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Use of healthy male volunteers in bioequivalence studies of antineoplastic drugs: A pivotal study with capecitabine

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Abstract

Bioequivalence of two 150mg tablet formulations (XelodaR and a new formulation from Eurofarma Laboratorios Ltda) of capecitabine in healthy male volunteers was evaluated using an open, randomized, two-period crossover design with a 1-week washout interval. Plasma samples for pharmacokinetics studies were obtained for up to 7h post dose from the 72 healthy male volunteers that participated in the study. Demographic data were: age: 29.3 (mean) } 9.19 (SD); 18 - 55 years (range), height: 1.75 } 0.07; 1.52 - 1.94m, body weight: 75.5 } 11.58; 52.0 - 106.0 kg, body mass index: 24.67 } 2.92; 19.26 - 29.68 kg/m2. The volunteers underwent a clinical evaluation before enrolment in the study. They presented no significant cardiac, hepatic, renal, pulmonary, neurological, gastrointestinal and hematological diseases, as assessed by the clinical examination, ECG and the following laboratory tests: blood glucose, urea, creatinine, AST, ALT, alkaline phosphatase, γ GT, total bilirubin and fractions, uric acid, total cholesterol, triglycerides, albumin and total protein, hemoglobin, hematocrit, total and diff erential white cell counts and urinalysis. All subjects were negative for HIV, HBV (except for serological scar) and HCV. An extra laboratory analysis was performed during the washout period and another one during the fi rst week aft er the second treatment. Volunteers underwent another clinical evaluation one week aft er the last treatment. Of the 72 volunteers that enrolled in the study, 69 successfully completed the evaluations. Two volunteers did not show up for the first treatment, and one did not show up for the second treatment. They were therefore considered dropouts. Three participants presented with moderate hypertriglyceridemia. One volunteer had a mild headache the following day of the first treatment, which resolved in about one hour with the use of a common oral analgesic. The study concluded that the use of healthy male volunteers for bioequivalence studies of capecitabine is safe.