Special Issue

In Vivo Predictive Dissolution (iPD): Experimental and Mathematical Approaches and Regulatory Applications

Message from the Guest Editors

In vivo predictive dissolution (iPD) methodology is a useful tool in predicting the in vivo behavior of the drug products. Many apparatus, media conditions and methodological mathematical approaches can be used to obtain the predicted plasma concentration profile of the studied drug products in human after oral administration. In vitro–in vivo correlations (IVIVC) can be product development tools, and eventually, they could be used with regulatory purposes to get biowaivers. The aim of this Special Issue is to cover all the aspects related with in vivo predicting dissolution from new apparatus, new media composition to mathematical modeling issues (such as time and magnitude scaling). We also aim to explore the advantages and shortcomings of custom-made models versus closed software applications and to discuss the implications of the different calculation methods as individual versus average profile use. Finally, we aim to revise the regulatory requirement standards for data presentation worldwide and to present practical examples of successful validated IVIVC that have served as BE surrogates.

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