WayScience

6th International Scientific and Practical Internet Conference

«Integration of Education, Science and Business in Modern Environment: Winter Debates»

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- biological sciences;
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- other professional sciences.

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Medical sciences
(Pharmaceutical sciences)

DEVELOPMENT OF DRAFT SPECIFICATIONS AND CONTROL METHODS FOR A DIETARY SUPPLEMENT CONTAINING INOSITOL

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Keywords: *Inositol, European Pharmacopoeia , specification, dietary supplement*

Introduction Inositol, also known as vitamin B8, is a naturally occurring substance that belongs to the sugar alcohol family. Although it is often classified as a vitamin, inositol is technically a pseudovitamin because the body is able to synthesize it on its own, mainly in the liver and kidneys. This compound is found in many foods, such as citrus fruits, legumes, grains, and nuts. Inositol plays an important role in regulating cellular functions, including cell signaling, metabolism, and maintaining the health of cell membranes. Inositol is used in dietary supplements due to its potential health benefits. The main forms of this substance are myo-inositol and D-chiro-inositol, which can be used alone or in combination. These forms are being actively studied for the treatment and prevention of a number of conditions. Inositol has a wide range of uses. One of its main benefits is supporting the nervous system. It helps to produce neurotransmitters such as serotonin and dopamine, making it useful for conditions related to anxiety, depression and stress [1]. There is evidence that inositol helps with obsessive-compulsive disorder and panic attacks. In addition, it plays an important role in supporting reproductive health. Myo-inositol is widely used to treat polycystic ovary syndrome, as it normalizes insulin levels, regulates ovulation and hormonal balance. Another important area of application is supporting metabolic health. Inositol improves insulin sensitivity, which makes it a promising tool in the prevention and treatment of type 2 diabetes, and also helps lower cholesterol levels [2]. Due to its effect on hormonal balance, inositol helps improve skin condition, reducing the appearance of acne, especially if it is caused by excess androgens. Dietary supplements with inositol have a high safety profile and are usually well tolerated by the body. Recommended doses vary depending on the needs: for general well-being, 500–2000 mg per day is commonly used, and for therapeutic purposes, up to 4 grams or more. Inositol is a versatile dietary supplement ingredient that helps support physical and emotional health, making it a popular choice for many people.

Materials and methods of research: bibliographic, analytical and comparative - study of current standards (Ukrainian Pharmacopoeia, USP, European Pharmacopoeia) for quality control of raw materials and finished products., logical, generalization.

Results: Quality control begins with chemical-analytical methods that allow determining the content of inositol and identify possible impurities. High-performance liquid chromatography (HPLC) is one of the most accurate methods of quantitative analysis of inositol, providing high selectivity and sensitivity. It is also possible to use spectrophotometry for quick identification of a substance by its optical properties. Gas chromatography (GC) and mass spectrometry methods are used to determine impurities, which help detect trace amounts of by-products. In addition, organoleptic (appearance, taste, smell) and physicochemical (pH, solubility, humidity) parameters are evaluated. To confirm the safety of the product, microbiological studies are required, including testing for the presence of pathogenic microorganisms (Salmonella, Escherichia coli, Staphylococcus aureus) and molds, as well as determining the total microbial count.The development of regulatory documentation for supplements with inositol includes the formation of

specifications describing the permissible limits of the content of the active substance and accompanying components. International pharmacopoeial standards, such as USP (United States Pharmacopeia) and Ph. Eur. (European Pharmacopoeia), as well as national regulations, for example, GOST and Technical Regulations of the Eurasian Economic Union.

Conclusions: The market of dietary supplements containing inositol was analyzed and it was shown that the most popular dosage is from 800 to 900 mg of active ingredient. The availability of monographs on the API of the dietary supplement was analyzed and a comparative table for different forms of inositol was created, on the basis of which a draft specification was proposed, which contains methods for qualitative and quantitative analysis of inositol in the composition of the dietary supplement. Possible methods of pharmaco-technological research for the dosage form "Capsules" were considered for further implementation in laboratory practice.

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