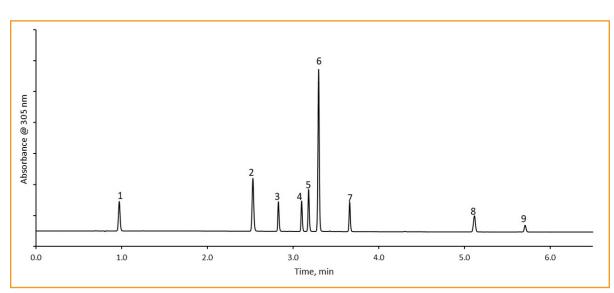


PHARMACEUTICALS

Modernized Omeprazole Separation on HALO® Elevate C18



TEST CONDITIONS:

Column: HALO 120 Å Elevate 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	5
	0.5	5
	10.0	95
	10.1	5
	16.0	5

Flow Rate: 0.4 mL/min Back Pressure: 460 bar Temperature: 30 °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 a 10 minute linear gradient. With a pKa of 9.3, omeprazole requires a high pH in order to achieve the best separation. By using the Elevate column at a pH of 10.6, a complete separation of 9 different peaks is obtained. With the retention of a C18 phase there is room to increase the speed of this separation, improving on the outdated USP method originally made for omeprazole.







