SELECTION OF THE OPTIMAL CONDITIONS FOR THE QUALITATIVE ANALYSIS OF SESQUITERPENE LACTONES AND INULIN IN THE MEDICINAL PLANT RAW MATERIAL OF ELECAMPANE BY THIN-LAYER CHROMATOGRAPHY

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Introduction. Rhizomes with roots of elecampane (*Inula helenium* L.) are one of the types of the medicinal plant raw material (MPRM), which is quite common on the territory of Ukraine and has a broad spectrum of the pharmacological action. The MPRM and medicines on its basis are used as expectorants, anti-inflammatory, antimicrobial, antibacterial, antifungal, and antiulcer agents. The main classes of biologically active substances (BAS) of rhizomes with roots of elecampane providing the therapeutic effect are represented by polysaccharides (inulin – up to 44 %, pseudo-inulin, inulenin), essential oil (up to 4.3 %) with bicyclic sesquiterpene lactones (mainly alantolactone and isoalantolactone), proazulen and α-tocopherol in its composition; there are also resins, gum, traces of alkaloids, organic acids, etc.

The requirements for quality of MPRM of elecampane are given in the State Pharmacopoeia of the USSR (SP XI), the State Pharmacopoeia of the Republic of Belarus, the Pharmacopoeia of the Republic of Kazakhstan, the French Pharmacopoeia and the British Herbal Pharmacopoeia (BHP). However, none of them contains methods for the qualitative and quantitative determination by the main classes of BAS – sesquiterpene lactones and polysaccharides. There are also no corresponding normative documents in the State Pharmacopeia of Ukraine (SPhU).

In the SPhU it is recommended to identify MPRM by chromatographic methods, including the method of thin-layer chromatography (TLC), in relation to reference substances (markers).

Aim. To select the optimal conditions for the qualitative analysis of sesquiterpene lactones (dihydroalantolactone, isoalantolactone, dihydroisoalantolactone) and inulin in MPRM of elecampane by TLC.

Materials and methods. In the study eleven samples of crushed rhizomes and roots of elecampane were used. The TLC analysis was carried out after acid hydrolysis of the MPRM powder using such markers as D-fructose and D-glucose, the structural polysaccharide components. Sesquiterpene lactones were studied in the essential oil after steam distillation by such markers as isoalantolactone, dihydroalantolactone and dihydroisoalantolactone.

Results and discussion. The most optimal conditions for detection of fructose and glucose in the composition of inulin are elution in the mobile phase of *acetic acid R – chloroform R – water R* (70:60:10) and detection with diphenylamine-aniline-phosphate reagent (allows performing differentiation of sugars differing in the type of the glycosidic bond). For the quantitative analysis of sesquiterpene lactones (isoalantolactone, dihydroalantolactone and dihydroisoalantolactone) it is advisable to use the mobile phase of *ethyl acetate R – toluene R* (5:95), and to carry out the identification with the solution of *anisic aldehyde R.*

Conclusions. In the given conditions the effective separation is achieved, and specificity of BAS detection in MPRM of elecampane is provided.

INVESTIGATION OF STAVUDINE BEHAVIOUR AT THE PRESENCE OF SOME STRUCTURAL ANALOGUES IN THIN LAYERS OF SORBENT

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Introduction. Problem of creation of new drugs faces to various stages – from stage of synthesis untill stage of consumption. And from this point of view a class of antiviral drugs is very important as from its necessity as from its effectiveness. Despite 50 years of research, our arsenal of antiviral drugs remains

dangerously small. For example, only about 50 antiviral drugs are available on the ukrainian doctors' arsenal - most against herpesviruses - persistent infections and influenca. Antiviral therapy at the present time is a well-organized discipline with a promising future. Based on economic, scientific, medical and pharmaceutical interests as well as the constant need for new drugs to avoid resistance, it is most likely that the development of antiviral drugs over the next 20 years will focus on the development of tools that will be effective in HIV prevention and treatment. It consequently requires optimizing of the existed methods of analysis for antiretrovirals and elaboration of the new ones. To solve this task were put following aims: To investigate possibilities of thin layer chromatography (TLC) for analysis of stavudine and its structural analogues; to elaborate conditions for TLC identification of stavudine at the simultaneous presence of its some structural analogues.

Materials and methods. For evaluating investigations were used systems of solvents of neutral and alkaline character; TLC plates of two types and three compounds with similar to stavudine structure. Chromatographic behavior of stavudine and some structural analogues from the group of xanthines, and plates for thin-layer chromatography were used; besides, composition of system of solvents has been chosen and taken according to TIAFT requirements and propositions.

Results and discussion. As it has been stated, the proposed conditions for chromatographic identification and separation technique for stavudine at the simultaneous presence of structural analogues allows carrying out not only separation but step-by step identification of the investigated substances on the TLC plates. The most sufficient system for identification of the investigated compounds is system of alkaline character, because here all the compounds have Rf in the range between 0.2 and 0.8. Besides, this system is also appropriate for separation stavudine from its structural analogues, because difference between the closest Rf >0.1

Conclusions. As it follows from the conducted researches and from the data can be applied in practice for separation, identification of stavudine at the simultaneous researches with some structural analogues.

DEVELOPMENT OF METHOD LC-MC FOR DETERMINATION IMPURITIES IN INJECTION SOLUTIONS OF AMIODARONUM

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Introduction. The methods of high performance liquid chromatography (HPLC) of determination of impurities are presently worked out both for the substance of Amiodaronum (monograph of the European pharmacopoeia) and for the prepared medicinal forms. However the existent methods of finding out the impurities of Amiodaronum are mainly intended for control of by-products of synthesis of Amiodaronum and does not allow to control being products degradations of substance to the impurities, especially on the initial stages of process. It does practically impossible using of well-known methodologies of determination of impurities for control of stability of the prepared medicinal forms of Amiodaronum.

Aim. Using of chromatographic methodology to determine impurities on principle of Mass-spectrometry discovery in injection solutions of Amiodaronum. Such approach allows not only to find out the subzero concentrations of the determined substances - at the level of billion stakes but also identify the structure of these substances.

Materials and methods. For realization of the described approach, measuring conducted the method of high-efficiency liquid chromatography in obedience to European Pharmacopoeia, 1, 2.2.29, N, using a next equipment: chromatograph of Agilent 1290 with a diode-array detector and Mass-selective by the time-of-flight detector of Agilent 6530 (THE USA). Also used a gravimetric equipment ER are 182 firms AND Japan and measure tableware of A class.

Results and discussion. With the use of the described equipment by us was worked out HPLC methodology of gradient elution, allowing to divide all identified impurities of Amiodaronum into the