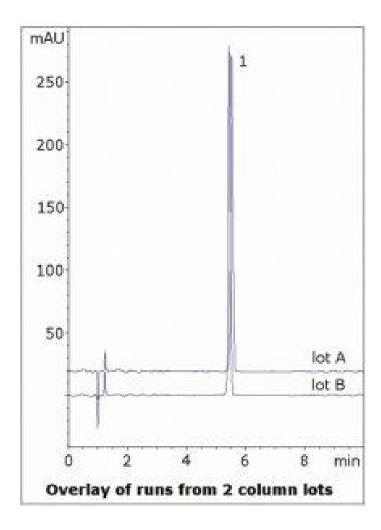


Tizanidine HCl Tablet Analyzed by HPLC - AppNote

Separation Method for Tizanidine Compatible with LC-MS

Tizanidine has numerous amine functional groups and can be a challenge for analysis by HPLC. The USP method uses Phosphate in the Mobile Phase which is not compatible with LC-MS. This Method however uses Formic Acid as the Mobile Phase additive and produces a sharp, symmetrical peak.

The USP system suitability for the tailing factor is not more than 1.6, and the Peak obtained has a value of 1.1. Data from two Column lots is shown in the figure, demonstrating Robustness of this Method.



Peak:

Tizanidine HCI

Method Conditions

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

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

Mobile Phase:

A: DI Water / 0.1% Formic Acid (v/v)
B: Acetonitrile / 0.1% Formic Acid (v/v)

Gradient:

Time (minutes)	%B
0	95
1	95
6	40
7	95

Post Time: 3 minutes Injection vol.: 1µL

Flow rate: 1.0mL / minute Detection: UV @ 230nm

Sample Preparation: 4mg strength Tizanidine HCL tablet was ground and weighed in a 10mL volumetric flask. A portion of 50:50 Solvent A / Solvent B diluent was added and the flask was sonicated 10 minutes. It was then diluted to mark and filtered with a 0.45µm Nylon Syringe Filter

(MicroSolv Tech Corp.).

to: 0.9 minutes

Note: Tizanidine is a centrally acting a2-adrenergic agonist used to treat spasms, cramping, tightness of muscles, and related conditions. It is available under the trade name Zanaflex® as well as generic versions.



Attachment

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