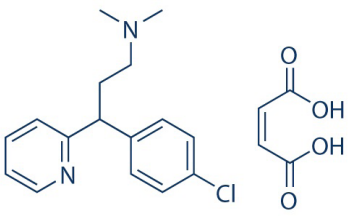
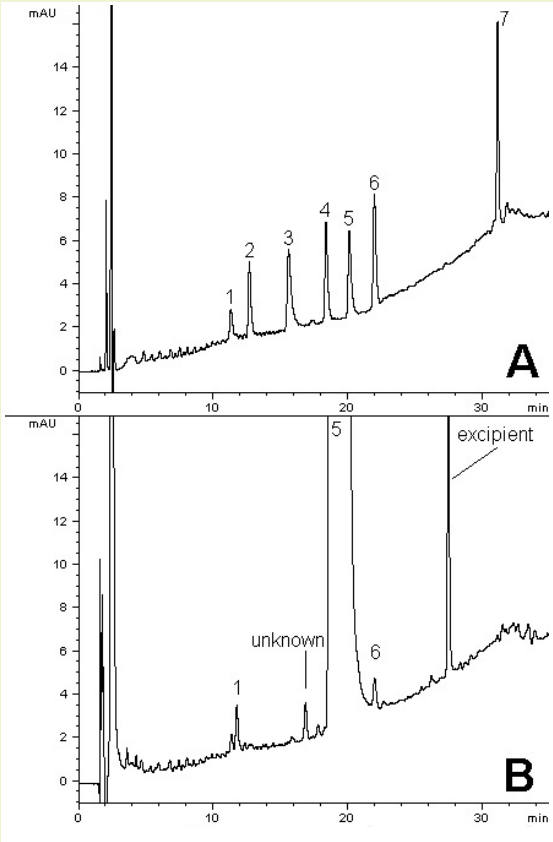
Chlorpheniramine Maleate Organic Impurities

Separation demonstrated in real commercial formulation extracts



Chlorpheniramine Maleate



Notes: Chlorpheniramine maleate is an active pharmaceutical ingredient that is one of numerous over-the-counter antihistamine medicines used to treat allergic reactions such as hay fever and urticaria (hives). As with other first generation antihistamines, drowsiness can be a common side effect of the medication. This is due to their greater ability to cross the blood-brain barrier compared to second generation antihistamines.

Method Conditions

Column: **Cogent Bidentate C8™**, 4µm, 100Å

Catalog No.: 40008-15P

Dimensions: 4.6 x 150 mm

Solvents: A: 95% DI H_2O/ 5% Acetonitrile/ 0.05% TFA (v/v)
B: Acetonitrile/ 0.05% TFA (v/v)

Gradient:

time (min.)	%B
0	0
20	15
30	30
34	30
35	0
40	0

Injection vol.: 10µL

Flow rate: 1.0 mL/min

Detection: UV 225 nm

Sample: **Fig.A:** 4.8 µg/mL each of USP chlorpheniramine maleate reference standard (RS), pheniramine, chlorpheniramine N-oxide, related compound (RC) A, B, C, and D.
Fig.B: 4 mg strength chlorpheniramine maleate tablet extract (2.4 mg/mL) spiked at 0.1% level with chlorpheniramine N-oxide dihydrochloride RS solution.

Peaks: 1. Pheniramine
2. Chlorpheniramine related compound A
3. Chlorpheniramine related compound B
4. Chlorpheniramine related compound C
5. Chlorpheniramine
6. Chlorpheniramine N-oxide
7. Chlorpheniramine related compound D

Discussion

Use of the Cogent Bidentate C8™ column allows for high resolution baseline separation of six specified impurities of chlorpheniramine maleate (Fig. A). Fig. B shows how the method can be applied to a real-world formulation, spiked with the N-oxide impurity to demonstrate resolution from the API peak. Currently, there is no public official standard for chlorpheniramine impurities analysis, and hence this method supports quality testing for safety of products.

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