

11 times more calcium than carbonate. That is, if you have high acidity, then it is better to apply the crushed egg shell. If the acidity is lowered, it is better to quench the egg shell powder with lemon juice. A dose-dependent effect of the pharmacotherapeutic calcium activity is also noted. In low doses, this metal is absorbed better than in high doses.

Conclusion. Summing up the work done, the following conclusions should be noted.

1. The mixture obtained can be used to accelerate the healing of broken bones and to fill the calcium deficit. We recommend daily consumption of 3 teaspoons of the biopreparation obtained by maceration for 7 days.
2. The percentage of calcium ions from the eggshell assimilable with lemon juice is about 50 percent, therefore it is recommended to use lemon juice for obtaining the extract of the crushed shell. To improve the taste, you can add a few spoons of honey.
3. The stability of the extract is increased by pasteurization at 84-87°C for 5 minutes and conditioning in the refrigerator in a sterile, tightly closed container of dark color

APPROACHES TO STANDARDIZATION FLAVONOIDS IN THE COMPOSITION OF MEDICAL PREPARATION

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Introduction. Over the past decade, the pharmaceutical industry has undergone major changes aimed at increasing the requirements for consumer characteristics of medicines. Significantly increased and complicated complex of studies necessary for the evaluation of effectiveness, chronic toxicity, teratogenicity, carcinogenicity and other indicators of safety of the drug.

In the treatment of periodontal diseases, gels are often used. These drugs are presented in a wide variety, their cost is low and gels can be purchased without a prescription. But, like any other medicine, the gel for gums should be selected by the doctor after examination of the oral cavity, the detection of problems and the diagnosis. A gel for gums can be used both with pronounced symptoms of a disease, and for preventive purposes. Unlike ointments, the gel for treating inflamed gums more quickly penetrates into the focus of inflammation and at the same time it is more securely fixed on the mucous membrane of the oral cavity.

Anti-inflammatory gels for gums on the basis of the biologically active substances included in the complex is prescribed for periodontitis, stomatitis and gingivitis if patients have swelling and reddening of the oral mucosa, bleeding gums during cleaning, painful sensations, fever and itching.

Often in the composition of such gels are included synthetic medicinal substances with anti-inflammatory and antimicrobial activity. However, in addition to synthetic pharmaceutical substances, herbal medicinal components are widely used in dental practice. The combination of synthetic and herbal substances allows to expand the pharmacological activity of the drug.

Thus, when developing a new dental gel for the treatment of inflammatory periodontal diseases, it was suggested to use choline salicylate and tincture "Phytodent". Phytodent is a complex medicinal product containing active components of herbal origin, the main ones of which are flavonoids. Phytodent has antiseptic, fungicidal, anticholinesterase, reparative-trophic and haemostatic activity. In addition, the drug has a pronounced anti-inflammatory effect. Phytodent promotes rapid healing of various lesions of the oral mucosa, reduces the severity of pain and reduces the swelling of the mucous membrane.

Aim. The development of this dosage form requires subsequent standardization of active components. In this connection, there was a need to develop techniques for identification and quantification of the flavonoid complex that is part of this dosage form. The aim of this work was the development of methods for the analysis of flavonoids in a new dental gel.

Materials and methods. For identification the sum of flavonoids in dental gel we propose using the chemical reactions. The quantitative determination was carried out by ultraviolet and visible absorption spectrophotometry after the complexation reaction.

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