Formulation and Evaluation of Orodispersible film

[1]Mr. Aditya Santosh Kakad, [2]Dr. Nitin S. Bhajipale, [3]Prof. Harish K. Kunjwani

[1]Research Scholar, S.G.S.P.S. Institute of Pharmacy Kaulkhed,
[2]Principal, S.G.S.P.S. Institute of Pharmacy Kaulkhed,
[3]Professor, S.G.S.P.S. Institute of Pharmacy Kaulkhed,
[1]Department of Pharmaceutics,
[1] **S.G.S.P.S. Institute of Pharmacy Kaulkhed,**
Akola–444004, (MH) India
[1]aditya.gsps.akola@gmail.com, [2]principal@akolapharmacy.in,[3]kunjwania@gmail.com,

Abstract **- The present research focuses on the formulation and evaluation of orodispersible films (ODFs) of Granisetron, an antiemetic agent, designed to enhance patient compliance and provide rapid therapeutic action. Orodispersible films offer a convenient and effective drug delivery system, particularly beneficial for pediatric, geriatric, and dysphagic patients. In this study, various formulations were developed using the solvent casting method, employing hydroxypropyl methylcellulose as the primary film-forming polymer along with suitable plasticizers and excipients to ensure desirable mechanical properties and rapid disintegration. The prepared films were evaluated for physical appearance, thickness, weight uniformity, folding endurance, disintegration time, drug content, and in-vitro dissolution profile. Among all formulations, the batch F5 exhibited optimal performance, demonstrating rapid disintegration and enhanced drug release, making it a promising candidate for improving bioavailability and onset of action. This investigation highlights the potential of orodispersible films as a patient-friendly alternative to conventional dosage forms for the management of nausea and vomiting.**

Key word: **Orodispersible film, Mouth dissolving film.**

INTRODUCTION:

Oral administration remains the most common and convenient route for drug delivery due to its simplicity, non-invasiveness, and ease of self-administration, which promotes better patient compliance. It supports diverse dosage forms like tablets, capsules, and solutions, allowing customization for specific patient needs such as pediatric or extended-release formulations. Despite variables like food and gastric pH affecting drug absorption, formulation strategies can enhance solubility and bioavailability. [1]

Orodispersible films (ODFs) are an innovative oral dosage form designed to rapidly disintegrate on the tongue, offering quick drug release and absorption, often bypassing the gastrointestinal tract. This makes them especially suitable for patients with swallowing difficulties, including children and the elderly. Typically composed of hydrophilic polymers (e.g., HPMC), plasticizers, and flavor enhancers, ODFs ensure flexibility, taste acceptability, and accurate dosing. They are manufactured using methods like solvent casting and evaluated for mechanical and dissolution properties. [2]

Due to their thin and flexible structure, ODFs provide an attractive alternative to conventional tablets, especially in emergency or travel situations where water may not be available. Additionally, their rapid disintegration enhances onset of action, making them ideal for drugs requiring immediate therapeutic effects. With increasing demand for patient-centric dosage forms, the development of ODFs continues to gain momentum in modern pharmaceutical research. Thus, ODFs offer a unique combination of convenience, safety, and efficiency, contributing to improved therapeutic outcomes. [3]

I. IDEAL CHARACTERISTICS FOR ORODISPERSIBLE FILM: [4,5]

ODF's should have the following qualities.

- ODFs should rapidly disintegrate and dissolve in the mouth within seconds, enabling quick onset of action without the need for water.
- They must have a pleasant taste, good mouth feel, and leave minimal or no residue to ensure patient comfort and compliance.
- The films should be mechanically strong, flexible, non-sticky, and able to withstand handling, packaging, and administration without damage.
- Uniform thickness, weight, and drug content are essential for accurate dosing and consistent therapeutic effect.
- ODFs must be stable under varying environmental conditions (e.g., temperature, humidity) and resistant to moisture absorption.
- They should be easy and cost-effective to manufacture using standard techniques like solvent casting or hot-melt extrusion.
- The drug release profile should suit the intended therapeutic use—immediate or modified—and ensure sufficient bioavailability.
- ODFs should be portable, easy to administer, and suitable for specific patient groups like children, elderly, and those with swallowing difficulties.

