

Conference abstract PPAT13

***In Vitro-In Silico* Tools to Identify Biorelevant Dissolution Specifications for the Selected Poorly-Soluble Model Drugs**

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Introduction:

The most commonly used drug physicochemical property to access its in vivo performance is in vitro dissolution of a drug product. It is, therefore, important to define drug release methodology that would be predictive of its bioperformance and to establish quantitative in vitro-in vivo correlation (IVIVC).

The objective of this study was to: i) to develop drug-specific absorption models for the selected BCS Class II model compounds (nimesulide, glimepiride, gliclazide) using gastrointestinal simulation technology (GST), ii) to use the generated absorption models to provide the target in vivo dissolution profiles for IVIVC, iii) to identify biorelevant dissolution specifications for IR tablet forms of the tested model drugs.

Experimental:

GST [1] was used for in silico prediction of oral drug absorption. The input parameters required for the simulation were experimentally determined, in silico predicted and/or taken from the literature. Parameter Sensitivity Analysis (PSA) was used to assess the sensitivity of the predicted rate and extent of drug absorption to the selected input parameters. A set of experimentally observed and virtual in vitro data were used for correlation purposes. Level A IVIVC was applied to assess the relationship between the in vitro and in vivo data.

Results:

The results obtained indicate that: i) PSA can aid to identify critical parameters affecting the rate and extent of drug absorption, ii) GST can be successfully used to predict drugs absorption profiles, iii) IVIVC in conjunction with GST can aid to identify biorelevant dissolution specifications for the in vitro assessment of the tested model compounds.

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- [1] Agoram B, Woltosz W, Bolger M. Predicting the impact of physiological and biochemical processes on oral drug bioavailability. Adv Drug Deliv Rev. 2001; 50: S41–S67.
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