Summary of Method Validation SOP:

The objective of analytical method validation nis to demonstrate that an analytical method is suitable for its intended use.

Typical analytical types:

* Assay
* Dissolution
* Related Substances/Impurities
* Residual Solvents
* Cleaning Validation

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| --- | --- |
| For Drug Substances | Compendial methods (USP, BP, EP, JP) suitability of use under actual conditions need to be verified.  Non-compendial (manufacturer, client-provided, etc.) the method validation data must be received and determined to be suitable for intended use at which point, additional method validation studies may be needed and suitability use under actual conditions need to be verified.  Refer to Table 1 and 2. |

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| For Drug Products | Compendial methods (USP, BP, EP, JP) all validation studies should be performed with the exception of linearity.  Non-compendial (manufacturer, client-provided, etc.) the method validation data must be received and determined to be suitable for intended use at which point, additional method validation studies may be needed and suitability use under actual conditions need to be verified.  Refer to Table 4 and 5. |

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Specific method validation tests based on HPLC, UPLC, GC:

Validation tests should typically be assessed upon the system suitability criteria being established in order to assess validity of the test.

| Validation Test | Acceptance Criteria |
| --- | --- |
| System Suitability | Meets system suitability requirement set forth by individual analytical procedure. |
| Linearity and Range | Range: Testing range to be validated. Typical ranges as follows:   * Assay: 50-150% of target sample concentrations * Dissolution: 10%-150% of target sample concentration * Related Substances/Impurities, Residual Solvents: QL-150% (QL defined as Quantitation Limit of the method)   Linearity: |
| Specificity (Identification, Interference) | Identification: Evaluate peak identities via retention time.  Matrix Interference: Assess interference of peak of interest from sources such as diluent and sample matrix. |
| Specificity (Forced Degradation) | — |
| Accuracy |  |
| Filter study (if used) |  |
| Precision/  Repeatability |  |
| Intermediate Precision/ Reproducibility |  |
| Quantitation Limit | Applies only to Related Substances, Impurities, Residual Solvents  Signal-to-Noise: not less than (NLT) 10 |
| Stability Solutions | Typical evaluations on standard, sample, mobile phase solutions |
| Robustness | — |

Abbreviations:

|  |  |
| --- | --- |
| NMT: | Not more than |
| NLT | Not less than |
| RSD | Relative standard deviation |
| CU | Content Uniformity (Uniformity of Dosage) |
| USP, BP, EP, JP | United States Pharmacopoeia, British Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia |