

Soloviev A.S.

State Administration of Ukraine on medicinal products

**Role of the State Pharmacopoeia in the general system of providing the population of Ukraine with drugs and they quality control**

The role of the State Pharmacopoeia in ensuring of the quality of drugs in Ukraine was outlined. A need in introduction of international standards and requirements for reforming the pharmaceutical industry of Ukraine was shown.

Gryzodub A.I., Evtifeeva O.A., Proskurina K.I.

*Pharmacopoeial center of Ukraine*

*National University of Pharmacy, Ukraine*

**Characteristics of pharmacopoeial approaches to quantifying of raw herbal drugs and combined herbal drugs**

A systematic analysis of the various approaches for the quantitative determination of raw hebal drugs and combined herbal drugs of the State Pharmacopoeia of Ukraine was conducted. Advantages and disadvantages of different approaches were examined. It was shown that the most reliable means of standardization were the assaying of conditional concentration by spectrophotometry and control signal components by chromatographic methods.

Kotov A.G.

*Pharmacopoeial center of Ukraine*

**Study on the development and introduction of monographs on herbal drugs and tinctures on this basis to the State Pharmacopoeia of Ukraine**

Data on the development and introduction to SPU 1.3-1.4 of 59 monographs on herbal drugs and 12 tinctures have been generalized. It was shown that on the basis of «Order of the development of monographs on herbal drugs» has been possible to develop a modern monographs on herbal drugs. It was concluded that an implementation of standardized methods for control of raw herbal drugs and preparations on this basis would lead to the improvement of their quality.

Chikalova S.O., Grizodub A.I.

*Pharmacopoeial center of Ukraine*

**Acceptance criteria of quality control data of substances using titration**

An estimation of the uncertainty of titration (the most frequently used method for the quantitative determination of pharmacopoeial substances) has been performed. The estimation was made using a generalized approach: the components of uncertainty were divided into two groups: those that contributed to the experimentally observed variability of the input variables and the ones that did not contribute to the experimentally observed variability of the input. According to the results of the assessment eligibility criteria for the convergence of the results in the performance of routine testing by titration were set. Acceptance criteria of glass burettes Class A and piston burettes (ISO 8655-3) for different titration were determined.

Tikhonova S.A., Tikhonov A.I., Gryzodub A.I., Yuryeva A.B., Gaidukova E.A., Tovmasyan E.K., Skrypnyk-Tikhonov R.I.

*Pharmacopoeial center of Ukraine*

*National University of Pharmacy, Ukraine*

**Proposals for projects of general monographs of the State Pharmacopoeia of Ukraine «Pillules for homeopathic preparations» and “Homeopathic pillules, impregnated»**

The analysis of the general monographs of the European Pharmacopoeia «Pillules for homeopathic preparations» and «Homeopathic pillules, impregnated» has been conducted and the relevant drafts of general monographs for SPU has been developed. Scientific studies proved an introduction into the drafts monographs of national requirements.

Koshovoy O.N.

*National University of Pharmacy, Ukraine*

### **Terpenoidic composition of eucalyptus leaves from different regions of the World**

The qualitative composition and quantitative content of terpenoids in 9 samples eucalyptus leaves, collected in different regions of the World, have been studied. In the essential oils from these leaves the dominant substances were 1,8-cineole (except leaves collected in Georgia), -pinene, globulol, *trans*-pinocarveol, -eudesmol, *p*-cymen, aromadendrene and viridiflorol. In general, in studied samples 95 substances have been identified. The conformity of the studied material to the requirements of the State Pharmacopoeia of Ukraine have been estimated.

Upyr T.V., Komisarenko N.A., Kovaleva A.M., Koshovoy O.N.

*National University of Pharmacy, Ukraine*

### **Isoprenoidic composition of alcoholic extract of *Ledum palustre* L. sprouts**

Qualitative and quantitative content of terpenoids in alcoholic extract of *Ledum palustre* L. sprouts have been studied by gas chromatography. 41 substances have been isolated, 17 of them have been identified. Chlorophylls *a* and *b* have been identified by TLC in comparison with authentic samples; the content of chlorophylls *a* and *b* has been determined by spectrophotometry.

Lyapunov N.A., Purtov A.V., Dunay E.V.

