WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.453
Volume 14, Issue 23, 1686-1697. Research Article ISSN 2277–7105

FORMULATION AND EVALUATION OF ANTIEMETIC ONDANSETRON HYDROCHLORIDE ORAL THIN FILM

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Article Received on 05 Nov. 2025,
Article Revised on 25 Nov. 2025,
Article Published on 05 Dec. 2025,

https://doi.org/10.5281/zenodo.17799930

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How to cite this Article: Jyoti H. Jankar*, Rucha V. Pandit*, Kalyani N. Shinde*, Hitakshi N. Keluskar*, Madhavi S. Pandhare*, Sampat S. Bangar*. (2025). Formulation and Evaluation of Antiemetic Ondansetron Hydrochloride Oral Thin Film. World Journal of Pharmaceutical Research, 14(23), 1686–1697.

ABSTRACT

Patient struggling to swallow traditional tablets or capsules could gain advantages from a medication delivery system that dissolves rapidly. The present research seeks to develop oral thin films of Ondansetron via the solvent casting technique. Ondansetron Hydrochloride is a 5-HT3 Receptor Antagonist used as an Anti-emetics, Serotonin Antagonists, Anti-anxiety Agents, Antipsychotics, Anti-pruritics agent with extensive first pass metabolism which results in less bioavailability. The fast releasing films were prepared using polymers such as HPMC E5, HPMC E15, PVA, PVP K 30, as either single polymer or in a combination of two, by solvent casting technique with the help of polyethylene glycol as a plasticizer and aspartame as a sweetening agent. The drug releasing 98.40% within 60 sec as compared to other formulations as well as conventional tablets. This review article discusses the benefits of oral dispersible films compared to other oral dosage forms, particularly oral dispersible tablets, as well as their various applications.

INTRODUCTION

Fast-dissolving films have become popular as a new method of drug delivery because they are easy to use and allow for quick onset of medication effects when taken sublingually. The sublingual mucosa, due to its thin membrane and rich blood supply, facilitates rapid drug absorption and immediate bioavailability, leading to prompt pharmacological effects. As the drug enters the systemic circulation directly, it bypasses degradation in the gastrointestinal

(GI) tract and the first-pass effect. Moreover, this method is expected to improve patient compliance since it does not require swallowing like a traditional tablet, making it beneficial for individuals with dysphagia or swallowing difficulties. The introduction of mucoadhesive polymers in the films helps them adhere to the sublingual mucosa, resulting in better retention and absorption of the medication In recent decades, there has been a surge in the development and manufacturing of innovative dosage forms to enhance patient compliance and quality of life. The feasibility of employing oral solid dosage forms is a serious concern in various patient populations, such as children, geriatrics, and patients with nausea and vomiting, or swallowing difficulties. ODFs are oral strips comprised of hydrophilic polymers that include active ingredients and excipients. When these lms come into touch with saliva, they dissolvcfabrication and a less expensive manufacturing technique. As well as flexibility and a greater likelihood of patentability. The films make it simple to deliver medications to youngsters, the elderly, and patients who are immobile. A film's flavor, stability, and ease of handling are all desirable features. A fast-dissolving oral thin film (FDF) is a solid dose medium; when put in the mouth without water or chewing, OTFs disintegrate or dissolve in 1 minute.

Fig. No. 1

As saliva runs down into the stomach, pre-gastric uptake from the mouth, throat, and esophagus improved the drug's therapeutic efficacy as it decomposed in the mouth. Fast-dissolving films may prefer adhesive tablet because of their flexibility and comfort. There are numerous polymers available for the production of FDF. Polymers, active pharmaceutical additives, film stabilizing agents, sweeteners, flavors, textures, saliva-inducing agents, preservatives, surfactants, and other ingredients are used in the prepration of the polymer is

the first and important ingredients that aids in film formulation. Oral thin film, compressed tablet based use and lyophilized devices are three categories of fast dissolve technologies.

ADVANTAGES

- Suitable for Pediatric and Geriatric patients.
- Convenient and Easy to Administer.
- Rapid Onset of Action.
- Increased Compliance.
- Portable and Discreet.
- Minimal drug interaction.
- Useful in Emergency Situations.

