

INNOVATIVE ASPECTS OF MATHEMATICAL MODELING IN THE INTRODUCTION OF NEW PHARMACEUTICAL FORMS

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Introduction. The pharmaceutical industry is one of the most important and scientifically and technically complex branches of modern medicine and biotechnology. The development and introduction of new pharmaceutical forms is an important task, as it contributes to the improvement of the quality of medical care and treatment of patients. However, this process requires a lot of effort, resources and time. Innovative approaches and tools are required to accelerate and improve the process of development and introduction of new pharmaceutical forms. In this context, mathematical modeling becomes a powerful tool to achieve this goal.

Mathematical modeling is a young field that became widely used in pharmaceuticals only in the 21st century. However, its foundations were laid back in the 1960s. In 1969, Lewis Scheiner, who ran a laboratory at the University of San Francisco, published a paper, Computer Modeling of Drug Action, in which he explored the modeling of warfarin, an anticoagulant. This work became the first in the field of mathematical modeling of pharmaceutical systems.

The accelerated development of mathematical modeling in pharmacy began in the late 1980s. Yes, the US Food and Drug Administration (FDA) has created a drug review center. By the early 2000s, the FDA was concerned about why so few new drugs were being developed. In response, the regulator introduced new requirements for pharmaceutical companies that required the use of mathematical modeling to assess the effectiveness and safety of new drugs.

Purpose: substantiation of prospects for the use of mathematical modeling in the development of pharmaceutical products.

Research methods: comparative and system analysis, forecasting, programming, mathematical modeling.

Research results and discussion. These requirements led to the fact that the world's pharmaceutical companies began to create their departments of mathematical modeling. Thus, by 2010, the number of such departments reached 100 researchers in companies from the top 10.

A new field of research related to the use of mathematical modeling for the development of new drugs appeared in Ukraine in the mid-2000s.

Mathematical modeling is an important tool for the development of new pharmaceuticals. It helps pharmaceutical companies improve the effectiveness and

safety of new drugs, as well as reduce the time and costs of their development. Mathematical modeling is an integral part of the development of all new drugs, both original and generic. It is especially important in areas such as anesthesiology, where the accuracy of drug dosage is critical for patient safety. Immunology is a branch of medicine that studies the body's immune system. In this field, mathematical modeling has become an important tool for studying the interaction between different components of the immune system.

In oncology, mathematical modeling is used to develop new cancer treatments, such as radiotherapy. For example, mathematical modeling helps determine optimal radiation doses for patients. Mathematical modeling is also helping to develop new drugs to treat cancer. For example, it helped accelerate the market launch of such blockbuster drugs as pembrolizumab and osimertinib.

The development of new medicines is a long and complex process that takes an average of 12 years. The first two stages of this process - the search for a target and a substance capable of binding to it - take relatively little time: no more than six months. The development of new drugs at the next stage moves to the study of the therapeutic effectiveness of APIs, and it is at this stage that various methods of mathematical modeling are used. The results of the work of pharmacometrics can be seen in every instruction for the use of drugs, where there are always sections on pharmacokinetics, pharmacodynamics and dosage. API dosages are calculated using mathematical models. With the help of mathematical models, the developers of the drug analyze the data received at all phases of clinical research and create the most informative instructions for use.

Mathematical models are not only of scientific importance, but also allow to reduce time and costs for the development of new drugs. For example, mathematical calculations help to optimize the design of clinical trials, which can lead to a reduction in the number of patients needed to obtain a statistically significant result. Since research costs are proportional to the number of patients, this can significantly reduce overall costs.

With the help of mathematical models, the duration of clinical studies can be shortened. In order to register the drug, it is often necessary to conduct additional studies, for example, in patients with kidney failure or who take other medications. These studies can take years. Mathematical models allow replacing these studies, while not reducing their evidentiary value and the accuracy of the instructions for use.

Another important point: mathematical modeling allows at the early stages of the development of new drugs to identify substances that are likely to be insufficiently effective and safe.

Therefore, the use of mathematic modeling allows pharmaceutical companies to develop new drugs faster, more efficiently and cheaper. This can lead to improved health for people around the world.

There is a shortage of mathematical modeling specialists in the pharmaceutical industry. Even in developed countries such as England, experienced pharmacometricians are rare. In the modern world, there are only two Master's programs that can be adapted to pharmacometrics.

We believe that for successful work in the field of mathematical modeling, it is important to have interdisciplinary knowledge. It is important to be able to work at the intersection of different disciplines, as this is the key to success in any applied field.

Innovative aspects of mathematical modeling in pharmaceuticals include:

- Using artificial intelligence and machine learning to create more accurate and reliable models.
- Development of new modeling methods that take into account the complexity of pharmaceuticals and the interaction between them.
- Implementation of mathematical modeling in new areas of pharmaceuticals, such as the development of personalized medicines.

Conclusions. Mathematical modeling is a powerful tool that can be used to solve a wide range of problems in pharmaceuticals.

To optimize the composition of pharmaceutical preparations - determination of the optimal set of ingredients, ratios and doses that provide the desired characteristics of the drug, such as effectiveness, safety and availability.

Research on the influence of environmental factors - predicting the impact of various environmental factors, such as temperature, humidity and light, on the quality of pharmaceuticals. Development of new forms of release of pharmaceutical preparations – development of new forms of release that ensure effective absorption and dosage of drugs. Forecasting the stability of pharmaceuticals - forecasting the influence of various factors on the preservation of the quality of pharmaceuticals throughout the shelf life.

Prospects for further research and development of the industry. Further research and development of mathematical modeling in pharmaceuticals may lead to the following prospects:

- Development of more effective and safer pharmaceutical preparations.
- Improving the availability of pharmaceuticals.
- Reducing the risk of side effects.
- Reduction of costs for the development and production of pharmaceuticals.