TABLE 3.1
Recommended Validation Characteristics of the Various Types of Tests

Type of Tests/ Characteristics	Identification	Testing for Impurities		Assay Dissolution (Measurement Only), Content/Potency	Specific Tests
		Quantitative	Limit		
Accuracy	–	+	–	+	+[a]
Precision-repeatability	–	+	–	+	+[a]
Precision-intermediate precision[b]	–	+[c]	–	+[c]	+[a]
Specificity	+[d]	+	+	+[e]	+[a]
Detection limit	–	–[f]	+	–	–
Quantitation limit	–	+	–	–	–
Linearity	–	+	–	+	–
Range	–	+	–	+	–
Robustness	–	+	–[f]	+	+[a]

Note: See draft guidance for analytical procedures and methods validation of FDA (August 2000). – signifies that this characteristic is not normally evaluated, and + signifies that this characteristic is normally evaluated.

[a] May not be needed in some cases.

[b] Ruggedness is considered as intermediate precision.

[c] In cases where reproducibility has been performed, intermediate precision is not needed.

[d] Lack of specificity for an analytical procedure may be compensated for by the addition of a second analytical procedure.

[e] Lack of specificity for an assay for release may be compensated for by impurities testing.

[f] May be needed in some cases.

One should keep in mind that although a noncompendial procedure has been validated, when a compendial procedure exists, an equivalency study is needed for the regulatory submission to demonstrate that the noncompendial procedure is equivalent to the compendial procedure. The method equivalency study is discussed in Method Equivalency Study. When a legal dispute occurs, the compendial procedure will be used to judge the product quality and compliance with the regulations.

Development of a Validation Protocol

The development of a method validation protocol should be based on the requirements of the product specification and regulatory guidelines including internal standard operating procedures (SOPs). A protocol should include the target method to be validated, preapproved validation elements, and acceptance criteria. It should also describe the requirements for protocol execution, experimental design, a plan or procedure when acceptance criteria are not met, and reporting items.