RESEARCH PAPER

Formulation and Evaluation of Taste-Masked Ondansetron Orodispersible Films Using Natural Cyclodextrin Complexes and Honey as a Plasticizer

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ABSTRACT

The present study aimed at the formulation and evaluation of Ondansetron Orodispersible Films (ODFs) using natural excipients to produce a fast dissolving and patient friendly drug delivery system. The films were made using the solvent casting method with pullulan, pectin, honey and β-cyclodextrin. FTIR studies confirmed that the drug is compatible with selected excipients. All formulations (F1-F13) were evaluated for equivocal parameters like thickness, folding endurance, tensile strength, surface pH, drug content, disintegration time and in vitro drug release. All the formulations displayed acceptable pharmaceutical characteristics, exhibiting rapid disintegration and drug release. The surface pH was between 6.3 and 6.8 indicating non-irritant to oral mucosa. The optimized formulation was F11 which showed 99.7% drug release in 15 min, also it was found to have good flexibility, mechanical strength and uniform drug content. Kinetic studies for release portrayed first-order and Higuchi's drug release controlled by the diffusion mechanism with an anomalous non-Fickian diffusion mechanism. Ondansetron ODFs are likely to be better alternatives than conventional oral dosage forms with enhanced patient compliance and rapid therapeutic action. The study concluded that Ondansetron ODFs can serve as an effective alternative to conventional oral dosage forms by providing rapid drug release, improved patient compliance, and ease of administration, especially for pediatric, geriatric, and dysphagic patients.

Keywords: Orodispersible Films, Honey, fast release, film, Oral drug delivery.

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Introduction

Because of their ease of administration, high patient acceptability, low cost and low manufacturing cost, oral drug delivery systems are one of the most widely used routes of drug delivery systems(Aulton & Taylor, 2013). Conventional oral dosage forms are often tablets and capsules. Although they are more accepted, these dosage forms may pose difficulties in swallowing for those pediatric, geriatric, bedridden, and dysphagic patients(Arya et al., n.d.). Furthermore, if patients are suffering from nausea and vomiting, they often experience discomfort while taking conventional oral drugs, which may lead to poor compliance and delayed therapeutic action. Researchers have started making use of the Orodispersible Films for drug delivery to overcome these limitations(Shah et al., 2022). ODFs are thin and flexible polymeric films, which get rapidly disintegrated in the oral cavity without requiring water and thus provide rapid drug release and better patient compliance(Dixit & Puthli, 2009). The disintegration of ODFs is very rapid and their large surface area increases dissolution and onset of action and patient acceptability(Ferlak et al., 2023). Ondansetron Hydrochloride is a selective antagonis of the 5-HT3 receptors. It is used for the prevention and treatment of vomiting and nausea in cancer therapy, radio therapy, gastroenteritis, postoperative, and others(Ye et al., 2001). Even though Ondansetron may be used in a conventional tablet and injectable dosage form, these formulations may not be appropriate for patients with severe nausea, difficulty in swallowing and reduced access to water. All in all, Orodispersible Films of Ondansetron can be a potential alternative to existing dosage forms which disintegrates rapidly, is easy to administer and improves therapeutic effect(Kohler & Goldspiel, 1991). Natural excipients are increasingly analyzed for the advancement of pharmaceutical formulations because they are biodegradable, biocompatible, low toxic and eco-friendly(Rowe et al., 2010). Pullulan is a natural polysaccharide that displays excellent film-forming ability, transparency and quick dissolution behaviour, and is, therefore, suitable for

preparing ODFs(Gupta et al., 2023). Pectin is a supporting polymer which provides strength to the film(Pauliuc et al., 2025). Honey is a natural plasticizer and sweetener that increased flexibility and palatability. β-cyclodextrin is a commonly used agent for solubility enhancement and taste masking. It produces inclusion complex with drug thus improving the dissolution and acceptability of drug(Dave & Mishra, 2018; Loftsson & Brewster, 2012; Osuna et al., 2022). The solvent casting method is one of the commonly used approaches for ODF formulation because it is easy to perform, reproducible, and suitable for the preparation of thin and uniform films(Preis et al., 2014; Reuther et al., 2025). The Ondansetron Orodispersible Films were made using pullulan, pectin, honey, and β-cyclodextrin by solvent casting method. Multiple formulations were prepared and then tested for evaluating how they performed with respect to several physicochemical parameters like appearance, thickness, weight variation, folding endurance tensile strength, surface pH, drug content uniformity and many more. Also, the mechanism of drug release was determined by release kinetic studies like Zero-order, First-order, Higuchi, and Korsmeyer-Peppas. Hence, the present study has been undertaken to develop a stable, fast dissolving and patient-friendly Ondansetron Orodispersible Film with improved dissolution characteristics, fast action and better compliance. According to the researchers' analysis, the ready-to-use formulation developed may be an effective substitute for common oral dosage forms, especially in pediatric, geriatric, bedridden and dysphagic patients in need of quick action in case of a need for nausea and vomiting.

