

In Silico Bioequivalence – to replace clinical trial

In silico SD Bioequivalence trial to replace clinical trial

20 May 2023 | In Silico Bioequivalence, Clinical Trials, Modeling and Simulation

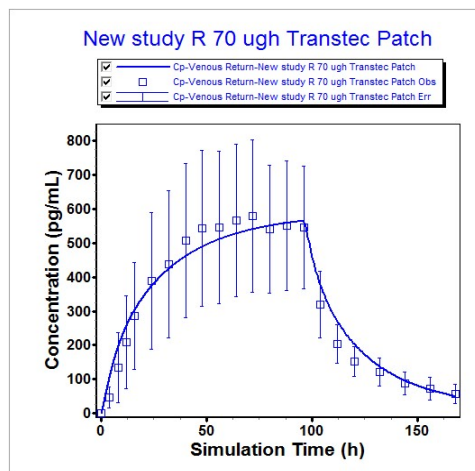
Background: The Sponsor intended to launch a new generation of a dermal patch already approved and established in the market. The Sponsor had performed a SAD study with the new generation patch.

Question of Interest: Could Modeling and Simulation replace the SD BE trial by a SD BE in silico?

Methods: SAD PK data of the new patch and SD PK data of the reference were used in the analysis. The in silico SD BE trial was performed by means of parametrized transdermal PBPK modeling.

Results:

A validated transdermal model (see figure) was developed and used to simulate the SD BE trial.



Impact:

- The Agency accepted the Sponsor's clinical development program including the in silico SD BE study.
- The Sponsor reduced costs and timelines of the new generation patch development program.