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Research

Formulation Development And In Vitro Evaluation Of Oral Dissolving Films Containing Palonosetron

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Abstract

Palonosetron is an 5-HT3 antagonist used in the prevention and treatment of chemotherapy-induced nausea and vomiting (CINV). It is used for the control of delayed CINV—nausea and vomiting and there are tentative data to suggest that it may be more effective than granisetron. Present work aimed at preparing quick onset of action which is beneficial in hypertension, aiding in the enhancement of bioavailabity and is very convenient for administration without the problem of swallowing and using water. The film were prepared by using polymers such asPolyvinyl alcohol, Maltodextrin and Propylene glycol by a solvent casting method. They were evaluated for physical characteristics such as Thickness, Weight Variation, Disintegration time, Drug content, Tensile strength, % Elongation, Folding Endurance and *Invitro* Dissolution Studies give satisfactory results. The *in vitro* dissolution time of the optimized batch F4 was found to be 98.97%. The optimized batch *in vitro* disintegration time was found to 14 sec.

Keywords: In Vitro, Films

INTRODUCTION

The oral route is one of the most preferred routes of drug administration as it is more convenient, cost effective, and ease of administration lead to high level of patient compliance. The oral route is problematic because of the swallowing difficulty for pediatric and geriatric patients who have fear of choking. Patient convenience and compliance oriented research has resulted in bringing out safer and newer drug delivery systems. Recently, fast dissolving drug delivery systems have started gaining popularity and acceptance as one such example with increased consumer choice, for the reason of rapid disintegration or dissolution, self-administration even without water or chewing. Fast dissolving drug delivery systems were first invented in the late 1970s as to overcome swallowing difficulties associated with tablets and capsules for pediatric and geriatric patients. Buccal drug delivery has lately become an important route of drug administration. Various bioadhesive mucosal dosage forms have been developed, which includes adhesive tablets, gels, ointments, patches, and more recently the use of

polymeric films for buccal delivery, also known as mouth dissolving films. The surface of buccal cavity comprises of stratified squamous epithelium which is essentially separated from the underlying tissue of lamina propria and submucosa by an undulating basement membrane.[1,2] It is interesting to note that the permeability of buccal mucosa is approximately 4-4,000 times greater than that of the skin, but less than that of the intestine.[3] Hence, the buccal delivery serves as an excellent platform for absorption of molecules that have poor dermal penetration.[4] The primary barrier to permeability in otiral mucosa is the result of intercellular material derived from the so-called 'membrane coating granules' present at the uppermost 200 μm layer.[5] These dosage forms have a shelf life of 2-3 years, depending on the active pharmaceutical ingredient but are extremely sensitive to environmental moisture.[6]

An ideal fast dissolving delivery system should have the following properties: High stability, transportability, ease of handling and administration, no special packaging material or processing requirements, no water necessary for application, and a pleasant taste. Therefore, they are very suitable for pediatric and geriatric patients; bedridden patients; or patients suffering from dysphagia, Parkinson's disease, mucositis, or vomiting. This novel drug delivery system can also be beneficial for meeting current needs of the industry. Rapidly dissolving films (RDF) were initially introduced in the market as breath fresheners and personal care products such as dental care strips and soap strips. However, these dosage forms are introduced in the United States and European pharmaceutical markets for therapeutic benefits. The first of the kind of oral strips (OS) were developed by the major pharmaceutical company Pfizer who named it as Listerine® pocket packs™ and were used for mouth freshening. Chloraseptic relief strips were the first therapeutic oral thin films (OTF) which contained[7] benzocaine and were used for the treatment of sore throat. Formulation of fast dissolving buccal film involves material such as strip-forming polymers, plasticizers, active pharmaceutical ingredient, sweetening agents, saliva stimulating agent, flavoring agents, coloring agents, stabilizing and thickening agents, permeation enhancers, and superdisintegrants. All the excipients used in the formulation of fast dissolving film should be approved for use in oral pharmaceutical dosage forms as per regulatory perspectives.

