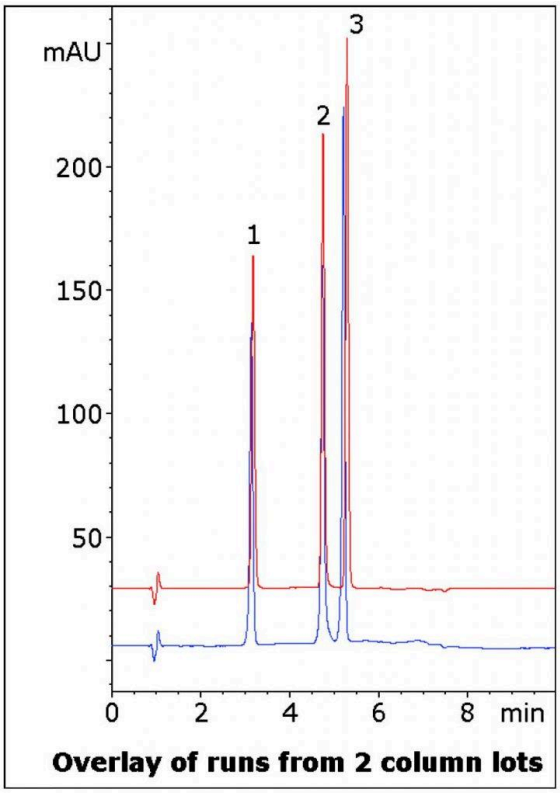
Sulfisoxazole Acetyl Analyzed with HPLC - AppNote

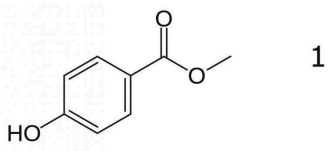
Separation of two Common Preservatives from the API in a Pharmaceutical Suspension

Orally administered suspensions with 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 to properly analyze the suspension. With this Method, excellent Separation is obtained between Standards of the three Compounds using a simple Gradient.

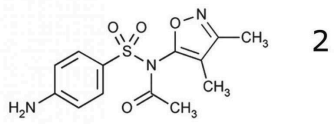
Data from two Column lots is shown in order to illustrate Method Consistency and Robustness.



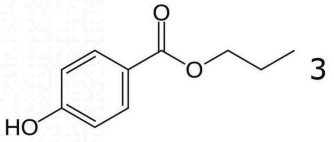
Overlay of runs from 2 column lots



1



2



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Peaks:

1. Methyl Paraben
2. Sulfisoxazole Acetyl
3. Propyl Paraben

Method Conditions

Column: Cogent Bidentate C8™, 4µm, 100Å
Catalog No.: 40008-75P
Dimensions: 4.6 x 75mm
Mobile Phase:
A: DI Water with 0.1% Trifluoroacetic Acid (TFA) v/v
B: Acetonitrile with 0.1% Trifluoroacetic Acid (TFA) v/v
Gradient:

Time *(minutes)*	%B
0	30
1	30
6	60
7	30

Injection vol.: 5µL
Flow rate: 1.0mL / minute
Detection: UV @ 254nm
Sample Preparation: Mixture of 0.2mg / mL Sulfisoxazole Acetyl, 0.01mg / mL Methyl Paraben, and 0.02mg / mL Propyl Paraben USP Reference Standards in 50:50 Solvent A / Solvent B diluent. Peak identities were confirmed with individual Standards.
t_0: 0.9 minutes

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.*

COGENT HPLC Columns™

Attachment

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