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Fast Dissolving Film of Ondansetron Hydrochloride

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ABSTRACT
The goal of this study was to develop a fast-dissolving film for a water-soluble drug, providing a more convenient and user-friendly alternative to conventional oral dosage forms. The films were fabricated using the solvent casting method with the film-forming polymer Hydroxypropyl Methylcellulose (HPMC). The release profile of Ondansetron HCl demonstrated rapid dissolution, with 97.5% release occurring within 35 seconds. Among all the optimized formulations, F2 exhibited the best performance, making it the most suitable batch. The stability study conducted over 90 days showed that the optimized F2 formulation maintained its physical appearance, drug content, and dissolution pattern without any changes. In conclusion, the F2 formulation, with its quick release and stability, holds great potential for the development of fast-dissolving films in the future.
Keywords: Ondansetron HCl, Fast-dissolving film, Super-disintegrant, Anti-emetic activity.

I. INTRODUCTION

Some patients experience difficulty swallowing or chewing solid dosage forms, which may result in choking hazards. This challenge with tablets has prompted the development of alternative drug delivery systems. Oral dissolving films (ODFs) are an innovative approach for delivering drugs orally. These films are particularly useful in the management of acute conditions such as pain, nausea, migraines, hypertension, congestive heart failure, and asthma, among others. ODFs have gained increasing popularity due to their availability in various sizes and shapes. They are designed to dissolve or disintegrate in seconds, offering benefits like ease of administration without the need for water, a rapid onset of action, and dosing convenience. For active pharmaceutical ingredients, fast absorption through the oral mucosa can enhance bioavailability.

The oral route remains the most commonly used and preferred method for drug delivery. While orally disintegrating tablets (ODTs) typically dissolve in one to two minutes, fast dissolving films (FDFs) disintegrate within seconds. FDFs were initially introduced for personal care products, such as breath fresheners, but their potential therapeutic benefits soon became evident. The first therapeutic FDF, Chloraseptic, which contained 7-benzocaine for sore throat relief, was launched in the market. These films are thin and placed on the tongue or mucosal tissue, where they dissolve quickly upon contact with saliva. This rapid dissolution is due to the large surface area of the film, which quickly absorbs moisture from the oral cavity.

FDFs serve as a modern alternative to traditional oral solid dosage forms like tablets, capsules, and syrups. They are developed using technology similar to that used in transdermal patches. Hydrophilic polymers are utilized in FDFs to allow the film to dissolve rapidly, delivering the drug directly into the systemic circulation via the buccal mucosa. This direct delivery leads to a faster onset of therapeutic effects. FDFs are particularly advantageous for drugs with low bioavailability due to extensive first-pass metabolism, enhancing their absorption. Additionally, FDFs are beneficial for pediatric and geriatric patients, who often struggle with swallowing conventional dosage forms, thereby improving patient compliance. Patients appreciate FDFs for their ease of use, as they do not require water, and for their faster onset of action compared to other oral dosage forms.

Special Features of Mouth Dissolving Films

1. Thin, elegant design

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2. Available in various sizes and shapes
3. Discreet and unobtrusive
4. Excellent adhesion to mucosal tissues
5. Rapid disintegration
6. Quick release of the drug

Ideal Characteristics for Drug Selection

1. The drug should have a pleasant taste.
2. The drug should be of a low dose, typically up to 40 mg.
3. Preference is given to drugs with smaller to moderate molecular weights.
4. The drug should be stable and soluble in both water and saliva.
5. The drug should be partially ionized at the pH of the oral cavity.
6. The drug should have the ability to permeate through the oral mucosal tissue.

