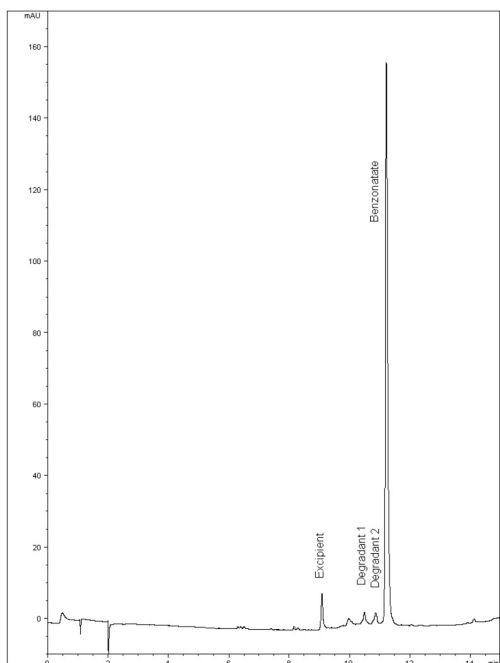
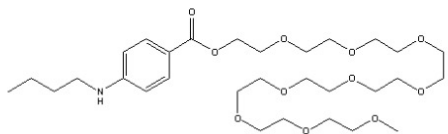


# Benzonatate Excipients & Degradants

Difficult to Separate due to Secondary Amine



**Notes:** Benzonatate or 2,5,8,11,14,17,20,23,26-nona-oxaoctacosan-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.

## Method Conditions

**Column:** Cogent Bidentate C18™, 4µm, 100Å

**Catalog No.:** 40018-75P

**Dimensions:** 4.6 x 75 mm

**Mobile Phase:** A: DI H<sub>2</sub>O/ 10 mM sodium phosphate monobasic  
B: 80% Acetonitrile/ 20% DI H<sub>2</sub>O/ 10 mM sodium phosphate monobasic

Gradient:	time (min.)	%B
	0	0
	15	100

**Temperature:** 40°C

**Injection vol.:** 10µL

**Flow rate:** 1.5 mL/min

**Detection:** UV 280 nm

**Peaks:** 1. Excipient  
2. Degradant  
3. Benzonatate

## 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.