*State Scientific Center of Drug and Medical Products*

“Universal agency “Pro-Pharma”” LTD

### **Optimization of properties of cationic antiseptic solutions for external use as a pharmaceutical form**

The effect of sodium chloride, disodium edetate (DSE), phenoxyethanol (PE) and ethanol on the critical micelle concentration (CMC) and the surface-active properties of solutions of some cationic surface-active agents (surfactants) investigated. It is shown that sodium chloride, DSE and PV reduce CMC of cationic surfactants and the surface tension of their aqueous solutions at low concentrations, significant for antiseptic drugs, and that enhance their ability to wetting and spreading. At certain concentrations of ethanol cationic surfactants do not form micelles and do not affect the surface tension of solutions, which depends only on the content of ethanol. Addition of ethanol (10-30 %) and sodium chloride (0.9 %) to a solutions of benzalkonium chloride did not affect the diameters of growth inhibition zones of *Pseudomonas aeruginosa* ATCC 9027, and the introduction of DSE (0.5 %) and PE (0.5 %) resulted to a significant increase in the diameters of the growth inhibition zones of test-microorganism.. The results of the studies were used in the development of drugs Virotek Intim solution 0.02 % and Virotek Clinic solution 0.05 %. The possibility of application of the product Virotek Clinic solution 0.05 % for application to the skin and the wound in the form of a spray. By laser diffraction method it is shown that the particle size distribution in the aerosol jet is characterized by a Gaussian curve with a mean particle diameter of about 40 microns, and the absence of particles with sizes less than 10 microns, which are unacceptable respirable fraction.

Mazur I.A., Belenichev I.F., Kucherenko L.I. Bukhtiyarova N.V., Georgievsky G.V., Pavlyuk I.V., Steblyuk V.S.

*State medical university, Zaporozhiye*

*SMO “Pharmatron”*

### **Approaches to the design and development of metabolitotropic drugs (derivatives of 1,2,4-triazole)**

Based on experimental and clinical data for thiotriazoline and combined dosage forms the structural fragments of molecules, which could have an impact on the presence and the manifestation of anti-ischemic, anti-inflammatory, antioxidant, neuroprotective, cardioprotective, energotropic effects have been identified; this allowed the SPA «Farmatron» to synthesize a new

substance based on 1,2, 4-triazole with the working name «Lyziniy» was found to be a metabolitotropic drugs, it demonstrated cardioprotective effects with the significant impact on the vascular endothelium of a myocardium. The lysine dosage forms (injection and oral dosage forms) have been developed.

Zinchenko A.A.

*Pharmacopoeial center of Ukraine*

**Determination of squalene in vegetable oils by gas chromatography**

Three options for gas chromatographic methods of qualitative and quantitative determination of squalene in vegetable oils without prior separation of unsaponifiable residue were developed; metrological characteristics of these methods were studied. It was shown that the presence of vegetable oils of high boiling compounds such as triglycerides of fatty acids affected to the metrological characteristics of the methods and did not allow the quantification of capillary columns with conventional wiring diagram. A pneumatic scheme with reverse blowing of the primary part of the chromatographic column in which the influence of triglycerides on the metrological characteristics of the method was minimized has been proposed.

Zinchenko A.A., Bobrova M.E., Andryushchenko T.L., Zinchenko I.A.

*Pharmacopoeial center of Ukraine*

*State Scientific Center of Drug and Medical Products*

**Determination of the concentration of Amlodipine by spectrofluorimetry in the dissolution mediums at the quality control of tablets according to the characteristic Dissolution**

A method of the determination of the concentration of Amlodipine in solutions within the control Amlodipine, tablets, according to the characteristic Dissolution by spectrofluorimetry was developed and studies of this metrological characteristics were conducted. Validation data's of the method have been studied in the range of 1 µg/ml to 13 µg/ml. It was shown that spectrofluorimetry could be used for quality control of dosage forms of Amlodipine.

Nikitina N.S., Deeva T.V., Gubar T.V., Somova Ya.V.

*State Scientific Center of Drug and Medical Products*

**Comparative study of the local irritating drug Valiskin**

At the comparative study of local irritating effect of an ointment Valiskin, manufactured by Phytopharm, Ukraine, and an ointment Desitin, manufactured by Pfizer Ink., USA. It has been found that Desitin and Valiskin did not possess local irritating effect.

Manskiy O.A., Filimonova N.I. Sayko I.V., Ribachuk V.D., Heyderikh O.G

*National University of Pharmacy, Ukraine*

**Therapeutic activity of irradiated samples of streptomycin sulphate in experimental purulent infection**

Data of the treatment of localized and generalized purulent-inflammatory infection by streptomycin sulphate, treated by γ-irradiation, were given.

Posilkina O.V., Khromikh A.G.

*National University of Pharmacy, Ukraine*

**Development of integrated logistics chains for insurance of the quality of biotech drugs in the management of their supply**

An expediency of the development of integrated logistics chains for the insurance of the quality of biotech drugs in the management of their supply was based. A definition of the nature of «cold chain» logistics in managing the supply of biotech drugs was improved.

Popova N.V., Dikhtyarev S.I., Litvinenko V.I.

*National University of Pharmacy, Ukraine*

*State Scientific Center of Drug and Medical Products*

**Inhibitors of an aromatase in the treatment of breast cancer. Future of the development of drugs of natural origin**

An analysis of the literature on the study of the potential antitumor activity of synthetic and natural plants' phenolic compounds in the treatment of breast cancer by inhibiting the enzyme aromatase has been conducted. A future of a drug of natural origin on the basis of certain groups of phenolic compounds was shown.