THE ROLE OF ANALYTICAL CHEMISTRY IN CLINICAL STUDIES OF DRUG RESEARCH

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Key Words: Method development, validation, clinical studies, pharmacokinetics

Analytical chemistry is the art and science of determining and quantifying the matter. A lots of clinical trials are being constructed in the world to evaluate the bioavailability and bioequivalence of pharmaceutical products.

Human volunteers are used in clinical studies. Relatively high number of volunteers who involved in the study with being health assurance. The assurance of these results for the volunteers may only be guaranteed if the analytical method for the conduction of the study has been previously developed and validated. The developing analytical method should meet the requirements of sensitivity and detectability of the drug, according to its plasma concentrations in the pharmacokinetic curve. The concentration range of method should cover the maximum plasma concentration of drug and be linear. Drug stability in biological fluids is the most important step in analytical side of clinical studies. The level of interferents should be evaluated and originated endogenous and exogenous.

In this study, important points of developing and validation of bioanalytical method for analyzing drug concentration from plasma which is necessary to evaluate clinical studies will be discussed.

References

2. Guidline on Good Laboratory Practice (21.12.1995/8863)