

APPROACHES TO DEFINITION OF «SPECIFICITY» TERM IN FORENSIC AND TOXICOLOGICAL ANALYSIS

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The objects of analysis in forensic toxicology are biological samples, that allow to attribute the procedures of forensic and toxicological analysis to the category of bio-analytical methods, which also should be validated according to the advices of International Conference on Harmonisation (ICH).

The purpose of this work is review of approaches to the definition of validation parameter «specificity» according to the requirements of Food and Drug Administration (FDA), European Medicines Agency (EMA), United Nations Office on Drugs and Crime (UNODC) and Scientific Working Group for Forensic Toxicology (SWGTOX) guidances and analysis of their positive and negative sides in relation to forensic toxicology.

The method of the work carrying out is comparative analysis.

The term «specificity» is used without differences from the term «selectivity» in the discussed papers.

The FDA guidance gives us the following definition: «selectivity is the ability of an analytical method to differentiate and quantify the analyte in the presence of other components in the sample».

The EMA guidance said: «selectivity is the ability of the bioanalytical method to measure and differentiate the analyte(s) of interest and internal standard in the presence of components, which may be expected to be present in the sample».

The UNODC guidance: «specificity/selectivity is 1) the parameter concerned with the extent to which other substances interfere with the identification and, where appropriate, quantification, of the analyte(s) of interest; 2) the measure of the ability of the method to identify/quantify the analytes in the presence of other substances, either endogenous or exogenous, in a sample matrix under the stated conditions of the method».

The SWGTOX guidance: «interference studies – interfering substances from common sources must be evaluated in all screening (except immunoassays), qualitative identification, and quantitative methods».

The «integrated» parameter «specificity/selectivity», which describes satisfactorily both screening methods and methods of identification and quantitative determination, should be introduced in forensic and medical toxicology for validation of the methods of discovery and determination of toxic substances in human body.