

# WayScience

International Scientific  
and Practical Internet Conference

«Development of Education, Science  
and Business: Results 2024»

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## DEVELOPMENT OF DRAFT SPECIFICATIONS AND CONTROL METHODS FOR A DIETARY SUPPLEMENT CONTAINING METHIONINE AND PYRIDOXINE HYDROCHLORIDE

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**Keywords:** *methionine, pyridoxine hydrochloride, specification, dietary supplement*

**Introduction:** Dietary supplements play an important role in maintaining health, in particular in providing the body with essential nutrients. Methionine is an essential amino acid that participates in protein synthesis and the metabolism of sulfur-containing compounds. [1] Pyridoxine hydrochloride (vitamin B<sub>6</sub>) contributes to the normalization of protein metabolism, the functioning of the nervous and immune systems. [2] The development of specifications and methods for quality control of such products is necessary to ensure their effectiveness, safety and stability. Based on the above, the aim of the work was to develop a draft specification and adapt modern quality control methods for a dietary supplement containing methionine and pyridoxine hydrochloride, in accordance with the requirements of current regulatory documents.

**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:** The monographs on APIs methionine and pyridoxine hydrochloride were analyzed, it was shown that the SFFU contains a monograph on methionine, and the European Pharmacopoeia – Methionine and DL- Methionine, and both pharmacopoeias contain a monograph on pyridoxine hydrochloride. The analysis methods include both physicochemical (IR and UV spectrophotometry, TLC, determination of specific optical rotation) and color identification reactions. For quantitative determination in both cases, it is proposed to use the method of acid-base titration in an anhydrous medium. A draft specification has been developed, containing a detailed description of the requirements for the quality of raw materials (methionine and pyridoxine hydrochloride) and finished products. The use of HPLC method for quantitative determination of methionine ( $\lambda=254$  nm) and pyridoxine hydrochloride ( $\lambda=290$  nm) is proposed, which can have high accuracy, linearity and reproducibility. [3] Optimal storage conditions of the product are established, ensuring its stability for 24 months.

**Conclusions:** The developed draft specification and validation of quality control methods allow to ensure compliance of the dietary supplement with methionine and pyridoxine hydrochloride with the requirements of international standards. This will contribute to increasing the trust in the product among consumers and its effective introduction into the pharmaceutical market.

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