

ТЕХНОЛОГІЯ ЛІКАРСЬКИХ ПРЕПАРАТІВ

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THE PROBLEM OF DEVELOPMENT OF THE DIRECTION FOR CREATION AND MANUFACTURE OF MEDICINES WITH BEE PRODUCTS IN UKRAINE

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Key words: products of beekeeping (propolis, pollen, honey, bee venom, bee bread); medicines with bee products; monographs; tuberculosis; prostatitis; sports medicine

The problem of progress in the direction of development and introduction into industrial production of new domestic medicines with bee products on the basis of biologically active substances of standardized bee products has been studied. Fundamental works of foreign and domestic scientists in solving the given problem by chemical, physical and chemical, biopharmaceutical, pharmacological, microbiological, pharmaceutical and technological methods of research are presented; their expediency in creation of highly effective and safe medicines has been proven. About 12 Doctors and 70 Candidates of Pharmacy and Medicine of high schools and the chemical and pharmaceutical industries of Ukraine, near and far abroad take part in the scientific and practical direction "Apitherapy". Over 25 new medicines on the basis of bee products and plants have been introduced in practical medicine and pharmacy; they are sold by pharmacies of Ukraine as finished and extemporaneous medicines, cosmetic preparations manufactured on the basis of technological instructions and regulations developed according to the requirements of the State Pharmacopeia of Ukraine. The world priority in the field of comprehensive investigations of products of beekeeping, development of classical technologies of obtaining of standardized biologically effective substances (propolis, pollen, honey, bee venom, bee bread) from their composition and creation of medicines, perfumery-cosmetic preparations on their basis, development of methods for quality control, specifications, State Standards belongs to scientists of the National university of Pharmacy.

Studying the natural medicinal resources of our country in order to find new sources of biologically active substances and to create national medicines with them is an urgent task of pharmacy. Products of beekeeping are attractive in this respect.

It is known that bees appeared in the Tertiary period of the Earth, i.e. approximately 56 million years before the appearance of the primitive man. Even in ancient times a bee was the subject of reverent worship. On the emblem of ancient Egypt there was a picture of a bee. It represented dedication, loyalty and fidelity for the Egyptians.

The history of apiculture development includes several stages. Until the 17-th century beekeeping existed only for honey hunting accompanied by barbaric destruction of bees.

In ancient Egypt, Greece and Rome the nomadic way of doing beekeeping was successfully used. Beekeeping was widely developed in Russ: honey and wax were the product of exceptional importance and export products to Greece.

In the 17-18-th centuries beekeeping industry became the branch of agriculture, which supplied the only

known valuable product – honey, as well as wax used for making candles.

A great role in development of beekeeping was played by a prominent Ukrainian scientist P.I. Prokopovych. He was the first in the world (1814) who constructed a frame hive. This invention rationalized beekeeping techniques, significantly increased its productivity and profitability.

In the 19-21-th centuries beekeeping is a highly organized agriculture industry, which supplies honey, propolis, pollen, bee venom, royal jelly, beeswax.

Beekeeping has made great strides on the path of development on a scientific basis. Both bee-keeping and selection of the products, are made in advanced machinery. Due consideration is given to all substances produced in the process of bee colonies in complete symbiosis with the environment.

Nowadays much attention is also paid for development of beekeeping in some European countries.

Thus, beekeeping is of great importance as:

- a source of high-value food products (honey, pollen);
- an important raw material for the pharmaceutical industry (beeswax, propolis, pollen, royal jelly);

- means of increasing crop yields;
- a source of the raw material for production of medicines on the basis of bee products;
- means of therapy (apitherapy) – the treatment using bee products and medicines on their basis.

Bee products have long been widely used in folk medicine for the treatment of various diseases. Fundamental research of national and foreign scientists proved their high biological value. They have a diverse pharmacological activity (anti-inflammatory, antimicrobial, anesthetic, antioxidant, immune-stimulating, radioprotective, hepatoprotective, etc.) and are almost harmless to the organism.

The use of bee products for prevention and treatment of a variety of human diseases studied, analyzed and generalized in terms of bee-keeping, botany, chemistry, microbiology, pharmacology, medicine and pharmacy has become a new specific area of medical practice, which is called apitherapy, i.e. treatment with bee products.

Clinical studies and laboratory experiments conducted by a growing number of doctors, chemists, biologists, technologists, observations of experts in the field of apitherapy and beekeeping, numerous requests from the public clearly indicate the growing interest in all bee products and demonstrate their effectiveness in various diseases when they are used alone or in combination with other medications.

