

turned C-18 phase, Amiodaronum itself and two unidentified impurities discovered in the process of realization of research.

Application of Mass-selective detector allowed to bring down the threshold of finding out admixtures on 2-3 orders for analysable impurities and to define mass of molecular ion for unknown before impurities.

Validation of methodology was conducted in accordance with the requirements of European Pharmacopoeia.

Before realization of basic validation tests, we controlled the presence of documents, testifying to the fitness of the used equipment, raw material and reagents. Validation of methodology was conducted on separate validation descriptions: specificity, linearity, convergence, precision, rightness and intralaboratory precision. The got results statistically treated a Ordinary least squares (OLS) method in obedience to the requirements of Pharmacopoeia.

**Conclusions.** During research methodology of high-efficiency liquid chromatography is worked out with the gradient mode of elution and Mass-spectrometry detection.

1. It is set by us, that the chosen terms of chromatography allow not only in number to determine all potential impurities in the prepared medicinal form but also conduct their authentication.
2. Validation of the worked out methodology is conducted and her fitness is well-proven.

## **MODERN APPROACHES TO POLYPHENOL COMPLEX' ANALYSIS IN MEDICAL PREPARATION**

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**Introduction.** The development of modern medicine can prevent and cure many diseases. At the same time, the number of chronic diseases has increased significantly, the frequency of allergic and toxic events associated with the use of allopathic remedies has increased significantly. In search of new effective and safe drugs, clinicians and pharmacologists turn to medicinal plants.

Particular attention in terms of relevance in medical practice deserves polyphenolic compounds. Polyphenols of diverse structure have a multidirectional pharmacological effect on the human body. To date, their antioxidant, anti-inflammatory, adaptogenic, capillary-strengthening properties have been proven.

The general interest and the possibility of widespread use of polyphenolic compounds necessitates the search for their new inexpensive and affordable raw materials. However, along with these, undoubtedly, positive moments regarding polyphenolic compounds, there is one significant factor that requires comprehensive refinement, conducting studies on data stamping - these are approaches to the standardization of polyphenols. In particular, the development of methods for qualitative and quantitative determination, which makes it possible to standardize polyphenols in the medicinal plant raw materials, as well as in the medicinal products containing it.

For identification of polyphenols phosphomolybdic acid is used as a reagent for staining phenolic compounds in thin layers of sorbent. Polyphenols can be studied by spectroscopy, especially in the ultraviolet spectrum, by fractionation or paper chromatography. The main methods of determining polyphenols due to the presence in their structure is easy oxidising hydroxyl, as well as chromophore groups are spectroscopic, chromatographic, electrochemical and chemical. However, the basic methods of analysis of real objects containing polyphenolic compounds are chromatographic and chemical. Also is very interesting for determination of polyphenols is method of spectroscopy.

**Aim.** Study the possibility of analyzing the sum of polyphenolic compounds in a combined dosage form by spectrophotometry.

**Materials and methods.** The sum of polyphenols was determined spectrophotometrically by reaction with phosphomolybdotungstic reagent.

**Results and discussion.** One of the important steps in the development of a quantitative analysis of plant components is the correct choice of the standard, which further defines and calculates quantitative indicators.

To analyze the sum of polyphenols in a combination drug, we propose to use the blue complex formation reaction after interaction with the phosphor-molybdenum-tungsten reagent in a sodium bicarbonate solution. The absorbance of the resulting solution was measured after 30 minutes at a wavelength of 758 nm. Calculation of the quantitative content of polyphenolic compounds was carried out according to the standard method. As a standard, we propose to use pyrogallol.

**Conclusions.** The described technique will be worked out on experimental samples of a new dosage form, in the composition of which it is planned to introduce a plant tincture containing polyphenolic compounds as biologically active compounds exhibiting pharmacological action.

## CONFORMITY OF COMPOUNDED CAPTOPRIL AND SPIRONOLACTONE SUSPENSIONS TO PHARMACOPOEIAL REQUIREMENTS

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**Introduction.** Extemporaneous oral liquid preparations are widely used in pediatrics due to convenience in administering prescribed doses. Requirements for such compounded oral liquids, in this case suspensions, include physical, chemical and microbial stability during the period of use. Doses administered from extemporaneous oral liquid formulations are required to be within permitted limits to check under-dosing or overdosing of prescribed substances. In line with this reasoning the conceptualization and development of tools to measure and predict the behaviour of suspended particles gave birth to tests such as uniformity of administered doses and masses and particle size of suspended active pharmaceutical ingredients. Depending on the viscosity of the continuous phase, the particle size may be a determining factor in the uniformity of the delivered dose or mass. The microbiological stability of these extemporaneously prepared suspensions in liquid continuous phase and as a result of interactions between drug components in liquid phase and periodical exposure to air during use may be altered.

**Aim.** The purpose of this work was to ascertain the compliance of compounded suspensions of captopril and spironolactone to pharmacopoeial requirements

**Materials and methods.** 2.5mg/ml of captopril, prepared using pure substance as active ingredient; and 5mg/ml spironolactone compounded using pure substances and tablets separately as sources of active pharmaceutical ingredients; all suspended in simple syrup 85% v/v were prepared, stored in the dark for 30 days and subjected to viscosity, change in pH, uniformity of dose, delivered mass from multidose containers and microbial stability tests according to methods described in general chapters «2.2.3. Potentiometric determination of pH», «2.2.9. Capillary viscometer method», «2.9.40 Criteria for uniformity of dosage units», «2.9.27. Uniformity of mass of delivered doses from multidose containers» and «2.6.12. Microbiological examination of non-sterile products: microbial enumeration tests» of the European pharmacopoeia. A drop from compounded samples each was examined under a microscope. UV spectroscopy and titrimetry were used to quantify our analytes.

**Results and Discussion.** The pH ( $\pm 5\%$ ) and viscosity ( $\pm 1\%$ ) values over the period of storage were within limits. Withdrawn and measured doses and masses were within their respective limits ( $\leq 15\%$ ,  $\leq 10\%$ ). The total aerobic microbial and yeast counts were also within permitted limits. Results of microscopic examination of samples show a relatively homogeneous mixture with the largest particle size  $\leq 50$  micrometres.

**Conclusion.** Compounded suspensions of captopril and spironolactone comply with pharmacopoeial requirements. The preparations were stable for 30 days.