Advantages of Oral Fast Dissolving Films

1. Fast-dissolving films can be taken without water, offering convenience anywhere and anytime.
2. The larger surface area of the films ensures rapid disintegration and dissolution within the oral cavity.
3. These films are flexible and portable, making them easy to carry, store, and handle.
4. They are ideal for pediatric and geriatric patients, as well as individuals who have difficulty swallowing, including those with mental disabilities, developmentally delayed individuals, and those who are uncooperative or on restricted liquid intake or experiencing nausea.
5. Fast onset of action makes them beneficial for conditions like motion sickness, acute pain, sudden allergic attacks, or coughing, where quick relief is required.
6. The drug remains in solid form until consumed, providing the stability of solid dosage forms and the bioavailability benefits of liquid forms.
7. Each film strip provides precise dosing, ensuring accurate administration compared to liquid formulations.
8. The oral or buccal mucosa, being highly vascular, allows for direct drug absorption into the systemic circulation, bypassing first-pass hepatic metabolism. This property is particularly beneficial for drugs affected by the first-pass effect, enhancing oral bioavailability.
9. The sublingual and buccal delivery routes using thin films can improve the onset of action, reduce dosing requirements, and increase the overall efficacy and safety of the medication.
10. These films offer new business opportunities, such as product differentiation, promotional advantages, and potential for patent extensions.

Disadvantages of Oral Fast Dissolving Films:

1. High-dose drugs cannot be effectively incorporated.
2. Ensuring uniformity in dosing presents a technical challenge.
3. Drugs that are unstable at the pH of the buccal cavity cannot be administered via this route.
4. Drugs that cause mucosal irritation are unsuitable for this dosage form.
5. Only drugs with small dose requirements can be administered using these films.
6. Taste masking is required for drugs with a bitter taste, which is common among many medications.
7. Special packaging is necessary to protect the fragile oral dissolving films from moisture.

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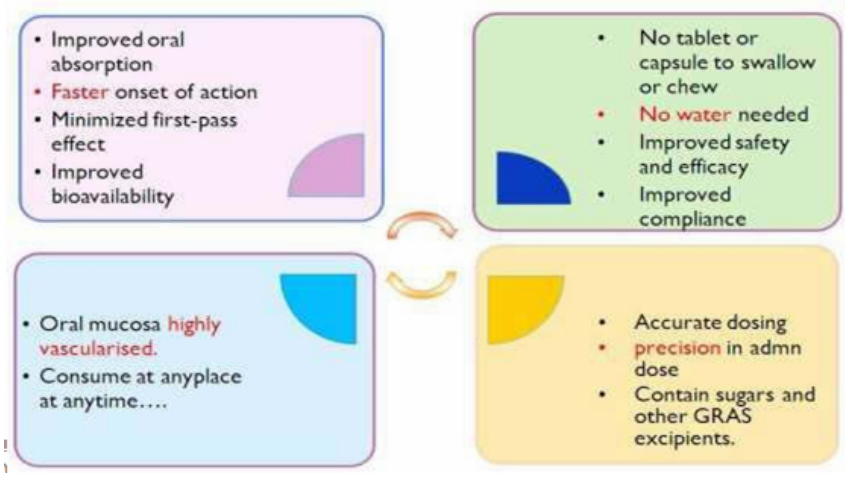

Fig 1:-Advantage of Fast dissolving films

Advantages	Description
Rapid Onset of Action	Fast-dissolving forms dissolve quickly in the mouth, leading to faster absorption and quicker therapeutic effects.
Convenience	Easy to use for individuals with swallowing difficulties, such as the elderly or children.
Improved Patient Compliance	No need for water, making it more convenient for patients to take medications, thus improving adherence to treatment.
Portability	Small and compact, fast-dissolving dosage forms are easy to carry and use on the go.
No Need for Water	Useful in situations where water is not available, such as while traveling or in emergencies.
Taste Masking	Can be formulated to mask the unpleasant taste of certain medications, making it more palatable.
Increased Bioavailability	Some formulations can enhance the bioavailability of drugs, improving overall therapeutic efficacy.
Enhanced Market Appeal	Attractive to patients due to ease of administration, leading to greater market acceptance.
Suitable for Paediatric and Geriatric Use	Ideal for populations that may find it difficult to swallow traditional tablets or capsules.
Quick Relief	Fast-dissolving formulations are beneficial for conditions that require rapid symptom relief.

II.

