ABSTRACT: Carbamazepine, a dibenzapine derivative with structure resembling that of tricyclic antidepressants, is used in the treatment of epilepsy. The major problem of this drug is very low solubility in biological fluids and poor bioavailability after oral administration. Carbamazepine fast dissolving tablets (FDT) have been prepared by direct compression method. Effects of superdisintegrants (such as croscarmellose sodium, crospovidone and sodium starch glycolate) on wetting time, disintegrating time, drug content, in vitro release, and stability parameters have been studied. The prepared tablets were characterized by DSC and FTIR Studies. No chemical interaction between drug and excipients was confirmed by DSC and FTIR studies. Disintegration time and dissolution parameters (t50% and t90%) decreased with increase in the level of croscarmellose sodium and crospovidone, whereas disintegration time and dissolution parameters increased with increase in the level of the sodium starch glycolate in tablets. Among all formulations F8 was considered best. The results concluded that fast dissolving tablets of poorly soluble drug carbamazepine, showing enhanced dissolution, will lead to improved bioavailability, improved effectiveness and hence better patient compliance.

KEYWORDS: Fast dissolving tablets; Carbamazepine; croscarmellose sodium; crospovidone and sodium starch glycolate

Introduction

Carbamazepine, a dibenzapine derivative with structure resembling the tricyclic antidepressants, is used in the treatment of epilepsy. One of the major problems with this drug is its very low solubility in biological fluids and its biological half-life between 18 to 65 hrs that results into poor bioavailability after oral administration (Reynolds JEF, 1993; McNaman JO, 1996). It shows erratic dissolution profile in gastric and intestinal fluid due to its poor water solubility. The peak plasma concentration C max and the time taken to reach C max (t max) depend upon extent and rate of dissolution of drug, respectively. The rate of dissolution can be increased by increasing the surface area of available drug by various methods (micronization, complexation and solid dispersion) (Martin A, 1993). The dissolution of a drug can also be influenced by disintegration time of the tablets. Faster disintegration of tablets delivers a fine suspension of drug particles resulting in a higher surface area and faster dissolution (Setty CM, 2008).

Of all the orally administered dosage forms, tablet is most preferred because of ease of administration, compactness and flexibility in manufacturing. Due to changes in various physiological functions associated with aging including difficulty in swallowing, administration of intact tablet may lead to poor patient compliance and ineffective therapy. The pediatric and geriatrics patients are of particular concern. To overcome this, dispersible tablets (Schiermeier S, 2002) and fast-disintegrating tablets (Mizumoto T, 2005) have been developed. Most commonly used methods to prepare these tablets are; freeze-drying/Lyophilization (Virley P, 1990), tablet molding (Dobetti L, 2000) and direct-compression methods (Bi Y, 1996). Lyophilized tablets show a very porous structure, which causes quick penetration of saliva into the pores when placed in oral cavity (Virley P, 1990; Patrick K, 1997). The main disadvantages of tablets produced are, in addition to the cost intensive production process, a lack of physical resistance in standard blister packs and their limited ability to incorporate higher concentrations of active drug can be rearranged in a better way (Schiermeier S, 2002). Moulded tablets dissolve completely and rapidly. However, lack of strength and taste masking are of great concern (Dobetti L, 2000; Chang RK, 2000). The main advantages of direct compression are low manufacturing cost and high mechanical integrity of the tablets (Bi Y,