

# CHIRAL TECHNOLOGIES

## Standard-Setting *Chiral* Stationary Phases

### Application Note

#### Introduction

The US Pharmacopeia (USP) is a nonprofit organization that sets standards for the quality and purity of drugs and food ingredients. The USP is a widely used source for established analytical methods. The method of measuring the *Enantiomeric Purity* of atorvastatin is specified in the USP Monograph and is based on the Daicel CHIRALPAK® AD-H brand of L51 columns. The typical retention time for atorvastatin elution is about 36 minutes. To improve the analysis throughput with a minimal loss in column efficiency, we developed a new method utilizing our CHIRALPAK IA-3 column.

#### Experimental and Discussion

A CHIRALPAK IA-3 column, 4.6 mm i.d. x 250 mm and packed with 3- $\mu$ m particles, was used to develop the separation of atorvastatin. The mobile phase was a mixture of n-hexane and ethanol. All chromatographic conditions are given in Figure 1.

The chiral selector – *tris* (3,5-dimethylphenylcarbamate) – of the CHIRALPAK IA-3 is immobilized on 3- $\mu$ m silica. Clearly, the analysis time can be greatly reduced to about 15 minutes, with column efficiency for Enantiomer 1 of 7,975 and column efficiency for Enantiomer 2 (atorvastatin) of 6,234. Use of the robust CHIRALPAK IA-3 column has resulted in the rapid and efficient Enantiomeric Purity analysis of atorvastatin.

[www.immobilizedchiralcolumns.com](http://www.immobilizedchiralcolumns.com)

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### Atorvastatin

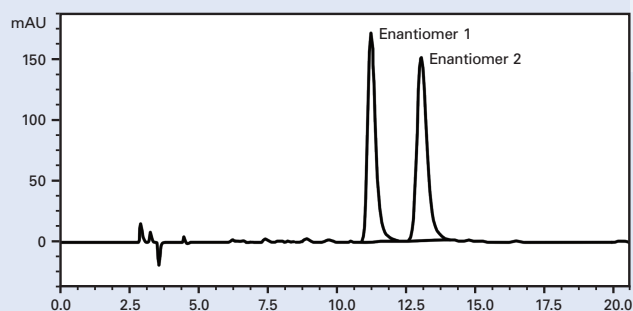
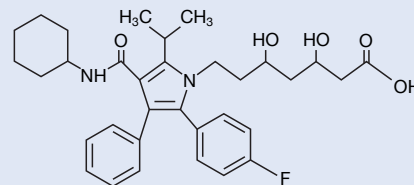


Figure 1: Separation of atorvastatin on CHIRALPAK IA-3

#### Chromatographic Conditions

<b>Column:</b>	CHIRALPAK IA-3, 4.6 mm i.d. x 250 mm, 3 $\mu$ m
<b>Mobile phase:</b>	n-hexane/ethanol/TFA (85/15/0.1)
<b>Flow rate:</b>	1 mL/min
<b>UV detection:</b>	245 nm
<b>Column temperature:</b>	25 °C

**Note:** Atorvastatin is in a class of statins, the medications that work by slowing the production of cholesterol in the body. The blockbuster drug Lipitor (atorvastatin), branded by Pfizer, generated global sales of \$11.9 billion during 2010. Pfizer held marketing exclusivity in the United States until November 2011.