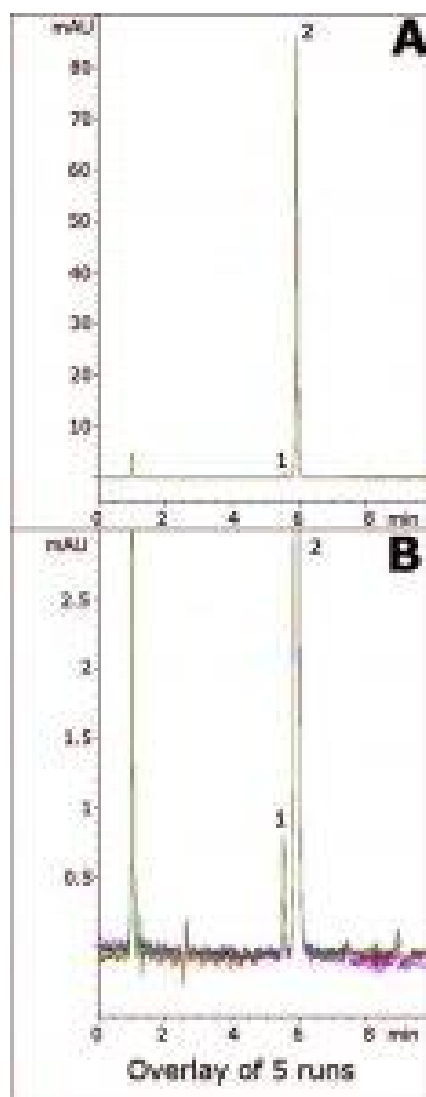


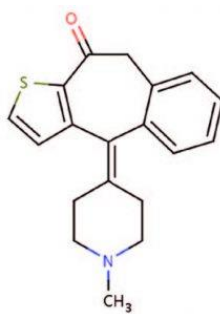
Ketotifen Analyzed by HPLC - AppNote

API with a Tertiary Amine can have a Great Peak Shape

The tertiary amine group of Ketotifen makes it a challenging compound to analyze in HPLC. In addition to good peak shape for this API, another peak can be identified which is baseline resolved from the main peak of interest.

This Method is suitable for routine assay of Ketotifen in ophthalmic solutions and is Precise as indicated by the overlay of 5 runs in *Figure B*. Also, the Method conditions were developed to be LCMS compatible which would be a great next step to identify peak 1.





Peaks:

1. Matrix component
2. Ketotifen

Method Conditions

Column: Cogent Silica-C™, 4µm, 100Å

Catalog No.: 40000-7.5P

Dimensions: 4.6 x 75mm

Mobile Phase:

A: DI Water / 0.1% Formic Acid

B: Acetonitrile / 0.1% Formic Acid

Gradient:

Time (minutes)	%B
0	95
2	95
6	40
7	95

Post Time: 3 minutes

Injection vol.: 1µL

Flow rate: 1.0mL / minute

Detection: UV @ 268nm

Sample Preparation: Equate® brand eye drop solution containing 0.035% Ketotifen Fumarate was filtered with 0.45µm Nylon Syringe Filter (MICROSOLV Tech Corp.) and used for injection.

t_o: 0.9 minutes

Note: Ketotifen is a second-generation noncompetitive H1-Antihistamine. In addition to ophthalmic solutions, it is also available in tablet formulations as well. In the latter case, it is used in treatment of asthma. It is marketed under trade names such as Zyrtec®, Zaditor®, and Alaway®.



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