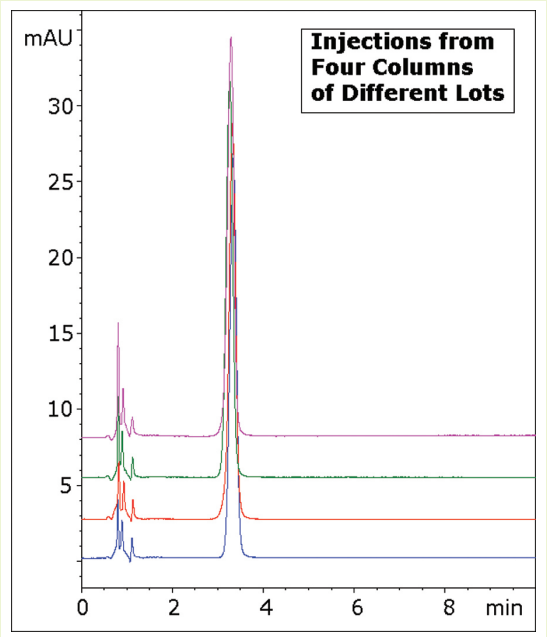
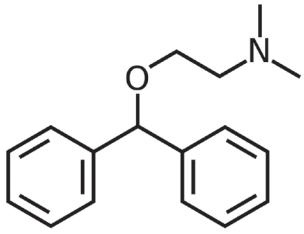
Benadryl® Gel Capsule

Assay method for diphenhydramine HCl without ion pair agents





Diphenhydramine

Note: Diphenhydramine is a first generation antihistamine used primarily to treat allergies. It also has a significant sedative property, which is sometimes an undesirable side effect of its intended use. However, it is used in many formulations as a sleep aid as well.

Method Conditions

Column: **Cogent Silica-C™**, 4µm, 100Å

Catalog No.: 40000-7.5P

Dimensions: 4.6 x 75 mm

Mobile Phase: 50% DI H_2O / 50% acetonitrile / 5 mM ammonium acetate

Injection vol.: 2µL

Flow rate: 1.0 mL/min

Detection: 254 nm

Sample: 25mg strength Benadryl® capsule was opened and placed in a 10mL volumetric flask with a portion of the mobile phase as diluent. It was sonicated 10 min and diluted to mark. Then a portion was filtered with a 0.45µm nylon syringe filter (MicroSolv Tech Corp.).

Peak: 1. Diphenhydramine

t_0: 0.9 min

Discussion

Diphenhydramine has a tertiary amine group that is susceptible to tailing with conventional HPLC columns. The USP method features a triethylamine additive in the mobile phase for this reason. These additives often take a significant time to completely load onto the column and therefore adversely affect throughput and robustness. On the other hand, this method featuring the Cogent Silica-C column produces an excellent peak shape with only ammonium acetate as the mobile phase additive. In addition, the batch-to-batch reproducibility of the Cogent Silica-C material is demonstrated through the overlay of four runs. Each run was performed with a Cogent Silica-C column of a different batch.

MANUFACTURED BY:
MICROSOLV TECHNOLOGY CORPORATION

9158 Industrial Blvd NE
Leland, NC 28451

p: 1.732.380.8900
f: 1.910.769.9435

customers@mtc-usa.com
www.Cogent-HPLC.com