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Perspective

Quality by Design in HPLC Validation Methods in Pharmaceutical Industry

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DESCRIPTION

The method of High-performance Liquid Chromatography (HPLC) is used to divide molecules into groups according to their size and surface charge, among other characteristics. After separation, the concentration of molecules can be measured by combining HPLC with Ultra Violet (UV) spectroscopy. The stationary phase consists of a column containing an absorbent substance, often granular silica or polymer. A pressurised liquid solvent mixture, frequently including water, acetonitrile, and/or methanol, makes up the mobile phase. Depending on the sample of interest and the makeup of the stationary phase, the mobile phase is selected.

Size-exclusion chromatography, molecules within a sample can be separated by size during HPLC. The stationary phase is made up of porous silica beads, which small molecules can enter, while larger molecules must go around the beads and pass through the spaces between them. This allows larger molecules to elute more quickly than smaller ones, since smaller molecules become stuck within the silica beads for longer periods. This method can be used to infer the tertiary and quaternary structure of proteins and is frequently used to determine the molecular weight of proteins, polysaccharides, or polymers. Ion-exchange chromatography, based on their attraction to the stationary phase, molecules within a sample can also be separated. For example, the surface of a silica stationary phase has exposed, negatively charged oxygen atoms. Negatively charged molecules in a sample are prevented from interacting with the stationary phase and dissolve more quickly. HPLC is a widely used and incredibly potent chromatographic method, with applications in fields like pharmaceutical, bio analytical, food and beverage, clinical, forensic, environmental, and drug development labs.

The capacity of the analytical method to distinguish between the analytic and the other elements in the sample matrix is known as specificity. If using an HPLC approach, full separation of the analyte peak from other peaks originating from the sample matrix is required. Specificity evaluation was done by injecting separately 20 µl solution of standard, sample, placebo, and blank into the chromatographic system. To test the method's linearity, mixed standard solutions of potassium guaiacolsulfonate and sodium benzoate were created by diluting stock standard solution with the mobile phase to obtain various exact concentrations of potassium guaiacolsulfonate (0.127, 0.204, 0.254, 0.305, and 0.382 mg/mL) and sodium benzoate (0.238, 0.381, 0.476, 0.571, and 0.714 mg/mL), corresponding to 50%, 80%, 100%, 120%, and 150% of target concentration, respectively. Different solutions of potassium guaiacolsulfonate and sodium benzoate were analyzed and the signal-to-noise ratio for each analyte was measured in order to determine the Limits of Detection (LOD) and limit of Quantitation (LOQ) for each analyte. The Limit of Quantitation (LOQ) is the concentration giving a signal-to-noise ratio of about 10:1, with an RSD of less than 10% with triplicate analysis. The Limit of Detection (LOD) is the concentration giving a signal-to-noise ratio of around 3:1. Recovery tests for sodium benzoate and potassium guaiacolsulfonate from the placebo matrix were used to evaluate the method's accuracy.

The amount of consistency between a series of measurements made using numerous samples of the same homogenous sample under the specified conditions is referred to as the precision of an analytical procedure. There are three types of accuracy, repeatability, intermediate precision, and reproducibility. Precision that can be maintained over a brief period of time while operating under the same conditions is known as repeatability. Assay precision is another name for it is evaluated either by preparing three samples in triplicate at three concentrations, encompassing the range indicated for the method, or by making six sample measurements at 100% concentration. Recurring analyses of the same sample are required. Variation within laboratories is expressed by intermediate precision: various days, different analysts, different equipment's, etc. It is a term that is equivalent to the USP definition of ruggedness. Depending on the conditions in which the process is to be employed, intermediate precision should be created to a certain level.

The range of an analytical method is the range between the higher and lower concentration of the analytic in the sample (containing these concentrations), for which it has been shown that the analytical method has an adequate level of precision, accuracy, and linearity. Normally, the assay method covers between 80 and 120 percent of the test concentration. Depending on the kind of dosage form, a minimum of 70 to 130 percent of the test concentration must be covered for content uniformity.

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