Development of a national system of standard samples of drugs in Ukraine

Leontiev D.A.
Pharmacopoeial center of Ukraine

Matter of the development of a system of pharmaceutical reference samples (RS) in Ukraine was studied. The most important task was to create a formal system of pharmacopoeial RS. This required the development of theoretical bases of the assessment of RS, the development of requirements to the maximum acceptable uncertainty of data of an analysis for the major pharmaceutical trials and tests (which, i. a., defines the requirements for the attestation of RS), the development of the attestation procedures for RS and system documentation. Developed approaches have been successfully applied to a system of local (secondary) RS of pharmaceutical companies, to the attestation of RS for the Programs for proficiency testing of laboratories,to the validation and to the equipment qualification. It was shown that in the present Ukraine was the only UIC countries in which all kinds of pharmaceutical RS were national. Currently, PSS of the SPU were widely used by most drug manufacturers of UIC countries, control laboratories, as well as in pre-registration studies.

Proficiency Testing Scheme in the pharmaceutical industry in Ukraine: features and prospects

Dmitrieva M.V.
Pharmacopoeial center of Ukraine

Features of the Proficiency Testing Scheme (PTS) of quality control laboratories of drugs in the pharmaceutical industry in Ukraine were examined. Approaches to the evaluation of test samples and evaluation data provided by participants were described. An attention was paid to the data obtained using PTS as an interlaboratory experiment.

Monographs on the preparations of the State Pharmacopoeia of Ukraine: history and development Strategy

Tovmasyan E.K., Krupa N.A., Matvienko T.N., Yudina I.I, Komarova Yu.A., Grizodub A.I.
Pharmacopoeial center of Ukraine

Analysis of the monographs for preparations introduced into a 1st edition of the SPU was conducted. Data on the cooperation on some questions concerning the SPU monographs with the USP were presented. Prospects and problems of development of monographs on preparations raised in the process of development of the SPU 2nd edition were discussed. The developed to introduce preparations in the 2nd edition of the New draft monographs on preparations for the SPU 2nd edition were given. The standard operating procedure of verification of analytical methods of quality control of drugs in research laboratories was discussed.

Study of amino acid and monosaccharide composition of alcoholic extract of *Eucalyptus viminalis Labill.* Leaves

Koshevoy O.N., Zaitsev G.P., Kovaleva A.M., Komissarenko A.N.
National University of Pharmacy, Ukraine

Amino acid and monosaccharide composition of alcoholic extract of Eucalyptus viminalis leaves were studied. 15 free and 14 bounded amino acids, 9 of which are essential (threonine, valine, methionine, isoleucine, leucine, phenylalanine, histidine, lysine and arginine) and 4 monosaccharides (glucose, galactose, arabinose and ramnoza) have been identified. In alcohol extract of Eucalyptus viminalis leaves the content of free ((0.21 ± 0.04) per cent) and bounded amino acids ((0.24 ± 0.02) per cent) and monosaccharides (1.54 ± 0.05) per cent) have been established; it has been demonstrated that content of monosaccharides increased after hydrolysis up to (3.87 ± 0.07) per cent.

Study of phenolic compounds of alcoholic extract of *Arctostaphylos uva-ursi* (L.) Spreng. Leaves

Komissarenko N.A., Geiderikh A.S., Kovaleva A.M., Koshevoy O.N.
National University of Pharmacy, Ukraine
The composition of phenolic compounds of alcoholic extract of *Arctostaphylos uva-ursi* (L.) Spreng. leaves has been studied. Particularly, arbutin, 3 phenolic acids (gallic, ellagic and protokatekhinic acids), hydroxycinnamic acids (chlorogenic and cumaric acids), 4 coumarins, 3 flavonoid aglicones (quercetin, luteolin and kaempferol), gallo- and ellagotannins have been identified and their structure have been determined. The content of hydroxycinnamic acid derivatives ((1.66 ± 0.02) per cent), arbutin ((12.08 ± 0.02) per cent), flavonoids ((4.76 ± 0.01) per cent) and of the sum of phenolic compounds ((17.14 ± 0.02) per cent) in dense alcohol extract of Arctostaphylos uvaursi leaves has been determined. These data would be used for further standardization of Arctostaphylos uva-ursi leaves.

