Use of enzymes in the pharmacopoeial test «Dissolution» for solid dosage forms

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The current pharmacopoeial practice of the use of enzymes at the dissolution test of solid dosage forms (capsules and coated tablets) has been examined. An importance and practice of implementation of specific Guidance on the use of enzymes in accordance with the USP article <711> "Dissolution" have been discussed; narrow points of this unharmonized with the European Pharmacopoeia part of the USP article have been demonstrated. Studies of the American Pharmacopoeia specialists on improvement of this requirement have been presented. The attention of users of the State Pharmacopoeia of Ukraine (SPU) has been focused on this problem; a possibility of introducing to the relevant SPU article of some national standardization requirements for the conditions of the performing of the test «Disolution» with the use of enzymes has been determined.

Key words: test «Dissolution», enzymes, standardization, solid dosage forms.

Metter of introduction to the State Pharmacopoeia of Ukraine of monograph «Melilot»

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A comparative analysis of approaches to standardization of herbal drug of melilot has been conducted. The necessity to introduce into the national part two species of melilot (*Melilotus officinalis* (L.) Pall. and *Melilotus altissimus* Thuill.) at the development the SPU monograph has been demonstrated. Based on the analysis of samples of herbal drugs have been developed sections «Macroscopy» and «Microscopy», validated spectrophotometric method for the quantification of the content of coumarins in herbal drugs. The SPU draft monograph «Melilot» with relevant national part has been developed.

Key words: Stale Pharmacopoeia of Ukraine, *Melilotus Thuill*, herbal drugs, standardization.

Quantitative determination of polysaccharides of leaves, seeds, flowers and roots of *Plantago major* L. and *Plantago lanceolata* L.

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The quantitative content of water-soluble polysaccharides in leaves, flowers, seeds and roots of Plantago major L. and Plantago lanceolata L. Differences in the content of in Plantago major L. and Plantago lanceolata L. have been determined.

Key words: Plantago major L., Plantago lanceolata L., polysaccharides.

Amino acid composition of herb and lyophylic extract of *Inula helenium* L.

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By HPLC in the herb and lyophylic extract of Inula helenium L. has been established the presence of up to 17 amino acids, 7 of which were essential. The largest content of plant protein and free amino acids were determined in I. helenium lyophylic extract (to 13.59 ± 1.32 per cent and 2.00 ± 0.18 per cent, respectively). I. helenium herb has been found to be promising for obtaining of soluble herbal drugs with anti-inflammatory and hepatoprotective effects.

Key word: Inula helenium L., lyophylic extract, amino acids, high performance liquid chromatography.

Chromato-mass-spectrometric study of volatile compounds of hawthorn flowers of *Oxyacantae Loud.*

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By chromato-mass spectrometery, a comparative study of volatile compounds of flowers of *Crataegus subrotunda Klok*. and *Crataegus turkestanica A. Pojark*. of *Oxyacanthae Loud*. has been performed. The terpenoide content in the flowers in the relation to the total substances content connections has been determined (9.3 per cent for C. subrotunda Klok.; 20.2 per cent for C. turkestanica A. Pojark.). Dominant terpenoide compounds for C. subrotunda Klok. were squalene (84.7 per cent) and -terpineol (9.5 per cent); for C. turkestanica A. Pojark. - linalool (27.2 per cent), squalene (20.3 per cent), α-terpineol (17.2 per cent) and geraniol (9.5 per cent).

Key words: chromato-mass-spectrometry, volatile compounds, Crataegus subrotunda Klok., Crataegus turkestanica A. Pojark.

Rationale of the synthesis direction and bringing of the chemical structure of 1-(-phenylethyl)-4-amino-1,2,4-thriazolium bromide

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A direction of synthesis has been grounded; the chemical structure of the new drug substance 1-(β-phenylethyl)-4- amino-1,2,4-thriazolium bromide has been proved. Direction of synthesis reaction has been bringing in accordance with calculations of the energy and geometric characteristics of the reactants and possible transition states of the molecule. The structure of the synthesized substance has been proved with the complex physical and chemical methods (UV-, IR- and NMRspectroscopy, HPLC, TLC, chromato-mass-spectroscopy, potentiometry and X-ray diffraction method).

Key words: synthesis, chemical structure, 1-(β-phenylethyl)-4-amino-1,2,4-thriazolium bromide, physical-chemical methods.

