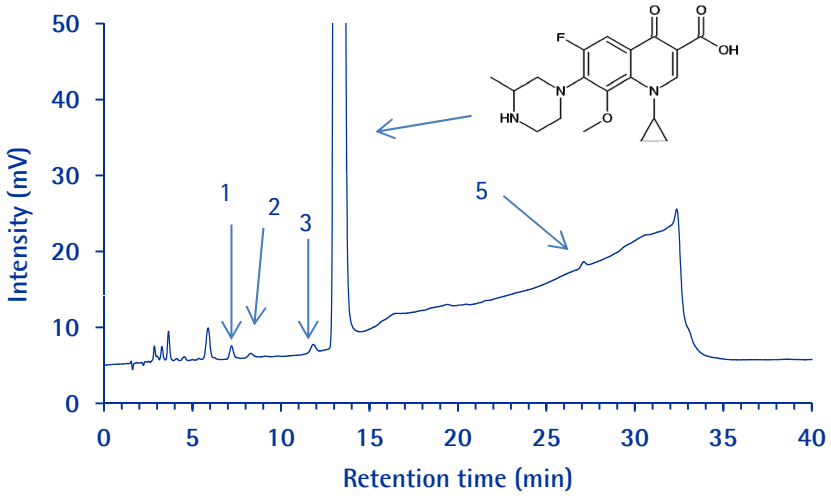
Gatifloxacin and Related Substances (Eye Drops)

Purospher®STAR RP-18 endcapped

Chromatographic Conditions

Column: Purospher® STAR RP-18 endcapped (5µm) Hibar® RT 250x4.6 mm 1.51456.0001
Injection: 20 µL
Detection: UV 240 nm and 285 nm
Flow Rate: 1.5 mL/min
Mobile Phase: Dissolve 6.6 mL of 40 % Tetrabutylammonium hydroxide solution and 6.6 g of di-ammonium hydrogen phosphate in 1000 mL water. Adjust pH to 9.5 ± 0.05 with ammonia solution (25%).
Filter through 0.45 µm nylon membrane filter, 47mm.
Solution A: Buffer and acetonitrile 84:16 (v/v)
Solution B: Buffer, acetonitrile and methanol 65:25:10 (v/v/v)
Gradient: See table
Temperature: 40 °C
Diluent: Water and acetonitrile 90:10 (v/v)
Standard: Dissolve 10 mg of Gatifloxacin in 100 mL of diluent. Dilute the stock solution 100 times with diluent.
Sample: Weigh 4 gm of eye drops and dilute to 20 ml with diluent.



Time	%A	%B
0.0	100	0
8.0	100	0
30.0	0	100
30.1	100	0
40.0	100	0

Chromatographic Data

No.	Compound	Retention Time (min)	RRT	Asymmetry
1	Desmethyl Gatifloxacin	7.2	0.55	1.1
2	8-Hydroxy Gatifloxacin	8.3	0.63	1.4
3	Isogatifloxacin	11.8	0.90	0.9
4	Gatifloxacin	13.2	1.00	1.3
5	Difluoromethoxy Gatifloxacin	27.1	2.05	1.1