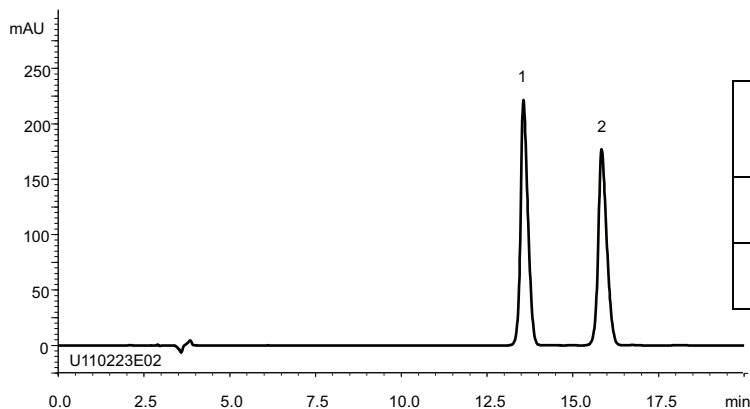


パロキセチン塩酸塩
Paroxetine Hydrochloride

U110301A

A) System suitability solution*

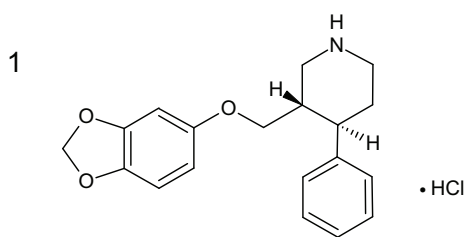
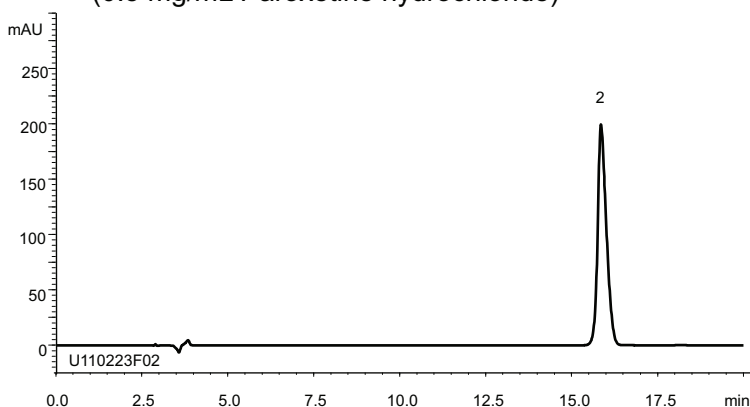
(0.5 mg/mL Paroxetine hydrochloride, 0.5 mg/mL Paroxetine related compound B)



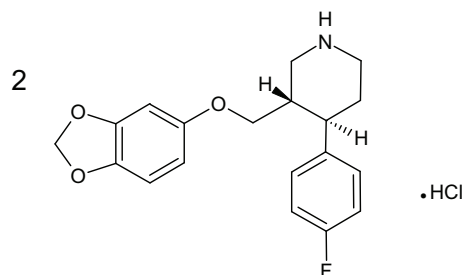
	System suitability requirement	result
Rs (Paroxetine related compound B, Paroxetine)	≥ 2.0	5.5
Tailing factor (Paroxetine)	≤ 2.0	1.26

B) Sample solution*

(0.5 mg/mL Paroxetine hydrochloride)



Paroxetine related compound B



Paroxetine hydrochloride

Column : YMC-Pack TMS (5 μ m, 12 nm)
250 X 4.6 mm I.D.

