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A Review on Formulation and Evaluation of Fast Dissolving Oral Film of Ondencetron

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Abstract
Rather than other dosage forms like orally disintegrating tablets, oral fast dissolving films (OFDFs) have recently been brought to the market because of their simplicity and use. As this technology developed over the last several years from the confection and dental care markets in the form of breath strips to become a novel and widely accepted form by consumers, OFDFs are attracting the attention of a significant number of pharmaceutical enterprises. The drug delivery method known as an orally fast dissolving film dissolves or disintegrates when it is placed in the mouth without the need for water in a matter of seconds. In terms of size, shape, and thickness, OFDFs resemble postage stamps a lot. There is a chance that these movies will introduce the substance into your system.

Keywords: Fast dissolving films, Fast disintegration, Oral strips, Tensile strength

INTRODUCTION :

Oral administration is the most widely used route due to its simplicity, ability to reduce pain, adaptability (to accommodate a variety of drug candidates), and, most importantly, patient compliance, oral administration is the most widely used route. Solid oral delivery systems also do not require sterile conditions, making them less expensive to produce.

Recently, a number of innovative oral administration methods have been made available to address the physicochemical and pharmacokinetic properties of medications while enhancing patient compliance. Further recently developed technologies include computer assisted three-dimensional printing (3DP) tablet production and electrostatic drug deposition and coating.

For juvenile and elderly patients who have trouble swallowing standard oral solid dosage forms, such as pills, capsules, and syrups, fast dissolving drug delivery systems were initially created in the late 1970s. Fast dissolve, rapid dissolve, rapid melt, and quick disintegrating tablets are examples of the revolutionary fast dispersing dosage forms technology. Yet, all of these dosage forms share a similar principle and function. Who may not have ready access to water.

Salient feature of fast dissolving drug delivery system

- Ease of administration for patients who are mentally ill disabled and uncooperative.
- Require no water.
- Overcomes unacceptable taste of the drugs.
- Can be designed to leave minimal or no residue in the mouth after administration and also provide a pleasant mouth feel.

- Ability to provide advantages of liquid medication in the form of solid preparation. 6. Cost effective.

Need for fast dissolving drug delivery systems

Drug delivery methods that dissolve quickly can increase adherence and acceptance in dysphasic patients. From a marketing perspective, the introduction of FDDS will help with medication life cycle management, particularly if the drug is patent-protected.

Market view

Due to low patient compliance with current administration regimens, a small market for pharmaceutical companies and medication users, as well as significant disease treatment expenses, the demand for noninvasive delivery systems is still present. One factor contributing to the rise in fast-dissolving/disintegrating products on the market is pharmaceutical marketing. Pharmaceutical companies frequently create a specific therapeutic entity in a new and enhanced dosage form as a drug entity approaches the end of its patent life. A dosage form enables the producer to increase the market exclusivity while providing a more practical dosage form or dosing schedule to its patient population. Fast dissolving/disintegrating formulations are comparable to several prolonged release formulations that are now widely accessible in this regard. A fast-dissolving or disintegrating dosage form can extend market exclusivity, which boosts sales while simultaneously focusing on the underserved and undertreated patient group.

Advantages

- These rapid dissolving films offer several advantages like,
- Due to the presence of large surface area, films provide rapid disintegrating and dissolution in the oral cavity.
- Convenient dosing.
- Fast disintegration or dissolution followed by quick effect which is desirable in some cases such as pain.
- Oral dissolving films can be administered without water, anywhere, anytime.
- No risk of choking.

Special features of mouth dissolving films

- Thin elegant film
- Available in various size and shapes
- Unobstructive
- Excellent mucoadhesion
- Fast disintegration
- Rapid release

Limitations of Fast Dissolving Oral Films

- High doses cannot be incorporated.
- Excessive bitter drugs are not feasible.
- Dose uniformity is a technical challenge.
- They require special packaging for the products stability and safety.
- Drugs which irritate the oral mucosa cannot be administered by this route.

FAST DISSOLVING FILMS

The more recent technology used in the production of oral disintegrating dose forms are oral films. These are attractive thin films made of ingestible, water-soluble polymers in a range of dimensions, such as square, rectangle, and disc. The stripes could be clear or opaque, flexible or brittle. They are created to break down quickly on the tongue without the aid of water. The specific surface area for disintegration in fast disintegrating films (FDFs) is considerable. The films overcome the shortfalls of oral rapid dissolving pills by reducing the risk or worry of choking, making them simple to handle and administer and easy to make. These dosage forms' low medication loading capacity and limited flavour masking possibilities are significant drawbacks.

A thin film with a surface area of 1–20 cm2 and a thickness of 1–10 mm is referred to as a fast dissolving film. Around 15 mg of medication can be ingested in a single dose. Due to a specific matrix constructed of water soluble polymers, which typically has minimal tack for easy handling and application, products dissolve instantly in saliva. Yet, the wet tack and muco adhesiveness characteristics of the system are intended to secure the film at the application location upon wetness. Films are chosen for their strength and flexibility to make production processes such as rewinding, die cutting, and packing easier. On the patient's tongue are mucosal tissue, which is quickly evaporating film, which is immediately moistened by saliva. The film quickly hydrates and sticks to the application place. The medicine is then quickly released for either gastric absorption when swallowed or for oral mucosal absorption.

