

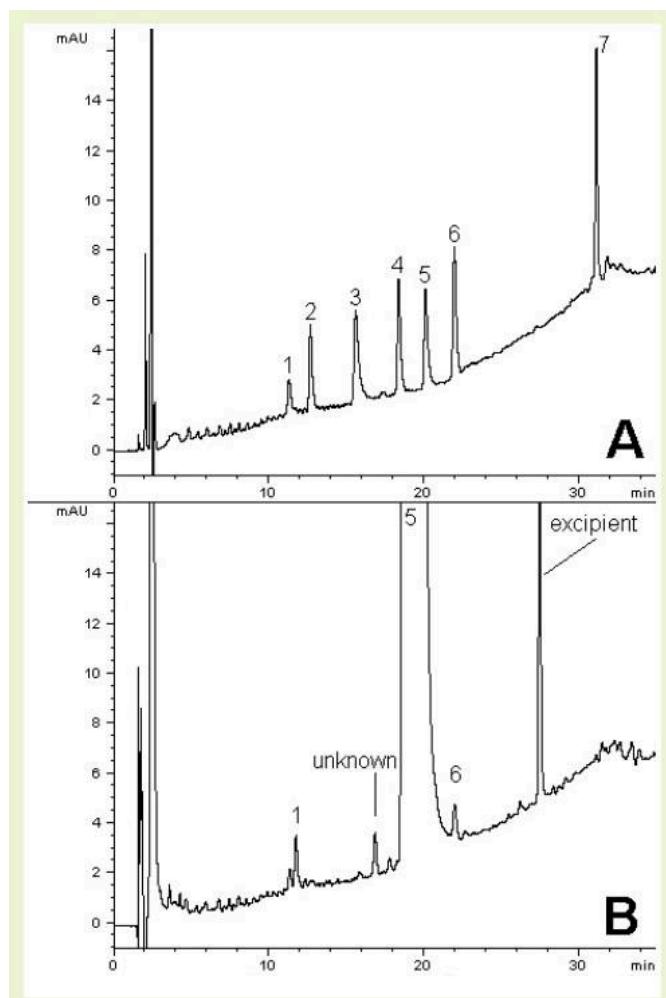


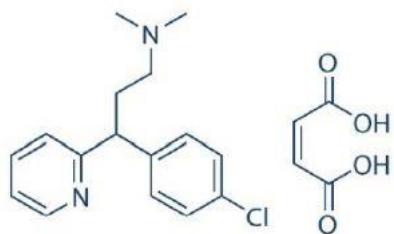
## Chlorpheniramine Maleate Organic Impurities Analyzed with HPLC - AppNote

### Separation demonstrated in real commercial formulation extracts

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, hence this method supports quality testing for safety of products.





Chlorpheniramine Maleate

### 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

## Method Conditions

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

**Catalog No.:** [40008-15P](#)

**Dimensions:** 4.6 x 150 mm

### Solvents:

A: 95% DI Water/ 5% Acetonitrile/ 0.05% TFA (v/v)

B: Acetonitrile/ 0.05% TFA (v/v)

### Gradient:

Time (Minutes)	%B
0	0
20	15
30	30
34	30
35	0
40	0

**Injection vol.:** 10µL

**Flow rate:** 1.0 mL/minute

**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.

**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.

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**Attachment No 368 Chlorpheniramine Maleate Organic Impurities.pdf 0.2 Mb** [Download File](#)

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**MicroSolv Technology Corporation**

9158 Industrial Blvd. NE, Leland, NC 28451

Tel: (732) 380-8900

Fax: (910) 769-9435

Email: [customers@mtc-usa.com](mailto:customers@mtc-usa.com)

Website: [www.mtc-usa.com](http://www.mtc-usa.com)