II. ADVANTAGES OF ORODISPERSIBLE FILM: [6]

- Fast onset of action – dissolves quickly in the mouth.
- No need for water – ideal for on-the-go use.
- Improved patient compliance – easy to take, especially for children and elderly.

- Better bioavailability – bypasses first-pass metabolism.
- Accurate dosing – uniform drug distribution.
- Pleasant taste – due to sweeteners and flavors.
- Reduced choking risk – safer than tablets or capsules.
- Non-invasive – alternative to injections.
- Portable and convenient – small, lightweight dosage form.
- Versatile formulation – suitable for various drugs and release profiles.
- Good stability – when properly packaged.
- Minimal residue – clean and comfortable after use.

III. Disadvantages of Orodispersible Film: [7,8]

- Limited drug dose – not suitable for high-dose drugs.
- Taste masking challenges – bitter drugs are hard to mask.
- Moisture sensitivity – requires special packaging.
- Fragile films – may tear or break during handling.
- Complex manufacturing – needs precise techniques.
- Drug stability issues – some APIs degrade in saliva.
- Limited to certain drugs – not suitable for all drug types.
- Possible mouth irritation – due to some excipients.
- Higher production cost – compared to conventional tablets.
- Need for patient education – on proper administration.

IV. Challenges in Development of Orodispersible Film: [9,10,11]

- Taste masking is essential as many APIs have a bitter taste, requiring suitable excipients and techniques to ensure palatability.
- Achieving fast disintegration without compromising film integrity or strength requires careful selection of disintegrants and formulation methods.
- Water-soluble drugs can form eutectic mixtures, causing drying issues and collapse, which may be controlled using crystallinity-inducing excipients like mannitol.
- ODFs are hygroscopic and prone to moisture absorption, demanding specialized, moisture-resistant packaging for stability.
- Mouthfeel must be optimized by minimizing particle size after disintegration and adding flavoring or cooling agents like menthol.
- Packaging design should be considered early to protect films from environmental hazards and maintain product quality.
- Stability is a major concern, as ODFs are sensitive to humidity and prone to degradation, necessitating robust formulation and packaging strategies.
- Uniform drug distribution is critical to ensure consistent dosing, especially when APIs vary in solubility or particle size.
- Excipients must be carefully selected for compatibility with the API and to maintain desired film properties like taste, disintegration, and texture.
- Regulatory compliance requires thorough documentation, testing, and adherence to GMP standards throughout formulation and production.

V. Ideal Candidate for Drug Delivery: [14]

- Low dose, less than 40mg, is required.
- Low molecular weight drugs are preferable.
- It should have a pleasant flavour.
- It should be reasonably stable in both saliva and water.
- It needs to be capable of penetrating the mucosal tissue of oral cavity.

VI. Composition of Orodispersible Film: [15,16]

- Drug (Active pharmaceutical Ingredients)
- Film forming agent
- Plasticizer
- Saliva stimulating agent
- Sweetening agent
- Flavoring agent
- Surfactant
- Colour, Filler

VII. Methods of Preparation of Orodispersible Film: [17,18,19]

- Solvent Casting Method
- Hot Melt Extrusion
- Semi Solid Casting Method
- Solid Dispersion
- Rolling Method

VIII. Evaluation Parameters of Orodispersible Film: [20,21]

- Physical Parameters
- Tensile strength
- Dryness / Tack test
- Young's modulus
- Percentage elongation
- Tear resistance
- Folding endurance
- Appearance

- Thickness
- Weight variation
- Contact angle
- Transparency
- Moisture content
- In-vivo test
- Surface pH
- Disintegration time
- Test for in-vitro dissolution
- Thermal analysis
- Assay / Uniformity of content

IX. TECHNOLOGIES FOR ORODISPERSIBLE FILM: [22,23,24]

- SOLULEAVES™
- WAFERTAB™
- FOAMBURST™
- XGEL™

METHODS AND MATERIAL:

I. LIST OF CHEMICALS USED

Sr. No.	Materials	Manufactures / Suppliers
1	Granisetron	Gifted by Alkem Lab, Mumbai.
2	Gelatin	Purchase from SD fine Chemicals.
3	Pullulan	Purchase from SD fine Chemicals.
4	Croscarmellose Sodium	S. D. Fine Chemicals
5	Aspartame	S. D. Fine Chemicals
6	Citric Acid	S. D. Fine Chemicals
7	Ethanol	S. D. Fine Chemicals

II. METHOD

1. Preformulation Studies: [23,24]
The melting point of Granisetron was determined using the capillary method. Solubility was assessed in various solvents, and λmax was identified via UV spectroscopy in phosphate buffer (pH 6.8). Drug-excipient compatibility was evaluated using FTIR spectroscopy.
2. Standard Curve: [25,26,27]
A standard calibration curve of Granisetron was prepared in phosphate buffer (pH 6.8) and absorbance was recorded at 303 nm using a UV spectrophotometer.
3. Formulation of Orodispersible Films: [28,29,30,31]
Granisetron-loaded orodispersible films were formulated by the solvent casting method using HPMC E5 or pullulan as film-forming agents. Other excipients included croscarmellose sodium (superdisintegrant), citric acid (saliva stimulator), glycerine (plasticizer), and aspartame (sweetener). The final solution was poured onto petri dishes and dried in a hot air oven at 60°C for 24 hours.

Calculation of drug quantity: -

The area of each film was 2 cm x 2 cm ($4cm^2$).

Diameter of petri dish = 11 cm.

Diagonal of square in circle is equal to diameter of circle,

So area of square was found to be,

Total Area of square = ½ $(diagonal)^2$

= ½ $(11\ cm)^2$

= 60.5 cm^2

No. of film per batch = 60.5 / 4 = 15.13 Approximately 15 film

Formula was developed for 15 films and each film contains 1 mg of Granisetron.

Composition of Orodispersible Film of Granisetron:

Ingredients (mg)	F1	F2	F3	F4	F5	F6
Granisetron	15	15	15	15	**15**	15
Gelatin	200	300	400	-	**-**	-
Pullulan	-	-	-	200	**300**	400
Croscarmellose Sodium	2	2	2	2	**2**	2
Aspartame	2	2	2	2	**2**	2
Glycerine (ml)	1	1	1	1	**1**	1
Citric Acid	10	10	10	10	**10**	10
Ethanol (ml)	5	5	5	5	**5**	5
Water (ml)	5	5	5	5	**5**	5
Orange	1	1	1	1	**1**	1

4. Evaluation of Films: [32,33,34]
The prepared films were evaluated for physical parameters such as thickness, weight uniformity, folding endurance, surface pH, drug content, disintegration time, and in-vitro drug release using standard protocols.

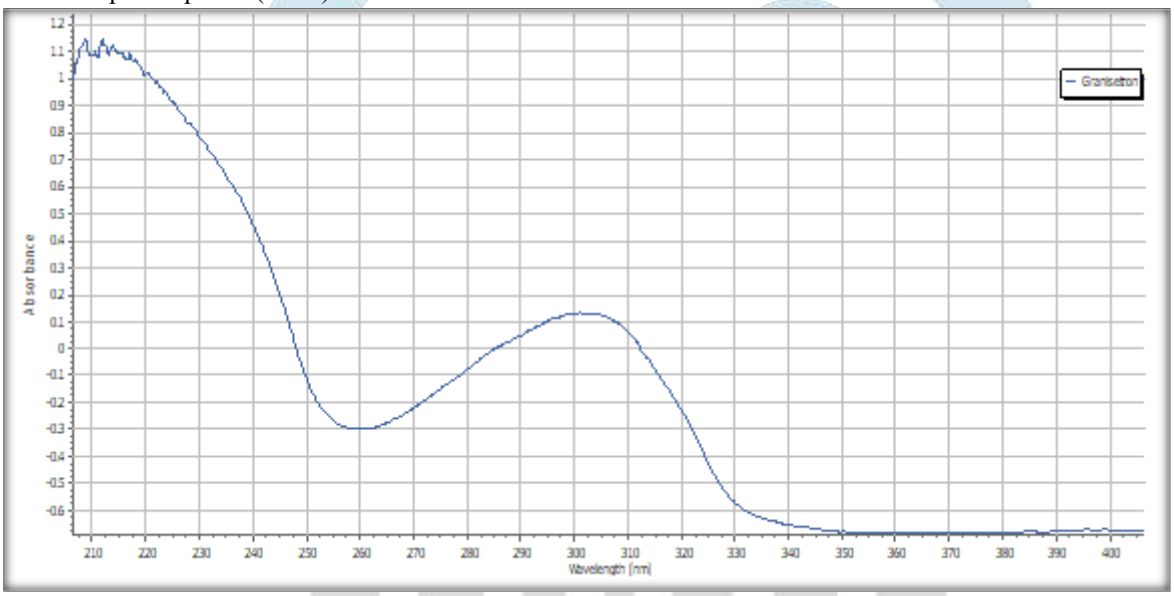
5. In-vitro Dissolution: [34,35,36]
   Dissolution studies were conducted using USP type II apparatus in phosphate buffer (pH 6.8) at 37±0.5°C. Samples were withdrawn at regular intervals and analyzed at 303 nm.
6. Stability Study: [37,38,39]
   The optimized formulation was subjected to accelerated stability testing as per ICH guidelines at 40°C and 75% RH for 3 months. Parameters such as appearance, folding endurance, disintegration time, drug content, and drug release were re-evaluated post-storage.

