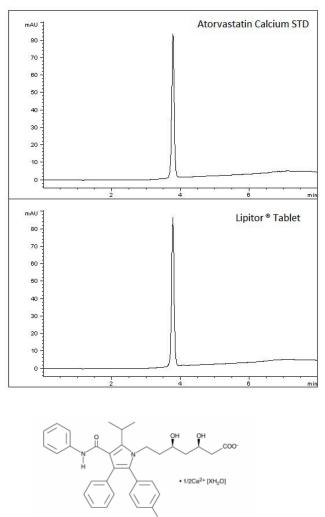


## Atorvastatin Tablets Analyzed with HPLC - AppNote

## A Robust Method for Analysis of a Hypercholesterolemia Medication

A robust and reproducible Method has been developed for this Cholesterol medication. A commercially available Drug Product was used as well as a reference Standard. The data below illustrates how the Standards and Drug Product share excellent peak shape using this easy Method.



Peak

1. Top Chromatogram – Atorvastatin Calcium Standard

2. Bottom Chromatogram - Atorvastatin API from Tablets - Generic

## **Method Conditions**

Column: Cogent Phenyl Hydride™, 4µm, 100Å Catalog No.: <u>69020-10P</u> Dimensions: 4.6mm x 100mm Mobile Phase: A: DI Water with 0.1% Formic Acid B: Acetonitrile with 0.1% Formic Acid

| Time (minutes) | %B |
|----------------|----|
| 0              | 50 |
| 1              | 50 |
| 5              | 85 |
| 6              | 85 |
| 7              | 50 |
| 8              | 50 |

Injection vol.: 2µL Flow rate: 1.0mL / minute

Detection: UV @ 254nm

Diluent: 50:50 DI Water / Acetonitrile with 0.1% Formic Acid

**Standard Preparation**: Atorvastatin Calcium standard prepared as 0.1mg / mL standard solution in diluent.

**Sample Preparation**: 20mg strength tablet (Atorvastatin Calcium) was added to a 10mL volumetric flask with a portion of Diluent. The solution was sonicated 10 minutes and diluted to mark with Diluent. It was then filtered through a 0.45µm Nylon Syringe Filter (MicroSolv Technology Corp.). The filtrate was diluted to final concentration of 0.1mg / mL.

to: 1.2 Minutes
K: 2.15
%RSD of 5 injections: <0.1%</li>

Notes: Atorvastatin can treat high cholesterol and triglyceride levels. This may reduce the risk of angina, stroke, heart attack, and heart and blood vessel problems. Atorvastatin is a specific inhibitor of HMGCR (HMG-CoA reductase). HMGCR is the enzyme that catalyzes the conversion of HMG-CoA to Mevalonate, an early step in Cholesterol Biosynthesis. Atorvastatin is used in the treatment of Hypercholesterolemia. Marketed by Pfizer as Lipitor® this AppNote used a generic version.

Notes: Calculation for Capacity Factor - Relative Retention  $\mathbf{k} = (tR-t0)/t0$ 



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