Eluent : acetonitrile/triethylamine/buffer (30/1/70) adjust pH 5.5 with acetic acid
buffer: 0.05M ammonium acetate in water and adjust pH 4.5 with acetic acid

Flow rate : 1.0 mL/min

Temperature : 25°C

Detection : UV at 295 nm

Injection : 10 μ L

(The United States Pharmacopoeia 32nd; Assay)

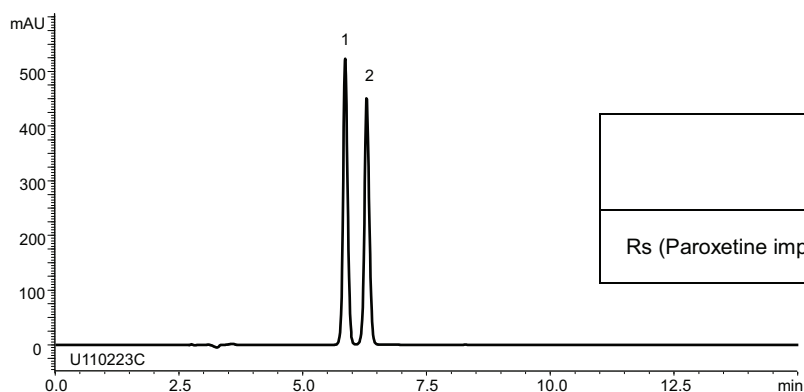
*These reagents for laboratory use

パロキセチン塩酸塩
Paroxetine Hydrochloride

U110301B

A) Reference solution (b)*

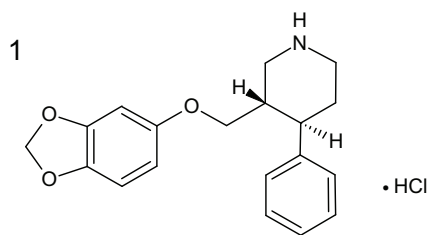
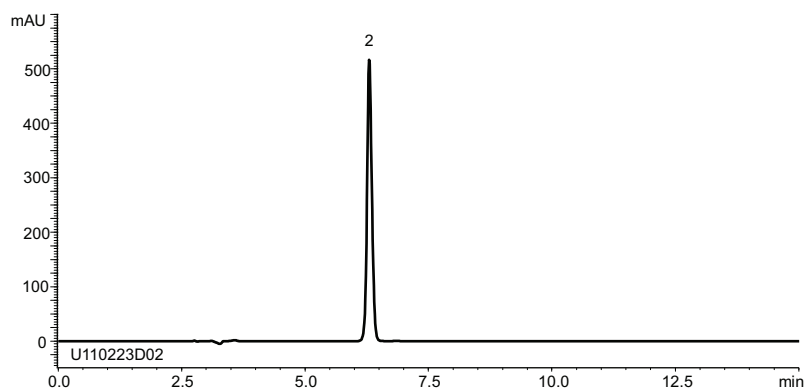
(0.5 mg/mL Paroxetine hydrochloride, 0.5 mg/mL Paroxetine impurity A)



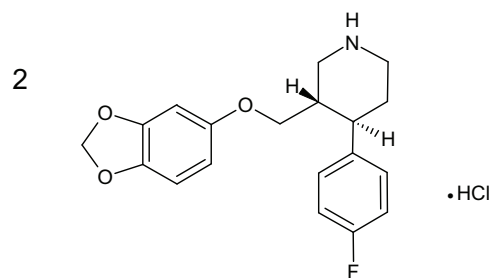
	System suitability requirement	result
Rs (Paroxetine impurity A, Paroxetine)	≥ 2.0	2.6

B) Test solution*

(0.5 mg/mL Paroxetine hydrochloride)



Paroxetine impurity A



Paroxetine hydrochloride

Column : YMC-Pack TMS (5 μm, 12 nm)
250 X 4.6 mm I.D.
Eluent : acetonitrile/triethylamine/buffer (40/1/60) adjust pH 5.5 with acetic acid
buffer: 0.08M ammonium acetate in water and adjust pH 5.5 with acetic acid
Flow rate : 1.0 mL/min
Temperature : 25°C
Detection : UV at 295 nm
Injection : 10 μL