RESULT AND DISCUSSION:

I. PREFORMULATION STUDIES:

Granisetron exhibited a melting point between 290°C–292°C, confirming its purity. It was found to be soluble in water and slightly soluble in ethanol and methanol. The λmax was observed at 303 nm in phosphate buffer (pH 6.8), consistent with reported values.

UV Absorption Spectra (λmax) of Granisetron at 303nm:



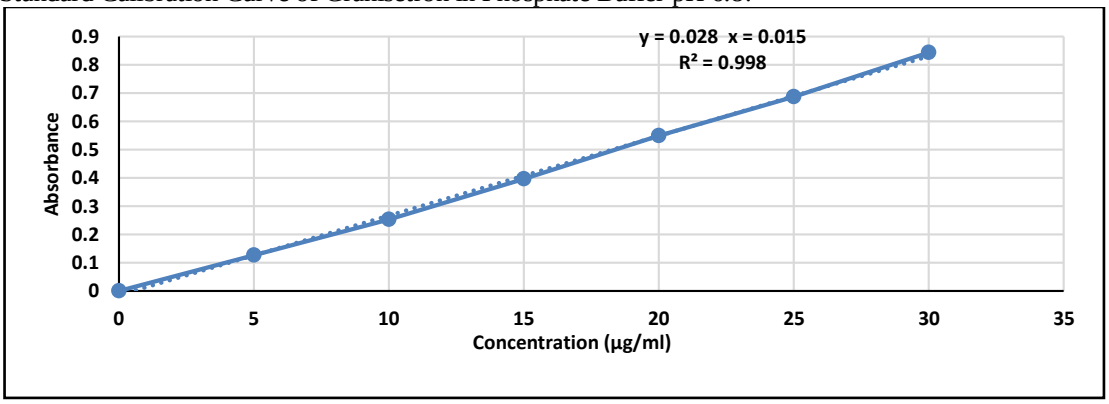
II. STANDARD CALIBRATION CURVE:

The calibration curve showed good linearity (R^2 = 0.998) across the concentration range of 5–30 µg/ml, confirming compliance with Beer-Lambert's law.

Standard Calibration Curve of Granisetron in PBS pH 6.8:

Sr. No.	Concentration (µg/ml)	Absorbance
1	5	0.126
2	10	0.253
3	15	0.396
4	20	0.548
5	25	0.687
6	30	0.843

