A work from Paulo Paixão, Luís Gouveia and José Morais entitled "An alternative single dose parameter to avoid the need for steady-state studies on oral extended-release drug products" published in the European Journal of Pharmaceutics and Biopharmaceutics was granted with the 2012 AAPS Outstanding Manuscript in Modeling and Simulation Award.

Research paper

An alternative single dose parameter to avoid the need for steady-state studies on oral extended-release drug products

Paulo Paixão, Luís Gouveia, José A.G. Morais

In this paper, simulation tools were used in order to evaluate the current standards in human clinical trials required from the EMA and FDA in order to establish the bioequivalence between two extended-release oral drug products. Their models have shown that the extra trials required by EMA (clinical trials with multiple administrations of the drug products) resulted in an increase ability to identify differences between two products when compared to the current requirements of the FDA, but at the cost of larger number of tested subjects and extended contact of the subjects with the drug products. Their simulations also identified an additional pharmacokinetic metric, which could be collected in a single dose assay as required by the FDA, and that could waive the extra clinical trials required by the EMA.

This study presents a rationale for the harmonization of the required clinical evidence between the two drug agencies, by reducing the number of trials and human subjects, without compromising the quality evaluation of the two drug products."