ABSTRACT

BSc. Martina Hloušková

Supervisor: Ing. Martin Drastík, Ph.D.

The aim of this diploma thesis was the optimization and validation of a HPLC method for miconazole determination in samples supplied by the Department of Pharmaceutical Technology. A gradual miconazole release dependent on the composition of the copolymere of glycolic and lactic acid was studied.

HPLC analysis was performed using a modern core-shell Column Ascentis Express RP-Amide, 10 cm x 3.0 mm; 2.7 μm. Optimized analytical conditions were: mobile phase methanol:water 70:30, flow rate 0.8 ml/min, temperature 45 °C, injection 5 μl and UV detection at 220 nm. Miconazole retention time was 5.65 min. The entire analysis was carried out in 7 minutes.

When the optimal conditions of analysis were determined, the method could be validated. The following parameters were monitored during validation: linearity, selectivity, efficiency, LOD, LOQ, repeatability and tailing factor. All of the monitored parameters met the requirements of the Czech Pharmacopoeia.