

# Analyzing Pharmaceutical Degradation Products Using the New ACQUITY UPC<sup>2</sup> Torus Columns

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## GOAL

To demonstrate the performance of the new ACQUITY UPC<sup>2</sup> Torus™ 2-PIC Column for analyzing low level pharmaceutical degradation products.

## BACKGROUND

During the manufacture of pharmaceutical compounds, it is important to fully understand any possible degradation products. This is especially true in the case of pharmaceutical compounds administered orally. These analyses are challenging due to the nature of the sample. Degradation samples typically have numerous peaks making it difficult to get separation between the active pharmaceutical ingredient (API) and the degradation products. Additionally, degradation of an API can generate unexpected products depending on the parameters. Traditionally, liquid chromatography would be used to perform these separations. However, an additional technique, UltraPerformance Convergence Chromatography™ (UPC<sup>2</sup>), exists to help an analyst perform these difficult separations.

## Analyzing low level pharmaceutical degradation products using the new ACQUITY UPC<sup>2</sup> Torus 2-PIC Column.

## THE SOLUTION

An ACQUITY UPC<sup>2</sup> System harnesses the power of liquid CO<sub>2</sub> as the mobile phase for the separation of complex samples such as pharmaceutical degradation samples. UPC<sup>2</sup> Technology offers orthogonal separation compared to reversed phase liquid chromatography. Using the newest column technology available on the UPC<sup>2</sup> platform, ACQUITY UPC<sup>2</sup> Torus Columns, an analyst can rapidly perform the analysis of these types of samples. The degradation of Omeprazole tablets, used in the treatment of acid reflux and heartburn, was analyzed on an ACQUITY UPC<sup>2</sup> System using the new ACQUITY UPC<sup>2</sup> Torus 2-PIC Column. This column, created using a two-stage bonding technique, has a 2-Picolylamine ligand (2-PIC). This stationary phase provides retention stability and a unique selectivity compared

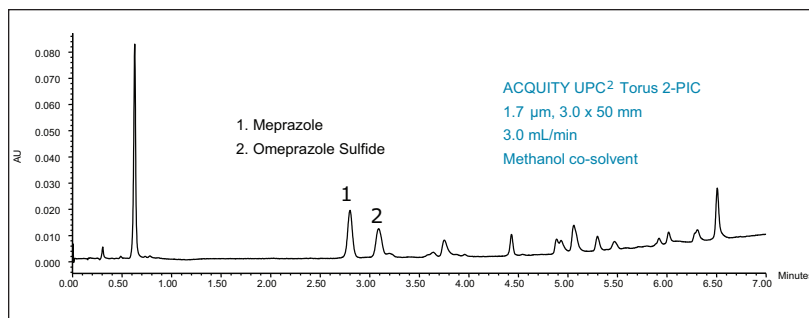


Figure 1. Analysis of the acid degradation products of an Omeprazole tablet.

to the other Torus Columns. The ACQUITY UPC<sup>2</sup> Torus 2-PIC Column is a good starting point when developing methods for supercritical fluid chromatography (SFC).

As Figure 1 shows, the separation of Omeprazole from the degradation products is achieved. By using the ACQUITY UPC<sup>2</sup> Torus 2-PIC Column numerous degradation products including Omeprazole Sulfide can be identified by using standard injections or mass spectrometry. The new ACQUITY® QDa® Detector was used to identify the Omeprazole and Omeprazole Sulfide peaks in this analysis. By using the UPC<sup>2</sup> along with the new Torus column chemistries, an analyst can perform separations of complicated matrixes while using minimal amounts of organic solvent per analysis, reducing analysis cost.

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## SUMMARY

The new ACQUITY UPC<sup>2</sup> Torus 2-PIC Column was used to analyze the acid degradation products of formulated Omeprazole. The active pharmaceutical ingredient was successfully separated from all of the degradation products. By using the ACQUITY UPC<sup>2</sup> Torus 2-PIC Column, the degradation peaks are well separated and can be identified by either standard injections or by using a mass spectrometer. The two stage bonding procedure of the ACQUITY UPC<sup>2</sup> Torus Columns ensures retention stability and a wide range of selectivity, making this column family a useful tool in sample analysis.

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