ABSTRACT

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Title of Diploma Thesis: Development and validation of HPLC method for the determination of ketoprofen in suppositories

The purposes of diploma thesis were development and validation of HPLC method for the determination of ketoprofen in Ketonal® 100 mg suppositories. Ketoprofen belongs to NSAID and it is used for symptomatic therapy of inflammatory, degenerative and metabolic rheumatic diseases and for palliative therapy of some urgent or chronic painful syndromes. During development of determination of ketoprofen in suppositories were used two methods, which were developed at the Faculty of Pharmacy in Hradec Králové. Method for determination of diclofenac in suppositories was default for sample preparation and method of HPLC determination of ketoprofen, methylparaben and propylparaben in gel was basic for conditions of HPLC analysis. Development of method consisted in modification of origin sample preparation method; chromatographic conditions have not been changed. During the experimental work was found to determine what influence has the various steps of sample preparation and extraction temperature. The time of extraction and centrifugation were minimized, the melting of suppositories and the homogenization in ultrasonic bath were totally eliminated. 50 minutes for sample preparation at the beginning were reduced to 10.5 minutes, in addition to temperature of water bath was reduced by 10 °C compared to origin method. Methods validation demonstrated, that developed method provides precise and accurate results and it is suitable for determination of ketoprofen in Ketonal® 100 mg suppositories. During robustness testing, influence of variations in mobile phase composition to retention time concretely, it was observed, that increasing of acetonitrile content in mobile phase is shorting the time of analysis. Further development of methods for the determination of ketoprofen in Ketonal® 100 mg suppositories may also consist of finding a mobile phase that allows the shortest analysis while maintaining a suitable resolution of chromatographic peaks ethylparaben and ketoprofen.