1.8.9. Robustness

Robustness of analytical procedure is a measure of its capacity to remain unaffected by small but deliberate variation in procedural parameters listed in the procedure documentation and provides an indication of its suitability during normal usage. Data obtained from robustness studies, though not usually submitted, are recommended to be included as part of method validation.

1.8.10. Peak purity

Peak purity testing in routine analysis adds important quality information to analysis results. A conventional single channel variable wavelength detector offers only quantitative information; information on peak purity is completely missing. Conventional multi-wavelength detectors allow calculating the ratio between two wavelengths signals as a first purity indication. If the spectral difference between the main component and the chemically similar impurity becomes is only visible at a spectral range different from two selected wavelength, the impurity becomes invisible of this detection technique. Representative HPLC chromatograms should be submitted for stressed and non-stressed samples that include impurities test method, preservative(s), etc, with the related placebo sample. Representative HPL chromatogram(s) to show selectivity by the addition of known extraneous compounds also should be submitted.

1.8.11. Resolution

This is a system suitability parameter that is used to calculate the efficiency of separation of two adjacent peaks to be well-resolved and it is expressed by the following equation:

$$Rs = \frac{2\ (tB\ -\ tA)}{WA + WB}$$

R= Resolution.