Formulation and material

- Active pharmaceutical ingredient
- Film forming polymer
- Plasticizer
- Sweetening agent
- Saliva stimulating agent
- Flavoring agent
- Coloring agent

❖ **Active pharmaceutical ingredient**

A typical composition of the film contains 1-25% w/w of the drug. Variety of APIs can be delivered through fast dissolving films. Small dose molecules are the best candidates to be incorporated in OFDFs. Multivitamins upto 10% w/w of dry film weight was incorporated in the films with dissolution time of less than 60 seconds. It is always useful to have micronized API which will improve the texture of the film and also for better dissolution and uniformity in the OFDF. Many APIs, which are potential candidates for OFDF technology, have bitter taste. This makes the formulation unpalatable especially for pediatric preparations. Thus before incorporating the API in the OFDF, the taste needs to be masked. Various methods can be used to improve the palatability of the formulation.

❖**Film forming polymers**

The primary use of all thin film oral dosage forms relives on the disintegration in the saliva of the oral cavity, the final film that is used must necessarily be water soluble. In order to prepare a thin film formulation that is water soluble, excipients or polymer must be water soluble with low molecular weight and excellent film forming capacity. It should be non-toxic, non-irritant and devoid of leachable impurities. It should have good wetting and spread ability property. It should not be very expensive and readily available. Microcrystalline cellulose was also used to decrease the disintegration time and improve the dissolution of the drug from the films. Examples of polymers are

- Guar gum
- Xanthum gum
- Acacia
- Tragacanth
- Polyethylene oxide
- Sodium carboxy methyl cellulose
- Hydroxyl propyl methyl cellulose
- Polyvinyl alcohol

❖ **Plasticizer**

Plasticizer helps to improve the flexibility of the strip and reduces the brittleness of the films. The selection of plasticizer will depend upon its compatibility with the polymer and also the type of solvent employed in the casting film. Examples of plasticizers are

- Glycerol
- Propylene glycol
- Polyethylene glycol
- Dimethyl phthalate
- Diethyl phthalate
- Triacetin
- Castor oil

❖ **Sweetening agents**

Sweeteners have become the important part of the formulation intented to be disintegrated or dissolved in the oral cavity. Generally sweeteners are used in the concentration of 3-6% w/w. both natural and artificial sweeteners are used in the formulation of these fast dissolving films. Polyhydric alcohols such as such as sorbitol, manitol, and isomalt can be used in combination as they additionally provide good mouth feel and cooling sensation. However it should be noted that they use of natural sugars in such preparation need to be restricted in people who all are on diet or in the case of diabetic patents. Due to this reason, the artificial sweeteners have gained more popularity in food and pharmaceutical preparations.

The first generation of the artificial sweeteners are

- Saccharin
- Cyclamate
- Aspartame

❖ **Saliva stimulating agents**

The purpose of using the saliva stimulating agents is to increase the rate of production of saliva that would aid in the faster disintegration of the rapid dissolving stripes formulations. Generally acids which are used in the preparation of food can be utilized as salivary stimulants. Examples are

- Citric acid
- Malic acid
- Lactic acid
- Ascorbic acid
- Tartaric acid
- These agents are used along are in combination between 2-6 % w/w of the stripes.

❖ **Flavoring agents**

Preferably upto 10 % w/w flavors are added in the OFDF formulations. The acceptance of oral disintegrating or dissolving formulation by an individual is largely depends on the initial flavor quality which is observed in first few seconds after the product has been consumed and the after taste of the formulation which lasts for at least about 10 min. The geriatric population like mint or orange flavors like fruit punch, raspberry etc. it can be selected from synthetic flavor oils, oleoresins peppermint oil, cinnamon oil, spearmint oil, oil of nutmeg are the examples of flavor oils while vanilla, cocoa, coffee, chocolate, and citrus are fruity flavors. Apple, raspberry, cherry, pineapple are few examples of fruit essence type.

❖ **Coloring agents**

FD&C approved coloring agents are used (not exceeding con centration levels of 1 percent; w/w) in the manufacturing of orally fast dissolving films. Eg titanium dioxide.

MATERIALS AND METHODS:

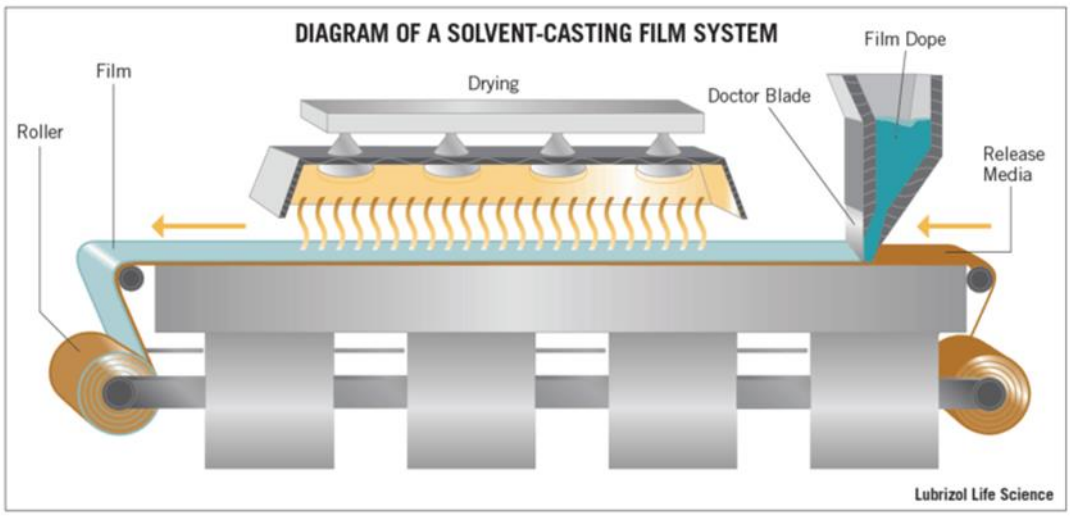
One or combination of the following process can be used to manufacture the mouth dissolving films**.**

