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# PREPARATION AND EVALUATION OF PALONOSETRON ORODISPERSIBLE FILMS USING POLYVINYL ALCOHOL, MALTODEXTRIN AND PROPYLENE GLYCOL

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**Abstract:**

*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. Present work aimed at preparing quick onset of action which is beneficial in hypertension, aiding in the bioavailabity enhancement and its convenience for administration. The film was prepared by using polymers Polyvinyl 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 disintegration time and dissolution time of the optimized batch F4 was found to be14 sec and 98.97% respectively.*

***Keywords:*** *Palonosetron, bioavailability, oral fast dissolving films.*

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## 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. Various bio-adhesive 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 super-disintegrants. 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.

**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 [4]. 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.[5]

**Film Forming Polymers [6]**

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.

**ORAL STRIP FORMULATION COMPONENTS**

- ✓ Active pharmaceutical ingredients
- ✓ Strip forming polymers
- ✓ Plasticizers
- ✓ Sweetening agents
- ✓ Saliva stimulating agents
- ✓ Flavoring agents
- ✓ Coloring agents
- ✓ Stabilizing and thickening agents

**Scope of Research**

Lower bioavailability of oral solid drugs, inconvenience of administering injections, inaccurate dosing by liquid formulations have turned the focus of pharmaceutical companies to develop novel oral dosage forms that eliminate several known limitations. Oral thin films are able to meet most of these challenges. In addition to the drugs, several hormones and vaccines are also being formulated into oral thin films with the aim of providing improved patient compliance. Some of the key players in this area include MonoSol Rx, Applied Pharma Research/Labtec GmbH, BioDelivery Sciences and NAL Pharma.

## MATERIALS AND METHODOLOGY:

**Materials**

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

**Methodology**

**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**

1. **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.
2. **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 excipient (plasticizer and sweetener) 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.

**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(mg) | 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 D.W= distilled water.

**EVALUATION OF FAST DISSOLVING FILMS**

**Thickness**

As the thickness of film is directly concern with drug content uniformity so it is necessary to ascertain uniformity in the thickness of the film. It can be measured by micrometer screw gauge or calibrated digital Vernier Calipers at different strategic locations. The thickness was measured at three different spots of the films and average was taken[1].

**Tensile strength**

Tensile strength is the maximum stress applied to a point at which the strip specimen breaks. It is calculated by the applied load at rupture divided by the cross-sectional area of the strip as given in the equation below

Tensile strength = Load at breakage/ Strip thickness × Strip Width

The instrument was designed such that it had horizontal wooden platform with fixed scale and attachments for two clips that holds patch under test. Out of the two clips one was fixed and other was movable. Weights were hanged to one end of pulley and the other end of pulley was attached with movable clip. The wooden platform was such fitted that it would not dislocate while the test is running. Three strips of patch were cut having 2cm length and

2cm breadth. The thickness and breadth of strips were noted at three sites and average value was taken for calculation. The rate of change of stress was kept constant with the increment of 0.5g per 2minutes. The elongation was observed and the total weights taken were used for calculation. The tensile strength was calculated by using following formula.
Tensile stress = applied force/ cross sectional area
$=m \times g / b \times t$
Where, S = tensile stress in 980 dynes/cm2
m = mass in grams
g = acceleration due to gravity (980 dynes/cm2)
b = breadth of strip in centimeters
t = thickness of strip in centimeters
The strain is change resulting in size of strip after the force was applied to its original size. Therefore, the strain can be given as,
Strain (E) = total elongation / original length = $L-L_o/ L_o$
Where, L = length after force was applied
L0 = original length

**Percent elongation**

When stress is applied, a strip sample stretches and this is referred to as strain. Strain is basically the deformation of strip divided by original dimension of the sample. Generally elongation of strip increases as the plasticizer.
% Elongation = Increase in length ×100 / Original length
The percent elongation at break was measured by formula given below.
Strain (E) = total elongation / original length × 100
= L-Lo/ Lo × 100
Where, L = length after force was applied,
Lo = original length

**Folding endurance**

Folding endurance is determined by repeated folding of the strip at the same place till the strip breaks. The number of times the film is folded without breaking is computed as the folding endurance value.

