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