1.Solvent casting
2.Semisolid casting
3.Hot melt extrusion
4.Solid dispersion extrusion
5.Rolling

1.Solvent Casting Method

In solvent casting method water soluble are dissolved in water and the drug along with other. Excipients are dissolved in suitable solvent then both the solutions are mixed and stirred and finally casted into the petri plate and dried.

Figure 1



2.Semisolid casting

In semisolid casting method firstly a solution of water soluble film forming polymer is prepared. The resulting solution is added to a solution of acid insoluble polymer (e.g cellulose acetate phthalate, cellulose

acetate butyrate), which was prepared in ammonium or sodium hydroxide. Then appropriate amount of plasticizer is added so toast a gel mass is obtained. Finally the gel mass is casted into the films or ribbons using heat controlled drums. The thickness of the film is about 0.15-0.5 inches. The ratio of the acid insoluble polymer to film forming polymer should be 1:4. Both mixtures are mixed to form homogenous viscous solution degassed under vaccum. Bubble free solution is coated on non-treated casting film coated film is sent to aeration drying oven. Film is cutting into desired shape and size.

3.Hot melt extrusion

In hot melt extrusion method firstly the drug is mixed with carriers in solid form. Then the extruder having heaters melts the mixture. Finally the melt is shaped into films by the dies. There are certain benefits of the hot melt extrusion. o Fewer operation units o Better content uniformity o An anhydrous process

4. Solid dispersion extrusion

In this method immiscible components are extruded with drug and then solid dispersions were prepared. Finally the solid dispersions are shaped into films by means of dies.

5.Rolling method

In rolling method a solution or suspension containing drug is rolled on a carrier. The solvent is mainly water and mixture of water and alcohol. The film is dried on the rollers and cut into desired shapes and sizes.

❖ **Table of Formulation trial**

INGRIDIENT	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
ONDENCETRON (mg)	1875	1875	1875	1875	1875	1875	1875	1875	1875	1875
HPMC (mg)	1217	11126	1035	1381	1309	1218	1217	1035	852	1400
PEG 400 (mg)	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
PROPYLEAN GLYACOL (mg)	-	-	1.5	1	1.5	1.5	1.5	1.5	1.5	1.5
CITIC ACID (mg)	200	200	200	200	200	200	200	200	200	200
SODIUM SACCARIN (mg)	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12	1.12
FLEVAR	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15
DISTIL WATER	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs

Evaluation of the films

1.Weight Variation

The weight variation test is determined by measuring the weight of the individual film of 2 cm x 2 cm area. For the measurement of the weight digital analytical balance was used. The weight of three films was measure and mean is taken.

2.Thickness

A thickness of the film should be measured by using micrometer screw gauge. Film should be measured at five position i.e. central and the four corners and four corners and the mean thickness are calculated. This test should be performed on six films of each formulation maximum variation in the thickness of the film should be less than 5% and mean ± S.D. measured.

3. Folding endurance

Folding endurance of the film is essential to study the elasticity of the film during storage and handling. The folding endurance of the films was determined by repeatedly folding one film at the same place till it break. This is considered to reveal good film properties. A film (3x 2 cm) was cut evenly and repeatedly folded at the same place till it breaks. All determinations were performed in triplicate.

4.Visual inspection

Oral fast dissolving films were inspected manually for their transparency and air bubble entrapment.

5.Surface pH study

The surface pH values of the formulation are given in all polymers resulted in the formulations that have neutral surface pH. The surface pH of the strips was ranging from 6.8 to 7. The neutral values of surface pH of films assured that there will be no irritation to the mucosal lining of the oral cavity.

6.In-vitro dissolution studies

Dissolution profile of mouth dissolving films were compared with pure drug Dissolution study was carried out using USP type 2 (paddle apparatus) with 300 ml of 14 pH phosphate buffer containing 2N NaOH as dissolution medium maintained at 37 +0.50 C. Medium was stirred at 50rpm for a period of 30 min. Samples were withdrawn at every 5 min interval, replacing the same amount with the fresh medium. Samples were suitable diluted with ethanol and analyzed for drug content at 205 nm.

Table : Parameters of dissolution studies

Test	**Observations**
Colour	White amorphous powder
Odour	Characteristic
Taste	Bitter

7.Content uniformity

The films were tested for content uniformity. Films of size one square inch was cut, placed in 100 ml volumetric flask and dissolved in water, volume was made up to 100 ml with water. Solution was suitably diluted. The absorbance of the solution was measured at 289 nm.

