Application Note

Determination of Cimetidine in Pharmaceutical Tablets by High-performance Liquid Chromatography

Introduction

Cimetidine is a Histamine H2 receptor antagonist, with a gastric pH lowering effect. Cimetidine is widely used as a therapeutic product in tablet form for peptic problems, such as peptic ulcers, reflux problems and Zollinger-Ellison syndrome. The analysis is performed to determine the content uniformity of an oral preparation. A high-performance liquid chromatographic method was developed in order to assay Cimetidine and its related impurities simultaneously. A reversed-phase system and diode-array detector were used.

Experimental conditions

Instrumentation

A Shimadzu liquid chromatograph equipped with a model LC-20AB binary pump, SIL-20AC autosampler equipped with cooling function, SPD-M20A diode array detector and a CTO-20AC oven were used to keep the temperature at 40°C. A CBM-20A system controller and LCsolution chromatography software were used.

Materials and Reagents

Mobile Phase A: H2O (Milli-Q grade) +0.1%TFA
Mobile Phase B: ACN (HPLC grade)
Solvent Composition: 97.5/2.5 isocratic
Temperature: 40°C
Flow: 1 mL/min
Detection: UV@220 nm

Column: Pathfinder® MR
Dimensions: 4.6 mm x 150 mm
Particle size: 3.5μm
Pore Size: 100Å
Part number: 920-12400-33

Figure 1. Cimetidine

Figure 2. Separation of the pharmaceutical drug Cimetidine (1: Uracil, 2: Cimetidine)
Results and Discussion

Separation was performed under the above described conditions. Cimetidine is a very polar compound with various basic sites embedded in the structure, which usually show poor performance on older types of reversed phases. Despite the basic character (pKa 6.8) an acceptable USP tailing factor (0.95) and high plate count (15000) were obtained. The substitutes in the tablets eluted in the void without showing absorbance at 220 nm and therefore did not disturb the analysis.

Pathfinder® columns have shown a high chemical stability in these acid mobile phases. The lifetime with regular c18 columns can be significant reduced by acid hydrolysis.

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