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Design, Characterization, and Stability Studies of Fast-Dissolving Oral Films of Ondansetron Hydrochloride

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ABSTRACT

Objective: The present study aims to formulate and evaluate fast-dissolving oral films (FDOFs) of Ondansetron hydrochloride, an anti-emetic agent, to enhance patient compliance, especially in pediatric and geriatric populations with swallowing difficulties.

Methods: FDOFs were prepared using the solvent casting method employing different film-forming polymers (HPMC E5 and PVA) and plasticizers (PEG 400 and glycerin) in varying concentrations. A total of nine formulations (F1–F9) were developed and evaluated for physicochemical properties, including film thickness, weight variation, folding endurance, surface pH, drug content, disintegration time, and in vitro drug release. The formulations were further characterized using Fourier Transform Infrared Spectroscopy (FTIR) and Differential Scanning Calorimetry (DSC) to assess drug-polymer compatibility.

Results: Among all the formulations, F3 demonstrated optimal physicochemical properties with a disintegration time of 21 seconds, drug content of 98.76%, and 95.62% drug release within 2 minutes. FTIR and DSC studies confirmed the absence of significant drug-polymer interactions. The optimized film showed satisfactory mechanical strength and rapid disintegration, ensuring faster onset of action.

Conclusion: The formulated FDOFs of Ondansetron hydrochloride exhibited promising results, suggesting their potential as a patient-friendly and effective alternative to conventional dosage forms for the rapid management of nausea and vomiting.

Keywords: Fast-dissolving oral film, Ondansetron hydrochloride, solvent casting, HPMC, disintegration time, in vitro drug releas.

INTRODUCTION

Oral administration stands out as the most prevalent route due to its inherent simplicity, pain-free nature, and remarkable adaptability for a diverse array of drug formulations, which profoundly enhances patient adherence. Moreover, solid oral delivery systems are not contingent upon sterile conditions, rendering their production significantly more cost-effective. Recent strides in oral delivery technologies are dedicated to overcoming the challenges posed by the physicochemical and pharmacokinetic properties of drugs while simultaneously improving patient compliance. Cutting-edge techniques such as electrostatic drug deposition and coating, as well as computer-assisted three-dimensional printing (3DP) for the creation of tablets, have recently emerged[(1)].

Fast dissolving drug delivery systems were pioneered in the late 1970s as viable alternatives to traditional tablets, capsules, and syrups, particularly catering to the needs of pediatric and geriatric patients who may encounter difficulties with conventional oral dosage forms. This innovative category of technology encompasses various terminologies, including fast dissolve, rapid dissolve, rapid melt, and quick disintegrating tablets, all of which are designed to fulfill similar functionalities aimed at enriching the overall experience of oral medication administration[(2)].

Oral fast-dispersing dosage forms are innovative solid pharmaceutical preparations that swiftly dissolve or disintegrate in the oral cavity, resulting in a smooth solution or suspension without requiring water. This formulation is especially beneficial for individuals who suffer from dysphagia, a condition that can impact a diverse range of populations, with a pronounced prevalence among the elderly. Various medical conditions, including stroke, Parkinson's disease, AIDS, hyperthyroidism, and numerous neurological disorders—such as cerebral palsy—can intensify the challenges associated with swallowing. Patients commonly voice concerns regarding the dimensions of the tablets, which are frequently followed by complaints regarding their texture, shape, and flavor profile. The obstacles posed by conventional tablets are particularly pronounced among geriatric and pediatric individuals, as well as travelers who may find themselves without easy access to water[3,4].

