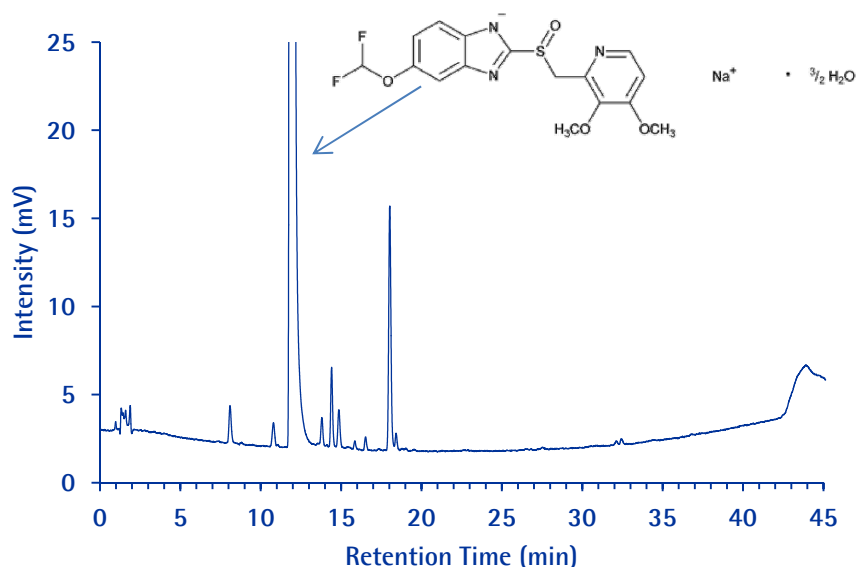


Pantoprazole Sodium Related Substances (USP)

Purospher®STAR RP-18endcapped

Chromatographic Conditions

Column:	Purospher®STAR RP-18endcapped (5µm) Hibar® RT 150x4.6 mm	1.51455.0001
Injection:	20 µL	
Detection:	UV 290 nm	
Flow Rate:	1.0 mL/min	
Mobile Phase:	Solution A: Prepare a solution of dibasic potassium phosphate (1.74 g/L) adjusted with a solution of phosphoric acid (330 g/L) to a pH of 7.00 ± 0.05. Solution B: acetonitrile	
Gradient:	See gradient table	
Temperature:	40°C	
Diluent	1:1 mixture of acetonitrile and 1 mM NaOH	
Sample:	460 ppm of Pantoprazole in diluent	
Pressure Drop:	101 to 56 Bar (1465 to 812 psi)	



Time	A (%)	B (%)
0-40	80→20	20→80
40-45	20→80	80→20
45-55	80	20

Chromatographic Data

No.	Compound	Time (min)	Relative Retention Time (RRT)	Resolution	Asymmetry (T _{USP})
1	Pantoprazole RS C	8.1	0.7	-	1.1
2	Pantoprazole RS A	10.8	0.9	-	1.0
	Pantoprazole Na	11.9	1.0	-	1.1
3	Pantoprazole RS F	13.8	1.2	-	1.1
4	Pantoprazole RS D	14.4	1.2	2.9	1.1
5	Pantoprazole RS E	14.7	1.2	2.0	1.1
6	Pantoprazole RS B	18.0	1.5	-	1.2