Overview of immunoassay methods in pharmaceutical industries.

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Editorial

An immunoassay is a bioanalysis method in which the quantification of an analyte depends on the reaction between the antigen (analyte) and the antibody. This type of method competes between a fixed amount of labeled form of the analyte and a variable amount of unlabelled sample analyte for a limited amount of binding site on a highly specific anti-analyte antibody. Based on the binding reaction, when these immunoassay reagents are mixed and incubated, the analyte binds to the antibody and forms an immune complex. This complex is separated from the unbound reagent fraction by physical or chemical separation techniques. Analysis is accomplished by measuring the labelling activity (eg, radiation, fluorescence or enzyme) in the bound or free fraction. A standard curve is established showing the signal measured as a function of the concentration of the unlabelled analyte in the sample. The concentration of the unknown analyte is determined from this calibration curve. Immunoassays are used in many important areas of pharmaceutical analysis, including disease diagnosis, therapeutic drug monitoring, clinical pharmacokinetics and bioequivalence studies in the drug discovery and pharmaceutical industries. Analysis in these areas usually involves the measurement of very low concentrations of low molecular weight heparin, high molecular weight biomolecules of interest in pharmaceuticals, metabolites, and / or biomarkers that indicate the diagnosis or prognosis of the disease increases. The importance and prevalence of immunoassays in pharmaceutical analysis is due to their unique specificity, high throughput, and high sensitivity for the analysis of a wide range of analytic in biological samples. The detection system for immunoassays relies on easily detectable markers (such as radioisotopes or enzymes) bound to one of the immunoassay reagents (analytes or antibodies). The use of these markers in immunoassays results in very sensitive and low detection limits. In situations where specific measurements of large molecules at the atomol level from femtomole in complex biological matrices are required, immunoassays are arguably the method of choice due to their high specificity and sensitivity.

Large numbers of specimens need to be screened in the early stages of drug discovery and development, especially in clinical pharmacokinetic studies of new drug candidates. This can only be achieved by using high-throughput analysis methods. Analysis of complex biological matrices (eg, blood or urine) by immunoassays based on specific fixation reactions can be accomplished without sample pre-treatment. The development of a new immunoassay method for the analyte can take several months (due to the time it takes to generate the antibody of interest), but when the appropriate immunoassay reagent becomes available, the chromatographic method is used. You can establish an immunoassay method in the same time frame. In addition, new technologies have been developed to enable the rapid production of specific antibodies. These technologies have dramatically reduced the time required to develop an immunoassay method. In addition to these potential advantages of immunoassays, the relatively low cost of instruments, tools, or reagents makes immunoassays the method of choice in many areas of pharmaceutical analysis.

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