VALIDATION OF UV-SPECTROPHOTOMETRIC METHODS OF QUANTITATIVE DETERMINATION IN FORENSIC AND TOXICOLOGICAL ANALYSIS: RECOVERY

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The validation parameter «recovery» is not used practically in pharmaceutical analysis. Such situation is explainable – the procedure of sample preparation in pharmaceutical analysis does not contain the stages, which require the extraction carrying out (result in the substance considerable losses), which efficiency is characterized by the parameter «recovery».

The purpose of this paper is to form the approaches to the procedure of recovery determination when carrying out the validation of UV-spectrophotometric methods of quantitative determination for forensic and toxicological analysis.

For recovery determination of the methods we suggest to carry out the analysis in the points of 25%, 50%, 100% and 175% (in the normalized coordinates). In this way we provide fulfilment of international requirements (three concentrations levels – low, medium and high) and control additionally the most critical part of the method analytical range – near LLOQ, where differences in recovery values are often observed.

For acceptability confirmation of the recovery value reproducibility we suggest to check fulfillment of two criteria simultaneously:

- the slope for linear dependence $R = f(c)$ should statistically insignificantly differ from zero on conditions the significance of absolute term (the linear dependence $R = bc + a$ goes over $R = a$ in ideal situation), i. e. it is necessary to prove that the value of b is less, and the value of a is more than the confidence interval of its uncertainty:

$$b \le \Delta_b; \quad a \ge \Delta_a;$$

- the relative confidence interval $\Delta_{R,r},\%$ should not exceed the extreme uncertainty of analysis Δ_{As} by the value:

$$\Delta_{R,r},\% \le \max\Delta_{As}.$$

Thus, the theoretical approaches to determination of recovery when carrying out the validation of UV-spectrophotometric methods of quantitative determination for forensic and toxicological analysis have been formulated; the acceptability criteria for the validation parameter have been suggested and ground.