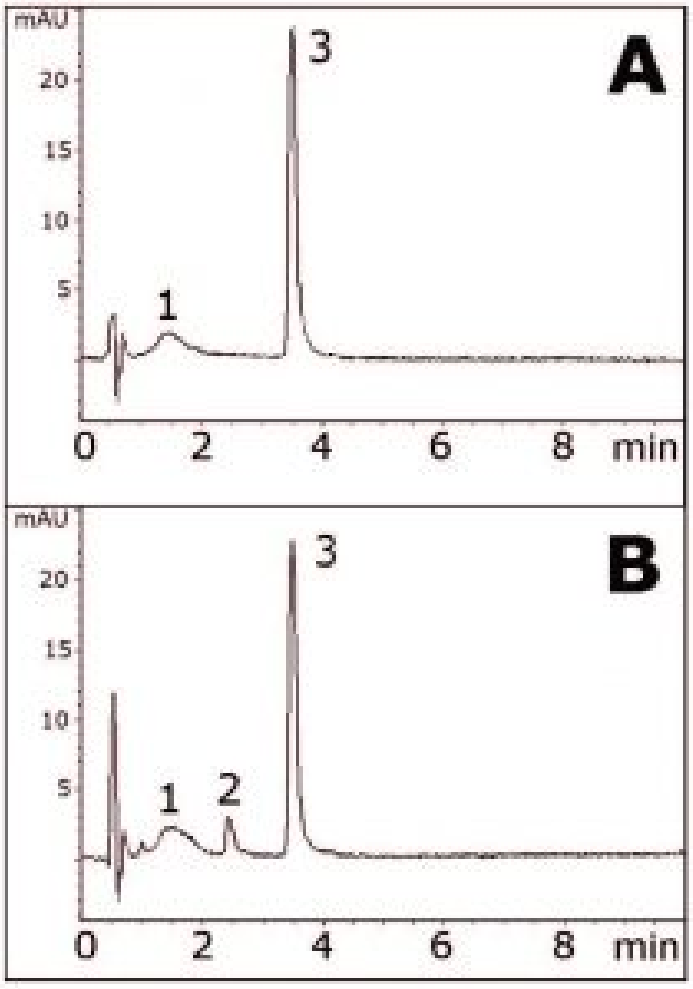
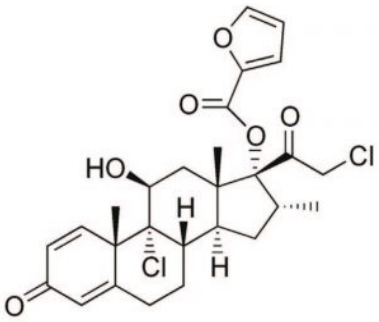
Mometasone Furoate in Topical Cream Analyzed with HPLC – AppNote

Separation of Prodrug from Acid Hydrolysis Products

This Method shows the Separation of an ester Prodrug, Mometasone Furoate, from another compound formed during acid hydrolysis. This Peak is quite possibly the active form, Mometasone. The two Chromatograms show the non-degraded extract (*Figure A*) and an acid hydrolysis extract (*Figure B*).

Hydrolysis of the ester group would make the resulting Mometasone API less hydrophobic, and therefore earlier elution is predicted. Indeed, this is what is observed in the data. An excipient Peak from the cream matrix is also observed just after the solvent front and does not interfere with either the Prodrug peak or the API.





Mometasone Furoate

Peaks:

1. Excipient
2. Degradant (possibly Mometasone)
3. Mometasone Furoate (Prodrug)

Method Conditions

Column: Cogent Bidentate C8 2.o™, 2.2µm, 120Å

Catalog No.: 40208-05P-2

Dimensions: 2.1 x 50mm

Mobile Phase: 50:50 DI Water / Acetonitrile (v/v)

Injection vol.: 2µL

Flow rate: 0.3mL / minute

Detection: UV @ 248nm

Sample Preparation: 5.0g of a 0.1% Mometasone Furoate USP topical cream was weighed in a 250mL Erlenmeyer flask with a stirring bar. 50mL Methanol was added and the flask was stirred for 1 hour with a stopper covering the flask. Then a portion was filtered with a 0.45µm Nylon Syringe Filter (MicroSolv Tech Corp.). Next, one portion of the filtrate was diluted 1:5 with Methanol (*Figure A*) and a second portion was diluted 1:5 with a diluent of 90:10 Methanol / 1N HCL and heated in a dry bath at 80°C for 10 minutes. *(Figure B*).

Note: Mometasone Furoate is a prodrug where the API is formed by hydrolysis of the ester group. It is used to reduce inflammation due a variety of ailments and is available under trade names such as Elocon®, Novasone®, and Asmanex®. In addition to a topical ointment, the drug is also available as a dry powder inhaler or a nasal spray depending on the application.

Attachment

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