DISADVANTAGES

- Slower Onset Than Injection.
- Taste or Aftertaste Issues.
- Limited Dosage Strength Option.
- Fragility and Storage Concerns.
- Generally more expensive than regular oral tablets.

IDEAL CHARACTERISTICS

- The drug should have a pleasant taste.
- The drug should be of a low dose, typically up to 40 mg.
- Preference is given to drugs with smaller to moderate molecular weights.
- The drug should be stable and soluble in both water and saliva.
- The drug should be partially ionized at the pH of the oral cavity.

COMPOSITION

Table No. 1

COMPONENT	FUNCTION
Ondansetron HCL	Active pharmaceutical ingredient (API)
Film-forming polymer	Forms the strip (e.g., HPMC, PVA, pullulan)
Plasticizer	Increases flexibility (e.g., glycerin, PEG-400, propylene glycol)
Saliva-stimulating agent	Enhances dissolution (e.g., citric acid)
Sweetener	Masks bitterness (e.g., sucralose, aspartame)
Flavoring agent	Improves taste (e.g., mint, orange)
Preservatives	For stability
Colorant (optional)	Aesthetic purpose
Solvent	Usually water or water-ethanol mix

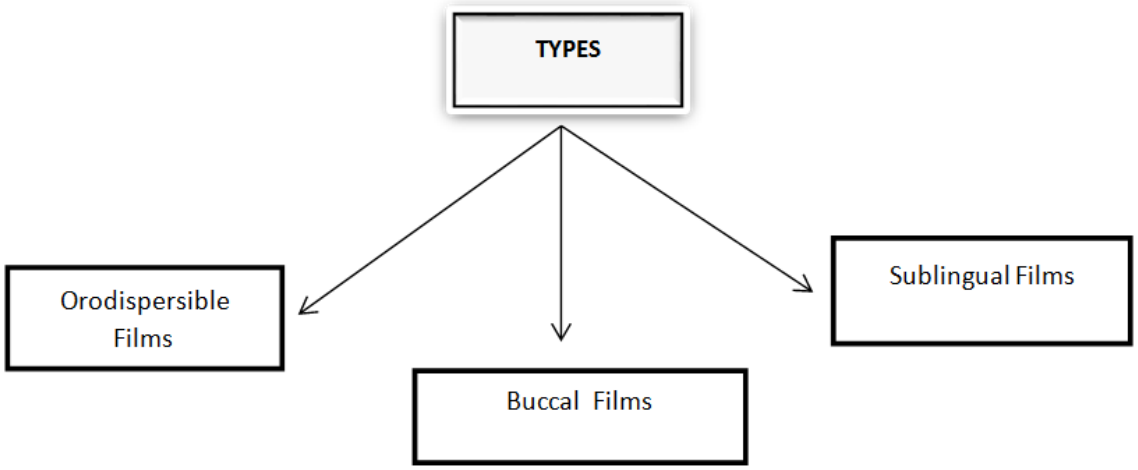

Fig. No. 2

MANUFACTURING

Based on initial physical observations of the films prepared, the most effective compositions were selected for the incorporation of Ondansetron. Gelatin and PVA polymers were dissolved in water while continuously stirring. The required amount of Ondansetron was dissolved in propylene glycol and then added to the polymer solution after the complete dissolution of the drug. Following this, propylene glycol (acting as a plasticizer) was mixed in to create a uniform solution, along with the addition of disintegrants. The resulting solution was poured onto a mercury substrate and kept in a hot air oven at 40ºC for 2 hours. The formed film was then cut into discs measuring 2 cm in diameter, with each film containing 10 mg of Ondansetron. The oral disintegrating thin films of Ondansetron were created using the solvent casting method, utilizing polymers such as Gelatin and PVA, with propylene glycol serving as a plasticizer. The necessary amount of polymer was dispersed in three-quarters of the total volume while being stirred continuously using a magnetic stirrer, with the final volume adjusted using distilled water.