8.Disintegration time

Test was performed using disintegration test apparatus. One square inch film was placed in the basket, raised and lowered it in such a manner that the complete up and down movement at a rate equivalent to thirty times a minute. Time required by the film, when no traces of film remain above the gauze was noted, Test was. Performed in triplicate,

9.Tensile strength

Tensile strength of the film was determined with digital tensile strength tester, which consist of two load cell grips. The one is fixed and upper one is moveable. The test film of specific size 3-inch 10 mm was fixed between these two cell grips and force was gradually applied till the film breaks.

10.Viscosity of film solution

Viscosity of the solution was determined by using the brook-field Viscometer.

11.swelling property

Film swelling studies are conducted using saliva solution. Each film sample is weight and placed in a previewed stainless steel wire mesh. The mesh containing the film sample was submerged into a 15ml medium in a plastic container. An increase in the weight of the film is calculated at preset time intervals until a constant weight is observed. The degree of swelling is calculated by using parameters

$\alpha = WT/WO$

WT is weight of film at time T

T and WO is weight of film at time zero.

12.Young's modulus

Young's modulus is the measure of the stiffness of the film. It is represented as the ratio of applied stress above strain in the region of elastic deformation as follows:

Young's modulus (Force at corresponding strain/cross section area)1/(corresponding strain)

13.Dissolution time

Dissolution time was determined by laying down the film (1.5 cm) on the petri dish and 2 drops of distilled water added by pipette. The time taken for the drop to dissolve the film and form the hole in the film was recorded.

14.Stability studies

Stability studies were performed at temperature of 40 +20° C / 75% RH for 3months in stability chamber. Each film was wrapped in a butter paper followed by aluminum foil and sealed in an air-tight plastic pouch. The drug content for 30 days, 60 days and 90 days after storage.

RESULT:

1.Preformulation studies

Preformulation studies of Ondansetron HCL was carried based on the following parameters 1. Organoleptic properties of Drug The drug was identified based on the organoleptic properties. Ondansetron HCL is and odor less, White to off white amorphous powder.

2. Solubility of drug

Ondansetron HCL was freely soluble in 0.1N HCL, Methanoland phosphate buffer pH 6.8. Sparingly soluble in ethanol. Slightly soluble in water.

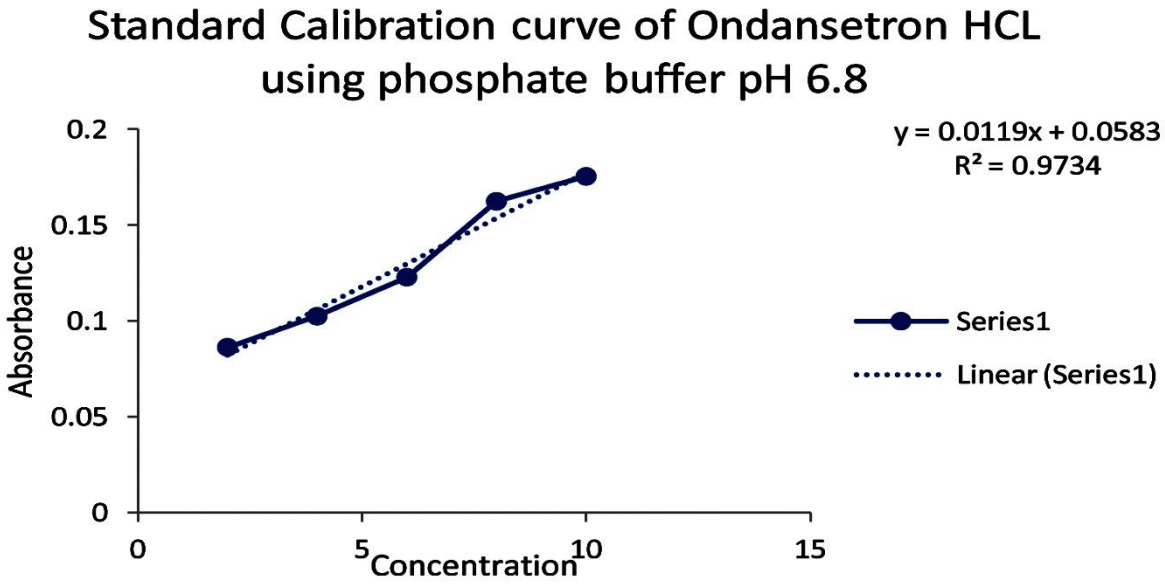
3. Melting point of Drug

The melting point of the Ondansetron HCL was found to be 231°C. The normal range of the melting point of Ondansetron HCL is 231-232°C, which shows that the melting point of the drug was lying between the ranges. The melting point indicates the purity of the drug

- **Calibration curve of Ondansetron HCL**

For the preparation of the calibration curve samples were prepared from a stock solution (2,4,6,8,10µg/ml). The absorbance of the samples was taken at 253 nm. The calibration curve of Ondansetron HCL is presented in Figure No 04 and data are presented in Table

