ABSTRACT

The comparative studies of new drug approval process between United States of America and India is carried out by extensive and exhaustive literature learning. The comparative study is planned in such a manner that the result would give insight of Indian New drug regulatory process and the gaps in Indian regulatory authority are identified which shall be helpful in finalizing the various future policies and upgradation of infrastructure and resources with regards to new drug approval process in India. Clubbed with subjective research, two clinical trials of Butorphanol formulation and two bio-equivalence studies of the new drugs Valsartan capsule and Deflazacort tablet are also planned. The clinical investigation and bio equivalence study are conducted as per GCP guidelines after obtaining the approval of Indian regulatory authorities and ethics committees. The comparative clinical trials of Butorphanol injection with Pentazocin injection is conducted in total number of 93 patients with postoperative pain after abdominal surgery and the clinical trial of Butorphanol nasal spray is conducted in 105 patients with postoperative pain after minor orthopedic surgery. Each bio equivalence study was conducted in 12 volunteers, cross over randomized design at regulatory authority approved center. All the pharmacokinetic parameters like Cmax, Tmax, AUC etc are determined and the relative bio equivalence is calculated. The data generated out of clinical trials and bio equivalence studies are submitted to regulatory authorities for approving the investigational drugs in Indian Market. Based on the data, the sponsor company got the approval of Butorphanol injection, nasal spray, Valsartan capsule and Deflazacort tablet.

Keywords: New Drug Approval process, Butorphanol, Valsartan, Deflazacort, Indian regulatory authority