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Formulation and Evaluation of Fast Dissolving Films of Taste-Masked Ondansetron Hydrochloride

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ABSTRACT

Fast dissolving oral films (FDFs) offer a patient-friendly alternative to conventional oral dosage forms, particularly for pediatric, geriatric, and dysphagic patients. In the present work, fast dissolving films of Ondansetron hydrochloride were developed using a solvent casting technique. Taste masking was achieved by preparing Ondansetron HCl–β-cyclodextrin inclusion complexes using microwave irradiation. Film-forming polymers such as gelatin, polyvinyl alcohol (PVA), and hydroxypropyl methylcellulose (HPMC) were employed along with crospovidone and microcrystalline cellulose (MCC) as superdisintegrants. Prepared films were evaluated for physicochemical properties, in-vitro disintegration, drug content uniformity, dissolution behavior, and stability. The optimized formulation exhibited rapid disintegration (≈7–10 s), high drug release (>99% within 30 min), and satisfactory stability, demonstrating the potential of crospovidone-based films for rapid oral delivery of Ondansetron HCl.

1. INTRODUCTION

Oral drug delivery remains the most preferred route of administration due to its convenience, safety, ease of manufacturing, and high patient compliance. However, conventional oral solid dosage forms such as tablets and capsules are associated with swallowing difficulties in pediatric and geriatric patients, as well as in individuals suffering from dysphagia, nausea, motion sickness, and neurological disorders. Dysphagia affects a significant portion of the population and often leads to poor medication adherence and compromised therapeutic outcomes.

Fast dissolving drug delivery systems have been developed to overcome these limitations, among which fast dissolving oral films have gained considerable attention. These films are thin, flexible polymeric strips that rapidly hydrate and disintegrate when placed on the tongue, releasing the drug into saliva without the need for water. The large surface area of the films facilitates rapid disintegration and dissolution, resulting in faster onset of action compared to conventional tablets and orally disintegrating tablets. Drug release and absorption through the oral mucosa following rapid film disintegration is illustrated schematically in Figure 1.

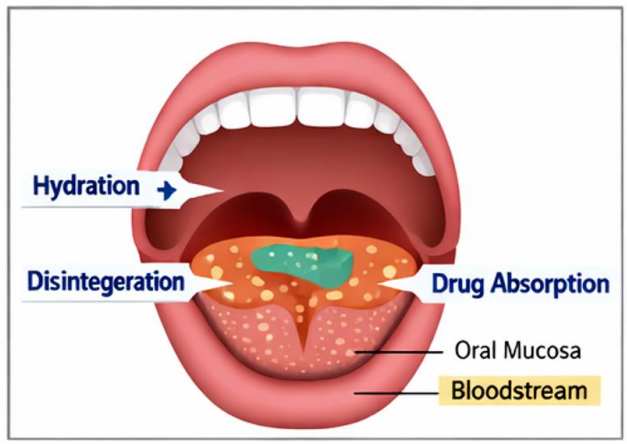

Figure 1. Schematic representation of fast dissolving oral film showing hydration, disintegration, and drug absorption through the oral mucosa.

Ondansetron hydrochloride is a selective serotonin (5-HT3) receptor antagonist extensively used in the management of nausea and vomiting associated with chemotherapy, radiotherapy, and postoperative conditions. Despite its therapeutic effectiveness, Ondansetron hydrochloride exhibits

an intensely bitter taste, which poses a major challenge in the development of patient-friendly oral dosage forms. Since fast dissolving films disintegrate directly in the oral cavity, effective taste masking becomes a critical formulation requirement.

Among various taste-masking approaches, inclusion complexation using cyclodextrins has been widely investigated due to its effectiveness and safety. β-Cyclodextrin, a cyclic oligosaccharide with a hydrophobic internal cavity and hydrophilic external surface, is capable of forming non-covalent inclusion complexes with drug molecules, thereby reducing their interaction with taste receptors. Microwave irradiation has emerged as a rapid and efficient technique for preparing drug–cyclodextrin inclusion complexes, offering advantages such as uniform heating, reduced processing time, and improved complexation efficiency compared to conventional methods.

