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**MODERN SCIENTIFIC RESEARCH:  
ACHIEVEMENTS, INNOVATIONS  
AND DEVELOPMENT PROSPECTS**



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# PHARMACEUTICAL SCIENCES

## DIRECTIONS AND PROSPECTS OF DRUG DEVELOPMENT IN THE CONTEXT OF STUDYING THE DISCIPLINE «DEVELOPMENT OF DRUGS»

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**Introductions.** The discipline «Development of drugs» is a theoretical and practical basis for a set of knowledge and skills that shape future professionals in the field of pharmacy, industrial pharmacy, and is a theoretical basis for a set of knowledge and skills that shape the profile of a specialist in science. The subject of study of the discipline «Development of drugs» are: the basic concepts of development schemes of modern drugs, modern biotechnological methods in the process of drug development, ways and methods to improve the use of natural resources to create new drugs and ensure quality of life and safety. It is known that such studies should be conducted during the life cycle of the product in order to create a quality drug, its registration and quality assurance in mass production. Quality cannot be tested in drugs - quality must be laid down during development. The purpose of pharmaceutical development is to develop a quality drug and its production process in order to constantly produce products with specified functional characteristics.

**Aim** - conducting an overview of literary data on complex experimental studies aimed at scientific substantiation of the composition of the medicinal product in this medicinal form, production process and its control, selection of packaging materials, as well as the study of physicochemical, biological and microbiological properties, which are the main tasks of pharmaceutical development.

**Materials and methods.** At the theoretical level of research, the following general scientific methods are used: analysis; synthesis; induction; deduction; comparison; formalization; abstraction; modeling.

**Results and discussion.** Pharmaceutical development purposefully identifies the most important stages controlled in routine production and shapes the quality of drugs, ensuring a high probability that each unit of the entire batch of the drug will have a quality that meets the expected efficiency and safety established in clinical trials. At the stage of pharmaceutical development, the foundations of safety and efficacy of drugs are laid. The urgent task today is to create an effective system of providing the population of Ukraine with medicines. The patient must be guaranteed the availability, clinical efficacy, safety and quality of the drug. Product quality assurance is a comprehensive concept. The quality of drugs should be guaranteed at all stages - from its development to implementation. This is achieved through the introduction of a set of good pharmaceutical practices: GMP, GLP, GCP, GDP, GPP and GSP. Pharmaceutical development is a mandatory component of the technological regulations and registration dossier for drugs. The main objects of pharmaceutical development research are the components of the drug, dosage form, process, packaging materials and validation of the production process. The components of the drug include medicinal substances and excipients, quantitative quality indicators (specifications), which are established experimentally. The drug substance (substance) in the production of drugs is considered as a therapeutic API, the choice of which is based on stability, biological activity and the presence of impurities. It is important to study the compatibility of the substance with excipients in the drugs both at the stage of production and during storage. Depending on the composition of the drug, interactions may occur between the substance and the

excipients, under which it is possible to obtain compounds-inclusions, complexes, etc. Physicochemical and biological properties of the medicinal product that may affect the functional characteristics of the medicinal product and the possibility of its production, or those characteristics of the medicinal product that are specifically established for it (eg properties for solids) should be identified and discussed. Examples of physicochemical and biological properties that may need to be investigated are solubility, water content, particle size, crystal properties, biological activity, and permeability. These properties may be interrelated, which may require consideration in combination. To evaluate the potential effect of the physicochemical properties of the drug on the functional characteristics of the drug, studies on the drug should be performed. The compatibility of the drug with excipients should be assessed. For drugs containing more than one drug, the compatibility of the drugs with each other should also be assessed.

The choice of excipients, their concentrations and characteristics that may affect the functional properties of the medicinal product (eg stability, bioavailability) or the possibility of its production should be discussed taking into account the relevant function of each excipient. All substances used in the manufacture of a medicinal product should be included, whether or not they are present in the finished product (for example, substances used for processing purposes). Compatibility of some excipients with others should be established if relevant (eg combination of preservatives in a dual preservative system). It is also necessary to prove the need for excipients to ensure their intended function (eg, antioxidants, permeation enhancers, disintegrants, release control substances), as well as the preservation of this function during the expected shelf life of the drug. Information on the functional properties of the excipient can be used, if necessary, to justify the choice and quality indicators of the excipient, as well as to justify the specification for the drug. A summary should be prepared describing the development of the composition and indicating those characteristics that are critical to the quality of the medicinal product, taking into account the intended use and route of administration. Information on formal experimental plans may be useful in identifying critical or interrelated variables that

may be important for drug quality assurance. The summary should cover the development of the composition from the initial idea to the final composition. The summary should also take into account the choice of drug components (eg, drug properties, excipients, container / closure system, any significant dosing devices), manufacturing process, and, if necessary, information obtained during development. similar drug (s). The development of new drugs is based on the synthesis of new chemical compounds. Substances of complex structure are obtained from plants (eg, cardiac glycosides), animal tissues (heparin), based on cultures of microorganisms (penicillin) or cultures of human cells (urokinase), as well as by genetic engineering (human insulin).