SR NO	CONCENTRETION	ABSORPTION
1	2	0.0682
2	4	0.1024
3	6	0.1225
4	8	0.1624
5	10	0.1754

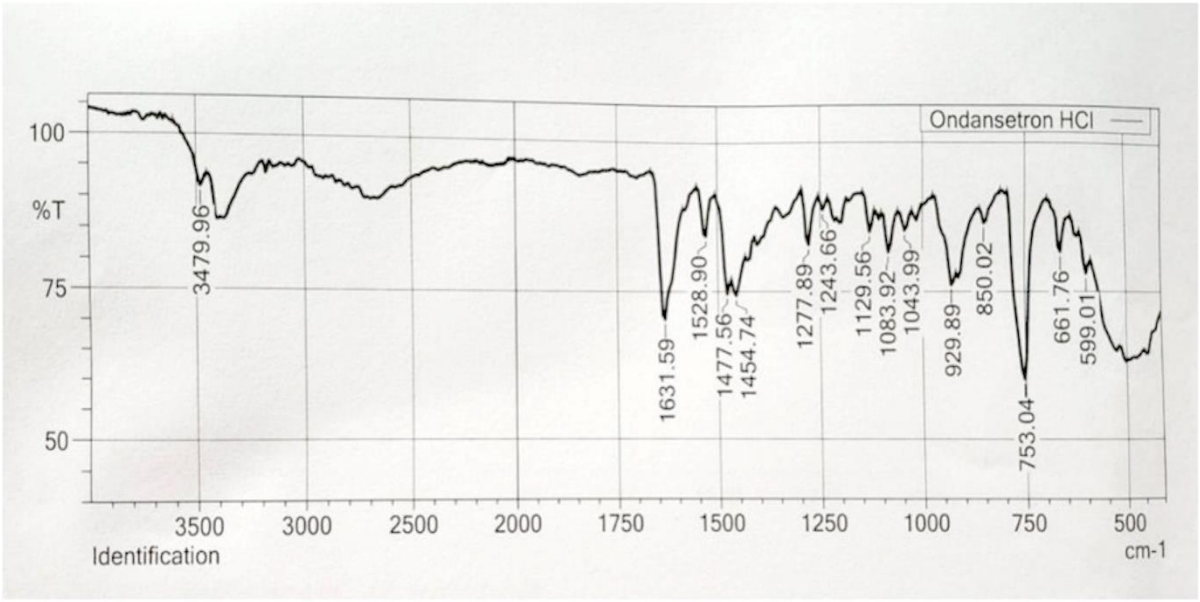


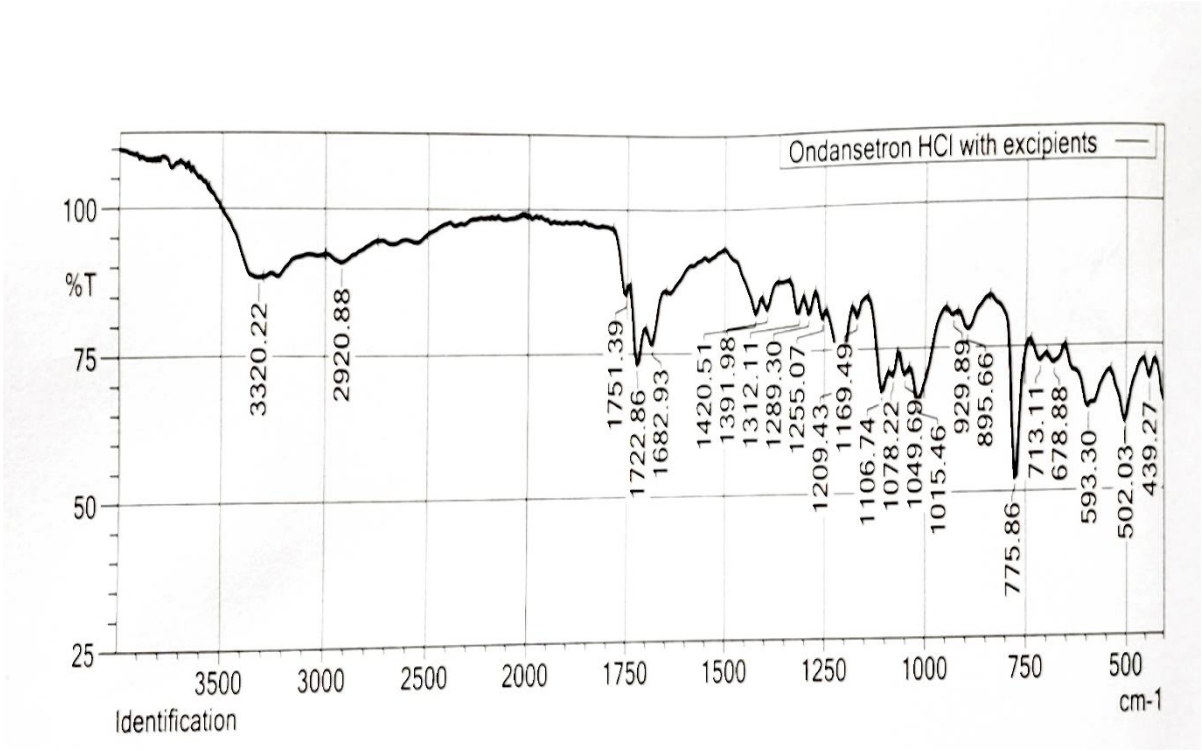
Calibration curve of Ondansetron HCL

Statistical data for calibration curve

Serial No.	Parameters	Value.
1	λmax (nm)	253
2	Beer law limits	2-10
3	Slope	0.0119
4	Constant	0.0583
5	R 2	0.9734

- **Fourier transform infrared (FTIR) interaction studies:** Compatibility studies of the drug and the polymer were carried out using the Shimadzu-FTIR spectrometer. The infra red of Ondansetron HCL and physical mixtures with ondansetron HCL, polymer HPMC and super disintegrant MCC, Starch, CC, Mannitol, citric acid were recorded by FTIR spectrometer as shown in figure No. 05 and 06 and the interpretation of the spectrum is shown in Table.


