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RESEARCH ARTICLE

DEVELOPMENT OF MICROSPHERES CONTAINING DICLOFENAC DIETHYLAMINE AS SUSTAINED RELEASE TOPICAL FORMULATION

Ganesh Dinkarrao Basarkar*, Gunwant Narendra Shirsath and Sanjay Bhivasan Patil

Department of Pharmaceutics, SNJB's Shriman Sureshdada Jain College of Pharmacy, Neminagar, Chandwad, Nashik-423 101, Maharashtra, India

**E-mail*: basarkarg@yahoo.com
Tel.: +91 9765942836.

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The aim of present work was to formulate diclofenac diethylamine microspheres using a natural wax, to be applied topically on the skin for the purpose of sustaining its release to avoid the side effects resulting from the oral administration of the drug and also to reduce the dosing frequency. Wax collected was purified using reported method and evaluated for physicochemical parameters. Drug excipients compatibility was performed using IR and DSC study. Following preliminary evaluations on process conditions for preparation of microspheres by cooling induced solidification technique, a 3^2 full factorial design was employed to investigate the influence of the formulation variables like concentration of wax and concentration of Tween 80 on the particle size, entrapment efficiency and drug release. Developed formulation followed Higuchi model for drug release from microspheres. Further, these microspheres were dispersed in carbopol 934 gel (1% *w/w*). The gel was evaluated for appearance, homogeneity, pH, spreadability, viscosity, drug content uniformity and *in vitro* drug diffusion study. Korsmeyer-Peppas equation was followed for *in vitro* drug diffusion from gel containing microspheres. Diffusion coefficient of Korsmeyer-Peppas equation indicated that the non-Fickian mechanism was basically involved in the drug release from gel containing microspheres.

Key words: Diclofenac diethylamine, Sustained release microspheres, Cooling induced solidification technique, Rice bran wax.

INTRODUCTION

In recent years, it has become more and more evident that the development of new drugs alone is not sufficient to ensure progress in drug therapy. A promising strategy involves the development of suitable drug carrier systems. Lipid particles based on triglycerides, waxes or fatty acids as matrix lipids are being intensively investigated as potential carrier systems, in particular for lipophilic substances (Nasir *et al* 2008). The microspheres system is a newly introduced lipid-based carrier system developed for parenteral and topical drug delivery of bioactive compounds. The solid phase porous microsphere is a vehicle technology comprising inert, porous, polymeric spherical microparticles designed to entrap active ingredient, allowing for a slower rate of delivery into skin. The term microspheres describe a monolithic spherical structure with the drug or therapeutic agent distributed throughout the matrix either as a molecular dispersion or as a dispersion of particles (Dahiya and Gupta, 2011; Yellanki *et al* 2010). They can also be defined as a structure made up of continuous phase of one or more miscible polymers in which the particulate drug is dispersed at the macroscopic or molecular level. Microsphere based drug delivery systems