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Evaluation of the quality indicators of promising pharmaceutical substance based on synthetic genistein

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Abstract

The most promising pharmaceutical substances and, accordingly, drugs based on these substances are of natural origin having wide spectrum of pharmacological actions of high efficacy and low toxicity. These substances include a natural isoflavone genistein the most widespread in the representatives of family of *Bean – Fabaceae*. Due to the fact that on the territory of the Russian Federation of natural resource base produce genistein is very limited, genistein synthesis scheme was designed and chemically pure pharmaceutical substance was obtained in the Research and Production Center "Pharmzaschita" of the Federal Medical and Biological Agency. The aim of this study is the evaluation of physical and chemical indicators of quality of the domestic synthetic genistein as a pharmaceutical substance for the development of a new drug. Studies of natural and synthetic genistein on the marked in the State Pharmacopoeia indicators – description, solubility, authenticity, melting point, specific absorption rate, impurities, loss on drying, quantitative determination was carried out. The physicochemical properties of synthetic genistein were also studied by spectrophotometry in the ultraviolet, infrared spectroscopy, high performance liquid chromatography with UV detection, and gas chromatography with mass selective detector. The studied indicators of quality of the pharmaceutical substance reflected in the draft of normative documents on a standard sample of genistein.