Medical and biological indices of eye drops: assurance of an osmolarity in the pharmaceutical development of drugs

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At the example of eye drops with active substances of different chemical nature and different pharmaco-therapeutic effects, approaches to optimal values of an osmolarity of ophthalmic solutions according to their therapeutic use and comfortable to the eye limits the application of values of the osmolarity have been demonstrated. Using theoretical calculation and experimental measurement of the osmolarity of eye drops, the contribution of active substances and excipients to the osmolarity eye drops according to their physico-chemical properties has been evaluated. It was shown that the main contribution to the osmolarity of the drug has been provided by buffer components. Experimentally obtained data of osmolality of the studied eye drops confirmed the correctness of theoretical calculations and applied approaches.

Key words: dosage form, eye drops, osmolarity, pharmaceutical development, quality index.

Determination of squalene in vegetable oils by high performance liquid chromatography

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Development has been performed and metrological characteristics of qualitative and quantitative determination of squalene in vegetable oils by HPLC without prior isolation of an unsaponifiable residue have been studied. It was shown that the main validation indices of method satisfied the requirements of the SPU.

Key words: squalene, vegetable oils, high performance liquid chromatography, validation, metrological characteristics, State Pharmacopoeia of Ukrane.

Validation of refractometric quantitative determination of series of concentrated solutions of pharmaceutical preparation

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For the first time a validation of techniques of refractometric assay for a series of concentrated solutions of pharmaceutical preparation and evaluation of alterations of the factor of increase the refractive index within a range of application of techniques have been conducted. According to obtained data, an application of refractometry in a pharmacy for the quality control of concentrated aqueous solutions up to modern standards has been found to be possible at conditions if extension of the active substance content tolerances to ± 10.00 per cent or increasing requirements for instrumentation and permissible error of measurement of the refractive index (not less than nD = ± 1.0 × 10-4).

Key words: refractometry, concentrated solutions, pharmaceutical preparation, assay, validation.

Morphological characteristic of adaptogenic effect of rhodiola liquid extract and aspen bark extract on a model of immobilization stress

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At rats on a model of chronic immobilization stress (15 days, 16 hours daily) aspen bark extract (1 mg / kg in the stomach during the period of immobilization) revealed cardio protective effect, prevented the development of dystrophy and focus of necrosis of the cardiac muscle, reduced dysfunction of microcirculation vessels, provided endothelial protective effect and reduced destructive changes in skeletal muscle fibers, promoted proliferation of miosatelitocites and hypertrophy of muscle fibers. According to the expressiveness of the protective effect on the heart and skeletal muscles aspen bark extract did not yield to classical phyto-adaptogen (rhodiola liquid extract (1 ml/kg with a similar mode of administration)).

Key words: immobilization stress, histostructure of miocard and skeletal muscles, aspen bark extract, rhodiola liquid extract.

Antioxidant profile of the new plant drug - a study on in vitro model systems

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Data on the study of antioxidant (antisuperoxidizing, antiradical, chelating) effect of complex tincture using in vitro methods. The assumption on the mechanism of antioxidant effect, implemented through the participation of biologically active compounds, including phenolic compounds in Fe2+binding ions, inhibiting the formation of OH- hydroxyl radical and $1O_2^-$ superoxide anion radical has been put forward.

Key words: methods in vitro, antioxidant effect, phonolic compounds, complex tincture.

The influence spirocyclic oxindolic derivative on parameters of the energy metabolism at experimental cerebral ischemia

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Data of the impact of spirocyclic oxindolic derivative at the dose of 5 mg/kg on cerebral energy metabolism in acute cerebral ischemia have been presented. It was found that the new compound prevented the development of energy deficit at disease model, increased ATP level, reduced the accumulation of ADP, and normalized the activity of respiratory chain enzymes. As for the effect on rates of energy metabolism, studied compound significantly exceeded the activity of the drug in comparison of Mexidol at the dose of 100 mg/kg. Obtained data indicated to the

feasibility of further pharmacological study of a new substance for the development of a new antihypoxic drug with the metabolic effects.
Key words: spirocyclic oxindolic derivative, energy metabolism, pharmacological study.

Preclinical studies of zirconium dioxide ceramics at the base of for cytotoxicity and biocompatibility
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Zirconium dioxide ceramics was found to be a promising material for stomatology, traumatology and orthopedics. Given study evaluated the cytotoxicity and biocompatibility of synthesized in SRU "BelSU" zirconium dioxide powder. Despite the fact that in vitro studies could not be directly transferred to the conditions in vivo, the substance could be used in clinical practice.
Key words: preclinical studies, cytotoxicity, biocompatibility, ceramics, zirconium dioxide.

Components of risks management in the modern pharmacy
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An actuality of a study risks in pharmacy, as well as the feasibility and importance of using risk-management system in the business have been demonstrated. A number of risks due to specific industry characteristics of the product itself and its consumption that occurred most often in the pharmacy or had features of consequences of risks have been revealed.
Key words: pharmacy, risks, management, quality.