Abstract

Charles University

Faculty of Pharmacy in Hradec Králové

Department of Analytical Chemistry

Candidate: Michaela Firleyová

Supervisor: doc. PharmDr. Ludmila Matysová, Ph.D.

Title of diploma thesis: Development and validation of UHPLC method for determination of terbinafine and its impurities

A new analytical method for the determination of terbinafine and its degradation products $-\beta$ -terbinafine, Z-terbinafine and 4-methylterbinafine - was developed by using ultra-high performance liquid chromatography.

The best separation of the analytes was achieved with a KinetexTM 1.7 μ m - Biphenyl 100A column (50 mm x 2.1 mm). The selected mobile phase was composed of the buffer pH 5.0, made up of the citrate and the phosphate buffer, and methanol (25:75, v/v). Propylparaben as the internal standard was detected at the wavelength of 254 nm, whereas the terbinafine and its three degradation products at 222 nm. The retention time of the terbinafine was 4.2 min, the total analysis time was within 6 minutes.

After finding the optimal conditions the method was validated.