability requirement	Result
Theoretical plate number (Quetiapine)	$\geq 6000$	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  $\mu$ m, 20 nm)  
250 X 4.6 mm I.D.  
Eluent : phosphate buffer (pH 6.5)\*<sup>2</sup>/methanol/acetonitrile (39/54/7)  
\*<sup>2</sup> Dissolve 2.6 g of  $(NH_4)_2HPO_4$  in 1000 mL of water, adjust pH 6.5 with  $H_3PO_4$   
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  $\mu$ L

(The Japanese Pharmacopoeia 16th Supplement I ; Assay, Related substances i )

\*<sup>1</sup> All standard solutions were prepared from Quetiapine fumarate supplied as a reagent for laboratory use.