

This API Method Validation Checklist Helps Avoid Common Mistakes

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Physiochemical Properties

- Solubility
- pH
- pKA
- Reactivity
- Melting point
- Boiling point
- Moisture sensitivity
- Light sensitivity
- Heat sensitivity
- Corrosivity
- Polymorphism
- Dissociation
- Other physical or chemical properties unique to the molecule of interest

Validation purpose

- Release of raw material?
- In-process control?
- Final product release testing?

Product questions

- Route of administration?
- Maximum daily dose?
- Length of administration?
- Components to be monitored for each sample?
- Specifications?
- Genotoxic impurities?
- Impurities profile?
- Maximum daily dose?
- Robustness against various parameters?
- Acceptance criteria?
- Filter studies
- Forced degradation testing/degradants
- Testing conducted under cGMP and ICH guidelines?
- Column challenge/column performance
- Upper and lower pH limits
- Limit of detection values
- Limit of quantitation values
- Method transfer
- Column cleaning procedure

Are these drug substance attributes supported in method validation?

- Identity
 - Strength
 - Quality
 - Purity
 - Potency
 - Reproducibility
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- Are all observations captured in methods validation report?
 - Has method validation been peer reviewed?
 - Has method validation been approved by QA?