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Analytical Method & Validation

Pharma, Chemicals & Life Sciences

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This guide explains what the tool produces, how to use the output, and what to watch for. The actual output (draft/report) is generated on the tool page.

Background

Builds an analytical method validation structure — specificity, linearity, accuracy, precision, LOD/LOQ, robustness and system suitability — with acceptance criteria and protocol/report documentation. Use this to validate a test method per ICH Q2. For the routine testing SOP use the QC Laboratory SOP.

Purpose of this tool & output

Validate the methods you test with

How the output is used

Use it to structure an analytical method and its validation so the methods you test with are proven fit for purpose.

Important cautions

AI-generated structure; follow ICH Q2 and pharmacopoeial requirements.

Companion documents

- QC Laboratory SOP
- Stability Study Protocol
- Certificate of Analysis (COA)
- OOS / OOT Investigation
- Quality Manual Builder
- Document Control & Data Integrity

This is AI-assisted guidance. Verify with a qualified professional before any binding decision. Fees, authorities and processes vary by state and change over time — confirm with your state authority.