Formulating two classes of power priors to leverage historical accelerated stability data

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Abstract:

This abstract presents the implementation of power priors for leveraging historical accelerated stability data to estimate shelf-life and long-term prediction. Power priors are the popular techniques of prior elicitation and are widely used in many areas where historical data are available. However, there is a lack of literature on the use of power priors for accelerated stability studies. Accelerated stability studies are an essential part of the drug development process as they provide a means to rapidly evaluate drug product stability over time by exposing the product to higher-than-normal temperatures and humidity levels. Furthermore, these studies provide valuable information on the stability and shelf-life of a product before it is released to the market. However, these studies can be expensive due to the specialized equipment, facilities, and personnel needed to carry out the testing, and the resulting data is usually limited. This study aims to fill these gaps by formulating and comparing two classes of power priors for leveraging historical accelerated stability information. For each class of power priors, a Bayesian kinetic model is fitted, which is usually used in accelerated stability studies to estimate the shelf-life and degradation kinetics of pharmaceutical products. The two classes of power priors are: (1) power prior with a fixed discounting parameter, (2) normalized power prior with a random discounting parameter. In summary, this study has two main contributions: (1) It provides a comprehensive framework for two classes of power priors to leverage historical accelerated stability data and (2) It allows for the incorporation of historical data to have more efficient and accurate estimation of shelf-life and long-term prediction when we have limited data.