Ondansetron HCl
100
%T
75
50
3479.96
1631.59
1528.90
1477.56
1454.74
1277.89
1243.66
1129.56
1083.92
1043.99
929.89
850.02
753.04
661.76
599.01
3500
3000
2500
2000
1750
1500
1250
1000
750
500
Identification
cm-1


Ondansetron HCl with excipients
100
%T
75
50
25
3320.22
2920.88
1751.39
1722.86
1682.93
1420.51
1391.98
1312.11
1289.30
1255.07
1209.43
1169.49
1106.74
1078.22
1049.69
1015.46
929.89
895.66
775.86
713.11
678.88
593.30
502.03
439.27
3500
3000
2500
2000
1750
1500
1250
1000
750
500
Identification
cm-1

❖ **Interpretation of FTIR spectrum**

Functional group	Observed frequency (cm-1) pure sample	Observed frequency (cm-1) with excipients
C-Cl Stretching	753.04	775.86
C-H bending	929.89	929.49
S=O Stretching	1129.56	1169.49
COOH Stretching	1277.89	1269.49
CH Bending	1454.79	1420.51
C=O Stretching	1631.59	1682.93
N-H Stretching	3479.96	3320.93

❖ **Evaluation of Mouth dissolving films:**

Physical appearance and Drug content of the formulated films

SL NO	Formulation	Physical appearance	Drug content (%)
1.	F1	White, smooth, Uniform & Flexible	97.37 ±0.85
2.	F2	White, smooth, Uniform & Flexible	99.40 ±0.36
3.	F3	White, smooth, Uniform & Flexible	97.97 ±0.95
4.	F4	White, smooth, Uniform & Flexible	97.47 ±0.85
5.	F5	White, smooth, Uniform & Flexible	97.77 ±0.68
6.	F6	White, smooth, Uniform & Flexible	95.90 ±0.62
7.	F7	White, smooth, Uniform & Flexible	96.23 ±1.07
8.	F8	White, smooth, Uniform & Flexible	96.77 ±1.45
9.	F9	White, smooth, Uniform & Flexible	96.20 ±0.95
10.	F10	White, smooth, Uniform & Flexible	98.57 ±0.45

All value are mean of three reading ± standard deviation The prepared films of all formulations were evaluated and results shown in table No. 6,7,8,9. All the films were evaluated for their physical appearance and they were found to be white, smooth, uniform and flexible. The drug content estimation data for all the formulations were found to be 95.90±0.62 to 99.40±0.36. The drug content was uniform in all the film formulations indicating uniform distribution of drug. Percentage drug content was found to be highest for combination of HPMC and starch compared to other combinations (F2 - 99.40±0.36). Which was determined using an ELICO spectrophotometer.

❖ **Evaluated for Thickness, folding endurance, disintegration time, Uniformity of Weight variation, moisture loss.**

Formulation Code	Film Thickness (mm)	Folding endurance	Disintegration Time	Uniformity Weight (mg)	Moisture Loss
F1	0.119±0.007	99±5	**13.37**±1.86	**66.80**±0.10	**2.18**±0.07
F2	0.102±0.003	100±5	**11.43**±0.67	**61.60**±0.06	**1.15**±0.01
F3	0.116±0.004	100±5	**19.80**±1.70	**64.83**±0.06	**2.63**±0.02
F4	0.121±0.004	98±5	**24.33**±1.57	**67.40**±0.10	**2.75**±0.04
F5	0.116±0.006	100±5	**23.67**±1.19	**65.53**±0.12	**1.90**±0.03
F6	0.112±0.004	98±5	**25.10**±1.91	**69.43**±0.15	**2.25**±0.01
F7	0.118±0.007	99±5	**15.10**±1.05	**82.82**±0.06	**1.85**±0.03
F8	0.128±0.006	98±5	**15.17**±1.47	**87.60**±0.10	**2.61**±0.02
F9	0.130±0.006	98±5	**28.10**±1.71	**67.63**±0.15	**2.25**±0.04
F10	0.125±0.004	98±5	**20.83**±1.50	**67.63**±0.15	**2.01**±0.01

All value are mean of three reading ± standard deviation The Film thickness was evaluated by using vernier caliper the thickness increases with the increase in the concentration of polymer the thickness was found to be 0.102 ±0.003mm to 0.130±0.006mm and the results was found to be within the limits. The folding endurance of all the formulations were measured manually and it was found to be 98±5 to 100±5. It shows good flexibility. Folding endurance results indicated that the film would not break. The disintegration time of all the formulations was found to be 11.43 ±0.67sec to 28.10±1.71sec. The combination of HPMC and starch showed fast disintegration compared to other combinations (F2 11.43±0.67). Prepared Films were evaluated for weight variation. Percentage deviation from the average weight was found to be within the prescribed official limits. The weight depends on the concentration of the polymer. The weight variation was found to be 61.60 ±0.10mg to 87.60 ±0.10mg. The moisture loss of films was found to be 1.15±0.01 to 2.75±0.04. The less moisture loss in the formulations helps the films to remain stable, brittle and free from complete drying.

