"The Posterior Probability of Passing a Compendial Test"

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Compendial tests, such as unit dose uniformity (UDU), represent standards against which product batches may be accepted or rejected. A lower bound on the probability of acceptance for such tests can be used as a batch acceptance or process validation criterion. Conformance to the lower bound can be determined from test data using sampling theory arguments (e.g., ASTM E2709). Such probability estimates reflect product quality and should also be useful to both regulators and manufactuerers for risk/ manufacturing/ cost assessment as well as life-cycle management. However, sampling theory probability estimates are not ideal for such uses. In this presentation, we argue that sound decision making based on probability estimates is facilitated by a Bayesian point of view. Methodology for estimating the posterior probability of passing the UDU test is described and its advantages compared to sampling theory approaches are illustrated.