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.

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

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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 Suscasp (Mepha). 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 N2O, acetylene.

The measurements were carried out on a Varian 220 FS Double Beam AA atomic absorption spectrometer equipped with a hollow cathode lamp specific to the corresponding element.

Scientific novelty and practical value of the results:

Atomic absorption analysis is used to determine about 70 elements. The gases and some non-metals whose resonance lines lie in the vacuum region of the spectrum (wavelength less than 190 nm) are not defined. So, using this rather sensitive method, we conducted the studies listed above for the presence of such important trace elements as Calcium, Zinc, Magnesium and Ferrum. Because their lack of medicines, or conversely excess, can significantly reduce the therapeutic effect of the drug, or lead to undesirable effects. After analyzing the DFUAT data on the content of these components in the drug substance, established over the past 5 years, we compared the results of our reference studies and determined whether our researched raw materials meet the quality standards.

Research results: During the course of the work, the definition of the vitamin and mineral composition of the preparations was made: Ketia Pharma Inc. (Mega Lifesciences), Vitiron Suscasp (Mepha). According to the results of work, it can be concluded that the content of calcium, zinc and iron in the investigated substances meets the standards of the SPU.

We also carried out a quantitative analysis of the solution of activated carbon on Zinc, Lead and Kuprom.

For DFU, zinc should contain no more than 0.0025%, Lead not more than 0.001%, Copper no more than 0.0025%.

The experiments conducted by us showed the following results: Zn = 0.019%, Pb = 2.3%, Cu = 0.003%

Consequently, we can conclude that there is a clear excess of the content of the Lead in the solution. All other metrics are within acceptable limits.

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ОРГАНІЧНІ ПАРФУМИ ПРОТИ СИНТЕТИЧНИХ АРОМАТИЗАТОРІВ

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ORGANIC PERFUME AGAINST SYNTHETIC FRAGRANCES

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Keywords: organic perfumes, synthetic fragrances, phthalates, parabens.

Did you know that over 60% of what you apply to the skin, the largest organ in your body, is absorbed into your bloodstream? 95% of chemicals in most commercial flavors - synthetic compounds derived from oil and natural gas, ie petroleum products. On average, 80% of the aromatic compositions consist of these chemicals, and in some cases, the 100% ratio can be synthetic.