

Analysis of Cetirizine Hydrochloride Using a Core Enhanced Technology Accucore HPLC Column

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Abstract

This application note demonstrates the use of the Thermo Scientific Accucore HILIC HPLC column for the fast analysis of cetirizine hydrochloride. The method of analysis can be used as an alternative to the USP monograph which uses an aggressive acid in the mobile phase.

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. The tightly controlled 2.6 µm diameter of Accucore particles provides much lower backpressures than typically seen with sub-2 µm materials.

Analyte properties that govern retention with Accucore HILIC are acidity/basicity, which determines hydrogen bonding, and polarizability which determines dipole-dipole interactions.

Cetirizine is an antihistamine, used commonly for the treatment of allergies and hay fever.

The USP uses an aggressive mobile phase containing sulphuric acid. We have demonstrated a similar separation using an alternative, non-aggressive buffer system.



Sample Preparation

Working standard contained 50 µg/mL of cetirizine hydrochloride in 5:95 water/acetonitrile (v/v)

Thermo Scientific Column	Part Number
Accucore HILIC 2.6 µm 50 x 2.1 mm	17526-052130
Measured pressure: 50 bar	

Thermo Scientific Accela HPLC system

Column temperature	30 °C
Injection volume	1.0 µL
Flow rate	0.4 mL/min
UV detection	230 nm

Mobile Phase

90:10 MeCN / ammonium acetate 200 mM pH5.0

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

Key Words

- Accucore HILIC
- Cetirizine hydrochloride
- USP
- Fused core
- Superficially porous
- Core Enhanced Technology

Results

The original USP analytical conditions were based on a L3 250 x 4.0 mm, 5 µm column using a mobile phase of acetonitrile, water and 1M sulphuric acid (93:6.6:0.4). Sulphuric acid is an aggressive acid which can damage steel HPLC components. Typical run times for the USP application are approximately 11 minutes.

The analysis was carried out on an Accucore HILIC 2.6 µm 50 x 2.1 mm column. Cetirizine is eluted in less than 1 minute (Figure 1), which demonstrates over a 10-fold reduction in analysis time in comparison to the original method. The USP acceptance criteria (Tailing factor <2.0, %RSD t_r <2.0 and %RSD peak area <2.0) were achieved (Table 1.) The statistical assessment is based on data from 6 replicate injections.

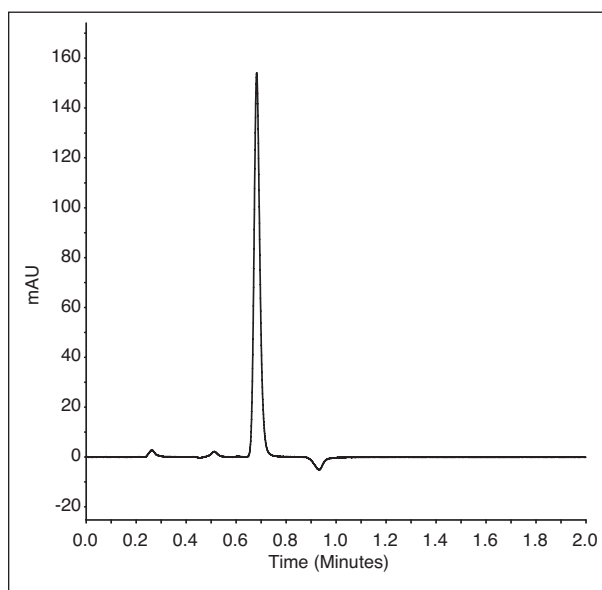


Figure 1: Chromatogram for cetirizine hydrochloride retained on an Accucore HILIC 2.6 µm 50 x 2.1 mm column

USP Specifications	Cetirizine Hydrochloride
Tailing factor <2.0	1.21
%RSD t_r <2.0%	1.39
%RSD area <2.0%	0.17

Table 1: Method precision (%RSD) for cetirizine hydrochloride (data calculated from six replicate injections)

Conclusions

The use of Accucore HILIC column successfully retained cetirizine hydrochloride without the use of an aggressive acid in the mobile phase, which is used in the USP method. The analytical results exceeded the requirements stated in the USP monograph. Accucore HILIC columns are therefore an excellent choice for the fast analysis of cetirizine hydrochloride allowing high sample throughput.

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