Abstract
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Title of Thesis: Development of capillary electrophoresis method for the determination of three pharmacopoeial impurities in indomethacin.

This thesis deals with the development of a micellar electrokinetic chromatography method for the determination of indomethacin impurities (4-chlorobenzoic acid, 5-methoxy-2-methyl-3-indolylacetic acid and 3,4-dichloroindomethacin). All separations were performed in a fused silica capillary with 50 μm id; total length 64.5 cm, effective length 56 cm and with extended light path (150 μm id) detection window. 1-naftylacetic acid (10 μg/ml) was used as an internal standard. The separations were carried out at 30 kV. The analytes were detected at the cathodic end of the capillary at 224 nm. A central composite design was applied for the optimization of the separation conditions. The effect of SDS concentration, content of methanol, concentration of phosphate buffer and buffer pH was studied at three levels. The optimized background electrolyte was: 20 mmol/L phosphate buffer (pH 7.57) containing 58 mmol/L SDS and 0% MeOH. The analysis time (with resolution of all compounds $R_s \geq 3.8$) was shorter than 10 minutes. The linearity of the method was tested in the range of 1.25 – 80 μg/ml of each impurity corresponding to 0.05 – 3.2 % relative to the concentration of indomethacin (2.5 mg/ml). The calibration curves were rectilinear with correlation coefficients ≥ 0.9997. The limit of quantification was 0.05 % (corresponds to 1.25 μg/ml) that complies with the reporting limits regarding the ICH Q3A