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Application of simultaneous dissolution-absorption apparatus for screening formulations before bioequivalence studies

Balint Sinko[1,2], Eniko Borbas, Konstantin Tsinman[1], Gyorgy Marosi and Zsombor K Nagy
[1]Pion Inc., USA
[2]Budapest University of Technology and Economics, Hungary

For generic drug development traditional dissolution tests have been used in the pharmaceutical industry to compare performance of different drug product formulations before conducting bioequivalence studies, even though the *in vivo* predictive power of these tests are questionable. When a poorly water-soluble API is formulated to enhance its dissolution, additives have an effect not only on dissolution, but also on flux through the membrane. The aim of this study was to demonstrate that a simultaneous dissolution-absorption test can be used as a predictive tool before bioequivalence studies are conducted. Telmisartan tablets were tested using MacroFLUX. Receiver chamber integrated with permeation membrane, overhead stirrer and UV probe was inserted in the standard 900 mL vessel of USP II apparatus. An artificial membrane with 3.8 cm^2 area was separating the dissolution compartment from the receiver compartment containing 15 mL of pH7.4 buffer. The dissolution and flux results of the brand name (Micardis) and generic (Actavis) Telmisartan 40 mg tablets were compared. Actavis showed a slower release kinetics than Micardis, though reached the same maximum concentration after 110 min. The flux from the generic product was found to be 0.240 ± 0.011 µg/(cm^2*min), which is only 71% of the flux of the brand name (0.337 ± 0.028 µg/(cm^2*min)). This *in vitro* result showed excellent correlation with the *in vivo* data from bioequivalence studies, where the appearence rate or the drug in blood from Actavis was 72 % of the rate from Micardis. The *in vivo* predictive power of the simultaneous dissolution-absorption test was demonstrated by comparing the *in vitro* fluxes to *in vivo* rate of appearance in blood of brand name and generic formulation of Telmisartan.

Biography

Bálint Sinkó received M.Sc. degree in Pharmacy at Semmelweis University in 2007. As a graduate student and a research fellow of KrisztinaTakács-Novák his work focused on chemical analysis of Pharmaceutical formulations. He has started his PhD in the same group in 2007 taking part in the installation of a new permeability lab. During his research he has developed a PAMPA model for the prediction of skin penetration that formed the main part of his PhD thesis. He received his PhD degree in 2012, while the developed Skin PAMPA model has been licensed to Pion Inc in the same year. After PhD he has joined Pion Inc. where he currently works as manager of technology development and support.

bsinko@pion-inc.com

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