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Forensic chemical investigation of nortadalafil and avanafilcomponents of falsified biologically active additives to food

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Abstract

Numerous cases of falsification of biologically active additives (BAA) to food for men are described in Russia and abroad. In violation of law, synthetic chemical substances, such as sildenafil, tadalafil, as well as non-medicinal products (thiosildenafil etc.), were added to the biologically active additives. At the end of the previous year, law enforcement agencies confiscated substances of two substances with unknown chemical composition, later identified as avanafil and nortadalafil, which belong to the pharmacological group of phosphodiesterase type 5 inhibitors. These substances are products of chemical synthesis and are not contained in products of plant and animal origin. Nortadalafil is a demethylated derivative of the medicinal substance tadalafil, which has the patented name Cialis[®] and has long been used with a medicinal purpose. Circumstances and described in the literature cases of seizures of similar substances suggested that these substances were prepared for application in biologically active food supplements intended for the treatment of erectile dysfunction. This act is criminally punishable, since on 31.12.2014 the corresponding amendment was introduced to Article 238 of the Criminal Code of the Russian Federation on the falsification of biologically active substances to food. Avanafil and nortadalafil are not used in the medical field in the territory of the Russian Federation to date. In the study the most effective systems for separating nortadalafil and avanafil by the method of chromatography in a thin layer of sorbent are selected, Rf values in various solvent systems are calculated, and reagents for staining are selected. The specificity of the test's color reactions of substances under investigation, as well as of vardenafil, udenafil, sildenafil and tadalafil allows them to be used in TLC screening of unknown substances of the group of phosphodiesterase type 5 inhibitors, not only in the singular content in BAA, but also in mixtures. The spectra of nortadalafil and avanafil were obtained by various physicochemical methods (UV spectroscopy, IR spectroscopy, GC-MS, HPLC-MS).

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