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New extended-release tablets of Benznidazole for chagas disease treatment: Pre-clinical pharmacokinetic studies

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In Brazil, the only drug available to treat Chagas disease is Benznidazole (BNZ). The drug is administered as immediate-release tablets of 100 mg for adults and 12.5 mg for children in two or three daily doses for 60 days. In the present study, we evaluated the preclinical pharmacokinetic profile of new extended-release tablets of BNZ aiming the reduction of the frequency of administration of the drug. The tablets were prepared using matrix system of hydroxylpropylmethyl cellulose with different viscosity grade (K4M and K100M) for changes in drug release. Twenty-one New Zealand white rabbits were divided in three groups: reference group received single 100 mg BNZ immediate-release tablet, ER-K4M and ER-K100M groups received single 200 mg BNZ extended-release tablet. Bioanalytical methods by UHPLC equipped with a UV-Vis detector were employed for quantification of BNZ in plasma and urine samples. The MRT was higher for extended-release tablets (ER-K100M=19.1 h, ER-K4M=12.8 h, Reference=9.6 h), demonstrating that BNZ remained in the plasma longer than the reference. The tmax was higher for extended-release tablets (ER-K100M=18.8 h, ER-K4M=11.1 h, Reference=6.0 h), showing that BNZ was released slowly in the administration of the new tablets. The Cmax was not statistically different between groups. Although the extended-release tablets contain the double dose, 200 mg, these tablets maintained plasma concentration levels similar to that of immediate-release tablet (reference). These data have shown that these extended-release tablets are promising for clinical trials to provide improvements in the treatment of Chagas disease.

Biography

Peccinini R G has a PhD in Toxicology from University of Sao Paulo. She is currently a Professor Assistant Doctor in Toxicology and Coordinator of the Bioequivalence Center of the School of Pharmaceutical Sciences in the Sao Paulo State University. She is also a Researcher in preclinical pharmacokinetic and toxicology of new molecules and formulations and has published more than 25 papers in reputed journals of pharmacokinetics, toxicology, drug discovery, biopharmaceutics, chromatography and others areas.

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