

## TITLE

### BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES OF CITRIC ACID AND MALONIC ACID BASED ASPIRIN EFFERVESCENT TABLETS

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The present investigation was aimed to compare pharmacokinetic profile (Bioavailability) of aspirin in tablet formulations which were prepared by using different effervescent excipients like citric acid and malonic acid. The relative bioavailability and pharmacokinetics of citric acid based aspirin effervescent tablet (Product A) and malonic acid based aspirin effervescent tablet (Product B) formulations were evaluated for *in-vitro* dissolution study and *in-vivo* bioavailability study in 10 normal healthy rabbits. The study utilized a randomized, crossover design with a 1-week washout period between doses. Blood samples were collected at 0, 1, 2, 3, 4, 6, 8, 10, 14, 24, 30, 36, and 48 h following 100 mg/kg dose. Plasma samples were assayed by High Performance Liquid Chromatography.  $T_{max}$ ,  $C_{max}$ ,  $AUC_{0-24}$ ,  $AUC_{0-\infty}$ , MRT,  $K_a$  and relative bioavailability were estimated using traditional pharmacokinetic methods and compared by paired t-test. In present study Product A and B showed their  $T_{max}$ ,  $C_{max}$ ,  $AUC_{0-24}$ ,  $AUC_{0-\infty}$ , MRT,  $K_a$  values as 2.5 h,  $2589 \pm 54.79$  ng/ml,  $9623 \pm 112.87$  ng.h/ml,  $9586 \pm 126.22$  ng.h/ml,  $3.6 \pm 0.10$  h,  $0.3698 \pm 0.003$  h<sup>-1</sup> for product A and 3.0 h,  $2054 \pm 55.79$  ng/ml,  $9637 \pm 132.87$  ng.h/ml,  $9870 \pm 129.22$  ng.h/ml,  $4.76 \pm 0.10$  h,  $0.3812 \pm 0.002$  h<sup>-1</sup> for product B respectively. The results of the paired t-test of pharmacokinetics data showed that there was no significant difference between the product A and B. Both from dissolution studies and *in vivo* bioavailability studies it has been concluded that the product A and B are bioequivalent.