Advantages

- Oral films have some special advantages over other oral dosage forms given as follows:
- Rapidly dissolved and disintegrated in the oral cavity because of large surface area which lowers dosage interval, improves onset of action, efficacy and safety profile of therapy.
- Oral films are more flexible, compliant and are not brittle as ODTS.
- Easily handled, storage and transportation.
- Accuracy in the administered dose is assured from every strip or film.
- Pharmaceutical companies and customers practically accepted OTFs as an alternative of conventional OTC dosage forms such tablets and capsules etc. (Frey, 2006).
- Oral film is desirable for patient suffering from motion sickness, dysphagia, repeated emesis and mental disorders.
- From commercial point of view, oral films provide new business opportunity like product differentiation, promotion etc.[8,9]

Disadvantages

The main disadvantage of this delivery system is we cannot incorporate high dose into strip or film. Novartis consumer health's Gas-x thin strip has loaded 62.5mg of simethicone per strip but there remain number of limitations with the use of film strips.[10]

Ideal Characteristics of a Suitable Drug Candidate[11]

- The drug should have pleasant taste.
- The drug to be incorporated should have low dose up to 40 mg.
- The drug should have smaller and moderate molecular weight.
- The drug should have good stability and solubility in water as well as saliva.
- It should be partially unionized at the pH of oral cavity.
- It should have ability to permeate the oral mucosal tissue.

Classification of oral films

There are three types of oral films: 1. Flash release; 2. Mucoadhesive melt away wafer; 3. Mucoadhesive sustained release wafers

Applications of oral films in drug delivery

- ✓ Oral drug delivery by sublingual, mucosal and buccal become preferable for therapies in which immediate absorption is required including those used to manage pain, allergies, sleep problems and CNS disorders.
- ✓ **Topical applications,** the oral films are ideal in the delivery of active agents like analgesic or antimicrobial ingredients for the care of wound and other applications.

- ✓ **Gastroretentive dosage systems**, poorly soluble and water soluble molecules
- ✓ of different molecular weights are found in film format [12]. Dissolution of oral films could be initiated by the pH or enzymatic secretion of GIT and are used to treat gastrointestinal disorders.
- ✓ **Diagnostic devices**, Oral films loaded with sensitive reagent to allow controlled release faced to biological fluid for separating multiple reagents to allow a timed reaction within diagnostic device.[13]

Film Forming Polymers [14]

A variety of polymers are available for preparation of fast dissolving oral films. The use of film forming polymers in oral films has attracted considerable attention in medical and nutraceutical applications. The selection of film forming polymers, is one of the most important and critical parameter for the successful development of film formulation. The polymers can be used alone or in combination to provide desired film properties. The polymers used in oral film formulation should be:

- ✓ Nontoxic and nonirritant.
- ✓ Devoid of leachable impurities.
- ✓ Should not retard disintegration time of film.
- ✓ Tasteless.
- ✓ Should have good wetting and spread ability property.
- ✓ Should have sufficient peel, shear, and tensile strength.
- ✓ Readily available.
- ✓ Inexpensive.
- ✓ Sufficient shelf life.
- ✓ Should not aid in causing secondary infections in oral mucosa.

Presently, both natural and synthetic polymers are used for the preparation of orally dissolving films. represent various natural and synthetic polymers used for preparation of fast dissolving films. represent the quality parameters of natural and synthetic polymers, respectively.

MATERIALS

Palonosetron-Procured From MSN labs, Hyderabad, India. Provided by SURA LABS, Dilsukhnagar, Hyderabad, Polyvinyl alcohol-Fisher Scientific, India, Maltodextrin-Morepen labs ltd, Parwanoo (HP), India, Propylene glycol-Praavar Chemtech, Mumbai, D.W-Millipore system, Citric Acid-S.d.fine chem. Ltd, Mumbai, India, Cross Povidone-Signet Chemical Corporation, Mumbai, Mannitol-S.d.fine chem. Ltd, Mumbai, India.

