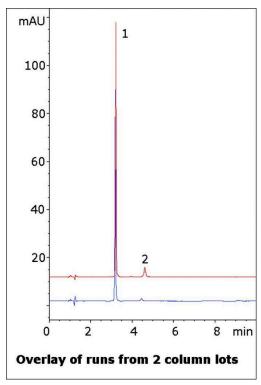


Oxymetazoline HCL Analyzed with HPLC - AppNote

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

Sample Preparation: Nasal spray solution containing 0.05% Oxymetazoline HCL was filtered with a

0.45µm 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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