

1.7. Chromatography and method validation

1.7.1. HPLC



High performance liquid chromatography (HPLC) is a widely accepted separation technique for both sample analysis and purification. It can be utilized in a variety of areas including the pharmaceutical, biotechnological, environmental, polymers and food analysis. (Patania V., 2002).

1.7.2. Principle of HPLC

Chromatography is a technique in which solutes are resolved by differential rates of elution as they pass through a chromatographic column. The separation is related to the distribution between the mobile and stationary phases. The use of liquid chromatography (LC) requires the right combination of operation conditions such as the type of column, column length and diameter, mobile phase type and flow rate and the column temperature (Pantania V., 2002).

1.7.3 Calibration of HPLC instrumentation

Calibration of HPLC instrumentation, also called “qualification”, is the procedure that ensures that the instrument is qualified and its performance complies with the method’s predetermined requirements, providing reliable and valid results. The equipment used in any study should be tested on site, within certain time intervals and after repair. It should be