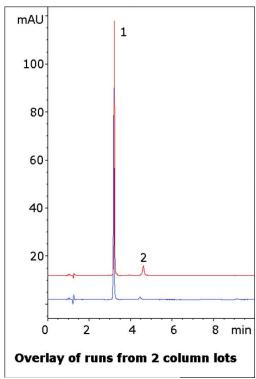


Oxymetazoline HCL Analyzed with HPLC - AppNote

Polar API Separated from a Matrix Peak

Oxymetazoline can be difficult to obtain a good Peak Shape with conventional HPLC Methods, and the USP System Suitability requires that the Tailing Factor be not more than 2.0. Also, the USP Method calls for a Cation Exchange (L9) Column for the Assay. This Method produces excellent Peak Shape also shows Separation of the API from a matrix component or another ingredient in the formulation.

Two runs from different Column batches are overlaid in the Chromatogram to show the Method Robustness and Precision.



Peaks:

1. Oxymetazoline

2. Matrix component

Method Conditions

Column: Cogent Diamond Hydride™, 4µm, 100Å

Catalog No.: 70000-7.5P **Dimensions**: 4.6 x 75mm

Mobile Phase:



A: DI Water with 0.1% Trifluoroacetic Acid (TFA)

B: Acetonitrile with 0.1% Trifluoroacetic Acid (TFA)

Gradient:

Time (minutes)	%B
0	97
1	97
6	40
7	97

Post Time: 3 minutes
Injection vol.: 1µL

Flow rate: 1.0mL / minute Detection: UV @ 280nm

 $\textbf{Sample Preparation}: \ Nasal\ spray\ solution\ containing\ 0.05\%\ Oxymetazoline\ HCL\ was\ filtered\ with\ a\ 0.45\mu m\ Nylon\ Nylon$

Syringe Filter (MicroSolv Tech Corp.) and used for injections.

t0: 0.9 minutes

Note: Oxymetazoline is a decongestant that acts as a selective alpha-1 agonist and partial alpha-2 agonist. It is the active ingredient in many nasal spray solutions. It also has vasoconstriction properties and is therefore used in eye drop solutions as well.



Attachment

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MicroSolv Technology Corporation

9158 Industrial Blvd. NE, Leland, NC 28451 tel. (732) 380-8900, fax (910) 769-9435

Email: customers@mtc-usa.com

Website: www.mtc-usa.com

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