

Analytical Method Validation in HPLC: A Regulatory Perspective Based on ICH Guidelines

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Abstract: *The ongoing processes of method development and validation follow the development of pharmaceutical goods. Existing analytical techniques may need to be modified in response to changes that occur throughout the drug development process. Further validation may be necessary as a result of these methodological changes. If the current methods are inconsistent or unreliable, time-consuming, or too costly, the introduction of new techniques and enhanced instruments in the area of analysis may pave the way for more sensitive, accurate, and precise approaches. Therefore, ongoing efforts to develop and validate novel analytical methods are crucial for the expanding drug development programs.*

Keywords: HPLC, Validation, Development, Precision, Accuracy, Linearity