HALO®

PHARMACEUTICALS

Modernized Omeprazole Separation on HALO® Elevate C18

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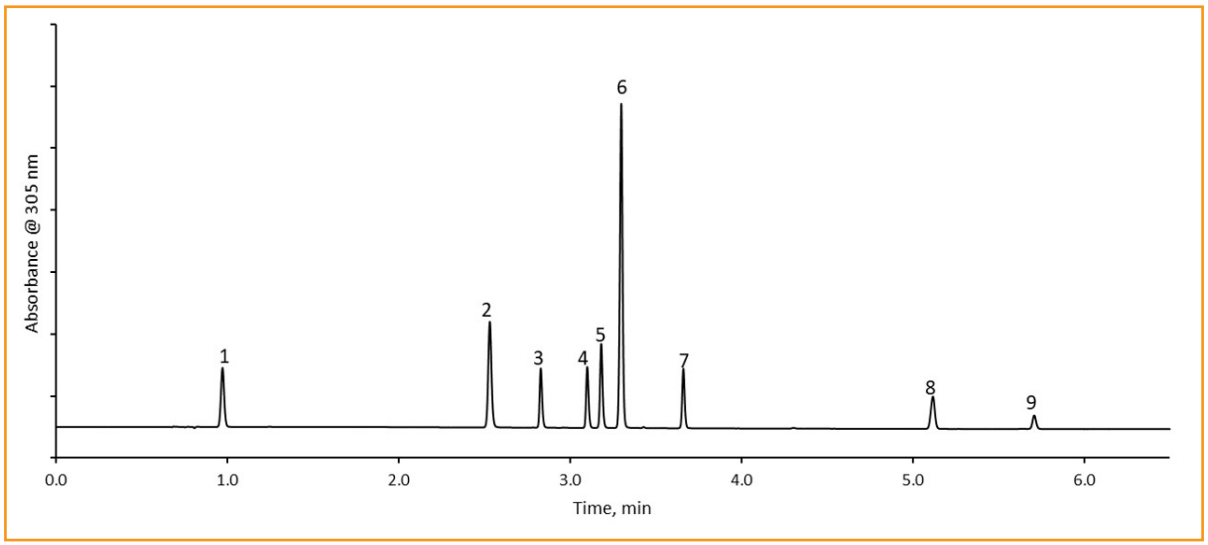

TEST CONDITIONS:

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 ºC
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 With the retention of a C18 phase there is room to increase the speed of this separation, improving on the outdated USP method originally made for omeprazole.

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