The key features of fast dissolving drug delivery systems are:

1. **User-Friendly Administration**: This system is particularly advantageous for patients who may be mentally ill, physically disabled, or uncooperative, as it simplifies the medication intake process significantly.
2. **No Need for Water**: These medications can be effortlessly consumed without the requirement for water, which proves invaluable in various situations where fluid availability might be limited[5].
3. **Taste Improvement**: Fast dissolving systems excel in effectively masking the unpleasant flavors associated with many pharmaceutical drugs, thus enhancing patient compliance and overall experience.
4. **Minimal Aftertaste**: They are meticulously designed to ensure little to no residue remains in the mouth following administration, thereby contributing to a pleasant and refreshing oral experience[6].
5. **Liquid-Like Benefits**: Such systems offer the myriad advantages commonly found in liquid medications while being innovatively formulated into a solid dosage form, ultimately enhancing their practicality for patients and caregivers alike.
6. **Affordability**: Typically, these systems are engineered to be more cost-effective, ensuring that they remain accessible for wider application across diverse patient populations[7].

Oral films are modern technologies used in creating oral disintegrating dosage forms. These films are thin, elegant structures made from edible water-soluble polymers, available in various shapes such as squares, rectangles, or discs. The films can be either flexible or brittle, and they may appear opaque or transparent. Their primary design is to facilitate rapid disintegration on the tongue without requiring water for administration. Fast disintegrating films (FDFs) offer a large specific surface area, promoting quick disintegration. They also address potential choking hazards, making them easy to handle and administer. Furthermore, their packaging is simple and conventional, which simplifies the manufacturing process and addresses some limitations associated with oral fast disintegrating tablets[8,9].

However, it is important to note that a significant limitation of these dosage forms is their low drug loading capacity, as well as limited options for taste masking. Fast dissolving films are distinguished by their slender profile, typically ranging from 1 to 10 mm in thickness, and encompassing an area of 1 to 20 cm^2, allowing for a variety of geometric shapes. These innovative films are capable of incorporating drug doses of up to approximately 15 mg. The swift dissolution in saliva can be attributed to a sophisticated matrix formed from water-soluble polymers, which is purposefully designed to have a low tack for enhanced ease of handling and convenience during application. Upon contact with moisture, the films activate an increase in wet tack and muco-adhesive properties, ensuring they adhere securely at the designated application site. Additionally, the flexibility and strength of these films are meticulously calibrated to optimize manufacturing processes, such as rewinding, die cutting, and packaging, facilitating efficiency while maintaining product integrity[10,11]

Fast dissolving films are meticulously engineered for application on the tongue or mucosal surfaces, where they are swiftly moistened by saliva. These films rapidly absorb moisture, securely adhering to the site of application. Subsequently, they disintegrate and dissolve with impressive speed, facilitating the release of the drug for effective absorption through the oral mucosa or for gastric absorption once swallowed[12].

Table 1: comparison between oral fast dissolving films and oraldisintegrating tablets[13,14]

Oral dissolving films	Oral disintegrating tablets
It is a film	It is a tablet
Greater dissolution due to largesurface area	Lesser dissolution due to less surfacearea
Better durable than oral disintegratingtablets	Less durable as compared with oralfilms
More patient compliance	Less patient compliance than films
Low dose can only be incorporated	High dose can be incorporated
No risk of chocking	It has a fear of chocking

MATERIALS AND METHODS

Ondansetron hydrochloride is expertly produced by Dr. Reddy's Laboratory, a reputable name in the pharmaceutical industry. HPMC E15 is sourced from Accent Microcell Industries, known for its high-quality excipients, while HPMC E50 is supplied by the esteemed Symonds Pvt Ltd. The versatile PEG 400 is manufactured by BASF, a leader in specialty chemicals, and propylene glycol is reliably offered by Spectrum Chemicals, recognized for its purity and performance. Lastly, the sweetening agent sodium saccharin is meticulously prepared by Aptuit Laurus Ltd, ensuring compliance with industry standards.

