temperature. The sample is analyzed over a specified period using the fresh standard solution.

1.6.8 Filter Compatibility

Any filter used in the analytical procedures should not absorb either the active ingredient or any analyte of concern. Filtration of the samples is usually necessary to prevent undissolved drug particles from entering the analytical sample system and further dissolving. In addition, filtration removes insoluble excipients that may cause high background or turbidity. Pre-wetting of the filter with the medium may be necessary. Filters can be in-line or at the end of the sampling probe or both. The pore size can range from 0.45 to 70 µm. Depth, disk, and flow-through filters are widely used.

1.6.9 Robustness

The robustness of an analytical procedure is a measure of its capacity to remain unaffected by small but deliberate variations in procedural parameters listed in the procedure documentation and provides an indication of its suitability during normal usage.

1.6.10 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 wavelength 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 for this detection technique.