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RESEARCH ARTICLE

FORMULATION AND IN-VITRO EVALUATION OF AMLODIPINE BESYLATE-HP-β-CD INCLUSION COMPLEX INCORPORATED MOUTH DISSOLVING TABLETS

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The objective of present study was to formulate and evaluate mouth dissolving tablets (MDTs) of poorly water soluble drug amlodipine by incorporating its inclusion complex with hydroxypropyl-β-cyclodextrin (HP-β-CD). The formulation of MDTs employed superdisintegrants crosspovidone and Ac-Di-Sol in different concentrations among which F3, consisting of 8 per cent of crospovidone was found to be the best formulation, as it exhibited minimum disintegration time (15 sec) and better drug release profile as compared to other formulations.

Key words: Cyclodextrin inclusion complex, MDT, Amlodipine besylate, HP-β-CD.

INTRODUCTION

Tablets are most preferred solid dosage forms because of easy administration, compactness and flexibility in manufacturing. Because of changes in various physiological functions associated with aging, including difficulty in swallowing; administration of the intact tablet may lead to poor patient compliance and ineffective therapy. The pediatric and geriatric patients are of particular concern. To overcome this, dispersible tablets, mouth dissolving tablets or fast disintegrating tablets have been developed. Most commonly used methods to prepare these tablets are freeze-drying/ lyophilization tablet molding and direct compression. The main advantages of direct compression are low manufacturing cost and high mechanical integrity of the tablets. Therefore, direct-compression appears to be an attractive option for manufacturing the tablets. The mouth dissolving tablets prepared by the direct compression method, in general, are based on the action established by superdisintegrants such as croscarmellose sodium, crospovidone, sodium starch glycolate. Moreover, preparation methods, characterization, recent advancements and current status of orally disintegrating tablets (ODTs) and mouth dissolving tablets (MDTs) have been thoroughly reviewed in the literature (Bandari *et al* 2008; Hirani *et al* 2009; AlHusban *et al* 2010; Badgujar and Mundada, 2011; Bhatere *et al* 2012; Yadav *et al* 2014). The recent findings also witness formulation and evaluation of ODTs and MDTs without or with incorporation of inclusion complex of poorly soluble drugs with cyclodextrins using various techniques (Cirri *et al* 2005; 2009; Ajit Shankarrao *et al* 2010; Wang *et al* 2013; Zeng *et al* 2013; Desai and Prabhakar, 2014). So, in the present work, amlodipine mouth dissolving tablets were prepared using HP-β-CD complex using different superdisintegrants like crospovidone and Ac-Di-Sol and evaluated for various parameters to establish the usefulness of inclusion complexation as well as direct compression technique.

MATERIALS AND METHODS

Materials

Amlodipine besylate obtained from matrix laboratories Bangalore. Hydroxypropyl-β-cyclo-