METHODOLOGY

I Drug Polymer Compatibility Studies Using FTIR
II Construction of Calibration Curve
III Preparation of Oral Disintegrating Films
IV Evaluation of Oral Disintegrating Films formulation

- Thickness
- Weight of films
- Percentage elongation
- Tensile strength
- Folding endurance
- Drug content estimation
- Disintegration test
- In vitro dissolution test

Drug –Polymer compatibility studies by FT-IR

Drug polymer compatibility studies were performed by FT-IR (Fourier transform infrared spectroscopy). In order to confirm that the entrapment of drug within the polymeric systems involve only the physical process and no interaction between drug and polymer. FTIR absorption Spectras were shows no significant interaction between drug and polymers.

Selection of the drug

- ✓ The Palonosetron which has significantly different pharmacokinetic profiles.
- ✓ Palonosetron is a 5-HT3 antagonist used in the prevention and treatment of chemotherapy-induced nausea and vomiting (CINV). It is used for the control of delayed CINV—nausea and vomiting and there are tentative data to suggest that it may be more effective than granisetron.

- ✓ Palonosetron was soluble in water and in solvents.
- ✓ Palonosetron was stable at salivary pH.

Construction of calibration curve for Palonosetron

Determination of λmax

Palonosetron λmax was determined by spectrophotometer using pH 6.8 buffer medium. First dissolve 10mg of pure drug in 10ml of 6.8 buffer medium. From this 10µg/ml solution was prepared by using 6.8 buffer. 10µg/ml solution absorbance was measured at 200-400 nm range by spectrophotometrically using 6.8 buffer as reference solution.

Preparation of calibration curve

Primary stock solution: Standard calibration curve of Palonosetron in 6.8 buffer were prepared. First dissolve 10mg of pure drug in 10ml of 6.8 buffers this is primary stock solution.

Second stock solution: From the above primary stock solution pipette out 1ml of solution and again make up to 10ml this is secondary stock solution. From this secondary stock solution different concentrations of Palonosetron (5, 10, 15, 20, and 25 µg/ml) in 6.8 buffer were prepared and absorbance of these solutions measured at 210 nm by spectrophotometrically using 6.8 buffer as reference solution.

Preparation of mouth dissolving films

General method of formulation of oral dissolving films

Following processes are generally used to manufacture the mouth dissolving film.

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

The current preferred manufacturing process for making this film is solvent casting method. In this method water soluble polymer is dissolved in suitable solvent to make homogenous viscous solution. In this other excipients (plasticizer and sweetner) including drug resinate complex were dissolved under stirring. Then the solution is degassed by keeping it in the sonicator. The resulting bubble free solution poured into petriplate and was kept in oven. Dried film is then cut into the desired shape and size for the intended application.

Preparation of blank films using different polymers

Procedure

- ❖ Accurately weighed quantity of polymer was dissolved in specific quantity of water.
- ❖ The dissolved polymer was made to a uniform dispersion using a homogenizer.
- ❖ During stirring other excipients (plasticizer and sweetner) were added.
- ❖ Then the solution is degassed by keeping it in the Sonicator.
- ❖ The bubble free solution poured into petriplate and was kept in oven.
- ❖ Then the dried films were used to select the best film forming polymers.

Selection of best film forming polymer

The polymer employed should be non-toxic, non-irritant and devoid of leachable impurities. It should have good wetting and spreadability property. The polymer should exhibit sufficient peel, shear and tensile strengths. The polymer should be readily available and should not be very expensive. Film obtained should be tough enough to avoid the damage while handling or during transportation.