1. Methodology

1.1. Materials

The model drug for Orodispersible Films (ODFs) preparation was Ondansetron Hydrochloride. The primary polymer used for film-forming was pullulan and as supporting polymer pectin was used. β-Cyclodextrin as solubility enhancer and taste masking agent while honey was added as plasticizer and sweetening agent. All the other chemicals and reagents used in this study were of analytical grade. API, polymers and excipients were obtained from Dev Bhoomi Uttarakhand University, Dehradun, Uttarakhand.

1.2. Preformulation Studies

1.2.1. Organoleptic Characterization

The drug was assessed for colour, odour, appearance and physical nature(Simpson & Hicks, 1996).

1.2.2. Melting Point Determination

The melting point of Ondansetron was determined by using a melting apparatus in order to check the purity and crystal nature of a drug. A capillary tube was prepared by sealing its one end with a flame, while it was continuously rotated. The finely powdered Ondansetron was filled in the capillary tube about 1-2 cm by tapping the capillary tube gently. We attached the capillary tube to the thermometer using a rubber band and immersed it in a Thiele's tube containing paraffin oil. The temperature was increased gradually till the melting of the drug was observed and recorded. The identification of impurity along with the confirmation of the drug substance' purity and identity is done using melting point determination(Kumria et al., 2013).

1.3. Characterization of drug

1.3.1. Determination of λmax

For the determination of the λmax, standard solution of Ondansetron Hydrochloride was prepared in phosphate buffer pH 6.8 which was scanned at 200–400 nm in UV-visible spectrophotometer(Koland et al., 2011).

1.3.2. Preparation of Calibration Curve

Various concentrations of Ondansetron Hydrochloride were prepared using phosphate buffer pH 6.8 and absorbance was measured at λmax. A plot of concentration versus absorbance was done(Koland et al., 2010; Sadangi et al., 2025).

1.3.3. Drug–Excipient Compatibility Study

Using Fourier Transform Infrared Spectroscopy (FTIR), compatibility studies on Ondansetron and selected excipients were performed to check for any drug–excipient interactions(Liu et al., 2019).

2. Formulation Optimization of Orodispersible Films formulation

Orodispersible Films of Ondansetron were prepared by Solvent casting method. Design expert software was used for optimization. A clear polymeric solution was obtained when the required amounts of pullulan and pectin were dissolved in distilled water under stirring. Honey was used as a plasticizer and sweetening agent, which was followed by addition of β-cyclodextrin to enhance solubility and taste masking. The solution was continuously stirred to give uniform wet mass after incorporation of Ondansetron Hydrochloride. The solution that was prepared was kept undisturbed to remove air bubbles that get trapped in it and cast on a suitable flat surface or petri plate. The films were dried at 40-45°C, carefully peeled off after complete drying. A total of thirteen formulations (F1–F13) were prepared in which the concentrations of pullulan, honey and β-cyclodextrin were varied while drug loading and pectin concentration were kept constant.

Table 1: Formulation Optimization using Box Benken design

levels	Pullulan	B-cyclodextrin	Honey
Low	600	300	300
Medium	900	400	400
High	1200	500	500

Table 2: Formulation table

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13
Ondansetron (mg)	100	100	100	100	100	100	100	100	100	100	100	100	100
B-cyclodextrin (mg)	300	500	300	500	300	500	300	500	400	300	500	400	400
Pullulan (mg)	600	600	1200	1200	600	600	1200	1200	900	900	900	600	1200
Honey (mg)	300	300	300	300	500	500	500	500	400	400	400	400	400
Pectin (mg)	300	300	300	300	300	300	300	300	300	300	300	300	300
Ethanol (ml)	5	5	5	5	5	5	5	5	5	5	5	5	5
Water (ml)	25	25	25	25	25	25	25	25	25	25	25	25	25

