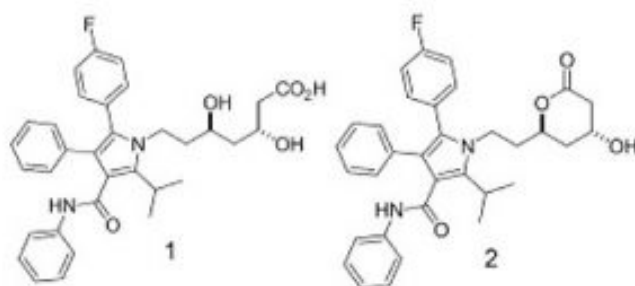
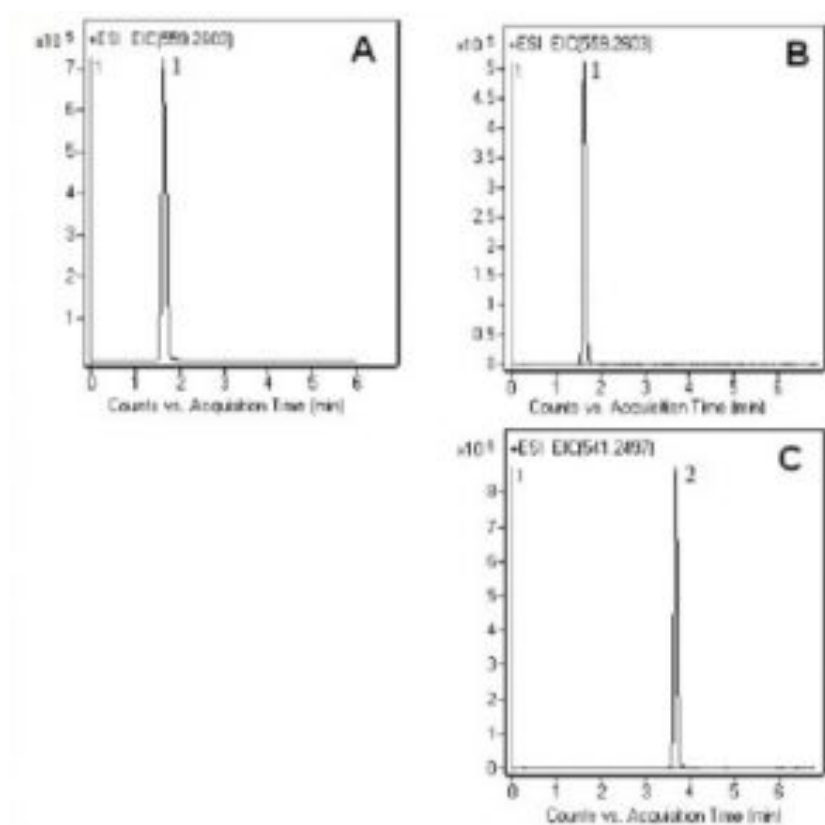


## Forced Degradation of Atorvastatin by LCMS – AppNote

### 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.



1. Atorvastatin
2. Atorvastatin Lactone

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Peaks:

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### Method Conditions

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

**Catalog No.:** 40018-05P-2

**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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