**Physical appearance and surface texture of patch**

These parameters were checked simply with visual infection of films and by feel or touch.

**Weight uniformity of films**

Film (size of 1 $cm^2$) was taken from different areas of film. The weight variation of each film is calculated.

**Drug Content uniformity or Assay of film**

The films were tested for drug content uniformity by UV Spectrophotometric method. Films of 1cm x 1cm square size were cut from three different places from the casted films. Each patch was placed in 10 ml volumetric flask and dissolved in 6.8 phosphate buffer. The absorbance of the solution was measured at 210 nm using UV/visible spectrophotometer. The percentage drug content was determined using the standard graph and the same procedure was repeated for all the formulations.

***In Vitro* Disintegration time**

The in vitro disintegration time of fast dissolving films was determined visually in a glass dish of 8 ml 6.8 pH phosphate buffer with swirling action. The disintegration time is the time when a film starts to break or disintegrate. The *in vitro* disintegration time was calculated for different patches of the same film and average value was taken.

***In Vitro* Dissolution Study**

In vitro dissolution of Palonosetron oral dissolving films was studied in paddle type dissolution test apparatus. 900ml 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. Percentage drug release was calculated and plotted against time.

## RESULTS AND DISCUSSION:

**Analytical Method Development for Palonosetron**

**Construction of Calibration Curve:**

Palonosetron $\lambda_{max}$ 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 $\lambda_{max}$ 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 $\lambda_{max}$ =210nm**

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

**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.

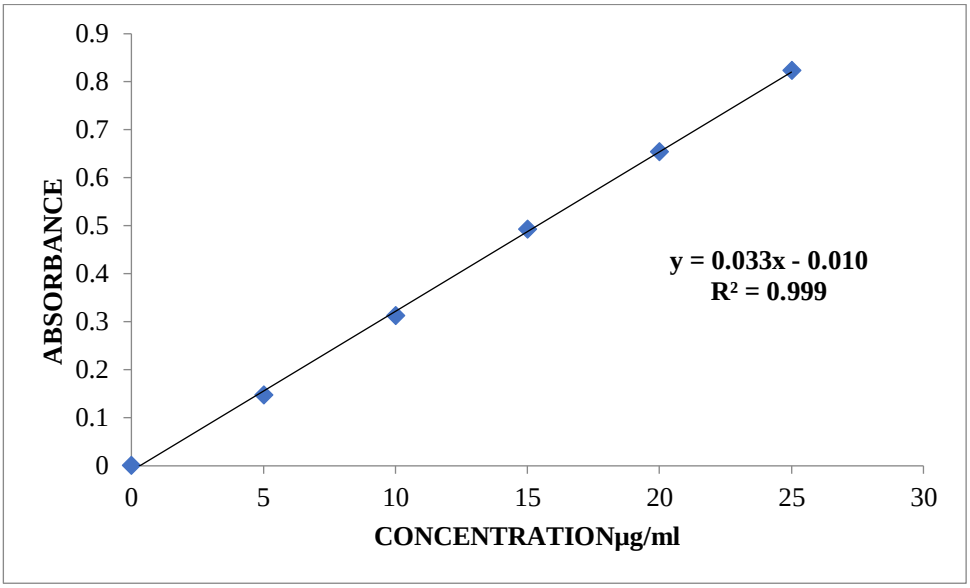


**Figure 1: Calibration curve of Palonosetron in pH 6.8 phosphate buffer at $\lambda_{max}$ =210 nm**

**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 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 3.

**Thickness**

The thickness of the drug loaded films was measured with screwguage. The results of thickness are shown in the Table 3.