3. DEVELOPMENT OF BUCCAL PATCH

3.1. Chemicals used

Table 3: API and excipients

S. No.	Material	Category/ Role	Purpose in Formulation
1	API (Drug)	Active Pharmaceutical Ingredient	Therapeutic activity
2	β-Cyclodextrin	Complexing/Solubility Enhancer	Improves solubility and taste masking
3	Pullulan	Film-forming polymer	Provides film structure and rapid disintegration
4	Pectin	Secondary polymer	Improves film strength and flexibility
5	Honey	Natural plasticizer	Enhances flexibility and mouthfeel

3.2. Preparation of Orodispersible film

3.2.1. Preparation of Ondansetron–β-Cyclodextrin Inclusion Complex

The inclusion complex of Ondansetron and β-cyclodextrin was prepared through the kneading method for 30–45 minutes using suitable solvent mixture to get uniform semi-solid mass. The doughy material was dried at a controlled temperature, ground in a mortar and pestle, and then passed through sieve #60 to obtain a fine, free-flowing powder(Sravya et al., 2013; Yassien & From, 2017).

3.2.2. Preparation of Polymeric Solution

The polymer pullulan was hydrated separately in distilled water with continuous stirring to get a clear

solution. A smooth dispersion of pectin was made separately in distilled water with gentle heating. The film-forming solution was obtained by uniform mixing of both polymeric solutions(Pauliuc et al., 2025; Prajapati et al., 2018; Shah et al., 2022).

3.2.3. Incorporation of Drug and Honey

The Ondansetron–β-cyclodextrin complex prepared was dispersed in minimum quantity of ethanol and was added slowly into the polymeric solution with continuous stirring for uniformity in drug distribution(Liu et al., 2019; Yassien & From, 2017).

3.2.4. Stirring and Degassing

The whole formulation was stirred continuously to achieve a uniform solution, followed by degassing through sonication to remove air bubbles(Preis et al., 2012).

3.2.5. Casting and Drying of Films

The film-forming solution prepared was poured into a clean and levelled 10 × 10 cm² Petri dish and allowed to spread uniformly. The films that were cast were dried at 40-45°C, until smooth, dry, and non-sticky films were formed(Prajapati et al., 2018; Sadangi et al., 2025).

Fig 1: Casting of homogenous Solution

3.2.6. Peeling and Cutting of Films

The dried films were removed from the Petri dish and peeled off carefully and cut into small 2 × 2 cm² film pieces that contained the required dose of Ondansetron which was used for further evaluation studies(Cilurzo et al., 2008; Sadangi et al., 2025).

4. Evaluation of Orodispersible Films

4.1. Physical Appearance

The films prepared were examined visually for colour, transparency, smoothness, flexibility, air bubbles and cracks.

4.2. Thickness

A calibrated Vernier calliper was used to measure the film thickness at various points on the film surface.

4.3. Weight Variation

Each film of specified sizes were weighed separately on a digital balance to check weight variation.

4.4. Folding Endurance

The film's folding endurance was measured by continuously folding at the same place until a break occurred. When the film cracked, the number of folds taken was noted.

4.5. Tensile Strength

Film's tensile strength was tested to determine the mechanical strength and flexibility of the prepared formulations.

4.6. Surface pH

The films were placed on moistened agar for a period of time, and its pH was measured using a pH meter. The study measured the pH of the film surface to find out the compatibility of the film with oral mucosa.

4.7. Drug Content Uniformity

The films were dissolved in phosphate buffer pH 6.8 at suitable dilutions and the contents were analysed for drug content uniformity.

4.8. Disintegration Time

The time of disintegration of the films was determined by placing the film in a petri dish containing phosphate buffer pH 6.8 and noting the time for complete disintegration.

4.9. In Vitro Dissolution Study

The dissolution examination was conducted with phosphate buffer pH 6.8 as dissolution medium. At predetermined times samples were taken out spectrophotometrically analysed and % drug release was determined.

4.10. Release Kinetic Study

The fit of formulation was determined by studying release kinetics using Zero-order, First-order, Higuchi, and Korsmeyer–Peppas models. To estimate the best-fit release model and the mechanism of drug release, regression coefficient (R^2) values were calculated.

5. RESULT

5.1. PRE FORMULATION STUDIES

5.1.1. Properties Of Drug

Table 4: Characteristic Properties of Ondansetron

Sr. No	Properties		Result/Observation
1.	Organoleptic Properties	Color	White solid powder
		Odor	Odorless
2.	Solubility		Soluble in water, ethanol and 6.8 phosphate buffer
3.	Melting point		231.6^{0}C

5.2. Characterization of drug and polymers

5.2.1. Determination of λmax

From the prepared stock solution, a suitable dilution of 10 µg/mL was prepared using phosphate buffer pH 6.8. The solution was scanned for a wavelength range of (200–400 nm) using UV–Visible spectrophotometer to find λmax (maximum absorption). Maximum absorbance of Ondansetron

was observed around 248 nm which was selected for the analytical study.

