3. **OBJECTIVES OF THE PRESENT WORK:**

- 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. Even with this enormous investment, there is no assurance that the innovative drugs will achieve market exclusivity and profitability. Consequently, it is crucial for the innovative drug maker to have in place effective patent protection for the innovative drug. Although a full term for a U.S. patent is twenty years, pharmaceutical companies often file for their patent applications during early stages of drug discovery and development. As a result, the effective patent term at the time of drug launch is significantly reduced. In order to recoup 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. 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.
• Gabapentin is novel antiepileptic agents and one of the first compounds to emerge from this era was Gabapentin. To understand the safety and efficacy of Gabapentin, bioequivalence study in health volunteer is required. Gabapentin has since gained world-wide recognition, not just for its antiepileptic properties, but also its efficacy in the management of chronic pain syndromes, especially neuropathic pain. Although the anti-spastic effects of Gabapentin proved to be modest, the drug demonstrated considerable efficacy in a range of experimental seizure model. Gabapentin (brand name Neurontin) is a medication originally developed for the treatment of epilepsy. Presently, Gabapentin is widely used to relieve pain, especially neuropathic pain. Gabapentin is well tolerated in most patients, has a relatively mild side-effect profile, and passes through the body unmetabolized.

• The Objective of this study is to compare the rate and extent of absorption of Gabapentin capsules USP 400 mg of Alkem Laboratories Limited, with Neurontin® (Gabapentin Capsules USP 400 mg) of Pfizer, USA in healthy adult male human subjects under fasting conditions. The objective is to monitor the safety of a single dose of Gabapentin capsules USP 400 mg in healthy adult male human subjects. The objective is also to help the human being regarding safe, efficacy and effectiveness of drug and to reduce the cost or price of drugs and easily available to patients.