III. MATERIAL AND METHOD

Drug Profile: Ondansetron HCl

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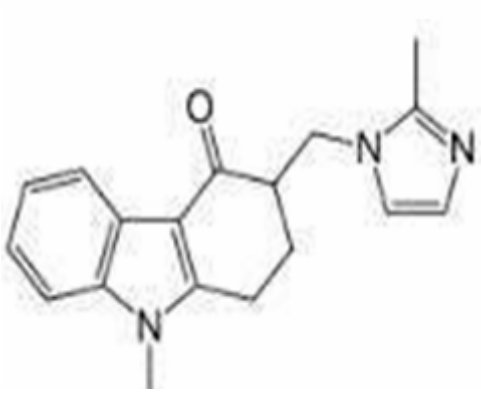

Fig: 2 Molecular structure of Ondansatron HCl

Ondansetron, marketed under the brand name Zofran, is a selective serotonin 5-HT3 receptor antagonist primarily used to prevent nausea and vomiting associated with chemotherapy, radiation therapy, and surgery. It has minimal effect on motion sickness-related vomiting and does not affect dopamine or muscarinic receptors. The drug is listed on the World Health Organization's List of Essential Medicines, which identifies the most crucial medications for a basic healthcare system.

Mechanism of Action: Ondansetron works by selectively blocking serotonin 5-HT3 receptors. Its antiemetic effect is achieved by inhibiting these receptors both centrally (in the medullary chemoreceptor zone) and peripherally (in the gastrointestinal tract). This inhibition reduces the visceral afferent signals to the vomiting center, likely through indirect action at the area postrema, as well as through direct suppression of serotonin activity in the area postrema and chemoreceptor trigger zone.

Drug Compatibility Study: Prior to formulating Ondansetron HCl fast-dissolving films, a compatibility study with the drug and excipients was conducted using Fourier Transform Infrared Spectroscopy (FTIR).

Formulation of Fast-Dissolving Films by Solvent Casting Technique: The fast-dissolving films of Ondansetron HCl were prepared using the solvent casting method with a range of ingredients at specific concentrations. First, Hydroxypropyl Methylcellulose (HPMC) was measured accurately and soaked for one hour to allow the polymer to swell. The specific compositions of the ingredients are detailed in Tables 1 and 2. Concurrently, Ondansetron HCl was accurately weighed and dissolved in 5 mL of distilled water in a separate beaker. This drug solution was then added to the polymer solution, and polyethylene glycol was incorporated as a plasticizer while mannitol was used as a sweetener. The mixture was thoroughly stirred using a magnetic stirrer. To ensure the removal of air bubbles, the solution was sonicated for 20 minutes.

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Table 1: List Various Ingredients used in preparation of films

Sr.No.	Ingredients	Use
1	Ondansetron HCl	**API**
2	Polyethyleneglycol[PEG]	**Plasticizer**
3	Hydroxypropylmethylcellulose[HPMC]	**polymer**
4	Glycerol	**Humectant**
5	Tween80	**Surfactant**
6	Mannitol	**Sweetener**
7	Polyvinylpyrrollidone	**Surfactant**
8	**FDA Approved Colorant (Yellow)**	**Colouring Agent**

A glass mould (Petridis) with a diameter of 9 cm was placed on a flat surface. Using a measuring cylinder, 10 mL of the solution was added to the mould slowly, drop by drop, and spread evenly. To ensure uniform evaporation, an inverted funnel was placed over the Petridis. The mould, containing the polymeric solution of the drug, was left to dry for 24 hours at room temperature. Once the films had dried, they were carefully removed from the mould. The same procedure was followed to prepare formulations F2, F3, and F4.

Table 2: Optimized composition of Fast Dissolving film

S. N.	Ingredients	F1	F2	F3	F4	F5	F6
1	Ondansetron HCl (mg)	80	80	80	80	80	**80**
2	HPMC (mg)	300	250	200	-	-	**-**
3	P.V.P. (mg.)	-	-	-	300	250	**200**
4	P.E.G.(mg.)	50	100	150	50	100	**150**
5	Mannitol(ml)	20	20	20	20	20	**20**
6	Tween80(ml)	30	30	30	30	30	**30**
7	**Water [ml]**	**10**	**10**	**10**	**10**	**10**	**10**

Evaluation of Fast Dissolving Films of Ondansetron HCl

1. **Weight Variation**

Three films from each formulation were weighed individually using a digital balance, and the average weight was calculated.

