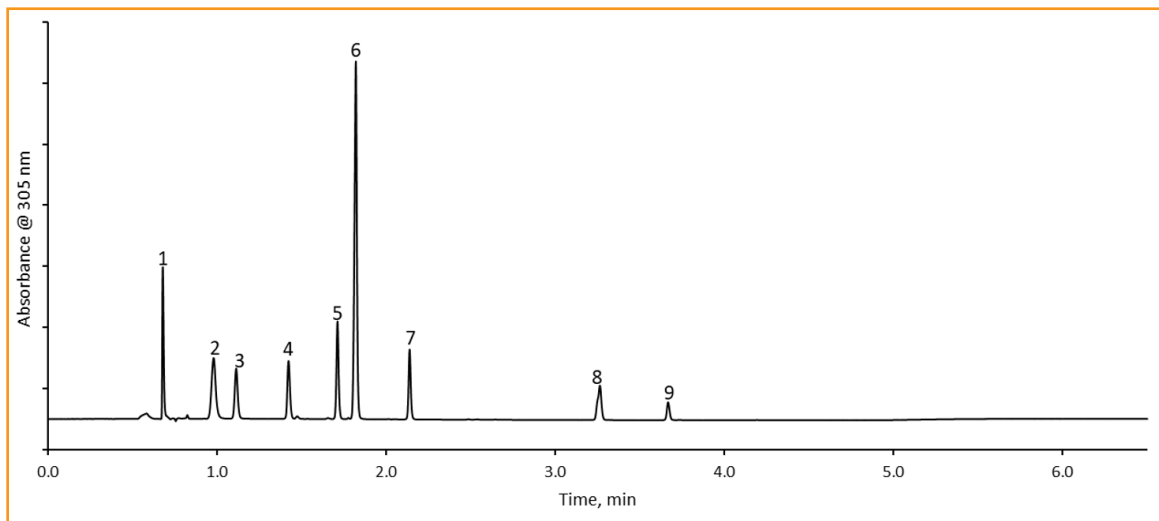




Omeprazole Analysis Using HALO® Elevate C18

373B



TEST CONDITIONS:

Column: HALO 120 Å ELV C18, 2.7 μm , 2.1 x 150 mm

Part Number: 92272-702

Mobile Phase A: Water + 0.1% Ammonium Hydroxide
(pH - 10.6)

Mobile Phase B: Acetonitrile

Gradient:	Time	%B
	0.0	13
	3.3	53
	3.8	53
	3.9	13
	9.0	13

Flow Rate: 0.4 mL/min

Back Pressure: 311 bar

Temperature: 60 °C

Injection: 1 μL

Sample Solvent: USP Diluent

Wavelength: PDA, 305 nm

Flow Cell: 1 μL

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
9. Impurity C

A separation of omeprazole, related compounds, and impurities is performed on the HALO® Elevate column. Using a high pH compatible stationary phase the separation is completed in less than 4 minutes. With a pKa of 9.3, omeprazole requires high pH for the best separations. By using the HALO® Elevate column at a pH of 10.6, a complete separation of 9 omeprazole related compounds and impurities is achieved.