

requirement and for two separate occasions, it is recommended to indicate the intermediate precision of the test method.

#### *1.8.5 Linearity*

Linearity is the method ability to elicit test results that are directly, or by a well-defined mathematical transformation, proportional to the concentrations of analyte in samples within a given range. It should be established initially by visual examination of plot of signals as a function of analyte concentration of content. If there appears to be a linear relationship, test result should be established by appropriate statistical methods (e.g., by calculation of regression line by the method of least squares). Linearity is usually expressed in terms of variance around the slope of the regression line calculated according to an established mathematical relationship from test result obtained by the analysis of samples with varying concentrations of analyte.

The linearity range for examination depends on the purpose of the test method. For example, the recommended range for an assay method for content would be  $NLT * 20\%$  and the range for an Assay/impurities combination method based on area % (for impurities) would be  $+20\%$  of target concentration down to the limit of quantitation of the drug substance or impurity. Under most circumstances, regression coefficient ( $r$ ) is  $> 0.999$ . Intercept and slope should be indicated.

#### *1.8.6. Range*

The range of an analytical method is the interval between the upper and lower levels of analyte in which is to be accurate, precise and linear.