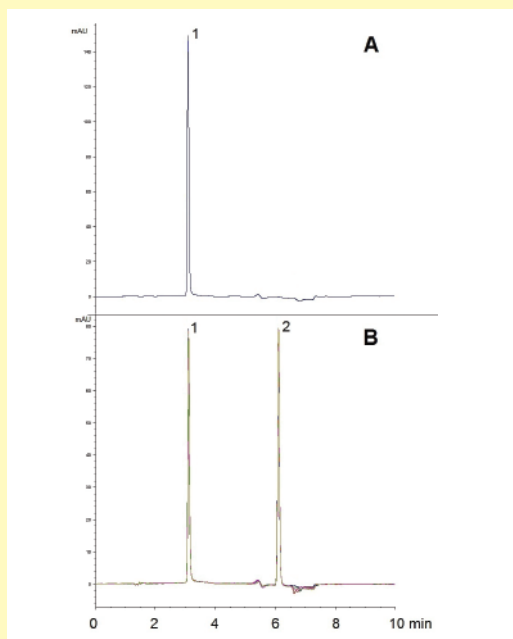
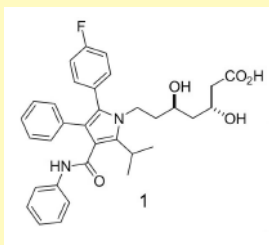


### Forced Degradation of Atorvastatin Separation of API from its main degradation product



**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, with the U.S. patent set to expire in November 2011.

#### Method Conditions

**Column:** Cogent Bidentate C18™, 4µm, 100Å  
**Catalog No.:** 40018-15P  
**Dimensions:** 4.6 x 150 mm  
**Solvents:** A: DI water / 10 mM ammonium acetate  
 B: 90% acetonitrile/10% DI water / 10 mM ammonium acetate.  
 Both solutions were vacuum filtered through a 0.45 µm nylon filter (MicroSolv Technology Corp. Eatontown, NJ, USA).

Gradient:	time (min.)	%B	time (min.)	%B
	0	40	6	40
	5	100		

**Flow Rate:** 0.8 mL/min

**Injection Volume:** 2 µL

**Sample:** A. Atorvastatin tablet extract  
 B. Degraded atorvastatin tablet extract  
 40 mg strength tablet ground, dispensed in 50 mL B in 100 mL volumetric flask. Vortexed 5 min, sonicated 5 min, then diluted to mark with A. Filtered through a 0.45 µm nylon membrane (MicroSolv Technology Corp. Eatontown, NJ, USA). Diluted 4x with A) 50:50 A:B or B) 1.0 N HCl in 50:50 A:B.

**Peaks:** 1. Atorvastatin 2. Degradant

**Detection:** UV 248 nm

#### Discussion

Atorvastatin is separated from its main degradation product using a Bidentate C18 column and a simple linear reverse phase gradient. The degradant is formed under acidic conditions and therefore its separation is important for stability indicating methods for pharmaceutical formulations of atorvastatin. For methods requiring non-degrading conditions, it is important to choose diluent and mobile phase conditions with this pH sensitivity in mind. As such, ammonium acetate was chosen for the diluent and mobile phase additives in order to avoid any degradation from these sources. Data obtained under non-degrading conditions is shown in Figure A. Figure B shows an overlay of five consecutive runs of the degraded extract. The repeatability of the method is demonstrated by the low atorvastatin retention time %RSD of 0.10.

For more information visit [www.MTC-USA.com](http://www.MTC-USA.com)

Cat. No.	Description
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40018-15P	Cogent Bidentate C18™ HPLC Column, 100A, 4µm, 4.6mm x 150mm
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