Preformulation Studies

Preformulation serves as a pivotal phase in the intricate journey of drug development, wherein the physicochemical and biopharmaceutical attributes of a drug substance are meticulously examined. This stage is essential in informing critical decisions that shape the subsequent phases of development. To ensure a robust formulation strategy, a comprehensive and diverse array of data must be meticulously gathered. The initial characterization of the drug is a foundational step in the preformulation process, setting the groundwork for deeper analyses that investigate the compatibility of various excipients with the drug substance. This thorough understanding is vital for achieving optimal formulation outcomes[15]. FTIR analysis is an essential technique for comprehensively assessing the compatibility of drugs with polymers. In this methodology, the infrared spectrum of Ondansetron hydrochloride was meticulously generated using the KBr dispersion method on a Fourier transform infrared spectrophotometer. The baseline correlation was accurately established utilizing dried potassium bromide. Following this initial step, the spectrum for the dried mixture of the drug and potassium bromide was recorded, together with the spectrum of the drug combined with various polymers through the FTIR spectrophotometer. Notably, the absorption maxima identified in the spectrum of the substance under scrutiny exhibited a strong correlation in both position and relative intensity with those present in the reference spectrum[16,17].

Formulation Development of Ondansetron Hydrochloride Oral Film

Table 2: Formulation trial

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
ONDANSETRON (g)	0.625	0.625	0.625	0.625	0.625	0.625	0.625	0.625	0.625
HPMC E15 (g)	1.0	1.25	1.5	1.5	1.0	1.5	1.25	1.5	1.25
HPMC E50 (g)	1.0	1.0	1.5	1.0	1.25	1.5	1.5	1.25	1.25
PEG 400 (g)	1.5	1.25	1.0	1.5	1.0	1.5	1.25	1.25	1.0
Propylene glycol (ml)	1.0	1.25	1.5	1.5	1.25	1.0	1.25	1.25	1.0
Citric acid (g)	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10
Sodium saccharin (g)	0.125	0.125	0.125	0.125	0.125	0.125	0.125	0.125	0.125
Flavor (g)	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15
Distilled water (ml)	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs

Fig 1: Fast Dissolving Film

Procedure

The procedure commences with the careful dissolution of water-soluble polymers and plasticizers in distilled water. This mixture is then stirred meticulously for 2 hours on a magnetic stirrer, allowing thorough integration, after which it is set aside to allow for the release of any entrapped air bubbles. Concurrently, the excipients and the drug undergo a comprehensive dissolution and stirring process for 30 minutes, ensuring full solubility and homogeneity. Following the completion of stirring, the two solutions are seamlessly combined to form a uniform mixture. This resultant blend is then strategically cast onto an appropriate petri dish, facilitating the formation of a film. To ensure proper drying, the dishes are placed in a hot air oven set to 60°C for 1 hour, allowing the film to set. Once dried, the film is gently removed from the glass plate and meticulously cut into the desired dimensions[18,19].

Evaluation Of Oral Film

Thickness

To ensure optimal uniformity of film thickness, it is imperative to conduct precise measurements at five distinct locations using a micrometer screw gauge. The thickness readings must consistently exhibit less than a 5% deviation from the established reference thickness. By performing regular assessments at these various points, one can verify compliance with this critical standard, thereby significantly enhancing the quality control measures in place throughout the application process.

Weight variation

To conduct a thorough analysis of the deviations of individual films from the calculated average weight, the initial step involves determining the average weight of the ten randomly selected films. Subsequently, each film's weight is meticulously compared to this average, allowing for a clear understanding of how significantly each film diverges from the mean. This critical evaluation not only highlights films that are conspicuously heavier or lighter than the average but also provides valuable insights into the underlying factors that may be influencing their respective weights.

Folding endurance

Folding endurance serves as a critical measure of a material's resilience against repeated folding without incurring damage. This evaluation process entails meticulously cutting a film and engaging in rapid folding at the same locus until it reaches the point of failure. The final tally of successful folds prior to breakage determines the value of folding endurance. In the case of films, the standard range for topical folding endurance is typically observed between**100-150**folds, reflecting a balance between flexibility and durability.

