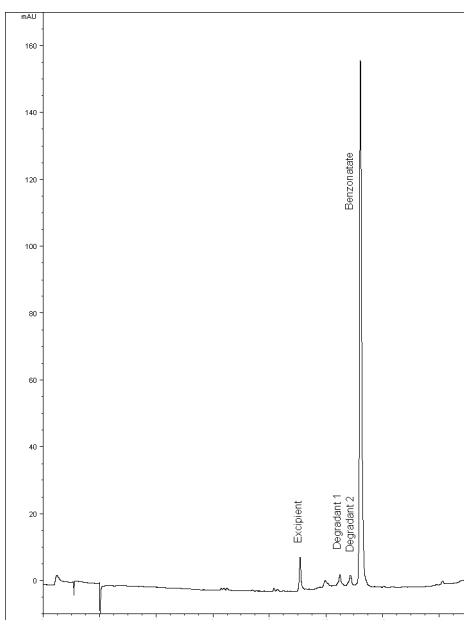
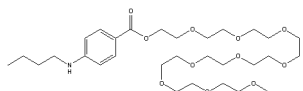


Benzonatate Excipients & Degradants Difficult to Separate due to Secondary Amine



Method Conditions

Column: Cogent Bidentate C18™, 4µm, 100Å
Catalog No.: 40018-75P
Dimensions: 4.6 x 75 mm
Mobile phase: A: 100% DI water + 10mM Sodium Phosphate Monobasic
 B: 80:20 Acetonitrile + 10mM Sodium Phosphate Monobasic
Gradient: Time=0 0%B
 Time=15 min 100% B (linear gradient)
Flow rate: 1.5 mL/min.
Peaks: 1: Excipient
 2: Degradant
 3: Degradant
 4: Benzonatate
Injection Volume: 10 µL
Detection: UV 280 nm
Temperature: 40°C

Discussion

This Gradient method will produce excellent separation of Benzonatate from excipients and degradants in a USP capsule formulation. Note the excellent resolution along with the excellent peak shape for this sometimes difficult molecule, which contains a secondary amine group.

For more information visit www.MTC-USA.com

Note: Benzonatate or 2,5,8,11,14,17,20,23,26-nonaooxaoctacosan-28-yl para-butylaminobenzoate is a non-narcotic oral antitussive (cough suppressant) drug, taken orally, which works by anesthetizing the tissues of the lungs and pleura responsible for the cough reflex. It has a numbing action similar to that of benzocaine that calms the stretch sensors in the lungs. It is the stretching of these sensors with breathing that causes the cough. Benzonatate begins to work within 15 to 20 minutes. Its effects last for approximately 3 hours. It is sold under the brand name Tessalon Perles (gelcaps) or Tessalon Capsules. The medication must be swallowed whole. If the capsules are bitten into or sucked on, it may make the mouth numb and in some cases cause choking.

Cat. No.	Description
40018-75P	Cogent Bidentate C18™ HPLC Column, 4mm, 100A, 4.6mm x 75mm