Table 6 ICH Validation Characteristics Versus Type of Analytical Procedures

Type of analytical procedure	Identification	Impurity testing		Assay
		Quantitative	Limit tests	
Accuracy	No	Yes	No	Yes
Precision				
Repeatability	No	Yes	No	Yes
Intermediate precision	No	Yes	No	Yes
Specificity	Yes	Yes	Yes	Yes
LOD	No	Yes	Yes	No
LOQ	No	Yes	No	No
Linearity	No	Yes	No	Yes
Range	No	Yes	No	Yes

Source: Refs. 35 and 37.

The difference in the USP and ICH terminology is for the most part one of semantics; however, there is one notable exception. In the ICH Guidelines, system suitability is part of validation, whereas the USP deals with system suitability under chromatography in the USP, called General Chapter <621> Chromatography (24). The FDA is already implementing the ICH Guidelines, and it is anticipated that the ICH definitions and terminology will become a part of the USP chapter on validation. It is probable that USP categories I and II will match the ICH categories of Assay and Impurity testing, respectively. The ICH has not yet chosen to address methods for performance characteristics (USP Category III) but has instead included analytical methods for compound identification. In this ICH category, it is only necessary to show that the method is specific for the compound being identified.

ICH Guidelines Q2B is complementary to ICH Guidance Q2A, which presents a discussion of characteristics that should be considered during the validation of analytical procedures. This guidance gives recommendations on how to consider the various validation characteristics for each analytical procedure. These recommendations will be discussed in detail under definition of validation parameters.

16.3. FDA Reviewer Guidance

The FDA Reviewer Guidance—Validation of Chromatographic Methods provides comprehensive description of typical validation parameters and how these are determined (40). This FDA guidance has similarities to the ICH Guidelines Q2A and Q2B, but has examples in form of tables or figures to demonstrate data representation for validation parameters. The purpose of this guidance is to present the issues to be considered when evaluating chromatographic test methods from a regulatory perspective. Examples of common problems, which can delay the validation process, have been included.

The validation characteristics to be evaluated according to this FDA guidance are