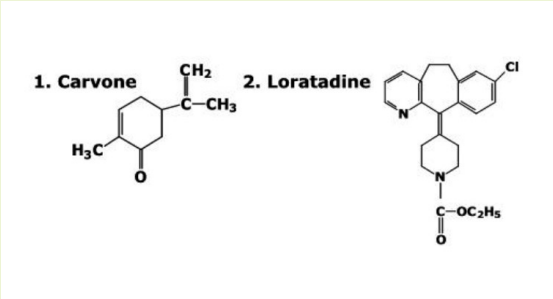
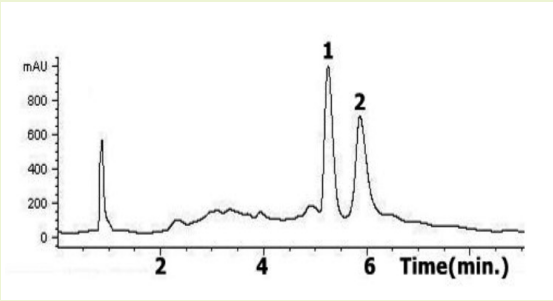
Pharmaceutical Preparation

General Method Using A Gradient In Classic Normal Phase Mode





Notes: Recently the USA National Cancer Institute and others are evaluating chemo-preventive and anti-carcinogenic properties of monoterpenes (naturally occurring non-nutrient dietary constitutes like Carvone). If administrated in the diet, they prevent or cause the regression of colon, hepatic and pancreatic cancers chemically induced in laboratory animals. Loratadine: (Lora) is a non-sedative second generation H1 receptor blocker. It is available commercially as mono component tablets (Claritin1).

Method Conditions

Column: **Cogent Bidentate C18™**, 4µm, 100Å

Catalog No.: 40018-75P

Dimensions: 4.6 x 75 mm

Solvents: A: Dichloromethane
B: Hexane

Gradient:

time (min.)	%B
0-0.5	100
7-10	50
10.5	100

Injection vol.: 10µL

Flow rate: 0.5 mL/min

Detection: UV at 254 nm

Sample: 0.1 mg/mL in Hexane/ DCM (1:1)

Peaks: 1. Carvone
2. Loratadine

Discussion

Both Carvone and Loratadine have similar polarity but they can be separated using Cogent Bidentate C18 column with significant retention (k > 2). When the mobile phase of 95% hexane and 5% dichloromethane is used the Loratadine is infinitely retained. The classic Normal Phase analysis shown above is simple, rapid and cost effective and can be used in routine quality control in the production or purity determination of both Carvone and/or Loratadine. The proposed method can be used as a general method for analysis of pharmaceutical compositions for oral administration containing an antihistaminic compound and a terpenoid compound, which are useful in the prevention or treatment of inter alia allergic rhinitis (hay fever) and mild asthma.

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