

**DEVELOPMENT OF METHODS FOR DETERMINING
THE MICROBIOLOGICAL PURITY OF ORAL AGENTS BASED
ON DERIVATIVES OF CAMPHOR ACID**

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It is known that natural carboxylic acids play an important role in the human body. But nowadays there is no treatment for male infertility based on their properties. In a public institution "V. Danilevsky Institute for Endocrine Pathology Problems National Academy of Medical Sciences of Ukraine". There was a development based on an original non-hormonal compound - a derivative of camphor acid, which is a low toxicity in experimental models in rats leads to restoration of male hypofertile. For practical application in medicine have been proposed to develop formulations containing these substances which are in different stages of learning. When the developing an oral dosage form based on camphor acid derivative started. There was a question of studying its microbiological characteristics, primarily microbiological purity characterizing the final product. High levels of microbial contamination significantly affects the quality indicators preparation shows great danger to its stability, may be cause of severe infectious diseases or lead to the loss of therapeutic activity. In this connection, the test "Microbiological purity" is an integral part of the analytical documentation to the drug. Microbiological purity samples freshly oral dosage form based on the derivative of camphor acid, which does not exhibit antimicrobial activity in the conditions of the test was carried out by direct seeding method for State Pharmacopoeia (SP) of Ukraine 1.4 (1:10 dilution). It was established that all samples tested do not contain bacteria of the genus Enterobacteriaceae - Escherichia coli, wherein the total number of aerobic microorganisms bacteria not more than 10 Colony Forming Unit per g (CFU/g), and the content of yeasts and molds was significantly less than 10 CFU/g. Thus, regulation of the microbiological purity of the oral dosage forms based on camphor acid derivative showed that it meets the quality criteria of acceptability nonsterile SP of Ukraine 1.4 - non-aqueous medicines for oral administration. It was performed by direct sowing in accordance with the requirements of SP of Ukraine 1 (2.6.12, 2.6.13). Today at the Department of Biotechnology of National University of Pharmacy together with the State institution "V. Danilevsky Institute for Endocrine Pathology Problems National Academy of Medical Sciences of Ukraine" determining the microbiological purity of new oral agents based on derivatives of camphor acid is conducted.