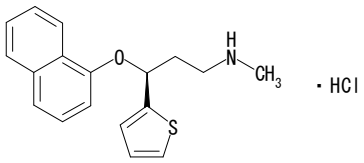
# U.S. Pharmacopeia method

DAICEL CORPORATION

## Duloxetine Hydrochloride :Limit of Duloxetine Related Compound A

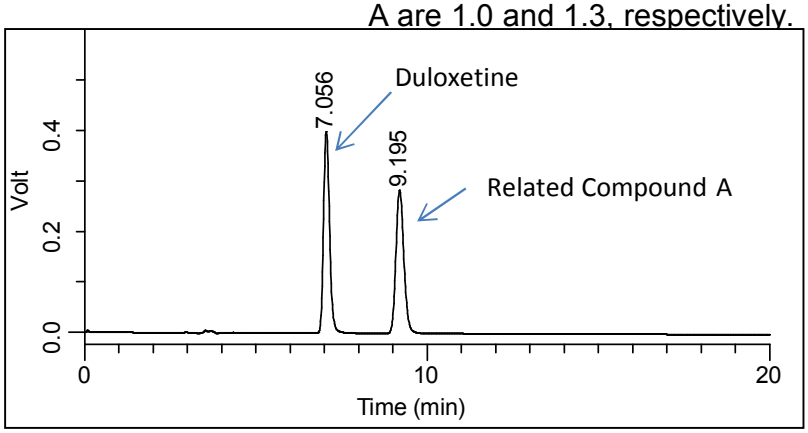


| | |
|---|---|
| Column | : CHIRALCEL® OD-H 0.46cmΦ × 25cmL (L40) |
| Mobile phase | : Hexane / Isopropyl alcohol / Diethylamine = 83 / 17 / 0.2 (v / v / v) |
| Flow rate | : 1.0mL/min. |
| Injection volume | : 10μL |
| Column temperature | : 40℃ |
| UV detection | : 230nm |

System suitability

Sample: 0.1 mg/mL each of USP Duloxetine Hydrochloride RS and USP Duloxetine Related Compound A RS in Mobile phase.

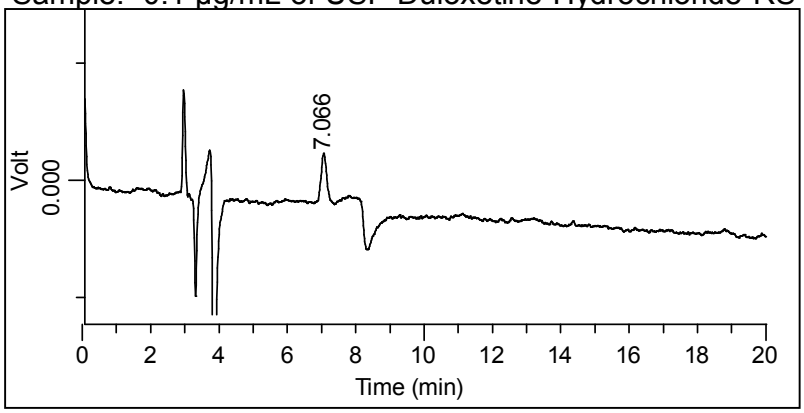
Relative retention times: duloxetine and duloxetine related compound A are 1.0 and 1.3, respectively.




| | Requirement | Result |
|---|---|---|
| Resolution | ≧3.5 | 5.7 |
| Tailing factor | Between 0.8 and 1.5 | 1.2 (Duloxetine)<br>1.2 (Compound A) |
| Relative standard deviation | ≦5.0% | 0.15% |

Sensitivity

Sample: 0.1 μg/mL of USP Duloxetine Hydrochloride RS in Mobile phase.




| | Requirement | Result |
|---|---|---|
| Signal-to-noise ratio | ≧3 | 14.4 |