The more we know about the relationship between the chemical structure of a substance and its effects, the more purposeful the search for a new drug. The creation of original drugs can be done on two levels. The original drugs that are ahead of the world level are those that are superior to known domestic and foreign counterparts in their therapeutic effect. The original medicines corresponding to the world level are those which on the medical action can be compared with the best foreign, but surpass domestic analogues. The process of creating an original drug lasts at least 10-12 years, and reproducible on the basis of foreign counterparts - 5-6 years.

**The development of the drug includes the following stages:**

1. The idea of creating a new drug. It usually occurs as a result of joint work of scientists of two specialties: pharmacologists and chemists-synthetics. Already at this stage, a preliminary selection of synthesized compounds, which, according to experts, may be potentially biologically active substances.

2. Synthesis of pre-selected structures. At this stage, the selection is also carried out, as a result of which substances characterized by instability, impossibility or excessive complexity of the synthesis, the high cost of starting materials, etc., are not subject to further study.

3. Pharmacological screening. The main stage, during which the hopeless substances synthesized at the previous stage are eliminated.

4. Clinical examination. It is performed only for promising biologically active

substances that have passed all stages of pharmacological screening.

5. Development of technology for the production of a new drug and the most rational dosage form.

6. Preparation of regulatory and technical documentation, including methods of quality control of both the drug and its dosage forms.

7. Introduction of the drug into industrial production and testing of all stages of its production in the factory.

The leading direction of creation of new medicinal substances is researches in the field of modification of structure of known natural biologically active compounds. One of the areas of search for new drugs is the chemical modification of already known drugs and prodrugs. This creates great potential for increased activity, removal of side effects, increasing the stability of drugs. Prodrugs are chemically modified forms of products (substances), which in the bioenvironment of the body due to metabolic processes are converted into drugs. Examples are enalapril maleate, which hydrolyzes to form enalaprilat. And it is the latter that inhibits the activity of ACE inhibitors, thereby inhibiting the formation of angiotensin II. At the same time, the food consumed at the same time does not affect the absorption of enalaprilat. Another example of a prodrug is capecitabine, an antitumor drug. It is converted to the cytotoxic compound fluorouracil directly in the tumor tissue under the action of tumor angiogenic factor - thymidine phosphorylase. The systemic effect of fluorouracil on healthy body tissues is minimized. Sequential enzyme metabolism creates high concentrations of the drug in tumor cells. When creating new drugs often need to increase activity, sometimes, on the contrary, it is advisable to slow down the absorption of the drug (sulfonamides). In some cases, for example when creating antitumor drugs, it is necessary that the drug acts only in relation to the desired organ or tissue. Prolongation of action can be achieved if the precursor drugs will accumulate in adipose tissue. Esterification (alcohols and acids) is also used to increase the duration of action. Alkyl esters of alcohols are resistant to acids and alkalis. Sometimes the conversion to ethers significantly changes the physicochemical and biopharmaceutical properties (penicillins). One of the most

important modern areas of search for new drugs is the study of endogenous physiologically active compounds, ie substances synthesized by the body that participate in the process of life. Currently, a large number of endogenous compounds representing the chemical structure of amines, amino acids, peptides, glucoproteins, purines have been isolated and identified. They affect the regulation of nervous processes, metabolism, immune responses, tissue growth and other vital functions. The study of these compounds is of great theoretical and applied importance for various fields of medical, chemical, pharmaceutical science. A team of specialists usually works on the creation of the drug: -technologists (development of recipes and production technologies, validation of technological and cleaning processes); -pharmacologists (preclinical studies of the safety profile); -analysts and microbiologists (development and validation of analytical and microbiological methods of quality control of raw materials, intermediate and finished product in the final package, the study of stability); -clinicians (clinical trials of the effectiveness of a generic drug compared to the reference).

