ACCEPTABILITY CRITERIA FOR LINEAR DEPENDENCE WHEN VALIDATING UV-SPECTROPHOTOMETRIC METHODS OF QUANTITATIVE DETERMINATION IN FORENSIC AND TOXICOLOGICAL ANALYSIS

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The purpose of this paper is to analyse the present approaches to acceptability estimation of the calibration model chosen for method description according to the requirements of the international guidances and to form the own approaches to acceptability estimation of the linear dependence when carrying out the validation of UV-spectrophotometric methods of quantitative determination for forensic and toxicological analysis.

It has been suggested to be guided by domestic developments in the field of validation of analysis methods for medicines and, particularly, by the approaches to methods validation in the variant of the method of calibration curve.

The next criteria and the order of acceptability estimation of linearity for UV-spectrophotometric methods of analytes quantitative determination in biological fluids used in forensic and toxicological analysis have been offered:

- acceptability estimation of linear dependence parameters is carried out in two stages – for the lines obtained using model solutions (without matrix) and calibration samples respectively;
- two approaches have been suggested for estimation of parameters of linear dependence obtained using model solutions; they are based on: 1) assumption of equality of the uncertainty related to the procedure of sample preparation of calibration standards and the uncertainty of the calibration curve plotted by model solutions; 2) assumption of insignificance of the uncertainty of the calibration curve plotted by model solutions; for both approaches the acceptability criteria have been offered for residual standard deviation RSD_0^{model} and correlation coefficient R_c^{model};
- for estimation of parameters of linear dependence obtained using calibration samples it has been suggested to proceed from assumption of equality of the calibration uncertainty and the uncertainty of measuring the absorbance and sample preparation of the sample to be analysed; within this approach the acceptability criteria have been offered for residual standard deviation RSD_0 and correlation coefficient R_c; the parameters of within-run (within-day) and between-run (between-day) linearity should satisfy these criteria.