Isoprenoid composition of alcoholic extract of Lavandula angustifolia Mill. Herb
Geyderih A.S., Upir T.V., Komissarenko A.N., Koshevoj O.N.
National University of Pharmacy, Ukraine
Qualitative and quantitative composition of terpenes in the soft alcoholic extract of Lavandula angustifolia Mill. herb was studied by the gas chromatography. In the first extraction 54 substances have been revealed; 27 substances have been identified. In the second extraction 46 substances have been revealed; 22 substances have been identified. In soft extract 59 substances have been revealed; 29 substances have been identified. TLC comparison with authentic samples of the extract allowed to identify a and b chlorophylls and their quantitative content have been determined by spectrophotometry.

Chromatography-mass spectrometric study of nimesulide
Yurchenko I.A., Buryak V.P., Kahanovsky F.M.
State medical university, Zaporojiye
"Central Bureau of Forensic" Ministry of health of Ukraine The identification of non-steroidal anti-inflammatory drug nimesulide after separating it from the biological material by gas chromatography-mass spectrometry has been studied.

Theoretical estimate of the total uncertainty of refractometric methods of quantification and influencing factors analysis
Evtifeyeva O.A., Proskurina K.I., Zdoryk O.A., Prisich A.G.
National University of Pharmacy, Ukraine
Systematic discussion of influencing factors on data of refractometric quantitative analysis was conducted. The theoretical prediction of complete uncertainty of refractometric analysis data for the most used in pharmaceutical formulations water solutions of different concentrations (from 3.00 per cent to 40.00 per cent), provided the use of refractometers with different measurement error, was conducted for a first time. Depending on the measurement error of the refractometric equipment with the prediction of the complete uncertainty for solutions with concentrations of 5.00 per cent, ≤ 5.00 per cent and ≥ 5.00 per cent, tolerances of content for which it was possible to obtain reliable test results have been determined.

Determination of some quality indices of Climedex, Pessaries
Levachkova Yu.V, Yarnykh T.G., Chushenko V.M.
National University of Pharmacy, Ukraine
The conformity of developed pessaries Climedex to the SPU requirements for the following indicators: description, identification, pH, uniformity, average weight, microbiological purity, assay of active ingredients was studied. Based on conducted studies, methods of control, allowing both the identification and quantification of active ingredients (metronidazole, clindamycin phosphate, fluconazole and dexamethasone sodium phosphate) in the pessaries by

HPLC were developed. Also, the method of quantitative determination of buckthorn oil in pessaries by spectrophotometric method was proposed.

Study on the development of composition of fitopreparations for stomatology

Beztsenna T.S., Shulga L.I., Zhuravel I.O., Piminov A.F.
National University of Pharmacy, Ukraine

A study of antibacterial and antifungal activity of aqueous extracts of certain herbal drugs has been conducted. On the basis of microbiological screening the qualitative composition herbal drug has been justified. The antimicrobial effect of infusions of model fitopreparations with different content of the selected components has been studied. The most rational ratio of plant material for the further development of herbal drug for the treatment of inflammatory dental diseases has been determined.

Study of the impact of technological parameters on the properties of liposomal nanoparticles

Shakhamaev A.V., Bida D.S., Volchik I.V., Krasnopolsky Yu.M., Shvets V.I.
NTU "Kharkiv polytechnic institute"
Pharmacopoeial center of Ukraine
Lomonosov Moscow University of Fine Chemical Technology

A study was dedicated to the technology of the manufacturing of liposomal nanoparticles with hydrophilic and hydrophobic active pharmaceutical substances. An influence of the size of liposome with lipid composition, ratio of components and method of manufacturing was examined. It was demonstrated that if in liposomes the acidic phospholipids such as phosphatidylinositol or diphosphatidylglycerol have been used, than the smaller nanoparticles were formed; the presence in liposomes of cholesterol increased the «rigidity» and particle size (by (20- 40) nm). An impact of manufacturing conditions on the degree of oxidation of liposome lipids was determined. The study of the influence of content of cryoprotector on the size of nanoparticles after lyophilisation was conducted.

