A single-dose, randomized

Health & Medicine

A single-dose, randomized, two-way crossover study comparing two olanzapine tablet products in healthy adult male volunteers under fasting conditions.

Methods: This bioequivalence study was carried out in healthy male volunteers using a single-dose, randomized, 2-way crossover design under fasting conditions. Statistical analysis of the pharmacokinetic parameters Cmax, AUC0-72, and AUC0 was conducted to determine bioequivalence (after log-transformation of data using analysis of variance and 90% CIs) and to gain marketing approval in Egypt. The formulations were considered to be bioequivalent if the log-transformed ratios of the 3 pharmacokinetic parameters were within the predetermined bioequivalence range (ie, 80%–125%), as established by the USFoodand Drug Administration (FDA).

After dosing, serial blood samples were collected for 72 hours. Plasma samples were analyzed using a sensitive, reproducible, and accurate liquid chromatography-tandem mass spectrometry method capable of quantitating olanzapine in the range of 0. 67 to 16. 7 ng/mL, with a lower limit of quantitation of 0. 167 ng/mL. Adverse events were reported by the volunteers as instructed or observed by the resident physician and were recorded, tabulated, and evaluated. The test/reference ratio of these parameters was within the acceptance range of the FDA criterion for bioequivalence. Both formulations were apparently well absorbed from the gastrointestinal tract (ie, no specific gastrointestinal tract-related adverse events were reported).

Conclusions: In this small study in healthy male volunteers, there were no statistically significant differences in any of the calculated pharmacokinetic parameters between the 10-mg test and reference tablets of olanzapine. The

90% CIs for the ratios of mean Cmax, AUC0-72, and AUC0 were within the range of 80% to 125% (using log-transformed data), meeting the FDA regulatory criterion for bioequivalence. Both formulations were well tolerated.