### Application Note: ANCCSZILEUTSYNC

# HPLC Analysis of Zileuton

Monica Dolci, Thermo Fisher Scientific, Runcorn, Cheshire, UK

## Key Words

- Zileuton
- HPLC

#### Abstract

This application note demonstrates the use of the Thermo Scientific Syncronis C18 column for the analysis of zileuton.

### Introduction

Zileuton is a 5-lipoxygenase inhibitor [1] which inhibits the immunoregulators leukotrienes. Leukotrienes are involved in defence mechanisms such as inflammations. Controlling their biosynthesis can lead to the treatment of asthma and other allergic conditions. Zileuton is used for the maintenance treatment of asthma.

The original immediate-release formulation of zileuton, known as ZYFLO, was introduced in 1996 by Abbott Laboratories. The structure of this compound is shown in Figure 1.

Zileuton is a moderately polar compound, with a log P of 1.4, and therefore its retention under reversed phase LC requires a retentive stationary phase.

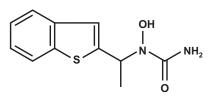
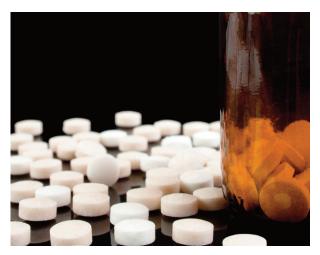


Figure 1: Structure of zileuton

Syncronis<sup>TM</sup> C18 columns are based on highly pure 100 Å silica, with a surface area of 320 m<sup>2</sup>/g and a carbon load of 16%. This ensures good retention of analytes with a range of hydrophobicities.

This application note shows an efficient and reproducible method for the analysis of zileuton, with excellent peak shape.



# **Experimental Detail**

Chemicals and Reagents	Part Number
Fisher Scientific HPLC grade water	W/0106/17
Fisher Scientific HPLC grade methanol	M/4056/17
Thermo Scientific 2 mL clear vial and Si/PTFE seal	60180-600

#### Sample Preparation

A 1000  $\mu g/mL$  standard solution of zileuton was prepared in mobile phase; this solution was then diluted to 20  $\mu g/mL$  in mobile phase and used for analysis.

Separation Conditions		Part Number
Instrumentation:	Thermo Scientific Accela HPLC/UHPLC system	
Column:	Syncronis C18 5 µm, 50 x 2.1mm	97105-052130
Injection volume:	1 µL	
Flow rate:	0.2 mL/min	
UV detection:	227 nm	
Mobile phase:	30:70 (v/v) acetonitrile/water	



#### Results

Zileuton was retained on the Syncronis C18 column using an isocratic method. Figure 2 shows the chromatogram obtained employing Syncronis C18 5  $\mu$ m, 50 x 2.1 mm column, with zileuton eluting at 3.49 min (retention factor of 3.36).

The following chromatographic parameters were monitored: retention time ( $t_R$ ), peak area, tailing factor and efficiency. Mean and % RSD values for the above parameters were based on data derived from six replicate injections, and are reported in Table 1.

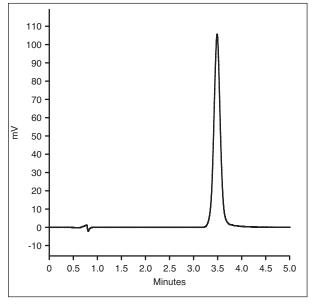


Figure 2: Chromatogram of zileuton, separated on a Syncronis C18 5  $\mu\text{m},$  50 x 2.1 mm column

Zileuton	t <sub>R</sub> (min)	Tailing Factor	Efficiency (Plates/m)	Peak Area
Mean	3.49	1.01	63646	10121320
% RSD	0.02	0.39	0.24	0.06

Table 1: Average and Method Precision (%RSD) of chromatographic parameters, for the analysis of zileuton on a Syncronis C18 5  $\mu$ m, 50 x 2.1 mm column (data calculated from six replicate injections)

## Conclusions

The use of a Syncronis C18 column allowed the successful retention of zileuton. Syncronis C18 columns are an excellent choice for the reversed-phase separation of zileuton, affording highly reproducible analysis.

#### References

[1] F.J. Alvarez and R.T. Slade, Pharmaceutical Research, Vol 9, N 11, 1992.

In addition to these offices, Thermo Fisher Scientific maintains a network of representative organizations throughout the world.

#### North America USA and Canada +1 800 332 3331

Europe France +33 (0)1 60 92 48 34

**Germany** +49 (0) 2423 9431 -20 or -21

**United Kingdom** +44 1928 534110

**Asia Japan** +81 3 5826 1615

China +86-21-68654588 or +86-10-84193588 800-810-5118

India +91-22-6742 9494

Thermo Fisher Scientific Australia Pty Ltd 1300 735 292 (free call domostic)

Thermo Fisher Scientific New Zealand Ltd 0800 933 966 (free call domestic)

**All Other Enquiries** +44 (0) 1928 534 050

#### Technical Support

North America 800 332 3331 Outside North America

#### www.thermoscientific.com/chromatography

© 2012 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific Inc. and its subsidiaries. Specifications, terms and pricing are subject to change. Not all products are available in all countries. Please consult your local sales representative for details.