Many countries around the world such Canada, France, Germany, Italy, Spain, the USA, Sweden, Poland, Bulgaria, Romania, Denmark, Russia, Ukraine, etc., develop apitherapy at the level of research work or practical medicine.

The research on studying bee products are carried out in the following directions:

- development of methods of collection and the storage conditions;
- identification of the origin and the chemical composition;
- research of the pharmacological activity and effects on various biological processes;
- application in medicine;
- creation of compositions and development of technology of medicines with bee products;
- development of methods for standardization;
- development of the technological equipment;
- distribution of medical practice and research in the field of apitherapy.

International symposia, congresses, conferences on apitherapy also make their practical and theoretical contribution to the inventory, check and unified systematization of multilateral knowledge on apitherapy.

The scientists of the National University of Pharmacy (NUPh) have priority in the field of technological, physical and chemical studies of bee products, obtaining of standardized biologically active substances (propolis, pollen, honey, bee venom), creation of medicines on their basis, development of quality control methods, technical specifications, technological regulations.

Thus, NUPh is the pioneer of industrial production of medicines with bee products in Ukraine.

Availability of its own raw material base in Ukraine, ease of manufacturing processes make medicines with bee products cheaper than imported ones and more accessible to the general public. For example, “Essentiale” costs 35 UAH and its analogue, a medicine with bee product – “Propolin” tablets with hydrophobic phenolic preparation of propolis – 10.50 UAH; “Festal” (No. 10) costs 10.25 UAH and “Polenzym” tablets (No. 50) – approximately 5.20 UAH; ophthalmic drops “Vizin” and others – from 3.80 to 7.0 UAH and ophthalmic drops “Propomiks” – 3.15 UAH. The benefit of medicines with bee products is not only their lower cost, but also a wide range of the therapeutic activity, no side effects and toxicity; it makes them promising for use in geriatric and pediatric practice.

In this regard, development of the scientific direction “Creation and production of medicines based on bee products. Apitherapy” is relevant and should be primarily oriented to:

- strengthening of the national pharmaceutical industry;
- development and expansion of the production activity of pharmacies (small businesses) for manufacturing medicines with bee products;
- provision of the population with domestic medicines with bee products intended for the treatment of gastrointestinal, otorhinolaryngological, dental, ophthalmic, dermatological, gynecological and other diseases;
- development of research in creating combined medicines based on bee products and other substances of the natural origin.

Considering the abovementioned it can be concluded that in Ukraine there are all the necessary conditions (raw material base, scientific development, scientific staff) for production of domestic medicines with bee products (both in pharmacies and pharmaceutical plants), and the further development of one of the fields of medicine – apitherapy. However, government support of this direction is required.

To solve this problem in Ukraine there is the scientific school dealing with development and introduction of domestic medicines based on standardized biologically active substances – bee products into practical medicine. For the first time the concept of the biologically active fractions of propolis, pollen, honey, bee venom has been theoretically generalized and experimentally developed, and the possibility of their complex use in the pharmaceutical and industrial production of medicines has been substantiated. For this purpose the methodical fundamentals of creating and manufacturing medicines from bee products have been developed; the ways of regulating technological properties of the native raw material, standardized biologically active substances, as well as methods for production of medicines with optimal physical, chemical and therapeutic properties have been grounded. Implementation of the scientific programme, which provides a theoretical basis for development of medicines based on biologically active compounds of bee products, is being carried out at the

Department of chemist's technology of drugs named after D.P. Salo for more than 30 years.

Scientific principles are reflected in 16 monographs, including "Healing properties of propolis" (1977), "Technology of bee products" (1986), "Wages in beekeeping" (1987) "Improving, the quality of bee products" (1988), "The use of bee products in the national economy" (1990), "Theory and practice of production of propolis medicines" (1998), "Flower pollen in pharmacy and medicine" (2006), "Bee venom" (2010), "Natural honey in medicine and pharmacy", etc.

According to the results of research and introduction of national products based on biologically active substances of standardized bee products in scientific medicine only recently 8 monographs devoted to the application of bee products in pharmacy and medicine have been published. Approximately 2000 scientific works have been published.

