ABSTRACT

Oral ingestion has been the most convenient and commonly employed route of drug delivery. Controlled drug delivery system for oral dosage forms offer greater advantages in minimizing the dosage frequency and thereby the toxicity and improves the patient compliance. These novel drug delivery system control the release of drug by diffusion or erosion or osmosis etc.

The present study was to develop stable and robust formulations of Alfuzosin hydrochloride ER tablets 10mg and controlled release tablets of Citicoline 1000 mg.

Alfuzosin hydrochloride is used to reduce the symptoms of benign prostatic hyperplasia (BPH). Citicoline is useful in the treatment of ischemic stroke, head trauma and neurodegenerative disease.

Design of controlled release drug delivery systems for highly soluble drugs is challenging to pharmaceutical scientists. Various techniques have been proposed in the design of controlled release systems of these moieties. Matrix tablets have gained popularity in the designing of controlled drug delivery systems. But it is difficult to control the release of high soluble drugs by simple matrix system.

Hence in the present study we aimed in the preparation of matrix dosage forms for alfuzosin and citicoline by using natural polymer (i.e. Guar gum), synthetic polymers (i.e. HPMC K100 M, HPC - HF, Eudragit RSPO & Eudragit RLPO) alone and in combination of polymers.
In case of alfuzosin we used different concentration of Eudragit RLPO, Guar gum 8000 cP and HPMC K100M alone and combination of HPMC K100M and guar gum 8000 cP. Among all formulations, the formulation B.No:ALF/10 (combination of HPMC K100M and guar gum 8000 cP) showed comparable results with respect to in vitro and in vivo tests, when compared with commercial reference formulation (UROXATRAL).

In case of citicoline we used combination of hydrophilic and hydrophobic polymers. Citicoline controlled release tablets were prepared by wet granulation method using non aqueous granulation fluid. The formulation B.No:CTC/14 (Eudragit RSPO- 12.5 % w/w and tablet coated with Eudragit RLPO) showed comparative results with respect to in-vitro tests, when compared with marketed formulation (STROLIN-OD) and also proven controlled drug release when compared with respect to in-vivo studies.

Both the formulations (B.No:ALF/10 & B.No:CTC/14) were fitted into zero order, first order, Higuchi’s, Peppas & Korsmeyer kinetics with super case II transport mechanism. They followed first order kinetics with diffusion mechanism.

Both the formulations (B.No:ALF/10 & B.No:CTC/14) were evaluated stability studies and they are proven stable at accelerated conditions of 40°C ± 2°C & 75% ± 5 % RH for 3 months.