

УДК 615.21/.26

Удовенко М. – ст. гр. БХФ1-14

*Київський національний університет технологій та дизайну*

## **ВИКЛИКИ НОВОГО ПРОЦЕСУ РОЗРОБКИ ЛІКАРСЬКИХ ПРЕПАРАТІВ У БІОФАРМАЦЕВТИЧНОМУ КОНТЕКСТІ**

Науковий керівник: старший викладач Звонук О.А

Udovenko M.

*Kyiv National University of Technologies and Design*

## **CHALLENGES OF NEW DRUG DEVELOPMENT PROCESS IN BIPHARMACEUTICAL CONTEXT**

Supervisor: Zvonok O.A.

Ключові слова: лікарський препарат, розробка ліків, біофармацевтична хімія  
Keywords: drug, development of a new drug, biopharmaceutical chemistry

The biopharmaceutical new product development process follows an established pattern. An exploratory discovery research finds a new target of potential therapeutic use, then a number of molecules are developed and optimized, and the best one among them is selected to be the product candidate. This product candidate then goes through the pre-clinical trial phase where a range of tests are run both in vitro and in animals to characterize the likely safety and effectiveness of this molecule in treating Chapter its target disease. Upon completion of the pre-clinical trial, the drug developer applies to regulatory authorities (e.g. FDA in USA) for approval to commence human clinical trials. Clinical trials are required to prove that the drug is safe and effective when administered to human patients.

There are three major phases of clinical trials before the product gets approval for commercialization: Phase I tests the safety of the product in human, Phase II assesses its efficacy and Phase III aims at definitively assessing the efficacy and dosage in a large number of patients. Upon completion of clinical trials, the drug developer is required to gather all pre-clinical and clinical data generated during the process, along with details of the production process used to make the drug and cGMP documentation, and submit to the regulatory authority for market entry approval. Once granted, the product developer can legally manufacture and sell the product. This study focuses on the development stages from pre-clinical to regulatory submission (i.e. the FDA review).

The activities prior to the pre-clinical trial stage are not covered in this model because the costs generated at these stages are often shared with other compounds. Therefore the stages from discovery to lead optimization are omitted, leaving pre-clinical and clinical trial stages as the major cost drivers in this model. The development pathway described in this study assumed that only the preclinical and clinical trials are on the critical path. To meet the timing requirement of activities on the critical path, the supporting process development and manufacturing activities occur off the critical path and hence are performed at risk before the go/no-go decision for the clinical trial is known. This model assumes for every development stage, the dependency exists that the occurrence of activities follows the path from process development to manufacturing, and then to the clinical trial. Manufacturing and process development activities are designed to meet the need of the clinical trials. In order to produce the products efficiently and at the required quality, the developer must, through a serious of process development activities, establish the manufacturing process and optimize it Chapter to

meet regulatory requirements as well as reduce cost. Detailed interdependencies between clinical trial, manufacturing and process development activities are depicted.

Pre-clinical trial materials are produced through an established cell line that provides products with low titre at a small scale. For Phase I and II clinical trials, process development focuses on process scalability and improvement of productivity, since more material is required for clinical trials. Process development for Phase III and regulatory approval mainly focuses on process characterization and validation. Initial process limit evaluation and validation studies commence at the early stage of process development prior to Phase III. Major characterization and validation studies run simultaneously with Phase III clinical trials in order to avoid causing any delay to submission to regulatory approval.

УДК 615.07:543.42

Кишка О.С –ст. гр. БХФ-2-14

*Київський національний університет технологій та дизайну*

## **ВИЗНАЧЕННЯ ВІТАМІННО-МІНЕРАЛЬНОГО СКЛАДУ ЛІКАРСЬКИХ ЗАСОБІВ МЕТОДОМ АТОМНО-АБСОРБЦІЙНОЇ СПЕКТРОСКОПІЇ**

Науковий керівник: д.т.н Звонок О.А.

Kishka Olga

*Kiev National University technology and design*

### **DETERMINATION OF THE VITAMIN-MINERAL COMPOSITION OF DRUGS BY ATOMIC ABSORPTION SPECTROSCOPY**

**Purpose and tasks:** To determine the vitamin and mineral composition of drugs, by atomic absorption spectroscopy. To investigate the drugs on the content of impurities. To clarify whether the available impurities do not exceed the permissible limits for the SPU.

**Objective:** To carry out quantitative determination of iron, zinc and calcium in the preparations of Gesticker, VitaCap, Vitiron and Sucaspas.

Determine the cationic anionic composition of the ivy of the ordinary, and determine the presence in the substance of inadmissible admixture, or substances present in large quantities.

Investigation of the solution of activated carbon on the content of Zinc, Lead and Copper.

**Object and subject of the study:** Medicinal herbal preparations: Ketika Pharma Inc. Mega Lifesciences, Vitirone Sucaspa (Мєpha). Alcohol extract of the usual ivy and powdered activated charcoal solution.

**Methods and means of research:** For the purpose of the experiment, we used the method of atomic absorption spectroscopy, the method of analytical chemistry, based on the selective absorption of electromagnetic radiation of a certain wavelength, free of all molecular bonds by the neutral atoms of the conditioned element. In the analysis of Ca and Zn acid extraction was used.

To avoid the interference of iron and other trace elements, a solution of lanthanum chloride was used.

In determining Ca, which forms hard dissociating compounds also used high-temperature flame (3000-3200 ° C), a mixture of N<sub>2</sub>O, acetylene.