Table 7 Comparison of Analytical Parameters Required for Assay Validation

USP General Chapter <1225>	ICH Q2A Guidelines	FDA Reviewer Guidance
Accuracy	Accuracy	Accuracy
Precision	Precision	Precision
No	Repeatability	Repeatability
		Injection
		Analysis
No	Intermediate precision	Intermediate precision
No	No	Reproducibility
Specificity	Specificity	Specificity/selectivity
Detection limit	Detection limit	Detection limit
Quantitation limit	Quantitation limit	Quantitation limit
Linearity	Linearity	Linearity
Range	Range	Range
Ruggedness	No	No
Robustness	Robustness	Robustness
System suitability[a]	System suitability	System suitability
		Sample solution stability

[a] System suitability discussed separately in USP 23 General Chapter <621>.

Accuracy
Detection and quantitation limits
Linearity
Precision
Repeatability
Injection repeatability
Analysis repeatability
Intermediate precision
Reproducibility
Range
Robustness
Sample solution stability
Specificity/selectivity
System suitability specifications and tests

A comparative discussion of validation parameters given in the FDA and ICH guidelines will be made under Sec. 17, "Definition of Validation Parameters." Analytical parameters needed for method validation as described in the General Chapter <1225>, ICH Guidelines Q2A, and the FDA Reviewer Guidance are summarized in Table 7.

17. DEFINITION OF VALIDATION PARAMETERS

In the literature, there are many articles on definition and interpretation of validation parameters required for assay validation as published by Krull and Swartz (38,39,41,42). Persson et al. (43) have discussed the evaluation of method