5.2.2. Calibration curve of Sitagliptin in 6.8 Phosphate buffer at 248 nm

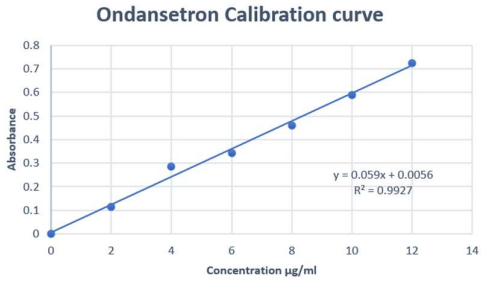


Fig 2: Calibration curve of Sitagliptin

5.2.3. Drug excipients compatibility study

a. FTIR study of pure drug

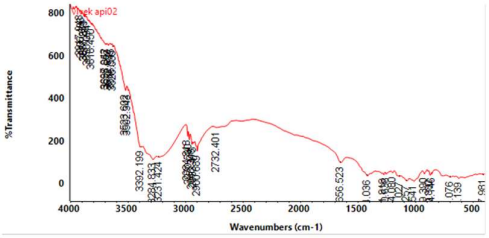


Fig 3: FTIR spectra of pure drug

FTIR analysis being done to characterize the functional groups that are present in Ondansetron and to check the purity of the drug before formulation. The spectrum has different bands, which infer to the functional groups of Ondansetron. The presence of characteristic peaks for N–H stretching, C=O stretching, aromatic C=C vibrations, and C–O stretching confirmed the structure of the drug molecule. The clearly defined and sharp peaks are an indication of stability of produced drug sample and absence of impurities. The spectrum of Ondansetron had all typical absorption peaks corresponds to functional groups of drug. The significant peak seen at 1656 cm-1 confirmed the presence of C=O (carbonyl) stretching. The peaks in the range of 3284–3231 cm-1 show the presence of N–H stretching vibrations. Aliphatic C–H stretching peaks were confirmed between 2984–2900 cm^{-1}. The spectrum we obtained exhibited a high level of similarity to the standard FTIR spectrum of Ondansetron that has been reported. No additional peaks indicating impurities or degradation products were observed.

b. FTIR study of Drug and polymers

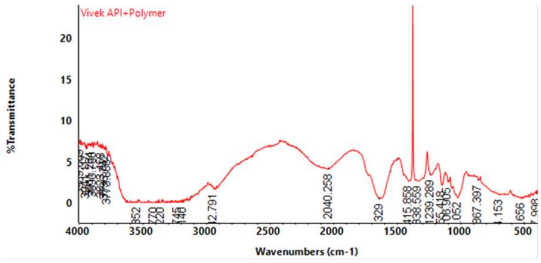
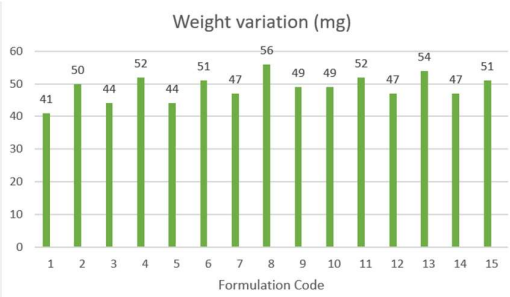


Fig 4: FTIR spectra of pure drug

FTIR spectroscopy was performed to assess the compatibility of Ondansetron with chosen excipients used for the formulation of oral dissolving films. The methyl peak of the drug was found at 2871 cm^{-1}, close to the peak of the pure drug at 2872 cm^{-1}. Likewise, the formulation mixture spectrum retained the N–H/ O–H stretching peaks and C–H stretching peaks. The presence of the hydrophilic polymers and possible hydrogen bonding interactions resulted in a slight broadness of some peaks. Nevertheless, there were no signals of new peaks indicating chemical incompatibility or degradation. The spectrum of the drug-polymer mixture retained the characteristic peaks of Ondansetron, which suggests that the drug's chemical structure did not get altered upon mixing with polymers and other excipients. The wide peaks between 3409 and 3184 cm−1 are assigned to the O–H stretching vibrations of both the polymers and honey, and N–H stretching of the drug molecule. The spectrum of the drug–polymer mixture showed the characteristic peaks of Ondansetron which confirms that the drug's chemical structure was not altered during mixing with polymers and other excipients. The wide peaks in the region of 3409–3184 cm^{-1} were attributed to the O–H stretching of the polymers and honey along with N–H stretching of drug molecule. The presence of original C=O stretching peak around 1644 cm-1 had shown no considerable chemical interaction between drug and formulation. The physical interactions involving hydrogen bonding are responsible for the slight broadening and intensity reduction of peaks observed in a polymeric film system. No further peaks or prominent shifts were noted here. Thus, the selected polymers and excipients are compatible with Ondansetron and can be used in the manufacture of stable oral dissolving film.

