Bulletin of Pharmaceutical Research 2015;5(1):14-9
An Official Publication of Association of Pharmacy Professionals
ISSN: 2249-6041 (Print); ISSN: 2249-9245 (Online)

RESEARCH ARTICLE

FORMULATION DEVELOPMENT AND EVALUATION OF CONTROLLED RELEASE TABLETS OF LAMOTRIGINE USING MIXED SOLVENCY CONCEPT

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Received: Sep 17, 2014 / Revised: Feb 27, 2015 / Accepted: Feb 28, 2015

In the present investigation, newly developed solid dispersion technology that precludes the use of organic solvent and also decreases the individual concentration of hydrotropic agents, simultaneously decreasing their toxic potential; was employed for preparing dispersions of lamotrigine. Prepared solid dispersions were evaluated for flow properties, XRD, DSC, SEM and were also compressed to form tablets. Dissolution studies of prepared tablets were carried out using USP Type II Apparatus. It was concluded that the concept of solid dispersion is novel, safe and cost-effective technique for enhancing the bioavailability of poorly water soluble drugs by dissolving drug in non-ionized form. The tremendous enhancement in solubility of Lamotrigine is clear indication of its potential to be used in future for other poorly water soluble drugs in which low bioavailability is major concern.

Key words: Mixed solvency, Lamotrigine, Eudragit, Controlled release tablet, Solid dispersion.

INTRODUCTION

Product development scientists often encounter significant difficulties in solving the problem of poor water solubility of drug candidates in the development of pharmaceutical dosage forms. Slow absorption rate results in an erratic and variable profile of drug level. A solid dispersion is a system in which the concentration of the drug is in excess of its saturation solubility at room temperature. The excess drug separates as a solid phase which is dispersed in the vehicle in crystalline or amorphous forms. Together with the permeability, the solubility behaviour of drug is key determinant of its oral bioavailability. There have always been drugs for which solubility has presented a challenge for the development of a suitable formulation for oral administration. Solid dispersion technologies are particularly promising for improving the oral absorption and bioavailability of BCS Class II drugs. As a matter of fact, more than one third of the drugs listed in the U.S. Pharmacopoeia fall into the poorly water-soluble or water-insoluble categories. It was reported a couple of decades ago that more than 41% of the failures in new drug development have been attributed to poor biopharmaceutical properties, including water insolubility. Water insolubility can postpone or completely halt new drug development, and can prevent the much needed reformulation of currently marketed product (Liu, 2008).

As per the mixed solvency concept (Agrawal and Maheshwari, 2011; Chandan and Maheshwari, 2013; Maheshwari, 2009a; 2009b; 2010a; 2010b; 2014; Maheshwari *et al* 2011a; 2011b; 2011c; 2012a; 2012b; 2013; Maheshwari and Karwande, 2013; Maheshwari and Rajagopalan, 2011; 2012; Maheshwari and Shilpkar, 2012; Bhawsar *et al* 2011; Pawar *et al* 2013; Soni *et al*