

develop generic product formulation to assure that the generic drug product is bioequivalent and stable, in addition to its quality and manufacturability in batch sizes exceeding 100,000 units.

Analytical method is an integral part in a QbD system. It is used to collect in-process information for timely control decisions. It is used for monitoring and trending process parameters and for monitoring product quality. The QbD system provides data to better understand the process. The data collected using analytical test methods can be used for continued process and product improvement. Analytical method for a specific drug product line and its extensions is part of the control strategy to assure process performance and product quality. Analytical methods and product specifications developed based on numerous product batch performance also provide information for risk management, which includes assessment of product efficacy and safety.

While scale-up of the new generic oral dosage form in one or more strengths is ongoing to prepare clinical supplies for pilot bioequivalence studies, in-process testing and methods for such testing are developed to assure proper control of the process and the quality of the drug product. Generally, test methods for finished dosage forms are stability indicating, and the information generated from accelerated stability test results of the drug product in the final packaging intended for commercialization is used by the product development team of scientists and regulatory staff to determine the drug product specifications, including those not specified by the compendia. The prime objective of the analytical chemist is to assure that the generic drug product in a final commercial packaging is in compliance with compendial standards in identity, potency, content uniformity, dissolution, and acceptable limits on impurities and related substances.

In this chapter, we have placed a strong emphasis on the importance of robust method development, in-process control methods, and validation approaches taken to finalize such methodologies for development. Also emphasized is the importance of documentation of dissolution and finished drug product specifications for the drug product for submission in the Chemistry, Manufacturing, and Controls sections of the ANDA, which is mainly reflected in Modules 2 and 3 of the common technical documents format required recently by the FDA. The reader is referred to several literature sources and Center for Drug Evaluation and Research guidances available on this topic [2–8].

METHOD DEVELOPMENT

Analytical test methods are used to generate data for establishing the identity, potency, purity, and overall quality of the drug substance and drug product. A well-developed test method not only can control the quality of the product but also can speed up the development process by shortening the development time for raw material vendor selection, qualification, and formulation screening. Further, a well-developed test method can enhance the efficiency for the downstream product launch and routine release tests. Analytical test methods are the stakeholders of product development in providing accurate and reliable data to support product formulation specifications, packaging specifications, process development, characterization and