2. **Film Thickness**

The thickness of each film was measured at different positions using a micrometer screw gauge, and the average thickness was determined.

3. **Surface Ph**

Each film was placed in a Petridish and moistened with 0.5 mL of distilled water, then allowed to stand for 1 hour. The pH was measured by placing the pH meter electrode on the surface of the film for 1 minute to allow equilibrium.

4. **Folding Endurance**

Folding endurance was assessed by repeatedly folding one film at the same location until it broke. The number of folds the film could withstand without breaking was recorded.

5. **Dissolving Time**

To measure the dissolving time, the film was placed in a beaker containing 50 mL of phosphate buffer (pH 6.8). The time taken for the film to dissolve completely was noted.

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6. **Drug Content**

A circular section of the film (2.5 cm in diameter) was cut and placed in a beaker containing 100 mL of phosphate buffer solution (pH 6.8). The solution was stirred using a magnetic stirrer to dissolve the film. The solution was then transferred to a 100 mL volumetric flask, and the absorbance was measured at 238.5 nm. If the absorbance exceeded 1 µg/mL, the solution was diluted further, and the absorbance was measured again.

7. **Disintegration Time**

The disintegration time was evaluated using a disintegration test apparatus. A 5 cm² film was placed in the basket and raised and lowered to simulate 30 cycles per minute. The time taken for the film to disintegrate completely, leaving no trace on the gauze, was recorded.

8. **In-vitro Dissolution Studies**

Dissolution studies were performed using a USP paddle dissolution apparatus with phosphate buffer (pH 6.8) as the medium. The temperature was maintained at 37 ± 0.5°C, and 5 mL of the sample was withdrawn at 50-second intervals, replacing the withdrawn volume with fresh buffer.

9. **Stability Studies**

The stability of the fast dissolving films was evaluated by storing them at 40 ± 2°C and 75% relative humidity in a stability chamber for 45 days. The films were analyzed for drug content after 45 days.

10. **Physical Appearance**

The films were visually inspected for their color, clarity, flexibility, and smoothness.

11. **Percent Elongation Break Test**

The films were subjected to elongation tests using a pulley system. Weights were added gradually until the film broke. The elongation was determined by noting the distance the pointer traveled before the film broke, and the percent elongation was calculated using the formula:

Percent Elongation = (L1 / L0) × 100,
where **L1** is the final length, and **L0** is the initial length.

IV. RESULTS AND DISCUSSION

Before formulating the fast dissolving films of Ondansetron HCl, drug-excipient compatibility was assessed using Fourier Transform Infrared Spectroscopy (FTIR), which confirmed that no interactions occurred between the components. The key functional groups of the drug were identified at their characteristic peaks.

The prepared films were evaluated for several parameters, with results confirming their excellent properties. The fast dissolving films of Ondansetron HCl exhibited the following values:

a. **Weight**: 52-63 mg
b. **Thickness**: 0.136-0.164 mm
c. **Surface pH**: 6.22-6.83
d. **Folding Endurance**: 119-135
e. **Dissolving Time**: 35-42 sec
f. **Drug Content**: 91.8-97.8%
g. **Disintegration Time**: 24-30 sec
h. **% Elongation**: 22.9-65.12

The formulation that showed an optimal weight of 61 mg, thickness of 0.145 mm, surface pH of 6.22, folding endurance of 124, dissolving time of 35 sec, disintegration time of 24 sec, and % elongation of 22.9 was selected for further in-vitro drug release and stability studies, due to its excellent efficacy and rapid onset of action compared to the other formulations.

