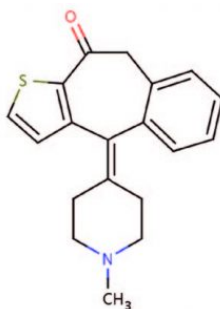
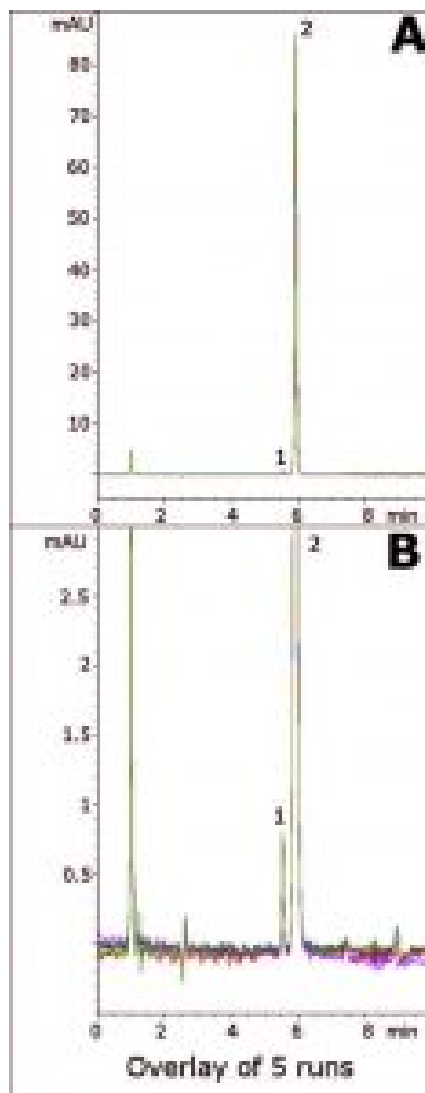


## API with a Tertiary Amine can have a Great Peak Shape

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

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## 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<sub>0</sub>:** 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®.

**Attachment****No 196 Tertiary Amine - Ketotifen Analyzed by HPLC pdf** 0.4 Mb [Download File](#)

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