

uncertainty has two components: the uncertainty of the specific absorbance and the uncertainty associated with the deviation of the calibration curve from a directly proportional dependence. The figure 1 shows the calculated values of each component of the uncertainty of the quantitative of the spectrophotometric determination of riboflavin, prednisolone sodium phosphate, prednisolone and chloramphenicol in the substances by specific absorbance.

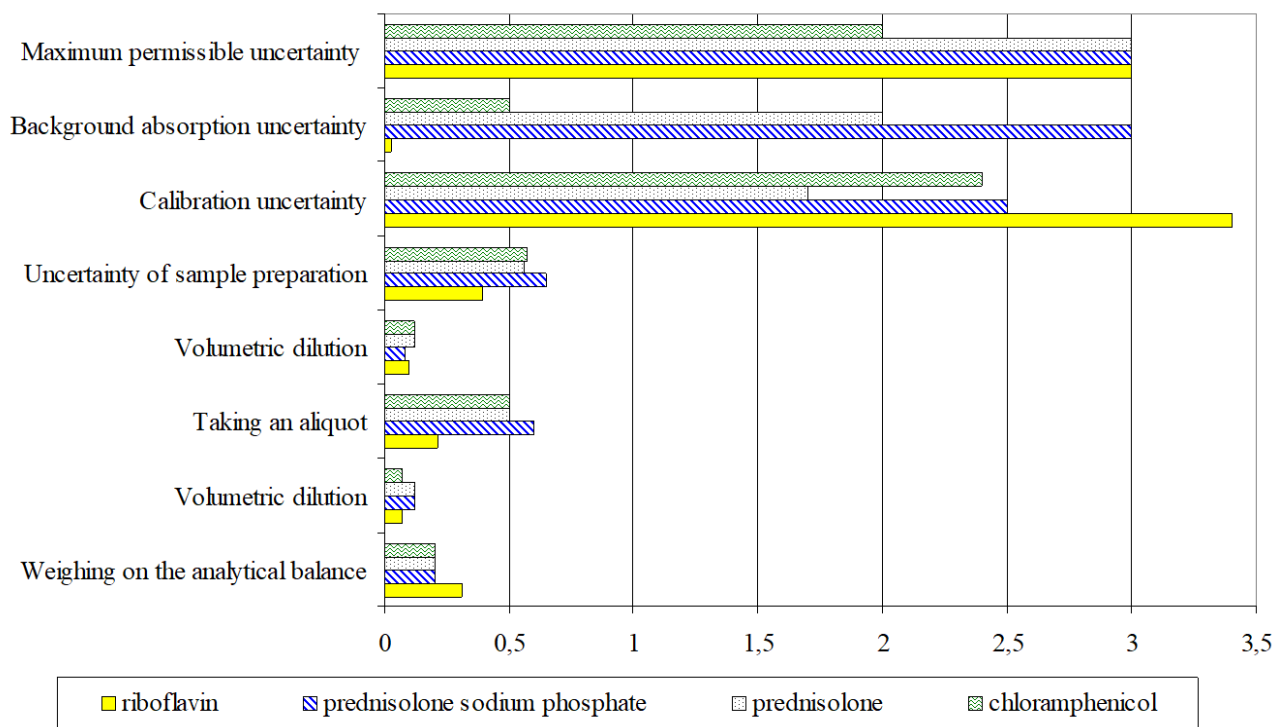


Figure 1. The results of a theoretical estimate of the total uncertainty of the spectrophotometric determination of riboflavin, prednisolone sodium phosphate, prednisolone and chloramphenicol in the substances by specific absorbance.

Conclusions. The main influence on the uncertainty of sample preparation is the uncertainty of the taking an aliquot. The requirements for the insignificant effect of impurities are satisfied only for the quantitative determination of riboflavin and chloramphenicol. The maximum influence on the value of the total uncertainty of the analysis results is due to the calibration uncertainty. The obtained results show that the uncertainty of graduation and background absorption cannot be insignificant in comparison with the uncertainty of the results of the analysis. In connection with the introduction in the pharmacopoeial articles on the substance of accurate chromatographic methods for controlling impurities, the main purpose of the section "Quantitative determination" is to prove that the content of the basic substance is not significantly different from 100%. Taking into account the results of the study, it is recommended to expand the tolerances of substance content in substances to 95%-105%.

