APPROACHES TO DETERMINATION OF SPECIFICITY IN FORENSIC AND TOXICOLOGICAL ANALYSIS

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There are two points of view on when a method should be regarded to be selective. One way to establish method selectivity is to prove the lack of response in blank matrix. However, this approach has been subject to criticism in some review, which stated from statistical considerations, that relatively rare interferences will remain undetected with a rather high probability. The second approach is based on the assumption that small interferences can be accepted as long as precision and bias remain within certain acceptance limits.

The purpose of this work is review of approaches to the determination procedure 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.

All considered documents foresee the carrying out of the blank-matrix samples analysis – both spiked with analyte and without it, and standardize their quantity – from five to ten. Thus the UNODC guidance has the differences in requirements to the quantity of such samples depending on the type of analysis, and the EMA guidance allows to use less quantity of sources in the case of rare biological matrices.

The true absence at the level of lower limit of quantification (FDA, UNODC) or a little higher (UNODC), or the response, not exceeding 20% from the lower limit of quantification for analyte and 5% for an internal standard (EMA) is accepted as an absence of response in blank-matrix. The SWGTOX guidance does not standardize this parameter.

The question about the number of blank-matrix sources used for parameter «specificity/selectivity» determination is in need of further discussion. From our point of view, this number should depend on the method of analysis used (for example, chromatography or spectrophotometry, thin layer chromatography or high-performance liquid chromatography at al.), and also should be different in the methods of qualitative and quantitative analysis.