Different Polymers Used For Trails

- PVA
- MD
- PG

Preparation of oral fast dissolving film

The fast dissolving films of Palonosetron were prepared by solvent casting technique. The fast dissolving films were prepared using different polymers like PVA ,MD and Propylene Glycol (PG). Propylene Glycol (PG) was used as plasticizer. The calculated amount of polymer was dispersed in the solvent with continuous stirring using magnetic stirrer and the homogenous solution is formed. Then add 4 ml of plasticizer. Then the sweetner and flavor was added to drug mixed polymeric solution. Then the solution was kept in sonicator for degassing. Then the bubble free solution was casted on to petriplate and was kept in hot air oven. Dried film is then cut into

the desired shape and size (1cm x 1cm) for the intended application. By carrying out the trial and error method different quantity of film forming polymers were used for optimizing the formulation.

Formulation of Palonosetron oral fast dissolving films

Table 1: Composition of Palonosetron oral dissolving films

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Palonosetron	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
Polyvinyl alcohol	25	50	75	-	-	-	-	--	-
Maltodextrin	-	-	-	25	50	75	-	-	-
Propylene glycol	-	-	-	-	-	-	25	50	75
D.W	qs	qs	qs	qs	qs	qs	qs	qs	qs
Citric Acid	10	10	10	10	10	10	10	10	10
Cross Povidone	15	15	15	15	15	15	15	15	15
Mannitol	15	15	15	15	15	15	15	15	15
Total weight	100	100	100	100	100	100	100	100	100

Drug = Palonosetron, PG = Propylene glycol

RESULTS AND DISCUSSION

Analytical Method Development for Palonosetron

Construction of Calibration Curve

Palonosetron λ_{max} was determined by spectrophotometer using pH 6.8 buffer medium. First dissolve 10 mg of pure drug in 10 ml of 6.8 buffer medium. From this 10 µg/ml solution was prepared by using 6.8 buffer. 10 µg/ml solution absorbance was scanned at 200 to 400 nm range by spectrophotometrically using 6.8 buffer as reference solution and λ_{max} was observed at 210 nm. A standard graph of pure drug in suitable medium was prepared by plotting the concentration (µg/ml) on X-Axis and absorbance on Y-Axis. An excellent correlation co-efficient (R^2=0.999) was observed.

Table 2: Calibration Curve values of Palonosetron in phosphate buffer pH 6.8 at λ_{max} =210nm

Concentration (µg/ml)	Absorbance λ_{max} =210 nm
0	0
5	0.147
10	0.313
15	0.492
20	0.654
25	0.823

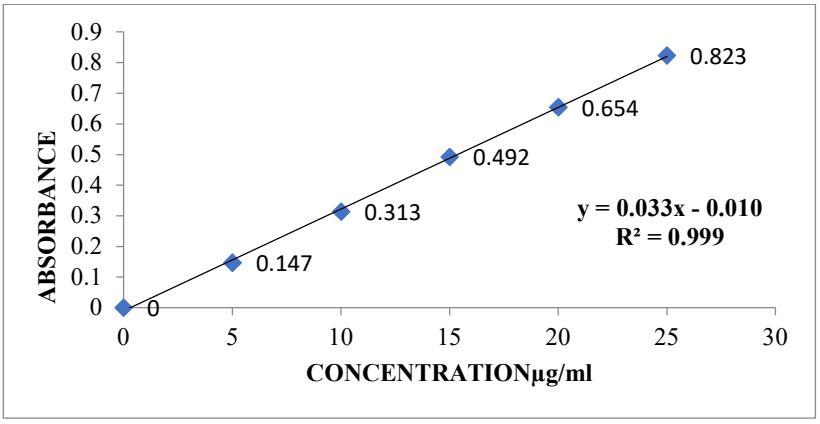

Fig 1: Calibration curve of Palonosetron in pH 6.8 phosphate buffer at λ_{max} =210 nm

Drug-Excipient Compatibility (FTIR studies)

IR spectral analysis was carried out using FT-IR and the results showed that there were no interactions between drug and Excipients.

