

Mefenamic Acid and Related Substances (USP)

Purospher®STAR RP-18 endcapped

Chromatographic Conditions

Column: Purospher®STAR RP-18endcapped (5 μm) Hibar® RT 250x4.6 mm 1.51456.0001

 $\begin{tabular}{lll} \mbox{Injection:} & 10 \ \mu\mbox{L} \\ \mbox{Detection:} & UV \ 254 \ nm \\ \mbox{Cell:} & 10 \ \mu\mbox{L} \\ \mbox{Flow Rate:} & 1.0 \ m\mbox{L/min} \\ \end{tabular}$

Mobile Phase: Buffer: 50 mM of monobasic ammonium phosphate, adjusted with 3 M ammonium hydroxide

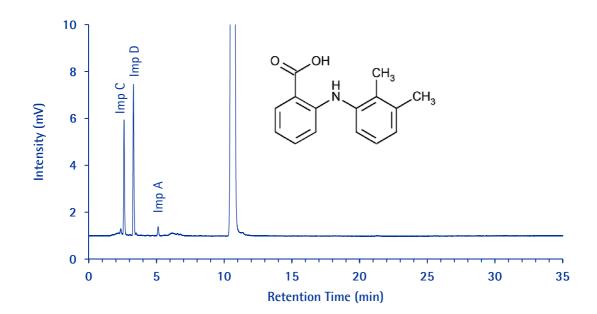
to a pH of 5.0. Mix tetrahydrofuran, buffer and acetonitrile 14:40:46 (v/v)

Temperature: 25°C

Diluent Mobile phase

Sample: 5 ppm of Impurity C and D, 0.1 ppm of Impurity A and 100 ppm Mefenamic Acid

Pressure Drop: 140 Bar (2030 psi)



Chromatographic Data

1 Impurity C 2.6 0.24 1.2 7697 2 Impurity D 3.3 0.31 1.2 11439 3 Impurity A 5.1 0.48 1.1 19510 4 Mefenamic acid 10.7 1.00 0.9 18758	No	Compound	Time (min)	Relative Retention Time (RRT)	Asymmetry	Plates
3 Impurity A 5.1 0.48 1.1 19510	1	Impurity C	2.6	0.24	1.2	7697
A M 5	2	Impurity D	3.3	0.31	1.2	11439
4 Mefenamic acid 10.7 1.00 0.9 18758	3	Impurity A	5.1	0.48	1.1	19510
	4	Mefenamic acid	10.7	1.00	0.9	18758