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Analytical Chemistry, Preformulation Research and Regulatory Requirements

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Abstract: *Experimental data for preformulation study is significant to develop a stable and safe drug product and forms the basis of preliminary information required to develop and design the final formulation. The experience, knowledge of drug substance components and ingredients planned to use in formulation, plays an important role in designing the preformulation studies. Co-ordination between the departments such as mainly analytical research and formulation research in conducting these studies i.e., interdepartmental co-ordination, exchange of information and knowledge to perform research experimentation is necessary, to understand the knowledge of the complete lifecycle of the drug product. Analytical chemistry deals with methods of analysis developed and planned to use for content determination of related substances/impurities leads to get noteworthy information required to develop stable formulation and to determine the stability of the drug product. The usage of multiple instrumental techniques for identification, estimation and characterization techniques are essential to get the results of the research studies. The cGMP and GLP requirements should be fulfilled and followed as per the respective country specific regulatory guidelines.*

Keywords: Analytical Instrumental Techniques, Methods of Analysis, Pharmaceutical Regulatory Authorities, Preformulation Study

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