5.3. Evaluation of Ondansetron buccal Patch:



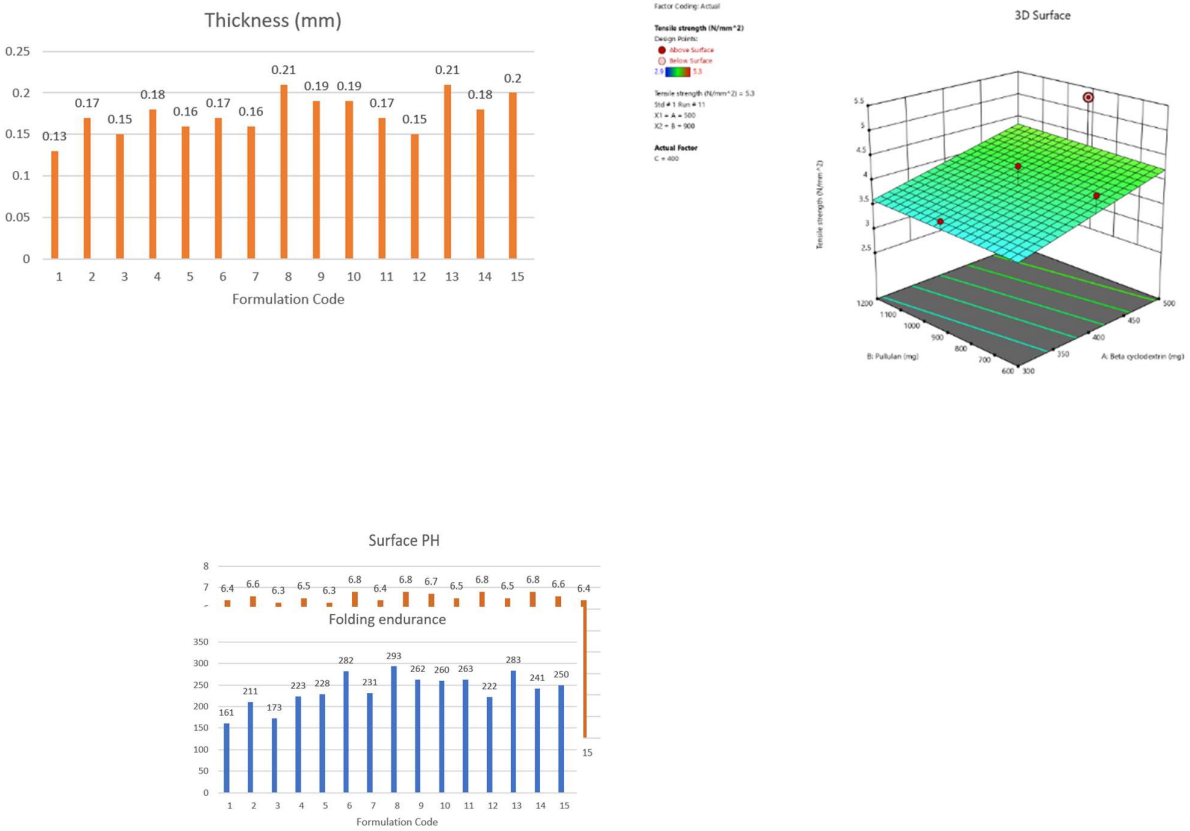
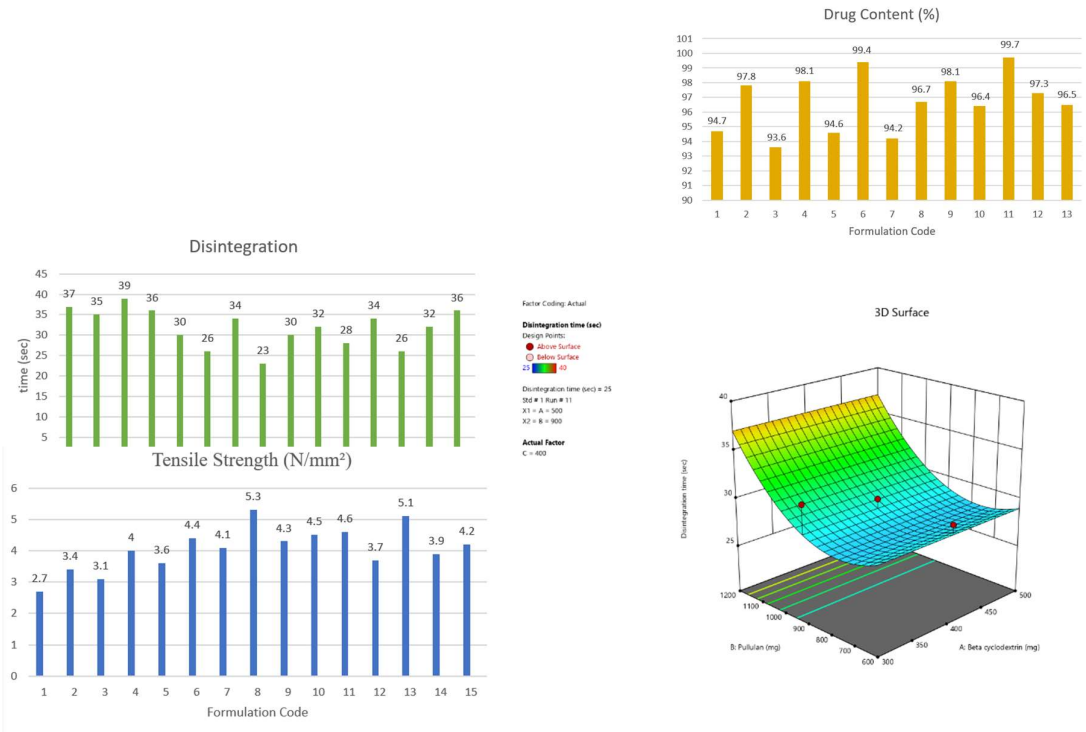


