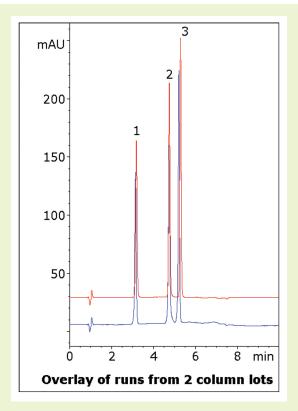




Sulfisoxazole Acetyl

Separation from two common preservatives



$HO \xrightarrow{O_{V}O_{CH_3}} 1$ $HO \xrightarrow{O_{V}O_{CH_3}} 2$ $HO \xrightarrow{O_{V}O_{CH_3}} 3$

Note: Sulfisoxazole acetyl is the prodrug form of sulfisoxazole, which is a sulfonamide antibiotic. It is available under brand names such as Truxazole® and Gantrisin®. Methyl and propyl paraben are common preservatives found in many food and drug products.

Method Conditions

Column: Cogent Bidentate C8™, 4µm, 100Å

Catalog No.: 40008-75P

Dimensions: 4.6 x 75 mm

Solvents: A: DI H₂O / 0.1% TFA (v/v) B: Acetonitrile / 0.1% TFA (v/v)

Gradient:	time (min.)	%B	
	0	30	
	1	30	
	6	60	
	7	30	

Injection vol.: 5µL

Flow rate: 1.0 mL/min

Detection: UV 254 nm

Sample: Mixture of 0.2 mg/mL sulfisoxazole acetyl, 0.01 mg/mL methyl paraben, and 0.02 mg/mL propyl paraben USP reference standards in 50/50 solvent A / solvent B diluent. Peak identities were confirmed with individual standards.

Peaks: 1. Methyl paraben

- 2. Sulfisoxazole acetyl
- 3. Propyl paraben

t₀: 0.9 min

Discussion

Orally administered suspension formulations of sulfisoxazole acetyl often contain the preservatives methyl and propyl paraben. As such, it is important to separate these compounds from the API in an HPLC assay method. Here excellent separation is obtained between standards of the three compounds using a simple gradient. Data from two column lots is shown in order to illustrate stationary phase lot-tolot consistency.

APP-A-207



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