Results and discussion. To identify the amount of flavonoids in the analyzed gel, we proposed a reaction with a solution of aluminum chloride.

A portion of gel was dissolved in 96% ethanol, an aluminum chloride solution was added, and yellow-green fluorescence was observed in UV light at a wavelength of 365 nm.

Quantitative determination of the amount of flavonoids The State Pharmacopoeia of Ukraine proposes to carry out by the method of absorption spectrophotometry in the UV and visible regions of the spectrum by the complexation reaction. We chose an interaction reaction with a solution of aluminum chloride in an acetic acid medium.

A portion of gel was dissolved in 96% ethanol and filtered. An aliquot of the resulting solution is placed in a volumetric flask, an aluminum chloride solution is added and adjusted to a mark with 5% acetic acid in methanol. In parallel, a blank solution is prepared in which a solution of aluminum chloride is not added. After 30 minutes, the absorbance of the resulting solution was measured at a wavelength of 410 nm. Calculation of the quantitative content is carried out according to the standard method, in recalculation for routine.

Conclusions. The developed methodology for the analysis of the amount of flavonoids in the combined dental gel will be used further in the development of the registration dossier, in particular Module 3 "Quality control" for a new drug.

THE JUSTIFICATION OF APPROACHES TO RELATED SUBSTANCES CONTROL IN THE PHARMACEUTICAL TECHNOLOGY OF ACTIVE PHARMACUTICAL INGREDIENTS

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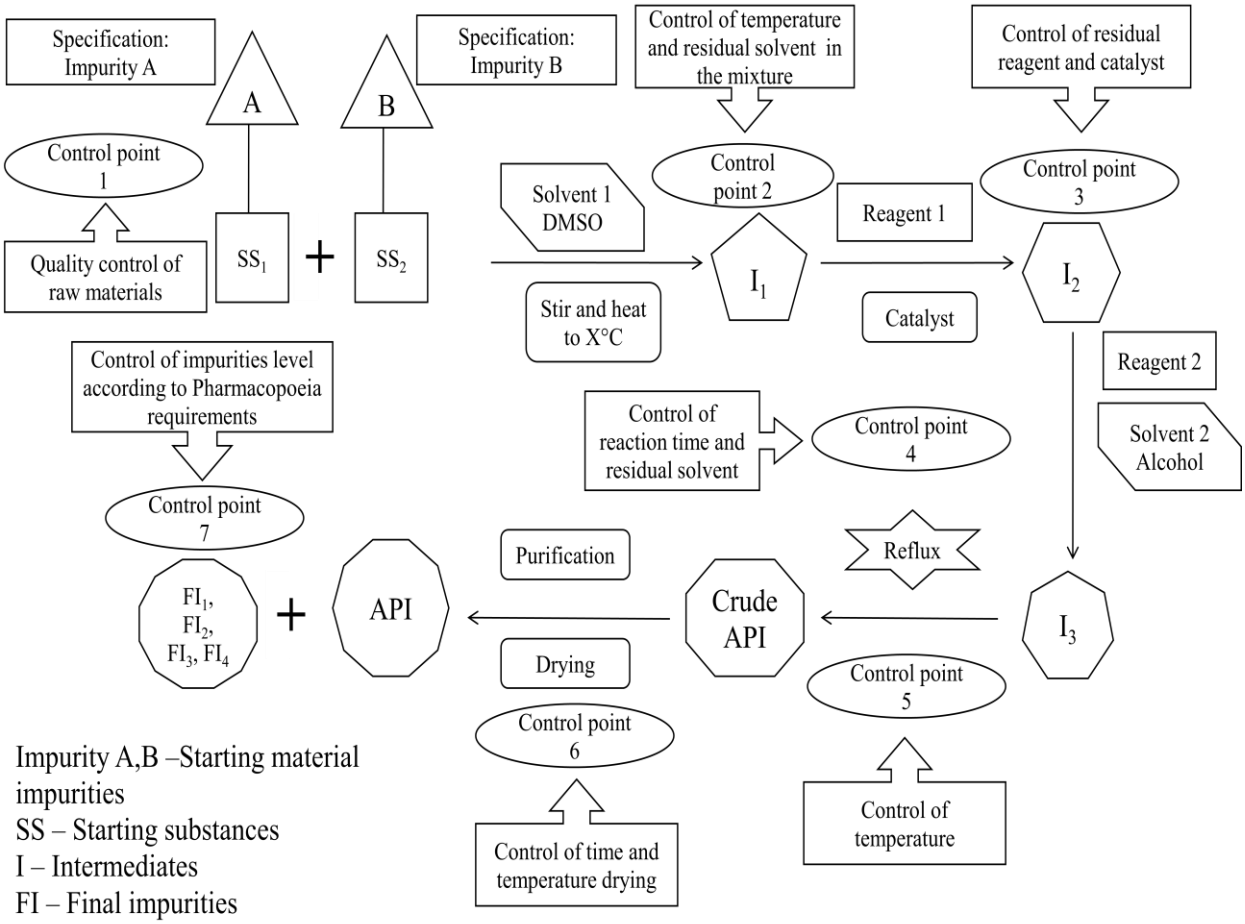
Introduction. The related substances are unwanted chemicals, which could be formed during production or storage active pharmaceutical ingredients (API). The presence of impurities in pharmaceutical products does not offer any therapeutic benefit for the patients and sometimes may influence the efficacy and safety of drugs. The control of impurities level is a currently critical issue to the pharmaceutical industry. Therefore they can be potentially toxic. The most common approach to control of related substances is analysis of end-product. With using process analytical technology (PAT) during production of substances an effective and comprehensive overall impurity control strategy can be developed to achieve the desired quality of API or drug.

