InSilicoMinds

LAI Bioequivalence prediction

To establish an IVIVR model for predicting the Bioequivalence outcome

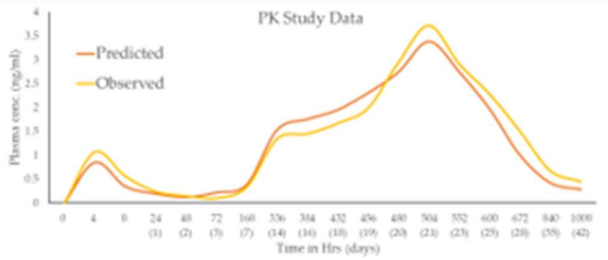
December 2021 | Bioequivalence, IVIVR, Microspheres

Background: The Sponsor intended to have a bio-predictive media followed by IVIVR model to predict the plasma exposure for different in-vitro release and different doses. The Sponsor had performed a pre-clinical study on the higher strength.

Question of Interest: Could Modeling and Simulation predicts the Human BE outcome without conducting actual BA BE study?

Methods: Pre-clinical BA BE data of the test product and the reference were used in the analysis.
The in silico BE predictions were done by means of IVIVC modeling followed by virtual BE

Results:
A validated IVIVC model (see figure) was developed and used to simulate the "BE outcome".



Drug Record	C_{max} (ng/mL)			AUC (ng/mL*h)		
	Obs.	Pred.	% Pred. Error	Obs.	Pred.	% Pred. Error
Microspheres (LAI)	3.72	3.39	**8.87**	1110	1005	**9.45**

Impact:

- The M&S methodology for IVIVR model building predicted the BE outcome for different in-vitro release profiles.
- The Sponsor reduced costs and timelines by decreasing the development timeline and number of clinical studies.