The performance of fast dissolving oral films is strongly influenced by the selection of film-forming polymers and superdisintegrants. Polymers such as gelatin, polyvinyl alcohol, and hydroxypropyl methylcellulose are widely used due to their excellent film-forming ability, flexibility, and biocompatibility. Superdisintegrants such as crospovidone and microcrystalline cellulose facilitate rapid water uptake and film breakup, thereby enhancing disintegration and drug release.

In view of the above considerations, the present study was designed to develop taste-masked fast dissolving oral films of Ondansetron hydrochloride using β-cyclodextrin inclusion complexes prepared by microwave irradiation technique and to systematically evaluate the influence of formulation variables on film characteristics, disintegration behavior, and in-vitro drug release.

2. LITERATURE REVIEW

Fast dissolving oral films, also referred to as oral thin films or oral strips, have been recognized as an advanced oral drug delivery platform that addresses the limitations associated with conventional oral dosage forms. Previous studies have reported that oral film technology provides rapid onset of action, improved bioavailability, and better patient compliance compared to tablets and capsules. The ability of films to deliver precise doses with rapid disintegration in the oral cavity makes them particularly suitable for pediatric and geriatric patients.

Several researchers have highlighted the prevalence of swallowing difficulties and their impact on medication adherence. Patients who are unable to swallow solid dosage forms often skip doses or discontinue therapy, leading to poor therapeutic outcomes. A high incidence of dysphagia has been reported among elderly patients, reinforcing the need for alternative oral dosage forms that do not require swallowing.

Taste masking is a major challenge in the formulation of oral films, as the drug comes in direct contact with taste buds upon administration. Various taste-masking techniques such as polymer coating, microencapsulation, ion-exchange resins, and inclusion complexation have been investigated. Among these approaches, cyclodextrin inclusion complexes have gained wide acceptance due to their simplicity, effectiveness, and regulatory safety. β-Cyclodextrin has been shown to significantly reduce bitterness and improve palatability of orally disintegrating dosage forms.

Microwave irradiation has been reported as a rapid and efficient method for preparing drug–cyclodextrin inclusion complexes. Compared to conventional kneading or solvent evaporation methods, microwave-assisted complexation offers uniform energy distribution, reduced processing time, and enhanced complexation efficiency. Several studies have demonstrated successful taste masking of bitter drugs using microwave-assisted cyclodextrin complexation.

The selection of film-forming polymers plays a crucial role in determining the mechanical strength, disintegration time, and drug release behavior of fast dissolving oral films. Gelatin provides excellent film-forming ability and flexibility, polyvinyl alcohol produces transparent films with good tensile strength, and hydroxypropyl methylcellulose offers uniform drug distribution and controlled hydration properties. Polymer type and concentration have been reported to significantly influence the performance of oral films.

Superdisintegrants are incorporated into oral films to enhance water uptake and promote rapid film breakup. Crospovidone acts primarily through rapid swelling and capillary action, leading to faster disintegration, whereas microcrystalline cellulose contributes through wicking and particle repulsion mechanisms. Crospovidone-based formulations have been reported to exhibit superior disintegration and dissolution characteristics.

Several formulation studies have been reported on fast dissolving dosage forms of Ondansetron hydrochloride, including orally disintegrating tablets and oral films. These studies emphasize the importance of effective taste masking for patient compliance. However, limited literature is available on the combined use of microwave-assisted β-cyclodextrin inclusion complexes and fast dissolving oral film technology for Ondansetron hydrochloride, indicating a clear research gap addressed in the present investigation.

3. MATERIALS AND METHODS

Ondansetron hydrochloride was used as the model drug, while β-cyclodextrin was employed as the taste-masking agent. Gelatin, polyvinyl alcohol, and hydroxypropyl methylcellulose were used as film-forming polymers. Crospovidone and microcrystalline cellulose served as superdisintegrants, and polyethylene glycol 400 was used as plasticizer. All materials used were of pharmaceutical grade.

Ondansetron hydrochloride–β-cyclodextrin inclusion complexes were prepared in different drug-to-carrier ratios using microwave irradiation technique. Accurately weighed quantities of drug and β-cyclodextrin were mixed thoroughly and subjected to microwave irradiation at controlled power and time. The irradiated mass was allowed to cool, pulverized, and passed through a sieve to obtain a uniform inclusion complex. The process of inclusion complex preparation is depicted schematically in Figure 2.