Aim. Introduce the PAT for detection and determination of related substances, which can be produce during synthesis of API.

Materials and methods. Instead of controlling the impurities by exhaustive testing of the end-product, the PAT allows strategic and science based approaches to control impurities at various stages. Control points such as raw materials, technological and synthesis process, intermediates, solvents and following API or drug product quality controls are main points to potentially control the level impurities.

Results and discussion. For control of impurities we should clearly understand the ways of formation, their following fate and methods purge of the impurities during the manufacturing process, and as result set up appropriate controls at places where they can enter or form during the manufacturing process of API or drug product. All impurities which can contaminate product we can divided into three group: organic impurities(by-products, intermediates, degradation products, starting materials, reagents, ligands and catalysts), residual solvents (class I - solvents to be avoided, class II - solvents to be limited, class III - solvents with low toxic) and inorganic impurities (elemental impurities, heavy metals and other residual metals). We present the hypothetical PAT for manufacture API, that shown on the picture 1. As you can see from picture 1, we give a planned set of controls, derived from current



Pic. 1 Process analytical technology of produce active pharmaceutical ingredient (hypothetical)

product and process that include understanding that ensures process performance and product quality. Also set of controls should include parameters and attributes related to drug substance and drug product materials and components, facility and equipment operating conditions, in-process controls, finished product specifications and the associated methods and frequency of monitoring and control.

Conclusions. This work outlines the development of technology that can help to prevent contamination of API or medicine by impurities. Overall control strategy is based on knowledge of the types impurities and their potential source of emergence. The control of related substances by PAT has benefits for all members of pharmaceutical market. For patients: they get product of high quality. For regulators: a clear control strategy from the manufacturers provides transparency and added assurance that risk of impurity has been controlled. For pharmaceutical companies: a clear control strategy is identified which ultimately facilitates successful production of medicines.

MODELING OF DISSOLUTION KINETICS OF ANTIBIOTICS WITH MINERAL WATERS

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Introduction. In the face of an increasing number of medicines, the problem of their rational use is acute. This is relevant both for over-the-counter and prescription groups of drugs, since the wrong reception of the latter, even if properly prescribed by a doctor, can lead to serious consequences. Currently, the concept is adopted that all medicines must be washed down with water. However, there are a number