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THE USE OF LIQUID CHROMATOGRAPHY IN RESEARCH OF BIOEQUIVALENCE

Evaluation of bioequivalence (or pharmokokinetic equivalence) of drug (drugs) is currently considered one of the main types of biomedical quality control of generics (the same drug in the same dose and the same dosage form as the original drug)). Before starting a detailed chemical study of any substance, it is necessary to isolate it in the possible purest form and in sufficient quantity. Therefore, the search for new, more perfect separation methods has been and is being continued.

The purpose of this work is to consider the use of HPLC (high-performance liquid chromatography) in bioequivalence studies.

In 1971, the Office of Technology Assessment (OTA) formed a group of experts to study the relationship between chemical (pharmacokinetic) and therapeutic equivalence of medicines. Liquid chromatography is an equally important component of bioequivalence analysis. Improvement of equipment, HPLC techniques leads to better analysis results.

Most of the drugs sold are not original drugs, but their analogues. Such copies of drugs are called generics. Two medicinal substances are considered bioequivalent if they are pharmaceutical equivalents and if their bioavailability after administration in the same molar dose is the same. Various methods can be used to determine the drug concentration in plasma, serum or whole blood. The method of chromatography-mass spectrometry for pharmacokinetic studies is one of the most selective and sensitive (but one of the most expensive). This method combines liquid chromatography and mass spectrometry, which is used to detect substances leaving the chromatographic column. Mass spectrometry is a method of studying substances subjected to

ionization, followed by the separation of the resulting ions by their masses and registration of the number of ions of each mass [2].

Most separations in liquid chromatography are based on adsorption effects. In this case, the separation is influenced by the interaction of the adsorbent, sample and eluent. HPLC is now widely used in drug analysis and separation. According to the mechanism of interaction of the analyte with the chromatographic system, modern HPLC is divided into a number of options: adsorption, distributive, ion exchange, exclusive, affine, etc. [1]. The advantages of HPLC are as follows: high separation power, giving good separation of the multicomponent mixture; high speed of movement of the chromatographic zone, allowing analysis in a short period of time; carrying out the chromatographic process under mild conditions, usually at room temperature. The most widespread use of HPLC in pharmacokinetic studies is reversed-phase and ion-pair chromatography. These include the great versatility of the method with respect to a very large number of drugs, the ability to analyze directly aqueous biological methods, or to reduce the process of sample preparation to a simple precipitation of proteins.[1].

Thus, the improvement of liquid chromatography methods will make it possible to more selectively and quickly separate the components of various mixtures, as well as to obtain more accurate data, which will positively affect both research in the field of bioequivalence and the development of the pharmaceutical industry in general.

References:

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