Fig 5: Evaluation Parameters of Ondansetron Orodispersible Film



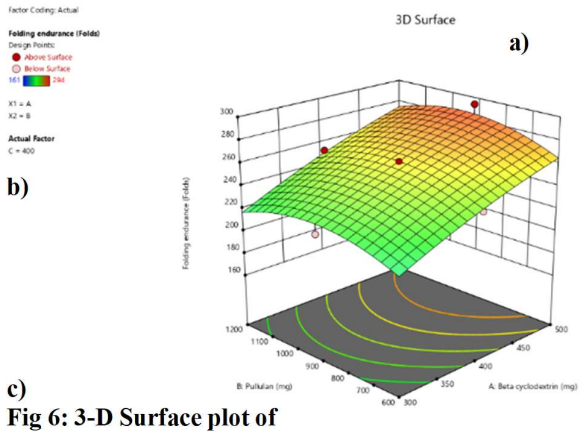


Fig 6: 3-D Surface plot of a) Disintegration time, b) Tensile strength, c) Folding endurance

Fig 7: Optimized buccal patch Formulation a) F8, b) F11, c) F12

The ondansetron content uniformity of all the formulations was in the range of 94.2 ± to 99.7 ± 0.8%, which is indicative of the uniformity of drug distribution throughout the films. The solvent casting method allowed for mixing of the drug and excipients. All formulations met the pharmacopeial requirements for content uniformity.

5.4. In vitro dissolution study

The dissolution study of Ondansetron Orodispersible Films in vitro showed the drug quickly and effectively released from all formulation in 15 mins. Results of dissolution behavior showed that increasing concentrations of β-cyclodextrin, pullulan, and honey altered the drug release behavior. Formulations containing higher concentration of β-cyclodextrin showed better release of drug due to improved aqueous solubility and the formation of the inclusion complex with Ondansetron. Honey was a natural plasticizer and quickly hydrated and swelled the film matrix to enhance their dissolution characteristics. The formulation F11 was found to release 99.7% of drug in 15 min which was higher than all other formulations followed F6 (98.1%), F12 (98.5%) and F9 (98.7%). F11 has a better dissolution profile perhaps due to the optimized ratio of β-cyclodextrin (500 mg), pullulan (900 mg), and honey (400 mg) which improved wettability, film disintegration and drug diffusion. The formulations that contained higher concentrations of pullulan (1200 mg), such as F3, F4, F7, and F8 showed comparatively lower initial release due to a denser polymeric matrix. Satisfactory cumulative release was accomplished after 15 minutes. Overall, the prepared ODFs were found to have rapid dissolution for immediate release. Based on the dissolution data study, F11 was considered the optimized formulation with the highest drug release with excellent performance.