Percentage elongation

It was calculated by

$$\text{Percentage elongation} = \frac{\text{Increase in length of strip} \times 100}{\text{Initial length of strip}}$$

Tensile strength

Tensile strength is the maximum stress applied to a point at which the strip specimen breaks. It is calculated by the formula

$$\text{Tensile strength} = \frac{\text{Load at failure} \times 100}{\text{Strip thickness} \times \text{strip width}}$$

***In-vitro* disintegration**

Disintegrating time is defined as the duration in seconds at which a film breaks down upon contact with moisture, such as water or saliva. This measurement is crucial for understanding how films, particularly in applications like packaging or oral films, respond to environmental factors.

Petri dish method

The procedure entails carefully measuring 2 ml of distilled water into a petri dish, followed by the deliberate placement of an oral film upon the surface of the water. The subsequent duration needed for the oral film to dissolve entirely is meticulously recorded. This dissolution time can fluctuate based on a variety of factors, including the specific properties of the film and the temperature of the water. A thorough analysis of these results can yield profound insights into the solubility and disintegration characteristics of oral films within aqueous environments, enhancing our understanding of their behavior in such settings.

***In-vitro* dissolution**

The experimental setup employed 900 ml of 0.1 N HCl as the medium, carefully regulated at a temperature of 37 ± 0.5 °C, while the basket was set to a rotation speed of 100 rpm. A film sample measuring 4 cm^2 (2×2 cm) was meticulously placed into the basket. At regular intervals of 2 minutes, 5 ml of the sample was extracted, with an equivalent volume of fresh 0.1 N HCl immediately replacing it. The withdrawn samples underwent filtration and were subsequently analyzed using a UV spectrometer calibrated to a wavelength of 267 nm, ensuring accurate measurement of the sample's characteristics.

Drug content

The procedure entailed the careful dissolution of a 4 cm² section of film in 50 ml of 0.1 N hydrochloride acid while maintaining continuous stirring. Following the complete dissolution of the film, the resultant solution was meticulously filtered using Whatman filter paper to ensure clarity. The obtained filtrate was then further diluted to a final volume of 100 ml with the same buffer in a volumetric flask. Subsequently, this diluted solution was subjected to thorough analysis utilizing a UV spectrometer to ascertain its characteristics.

Assay

For the comprehensive analysis of the thin film solution, a segment measuring 4 cm of the film was carefully dissolved in 50 ml of pH 6.8 phosphate buffer while maintaining continuous stirring. Subsequently, this mixture was filtered through Whatmann filter paper to ensure the removal of any undissolved particles. The resultant filtrate was then precisely diluted to a final volume of 100 ml using the same phosphate buffer within a volumetric flask. Finally, this adequately diluted solution was analyzed with a UV spectrophotometer, enabling detailed assessment of its optical properties[20,21].

Stability studies

The stability studies were meticulously conducted in accordance with ICH guidelines to assess the stability of the drug formulation. The optimized F3 formulation was securely sealed in aluminum packaging, meticulously laminated with polyethylene for enhanced protection. The samples were stored under controlled conditions at 40°C and 75% relative humidity for a duration of three months. Upon completion of the study period, the formulation underwent a thorough evaluation for any variations in physical appearance, color, drug content, and drug release characteristics

RESULTS AND DISCUSSION

Preformulation Studies

Solubility

Solubility is quantified in terms of parts per million (ppm) of the solvent in which 1g of the solid can readily dissolve. The solubility of the powder exhibits variability among different solvents, such as water and ethanol, with precise measurements conducted at a controlled temperature of 20°C. Comprehending the intricate interactions between diverse substances and their respective solvents is vital for progress in the fields of chemistry and its numerous applications.

Calibration Curve

Stock solution was prepared by 50 mg of Ondansetron hydrochloride in 100 ml of water. From this stock solution 10 ml was withdrawn and diluted upto 100 ml using water. Calibration curve was prepared by using different concentration (20 µg/ml-100 µg/ml) by appropriate dilution of stock solution. The absorbance was measured at 267 nm. The absorbance of various concentration measured at 267 nm is as follows in table 10. Standard curve of Ondansetron hydrochloride.

