BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES OF CARBAMAZEPINE FORMULATIONS IN CUBAN POPULATION.

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INTRODUCTION

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 of Pharmaceuticals.

Through a selected example (carbamazepine) we disclose the several stages of the studies, according to national and international regulations.

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 of Pharmaceuticals. Through selected example we disclosed the several stages, such as analytical method selection, information required for the protocol concerning analytical method development and validation, as well as design, conduction and statistical analysis of the studies, according to national and international regulations.

SOME BIOEQUivalence STUDIES CARRIED OUT LATELY

SELECTED EXAMPLE

Carbamazepine was discovered in 1953. It was first marketed in 1962. It is available as a generic medication. It is on the WHO Model List of Essential Medicines, the most important medications needed in a basic health system.

The time-course of plasma carbamazepine concentrations were followed in a properly 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 four (two Cuban, two imported) formulations. Correlation of dissolution test and pharmacokinetic parameters were discussed, as well as variability intra formulation, intra volunteers and the sex influences on these parameters.

Based on statistical inferences, it was concluded that carbamazepine formulations have similar trends in Cuban population, source.

DISOSLUTION TEST

RESULTS

LITERATURE CITED