DEPARTMENT OF PHARMACEUTICAL AND TOXICOLOGICAL CHEMISTRY

408. VALIDATION OF ANALYSIS METHODS IN DRUG QUALITY CONTROL

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Introduction. An important role in the pharmaceutical product quality assurance system plays the analytical control of raw materials, intermediates and products. Analytical methods begin to be applied at the phase of development and testing of drugs, production technologies and continue to be used in serial release of pharmaceutical products. This control should ideally be carried out in accordance with the specifications, developed and validated during drug development. This ensures that the quality specifications can be applied both to pharmaceutical products used to establish the biological characteristics of the active substances and to dosed drugs. At the same time, materials presented in the US Pharmacopoeia "Validation of Compendial Methods" and documents of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) must be well studied and taken into consideration. After the completion of the examination, the quality of all subsequent series will be evaluated only on the basis of these specifications.
Aim of the study. The analysis of special literature and evaluation of the basic aspects in the field of validation of analysis methods.
Materials and methods. Advanced complex bibliographic study using such data and bases as GMP training workshop, studbooks of Metrology Methods in Pharmaceutical Analysis, Validation of Compendial Methods, etc. Were evaluated over 150 bibliographic sources.
Results. Validation is the most important stage in the development of analysis methods, that evaluates their suitability and authenticity. Analytical control of drugs or certain ingredients in a drug is necessary to guarantee their safety and efficiency throughout their shelf life, including storage, distribution and utilization. Validation is the process of experimental confirmation that the analytical method provides the necessary and reliable information about the object of analysis and is suitable for practical use.
Conclusions. Increasing quality requirements of drugs demands increasingly advanced methods of analysis, and therefore there is an increasing need for validation of all analytical methods as one of the elements of validation of the entire process of drug production.
Key words: Drug, analysis methods, validation.

409. METHODS FOR TESTING THE BIOAVAILABILITY OF EAR DROPS

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Introduction. A very important pharmaceutical parameter in exercising a maximum pharmacological effect is the bioavailability of medicines, which represents the quantity and

speed of disposal of the active substance by a pharmaceutical form, its absorption in the body, its transport to the site of action and its biological response.
Aim of the study. Advanced bibliographic study on the diversity of methods used in the study of bioavailability of ear drops.
Materials and methods. 87 abstracts and scientific articles from the Cochrane Electronic Library, MEDLINE databases, CAB Abstracts © and SciSearch © The Thomson Corporation.
Results. The bibliographic evaluation of the sources studied has highlighted the importance of the basic physico-chemical characteristics of the drug substances incorporated in the pharmaceutical form, which directly influence the bioavailability. For example: drugs with high molecular weight or high electrical charge cross the blood-brain barrier (inner ear membrane) with passive difficulty, as well as protein-binding substances, while high liposolubility of drug substances facilitates passage. It has been established that there are several methods used to investigate the bioavailability of active principles from ear drops, using Franz diffusion vertical cells. Animal skin is often recommended for preliminary evaluations of new formulations as a membrane for yield. Animal models used to replace human skin are domestic pigs, rats, mice, guinea pigs and snakes. Thus, 26% of the evaluated sources propose the use of the skin of newborn pigs. In most articles (68%) it is proposed to use the skin on the inner side of the pig's ear, as results are comparable to those obtained on human skin due to similar thickness, vascular anatomy and arrangement of collagen fibers in the dermis of the ear, as well as due to the identical glycosphingolipid and ceramide content. The bioavailability assessment is done by determining the concentration of the substances (usually by chromatographic or spectral methods) at equal intervals in the yield medium.
Conclusions. Bioavailability is extremely important for the preformulation and drug formulation process, and the correct selection of the *in vitro* determination method facilitates the correlation of results with those obtained *in vivo*.
Key words: Bioavailability, ear drops, test methods.

410. CONTRIBUTION TO THE STUDY OF THE QUALITY OF DRINKING WATER SOURCES IN THE SOUTHERN DISTRICTS OF THE REPUBLIC OF MOLDOVA

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Introduction. Water use is multiplied. The closest concern is for drinking water for which the insurance conditions are quite special, are regulated by the state by norms and standards. The present paper presents data and information on the quality of drinking water sources in the southern districts of the Republic of Moldova such as Cahul, Taraclia and Cantemir.
Aim of the study. Control and monitoring of water quality in order to verify that the water distributed to the consumer is in accordance with the quality requirements and does not create risks for the population's health.
Materials and methods. Laboratory data obtained by physico-chemical and microbiological analysis, normative acts regarding drinking water and its quality.
Results. As a result of the laboratory investigations of the water samples taken from the water sources in the southern districts of Moldova (Cahul, Cantemir, Taraclia), most of them