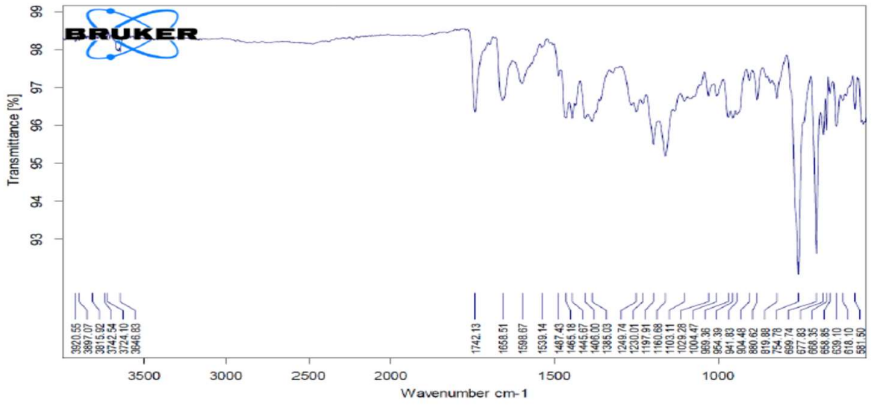

Fig 2: Palonosetron Pure Drug FTIR

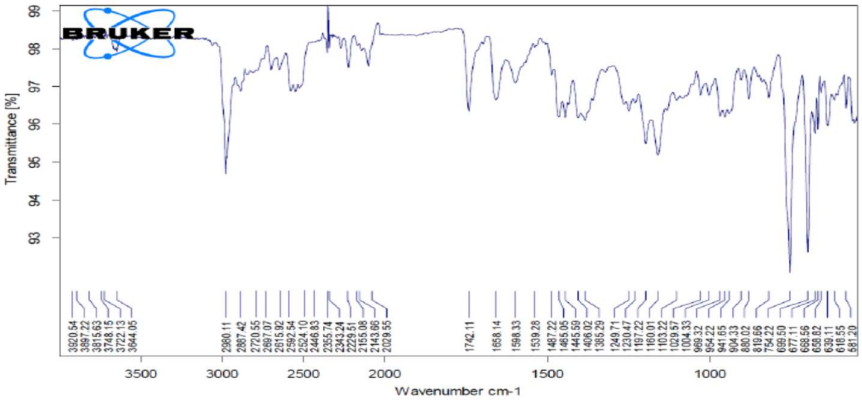

Fig 3: Palonosetron Optimised Formulation FTIR

There was no disappearance of any characteristics peak in the FTIR spectrum of drug and the polymers used. This shows that there is no chemical interaction between the drug and the polymers used. The presence of peaks at the expected range confirms that the materials taken for the study are genuine and there were no possible interactions. Palonosetron are also present in the physical mixture, which indicates that there is no interaction between drug and the polymers, which confirms the stability of the drug.

Evaluation of oral disintegrating films

Oral Disintegrating Films were evaluated for the following parameters.

Palonosetron Oral Disintegrating Films were evaluated for

1) Weight Variation
2) Thickness
3) Tensile strength
4) Percent elongation
5) Folding endurance
6) Disintegration time
7) Content uniformity
8) *In Vitro* dissolution studies

Weight Variation

Nine films of Palonosetron each of 2x2 cm^2 size were cut at five different places from casted films and weight variation was measured. Weight variation varies according to official limits. The results of weight variation are shown in the table.

Thickness

The thickness of the drug loaded films was measured with screwguage. The results of thickness are shown in the table.

Tensile strength& Percent elongation

Tensile strength of the film was determined with digital tensile tester. The film of specific size 3 inch x 10 mm was taken for the test. From the results it is clear that as the concentration of polymer increases the tensile strength of the film also increases. The formulation F4 shows the maximum tensile strength, percent elongation and folding endurance. This might be formation of strong hydrogen bonds between polymer and plasticizer there by imparting flexibility to withstand rupture. The results of Tensile strength & Percent elongation of the film was mentioned in the table.

