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RESEARCH ARTICLE

FORMULATION AND EVALUATION OF SUSTAINED RELEASE FLOATING MICROBALLOONS OF KETOROLAC TROMETAMOL

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The present study was aimed at the design of sustained release floating microballoons of ketorolac trometamol (ketorolac tromethamine) using two polymers ethyl cellulose and HPMC K4M with different permeability characteristics. Ketorolac microballoons were prepared by solvent diffusion method using different concentrations of both polymers and studied for *in vitro* and *in vivo* parameters. Prepared microballoons were spherical in shape, stable, float on simulated gastric fluid for more than 8 h and was significantly less ulcerogenic ($p<0.001$) than plain ketorolac trometamol.

Key words: Ketorolac trometamol, Microballoons, Sustained release, HPMC K4M, Ethyl cellulose.

INTRODUCTION

Ketorolac trometamol, is an analgesic, anti-inflammatory agent inhibit the bodily synthesis of prostaglandins by competitive blocking the enzyme cyclooxygenase (COX) non-selectively. Dose requirement of ketorolac trometamol is 60 to 120 mg/day and more frequent use can cause high incidence of GI side effects and toxicity (McDaid *et al* 2010). Therefore, continued efforts are being made to improve the formulation of ketorolac trometamol in order to achieve an optimal therapy. Various researchers have used various polymers and their combinations to formulate multiparticulate drug delivery system for sustained drug delivery (Dahiya and Gupta, 2011; Tripathi *et al* 2011; Basarkar *et al* 2013; Tyagi and Kori, 2013; Verma *et al* 2014).

Floating microballoons are spherical particles with size varying from 50 nm to 2 mm possessing a characteristic internal hollow structure and show an excellent *in vitro* floatability (Vyas and Khar, 2002). Gastric floating drug delivery system (FDDS) can overcome the problems associated with oral controlled release drug delivery systems. The FDDS is able to prolong the retention time of a dosage form in the gastro intestinal tract, thereby improving oral bioavailability of the drug, particularly useful for drugs that are primarily absorbed in the duodenum and upper jejunum segments (Shakya *et al* 2013).

MATERIALS AND METHODS

Materials

Ketorolac trometamol was obtained as a gift sample from Sun Pharma Global Inc., Vadodara, HPMC K4M was obtained as a gift sample from Colorcon Pvt. Ltd., India. Dichloromethane was purchased from Loba Chemie, Mumbai and ethyl cellulose, sodium lauryl sulphate (SLS), tween-80, ethanol, methanol were purchased from S.D. Fine Chemicals Ltd., Mumbai. All chemicals used in research work were of analytical grade.

Methods

Preparation of floating microballoons

Microballoons containing ketorolac trometamol were prepared by solvent evaporation method. Weighed quantity of both polymers was dissolved in dichloromethane at the mentioned