



Development, optimization and characterization of hydrocolloid based mouth dissolving film of Telmisartan for the treatment of hypertension



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ABSTRACT

Telmisartan, a BCS class II antihypertensive, has low oral bioavailability due to first-pass metabolism and a poor solubility profile, causing dissolving problems. Telmisartan is a suitable choice for the Rapid Release Drug Delivery System since it needs rapid absorption for a quick beginning of the activity. The goal of this research was to create and describe a solid dispersion employing hydrocolloid incorporated mouth dissolving film of Telmisartan. To make a Mouth Dissolving Film, first, prepare a solid dispersion using the Kneading Method, then use the Solvent Casting Method of screening Carrier for the further formulation, solid dispersion is assessed for solubility, drug content, and drug release rate. The in-vitro drug release investigation revealed that solid dispersion had better solubility and rapid drug release than pure drug. Physical appearance, surface PH, thickness uniformity, disintegration duration, drug content uniformity, folding durability, and in-vitro drug release were among the physicochemical and mechanical parameters assessed on the produced films. A 3²-level factorial design was used to improve the approach. The effects of film appearance, disintegrating time, and in-vitro drug release behavior on the composition of Film-forming polymer(hydrocolloids) and Super disintegration were investigated. The in-vitro drug release and disintegration time of the optimized batch were found to be 91.83 percent and 29 sec, respectively. These positive conclusions demonstrated that mouth dissolving film of Telmisartan can be formulated using HPMC E15 as a film-forming polymer and Sodium Starch Glycolate as a super disintegrant for improving bioavailability and therapeutic outcome.

Introduction

Many people find tablets and hard gelatin capsules difficult to chew and may not take their medications as advised. Approximately 35% of the general population suffers from swallowing difficulties, often known as dysphagia. Other categories that may have difficulty ingesting solid dose forms include the mentally ill, cognitively challenged, uncooperative patients, and those with limited liquid intake plans or nausea (Arya et al., 2010). Stroke, Parkinson's disease, AIDS, head, and neck radiation therapy, and other neurological disorders such as cerebral palsy are all linked to dysphasia. In some cases, such as motion sickness, a sudden episode of allergic attack or coughing, and a lack of water, swallowing tablets or capsules becomes difficult. Several fast-acting drugs have been developed to help these people (Satoskar et al., 2008). To address these issues, scientists have created "melt in the mouth" or "mouth dissolve (MD)" tablets, which are novel medication delivery techniques (Ghourichay et al., 2021). Their expanding relevance was highlighted when the European Pharmacopoeia (European Pharmacopoeia 5.0, 2005) defined Oro-dispersible tablets as a tablet that

is put in the mouth and dissolves in less than 3 minutes before being swallowed (Sumitha et al., 2009).

A new oral fast dissolving dosage form such as fast-dissolving film has been developed which offers the combined advantages of ease of dosing and convenience of dosing in the absence of water (Alkahtani et al., 2021). "Oral fast-dissolving film is relatively a new dosage form in which thin film is prepared using hydrocolloids, which rapidly dissolves on tongue or in buccal cavity" (Dixit & Puthli, 2009). Oral Fast Dissolving Films (FDF) are also known as Mouth dissolving films (MDF), oral strips, Orodispersible films (ODF). The saliva containing the dissolved or dispersed medicament is then swallowed and the drug is absorbed in the normal way. Some drugs are absorbed from the mouth, pharynx, and esophagus as the saliva passes down into the stomach & it may produce rapid onset of action. In such cases, the bioavailability of the drugs is significantly greater than those observed from conventional tablets dosage form (Rowe et al., 2009). The urge for the development of a mouth dissolving film is patients who find swallowing standard tablets and capsules troublesome for one purpose or another can benefit from fast dissolving dosage forms. Individuals with hand tremors and dysphasia mainly geriatric patients, Pediatric patients

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