3. OBJECTIVES OF THE PRESENT WORK:

- In US Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, commonly called “the Hatch-Waxman Act.” to balance the needs of innovative and generic drug manufacturers (Certain provisions of the Hatch-Waxman Act were amended in 2003 in the Medicare Modernization Act to address concerns arising from applying the Act to the generic drug approval.). On one hand, the innovative drug manufacturers seeking regulatory approval of new drugs were given greater patent protection in the face of expensive and time-consuming regulatory hurdles. On the other hand, the generic drug manufacturers were given an abbreviated, less expensive regulatory approval process for generic versions of innovative drugs, as well as incentives to challenge the patent protection of the innovative drugs. Thus, the generic drug manufacturers got faster entry into the market for the generic version of innovative drugs. This abbreviated drug approval process, known as “Abbreviated New Drug Application (ANDA),” did not require the generic drug manufacturers to conduct independent safety and efficacy studies for the generic drug. Instead, the generic drug manufacturers can rely on the previously submitted safety and efficacy data by the innovative drug makers. Generic companies are only required to demonstrate bioequivalence, i.e., the generic drug has the same active ingredient, the same basic pharmacokinetics.

- Pharmaceutical companies face a unique challenge in developing their innovative drugs due to the research and development costs incurred in bringing the innovative drugs to the market. The current estimate of the average cost for a pharmaceutical company to bring an innovative drug to the market is nearly $800 million to $1 billion. In order to re-coup the R & D investments and achieve profitability from selling an innovative drug, pharmaceutical companies often set high drug prices, which results in a lack of affordable medicines for customers in need.

- The objective of this study is to compare the rate and extent of absorption of Topiramate Tablets 25 mg of Alkem Laboratories Limited, with Topamax® Tablets (Topiramate Tablets 25 mg) of Ortho-McNeil Neurologics, Inc., USA in healthy adult male human subjects under fasting conditions and to monitor the safety, efficacy and effectiveness of a single dose of Topiramate Tablets 25 mg in healthy adult male human subjects. Also to reduce the cost or price of drugs and easily available to patients.