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A Bayesian approach to accelerated stability modeling and shelf-life determination

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Chemical and physical stability of drug substances and drug products are critical in the development and manufacturing of pharmaceutical products. Classical stability studies, conducted under defined storage conditions of temperature and humidity and in the intended packaging, are resource intensive and are a major contributor to the development timeline of a drug product. To provide support for shelf life claims and expedite the path to clinical implementation, accelerated stability studies in combination with stability modeling have become common practice in the pharmaceutical industry.

In this context, a unified Bayesian kinetic modeling framework is presented, accommodating different types of nonlinear kinetics with temperature and humidity dependent rates of degradation. In comparison to kinetic modeling based on nonlinear least-squares regression, the Bayesian framework allows for interpretable posterior inference, straightforward inclusion of the effects of the packaging in shelf life prediction, flexible error modeling and the opportunity to include prior information based on historical data or expert knowledge. Both frameworks perform comparably for sufficient data from well-designed studies. However, the Bayesian approach provides additional robustness when the data are sparse or of limited quality. This is illustrated with several examples of modeling and shelf life predictions.

Type of presentation

Talk

Classification

Both methodology and application

Keywords

Accelerated stability studies, Shelf life prediction, Bayesian kinetic modeling

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