



ANP

Tertiary Amine - Ketotifen

Method with excellent peak shape





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*.

Method Conditions

Column: Cogent Silica-C™, 4µm, 100Å

Catalog No.: 40000-7.5P

Dimensions: 4.6 x 75 mm

Mobile Phase: A: DI H₂O / 0.1% formic acid B: Acetonitrile / 0.1% formic acid

Gradient:	time (min.)	%B
	0	95
	2	95
	6	40
	7	95

Post Time: 3 min

Injection vol.: 1µL

Flow rate: 1.0 mL/min

Detection: 268 nm

Sample: 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.

Peaks: 1. Matrix component 2. Ketotifen

to: 0.9 min

Discussion

The tertiary amine group that makes ketotifen a challenging compound in HPLC can be chromatographed with excellent results using this method with a Cogent Silica-C stationary phase. In addition to excellent peak shape that results for the main ingredient, 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 very 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.

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