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Some practical considerations for linearity assessment of calibration curves as function of concentration levels according to the fitness-for-purpose approach

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Abstract

Since linear calibration is mostly preferred for analytical determinations, linearity in the calibration range is an important performance characteristic of any instrumental analytical method. Linearity can be proved by applying several graphical and numerical approaches. The principal graphical criteria are visual inspection of the calibration plot, the residuals plot, and the response factors plot, also called sensitivity or linearity plot. All of them must include confidence limits in order to visualize linearity deviations. In this work, the graphical representation of percent relative errors of back-calculated concentrations against the concentration of the calibration standards is proposed as linearity criterion. This graph considers a confidence interval based on the expected recovery related to the concentration level according to AOAC approach. To illustrate it, four calibration examples covering different analytical techniques and calibration situations have been studied. The proposed %RE graph was useful in all examples, helping to highlight problems related to non-linear behavior such as points with high leverage and deviations from linearity at the extremes of the calibration range. By this way, a numerical decision limit which takes into account the concentration of calibration standards can be easily included as linearity criterion in the form of $\%RE_{Th}=2 \cdot C^{-0.11}$. Accordingly, this %RE parameter is accurate for the decision-making related to linearity assessment according to the fitness-for-purpose approach.

Keywords: calibration curves; fitness-for-purpose approach; linearity; response factor; relative error

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