Development and production of standardized substances based on propolis and flower pollen allowed to substantiate scientifically the prospects of their application in different industries of pharmacy, medicine, veterinary medicine and beekeeping. Five original substances have been created ("Phenolic hydrophobic preparation of propolis", "Phenolic hydrophilic preparation of propolis", "Polinaza" complex of biologically active compounds of the enzymatic nature, lipophilic extract of bee pollen, "Natural powdered honey"); they have become the basis for development of about 59 medicines with bee products for industrial production. Among them 14 medicines are commercially available in Ukraine and Russia ("Tincture of propolis", "Propolin" and "Polenzim" tablets, "Polinaza" powder, "Apiprost" capsules, "Proposol" aerosol, "Propomiks" ophthalmic drops, "Propolis" suppositories, "Inflarax" ointment, "Ravisol" tincture, etc.), about 30 medicines are at the different stages of introduction. They are "Polenzim" tablets, "Polenzim-D" tablets, "Ophthalmic medicinal films with propolis", "Propofen" suppositories, "Feprogit" tablets, "Propoltin" tablets, "Proporhinol" nasal drops, "Propaskan" paste, "Propomedin" syrup, "Prolidoxide" ointment, "Protrioxide" ointment, "Flait" granules, "Protrimexide" ointment, "Melin" powder for preparation of the solution for injections, "Apiven" tablets, "Spirumel" tablets, "Propotid" ear drops, "Propocide" dusting powder, "Enterosil" suspension, "Meflofit" tincture, "Api" basic homeopathic medicine, "Api-gran" homeopathic granules, "Gretavosk" tincture, "Apitar" tablets, "Api-derma" homeopathic ointment, "Tonus-active" homeopathic granules, "Cyclorin" granules, etc.

Scientific developments and inventions are protected by 14 copyright certificates and 60 patents of Ukraine and Russia (Patents of Ukraine No. 1738, 1739, 1740, 1741, 4134, 13347, 25669, 25669A, 25670A, 27140, 28428A, 29374, 30178, 45503, 47159A, 48030, 50802, 54117, 54169A, 54661, 55059, 55059A, 59638A, 59680A, 59683A, 60849, 60849A, 62577, 62577A, 63611A, 65646, 65915A, 66796, 71367A, 73449, 75185, 75205, 77331, 80953, 83248, 83579, 87051, 89115, 44193, 45503, 46384, 46400, 46867, 47160A, 47195A, 47580A, 48030, 10054, 92933; patents of Russia No. 1390834, 1264946, 1660251,

2020946, 2057538, 057538, 484871, 8560, 139034, 2057538, 1154758, 1748318, etc.).

In the given period of time in the field of apitherapy 12 doctors and 70 candidates of sciences have been trained; they successfully work in many departments of NUPh, in other universities and research institutes of Ukraine, CIS and other foreign countries (the Baltic States, Germany, Australia, Russia, Kazakhstan, Georgia). The scientific school of technologists in the field of creation of medicines with bee products (professors Yarnykh T.G., Budnikova T.M., Pashnev P.D., Yegorov I.A., Demyanenko V.G., Syatynya M.L., Kurchenko I.M., Gudzenko A.P., etc.) is constantly enlarged by new scientists, among them are Sokolova L.V., Kotenko A.M., Pasichnik M.F., Chernykh Yu.V., Dorovskoy V.A., etc. The number of scientists is constantly growing thanks to new followers – such candidates of Pharmacy as Okonenko V.U., Utkin D.V., Klimas R.M., Goncharov V.G., Kazakova N.T., Mamontova N.S., Yavtushenko S.V., Belova N.D., Kutsenko V.V., Bertulis A.P., Maravina I.M., Smirnova O.S., Gendzhamtsin Erdenetsetseg, Dadeshidze I.A., Lao Savetkhi, Merkurieva G. Yu., Sirota P.S., Martynyuk T.V., Shulga N.N., Murashko A.M., Andreeva S.V., Levkovsky V.M., Litka V.V., Chernenko V.P., Yakovenko L.I., Kolesnik V.S., Tkachuk I.A., Yakovenko V.K., Tsigankova V.A., Givora N.V., Tulyakov V.A., Podorozhnaya L.N., Kovtun Yu.V., Kalinichenko T.V., Batrak O.A., Azarenko Yu.M., Sokurenko I.A., Osipenko S. Yu., Zyikina S.S., Scheblykina L.I., Andreeva I.V., Kozyr G.R., Makarova O.E., Shpichak O.S., Khodarchenko A.B., Gritsenko S.V., Sidorenko O.V., Zubchenko T.N., Timchenko A. Yu., Chernaya N.A., Krivovyaz E.V., Unguryan L.N., Mikhaylenko V.V., Trutaev S.I., Oleynik S.V., Kovalyova O.A., etc. All of them develop the ideas of the scientific school of technology of medicines based on bee products of NUPh founded by Academician of Ukrainian Academy of Sciences A.I. Tikhonov [1-18].

