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In-vitro bioequivalence studies in tablet formulation containing 625mg of Colesevelam hydrochloride

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Colesevelam is a second generation bile acid sequestrant that is used principally for treatment of elevated LDL cholesterol. Additionally, Colesevelam is indicated to improve glycemic control in adults with type 2 diabetes mellitus. Colesevelam is an insoluble, non-absorbed polymer that binds bile acids in the intestine, impeding their reabsorption. Conventional *in vivo* bioequivalence (BE) study with pharmacokinetic endpoints such as C_{max} and AUC is neither appropriate nor feasible for this locally acting drug. The present abstract focuses on the study of *in vitro* BE in tablet formulation containing 625 mg of Colesevelam HCl. Bile acid sodium salts of glycocholic acid (GCA), glycochenodeoxycholic acid (GCDA) and taurodeoxycholic acid (TDCA) were used *in vitro* BE studies. The binding capacity HPLC method was developed and validated for these bile acid salts. The equilibrium binding study that is the pivotal BE study and *in-vitro* kinetic binding study that is the support the pivotal equilibrium binding study were repeated 12 times. In the *in vitro* equilibrium binding studies, the Langmuir binding constants k1 (affinity) and k2 (capacity) were calculated for the three salts, individually and combined (GC+GCDC+TDC) using linear Langmuir equation for the test and reference products. The calculated capacity (k2), the more important parameter, were obtained very similar between test and reference products in the 90% confidence interval and acceptance criteria of 80% to 120%. The test/reference ratio for k2 was obtained within 0.82-1.07 from the equilibrium binding study for without acid pre-treatment and 0.96-1.08 from the equilibrium binding study for with acid pre-treatment.

Biography

Gulcin Tok has completed her Master's degree in Organic Chemistry from Gazi University in 2011. She has been working in pharmaceuticals industry for 5 years as a R&D Scientist. She develops generic drugs and she is responsible for all process to come onto the market from the beginning of product. Additionally, she has published patent about generic formulation and has published the papers in reputed journals.

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