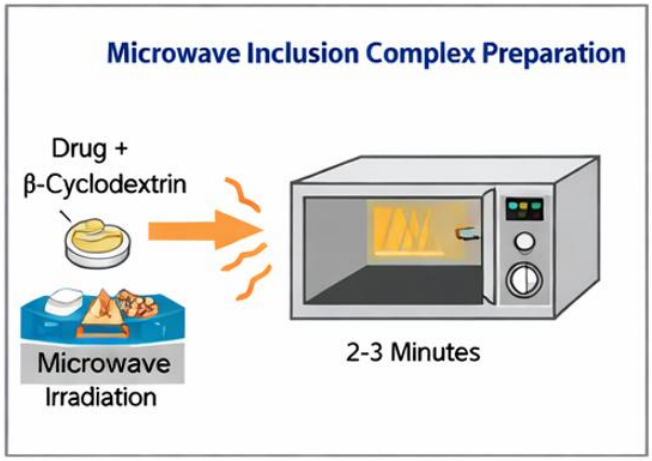

Figure 2. Preparation of Ondansetron hydrochloride–β-cyclodextrin inclusion complex by microwave irradiation technique.

Fast dissolving oral films were prepared by solvent casting technique. The required quantity of polymer was dissolved in distilled water with continuous stirring to obtain a clear polymeric solution. The drug or drug–β-cyclodextrin inclusion complex was incorporated into the polymer solution, followed by addition of plasticizer, superdisintegrant, sweetener, and other excipients. The resulting solution was cast onto leveled surfaces and dried under controlled conditions. The dried films were carefully peeled off and cut into uniform sizes corresponding to the desired dose, as illustrated in Figure 3.

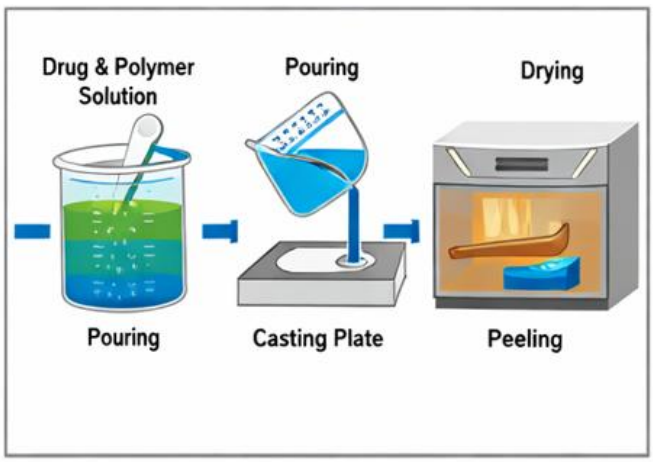

Figure 3. Schematic illustration of solvent casting method for the preparation of fast dissolving oral films.

Compatibility between the drug and excipients was assessed using Fourier transform infrared spectroscopy, while thermal behavior and inclusion complex formation were confirmed using differential scanning calorimetry. Prepared films were evaluated for physical appearance, weight uniformity, thickness, folding endurance, surface pH, in-vitro disintegration time, drug content uniformity, and in-vitro dissolution behavior using standard procedures.

4. RESULTS AND DISCUSSION

The prepared fast dissolving oral films were clear, smooth, and uniform in appearance, indicating homogeneous distribution of polymer and drug. Weight and thickness variation studies showed low variability, confirming uniformity of the solvent casting process and reproducibility of film preparation. Folding endurance values indicated adequate mechanical strength and flexibility, ensuring that the films could withstand handling and packaging stresses.

Surface pH of the films was found to be close to neutral, suggesting minimal risk of irritation to the oral mucosa. In-vitro disintegration time was significantly influenced by the type and concentration of superdisintegrant used. Films containing crospovidone exhibited faster disintegration compared to those containing microcrystalline cellulose, which can be attributed to the rapid swelling and capillary action of crospovidone. The comparative disintegration behavior of different formulations is shown in Figure 6.