Experimental pharmacological studies of a new dosage form - Uronefron, tablets

Maslova N.F, Nosalskaya T.N., Nikitina N.S., Kotlyar V.A., Leontieva T.L., Gubar T.V., Borshchevskaya M.I.
State Scientific Center of Drug and Medical Products
PC "Farmak"

Experimental studies of pharmacological effect and acute toxicity of a new dosage form - Uronefron, tablets, in comparison with Uronefron, drops, which were identical in composition of active substances, have been conducted. It was established that the specific effect and the level of acute toxicity of the drug Uronefron, tablets, were at the same level as respective parameters of drug comparison.

Comparative study of acute toxicity of Valiskin

Nikitina N.S., Leontieva T.L., Somova Y.V., Deeva T.V., Gubar T.V., Chekrizhova A.V.
State Scientific Center of Drug and Medical Products
PC "Fitopharm"

Comparative study of acute toxicity of the ointment Valiskin (PJSC Phytopharm, Ukraine) and the ointment Desitin (Pfizer Ink., USA) has been conducted. It was found that the level of acute toxicity of the drug Valiskin corresponded to the reference drug Desitin.

Assessment of immunotoxic effect of suppositories with lipophilic extracts of bee pollen

Gevoyan S.R., Zaychenko A.V., Faizullin A.V., Kudina A.V.
National University of Pharmacy, Ukraine

Immunotoxic effect of a new drug - suppositories with a lipophilic extract of bee pollen (LEFP) has been studied. It was established, that prolonged use of the drug in doses of 22 mg/ kg and 220 mg/kg did not alter levels of haemagglutinin titres in the serum and the number of antibody-forming cells (AFC) in the spleen of mice, did not affect to the value of the reaction index (IR), which indicated the absence of negative effect on the humoral and cellular immunity of animals.

Introduction of quality management in the pharmaceutical industry of the Republic of Kazakhstan: problems and prospects

Baizhanova K.F., Mnushko Z.N, Bayzoldanov T.B., Yevtushenko E.N., Zheterova S.K.
National University of Pharmacy, Ukraine
KAZAKH National Medical University named S.D.ASFENDIYAROVA

The Quality Management System (QMS) in the pharmaceutical industry in the Republic of Kazakhstan has been studied. The experience of QMS implementing allowed to identify the weaknesses of execution of individual processes, to determine the level of effectiveness of certain relationships and to devote the necessary resources for the improvement of product's quality and customer's satisfaction. During the study most pressing problems have been identified and the dynamics of the implementation of quality standards in the enterprises of the Republic of Kazakhstan has been described. Recommendations for the implementation of QMS in pharmaceutical enterprises in the country have been given.

Pharmacoeconomic estimation of the use of chondroprotectors in therapy of osteoarthritis by «minimizing expenses» method

Zaritskaya G.M., Panfilova G.L., Chigrinova M.G.
National University of Pharmacy, Ukraine

Data of pharmacoeconomic studies of economic efficiency of the use of chondroprotectors in osteoarthritis treatment with the methods of «disease cost» and «expenses - effectiveness» have been given. It was found that the least costly has been the use of the drug regimen of glucosamine and most expensive has been the treatment with diatsereine. It was shown that the most important values of economic performance have been observed in the case of regimen of drugs produced by American company «Unipharm». Data of pharmacoeconomic studies would be used in developing of insurance lists of drugs with chondroprotective effect with the mandatory reimbursement by Funds of obligatory medical insurance.

Major trends of the development of the national market of medical cosmetics

Kobets M.M., Olkhovskaya A.B., Filonenko L.S.
National University of Pharmacy, Ukraine

The major trends in the domestic market of medical cosmetics were analysed. The popularity of different brands of medical cosmetics was determined. A quantitative assessment of the range of medical cosmetics in pharmacies was conducted. Analysis of price conjuncture of medical cosmetics and certain ratios of liquidity, solvency adequacy and competitiveness were performed. A forecasting sales of medical cosmetics was given.

Inhibitors of 5-α-reductase and aromatase in the treatment of benign prostatic hyperplasia. Prospects for the development of natural medicines

Popova N.V., Dihtyarev S.I., Litvinenko V.I.
National University of Pharmacy, Ukraine
State Scientific Center of Drug and Medical Products

A review of the literature on the study of drugs - inhibitors of 5-α-reductase and aromatase synthetic and natural origin in the treatment of benign prostatic hyperplasia has been conducted. The prospects of a development of drug on the basis of certain groups of natural compounds has been demonstrated.