The required amount of Ondansetron was included in the polymer solutions after levitating with the needed volume of PEG. After being cast onto a mercury substrate, the solution was placed in a hot air oven at 40ºC. The films were then cut out to a size of 2 cm in diameter, each containing 10 mg of Ondansetron.

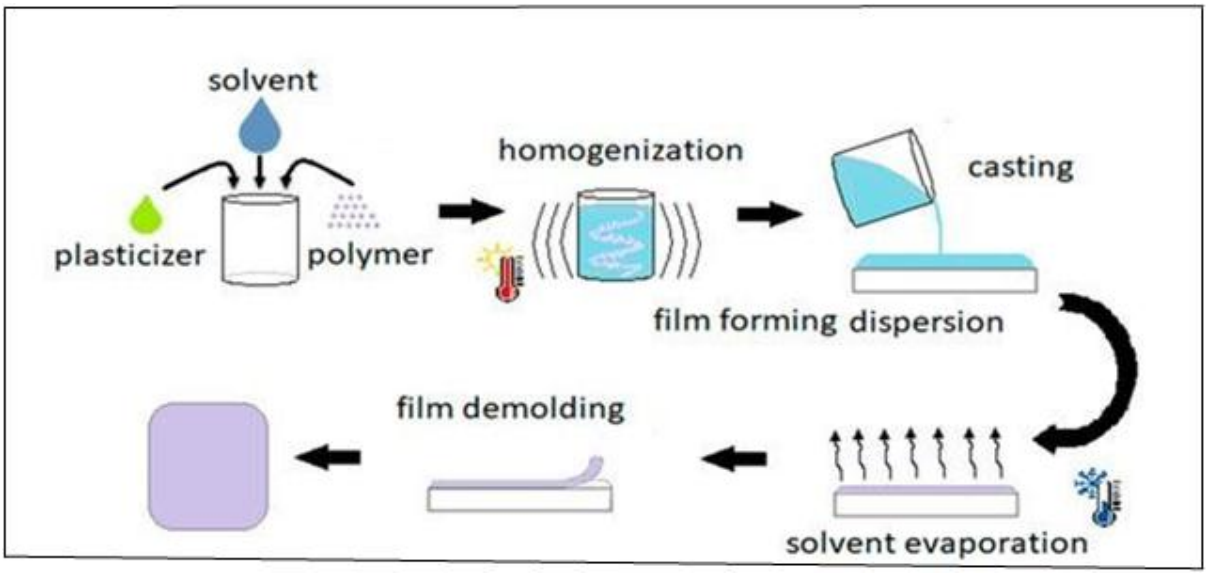

Fig. No. 3

Through a trial-and-error approach, various concentrations of film-forming polymers like Gelatin and PVA were tested. It was determined that a concentration of 4.5% gelatin and 3.5% PVA produced superior films. These films were prepared by dissolving different quantities of the film-forming polymers in 10 ml of water.

FORMULATION DETAILS OF ONDANSETRON ORAL THIN FILM

Table No. 2

Compound	Ondansetron (mg)	Gelatin (%)	PVA (%)	Citric Acid (mg)	Flavouring agent (mg)	Propylene glycol (mg)
F1	90	4.5	-	4	8	30
F2	90	4.5	-	4	8	30
F3	90	4.5	-	4	8	30
F4	90	4.5	-	4	8	30
F5	90	4.5	-	4	8	30
F6	90	-	3.5	4	8	30
F7	90	-	3.5	4	8	30
F8	90	-	3.5	4	8	30
F9	90	-	3.5	4	8	30
F10	90	-	3.5	4	8	30

EVALUATION TEST

I) Physical Appearance and Surface Texture of the Patch

This property was assessed through visual examination of the films and by manually feeling their surface to evaluate texture.

II) Weight Uniformity of the Films

Three film samples, each with a diameter of 2 cm, were individually weighed using a digital balance. The average weight was then calculate

II) Folding Endurance

The flexibility of the films was assessed by determining their folding endurance. A strip approximately 2×2 cm in size was repeatedly folded at the same spot until it broke. The number of folds the film withstood before breaking was recorded as the folding endurance value.

