Application of HPLC method for the comparison of the tablets of analgen provided by two different companies

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Background. HPLC (High Performance Liquid Chromatography) is a powerful separation method and must be able to resolve mixtures with a large number of similar analytes. It is a separation process in which the sample mixture is distributed between two phases in the chromatographic bed (column or plane). One phase is stationary while the other passes through the chromatographic lumen. The stationary phase is either a solid, porous, surface-active material in small-particle form or a thin film of liquid coated on a solid support or column wall. The aim of the work was comparison of products from two companies with each other without application of the absolute analytical method of calculation of the amount of the medicine in the tablets.

Methods. For the experimental analyses we used the Shimadzu LC system, which consists from the Controller CBM -20A, Pump A-LC-20AD, Autosampler –SIL- 20 A, Oven, CTO-20A, PDA-SPD-M20A. For the analyses it was also used the Column Waters Symmetry 300^{TM} C18, with the pore size 5 mcm, parameters of the column is the following 4.6x250 mm. For the delineation of the specific maximums of absorption of Analgen spectrophotometric method was applied (Carry 60, Agilent, USA). Flow rate equal to 1 ml/min was chosen as the best condition for obtaining of high-resolution chromatogram of Analgen.

Results and conclusions. The gradient type of elution for the detection of Analgen by RP-HPLC was the most effective one. The second Sample contained a greater number of impurities as well as excipients in comparison with Sample

1. We suggest, Sample 2 contains more amounts of the impurities in accordance to “Substances for pharmaceutical use (2034)” guideline.

Key words: HPLC, comparison, analyses, Analgen.

Comparison of the content of two tablets of Paracetanol produced by two different companies

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Background. High performance liquid chromatography (HPLC) is one of the main methods for the analyses of the medicines, detection of their impurities or the products of their degradation.

By changing of the column of the HPLC it is possible to change the type of the chromatography to gel-filtration, ion-exchange, affinity type or even reverse phase, which is appropriate for the separation of the compounds based on their hydrophilic as well as hydrophobic natures.

Accordingly, HPLC system is allowing separation of the compounds based on their molecular masses, surface ion charge, specific structure, etc.

The aim of the work was the comparison of two types of Paracetamol tablets produced by two companies. The results were comparative and not absolute.

Methods. In accordance with European Pharmacopeia, it was prepared the test solution for HPLC analyses by the following way: it was dissolved 50.0 mg of the substance, which was supposed to be examined in the solvent mixture and diluted to 5.0 mL with the solvent mixture.

For the experimental analyses we used the Shimadzu LC system, which consists from the Controller CBM -20A, Pump A-LC-20AD, Autosampler –SIL-20 A, Oven, CTO-20A, PDA-SPD-M20A. For the analyses it was also used the Column