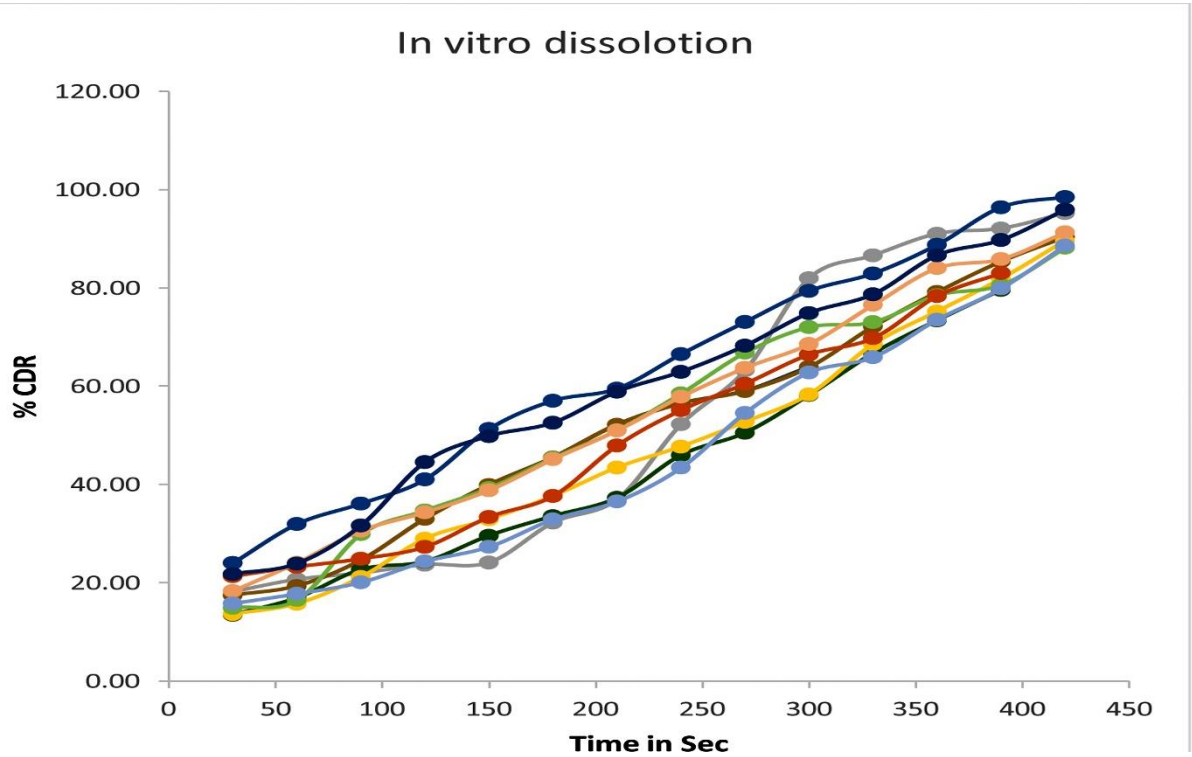
Evaluated for Surface pH, tensile strength, percentage elongation.

Formulation code	Surface pH	Tensile strength (kg/mm^2)	Dispersion Test	Percentage elongation
F1	6.75±0.025	1.021±0.2	Passed	153.23±2.14
F2	6.80±0.031	1.332±0.1	Passed	126.42±1.44
F3	6.72±0.021	0.903±0.3	Passed	110.33±2.54
F4	6.90±0.008	0.813±0.5	Passed	125.54±3.14
F5	7.07±0.051	1.143±0.3	Passed	155.52±1.59
F6	6.81±0.014	1.021±0.2	Passed	132.63±2.72
F7	6.70±0.025	0.865±0.1	Passed	164.37±3.09
F8	6.54±0.032	0.942±0.5	Passed	129.43±2.43
F9	6.61±0.016	1.232±0.2	Passed	130.35±2.55
F10	6.82±0.009	1.012±0.3	Passed	145.22±2.16

All value are mean of three reading ± standard deviation The surface pH of all the films was found to be 6.54±0.032 to 7.07±0.051. Since the surface pH of all the film was found to be around neutral pH, there will not be any kind of irritation to the mucosal oral cavity. The tensile strength of film was found to be 0.813±0.5 to 1.332±0.1. The film passed the dispersion test. The percentage elongation of film was found to be 110.33±2.54 to 164.37±3.09. This represents the elasticity of the film.

❖ **In Vitro Dissolution study**

Time (Sec)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
30	18.19	24.05	17.45	13.49	13.63	14.91	21.36	18.34	15.80	21.78
60	20.69	31.97	19.33	16.90	15.74	16.53	23.25	24.08	17.79	23.90
90	21.97	36.13	24.60	22.67	21.19	29.92	24.89	30.62	20.11	31.66
120	23.69	41.06	33.02	24.30	28.98	34.72	27.32	34.34	24.37	44.58
150	24.13	51.32	39.90	29.56	32.93	39.28	33. 40	38.84	27.35	49.85
180	32.26	57.06	45.50	33.55	37.67	45.43	37.67	45.17	32.92	52.58
210	37.00	59.52	52.16	37.29	43.46	51.07	47.95	51.00	36.58	58.90
240	52.29	66.55	56.50	45.98	47.72	58.56	55.14	57.89	43.47	62.94
270	63.27	73.10	59.03	50.54	52.76	66.86	60.53	63.76	54.58	68.27
300	82.00	79.41	63.91	58.22	58.34	72.05	66.46	68.62	62.82	74.90
330	86.64	82.96	72.19	66.72	68.56	73.07	69.81	76.59	65.93	78.73
360	91.05	88.80	79.20	73.42	75.22	78.54	78.37	84.07	73.56	86.67
390	92.12	96.43	85.45	79.62	81.89	80.63	83.05	85.90	79.93	89.77
420	95.25	98.52	90.42	86.89	89.62	88.21	92.70	91.34	88.64	95.96