II) Surface pH of the Films

To measure surface pH, each film was moistened with 1 ml of distilled water. After allowing it to equilibrate for one minute, a pH paper or glass electrode was brought into contact with the surface, and the pH was recorded.

IV) Film Thickness

The thickness of each film was measured at multiple points using a screw gauge with a precision of 0.01 mm.

V) In Vitro Disintegration Time

The disintegration time was evaluated using a USP disintegration test apparatus with 0.1N hydrochloric acid as the test medium.

VI) Drug Content Uniformity Study of Films:

To evaluate the uniformity of drug content, a UV-Visible spectrophotometric method was employed. Circular film samples with a diameter of 2 cm were cut from three different locations on the prepared film. Each sample was placed into a 100 ml volumetric flask and dissolved in 0.1N hydrochloric acid (HCl). From this solution, 0.2 ml was withdrawn and further diluted to 10 ml with distilled water before analysis.

VII) In-vitro Dissolution Study

The dissolution behavior of the Ondansetron oral disintegrating thin films was assessed using a USP XXIV dissolution test apparatus. A volume of 900 ml of 0.1N HCl was used as the dissolution medium. The apparatus was operated at a paddle rotation speed of 50 rpm, with the temperature maintained at 37±0.5°C throughout the test. One film sample was used per test. At predetermined time intervals, 5 ml samples of the dissolution medium were

withdrawn using a syringe fitted with a pre- filter and analyzed for drug release by measuring the absorbance at 310 nm.

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- **Drug Release Kinetics**

To understand how the drug is released from the dosage form over time, the data collected were analyze using different kinetic models

Zero-Order Kinetics

In zero-order kinetics, the drug is released at a constant rate, regardless of its concentration. The equation used is:

$$F = K \times t$$

Where,

F is the amount of drug released **K** is the zero-order rate constant **t** is time

First-Order Kinetics

In first-order kinetics, the drug release rate depends on the concentration of the drug remaining. The equation used is:

$$\log C = \log C_0 - (K \times t) / 2.303$$

Where:

C is the drug concentration at time t

$\mathbf{C_0}$ is the initial drug concentration

K is the first-order rate constant

t is time

RESULT AND DISCUSSION

Solubility: The solubility of Ondansetron was determined at 25°C using 0.1 N hydrochloric acid, pH 6.8 phosphate buffer, and purified water.

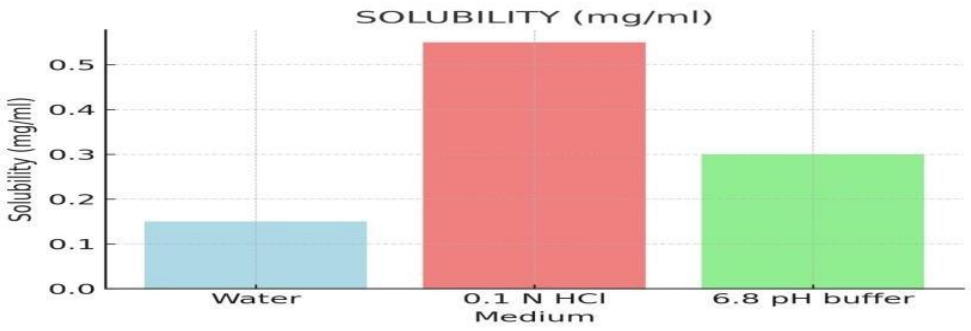
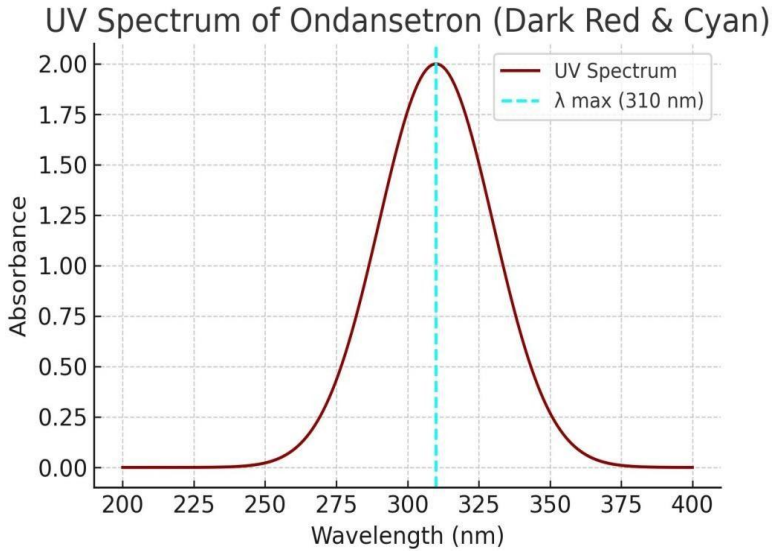