Drug content uniformity studies demonstrated uniform distribution of Ondansetron hydrochloride throughout the films, with values generally ranging between 95 and 99%, indicating efficient mixing and casting. In-vitro dissolution studies revealed rapid drug release from all formulations. Crospovidone-based films exhibited maximum drug release of approximately 99% within 30 minutes, whereas microcrystalline cellulose-based formulations showed slightly slower release.

Fourier transform infrared spectra of the inclusion complexes showed characteristic peaks of Ondansetron hydrochloride with minor shifts, indicating the formation of inclusion complexes without chemical interaction, as illustrated in Figure 4.

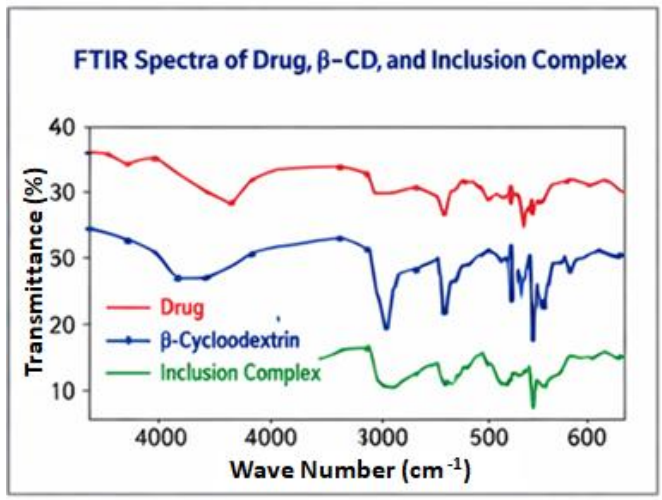

Figure 4.FT-IR spectra of pure Ondansetron hydrochloride, β-cyclodextrin, and Ondansetron hydrochloride–β-cyclodextrin inclusion complex.

Differential scanning calorimetry thermograms further confirmed inclusion complex formation by showing a reduction or shift in the melting endotherm of Ondansetron hydrochloride, as shown in Figure 5.

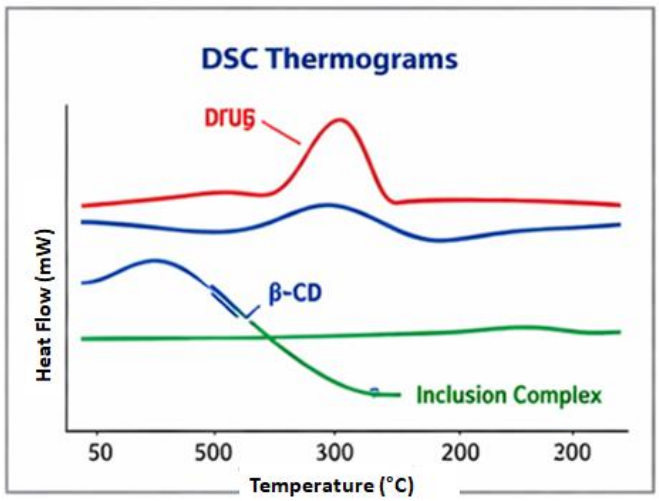

Figure 5. Differential scanning calorimetry (DSC) thermograms of pure Ondansetron hydrochloride, β-cyclodextrin, and Ondansetron hydrochloride–β-cyclodextrin inclusion complex.

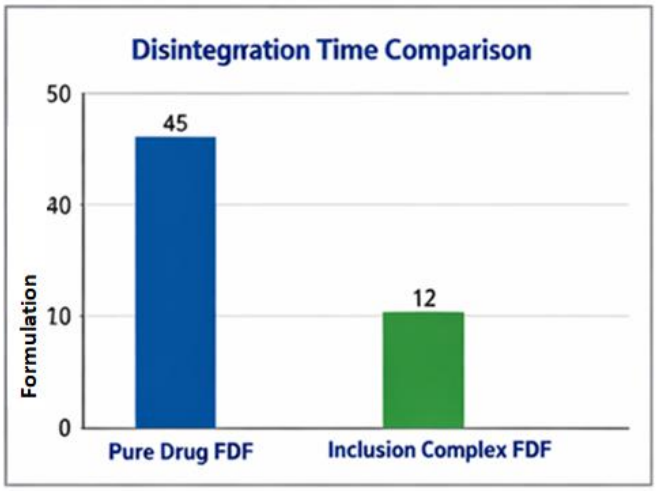

Figure 6. Comparison of in-vitro disintegration time of fast dissolving oral films containing pure drug and inclusion complex.

