THE ROLE OF AND THE PLACE OF METHOD VALIDATION IN DRUG ANALYSIS USING ELECTROANALYTICAL TECHNIQUES

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Analytical method development and validation play a major role in the discovery and manufacture of pharmaceutically active compounds. In the pharmaceutical industry, analytical method validation is a major issue as analysis is used primarily to control drug quality.

Electroanalytical methods are chosen for the sensitive analysis of pharmaceutically active compounds in their dosage forms and in biological samples. Electroanalytical method validation is the process used to confirm that the determination procedure employed for a specific test is suitable for its intended use like other analytical methods. Results from electroanalytical method validation can be used to judge the quality, applicability, reliability and consistency of analytical results; it is an integral part of any analytical procedure. Also in electroanalytical drug analysis, important decisions are taken which are based on data obtained from real samples.

Validation applies to a defined protocol, for the determination of investigated compound and concentration ranges in a particular type of the test material used for a specified purpose. During last two decades, validation has become traditional to represent different aspects to method performance by reference to the separate items for different analytical techniques, and to a considerable extent these guidelines reflect that pattern. The requirements are clearly defined in ICH guidelines and some Pharmacopoeias such as United States (USP) or European (EP) Pharmacopoeias. However, the parameters considered necessary for the method validation of different types of analytical processes are shown some small differences.

Method validation is an essential component of the measures that a laboratory should implement to permit it to produce reliable electroanalytical data. In method validation, the quantitative characteristics of interest relate to the accuracy and precision of the result likely to be supplied. It is recommended to prove the suitability of the method for its intended use in initial experiments and design of the electroanalytical techniques, if there is little or no information on performance characteristics of the method. These studies should include the detection limit, linearity and range, accuracy and the approximate precision. If this preliminary validation data appear to be inappropriate, the method itself, the equipment, the electroanalytical technique or the acceptance limits should be changed.

The electroanalytical experiments including all the steps of the sample preparation should be applied as far as possible, when performing validation studies. Validation parameters are determined based on the analysis of the measured electroanalytical values and that is something to be kept in mind during the validation of an electroanalytical procedure. In electroanalytical drug analysis, important decisions are taken which are based on data obtained from real samples. The quality of electroanalytical data is the key to drug development programme success and the process of method development and validation has a direct impact on the quality of these data. Therefore, it is generally accepted that method validation is required to demonstrate the performance of the method and the reliability of the analytical results. Method validation is an essential component of the measures that a laboratory should implement to permit it to produce reliable electroanalytical data. Acceptance criteria can be dependent on the nature of the sample, the type of analytical methodology, and the purpose of carrying out the analysis.

Validation parameters help assure that the electroanalytical methods ensure the correct identity, strength, quality, accurate, precise, selective, robust and sensitive. A well-defined and well-documented validation process provides regulatory agencies with evidence that the system and method suitable for its intended use.