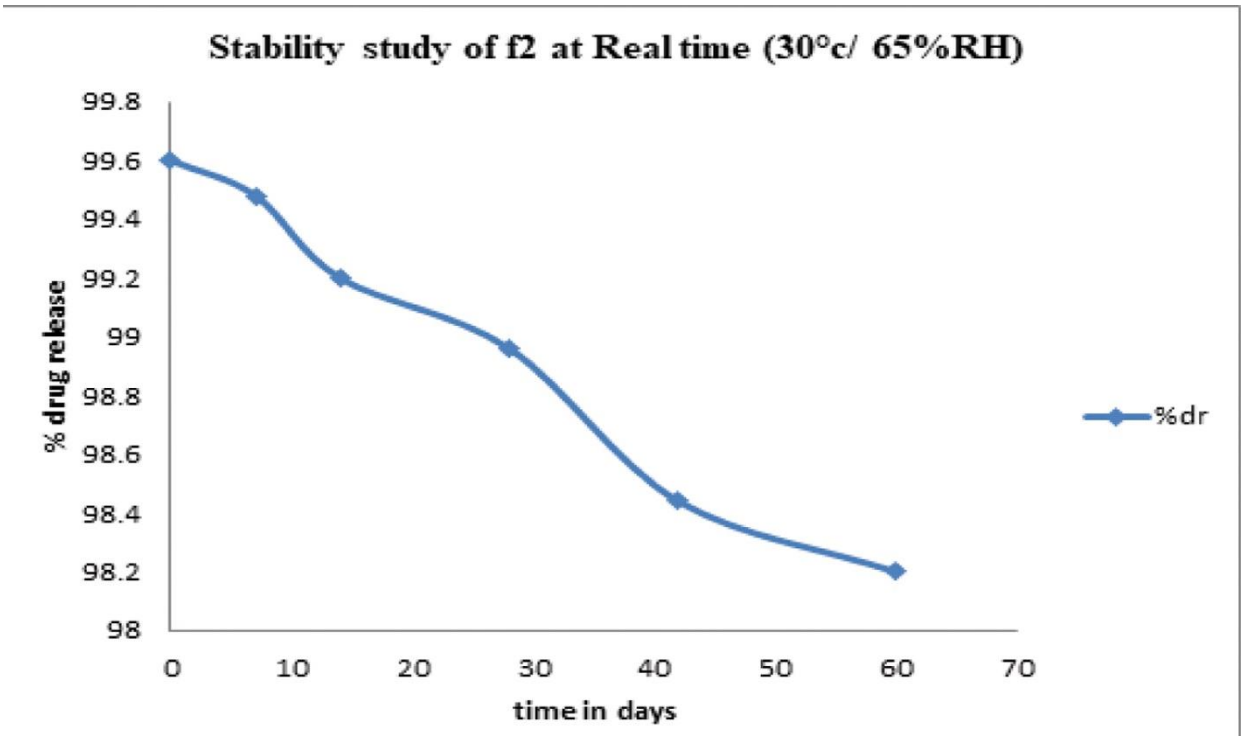


❖ **I n vitro dissolution profile of ondansetron hydrochloride from all films**

Drug release profile was studied using percentage drug release versus time (Sec) plot. Formulations F1, F2, F3 and F4 showed 95.25%, 98.52%, 90.42% and 86.89%. Release of drug respectively at 7 min. Formulations F5, F6, F7, F8, F9and F10 showed 86.89%, 88.21%, 92.70%, 91.34%, 88.64% and 95.96% respectively. F2 formulation showed the best drug release compared to other combinations.

Stability studies for optimized formulations. Stability studies of F2 formulation at Real time 30°c/ 65%RH and Accelerated 40°c/75%

Time in days	Real time (30°c/ 65%RH)		Accelerated (40°c/75% RH)	
	% drug release	Drug content (mg)	% drug release	Drug content (mg)
0	99.6	98.52	99.6	98.52
7	99.48	98.09	99.36	98.11
14	99.2	97.41	98.88	97.38
28	98.96	97.3	98.72	97.13
42	98.44	96.9	97.96	96.7
60	98.2	96.1	97.24	96.03



The results of the Stability study for F2 formulation are given in Table No. 10. The stability studies carried out as per ICH guidelines for 2 months the results showed that the formulations were stable and intact without any interaction. F2 were subjected for stability studies the results observed were not much varied in integrity of the Films at different temperature conditions. There was no significant change in drug content and in-vitro release study.

CONCLUSION:

OFDFs are not well defined in the literature but, no doubt a revolutionary and an innovative drug delivery system for all the population groups, specifically geriatric, pediatric patients and patients with swallowing difficulties. OFDFs are also having great potential of delivering the medicinal agent systemically as well locally and have several advantages over many dosage forms even over the fast disintegrating tablets. This explains the extensive research actively going on this technology

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