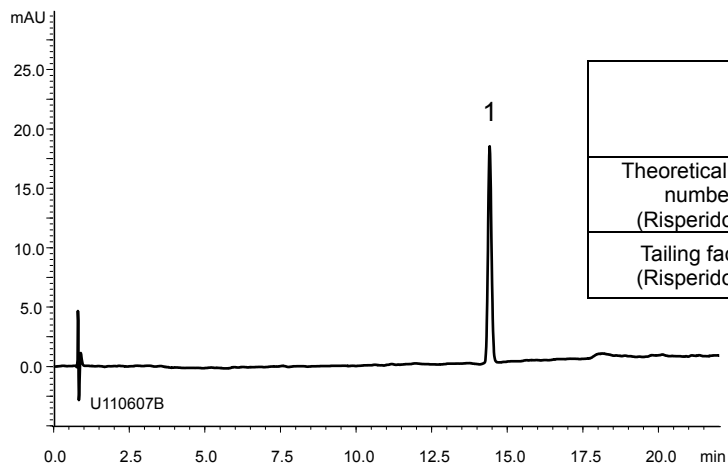


リスペリドン  
Risperidone

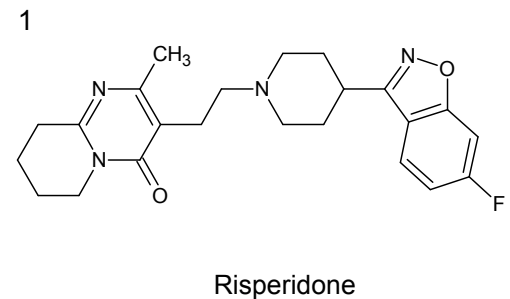
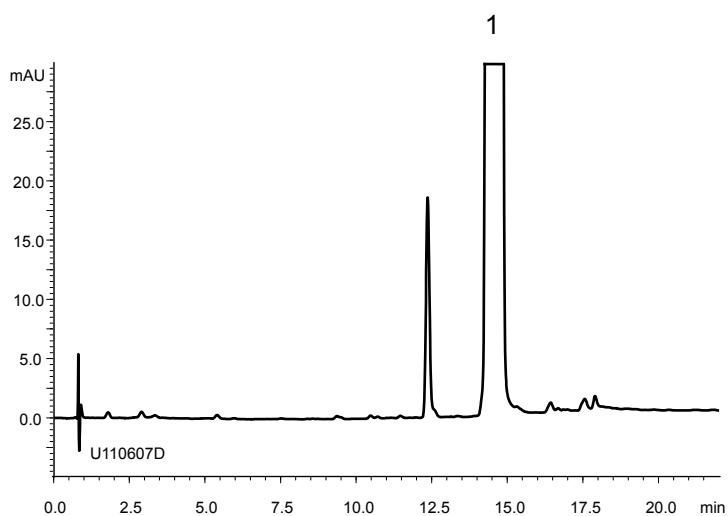
U110611A

A) Standard solution (0.02 mg/mL Risperidone)



	System suitability requirement	result
Theoretical plate number (Risperidone)	$\geq 10000$	71800
Tailing factor (Risperidone)	$\leq 2.0$	1.14

B) Sample solution (10 mg/mL Risperidone)



Column : YMC-Triart C18 (3  $\mu$ m, 12 nm)  
100 X 4.6 mmI.D.

Eluent : A) 65 mM CH<sub>3</sub>COONH<sub>4</sub>  
B) methanol  
30%B(0-2 min), 30-70%B(2-17 min), 70%B(17-22 min)

Flow rate : 1.5 mL/min

Temperature : 30°C

Detection : UV at 260 nm

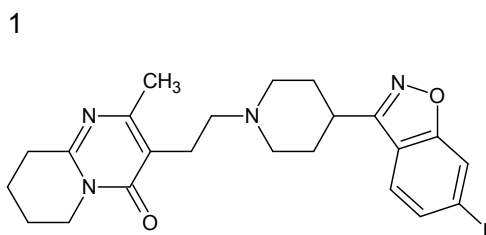
Injection : 10  $\mu$ L

(The Japanese Pharmacopoeia 16th; Related substances)

