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In our blog today, we like to distinguish between the detection limit (LOD) and the quantitative estimation limit (LIS). Both terms are terms related to method analysis. The DETECTION Limit (LOD) LOD detection limit (or detection limit, DL) is the lowest possible concentration at which the method can detect (but not quantitatively!) analitis in the matrix with a certain degree of confidence. It is also defined as the lowest concentration, which can be separated from background noise with some reliability. Depending on whether the method is instrumental or non-instrumental, various recommendations are sticking out of the ICH No2 (R1) test guide. LOD can be evaluated three different: 1. Visual consideration: This detection path is mostly common for methods that do not use any instruments. One example would be the detection of the minimum concentration of antibiotics needed to inhibit bacterial growth. Detection is checked with the help of antibiotic discs, and then by calculating the braking zone. 2. Determining the signal-to-noise ratio (S/N): This detection method can only be used for methods that show underlying noise, such as HPLC methods. This is a measure by comparing the signals of samples containing low concentration of analytic, with the signal of emptiness and the definition of a minimum concentration at which the analyte signal could be reliably detected. The generally acceptable ratio of the signal to noise to estimate the detection limit is 3:1 (or previously used 2:1). 3. Standard Deviation (SD) and Tilt: This method of evaluation is also for analytical tests using tools. There are two possibilities for SD and slope detection: a. SD-based space detection: This involves measuring the required number of blank samples and calculating the SD from the resulting values. B. Detection based on the calibration curve: The calibration curve (A) must be obtained using samples containing analysis in the LOD range. The ICH No2 (R1) manual recommends the use of standard regression line deviation as a standard deviation that will be inserted into the formula below (meaning that not only one but several calibration curves have been generated previously) or a residual standard deviation of the regression line. Since we haven't had the opportunity to follow this approach in any of our client's projects, we've had a short internal discussion about what this might mean. We can imagine calculating SD within the same regression line when normalizing all values, for example, up to 100%, but we're not quite sure if that's what ICH wants. We will follow this issue and report in a future blog article. Regardless of the evaluation methodology, LOD is calculated as follows: LOD No. 3.3 - σ / S Where, σ - SD Results S and calibration curve. Calibration, this assessment approach uses photometric content definitions or ELISAs. The quantitative estimation limit (LIC) Limit of quantitative assessment of the DOA (or sometimes also called the quantitative estimation limit, THE PRODUCT) is the lowest possible concentration of analitis, which can be quantified in a reliable way. Reliable means that the right accuracy and truth must exist and be demonstrated. Like LOD, THE LLD can also be defined differently depending on whether the method uses the tool. 1. Visual survey: Detection by analysing samples with known analyzer concentrations and assessing the minimum level at which concentration can be quantified. Two chemicals are a good example for visual study of the DOS. The known concentration of analitis is added until the color of the mixture changes. 2. Determining the signal-to-noise ratio (S/N): As explained in LOD, THE LLP can also be determined by the noise signal approach, in which signals of a known analyth concentration are compared to space signals and set a concentration at which it could be quantified with some certainty. The ratio of S/N 10:1 is generally accepted. Examples are chromatographic methods. 3. Standard Deviation (SD) and Tilt: As with LOD, there are two possibilities for determining SD and slope for calculating THE DOP: a. Based on SD space: Same as in LOD. Measure a few blank samples and calculate the SD from the responses you receive. B. Based on the calibration curve: Using samples containing analysis in the DOP range, it is necessary to obtain and examine (a) the calibration curve (s). The valuation opportunities are the same as for LOD with the same - currently resolved - issue. THE DOP is calculated as follows: LOZ No. 10 - σ/S Where, σ - SD Results S - Slope Curve Calibration. In conclusion, the definition of the detection limit as well as the limit of quantification is important, as both are consistent with the sensitivity of the analytical method of interest. Especially in the case of methods of detecting a very small number of impurities, these two values are very useful. To determine potency or content (analyses) they are not required in ICH No. 2 (R1) guide, which absolutely makes sense, as for these definitions, usually 100% of the concentration of the test is used. The LOD and DOC assessment methods are very similar, with the exception of acceptable values for S/N approaches and constant values used to be determined using SD and tilt (3.3 for LOD and 10 for LS). The reason is logical: confidence in the confidence in the results should be higher when you still want to quantify (LAS), not just detection (LOD). Page 2 In our blog today, we would like to limit limit (LOD) and the quantitative estimation limit (LS). 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