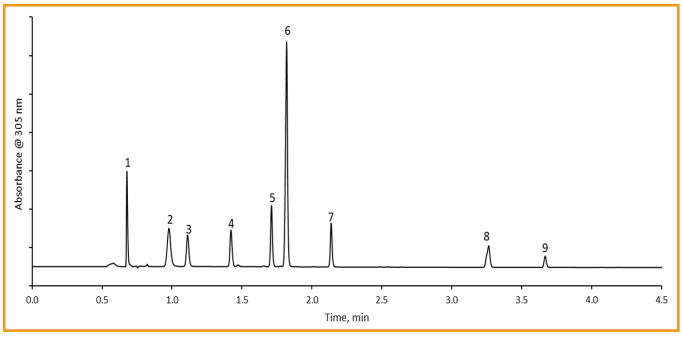
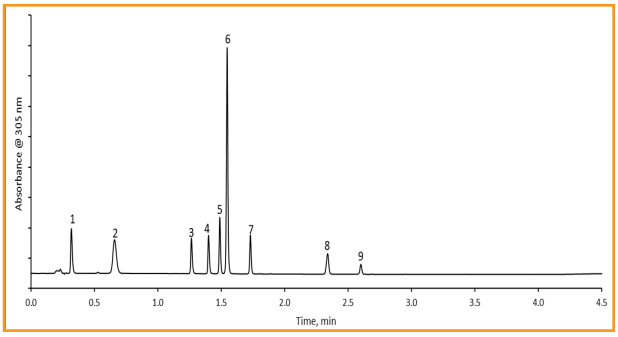
HALO®

PHARMACEUTICALS

Omeprazole Improvements on HALO® Elevate C18

373A





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

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

Column: HALO 120 Å ELV C18, 2.7 µm, 2.1 x 50 mm
Part Number: 92272-402
Mobile Phase A: Water + 0.1% Ammonium Hydroxide (pH - 10.6)
Mobile Phase B: Acetonitrile
Gradient:

Time	%B
0.0	5
3.0	55
3.5	55
3.6	5
6.0	5

Flow Rate: 0.4 mL/min
Back Pressure: 167 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

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 using a 10 minute linear gradient. With a pKa of 9.3, omeprazole requires high pH in order to get the best separation. By using the Elevate column at a pH of 10.6, a complete separation of 9 different peaks is achieved. This method was improved upon by using DryLab® software, decreasing the runtime from 9 minutes to 6 minutes total. The efficiency of the Fused-Core® particle can be seen in full affect with the decrease in runtime. With the retention of a C18 phase there is room to increase the speed of this separation, improving on the current USP method for omeprazole.

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