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Table-3: Evaluation of fast dissolving films-

S.N.	Parameter	F1	F2	F3	F4	F5	F6
1	Weight [mg]	55	61	52	62	63	**57**
2	Thickness [mm]	0.136	0.145	0.153	0.164	0.159	**0.148**
3	Surface pH	6.51	6.22	6.45	6.83	6.81	**6.54**
4	Folding endurance	119	128	124	132	123	**135**
5	Dissolving time [sec]	41	35	38	40	42	**39**
6	Drug content %	93.9	97.8	92.9	92.45	91.8	**92.3**
7	Disintegration time [sec]	27	24	30	25	28	**27**
8	**% Elongation**	**65.12**	**22.9**	**36.2**	**40.7**	**52.3**	**38.9**

In vitro dissolution studies were conducted for various formulations (F1, F2, F3, F4, F5, and F6) of Ondansetron HCl mouth dissolving films using a USP paddle dissolution apparatus in phosphate buffer at pH 6.8. After a 35-minute dissolution period, formulation F2 exhibited the highest dissolution rate of 97.5%, making it the most effective formulation among all six tested.

Table-4: In-Vitro Dissolution studies–

Time	F1	F2	F3	F4	F5	F6
5 min.	27.7	29.7	27.2	20.4	30.16	**16.03**
10 min.	39.2	46.6	35.8	38.9	46.6	**34.1**
15 min.	50	62.69	52.2	55.5	58.3	**47.09**
20 min.	62.6	81.64	64.2	69.4	71.4	**61.23**
25 min.	80	87.48	73	79.02	85.5	**74.35**
30 min.	88.8	93.31	86.4	88.93	91.12	**87.48**
35 min	**93.6**	**97.5**	**91.8**	**96.08**	**95.5**	**96.0**

The results of the study indicated that formulation F2 exhibited the highest dissolution rate and in vitro drug release, along with the highest drug content among all six formulations, demonstrating its superior efficacy. Additionally, formulation F2 had the shortest dissolving time compared to the other formulations, indicating its rapid onset of action.

FTIR of Drug and Polymer Used for fast dissolving Film

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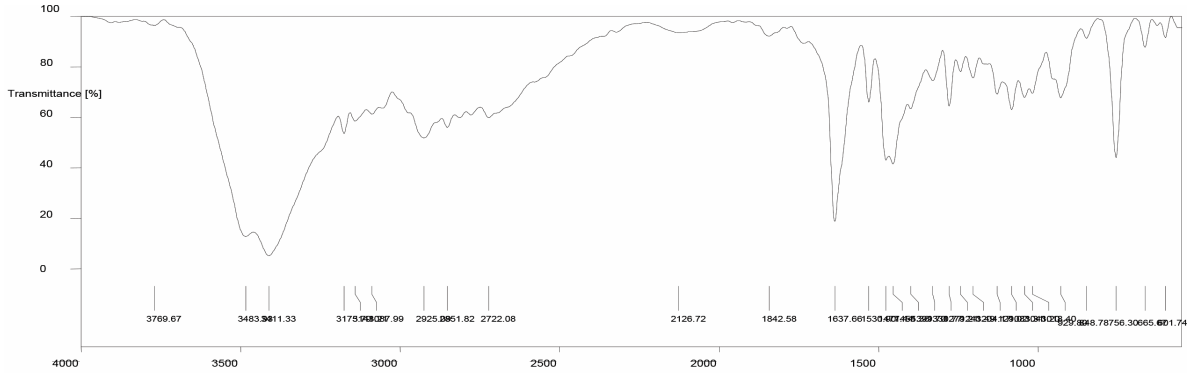

Fig.1:Drug Name: Ondensterone HCl **Fig.2:Drug+HPMC**

V. VI. CONCLUSION AND FUTURE PROSPECTS

The primary goal of this study was to develop and assess a fast-dissolving film of Ondansetron Hydrochloride. The aim was to create a formulation that can be conveniently administered without water, allowing for ease of use anywhere and at any time. This formulation is particularly beneficial for geriatric and pediatric patients, as well as individuals with difficulty swallowing, mentally ill or developmentally disabled patients, or those who are uncooperative, have limited liquid intake, or are experiencing nausea.

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