Design and evaluation of a controlled-release theophylline tablet preliminary communication

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A 300 mg controlled-release theophylline formulation was developed as a tablet prepared by wet granulation using the acrylic resins Eudragit S 100(R) and Eudragit RSPM(R). The tablet was compared with a marketed controlled-release capsule using in vivo and in vitro tests. The in vitro dissolution of theophylline from the tablets followed an apparent zero order kinetics. The in vivo comparison was performed in a cross over fashion in four healthy volunteers who received one tablet or capsule every 12 hours during seven days. The results showed no statistically significant differences in AUC, t(max) and in plasma theophylline concentrations at the different times. Nevertheless, concentrations were lower after the administration of the tablets than when the volunteers received the capsules. On the other hand, the apparent elimination half lives obtained after the tablets were longer than with the capsules. An excessive retardation in the release of theophylline from the tablet could be re