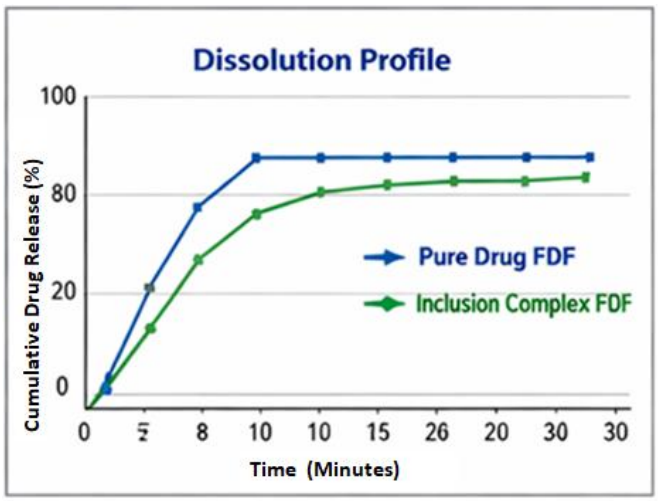

Figure 7. In-vitro dissolution profiles of Ondansetron hydrochloride from fast dissolving oral films prepared with pure drug and β-cyclodextrin inclusion complex.

Short-term stability studies carried out under accelerated conditions indicated no significant changes in physical appearance, drug content, or in-vitro disintegration time, confirming the stability of the optimized formulation.

The in-vitro dissolution profile of Ondansetron hydrochloride from fast dissolving oral films prepared with pure drug and β-cyclodextrin inclusion complex is shown in the figure. A rapid increase in cumulative drug release was observed for both formulations during the initial phase, indicating fast hydration and disintegration of the oral films upon contact with the dissolution medium.

The fast dissolving films containing the pure drug exhibited a comparatively faster initial drug release, achieving approximately 75–80% release within the first 5–8 minutes and reaching about 88–90% cumulative drug release by 10 minutes. Thereafter, the release profile remained almost constant, indicating completion of drug release from the film matrix.

In contrast, the films formulated with the Ondansetron hydrochloride–β-cyclodextrin inclusion complex showed a comparatively slower initial release, with approximately 60–70% drug release within the first 5–8 minutes, followed by a gradual and sustained increase in cumulative drug release. The inclusion complex-based films achieved around 82–85% drug release by 30 minutes.

The relatively slower release observed for the inclusion complex formulation may be attributed to the encapsulation of Ondansetron hydrochloride within the hydrophobic cavity of β-cyclodextrin, which results in a controlled release of the drug from the complex into the dissolution medium. However, despite the slightly slower release rate, the inclusion complex formulation demonstrated sufficient and complete drug release within the required time frame for fast dissolving oral films.

Overall, the dissolution study confirms that both formulations exhibit rapid drug release suitable for fast dissolving oral delivery systems. The inclusion complex formulation offers the additional advantage of effective taste masking while maintaining satisfactory dissolution characteristics, making it more suitable for patient-friendly oral administration.

5. CONCLUSION

Taste-masked fast dissolving oral films of Ondansetron hydrochloride were successfully developed using β-cyclodextrin inclusion complexes prepared by microwave irradiation technique and solvent casting method. The selection of appropriate polymers and superdisintegrants played a crucial role in achieving rapid disintegration and high drug release. Crospovidone-based formulations exhibited superior performance in terms of disintegration time and dissolution behavior. The developed fast dissolving oral films demonstrated satisfactory physicochemical properties, effective taste masking, rapid drug release, and stability,

indicating their potential as a patient-friendly alternative to conventional oral dosage forms of Ondansetron hydrochloride.

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