

Guidance Number: 002

Table 1: Methods types and their recommended risk levels

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Risk Level	Analytical Method Type
Higher	<ul style="list-style-type: none">Registered Methods for Raw Materials, Intermediates and IPC's (e.g. impurities, assay, stability)Methods Testing Critical Quality Attributes of IntermediatesMethods to test Critical Process ParametersMethods identified from QARs or the APR process that are not robust (e.g. are troublesome, failing methods)
Medium	<ul style="list-style-type: none">Non-critical IPC methods for intermediatesMethods Testing Critical Quality Attributes of Raw Materials

Lower	<ul style="list-style-type: none">Other Methods to test API raw materials
No Validation Required (No impact to API quality). Note: although validation isn't required to meet GMP expectations, validation should be considered as a valuable tool to assure that safety and environmental methods provide accurate information	<ul style="list-style-type: none">Assays that generate data used only for safety, environmental, operational decisions, efficiency, yield (no quality impact)Methods used during a processing step that are redundant with a validated release method.