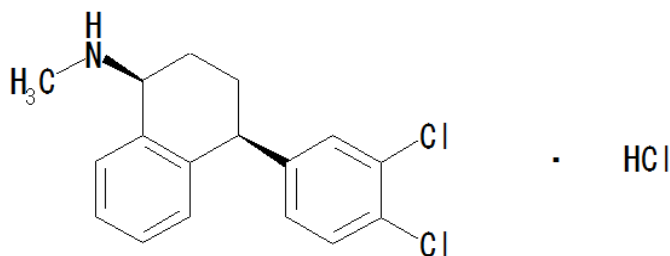


U.S. Pharmacopeia method

Sertraline Hydrochloride :Limit of (*R,R*)-Sertraline Hydrochloride

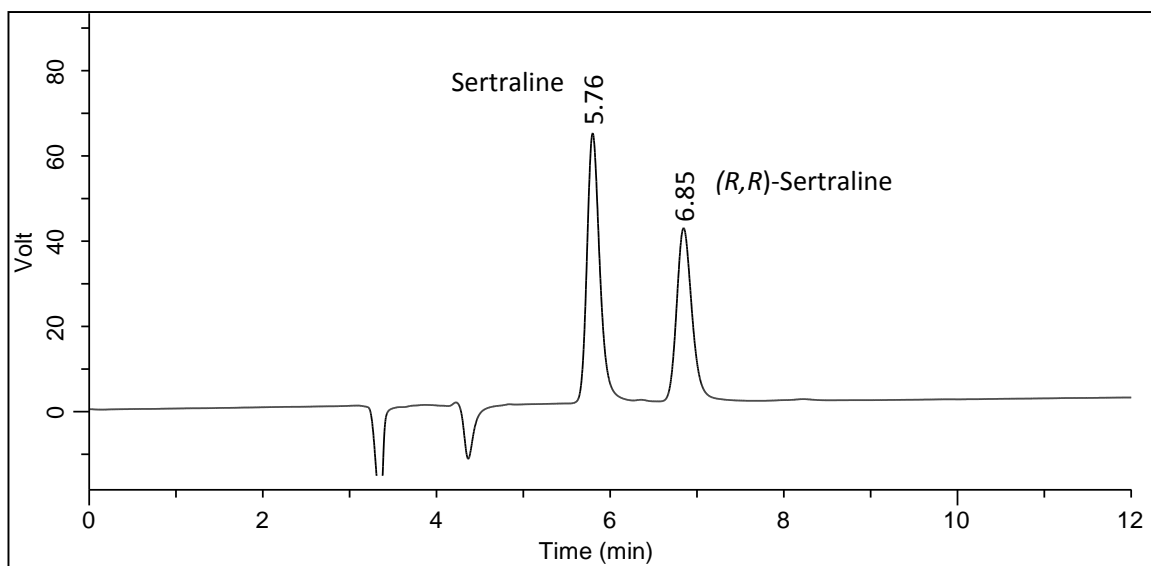


Column : CHIRALCEL® OD-H 0.46cmΦ × 25cmL (L40)
Mobile phase : Hexane / 2-propanol / Diethylamine = 960 / 40 / 1.5 (v / v / v)
Flow rate : 1.0mL/min.
Injection volume : 20μL
Column temperature : 5°C
UV detection : 235nm

System suitability test

Sample: Transfer 10 mg of USP Sertraline Hydrochloride Racemic Mixture RS into a 20-mL volumetric flask. Add 4 mL of diluted ammonia water (1 in 10) and 10 mL of hexane. Shake well until the organic phase is clear. Wait for phase separation, transfer about 2.0 mL from the top layer into a 20-mL volumetric flask, and dilute with hexane to volume.

Relative retention times: Sertraline and (*R,R*)-Sertraline are about 1.0 and 1.16, respectively.



	Requirement	Result
Resolution	≥2.8	3.6
Relative standard deviation	≤10.0%	4.9%

For details of monograph, please check pharmacopeia.