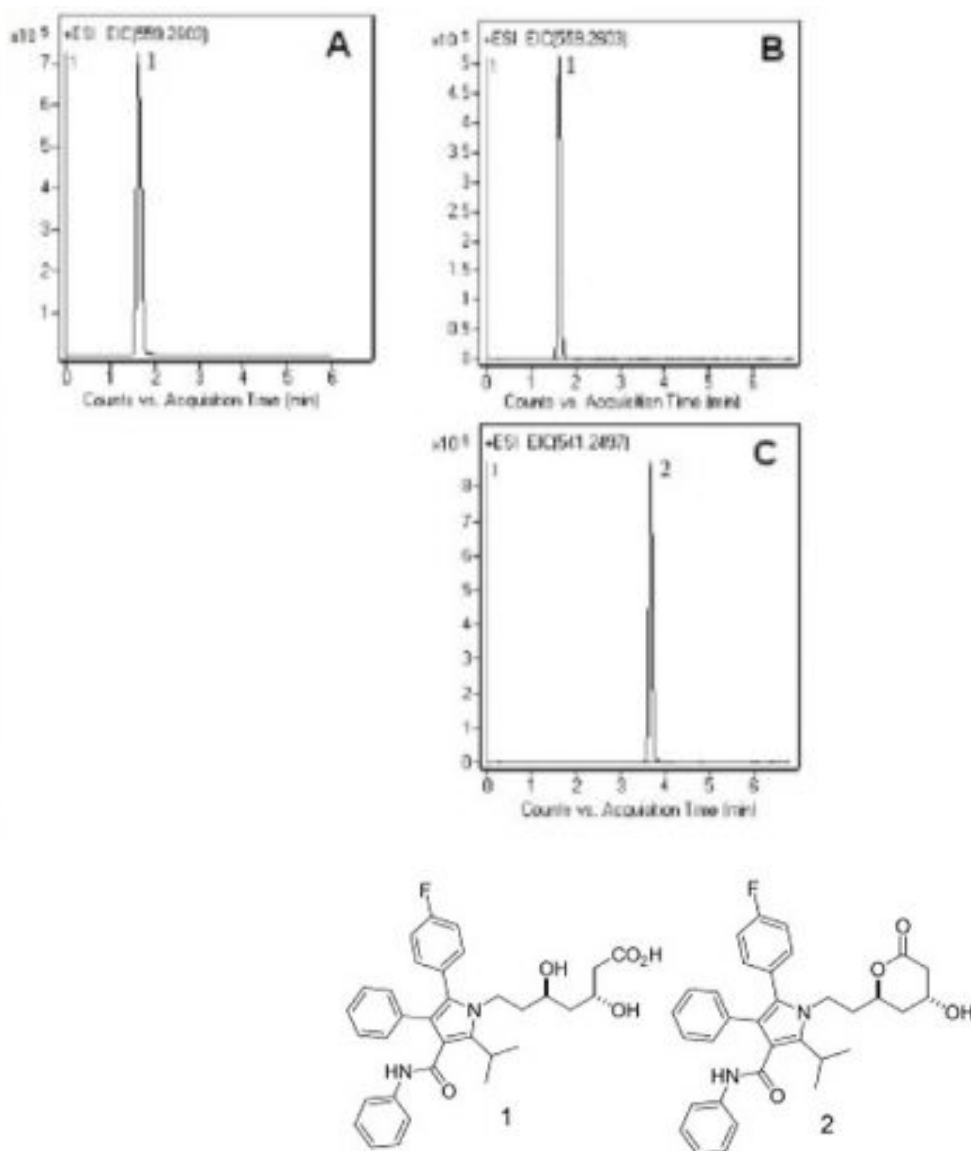


Separation of API from its Lactone Degradation Product

Atorvastatin is separated from its main Degradation product in this Method with a simple linear Reversed Phase Gradient. With the use of LCMS, the identity of the Degradant can be confirmed from its m/z value. The Degradation is an intramolecular Fischer esterification, which is catalyzed under Acidic conditions.

Figure A shows the extracted Ion Chromatogram (EIC) corresponding to Atorvastatin for the Non-Degraded extract. Figures B and C show the EICs of Atorvastatin and the Lactone Degradant respectively for the Acid-Degraded extract.



Peaks:

1. Atorvastatin
2. Atorvastatin Lactone

Method Conditions

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

Catalog No.: 40018-05P-2

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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
Website: www.mtc-usa.com

Dimensions: 2.1 x 50mm

Mobile Phase:

A: 50% DI Water / 50% Methanol / 10mM Ammonium Acetate

B: 90% Acetonitrile / 10% DI Water / 10mM Ammonium Acetate

Gradient:

| Time (minutes) | %B |
|----------------|-----|
| 0 | 30 |
| 10 | 100 |
| 12 | 30 |

Flow rate: 0.4mL / minute

Detection: ESI — POS - Agilent 6210 MSD TOF Mass Spectrometer

Sample Preparation:

Tablet Stock Solution: A 40mg strength tablet was ground and added to a 100mL volumetric flask. A 50mL portion of Solvent B was added to the flask. The solution was vortexed 5 minutes, sonicated 5 minutes, and diluted to mark with Solvent A. It was then filtered through a 0.45µm Nylon Syringe Filter (MicroSolv Technology Corp.).

Degraded Tablet Stock Solution: A 40mg strength tablet was ground and added to a 100mL volumetric flask. A 50mL portion of Solvent B was added to the flask. It was then vortexed 5 minutes, sonicated 5 minutes, and diluted to mark with 3M HCl. It was then filtered through a 0.45µm Nylon Syringe Filter (MicroSolv Technology Corp.).

Fig. A: 10µL tablet stock diluted with 990µL 50:50 A:B

Fig. B and C: 10µL degraded tablet stock diluted with 990µL 50:50 A:B

Note: Atorvastatin is a competitive inhibitor of 3-Hydroxy-3-Methylglutaryl Coenzyme A (HMG- CoA) Reductase, which Catalyzes the rate limiting step in Cholesterol Biosynthesis. As such, Atorvastatin is used to reduce plasma levels of low-density Lipoprotein (LDL) Cholesterol, which are known to contribute to the development of Atherosclerosis. Atorvastatin is currently marketed by Pfizer under the trade name Lipitor.



Attachment

No 126 Forced Degradation of Atorvastatin by LCMS pdf 0.1 Mb [Download File](#)

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