ABSTRACT

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Title: Evaluation of dissolution profile of suppositories containing diclofenac sodium salt
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Suppositories are a promising dosage form, which is advantageously used in cases where it is not possible to use other dosage form (e.g. in children, non-cooperating patients or patients with swallow inability). Dissolution tests serve both as qualitative tests of medicinal products and on the other hand, provide valuable information during formulation of new ones.
The aim of this work was to study the dissolution process of diclofenac sodium from suppositories. The theoretical part focuses on the description of dissolution methods, the preparation of suppositories and the active substance used. The tested suppositories were prepared by three methods (manually, by Unguator technology and industry made ones), in experimental part. All suppositories contained 100mg of the active ingredient suspended in the solid fat base. Dissolution tests for lipophilic solid dosage forms by flow-through apparatus containing suppository cell according to the Czech Pharmacopoeia were performed at three media flow rates.

It was found that the maximum release of diclofenac in all suppositories occurred within three hours. The time required for maximal active substance release shortened with the increasing flow rate of the medium and the most significant changes in concentration occurred in first ten minutes of dissolution test. At the lowest flow rate, the initial increase in concentration was slow and the total amount of released diclofenac was statistically lower. This was probably caused by insufficient flushing of diclofenac from molten suppository mass in the chamber of flow-through cell. The standard deviations of the results were the greatest in handmade suppositories and much smaller in industrial and Unguator-made ones. According to these findings, it can be assumed that the variance of the results and the rate of diclofenac release depend on the dissolution medium flow rate and also on the suppository preparation method.

Key words: dissolution, dissolution testing, diclofenac, suppositories