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# 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.

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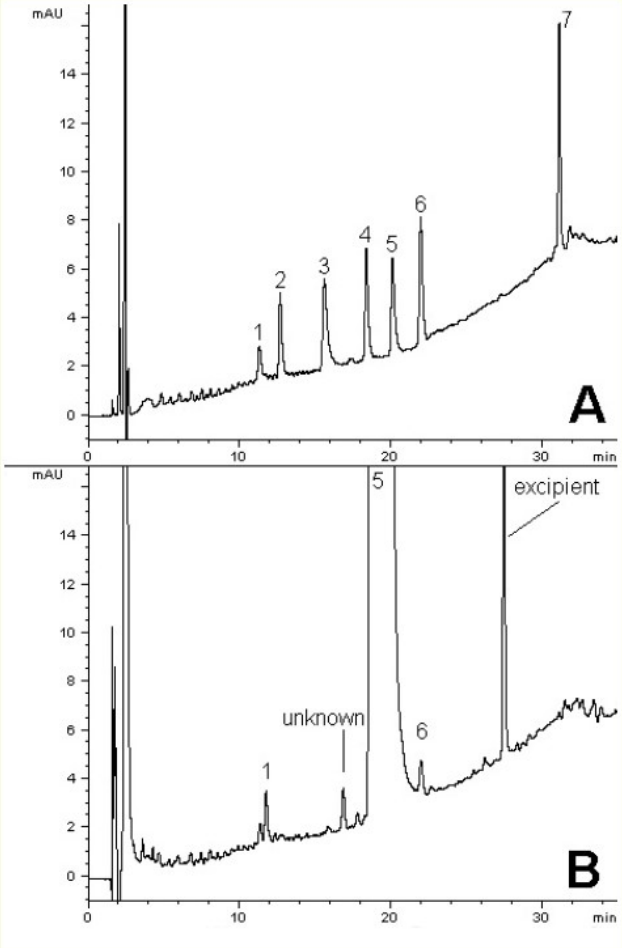

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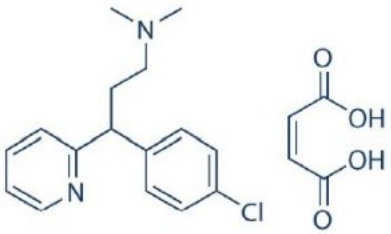


Chlorpheniramine Maleate

## 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.*

**Attachment**

**No 368 Chlorpheniramine Maleate Organic Impurities.pdf** 0.2 Mb Download File