

Rapid spectrophotometric determination, characterization and anti-inflammatory efficacy evaluation of nanoencapsulated diclofenac sodium

ABSTRACT

This study was aimed to develop a simple and reproducible spectrophotometric method for the characterization of diclofenac sodium (DS) and to evaluate the efficacy of orally administered liposome encapsulated as well as free form DS in animal model. A simple, rapid and economical spectrophotometric analytical procedure with estimation in UV-visible region was performed on DS using dimethyl sulfoxide as solvent. Parameters such as time, temperature and types of solvent were studied for 20 g/mL DS solution at 295 nm. All parameters and results of analysis were statistically validated. Liposome-encapsulated and free form DS samples were subjected to characterization study that includes entrapment efficacy determination and particle size analysis. Drug samples were further tested for their in vivo anti-inflammatory efficacy using histamine-induced paw edema test. Under optimized parameters, the Beer's law is obeyed in range of 0.625-40 g/mL at max 295 nm. A linear working range of 5-35 g/mL with regression coefficient of 0.9978 was obtained by using seven triplicate analyses of drug samples at seven different concentrations. The limit of detection and limit of quantitation was 1.19 and 3.62 g/mL, respectively. Result of characterization study showed that the optimum formulation, which has high entrapment efficacy of 87 %, homogenous in size (polydispersity index 0.27), stable and reproducible, were obtained by using the Pro-Lipo Duo with 10 h hydration time and 16 mg/g DS. The liposome encapsulated DS resulted in significant ($P < 0.05$) inhibition up to 86 % in histamine-induced paw edema test. Present study successfully demonstrated an optimized procedure as per ICH guidelines in detection and evaluation of DS. In addition, nano-encapsulation of DS using liposome was found to demonstrate a potential enhancement in therapeutic efficacy.

Keyword: Diclofenac sodium; UV-visible spectroscopy; Spectrophotometry; Liposome; Characterization