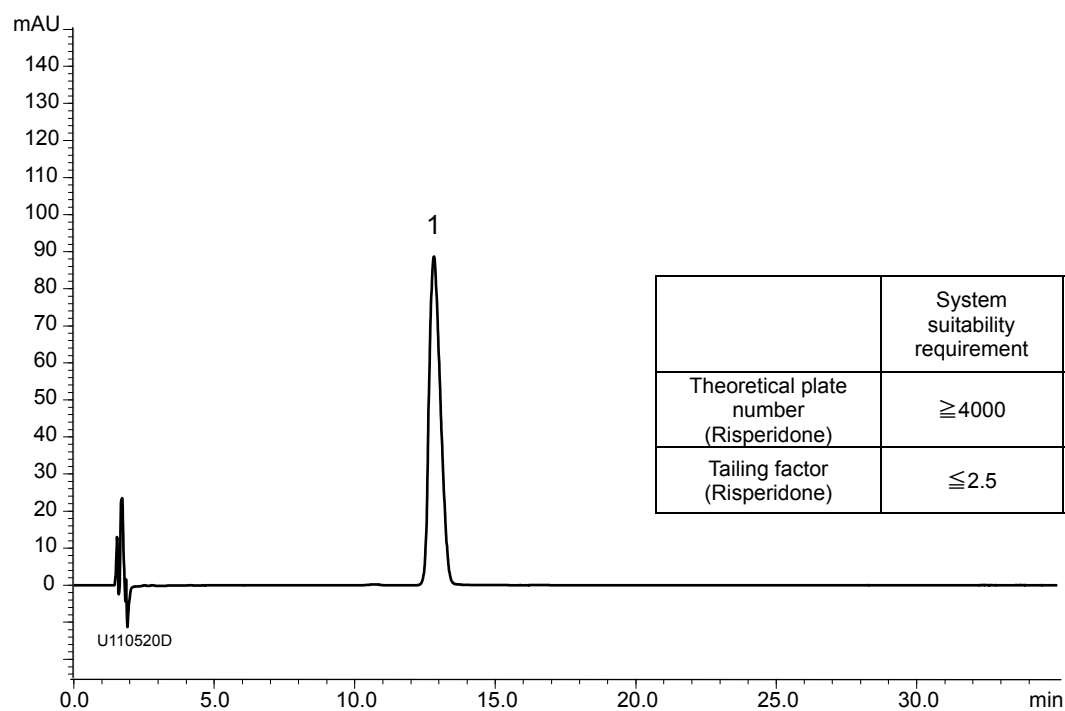
リスペリドン錠・細粒・内服液

Risperidone Tablets, Fine Granules and Oral Solution

U110604A



Risperidone



Column : YMC-Pack ODS-A (3  $\mu$ m, 30 nm)  
150 X 3.0 mmI.D.

Eluent : acetonitrile/water/TFA (20/80/0.15) adjust pH 3.0 with 28% ammonia solution

Flow rate : 0.55 mL/min (*adjust the flow rate so that the retention time of risperidone is about 13 min*)

Temperature : 25°C

Detection : UV at 275 nm

Injection : 10  $\mu$ L (0.1 mg/mL)

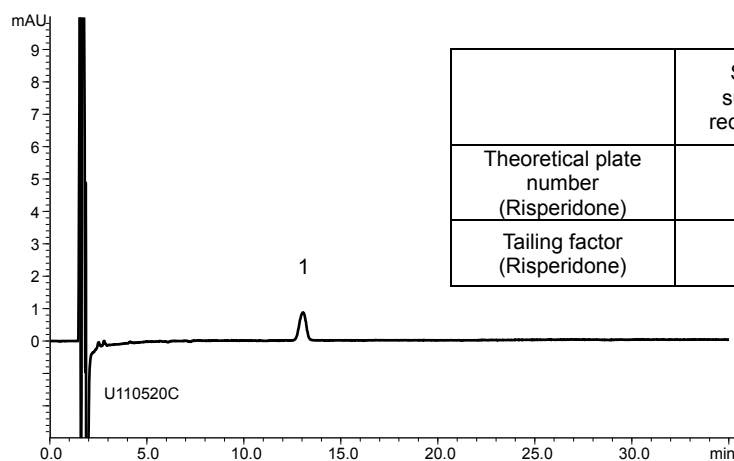
(The Japanese Pharmacopoeia 16th; Assay)

リスペリドン錠・細粒・内服液

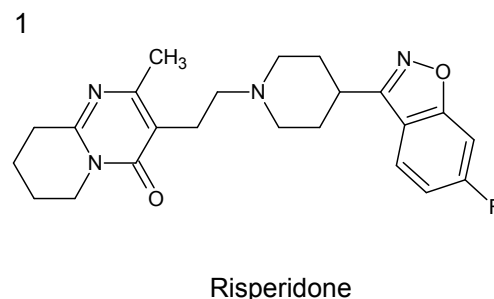
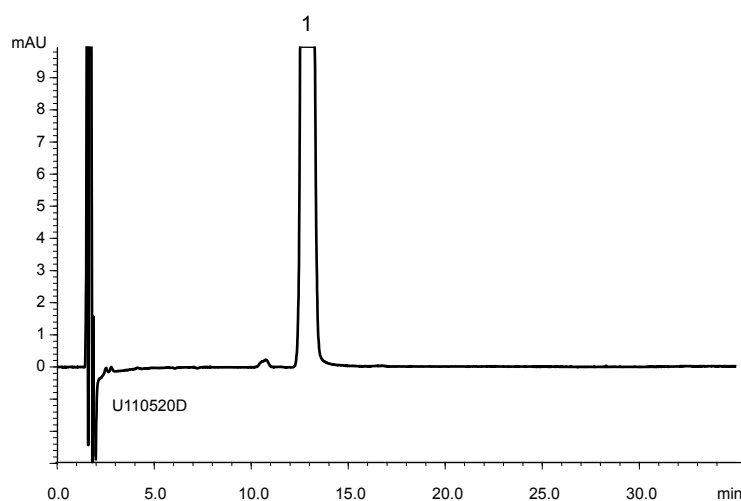
Risperidone Tablets, Fine Granules and Oral Solution

U110604B

A) Standard solution (0.001 mg/mL Risperidone)



B) Sample solution (0.1 mg/mL Risperidone)



Column : YMC-Pack ODS-A (3  $\mu$ m, 30 nm)  
150 X 3.0 mmI.D.

