# THE NECESSITY TO USE MATHEMATICAL METHODS IN DRUG PRODUCT DEVELOPMENT

Popova V.P., Moskalyk N.Yu., Zhovtonizhko I.M.
The National University of Pharmacy, Kharkiv, Ukraine
popovaviktoria17@gmail.com

Nowadays, progress in science and technology in the field of pharmacy is intimately connected with intensification of scientific research, which, in its turn, requires mathematical data description. In particular, use of various mathematical methods is an integral part of application pendency during registration of new drug products, introduction of amendments to the instruction on medical use of any drug product, as well as theoretical grounding of experimental studies and assessment of the results obtained during scientific experiments. In addition, mathematical approach not only facilitates precise quantitative description of a certain task via construction of one or another appropriate model, but also provides means for its solution.

As a rule, drug product development contains certain stages, which may vary due to particular tasks of experimental studies, such as: collecting and processing of independent information; experimental selection of factors, which are to be studied in detail; experimental search for an optimal site; obtaining mathematical model of the process in the optimal site; mathematical study of the process model in order to find optimal modes; experimental check of optimal modes.

In order to reflect the key points of experimental studies, it is reasonable to use methods of mathematical experiment design, which are based on analysis of variance and regression analysis. Their use is appropriate when solving such tasks as selection of most significant factors (sampling experiment), conduction of comparisons (comparative experiment), search for optimal conditions (optimization), assessment and clarification of theoretical model invariables, in particular, kinetic ones, investigation of "composition-characteristics" diagrams, etc.

It should be noted that nowadays there are methods that allow use of mathematical models at different stages of drug product development. For example, biological modeling on the basis of various data on physiology, biochemistry, and regulation of processes that occur in a human organism, allow conduction of quantitative estimation of a drug product interaction with the target and the rate of its distribution in the body. This, in its turn, provides the opportunity for better understanding of target potential and selection of those molecules that posses an optimal combination of biotherapeutical characteristics at the early stages of drug product development under conditions of limited clinical information available.

Thus, it is possible to state with assurance that today mathematical modeling is one of the most promising methods to be used in order to improve the efficiency of the process of new drug product development.