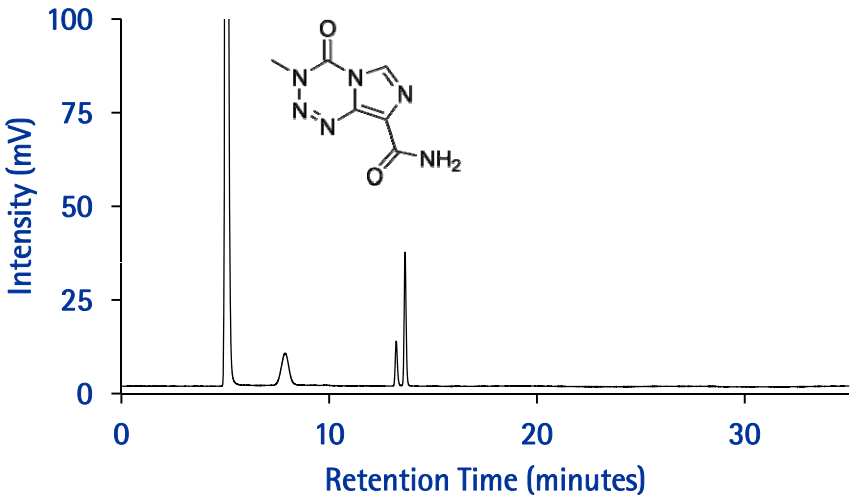
Separation of Temozolomide and Related Impurities

ZIC®-HILIC

Chromatographic Conditions

Column:	SeQuant® ZIC®-HILIC 250×4.6 mm, 5.0 µM, 200 Å	1.51458.0001
Injection:	10 µL	
Detection:	Shimadzu Prominence, UV 254 nm	
Cell:	10 µl	
Flow Rate:	0.8 mL/min	
Mobile Phase (v/v):	A: Dissolve 3.08 g of ammonium acetate in 1000 ml water (40 mM). B: 100% Acetonitrile	
Gradient:	0.00-2.0 min 97 % B, 2.01-25.0 min increase % A from 97-50 %; 25.01-30.0 min 50 % of each A and B. 30.01-35.0 97 % B and 3% A	
Temperature:	25 °C over column and autosampler cooler set at 15 °C	
Diluent	Mobile phase	
Sample:	400 ppm of Temozolomide & 1 ppm of each impurity A, B & C in acetonitrile. Keep the solution for 4 hrs in amber glassware before analysis for stabilization. Use amber coloured vial for analysis.	



Chromatographic Data

No.	Compound	Time	Tailing Factor	Resolution*
1	Temozolomide	5.1	1.3	0.0
2	Impurity C	7.9	1.0	6.3
3	Impurity B	13.2	1.1	12.5
4	Impurity A	13.7	1.1	2.4

Merck Millipore is a division of Merck KGaA, Darmstadt, Germany
www.merck-chemicals.com/chromatography
chromatography@merckgroup.com