Eluent : acetonitrile/water/TFA (20/80/0.15) adjust pH 3.0 with 28% ammonia solution

Flow rate : 0.55 mL/min (*adjust the flow rate so that the retention time of risperidone is about 13 min*)

Temperature : 25°C

Detection : UV at 275 nm

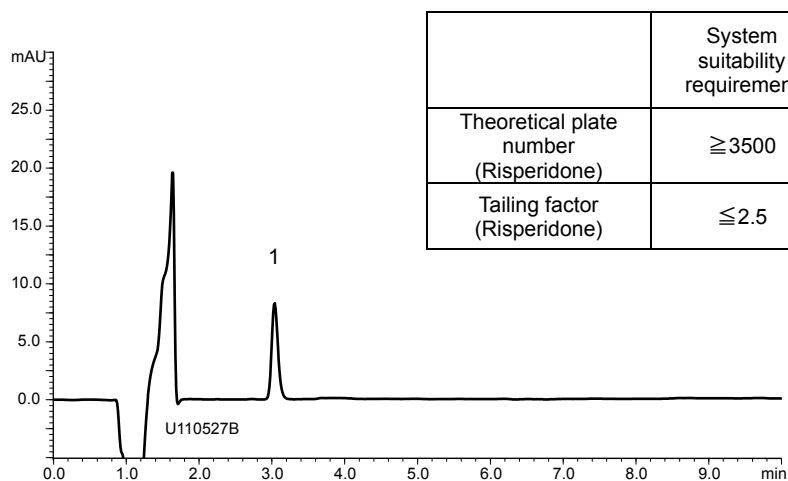
Injection : 10  $\mu$ L

(The Japanese Pharmacopoeia 16th; Related substances)

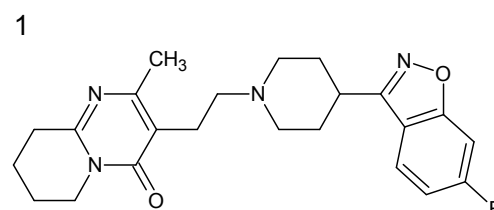
リスペリドン錠・細粒  
Risperidone Tablets and Fine Granules

U110604C

A) Risperidone Tablets standard solution  
(0.00056 mg/mL Risperidone)

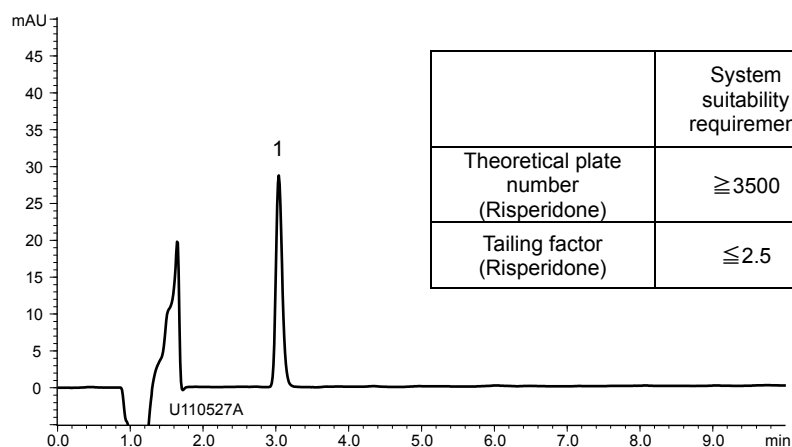


	System suitability requirement	result
Theoretical plate number (Risperidone)	$\geq 3500$	5900
Tailing factor (Risperidone)	$\leq 2.5$	1.26



Risperidone

B) Risperidone Fine Granules standard solution  
(0.00168 mg/mL Risperidone)



	System suitability requirement	result
Theoretical plate number (Risperidone)	$\geq 3500$	5900
Tailing factor (Risperidone)	$\leq 2.5$	1.28

Column : YMC-Triart C18 (5  $\mu$ m, 12 nm)  
150 X 4.6 mmI.D.

Eluent : acetonitrile/water/TFA (35/65/0.1) adjust pH 3.0 with 28% ammonia solution

Flow rate : 1.4 mL/min (adjust the flow rate so that the retention time of risperidone is about 3 min)

Temperature : 25°C

Detection : UV at 237 nm

Injection : 100  $\mu$ L

(The Japanese Pharmacopoeia 16th; Dissolution)