Alejandro Saúl Padrón Yaquis, J Bioequiv Availab 2016, 8:5 (Suppl)
http://dx.doi.org/10.4172/0975-0851.C1.025

conferenceseries.com

7th World Congress on

Bioavailability & Bioequivalence: BA/BE Studies Summit

August 29-31, 2016 Atlanta, USA

Bioavailability and bioequivalence studies of Carbamazepine formulations in Cuban population

Alejandro Saúl Padrón Yaquis
BioCubaFarma, Cuba

The Cuban industry produces about 70% of pharmaceuticals (generic) included in the National List of Basic Drugs. The focus of this work is to share with pharmaceutical scientists, academic researchers, regulators and key opinion leaders; the Cuban experiences on bioavailability and bioequivalence studies on pharmaceuticals. Through a selected example (carbamazepine), we disclosed the several stages of the studies, according to national and international regulations. Carbamazepine was discovered in 1953 and was first marketed in the year 1962. It is available as a generic medication and it is on the WHO model list of Essential Medicines, the most important medications needed in a basic health system. The time-courses of plasma carbamazepine concentrations were followed in apparently healthy adult subjects who, at different times, took single oral drug dose of 200 mg. Volunteers received a single dose with 240 mL of water on each treatment days separated by a 2 week washout period. After dosing, serial blood samples were collected for a period of 190 h. Plasma was analyzed for carbamazepine by a sensitive, reproducible and accurate HPLC method. Various pharmacokinetic parameters were calculated from plasma concentration of 4 (2 Cuban, 2 imported) formulations. Correlation of dissolution test and pharmacokinetic parameters were discussed, as well as variability intra formulation, intra voluntaries and the sex influences on these parameters. Based on statistical inferences, it was concluded that carbamazepine formulations have similar tends in Cuban population.

Biography

Alejandro Saúl Padrón Yaquis has completed his PhD from Habana University. He has graduated from Dmitry Mendeleev University of Chemical Technology of Russia. He is the General Director of the Center for Pharmaceuticals Research and Development at BioCubaFarma Organization. He has published more than 25 papers in reputed journals and has been serving as the Director of a Bioequivalence Unit. He has provided training and support for the conduction of BE study in other countries.

alejandro.padron@cidem.cu

Notes: