process controls, stability and release, pharmacokinetics and bioequivalence, and regulatory filing.

The time and effort spent in developing a robust and efficient test method is well worth it for the downstream method users such as laboratory technicians and chemists in the quality-control laboratories of the generic drug manufacturer. A test method with shorter run time and less use of solvents can save much labor and cost for the quality-control laboratories for years to come in future production.

The performance of a test method is determined primarily by the quality of the procedure itself. Timing is critical for method development because "first to approve" means substantially high profit versus the late comers.

Before developing a test method, one must define the scope and requirements for the test method. The objectives for the test method will ultimately define the extent of the development and optimization. The requirements for the test method include the following issues to be addressed: (1) regulatory compliance, (2) technical requirements, (3) practical requirements, (4) validation requirements, and (5) transfer requirements. Once these requirements have been addressed, the method development scientist can start with a literature search and information gathering. A plan can be developed with clear objectives for the method, such as requirements for the separation of known compounds, chromatographic procedures, and a targeted timeline. Adequate resources should be allocated for method development before initiating the bench work. Typical sample solution and standard solution can be used to evaluate different chromatographic conditions. It is suggested that one should fully utilize the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines [9–11] regarding the reporting threshold, identification threshold, and qualification threshold. The ICH and USP chapter <467> defined residual solvent classes, and allowable limits can be used for method development and release specification. When the main objectives are met, the test method can be further optimized to make it more economical and user-friendly. Once the optimization is completed, the method is challenged to see if it can be validated. For chromatographic procedures, the challenges are often method sensitivity and method selectivity. These method prevalidation evaluations can determine if the method is ready for validation.

The following are the commonly needed test methods in the development and manufacturing of generic oral pharmaceutical solid dosage forms.

API Test Methods

The objectives for the development of the API test methods are for raw material vendor selection and raw material release. Where multiple vendors of an API are available, test methods are needed to characterize each lot of API and evaluate the raw material quality. The quality and characteristics of the APIs can often influence the formulation development concerning the dissolution profile and stability of the final dosage form in development.

Typical test methods for the API release include identification, assay, chromatographic purity, residual solvents, particle size measurement, and polymorph determination in addition to commonly required compendial tests such as water content (loss