Folding endurance

Folding endurance was measured manually. A strip of 2 cm^2 was cut and subjected for this study. As the concentration of polymer increases folding endurance of the film also increases. The result of folding endurance of the film was mentioned in the table.

Disintegration Time

Disintegration test was performed in the USP disintegration testing apparatus. Phosphate buffer of pH 6.8 was used as medium. The films were placed in the tubes of the container and the disks were placed over it. Disintegration time of the films was found to be increased with increase in the concentration of the polymer. The results are reported in the table.

Drug Content Uniformity

The prepared formulations were analyzed for drug content and it was observed that all the formulations found to contain almost uniform quantity of drug. The results are reported in the table.

***In- Vitro*-dissolution studies**

Dissolution profiles from films of Palonosetron were carried out in USP dissolution apparatus-II. The results are reported in the table.

Table 3: Mechanical properties of all formulations

Formulation Code	Tensile strength (kg)	% Elongation	Folding Endurance
F1	2.18 ± 0.11	6.1 ± 0.93	128.66 ± 5.87
F2	1.98 ± 0.16	6.34 ± 0.81	120.66 ± 5.29
F3	2.1 ± 0.10	6.67 ± 0.62	122.35 ± 6.45
F4	0.760 ± 0.72	2.4 ± 0.59	105.25 ± 4.56
F5	0.810 ± 0.51	2.74 ± 0.69	103.33 ± 9.87
F6	0.732 ± 0.66	2.24 ± 0.57	93.66 ± 8.12
F7	0.670± 0.635	2.29 ± 0.78	95.66 ± 6.23
F8	0.628 ± 0.59	1.99 ± 0.67	98.41 ± 5.88
F9	0.606 ± 0.61	1.92 ± 0.82	99.33 ± 7.67

Table 4: Physical evaluation parameters of all formulations

Formulation Code	Thickness (mm)	Weight Variation (mg)	Disintegration time (sec)	Drug content (%)
F1	1.14	99	15	98.32
F2	1.26	98	20	99.14
F3	1.28	97	18	98.96
F4	1.33	100	14	99.54
F5	1.19	98	22	99.22
F6	1.19	99	19	99.31
F7	1.24	99	17	98.07
F8	1.12	97	21	98.13
F9	1.25	100	19	99.10

***Invitro* Dissolution Studies**

Invitro dissolution of Palonosetron Oral Disintegrating Films was studied in paddle type dissolution test apparatus. 900 ml of 6.8 phosphate buffer solution was used as dissolution medium. The stirrer was adjusted to rotate at 50 rpm. The temperature of dissolution medium was maintained at 37±0.5ºC throughout the experiment Samples of dissolution medium (5ml) were withdrawn by means of syringe fitted with pre filter at known intervals of time and analyzed for drug release by measuring the absorbance at 210 nm. The volume withdrawn at each time interval was replaced with fresh quantity of dissolution medium. Cumulative percent of Palonosetron release was calculated and plotted against time.

Table 4: *In vitro* drug releases for F1 to F9 formulations

TIME	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
5	39.22	41.33	43.88	49.22	47.55	43.55	38.22	42.66	47.52
10	48.59	52.71	55.38	63.58	61.9	57.40	46.33	54.33	58.61
15	61.17	65.31	69.44	73.75	66.27	64.06	59.72	71.27	68.77
20	72.31	76.46	78.05	86.52	82.89	75.34	71.11	83.61	79.16
30	86.33	89.60	91.75	98.97	96.33	94.35	89.88	93.57	88.61