By the results of the research conducted and the study of physical and chemical properties these scientists have created normative and technical documentation, specifications allowed to introduce medicines with bee products in industrial production and register them in the Ministry of Public Health of Ukraine. So, for the last two years "Propolis" suppositories based on the phenolic hydrophobic preparation of propolis was introduced into production; this anti-inflammatory agent is used for the treatment of proctitis, anal fissures, and postoperative wounds of the distal part of the intestine. The medicine is produced by "Lekhim-Kharkov" JSC (Kharkov) from 2008.

"Apiprost" capsules have been developed on the basis of two active substances – phenolic hydrophobic preparation of propolis and bee pollen. The composition of the medicine stipulates a wide range of its pharmacological properties: anti-inflammatory, antioxidant, analgesic, reparative activity and corrective effect on the level of androgens.

Pharmacological effects of phenolic hydrophobic preparation of propolis and bee pollen provide a major impact on the pathogenesis of prostatitis: contribute to

regeneration of cells of the prostate gland, reduce pain and eliminate the inflammatory response. The medicine is used in the treatment of chronic abacterial prostatitis and benign prostatic hyperplasia. "Apiprost" capsules when using them for a long time have little or no toxic effect on spermatogenesis, show no allergenic effect and no effects on the cellular and humoral immunity, no signs of local irritation, mutagenic, cumulative, ulcerogenic effect and no effect on the secretory activity of the glands of the stomach and do not have any toxic effect on the function of vital organs and systems of the body. This medicine was introduced into production of the Pharmaceutical Company "Zdorovye", Ltd., Kharkov in 2008. "Apiprost" medicine was awarded a gold medal and diploma of the winner at the All-Ukrainian competition-exhibition "development and production of Pharmaceutical Products", as well as it was marked by the diploma of the Head of Kharkov Regional State Administration M.M. Dobkin.

In perspective the following medicines are being developed at the Department of Chemist's Technology of drugs named after D.P. Salo. "Liproprost" suppositories on the basis of the phenolic hydrophobic preparation of propolis and the lipophilic extract of bee pollen is an anti-inflammatory agent for treating chronic prostatitis, proctitis, anal fissures, etc. The medicine has successfully passed preclinical trials. Its introduction into production of «Lekhim-Kharkov» JSC is planned.

"Propolis-LM" syrup is a natural immune stimulant based on natural powdered honey and the aqueous extract of propolis. The medicine has successfully passed preclinical trials. Its introduction into production of the Pharmaceutical Company "Zdorovye", Ltd., Kharkov is planned.

The preclinical studies of "Apitar" tablets, "Api-derma" homeopathic ointment, "Femiprolen" pessaries with propolis and sea buckthorn oil, "Apiart" combined gel with NSAIDs and bee venom, "Tonus-active" complex homeopathic remedy in the form of granules have been completed.

"Propotit" ear drops and "Gretavosk" tincture are under the preclinical studies.

Physical and chemical studies of such medicines as "Antisept-Api" for using in veterinary medicine and "Propolis-C" ointment for treating microtrauma are conducted.

One of the priorities of NUPh is to create medicines for the treatment of tuberculosis. The relevance of developments on this subject is conditioned by the fact that throughout the world there is threatening situation with tuberculosis at epidemic levels.

Today the treatment of tuberculosis is mainly directed to the use of standard regimens using some synthetic medicines. But resistance of bacilli to the majority of them develops very fast; in addition, xenobiotics often show pronounced side effects. Thus, in this regard the use of medicines with bee products is promising. propolis and bee moth have been selected as the research objects. As a result of this work, two medicines – tinctures "Gretavosk" and "Melofit" with antimicrobial and immunomodulating properties have been developed; they are used in the complex treatment of the respiratory system and tuberculosis.

Medicines based on a standardized biomass of large bee moth exhibit antimicrobial, immunomodulating, mucolytic, anti-inflammatory, antioxidant (inhibit lipid and biomolecules peroxidation), cardioprotective (increase the resistance of the heart muscle to hypoxia, stimulate the accumulation of glycogen), adaptogenic, tonic activity (increase the body's resistance to various stresses, accelerate the regeneration of tissues, stimulate the mental and physical energy).

