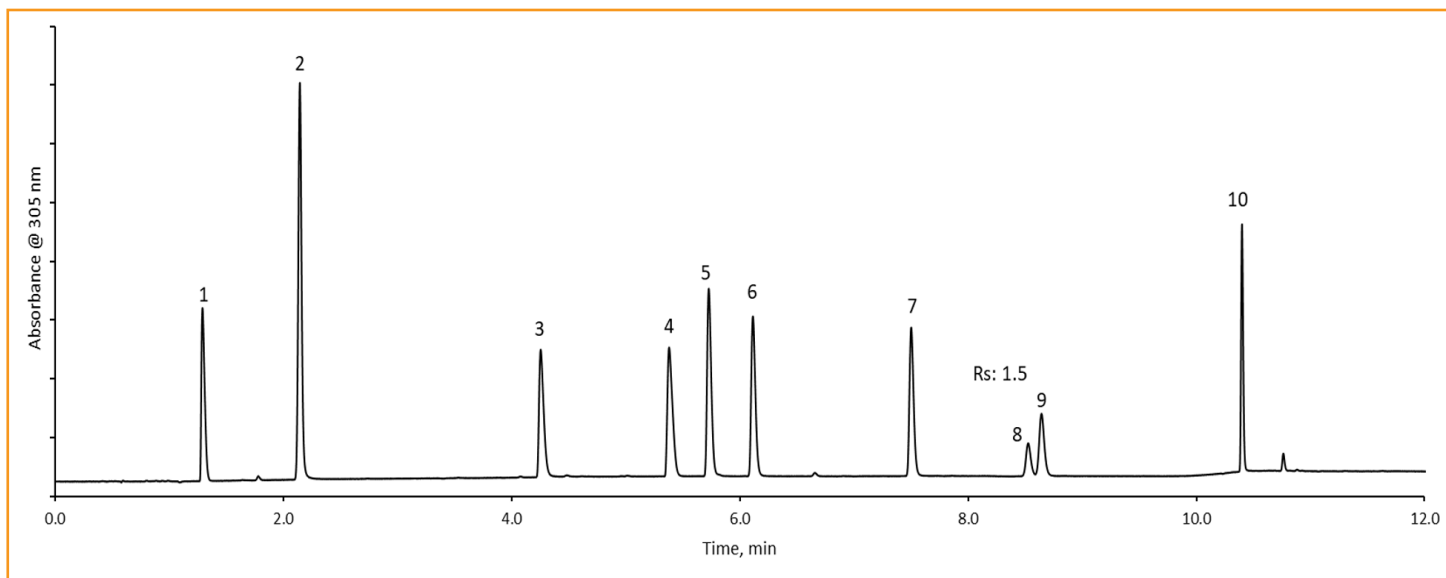




Separation of Omeprazole and Related Impurities

395



TEST CONDITIONS:

Column: HALO 120 Å Elevate C18, 2 μ m, 2.1 x 100 mm

Part Number: 91272-602

Mobile Phase A: Water + 0.03% Ammonium Hydroxide
(pH - 10.65)

Mobile Phase B: Methanol

Gradient:	Time	%B
	0.0	12
	7.0	45
	9.0	45
	9.5	70
	11.0	70

Flow Rate: 0.4 mL/min

Back Pressure: 485 bar

Temperature: 60 °C

Injection: 1 μ L

Sample Solvent: USP Diluent

Wavelength: PDA, 305 nm

Flow Cell: 0.1 μ L

Data Rate: 40 Hz

Response Time: 0.05 sec.

LC System: Shimadzu Nexera X2

PEAK IDENTITIES:

1. Related Compound F & G
2. Related Compound B
3. Related Compound E
4. Related Compound A
5. Impurity B
6. Omeprazole
7. Impurity H
8. N'-Methyl Omeprazole isomer 1
9. N'-Methyl Omeprazole isomer 2
10. Impurity C

A separation of omeprazole, related compounds, and impurities is performed on the HALO® Elevate 2 μ m column. Using a high pH compatible stationary phase the separation is completed using an 11 minute gradient. With a pKa of 9.3, omeprazole requires high pH in order to achieve the best separation. By using the Elevate column at a pH of 10.6, a complete separation of 10 different peaks is accomplished.