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# Single dose relative bioavailability and safety of a new quetiapine fumarate extended release formulation: Is there a food effect on XR performance

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Quetiapine is a dibenzothiazepine derivative that has been established as an effective therapy for schizophrenia and bipolar disorder. The bioequivalence and safety of a new XR formulation of quetiapine 300 mg (Quetia® XR, Gautier, Uruguay) was assessed versus an XR globally marketed product in fasting and fed conditions. Two single-dose, two-way, crossover, in vivo, fasting and fed studies were performed. One tablet of quetiapine XR 300 mg (test and reference formulations) was administered as a single oral dose, and blood samples were collected throughout 36 hours. The AUC0-36 , AUC0-_, Cmax and Tmax were calculated. Bioequivalence was concluded if the 90% confidence interval (90% CI) of the T/R ratios for area under the curve (AUC) and peak concentration (Cmax) fell within 0.80 and 1.25. Adverse events were determined using clinical assessment, laboratory results, monitoring of vital signs and by recording any sign or symptom reported during the study. Forty healthy volunteers were enrolled and completed the studies. Results showed that the ratio of GM for AUC and Cmax in posprandial state met bioequivalence criteria (0.80-1.25). The extent and rate of absorption as well as disposition of quetiapine XR was affected by food. Hypotension, dry mouth, dizziness, headache and nausea were the most frequent adverse events found in the studies. As a conclusion: this single dose studies showed that the test product met regulatory criteria for bioequivalence and that both formulations were generally well tolerated. As per the present study food had an apparent effect the bioavailability and disposition of quetiapine.

## Biography

In the 80´s, Dr. Estevez-Carrizo got his M.D. degree and also graduated as specialist in Pharmacology and Therapeutics at the State University, Montevideo. Got the Ph.D. in Clinical Pharmacology at the Karolinska Institute, Stockholm and was Fullbright Scholar at the Pennstate University. In 1993 he was appointed Associate Professor of Pharmacology and Therapeutics at the State University. In 1997, visiting professor at the School of Pharmacy of the University of Minnesota. Since 2002 he is full Professor of Clinical Pharmacology at the University of Montevideo. His main scientific interest is on BABE studies, publishing more than 50 peer reviewed papers.