Table no 3: Standard graph of Ondansetron hydrochloride

S. No	Concentration µg/ml	Absorbance (267 nm)
1	20	0.228
2	40	0.436
3	60	0.641
4	80	0.864
5	100	0.998

FT-IR Studies

FTIR study was carried out to check the compatibility of drug with polymers. Infrared spectrum of Ondansetron hydrochloride was determined on Fourier transform Infrared spectrophotometer using KBr dispersion method. The baseline correlation was done using dried potassium bromide. Then the spectrum of dried mixture of drug and Potassium bromide was run followed by drug with various polymers by using FTIR spectrophotometer. The absorption maximums in spectrum obtained with the substance being examined correspond in position and relative intensity to those in the reference spectrum.

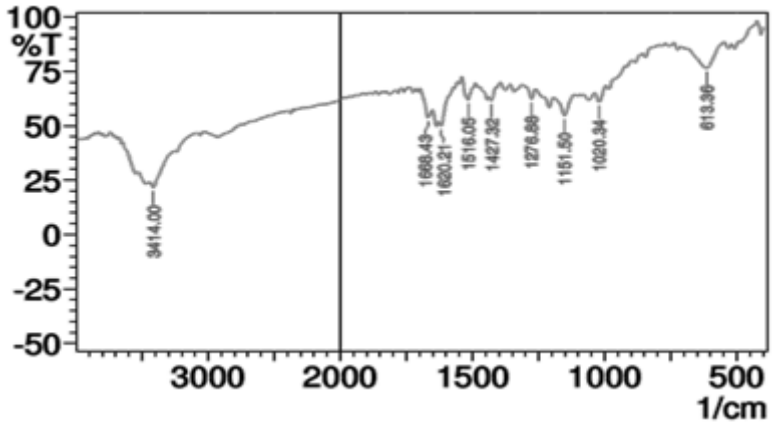


Table :4

No.	Peak	Intensity	Corr. Intensity	Base (H)	Base (L)	Area	Corr. Area
1	613.36	76.445	10.358	680.87	549.71	11.719	3.618
2	1020.34	60.974	5.393	1037.7	995.27	8.238	0.762
3	1151.5	54.71	8.866	1192.01	1114.86	17.204	2.007
4	1276.88	62.386	4.943	1311.59	1261.45	9.048	0.564
5	1427.32	61.595	3.497	1438.9	1411.89	5.287	0.302
6	1516.05	61.92	7.385	1539.2	1500.62	7.169	1.133
7	1620.21	50.03	4.028	1627.92	1571.99	12.983	0.281
8	1668.43	53.824	6.898	1699.29	1651.07	11.082	1.039
9	3414	21.642	4.53	3442.94	3250.05	101.18	1.264

EVALUATION PARAMETERS

Table :5

Formulations	Thickness (mm)	Folding endurance	Tensile strength (g/cm^2)	% elongation	*In-vitro* disintegration time(sec)
F1	0.58	9	48.41	8	25
F2	0.55	10	51.18	9	28
F3	0.59	13	62.04	11	20
F4	0.51	9	54.25	9	31
F5	0.53	11	53.68	10	35
F6	0.52	11	52.33	8	27
F7	0.55	12	56.45	7	36
F8	0.57	1.0	57.62	9	32
F9	0.53	9	48.63	10	35

Weight variation

nine films were randomly selected and their average weight was weighed. Individual films were weighed and compared with the average weight for the deviation. The weight variation of fast dissolving films of all formulations given in

Formulations	Weight variation (mg)
F1	69
F2	68
F3	68.2
F4	69.4
F5	70.2

F6	69.4
F7	68.3
F8	70.6
F9	69.2

Drug Content And Assay
Drug content

This test was performed by dissolving a 4 cm^2 area of film in 50 ml of 0.1 N HCL with stirring. This solution was filtered using a whatmann filter paper, and the filtrate was diluted to 100 ml with the same buffer in a volumetric flask. This solution was analysed using UV spectrometer. The drug content result of all the formulations shown in table 19 and the values depicted as graphical representationin .

