Waters™

Nota applicativa

Chromatographic Assay of Dapsone Tablets Using the ACQUITY UPC^2 System

Waters Corporation

This is an Application Brief and does not contain a detailed Experimental section.

Abstract

This application brief successfully demonstrates to convert the compendial normal phase HPLC method for the assay of dapsone tablets to a supercritical fluid chromatography (SFC) method using the Waters ACQUITY UPC^2 System.

Benefits

The ACQUITY UPC^2 System is an ideal solution for laboratories looking for more efficient and cost effective methods for the analysis of dapsone tablets while enhancing health, safety, and environmental concerns.

Introduction

Currently, the United States Pharmacopeia (USP) specifies a normal phase HPLC method for the assay of tablet samples containing the drug dapsone (4,4′-Sulfonylbisbenzeneamine, CAS #*80-08-0*). This isocratic separation is done using a 4.0 x 300 mm, 10 µm silica column (L3) with a mobile phase that consists of 7:1:1:1 *n*-hexane, isopropanol, acetonitrile, and ethyl acetate. Run time of this method is approximately 12.5 minutes (2X of the last major peak at 1.5 mL/min). Like most compendial methods, this method is proven and reliable; it does, however, use solvents (hexane and ethyl acetate) that many laboratories would like to reduce for health, safety, environmental, and cost reasons. SFC is a normal phase separation technique that uses carbon dioxide as the main mobile phase and often employs the use of polar modifiers such as methanol. Since the principles of SFC are similar to those of HPLC, methods could be converted to SFC reducing solvent usage and disposal which will lower cost per analysis while enhancing green initiatives. Methods converted to an SFC solution must maintain data quality and must produce results that are equivalent to the current normal phase method.

Experimental

SFC method conditions

Column:	ACQUITY UPC^2 BEH, 3.0 x 50 mm, 1.7 µm

Temp.:	45 °C
Mobile phase:	85% Carbon dioxide:15% methanol
Flow rate:	3.0 mL/min
Back pressure:	130 bar/1885 psi
Detection:	UV/PDA at 254 nm

Results and Discussion

A standard and a tablet sample of dapsone were prepared and analyzed as shown in Figure 1 using the current USP method (this sample was also used for the SFC work). The results of this analysis were used to compare the results obtained with the method developed on an ACQUITY UPC^2 System as shown in Figure 2.

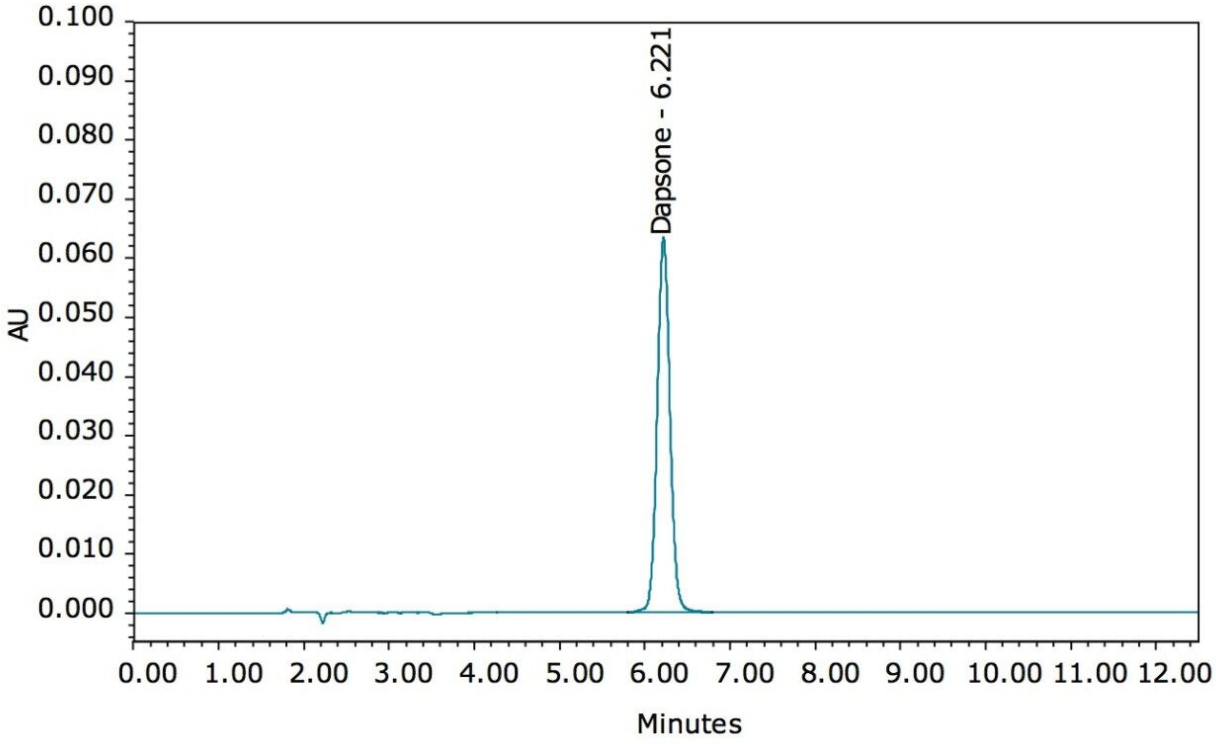

Figure 1. Normal phase HPLC analysis of dapsone.