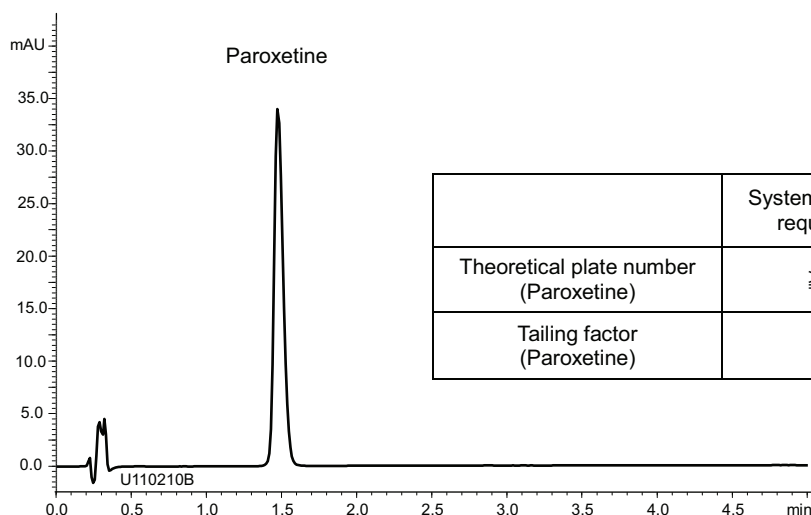
(The European Pharmacopoeia 6.0; Assay)

*These reagents for laboratory use

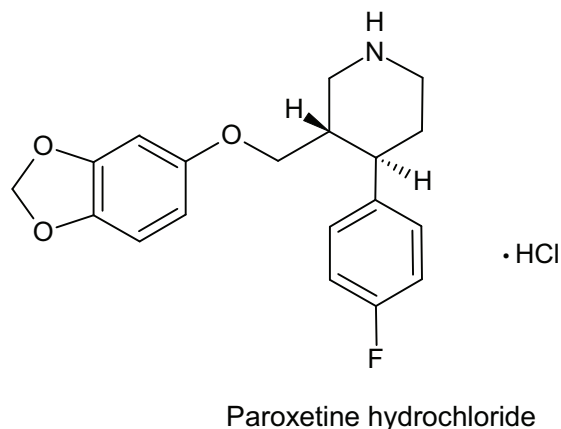
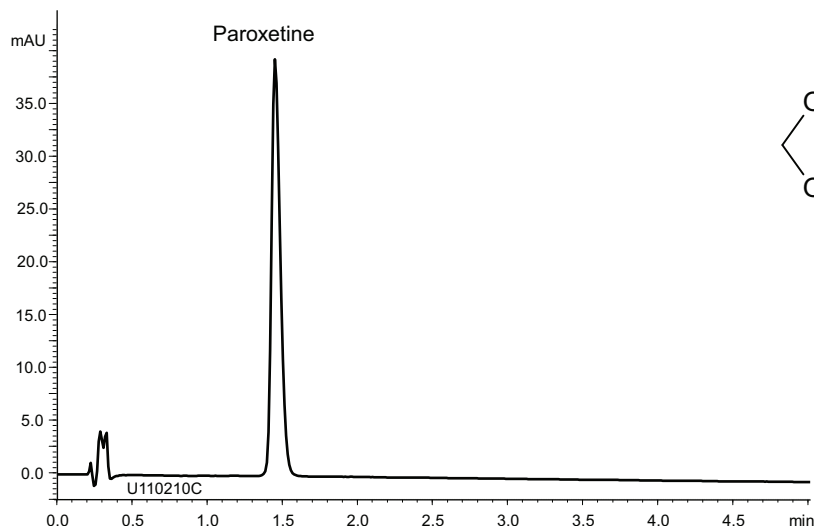
パロキセチン錠
Paroxetine tablets

U110215A

A) Standard solution*
(0.1 mg/mL Paroxetine hydrochloride)



B) Assay solution*
(0.1 mg/mL Paroxetine hydrochloride)



Column : YMC-Pack Pro C8 (3 μ m, 12 nm)
35 X 4.6 mm I.D.
Eluent : acetonitrile/buffer (30/70)
buffer: water/phosphoric acid/triethylamine (100/0.6/0.3)
Flow rate : 2.0 mL/min
Temperature : 25°C
Detection : UV at 295 nm
Injection : 5 μ L
(The United States Pharmacopoeia 32nd)

*Standard solution was prepared from Paroxetine HCl supplied as a reagent for laboratory use.
Assay solution was prepared from Paroxetine HCl tablets.