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An Enhanced Approach in Validating Analytical Methods Using Tolerance-Based Design of Experiments (DoE)

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Abstract : The effective validation of analytical methods forms a crucial component of pharmaceutical manufacturing. However, traditional validation techniques can occasionally fail to fully account for inherent variations within datasets, which may result in inconsistent outcomes. This deficiency in validation accuracy is particularly noticeable when quantifying low concentrations of active pharmaceutical ingredients (APIs), excipients, or impurities, introducing a risk to the reliability of the results and, subsequently, the safety and effectiveness of the pharmaceutical products. In response to this challenge, we introduce an enhanced, tolerance-based Design of Experiments (DoE) approach for the validation of analytical methods. This approach distinctly measures variability with reference to tolerance or design margins, enhancing the precision and trustworthiness of the results. This method provides a systematic, statistically grounded validation technique that improves the truthfulness of results. It offers an essential tool for industry professionals aiming to guarantee the accuracy of their measurements, particularly for low-concentration components. By incorporating this innovative method, pharmaceutical manufacturers can substantially advance their validation processes, subsequently improving the overall quality and safety of their products. This paper delves deeper into the development, application, and advantages of this tolerance-based DoE approach and demonstrates its effectiveness using High-Performance Liquid Chromatography (HPLC) data for verification. This paper also discusses the potential implications and future applications of this method in enhancing pharmaceutical manufacturing practices and outcomes.

Keywords : tolerance-based design, design of experiments, analytical method validation, quality control, biopharmaceutical manufacturing
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