**There fore, currently the main areas of search for new drugs are:**

1) Empirical study of a particular type of pharmacological activity of various substances obtained chemically. This study is based on the method of "trial and error", in which pharmacologists take existing substances and determine using a set of pharmacological techniques their belonging to a particular pharmacological group. Then among them select the most active substances and establish the degree of their pharmacological activity and toxicity in comparison with existing drugs used as a standard. In the English literature, this way of selecting pharmacological substances is called screening (in translation - selection, screening) - a directed study of drugs. This system consists in the selection of compounds with one specific type of pharmacological activity. The advantage of this system is the faster selection of pharmacologically active substances, and the disadvantage is the lack of detection of other, perhaps very valuable types of pharmacological activity. In essence, this is a limited screening.

2) Modification of the structures of existing drugs. This way of finding new

drugs is now very common. Synthetic chemists replace one radical in the existing compound with another, for example methyl - ethyl, propyl, or, conversely, introduce into the original molecule other chemical elements, such as selenium, or make other modifications.

3) Purposeful synthesis of drugs means the search for substances with predetermined pharmacological properties. The synthesis of new structures with the expected activity is most often carried out in the class of chemical compounds, where substances have already been found that have a certain direction of action on a given organ or tissue. Purposeful synthesis of drugs becomes successful when it is possible to find a structure that in size, shape, spatial position (conformation), electron-proton properties and a number of other physicochemical parameters will correspond to the living structure to be regulated.

4) Synthesis of antimetabolites, ie antagonists of those substances that are involved in the life of the organism (transmitters, vitamins, hormones, enzymes). For example, a very active, albeit small group of antitumor drugs, is a group of antimetabolites - antagonists of natural metabolites. The chemical structure of this group is a structural analogue of amino acids, purine and pyrimidine bases, ie precursors of nucleic acids, folic acid, vitamins, hormones, coenzymes and other substrates responsible for the normal functioning of cells and tissues. The mechanism of action of antimetabolites is based on their ability to enter into competitive relationships with similar metabolites of the body, which causes a lack of the corresponding metabolite and reduced activity of vital biochemical processes in the cell.

5) Synthesis of stereoisomers. Pharmacological activity is determined not only by the size and shape of the molecule, but also to a large extent - their stereometry. Geometric isomers can change not only pharmacological activity but also toxicity. In experiments on mice, the toxicity of cystamine is 6 times less than that of transamine, so in a targeted study of a new synthetic drug, there is a need to study its isomers. Optical isomerism has a significant effect on the degree of pharmacological activity of the substance. There is no chemical difference between isomers or "antipodes", but



each of them rotates the plane of polarization of light in the opposite direction.

6) Biotechnology - one of the main directions of obtaining drugs from microorganisms, plant and animal tissues. At the same time receive complex drugs, and also allocate individual substances which need biological standardization. Genetic engineering methods are of great importance. One of the directions is the transplantation of a gene that produces in the cells of the body physiologically active substances of protein structure, in non-pathogenic microorganisms, such as *Escherichia coli*. By this method, by the end of the 1970s, the first commercial drug, human insulin, had been obtained.

7) The creation of combination drugs is one of the most effective ways to find new drugs. Combined drugs are also based on the principle of including in them such additional ingredients that eliminate the negative effects of the main substance. For example, a combined drug containing a broad-spectrum antibiotic - tetracycline - is available. In this drug it is combined with nystatin. The drug contains two active components with antibacterial activity. The presence of two active substances contributes to the potentiation of the therapeutic effect and reduce the dosage of each individual component. In addition, the spectrum of antibacterial activity of the drug is expanding. Tetracycline has a bacteriostatic effect (inhibits the growth of bacteria) and belongs to the group of the same name.

The mechanism of action is based on blocking the reactions of nucleic acid replication, which makes it impossible to divide the cells of the pathogen, as well as the reaction of biosynthesis of bacterial proteins. Nystatin - the second component of drugs, has weak antibacterial activity, but has a pronounced antifungal effect. Included in the group of polyenes. The mechanism of action of this drug is based on the ability of the molecule to integrate into the membrane of the pathogen, which leads to uncontrolled penetration of electrolytes into the cell and subsequent death of the microorganism.

**Conclusions.** Therefore, it is very important that in the process of professional training of specialists in the pharmaceutical industry, the basic concepts of the scheme of development of modern drugs and methods of their further verification are

formed; acquaintance with modern biotechnological methods used in the process of drug development and identify ways and methods to improve the efficiency of natural raw materials. The solution of these problems and tasks is within the power of specialists who have the appropriate training to address issues that arise in the pharmaceutical industry.