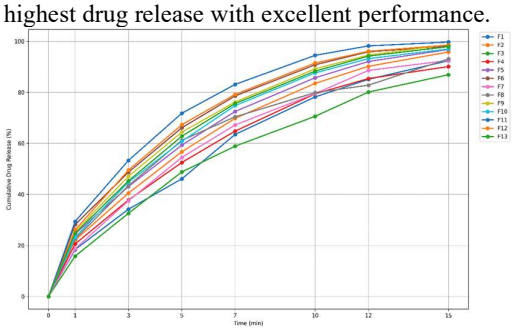


Fig 8: In- vitro Drug Release profile of Formulations F1-F13

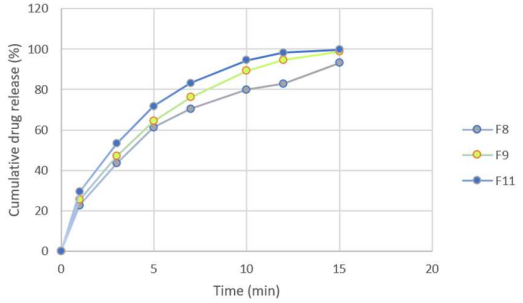


Fig 9: In- vitro release profile of optimised Formulations F8, F9 and F11

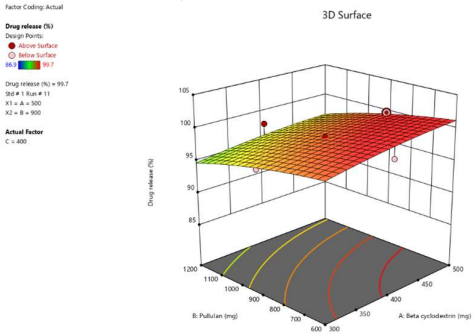


Fig 10: 3-D response surface plot of Beta cyclodextrin and pullulan on in-vitro drug release

5.5. Dissolution Study of Optimized Ondansetron Orodispersible film

5.4.1. Zero Order - The zero-order model showed somewhat lesser linearity ($R^2 = 0.86$) which shows that release was not constant with progression of time.

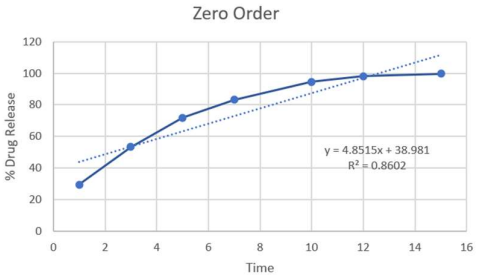


Fig 11: Zero order release kinetic study

5.4.2. First Order - The first order model gave the highest value of regression coefficient R^2=0.96, thus indicating that the drug release followed First-order kinetics of all the kinetic models. This indicates that the rate of release was dependent on the concentration of drug remaining in the formulation.

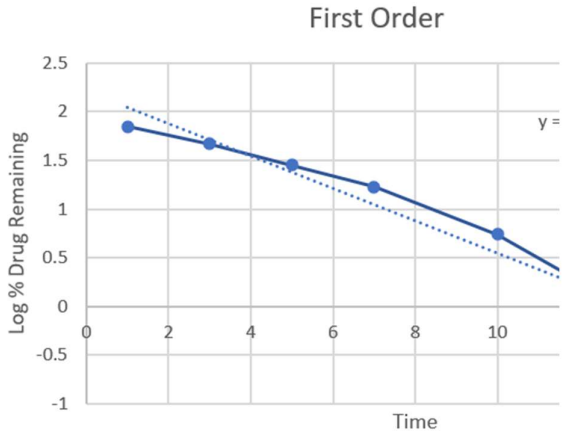


Fig 12: First order release kinetic study

5.4.3. Higuchi model- The Higuchi model also showed satisfactory linearity (R^2 = 0.96) which indicated a diffusion-controlled release of Ondansetron from the polymeric matrix in the tablets.

