Summary - Analytical Test Method Validation - Quantitation and Detection Limit

Guidance for quantitation and detection limit testing is provided, including approaches, recommended data and acceptance criteria.

Quantitation Limit
The procedure is a non-instrumental or instrumental method. Determination of quantitation limit is not normally required for assay or identification tests.

The quantitation limit is generally determined by the analysis of samples with known concentrations of analyte and by establishing the minimum level at which the analyte

Based on Signal-to-Noise Approach:
Samples with known low concentrations of analyte with those of blank samples and by signal-to-noise ratio is 10:1.

Quantitation limit may be constructed in the validation documentation based on the calibration

The actual limit of quantitation would still be presented in numerical terms relevant to the assay method based on the discussion.

The quantitation limit (QL) may be expressed as: QL = 10 σ/ S where, σ= the deviation of the response; S = the slope of the calibration curve.

The residual standard deviation of a regression line or the standard deviation of y-intercepts of regression lines may be used as the standard deviation.

In all cases, the quantitation limit can be subsequently validated by the analysis of a suitable number of samples known to be near or prepared at the quantitation limit or reporting level.

The quantitation limit and the method used for determining the quantitation limit should be presented. For validation of the actual quantitation limit or reporting level:

Detection Limit
The detection limit is estimated as the concentration that corresponds to 3 times the standard deviation of the responses for the six injections.

A signal-to-noise ratio between 3 or 2:1 is generally considered acceptable for estimating the detection limit.

The detection limit (DL) may be expressed as: DL = 3.3 σ/ S where, σ= the standard
Determination of detection limit is not normally required for assay or identification tests.

It is recommended that the detection limit and the method used for determining the detection limit should be presented. It is suggested that for limit tests, the detection limit should be less than one-half the specification limit where technically feasible. The detection limit should be less than the required reporting level.

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