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Analytical Method Validation: A Comprehensive Review

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Abstract: The creation of reliable analytical method(s) is essential to the process of discovering novel medications, bringing them to market, and refining them further to obtain marketing clearance. This research examines the creation, refinement, and verification of the medication's method. Product from the initial creation of the formulation to the commercial batch. Approach development for the interested party in process tests, the sample, or the final product manufacturing of the therapeutic product and to provide practical methods for determining the following: linearity, range, accuracy, precision, stability of the recovery solution, specificity, detection limit, quantitation limit, selectivity, and the resilience and robustness of liquid chromatographic techniques to enable routine, in-process, and stability analysis.

Keywords: Analytical Method Development, Validation Parameters, Acceptance Criteria



