**Development of Methods for Standardizing the Active Pharmaceutical Ingredient Based on Humic Substances and Silver Nanoparticles**

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Keywords: humic substances, silver nanoparticles, standardization Introduction. The problem of registering humic-based drugs is due to their complex structure and stochastic composition. Nanocomplexes of humic substances with silver (HS-AgNPs) exhibit antibacterial, wound healing and anti-inflammatory activities. To develop a drug based on these, it is necessary to develop methods for standardizing the main active components of the active pharmaceutical ingredient (API). Therefore, this study represents the first step towards solving the problem of standardizing humic preparations. The test sample (HS-AgNPs) was synthesized in the Laboratory of Natural Humic Systems of the Faculty of Chemistry, Lomonosov MSU. The goal of this study is to develop methods for standardizing the API and the finished dosage form to form a set of regulatory documents for a pilot-industrial regulation and a registration dossier.

Materials and Methods. The development of methods for quality control of the pharmaceutical substance and the finished dosage form is based on the general pharmacopoeial principles described in the State Pharmacopoeia of the Russian Federation, General Pharmacopoeial Monograph 1.1.0006 “Pharmaceutical substances” and in the pharmacopoeial monographs of individual types of drugs (gels, solutions, ointments, etc.). Given the nanostructure of the pharmaceutical substance, additional parameters characterizing quality, and hence the efficacy and safety of the drug, should include characteristics such as particle size and zeta potential. The initial stage of the study involved the development of general pharmacopoeial quality parameters for the substance: description, solubility, authenticity, transparency and color of the solution, pH of the solution of the substance.

Results. The following results were obtained when determining the quality parameters of the API. The substance samples are dark (almost black) crystalline powders, well soluble in water (with ultrasonic treatment) and aqueous alkali solutions, forming a dark brown colloidal solution. The particle size of the colloidal solution and zeta potential were determined under experimental conditions. It was shown that solutions in the lower concentration range, where spectrum analysis is possible, have acceptable optical densities. To determine the authenticity by UV spectroscopy, the method of calculating relative optical densities (ROD) 300/500; 350/500; 400/500; 450/500 was proposed. For color determination, the solution was diluted to a concentration of 0.05 mg/ml, and the color intensity should not exceed the intensity of solution B0. The pH value was determined to be between 6.8 and 7.20. The loss on drying should not exceed 10%.

Conclusion. Thus, approaches for standardizing the API based on humic substances and silver nanoparticles are proposed, which is a necessary step in the process of developing pharmaceuticals.
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