STANDARTIZATION OF ACTIVE PHARMACEUTICAL INGREDIENTS IN COMBINED DOSAGE FORM

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Introduction. The developed drug is intended for application as a dry cough mixture - a multicomponent combination preparation with expectorant action. The quality control of the dosage form includes both the analysis of medicinal substances in its composition and the quality indicators that characterize the dosage form, taking into account modern requirements. Qualitative chemical evaluation covers identification and characterization of drugs with respect to phytochemical constituent. Critical is the need for appropriate analytical methods to determine identity, quality and relative effectiveness.

Aim. Carry out identification using chemical reactions and quantitative determination of the combined dosage form. Investigate stability during storage and develop quality standards for this dosage form.

Materials and Methods. The selection of methods of analysis was based on the results of experimental studies of test formulations, as well as studies of physical-chemical properties of their components, i.e. the active pharmaceutical ingredients and excipients. This covers screening, identification and assay of the active chemical components. Chemical analysis of the drug is done to assess the potency of chemical components with vegetable material in terms of its active principles. The chemical screening or tests may include color reaction test, which help to determine the identity of the drug substance and possible adulteration.

Results and discussions. Our study was based on physicochemical properties sodium hydrogen carbonate and sodium benzoate in combined dosage form, some published data, and preliminary results of stability in the course of time. The study included the selection of QC parameters, their valuation in the accordance with modern requirements for liquid dosage forms for oral administration, and development of QC methods.

Conclusions. Our studies resulted in the development of the optimal methods of QC of the combined dosage form that can be used in the development of a draft of normative documentation of this pharmaceutical composition. This draft documentation includes the following sections: description, identification, pH, microbiological purity, assay, packaging, labeling, storage, shelf life.

DEVELOPMENT OF THE METHODS TO CONTROL THE QUALITY OF NITROFURAL IN THE ALCOHOL SOLUTION

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Introduction. Today in Ukraine there is a reborn of the development of an extemporal medicines. The assortment of drugs of pharmaceutical manufacture is expanding, their composition and chemical analysis is improved. These dosage forms contain substances of various chemical groups, to separate, qualitative and quantitative determination of which requires fast, accessible and reliable methods of analysis. Therefore, intra-pharmacy control is one of the most important factors that determines the quality of drugs manufactured in a pharmacy.

One of the widely used medicinal substances is nitrofur. This synthetic antimicrobial agent of the nitrofur derivative group violates the formation of acetyl-CoA from pyruvic acid, namely energy metabolism and synthetic processes in the microbial cell. Suppresses growth and reproduction of staphylococci, streptococci, dysentery and E. coli, paratyphoid sticks, gas gangrene pathogens and other gram-positive and gram-negative microorganisms. It is used in such medicinal forms as tablets, ears drops, tablets for preparation a solution for external use, a alcohol solution for external use.

Aim. The purpose of the work is to develop methods for the identification and quantitative determination of nitrofur in medical form "a solution of furacilin 0.066% alcohol".

Materials and methods. Photoelectrocolorimetry «CMC-II», weighing «AXIS» ANG 200 (Poland), reagent's that meet SPhU and measuring vessel class A.

Results and discussion. To identify nitrofur in consisting of a medical form suggested to use a sensitive reaction to a molecule of a nitro group – a reaction with a solution of sodium hydroxide. This reaction became the basis for the development of photolorimetric method for quantitative determination of nitrofur in medical form. In addition, it is proposed in the solution to qualitatively and quantitatively determine ethanol. To identify the ethyl alcohol, the reaction with a solution of iodine in alkaline medium was used. Alcohol concentration was determined by refractometrically.

Conclusions. Thus, the developed reactions of identification and quantification determination allow the determination of both the active pharmaceutical ingredient of the medicinal product and the solvent.