Another promising research direction of scientists in NUPh is creation of medicines on the basis of bee products for sports medicine with a wide range of the therapeutic activity, such as anti-inflammatory, reparative, local anesthetic and capillary restorative; it allows to perform differential treatment of local micro-traumas in athletes depending on the stage of injury. In this respect propolis and its fractions having a wide range of pharmacological properties are of considerable interest. Besides, it is a natural product that has practically no side effects, does not show the effect of doping and other adverse responses.

At present compositions and technologies of series of soft dosage forms with polyvalent action for the treatment of sports injuries of various etiologies have been developed.

Thus, NUPh is one of the leading research centers in Ukraine and the CIS countries in creating medicines with bee products and their standardized substances.

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ПРОБЛЕМА РОЗВИТКУ ГАЛУЗІ СТВОРЕННЯ ТА ВИРОБНИЦТВА ЛІКАРСЬКИХ ПРЕПАРАТІВ З ПРОДУКТАМИ БДЖІЛЬНИЦТВА В УКРАЇНІ

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Ключові слова: продукти бджільництва (прополіс, пилок квітковий, мед, бджолина отрута, перга); апіпрепарати; монографії; туберкульоз; простатит; спортивна медицина

Вивчена проблема розвитку напрямку розробки та впровадження у промислове виробництво нових вітчизняних лікарських апіпрепаратів на основі стандартизованих біологічно активних субстанцій продуктів бджільництва. Представлені фундаментальні розробки зарубіжних і вітчизняних учених у вирішенні даної проблеми, хімічними, фізико-хімічними, біофармацевтичними, фармакологічними, мікробіологічними, фармакотехнологічними методами досліджень доведена їх доцільність у створенні вискоєфективних, практично нешкідливих лікарських засобів. У розвитку даного науково-практичного напрямку «Апітерапія» беруть участь близько 12 докторів та 70 кандидатів фармацевтичних та медичних наук ВНЗ і хіміко-фармацевтичних підприємств України, ближнього та дальнього зарубіжжя. У практичну медицину і фармацію впроваджено понад 25 нових лікарських апіфітопрепаратів, які реалізуються аптеками України, як готових, так і екстемпоральних лікарських, косметичних засобів, вироблених на основі технологічних інструкцій і технологічних регламентів, розроблених відповідно до вимог ДФУ. Світовий пріоритет в області всебічних досліджень продуктів бджільництва, розробки класичних технологій отримання з їх складу стандартизованих біологічно активних субстанцій (прополісу, пилку квіткового, меду, бджолиної отрути, перги) і створення

на їх основі лікарських, парфумерно-косметичних препаратів, розробки методик контролю якості (МКК), технічних умов (ТУ), ГОСТів належить ученим Національного фармацевтичного університету.

ПРОБЛЕМА РАЗВИТИЯ ОБЛАСТИ СОЗДАНИЯ И ПРОИЗВОДСТВА ЛЕКАРСТВЕННЫХ ПРЕПАРАТОВ С ПРОДУКТАМИ ПЧЕЛОВОДСТВА В УКРАИНЕ

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Ключевые слова: продукты пчеловодства (прополис, пыльца цветочная, мед, пчелиный яд, перга); апипрепараты; монографии; туберкулез; простатит; спортивная медицина

Изучена проблема развития направления разработки и внедрения в промышленное производство новых отечественных лекарственных апипрепаратов на основе стандартизованных биологически активных субстанций продуктов пчеловодства. Представлены фундаментальные разработки зарубежных и отечественных ученых в решении данной проблемы, химическими, физико-химическими, биофармацевтическими, фармакологическими, микробиологическими, фармакотехнологическими методами исследований доказана их целесообразность в создании высокоэффективных, практически безвредных лекарственных средств. В развитии данного научно-практического направления «Апитерапия» принимают участие около 12 докторов и 70 кандидатов фармацевтических и медицинских наук вузов и химико-фармацевтических предприятий Украины, ближнего и дальнего зарубежья. В практическую медицину и фармацию внедрено свыше 25 новых лекарственных апифитопрепаратов, которые реализуются аптеками Украины, как готовых, так и экстенпоральных лекарственных, косметических средств, производимых на основании технологических инструкций и технологических регламентов, разработанных в соответствии с требованиями ГФУ. Мировой приоритет в области всесторонних исследований продуктов пчеловодства, разработки классических технологий получения из их состава стандартизованных биологически эффективных субстанций (прополиса, пыльцы цветочной, меда, пчелиного яда, перги) и создания на их основе лекарственных, парфюмерно-косметических препаратов, разработки методик контроля качества (МКК), технических условий (ТУ), ГОСТов принадлежит ученым Национального фармацевтического университета.