1.8.7. Accuracy

Accuracy is the closeness of test result obtained by the procedure to the true value (reference one). Accuracy may often be expressed as percent recovery by the assay of known added amounts of analyte. Accuracy is the measure of exactness of analytical procedure.

Accuracy can be accomplished in a variety of ways, including evaluating of recovery of the analyte (% recovery) across the range of the assay, or evaluating the linearity of the relationship between estimated and actual concentrations. For a drug product, this is performed frequently by the addition of known amounts of drug by weight or volume (dissolved in diluent) to the placebo formulation working in the linear range of detection of tile analyte. This would be a true recovery for liquid formulations. For formulations such as tablet, suppository, transdermal patch, this could mean evaluating potential interaction of the active drug with the excipients in the diluent. From a practical standpoint, it is difficult to manufacture a single unit with known amount of active drug to evaluate recovery. This test evaluates the specificity of the method in the presence of the excipients under the chromatographic conditions used for the analysis of the drug product. It will pick up recovery problems that could be encountered during the sample preparation and the chromatographic procedures. However, it does not count the effect of the manufacturing process.

1.8.8. Stability of analytical solutions

The standard solution is stored under conditions that ensure stability. The stability of the standard is analyzed over a specified period, using a freshly prepared standard solution at each time interval comparison. The sample solution is typically stored at room temperature. The sample is analyzed over a specified period using the original sample solution response for comparison.