periodically inspected, cleaned, maintained and calibrated according to the Standard Operating Procedures (SOP) (Cazes J., 2004).

1.8. Parameters for validation of the analytical HPLC method (USP)

1.8.1 Precision

The precision of an analytical method is the degree of agreement among individual test result when the procedure is applied repeatedly to multiple sampling of a homogenous sample. The precision of an analytical procedure is expressed as the standard deviation. As part of method validation, a minimum of 10 injections with an RSD of 11% is recommended. On the other hand, an RSD of < 1% RSD is recommended for the precision of the system suitability from at least five injections (n > 5) of the active drug.

1.8.2 System precision

It is used to ascertain injection repeatability and system suitability. It ascertains the effectiveness of the operating system as a single system.

1.8.3 Method precision

It is used to ascertain analysis repeatability by evaluating a number of samples containing known amounts of analyte.

1.8.4 Intermediate precision

Intermediate precision is the degree of reproducibility of test result obtained by the analysis of the same sample under a variety of conditions such as different laboratories, analysts, instruments and days. It is calculated by measuring the standard deviation. As a minimum