

Evaluation of the effect of 3 different diets on the bioavailability of 2 sustained release theophylline matrix tablets

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Food-induced changes on bioavailability of 2 sustained release theophylline matrix tablets, which uses an hydrophilic matrix of Carbopol 974P and a lipid matrix of hydrogenated castor oil (Cutina HR) as sustaining agents, have been studied in 2 different groups of 12 healthy male volunteers. The study design was a 4 x 4 Latin square involving 12 subjects who received a single dose of the tablet while fasting or with a standardized normal, high fat or high fat/high protein meal. The results for both formulations showed no differences in $t(1/2)$ and MRT when the tablets were administered with any type of diet. No differences in $t(max)$ and AUC were found when the Carbopol matrix tablet was administered with any class of diet. Higher $C(max)$ were obtained when the tablet was administered with any class of meal. The analysis of the ratio $C(max)/AUC$ evidenced that changes in $C(max)$ for normal and high fat diet were attributable to higher rate of absorption, probably due to a delay in gastric em