# *IN VIVO* EVALUATION OF OPTIMIZED FORMULATION OF DAPAGLIFLOZIN AND SAXAGLIPTIN BILAYERED TABLETS

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**ABSTRACT**

Combining dapagliflozin and saxagliptin presents a promising strategy for managing type 2 diabetes mellitus by leveraging their distinct, yet complementary, mechanisms of action. A novel bilayer tablet with a 5 mg sustained release layer of saxagliptin and a 10 mg immediate release layer of dapagliflozin was developed. Live animal studies (*in vivo*) were conducted on rabbits to evaluate the effects of an optimized formulation. Based on *in vivo* performance, the novel bilayer tablets demonstrated greater bioavailability. A new, easy-to-use technique was created to simultaneously measure the two drugs (dapagliflozin and saxagliptin) in rabbit blood plasma. Evaluation of the technique's parameters were done on rabbit plasma in accordance with ICH guidelines. The parameters for pharmacokinetic analysis were ($AUC_{0-\infty}$), ($C_{max}$), $T_{max}$ and others. Direct calculations of the $C_{max}$ and $T_{max}$ were made using experimental plasma concentration versus time data. The $AUC_{0-\infty}$ was produced by adding the computed $AUC_{0-24h}$ using the trapezoidal rule. Using sample analysis of variance or independent sample t tests, average data variation was compared (one way analysis of variance). Statistical significance (p=0.05) was assessed using a 95% confidence interval.