Abstract

ABSTRACT
Objective: The study was designed to prepare Nano-sponge formulation loaded with nifedipine. Studying parameters which affecting the formulas in addition to pharmacokinetics and toxicity tests.

Methods: Nine Nano-sponge formulations were prepared by the solvent evaporation technique. Different ratios of polymer ethylcellulose, Copolymers β-cyclodextrin and hydroxypropyl β-cyclodextrin in addition to solubilizing agent polyvinyl alcohol were used. Thermal analysis, X-ray powder diffraction (XRPD), shape and surface morphology, particle size, %production yield, %porosity, % swelling, and % drug entrapment efficiency of Nano-sponge were examined. Release kinetic also studied besides comparison of pharmacokinetic parameters of the optimum choice formula and marketed one in addition to Toxicological consideration.

Results: Particle size in the range of 119.1 nm to 529 nm which were increased due to the increase in the concentration of polymer to the drug. Nano-sponge revealed porous, spherical nature. Increased in the drug/polymer molar ratios (1:1 to 1:3) may increase their % production yield ranged from 62.1% to 92.4%. The drug content of different formulations was in the range of 77.9% to 94.7%, and entrapment efficiency was in the range of 82.72% to 96.63%. Drug released in controlled sustained pattern and followed Higuchi’s diffusion mechanism. Pharmacokinetic parameters of optimized formula showed significant higher maximum plasma drug concentration, area under plasma concentration-time curve, volume of distribution and mean residence time. Nano-sponge loaded drug proved biological safety at low concentrations.

Conclusion: Nano-sponge drug delivery system has showed small Nano size, porous with controlled drug release and significant-high plasma drug concentration that improved solubility, drug bioavailability and proved safety.

Keywords: Cyclodextrins, Polymeric drug delivery system, Controlled release, Nanotechnology, Preclinical pharmacokinetics, Cytotoxicity.