

Analysis of Fenopropfen Using a Core Enhanced Technology Accucore HPLC Column

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Key Words

- Accucore RP-MS
- Fused core
- Superficially porous
- Fenopropfen
- USP

Abstract

This application note demonstrates the use of the Thermo Scientific Accucore RP-MS HPLC column for the fast analysis of fenopropfen. The method of analysis is based on the USP monograph, and was scaled down by using an in-house method transfer calculator [1].

Introduction

Accucore™ HPLC columns use Core Enhanced Technology to facilitate fast and high efficiency separations. The 2.6 µm diameter particles are not totally porous, but rather have a solid core and a porous outer layer. The optimised phase bonding creates a series of high coverage, robust phases. Accucore RP-MS uses an optimized alkyl chain length for more effective coverage of the silica surface. This coverage results in a significant reduction in secondary interactions and thus highly efficient peaks with very low tailing. The tightly controlled 2.6 µm diameter of Accucore particles provides much lower backpressures than typically seen with sub-2 µm materials.

Fenopropfen (tradename: Fenopron in UK, Nalfon in USA), is a non-steroidal anti-inflammatory drug (NSAID). It is used for relief of pain, fever and inflammation in rheumatic conditions and disorders of the joints. Fenopropfen is an FDA approved medication [2]. The United States Pharmacopeia (USP) provides worldwide guidance for the chromatographic analysis of fenopropfen [3], which is based on High Performance Liquid Chromatography (HPLC). The implementation of Accucore RP-MS in this method allowed for the fenopropfen to be analysed according to the USP monograph.



Sample Preparation

A 1000 µg/mL of fenopropfen and a 1000 µg/mL of gemfibrozil standard solutions were prepared in 50:50 methanol:water; these solutions were then mixed and diluted in water to give a final concentration of 100 µg/mL each.

Thermo Scientific Column	Part Number
Accucore RP-MS 2.6 µm 100 x 2.1 mm	17626-102130
Measured pressure: 200 bar	

Thermo Scientific HPLC system

Column temperature	30 °C
Injection volume	3.0 µL
Flow rate	0.4 mL/min
UV detection	272 nm

Mobile Phase

50:49.6:0.4 acetonitrile:water:phosphoric acid

Consumables	Part Number
Fisher Scientific HPLC grade water	W/0106/17
Fisher Scientific HPLC grade acetonitrile	A/0626/17
NSC Mass Spec Certified 2 mL clear vial with blue bonded PTFE silicone cap	MSCERT4000-34W

Results

The original USP analytical conditions, based on a L1 250 x 4.0 mm, 5 µm column were scaled down using our method transfer calculator to accommodate for the column geometry reduction. The analysis was carried out on an Accucore RP-MS 2.6 µm 100 x 2.1 mm column. As shown on Figure 1, fenoprofen eluted at 1.6 min. The USP acceptance criteria (Tailing factor, $T_f \leq 2.0$, Resolution > 8) were met, as demonstrated in Table 1. The statistical assessment is based on data from 6 replicate injections.

Conclusions

The use of Accucore RP-MS column allowed to successfully scale down the USP method for the analysis of fenoprofen, in order to increase sample throughput. The analytical results exceeded the specifications stated in the

USP monograph. Accucore RP-MS columns are therefore an excellent choice for the fast analysis of fenoprofen, allowing high sample throughput.

References

- [1] <http://www.hplctransfer.com/>
- [2] <http://www.fda.gov>
- [3] http://www.pharmacopeia.cn/v29240/usp29nf24s0_m32720.html#usp29nf24s0_m32720

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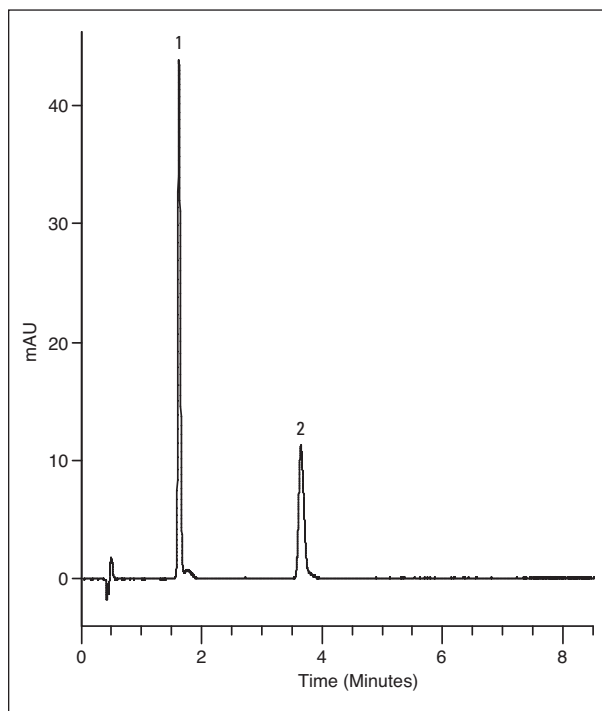


Figure 1: Chromatogram for 1. fenoprofen and 2. gemfibrozil separated on an Accucore RP-MS 2.6 µm 100 x 2.1 mm column

	Fenoprofen		Gemfibrozil		Resolution
	t_r (min)	T_f	t_r (min)	T_f	
Mean	1.63	1.23	3.67	1.22	14.10
%RSD	0.39	0.99	0.39	2.02	0.69

Table 1: Method precision (%RSD) for fenoprofen and gemfibrozil (data calculated from six replicate injections)

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