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Multivariate Bayesian Mixed Model for Method Comparability

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In pharmaceutical manufacturing, the analytical method to measure the responses of interest is often changed during the lifetime of a product due to new laboratory included, new equipment, or different source of starting material. To evaluate an impact of such change, method comparability assessment is needed. Method comparability is traditionally evaluated by comparing summary measures such as mean and standard deviation to a certain acceptance criterion, or by performing two one sided tests (TOST) approach. In this work, method comparability is applied in the context of two Malvern Mastersizer laser diffraction instruments MS2000 (old platform) and MS3000 (new platform) that are used to measure particle size distribution. A design of experiment is implemented, followed by the formulation of a multivariate Bayesian mixed model that was used to encompass a complex scenario. A Bayesian approach allows for a posterior distribution-based evaluation of method comparability. Aside from traditionally used summary criteria, posterior predictive distributions were also computed and compared for the two platforms. Moreover, a risk-based assessment of method transition was done through computation of probability of success of passing certain specification limits for the two platforms, and through assessment of the impact of changing the method on the performance of the overall process. The workflow has been successfully applied to multiple drug substances and drug products.

Keywords

Method Comparability, Multivariate Bayesian mixed model, Laser diffraction, Probability of success

Classification

Both methodology and application

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