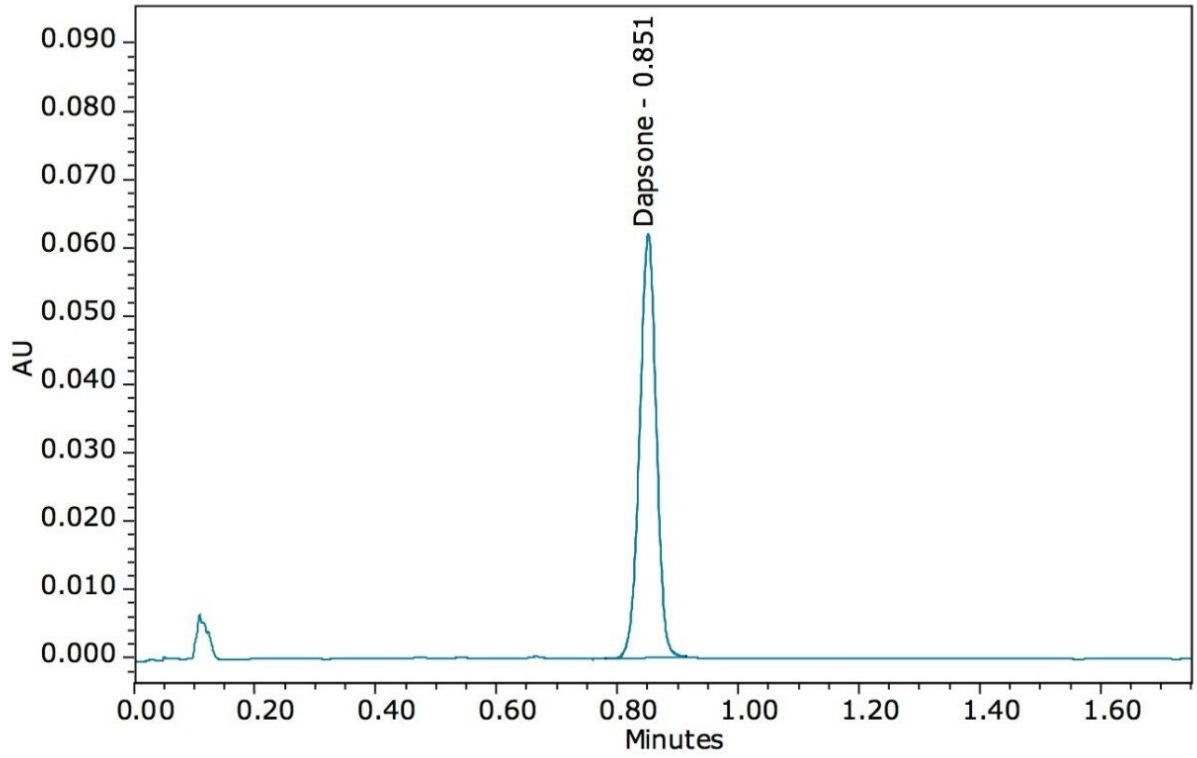

Figure 2. ACQUITY UPC^2 analysis of dapsone.

Listed suitability requirements from the compendial method were minimal (relative standard deviation is not more than 2%). The current normal phase HPLC method generated a %RSD for RT of <0.1% and for area <1.1% from six replicate injections of the standard. Suitability results from the new UltraPerformance Convergence Chromatography (UPC^2) method met required USP suitability values (0.8% fo RT and 0.9% for area) from six replicate injections and had a significantly faster run time (1.75 min). The results of the analysis of tablet sample were in good agreement between the two methods. In this example, each normal phase HPLC run used 13.1 mL of hexane and 1.9 mL each of isopropanol, acetonitrile, and ethyl acetate. In contrast, the UPC^2 method used roughly 0.50 mL of methanol. This demonstrates the significant reduction in organic solvent use that can be achieved by moving normal phase HPLC methods to UPC.[2] Based on current solvent prices, each normal phase HPLC run costs roughly $1.08 compared to $0.01 for each UPC^2 run.

Conclusion

A USP compendial HPLC method was successfully converted to a UPC^2 method, using the ACQUITY UPC^2 System. This new UPC^2 method produced data of equal or better quality than the current HPLC method, was seven times faster, and consumed less solvent. When high quality results are produced faster, laboratory productivity increases and cost per sample decreases. The ACQUITY UPC^2 System is an ideal solution for laboratories that want to convert current normal phase HPLC methods to more efficient and cost effective methods while enhancing health, safety, and environmental concerns.

Featured Products

ACQUITY UPC2 System <https://www.waters.com/134658367>

720004241, February 2012