High-Performance Liquid Chromatography

High-performance liquid chromatography (HPLC) is an analytical technique used in both pharmaceutical and clinical laboratories to separate mixtures into their components. It is based on the principle that different substances will adsorb differently to a stationary phase (a solid support) and be eluted at different times when a mobile phase is passed through the column.

Microbiological Methods

In microbiological testing, the measure of interest is the volatile content. The volatile content is the amount of volatile matter driven off under specified conditions. Therefore, the nonpolar compounds are adsorbed less strongly to the stationary phase (which is more polar than the mobile phase). RPC is more common than NPC. In this mode, the mobile phase is more polar than the stationary phase (which is nonpolar).

Other chromatographic methods for specific applications include:

- Affinity chromatography: Separation is based on the interaction of a specific ligand attached to a solid phase with the analyte of interest.
- Ion-pair chromatography: A counter ion is added to the mobile phase to improve the separation of charged analytes.

Analytical Instrument Qualification

The goal of the laboratory is to ensure that the equipment is capable of consistently operating within specified limits. This is achieved through the process of instrument qualification, which includes:

- Accuracy: The degree to which a measured value agrees with the true value.
- Precision: The degree to which repeated measurements under unchanged conditions show the same value.
- Repeatability: The ability of the instrument to produce the same result under identical conditions.
- Reproducibility: The ability of the instrument to produce the same result when operated in different locations.

Accuracy

The degree to which a measured value agrees with the true value.

Verification

External standards used to measure the weight of volatile weight, and ion balance weights are defined as the mass of a chemical and the mobility phase.

Eccentricity

Weighing at least 30% of the maximum weight of the balance to examine the eccentricity of the instrument. Several batches of weights, each containing 20 distinct weights, are weighed at the same time.

Linearity

Degree to which the measured values of a substance in a specified range are linearly related to the concentration of the substance present.

Mass Spectrometry

Mass spectrometry is a powerful analytical tool and has significantly impacted the analysis of pharmaceuticals and other compounds. It is based on the principle that different substances will adsorb differently to a stationary phase (a solid support) and be eluted at different times when a mobile phase is passed through the column.

Loss on Drying (LOD)

This procedure determines the amount of volatile material lost under specified conditions. It is used to assess the moisture content of a material, typically a bulk powder or a dry substance.

Loss on Ignition (LOI)

This procedure determines the amount of inorganic material remaining after a specified temperature for a specified period of time. It is used to assess the moisture content of a material, typically a bulk powder or a dry substance.

Laboratory Balances

Laboratory balances are used in various applications to measure masses. They are designed to provide accurate and precise measurements over a wide range of mass values.

Clinical laboratory procedures typically involve the use of electronic balances, which are designed to provide accurate and precise measurements over a wide range of mass values. These balances are commonly used to weigh and measure the masses of various substances, including biological samples, pharmaceutical products, and other materials.

Internal Calibration/Adjustment

Historically, comparison with a reference mass, internal calibration using an equation, or reference mass where the balance is stable.

Repeatability

The smallest amount of mass difference in identical measurements against the standard mass.

Precise

The degree to which the measurement is reproducible under the same conditions.

Preservation

The degree of care taken to preserve the sample from degradation during storage.

Quality of the analytical results obtained in various factors, the most important of which include: Analysis, Instrument, and Interference.

References: