

Table 1: Methods types and their recommended risk level

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

Lower	<ul style="list-style-type: none"> <li>Other Methods to test API raw materials</li> </ul>
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"> <li>Assays that generate data used only for safety, environmental, operational decisions, efficiency, yield (no quality impact)</li> <li>Methods used during a processing step that are redundant with a validated release method.</li> </ul>

**Evaluation Process:**

Conduct a cross functional and documented analytical test method evaluation based upon an understanding of the test data utilization by the Site Quality Authority and other site functions.

This cross functional review might be conducted by colleagues drawn from the Site Quality Authority, Site Production Operations, development support and other site based or center technical functions as necessary.