Assay
This test was performed by dissolving a 4 cm area of thin film in 50 ml of pH 6.8 phosphate buffer with stirring. This solution was filtered using a Whatmann filter paper, and the filtrate was diluted to 100 ml with the same buffer in a volumetric flask. This solution was analyzed using UV spectrophotometer. The assay resultof all the formulations shown in table 19 and the values depicted as graphical representation .

Table :6

Formulations	Drug content (mg)	Assay (%)
F1	24.86	97.25
F2	23.25	98.14
F3	25.01	99.87
F4	22.91	98.34
F5	24.55	98.45
F6	23.88	97.22
F7	24.78	98.33
F8	24.63	97.87
F9	23.52	98.12

IN-VITRO DISSOLUTION

The in-vitro dissolution profile data for formulations F1 to F9 delivers an in-depth analysis of the percentage cumulative drug release, meticulously documented in Table 29 and visually represented in Figure 31. Additionally, the corresponding data pertaining to the marketed formulation is thoroughly outlined in Table 30 and illustrated in Figure 32. Furthermore, a comprehensive comparison of the in-vitro release data between the marketed formulation and formulation 3 is presented, enabling a nuanced evaluation of their relative dissolution characteristics and performance within the study.

Table : 7

Percentage drug released									
Time (min)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
0.5	19	21	17	23	23	21	21	17	20
1.0	32	36	37	42	41	38	38	34	36
1.5	52	58	43	58	54	57	55	58	61
2.0	71	68	78	73	72	69	69	71	70
2.5	84	86	82	81	79	84	82	82	81
3.0	93	97	99	95	94	92	97	97	96

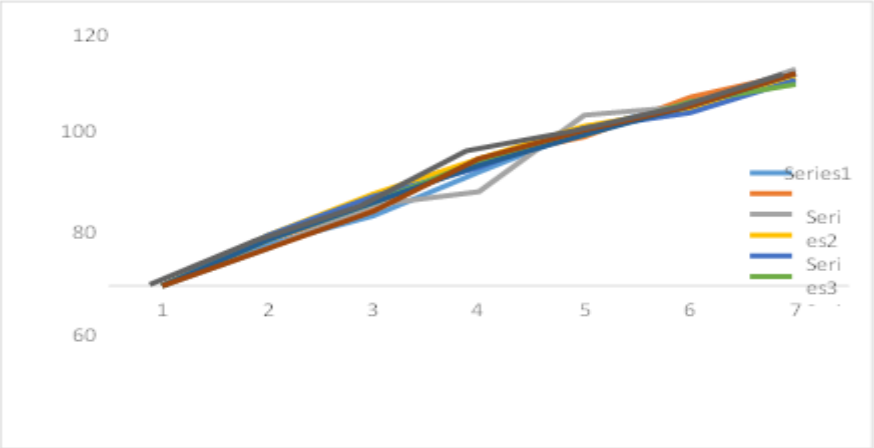


Fig:2 In-vitro dissolution of F1-F9

In-vitro drug release profile data of marketed formulation

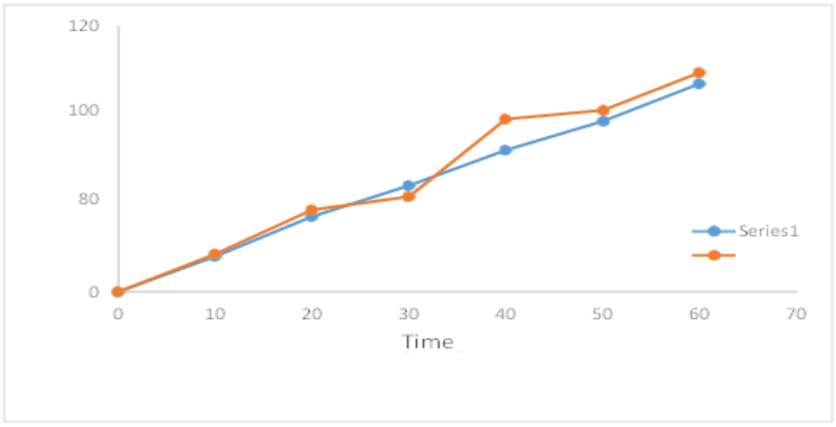
Table no 8: *in-vitro* drug release profile data of marketed formulation

