Analytical Method Performance, Validation, and Documentation Requirements vary per Phase of Development

	Phase I	Phase II	Phase III	Typical Number of Methods
Raw Materials	COA ID test Use test No validation	COA Specificity Use test Linearity	Phase II activities + Intermediate precision + Robustness	2-4 Per Raw Material
In-process controls	Use test Specificity	Use test Specificity Linearity	Phase II activities + Robustness	Drug Substance: 12-18 per process Drug Product: 3-5
Drug Substance and Drug Product	Specificity Linearity Accuracy + Precision LOD/LOQ	Phase I activities + Intermediate precision	Full ICH (Phase II activities + Reproducibility + Robustness + Specificity*)	Drug Substance: 3 Drug Product: 3 per strength (average 3 strengths)