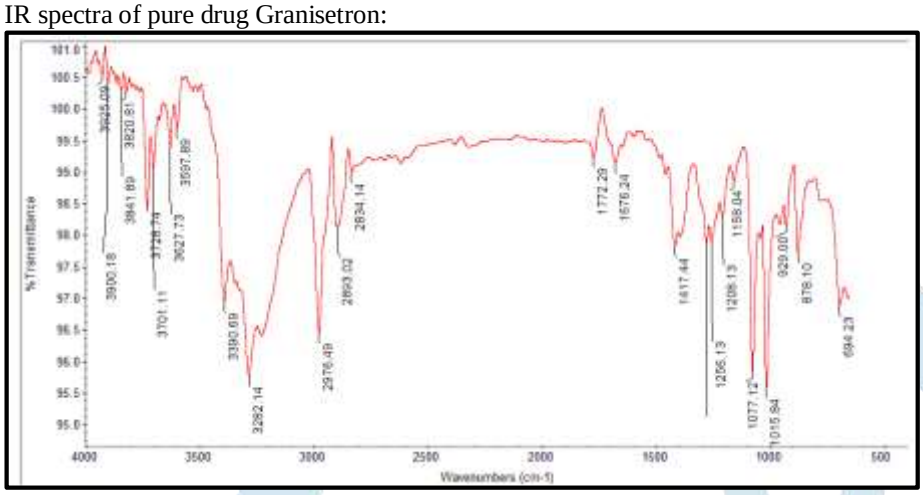
Standard Calibration Curve of Granisetron in Phosphate Buffer pH 6.8:



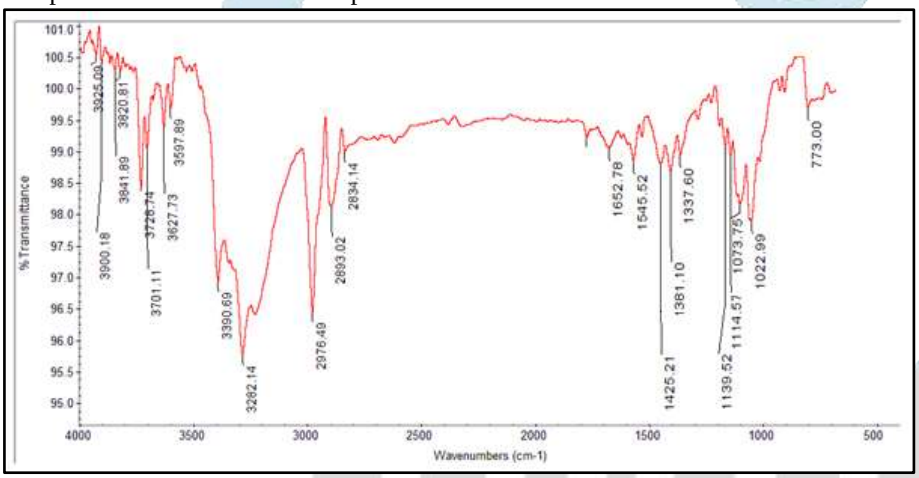
III. Compatibility Studies:

FTIR analysis revealed no significant interaction between Granisetron and the excipients, confirming their compatibility for formulation.

IR spectra of pure drug Granisetron:



IR Spectra of Granisetron Orodispersible Film:



IV. Evaluation of Orodispersible Films:

All six batches (F1–F6) showed acceptable physical properties. Pullulan-based films (F4–F6) demonstrated better mechanical strength and faster disintegration compared to gelatin-based films (F1–F3). Batch F5 (Pullulan 300 mg) had the best results with high folding endurance (188.61), rapid disintegration (28.12 sec), ideal surface pH (6.7), and uniform drug content (99.52%).

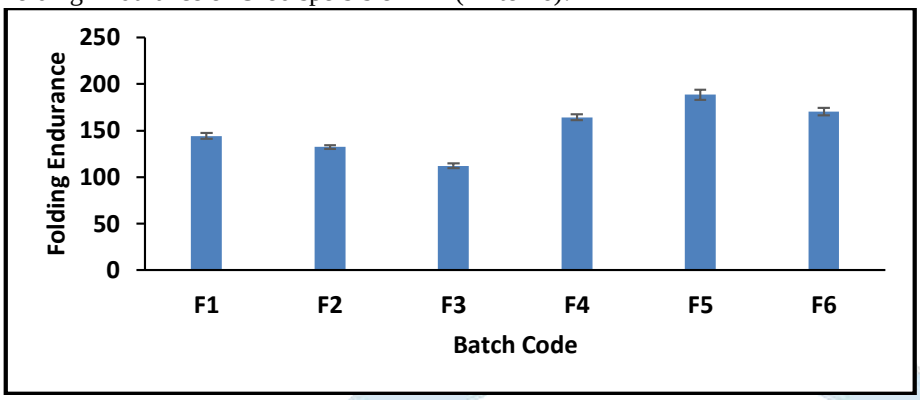
Evaluation of Appearance, Thickness and Weight variation of Granisetron Orodispersible Film (F1 to F6):

