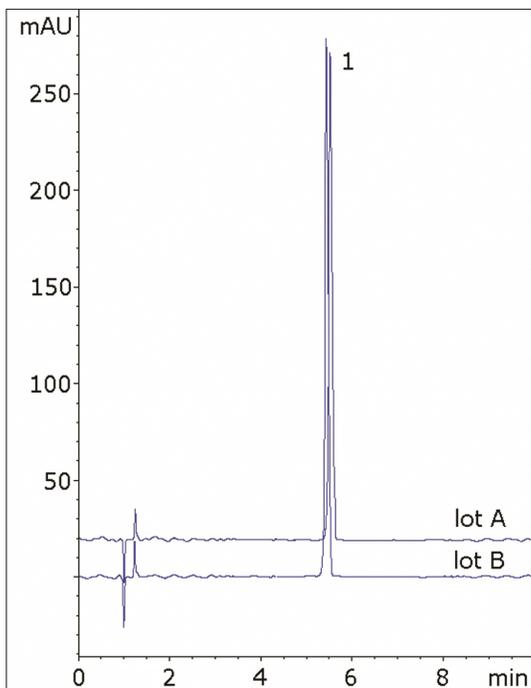
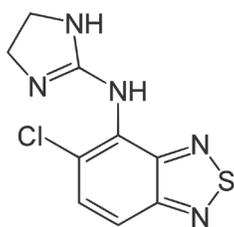


Tizanidine HCl Tablet

Excellent peak shape for amine



Overlay of runs from 2 column lots



Tizanidine

Note: Tizanidine is a centrally acting α_2 -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.

Method Conditions

Column: Cogent Diamond Hydride™, 4 μ m, 100Å

Catalog No.: 70000-7.5P

Dimensions: 4.6 x 75 mm

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

Gradient:	time (min.)	%B
	0	95
	1	95
	6	40
	7	95

Post Time: 3 min

Injection vol.: 1 μ L

Flow rate: 1.0 mL/min

Detection: UV 230 nm

Sample: 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 min. It was then diluted to mark and filtered with a 0.45 μ m nylon syringe filter (MicroSolv Tech Corp.).

Peak: 1. Tizanidine HCl

t₀: 0.9 min

Discussion

Tizanidine has numerous amine functional groups and can be a challenge for analysis by HPLC. The USP method uses phosphate in the mobile phase and is not compatible with LC-MS. This method however uses only formic acid as the mobile phase additive and produces a sharp, symmetrical API peak. The USP system suitability for the tailing factor is not more than 1.6, and the peak obtained is within this specification with an obtained value of 1.1.

The Cogent Diamond Hydride column is an excellent choice for amines. Data from two column lots is shown in the figure, demonstrating lot-to-lot consistency.