Bulletin of Pharmaceutical Research 2015;5(2):59-69
An Official Publication of Association of Pharmacy Professionals
ISSN: 2249-6041 (Print); ISSN: 2249-9245 (Online)

RESEARCH PAPER

DEVELOPMENT AND CHARACTERIZATION OF FENOFIBRATE SELF-MICROEMULSIFYING DRUG DELIVERY SYSTEM (SMEDDS) FOR BIOAVAILABILITY ENHANCEMENT

Nirali Padia*, **Arunkumar Shukla and Pragna Shelat**

Department of Pharmaceutics, K. B. Institute of Pharmaceutical Education and Research, Kadi Sarva Vishwavidyalaya, Gandhinagar-382 023, Gujarat, India

**E-mail*: niralitailor@gmail.com
Tel.: +91 9510591235.

Received: Jun 15, 2015 / Revised: Aug 18, 2015 / Accepted: Aug 19, 2015

Fenofibrate is lipid regulating agent, which is insoluble in aqueous solution and bioavailability after oral administration is low. The objective of present work was to develop a self-microemulsifying drug delivery system (SMEDDS) to enhance the oral bioavailability of poorly water soluble fenofibrate. SMEDDS is a mixture of oil, surfactant, and cosurfactant, which are emulsified in aqueous medium under gentle digestive motility in the gastrointestinal tract. Psuedoternary phase diagrams were constructed to identify the efficient self-emulsifying region. A SMEDDS were further evalauted for its percentage transmittance, emulsification time, drug content, phase separation, globule size, zeta potential, pH, refractive index, X-ray diffraction, Differential scanning calorimetry and in vitro dissolution studies. Optimized formulation was also compared with marketed product in male sprague dawley rats. The pharmacokinetic study exhibited 1.87 fold increase in the oral bioavailability of fenofibrate SMEDDS compared with the marketed product.

Key words: SMEDDS, Fenofibrate, Pharmacokinetic study, Globule size, *In vitro* release studies.

INTRODUCTION

Fenofibrate is a fibric acid derivative whose lipid modifying effects reported in humans are mediated via activation of Peroxisome Proliferator Activated Receptor type alpha (PPARα). Through activation of PPARα fenofibrate increases the lipolysis and elimination of atherogenic triglyceride-rich particles from plasma by activating lipoprotein lipase and reducing production of apoprotein CIII. Activation of PPARα also induces an increase in the synthesis of apoproteins AI and AII, which leads to a reduction in very low and low density fractions (VLDL and LDL) containing apoprotein B and an increase in the high density lipoprotein fraction (HDL) containing apoprotein AI and AII. Fenofibrate is BCS class-II drug with a log P value of 5.3. Fenofibrate is a lipophilic drug with a low aqueous solubility. Thus, the low oral bioavailability of fenofibrate is due to its solubiliy and dissolution limitations. (Amidon *et al* 1995; Horter and Dressman, 2011).

The oral route has been traditionally preferred for prolonged use. However, oral delivery of poorly soluble drugs creates critical problems during their formulation. Approximately, 40% of new drug candidates have poor water solubility and the oral delivery of such drugs is frequently associated with low bioavailability, high intra and intersubject variability and a lack of dose proportionality (Gursoy and Benita, 2004; Abdalla *et al* 2008). Several recent techniques have been used for their solubilization including micronization, complexation, solid dispersion, cyclodextrins, nanoparticles and co-precipitation (Pabreja and Dua, 2001; Dahiya and Tayde, 2013; Prusty, 2014). Recently, much attention has been paid to lipid based formulations with