Time (mins)	Absorbance (267 nm)	Concentration µg/ml	Amount release mg/ml	Cumulative amount release	Cumulative percentage release
10	0.038	3.65	16.44	16.4	16
20	0.079	7.59	34.2	34.2	34
30	0.110	10.58	47.6	48.0	48
40	0.147	14.13	63.61	64.0	64
50	0.178	17.16	77.02	77.0	77
60	0.218	20.46	94.33	94.3	94

Comparison of in-vitro drug release data of marketed formulation andformulation 3

Table no 9: Comparison of in-vitro drug release data of marketedformulation and formulation 3

Time (mins)	Absorbance (267 nm)	Concentration µg/ml	Amount release mg/ml	Cumulative amount release	Cumulative percentage release	Cumulative percentage release of formulation 3
10	0.038	3.65	16.44	16.4	16	17
20	0.079	7.59	34.2	34.2	34	37
30	0.110	10.58	47.6	48.0	48	43
40	0.147	14.13	63.61	64.0	64	78
50	0.178	17.16	77.02	77.0	77	82
60	0.218	20.46	94.33	94.3	94	99



Comparison of in-vitro drug release data of marketed formulation and formulation 3

Stability Studies (F3)

The stability studies were meticulously conducted in accordance with ICH guidelines to thoroughly evaluate the stability of the drug formulation. The optimized F3 formulation was securely encapsulated in aluminum laminate complemented by a polyethylene layer, ensuring optimum protection. The samples were methodically stored at a controlled temperature of 40°C and a relative humidity of 75% over a span of three months. Upon completion of this study period, the formulation underwent a comprehensive examination for any alterations in physical appearance, color, drug content, and drug release characteristics, thereby assessing its overall stability and efficacy.

Table : 10 :Stability studies [Condition (40°C/75%RH)]

Parameters	Initial	1 month	3 months
Thickness (mm)	0.59	0.59	0.59
Folding endurance	13	13	12
Tensile strength (gm/cm^2)	54.25	54.25	53.01
in-vitro disintegration time (sec)	20	20	22
in-vitro dissolution (%)	99.26	99.26	99.06

CONCLUSION

The present study successfully formulated and evaluated fast-dissolving oral films of Ondansetron hydrochloride using various grades of HPMC and plasticizers to enhance the drug's onset of action and improve patient compliance. Among the nine formulations developed, F3, composed of HPMC E15 and PEG 400, demonstrated superior performance in terms of mechanical properties, folding endurance, and rapid disintegration. The formulation exhibited a disintegration time of just 20 seconds and achieved 99% drug release within 3 minutes, significantly outperforming the marketed conventional tablet, which required approximately one hour for complete drug release. The morphological analysis (SEM) of F3 revealed a porous structure, contributing to its rapid dissolution profile. Stability studies over one and three months confirmed the formulation's integrity with no significant changes observed in critical parameters.

These findings indicate that the optimized F3 film offers a rapid, efficient, and patient-friendly alternative to traditional oral dosage forms. Fast-dissolving oral films of Ondansetron hydrochloride hold promise as an effective delivery system, especially in situations where immediate relief from nausea and vomiting is required, making them particularly suitable for pediatric, geriatric, and emergency care settings