Batch No.	Appearance	Thickness (mm)	Weight Variation (mg)
F1	Translusant	0.12±0.02	15.12±0.07
F2	Translusant	0.14±0.03	22.10±0.03
F3	Translusant	0.17±0.03	28.14±0.02
F4	Translusant	0.12±0.02	15.02±0.02
F5	Translusant	0.13±0.03	21.06±0.03
F6	Translusant	0.16±0.03	27.14±0.03

Folding Endurance of Granisetron Orodispersible Film (F1 to F6):

Batch No.	Folding Endurance
F1	144.21±3.05
F2	132.34±2.21
F3	112.18±2.67
F4	164.34±3.26
F5	188.61±5.41
F6	170.28±4.06

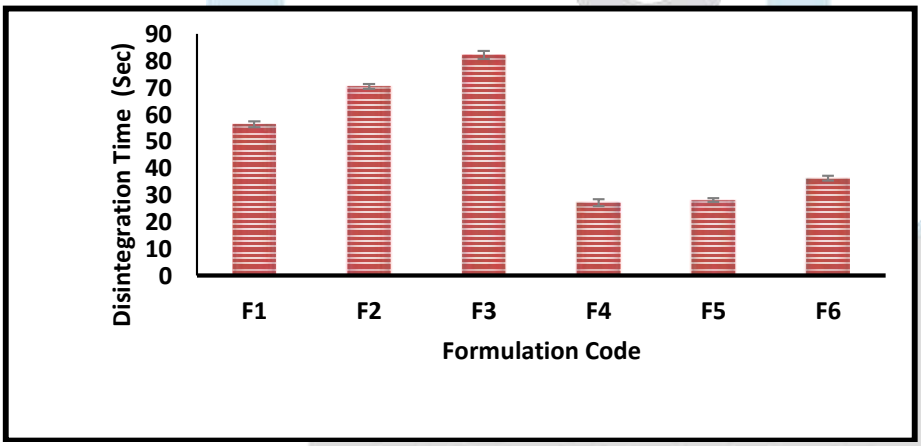
Folding Endurance of Orodispersible Film (F1 to F6):



In-Vitro Disintegration Time of Films Granisetron Orodispersible Film:

Batch No.	Disintegration Time (Sec)
F1	56.41±1.13
F2	70.47±0.89
F3	82.16±1.52
F4	27.18±1.22
F5	28.12±0.65
F6	36.26±0.91

Disintegration Time of Orodispersible Film (F1 to F6):



Evaluation Orodispersible film of Granisetron:

Batch No.	Appearance	Folding endurance*	DT (Sec)*	Thickness (mm)*	Weight Variation (mg)*	Drug content (%)*	Surface pH
F1	Translusant	144.21±3.05	56.41±1.13	0.12±0.02	15.12±0.07	98.20±1.43	6.6
F2	Translusant	132.34±2.21	70.47±0.89	0.14±0.03	22.10±0.03	98.53±1.20	6.7
F3	Translusant	112.18±2.67	82.16±1.52	0.17±0.03	28.14±0.02	96.56±1.30	6.6
F4	Translusant	164.34±3.26	27.18±1.22	0.12±0.02	15.02±0.02	97.52±0.85	6.7
F5	Translusant	188.61±5.41	28.12±0.65	0.13±0.03	21.06±0.03	99.52±1.14	6.7
F6	Translusant	170.28±4.06	36.26±0.91	0.16±0.03	27.14±0.03	97.30±1.10	6.7

All the values are expressed as mean ± SD, n=3.

