

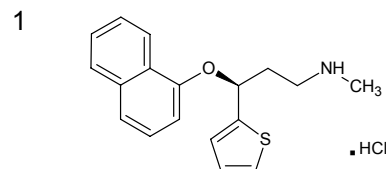
デュロキセチン塩酸塩 (米国薬局方記載条件)

Duloxetine hydrochloride (The United States Pharmacopeia)

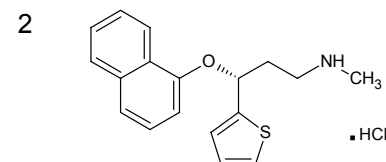
F130930A

System suitability solution*

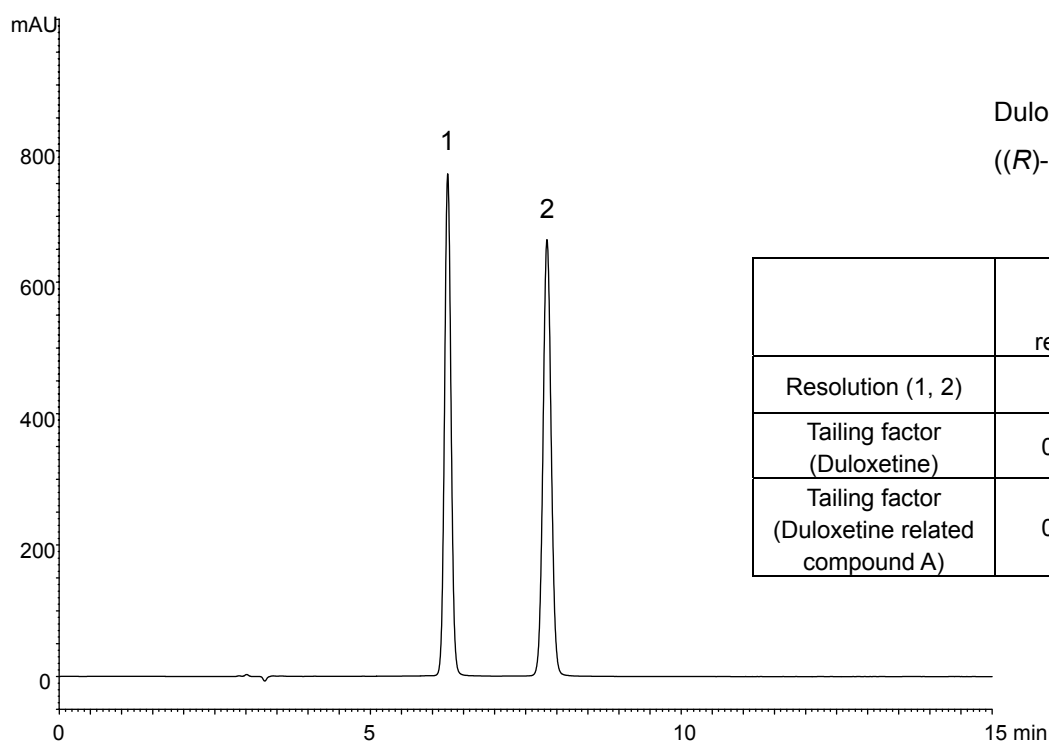
(0.1 mg/mL Duloxetine hydrochloride, 0.1 mg/mL Duloxetine related compound A)



Duloxetine hydrochloride
((S)-Duloxetine hydrochloride)



Duloxetine related compound A
((R)-Duloxetine hydrochloride)



	System suitability requirement	Result
Resolution (1, 2)	≥ 3.5	7.4
Tailing factor (Duloxetine)	0.8 ~ 1.5	1.1
Tailing factor (Duloxetine related compound A)	0.8 ~ 1.5	1.0

Column : CHIRAL ART Cellulose-C (5 μm)
250 X 4.6 mmI.D.

Eluent : *n*-hexane/2-propranol/diethylamine (83/17/0.2)

Flow rate : 1.0 mL/min

Temperature : 40°C

Detection : UV at 230 nm

Injection : 10 μL

(The United States Pharmacopeia 37th; Limit of Duloxetine related compound A)

* System suitability solution was prepared from duloxetine hydrochloride and duloxetine related compound A supplied as reagents for laboratory use.