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