ISSN 2450-4777

Lomza State University of Applied Sciences
Natur Produkt Pharma

International Conference:

SAFETY OF BOTANICALS AND BOTANICAL PREPARATIONS USED IN FOOD SUPPLEMENTS PRODUCTION

Date of the Conference:
20th March 2019

Organizers:
Faculty of Computer Science and Food Science,
Lomza State University of Applied Sciences, Poland
and Natur Produkt Pharma, Ostrów Mazowiecka, Poland

Venue of the Conference:
Lomza State University of Applied Sciences building, Assembly Hall named after Professor Antoni Jakubczak,
Akademicka 1 Street, 18-400 Lomza, Poland

NP
Pharma

15lat PWSIP
PAŃSTWOWA WYŻSZA SZKOŁA INFORMATYKI I PRZEDSIĘBIORCZOŚCI W ŁOMŻY

Lomza 2019

REGISTRATION REQUIREMENTS FOR BOTANICALS USED IN PHARMACEUTICAL INDUSTRY IN BELARUS

IVAN DARASHKEVICH

Economics Department
Grodno State Agrarian University, Grodno, Belarus

E-mail: atalez@tut.by

Abstract: Citizens of Belarus, like past generations, retain a strong tradition of gathering herbs, berries, and mushrooms from the forest. That is why Belarusians employ medicinal herbs to treat a lot of ailments. According to some authors about 40% of medicines in Belarus today are botanicals and botanical preparations. Nowadays phytomedicines are available exclusively through more than 3300 pharmacies located throughout the country. State regulatory bodies have become more aware of this and are intensify their attempts to ensure the safety of botanicals. Pharmaceutical activities related to the spheres of herbal medicine are strongly institutionalized and regulated by the government.

Belarus follows State Pharmacopoeia of the Republic of Belarus of 2007-2009. This is a collection of general and private pharmacopoeia monographs that establish requirements for the quality of drugs, botanicals, pharmaceutical substances and reagents. Private pharmacopoeia monographs on botanicals, as a rule, contain the name in Russian, English and Latin, sections: description, authenticity (external signs, microscopy, TLC or qualitative reactions), tests (permissible impurities - non-raw parts of plants, organic and mineral impurities), weight loss on drying, total ash, hydrochloric acid insoluble ash, quantitative determination (liquid chromatography, spectrophotometry, determination of essential oil, etc.). Currently the control of impurities is a critical issue for the pharmaceutical industry. The release of the 2nd edition of the State Pharmacopoeia of the Republic of Belarus combined pharmacopoeia monographs, including 136 pharmacopoeia articles (monographs) on medicinal plant raw materials (botanicals), based on the requirements of the European Pharmacopoeia (EP 8.0–8.4). The registration procedure for herbal drugs includes several stages; preparation of the registration dossier, its examination; testing; inspection of industrial production to check the compliance with the requirements of GMP; decision by the Ministry of Health on state registration of drug and entry of the information about them into the State register. The procedure of state registration should be conducted within 210 days without considering the time for remarks responses. In 2018 the whole pharmaceutical market volume just for the packaged botanicals in Belarus was worth about 3 millions EUR.