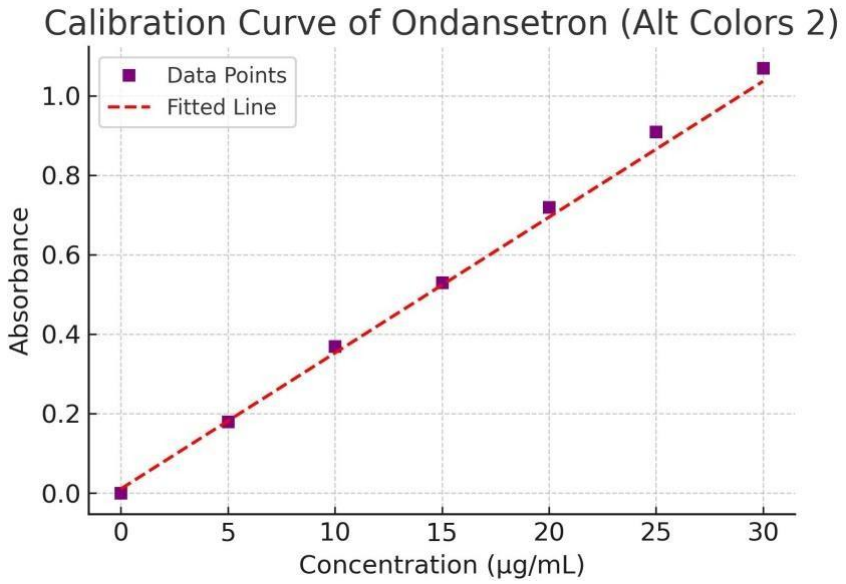
Fig. No. 3

Discussion: Based on the solubility studies carried out in different buffer solutions, it can be concluded that 0.1 N HCl exhibits higher solubility than the other buffers tested.



Absorption maxima of Ondansetron in 6.8 pH Phosphate Buffer

Fig. No. 4



Standard Calibration Curve Of Ondansetron In 6.8 pH Phosphate Buffer.

Fig. No. 5

CONCLUSION

In this study, an oral disintegrating drug delivery system for Ondansetron was successfully developed as thin films that dissolve quickly in the mouth. This approach offers an effective and convenient way to achieve rapid disintegration and dissolution, enhancing the drug's bioavailability. Crospovidone and Ludiflash were utilized as super disintegrants to formulate these oral thin films of Ondansetron.

Pre-formulation studies included the characterization of the active pharmaceutical ingredient (API) and compatibility testing between the drug and excipients. The API characterization confirmed that it met the required drug specifications. The choice of disintegrants and other excipients for the final formulation was based on positive results from drug-excipient compatibility tests.Using the solvent casting method with polyvinyl alcohol and Ludiflash as disintegrants, the optimal formulation (F5) was developed. This formulation showed a rapid disintegration time of 6 seconds and a high in vitro drug release rate of 98.34%.Comparing batches with Ludiflash and Crospovidone as disintegrants, formulation F5 demonstrated a better in vitro release profile in a shorter time compared to those with Crospovidone. The solvent casting technique proved to be the best method for achieving fast drug release. Based on these results, the formulations will proceed to bioavailability testing, and if they meet all criteria, they will be considered for commercial production.

MARKEDED EXAMPLE

I) BRAND NAME- ZUPLENZ

Company Name- Galena Biopharma Strength- 4mg

II) BRAND NAME-SETOFILM

Company Name-Lavasta Pharma Strength-4mg

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