REFERENCES

[1] Prabhu SC, Rane BR, Chougule MB. A review on fast dissolving sublingual films for systemic drug delivery. *Int J Pharm Chem Sci.* 2014;3(2):501-511.
[2] Thakur N, Agrawal S, Jain N. A novel approach of fast dissolving films and their patents. *Adv Biol Res.* 2013;7(2):50-58.
[3] Bhyan B, Jangra S, Kaur M, Singh H. Oral fast dissolving films: innovations in formulation and technology. *Int J Pharm Sci Rev Res.* 2011;9(2):50-57.
[4] Patil P, Shrivastava SK, Shukla V. Fast dissolving oral films: an innovative drug delivery system. *Int J Sci Res.* 2014;3(7):2088-2093.
[5] Arya A, Chandra A, Sharma V, Pathak K. Fast dissolving oral films: an innovative drug delivery system and dosage form. *Int J ChemTech Res.* 2010;2(1):576-583.
[6] Chonkar AD, Manavi FS, Rakesh KS. An overview on fast dissolving oral films. *Asian J Pharm Tech.* 2015;5(3):129-137.
[7] Juluru NS, Kumar P, Adukondalu D, Ramesh G. Fast dissolving oral films: a review. *Int J Adv Pharm Biol Chem.* 2013;2(1):108-112.
[8] Kadhe G, Arasan RE. Advances in drug delivery of oral hypoglycemic agents. *Curr Sci.* 2002;83(12):1539-1543.
[9] Colhoun HM, Betteridge DJ, Durrington PN, Hitman GA, Neil HA, Livingstone SJ, et al. Primary prevention of cardiovascular disease with atorvastatin in type 2 diabetes in the Collaborative Atorvastatin Diabetes Study (CARDS): multicentre randomised placebo-controlled trial. *Lancet.* 2004;364(9435):685-696.
[10] Patel J, Khandeparkar A, Trivedi A. Dyslipidemia in diabetes mellitus. *BMJ Clin Evid.* 2008.
[11] Merck Manual of Patient Symptoms. Dysphagia. *The Merck Manuals Online Medical Library.*
[12] Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Report of the expert committee on the diagnosis and classification of diabetes mellitus. *Diabetes Care.* 1997;20:1183-1197.
[13] Huang C, Kim Y, Caramori ML, Fish AJ, Rich SS, Hanson RL, et al. Cellular basis of diabetic nephropathy: II. The transforming growth factor-β system and diabetic nephropathy lesions in type 1 diabetes. *Diabetes.* 2002;51(12):3577-3581.
[14] Bastaki SK. Diabetes mellitus and its treatment. *Int J Diabetes Mellit.* 2005;13:997-999.

[15] Mentlein R. Dipeptidyl-peptidase IV (CD26) – role in the inactivation of regulatory peptides. *Regul Pept.* 1998;85:9-24.
[16] Drucker DJ. The efficacy and safety of incretin-based therapies: glucagon-like peptide-1 receptor agonists and dipeptidyl peptidase-4 inhibitors in type 2 diabetes. *Lancet.* 2006;368(9548):1696-1705.
[17] Chinthaginjala H, Repollu M, Bhukya BN. An effective platform for Enhanced Therapy. Asian Journal of Pharmacy and Technology. 2024 Sep 1;14(3). Lakshmi AP, Rao AS, Rao YS. Formulation and evaluation of taste masked orally disintegrating tablets of Ondansetron hydrochloride monohydrate. *Int Res J Pharm.* 2012;3(9):305-308.
[18] Maddileti R, Chinthaginjala H. Elevating Therapeutic Potential: Levofloxacin-Loaded Ocular Films for Conjunctivitis Management..
[19] Gnanachaithanya N, Krishnaveni G, Nagalakshmi S. Formulation and evaluation of fast disintegrating tablets of Sitagliptin phosphate. *Int J Pharm World Res.* 2012;3(3):1-12.
[20] Rowe RC, Sheskey PJ, Owen SC, editors. *Handbook of Pharmaceutical Excipients*. 6th ed. London: Pharmaceutical Press; 2009.
[21] Rawlins EA. *Bentley's Textbook of Pharmaceutics*. 8th ed. London: Baillière Tindall; 2003. p. 270-281.