ABSTRACT

The objective of the present work is to formulate controlled release drug delivery system (two tablets packed in capsule of "0" size) of terbutaline sulphate, which has variable bioavailabilty because of variable absorption in acidic and neutral pH. One of the tablet releases the drug in the stomach by neutralizing the acidic pH of the stomach and the other releases the drug only in the small intestine for the remaining period of time. Three formulations of immediate release tablets of terbutaline sulphate were prepared by wet granulation technique using polymers Eudragit L100, HPMC K4M and calcium carbonate as a buffering agent. Seven formulations of sustained release tablets were prepared by direct compression method using the polymers Eudragit RS100, Eudragit RL100 and HPMC K4M. The formulated immediate release tablets and sustained release tablets were subjected for thickness, hardness, friability, weight variation, tensile strength, drug content, and *in vitro* release data. In addition, the immediate release tablets were also checked for their buffering capacity and disintegration time. Analysis of the drug release profile infers that drug release from the tablets was strongly dependent on the ratio and type of the polymers used in the formulations. Fitting of drug release data into kinetic models indicated zero order kinetics and the mechanism of drug release is found to be anomalous diffusion. Satisfactory formulation was checked for stability at 30±2°C/65±5% RH and at 40±2°C/75±5% RH for two months and showed no significant change in hardness, drug content and *in vitro* release profile.

Keywords: Terbutaline sulphate, controlled release drug delivery system, Eudragit L100, HPMC K4M, Eudragit RS100, Eudragit RL100, anomalous diffusion.