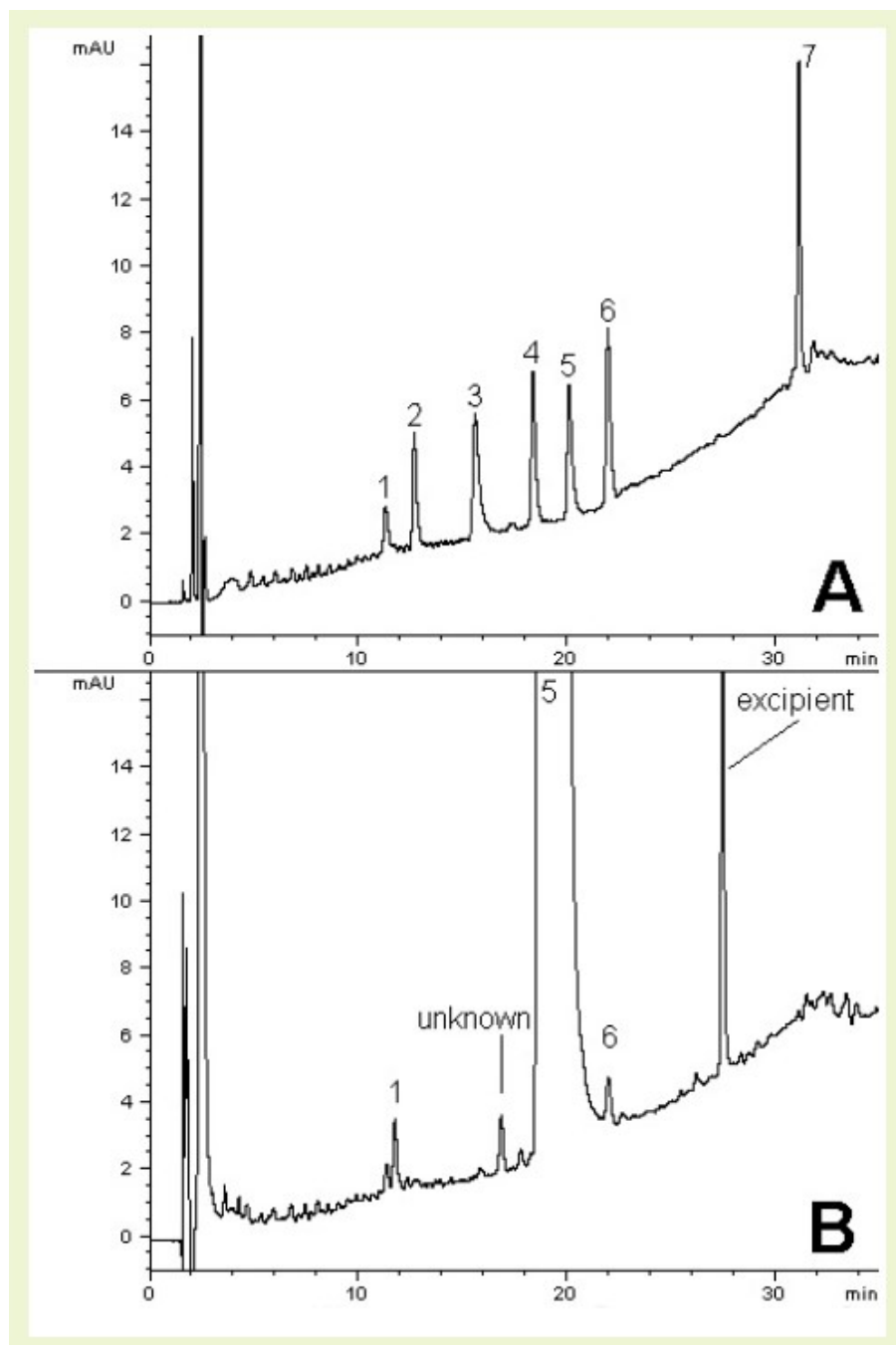


Separation demonstrated in real commercial formulation extracts

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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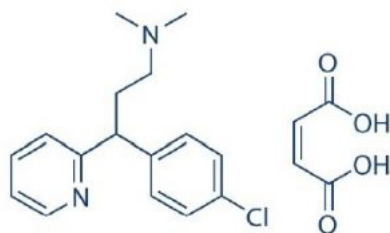
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Chlorpheniramine Maleate

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.

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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](#)

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