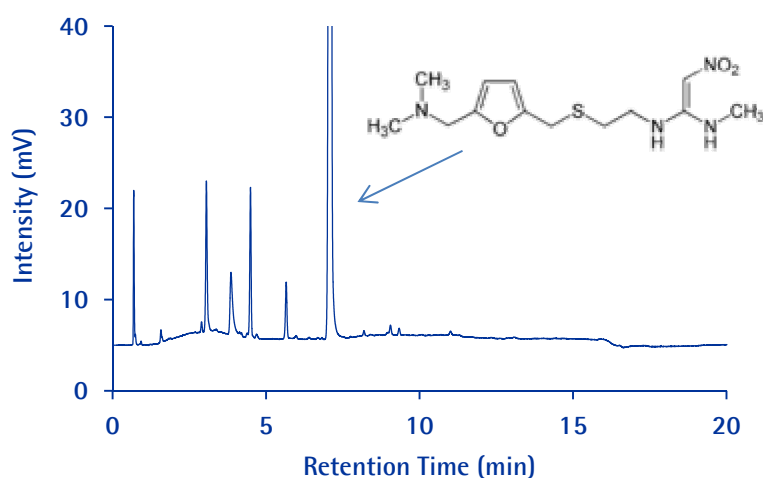


Ranitidine HCl and Related Substances

Purospher® STAR RP-18 endcapped

Chromatographic Conditions

Column:	Purospher® STAR RP-18 endcapped (3µm) Hibar® RT 100x4.6 mm	1.50469.0001
Injection:	10 µL	
Detection:	UV 230 nm	
Cell:	10 µL	
Flow Rate:	1.5 mL/min	
Mobile Phase:	Buffer: Place 1900 mL of Milli-Q water in 2L volumetric flask. Add 6.8 mL of phosphoric acid and mix. Add 8.6 mL of 50% sodium hydroxide solution and dilute to final volume. If necessary adjust the pH to 7.1 with 50% sodium hydroxide solution. Solution A: buffer and acetonitrile 98:2 (v/v): Solution B: buffer and acetonitrile 78:22(v/v)	
Gradient:	See table	
Temperature:	35 °C	
Diluent	Solution A	
Sample:	Dissolve 1.3 mg of resolution mixture in diluent & dilute to 10 ml with same solvent.	
Pressure Drop:	154 to 175 Bar(2233 to 2537 psi)	



Time (min)	%A	%B
0.0	100	0
10.0	0	100
15.0	0	100
16.0	100	0
20.0	100	0

Chromatographic Data

No.	Compound	Retention Time (min)	RRT	Asymmetry
1	Ranitidine Oxime	1.6	0.22	1.4
2	Amino alcohol	3.1	0.44	1.3
3	Ranitidine diamine	3.9	0.55	1.8
4	Ranitidine S-oxide	4.5	0.63	1.0
5	Complex nicotinamide	5.7	0.80	1.0
6	Ranitidine	7.1	1.00	1.0
7	Formaldehyde adduct	9.3	1.31	1.0