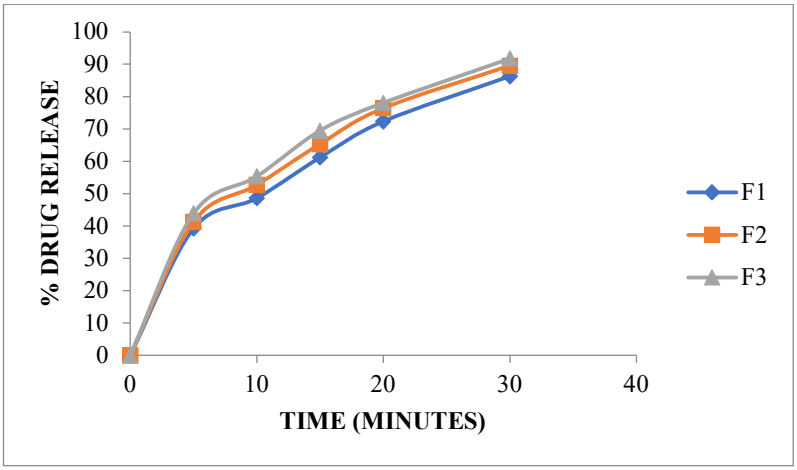

Fig 4: Comparison curve of *Invitro* drug release for F1- F3 formulations

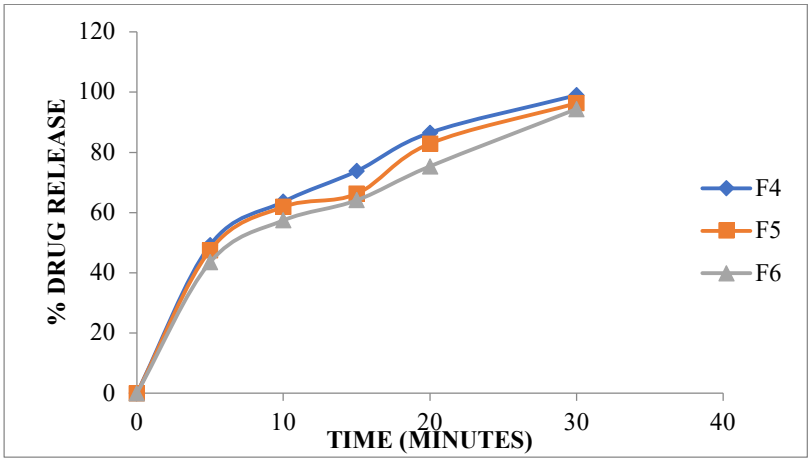

Fig 5: Comparison curve of *Invitro* drug release for F4- F6 formulations

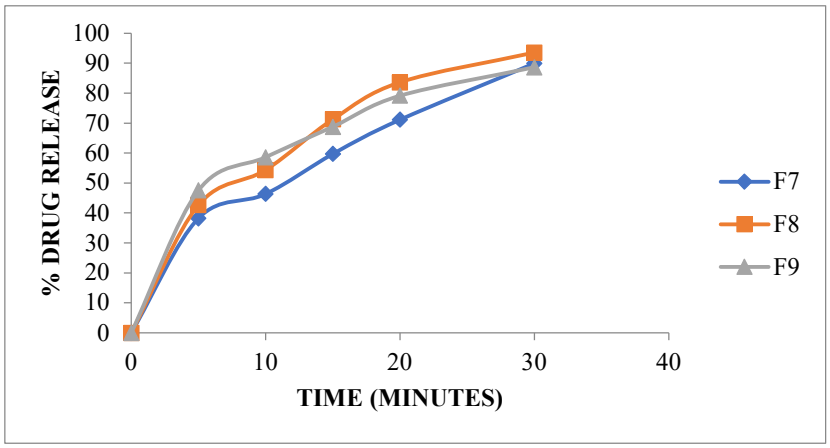

Fig 6: Comparison curve of *Invitro* drug release for F7- F9 formulations

Invitro dissolution study of formulations F1-F9 shown Good drug release respectively within 30min. Among the all formulations F4 showed good dissolution property. F4 batch contain MD as film forming polymer.

