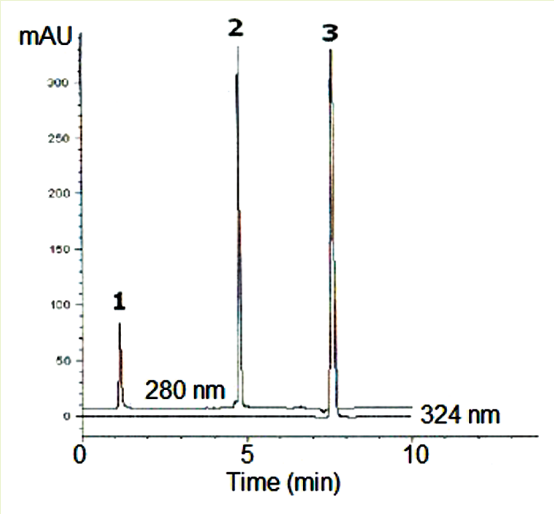
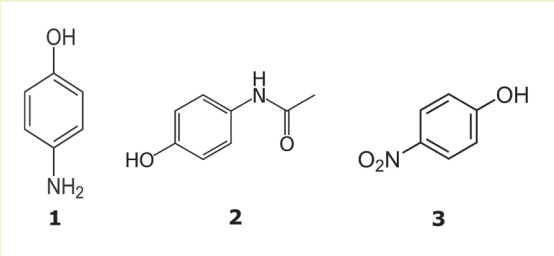
Acetaminophen Impurities Method

Robust, easy, APAP method





Note: Acetaminophen (n-acetyl-p-aminophenol, APAP) is a non-steroid anti-inflammatory drug. There are several impurities that can be present in a final drug (depending on the synthetic route, the quality of starting materials, reagents, etc.) which can have safety implications. Analytical methods are needed to detect and identify these impurities and quantify them.

Method Conditions

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

Catalog No.: 40018-75P

Dimensions: 4.6 x 75 mm

Solvents: A: DI H_2O / 0.1% formic acid
B: Acetonitrile / 0.1% formic acid

Gradient:

time (min.)	%B
0	0
1	0
4	30
6	30
6.01	10
10	10

Post Time: 3 min

Injection vol.: 5µL

Flow rate: 1.0 mL/min

Detection: UV 280 (4-aminophenol, acetaminophen) and 324 nm (4-nitrophenol)

Sample: The stock solution was prepared by dissolving 1.0 mg of standards in 10.00 mL of the mobile phase (50%A/50%B). The solution was then filtered with a 0.45 micron nylon syringe filter (MicroSolv Tech Corp.). The injection sample was diluted 1 : 10.

Peaks: 1. 4-aminophenol 1.072 min
2. Acetaminophen 4.668 min
3. 4-nitrophenol 7.588 min

t_0: 0.9 min

Discussion

Acetominophen and two of its major impurities were analyzed using the Cogent Bidentate C18 column and a simple mobile phase. The peak shapes were very high. The repeatability of the results was extremely good (%RSD = 0.01).

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