V. IN-VITRO DISSOLUTION STUDY:

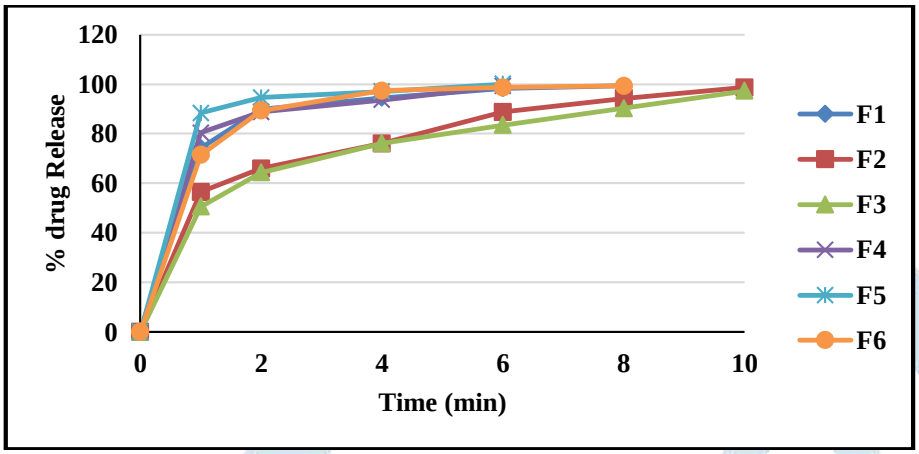
Pullulan films released the drug faster than gelatin films. F5 exhibited the most rapid and complete drug release—88.27% within 1 minute and 100.04% within 6 minutes—indicating optimal formulation characteristics for fast onset of action.

In-Vitro Drug Release Data of Granisetron Orodispersible Film:

Time (Min)	Cumulative percentage Drug Release					
	F1	**F2**	**F3**	**F4**	**F5**	**F6**
0	0	0	0	0	0	0
1	74.07±1.12	56.48±1.22	50.52±0.80	80.33±1.10	88.27±1.17	71.42±1.25
2	89.87±1.66	65.96±2.34	64.35±1.27	88.71±1.45	94.56±1.21	89.28±1.60
4	94.42±2.19	76.04±1.34	76.17±2.07	93.63±2,35	97.05±1.55	97.34±1.94
6	98.35±1.93	88.78±1.24	83.46±2.65	99.16±1.76	100.04±2.21	98.64±1.55
8	99.25±1.10	94.22±2.18	90.25±1.33	-	-	99.34±2.37
10	-	98.68±1.89	97.23±1.60	-	-	-

All the values are expressed as mean ± SD, (n=3).

Comparative Dissolution Profile of Batch F1to F6:



VI. Stability Study:

F5 was subjected to accelerated stability testing (40°C/75% RH) for 3 months. No significant changes were observed in drug content, disintegration time, or drug release, confirming the formulation's stability.

Stability Data of Optimized Formulation F5:

Formulation Code	Parameter	Before storage (0 month)	After storage (3 month)
F5	**Folding Endurance**	188.61±5.41	187±2.64
	Drug Content (%)	99.52±1.**14**	99.12±1.02
	Disintegration Time (sec)	28.12±0.65	29.18±0.35
	% Drug Release	100.04±2.21	99.72±1.33

Conclusions:

From the current study, it can be concluded that, Granisetron orodispersible films were successfully developed using gelatin and pullulan as film-forming agents. Pullulan-based films demonstrated superior performance compared to gelatin-based films in terms of folding endurance, rapid disintegration, and faster drug release. Among all formulations, Batch F5 (Pullulan 300 mg) emerged as the most promising, with Highest folding endurance (188.61 ± 5.41), Rapid disintegration time (28.12 ± 0.65 seconds), Near-complete drug release within 6 minutes (100.04%), High drug content uniformity (99.52% ± 1.14%), and Stable under accelerated conditions for 3 months.

Thus, F5 can be considered the optimized batch for fast-dissolving oral film formulation of Granisetron, offering a rapid onset of action, improved patient compliance, and ease of administration.

The study successfully demonstrates that Pullulan is an excellent film-forming polymer for the design of orodispersible films intended for immediate release therapeutic applications.

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