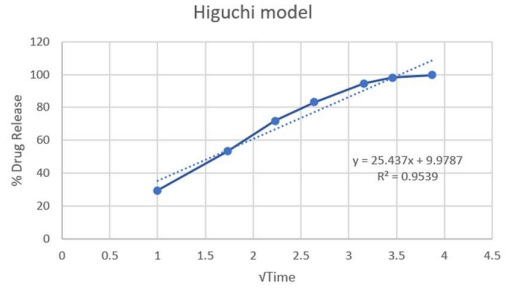


Fig 13: Higuchi model release kinetic study

5.4.4. Korsmeyer–Peppas model - The Korsmeyer–Peppas model indicated the formulation followed anomalous non-Fickian diffusion based on the value of R^2 (0.976), n (0.61). The results indicated the drug release mechanism involved drug diffusion and relaxation/swelling of the polymeric network.

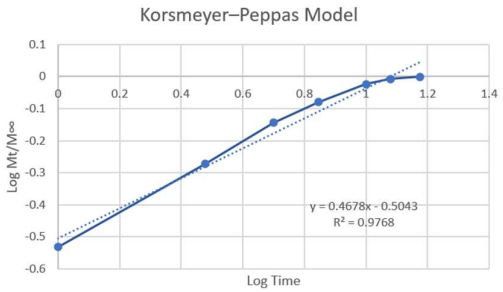


Fig 14: Korsmeyer–Peppas model release kinetic study

In conclusion, the release kinetic indicates that formulation F11 exhibited rapid, controlled and diffusion mediated drug release with excellent dissolution performance, thus it is the optimized formulation of all prepared formulations.

6. DISCUSSION

In this study, Ondansetron Orodispersible Films (ODFs) were formulated and evaluated using pullulan, pectin, honey and β-cyclodextrin by solvent casting method. The films obtained were smooth and flexible and exhibited satisfactory properties. FTIR results confirmed that the Ondansetron and the selected excipients were compatible and did not interact. All formulations showed acceptable thickness, weight variation, folding endurance, tensile strength, surface pH and drug content uniformity. The range of surface pH was 6.3 to 6.8, which indicated that the films would be non-irritant to oral mucosa. Because pullulan and pectin are hydrophilic materials, the films quickly disintegrated due to enhanced dehydration and disintegration of these films. The flexibility and taste of Ondansetron were improved owing to the inclusion of honey, while the β-cyclodextrin improved solubility and dissolution. The optimal formulation was established as F11 due to its superior physicochemical evaluation and dissolution profile among all formulations. The drug release is 99.7% in 15 Minutes with Good Mechanical Strength and Rapid Disintegration of Formulation. The release kinetics studies was proven that the best fit for the formulation was First order and Higuchi models which clarifies the kinetics of the formulation was concentration dependent and drug released by diffusion mechanism. Anomalous non-Fickian diffusion was seen by Korsmeyer-Peppas model. The study shows that Ondansetron Orodispersible Films can serve as an effective and patient-friendly alternative to traditional oral dosage forms owing to their improved dissolution, fast action, and increased patient compliance.

7. CONCLUSION

Using the solvent casting method, the present study successfully formulated and evaluated Ondansetron Orodispersible Films (ODFs) using natural excipients like pullulan, pectin, honey, and β-cyclodextrin. They were characterized by good flexibility, surface pH, drug content uniformity,

disintegration and increased drug release, etc. of the prepared films. FTIR studies showed that Ondansetron compatible with the selected excipients. According to, F11 showed superior dissolution profile and physicochemical characteristics thus hence it was selected as optimized formulation among all. The optimized formulation demonstrated 99.7% drug release within 15 minutes and pronounced mechanical strength, rapid disintegration, etc. Findings from the release kinetic studies suggested that non-Fickian diffusion mechanism was annihilative and drug release was First-order and Higuchi. The researchers concluded that Ondansetron Orodispersible Films could be used as a substitute for classical oral dosage forms, with a rapid onset of action, quick dissolution, improved ease of administration and patient compliance. The formulation can be very useful for pediatric, geriatric, bedridden and dysphagic patients suffering from nausea and vomiting.

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AUTHOR'S CONTRIBUTION

Vivek Kumar Singh: Write the research paper, Dr, Tarun Parasher: Guided to write the research paper, Mrs. Chavi Mittal & Mr. Bhupendra Kumar: Reviewed the manuscript in correct format.

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CONFLICT OF INTEREST:

NA

DECLARATION OF ARTIFICIAL INTELLIGENCE

(AI) Assistance

I acknowledge that minimal AI tools were used solely for formatting, and improving clarity. All conceptualization, analysis, interpretation, and conclusions are original.

Ethics Approval

All the Figures and tables are self-made; this study does not involve human participants or animals.

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