DISCUSSION

Analytical method development for Palonosetron λ max determination: Λ max determination of Palonosetron pH 6.8 phosphate buffer was determined by using UV Spectrophotometer at 210 nm.
Development of standard graph: Standard plot of Palonosetron pH 6.8 phosphate buffer were plotted to concentration vs absorbance at 210 nm and the slope value and R^2 value were found to be 0.999.
Evaluation properties: The different Palonosetron film formulations were evaluated for mechanical properties like thickness, drug content uniformity, folding endurance, tensile strength, weight uniformity, disintegration time, *in vitro* dissolution studies.

Thickness

The thickness of the films from F1-F9 formulations were ranged from 1.12 to 1.33 and F4 formulation had the maximum thickness values in all the formulations. From the thickness values it is concluded that as the polymer concentration increases, thickness also increased.

Tensile strength& Percentage elongation

The tensile strength of the films from F1-F9 formulations were ranged from 0.606 ± 0.61 to 2.18 ± 0.11 kg. elongation 1.92 ± 0.82 to 6.67 ± 0.62. F4 formulation had the maximum tensile strength and. From the tensile strength values it is concluded that as the polymer concentration increases, tensile strength and percentage elongation also increased.

Drug content uniformity

The drug content uniformity of the films from F1-F9 formulations were ranged from 98.07 % to 99.54 %. F4 formulation had the maximum drug content uniformity.

Folding endurance

The folding endurance value of the films from F1-F9 formulations were ranged from 93.66 ± 8.12 to 128.66 ± 5.87. In MD containing formulations as polymer concentration increases folding endurance values were also increased.

Weight uniformity

Weight uniformity of films were carried out for all the formulations and weight variation varies from 97 to 100 mg.

Disintegration time

The disintegration time is the time when a film starts to break or disintegrate. The *in vitro* disintegration time was calculated for all the formulations and it ranges from 14sec to 22 sec Disintegration time of the films was increased with increase in concentration of the polymer, as more fluid is required to wet the film in the mouth. F3

formulation was quickly disintegrated that is in 14 sec. Finally selection of the best formulation from all the formulations was carried by using *In Vitro* dissolution studies.

***In vitro* dissolution studies**

In vitro dissolution study of F1-F9 formulations were showed different drug release of 91.75 %, 98.97 %, 93.57 %, respectively within 30min. Among the formulations F4 showed good dissolution property hence it is optimized and it contain 25 mg of Maltodextrin as film forming polymer. Small differences were observed in dissolution of drug from the different formulations of the film. Present study reveals that maximum all formulated films showed satisfactory film parameters. Among the optimized formulations F4 formulation showed better drug release of 98.97% within 30 min. So, it is assumed that 25 mg Maltodextrin containing oral fast dissolving film was optimized in which it showed a drug release of 98.97% compared with other batch formulations.

CONCLUSION

The Palonosetron oral films could be promising one as they, increase bioavailability, minimize the dose, reduces the side effects and improve patient compliance and also Palonosetron might be a right and suitable candidate for oral delivery. Low dose of drug can be suitable for oral films with low density of polymers. ODF are the thin film with more surface area they get wet quickly and disintegrate then dissolve faster than other formulations. From the present investigation it can be concluded that Oral Disintegrating Films formulation can be a potential novel drug dosage form for pediatric, geriatric and also for general population. The prepared Palonosetron oral films were characterized based upon their physiochemical characteristics like tensile strength, Disintegration time, thickness, weight uniformity, folding endurance, drug content uniformity, dissolution studies. all the results were found to be were found to be within the pharmacopeia limits. Based on the results F4 was the best one when compared to other. Based on disintegration and drug releases faster of the ODF formulation F4 has less disintegration time and compare to F1, F8 and F7. So ODF formulated with Maltodextrin Polymer F4 is best formulation.

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