**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 3.

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**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 3.

**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 3.

**Table 3 Physical evaluation parameters of all formulations**

| Formulation Code | Tensile strength(kg) | % Elongation | Folding Endurance | Thickness (mm) | Weight Variation (mg) | Disintegration time (sec) | Drug content (%) |
|---|---|---|---|---|---|---|---|
| F1 | 2.18 ± 0.11 | 6.1 ± 0.93 | 128.66 ± 5.87 | 1.14 | 99 | 15 | 98.32 |
| F2 | 1.98 ± 0.16 | 6.34 ± 0.81 | 120.66 ± 5.29 | 1.26 | 98 | 20 | 99.14 |
| F3 | 2.1 ± 0.10 | 6.67 ± 0.62 | 122.35 ± 6.45 | 1.28 | 97 | 18 | 98.96 |
| F4 | 0.760 ± 0.72 | 2.4 ± 0.59 | 105.25 ± 4.56 | 1.33 | 100 | 14 | 99.54 |
| F5 | 0.810 ± 0.51 | 2.74 ± 0.69 | 103.33 ± 9.87 | 1.19 | 98 | 22 | 99.22 |
| F6 | 0.732 ± 0.66 | 2.24 ± 0.57 | 93.66 ± 8.12 | 1.19 | 99 | 19 | 99.31 |
| F7 | 0.670± 0.635 | 2.29 ± 0.78 | 95.66 ± 6.23 | 1.24 | 99 | 17 | 98.07 |
| F8 | 0.628 ± 0.59 | 1.99 ± 0.67 | 98.41 ± 5.88 | 1.12 | 97 | 21 | 98.13 |
| F9 | 0.606 ± 0.61 | 1.92 ± 0.82 | 99.33 ± 7.67 | 1.25 | 100 | 19 | 99.10 |

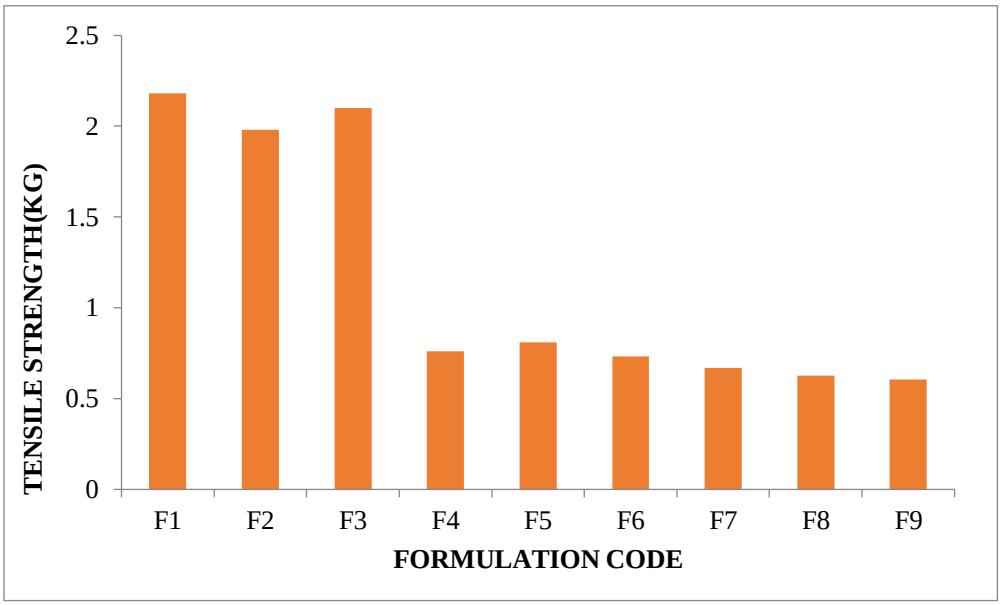


**Figure 2 Tensile strength(kg)**

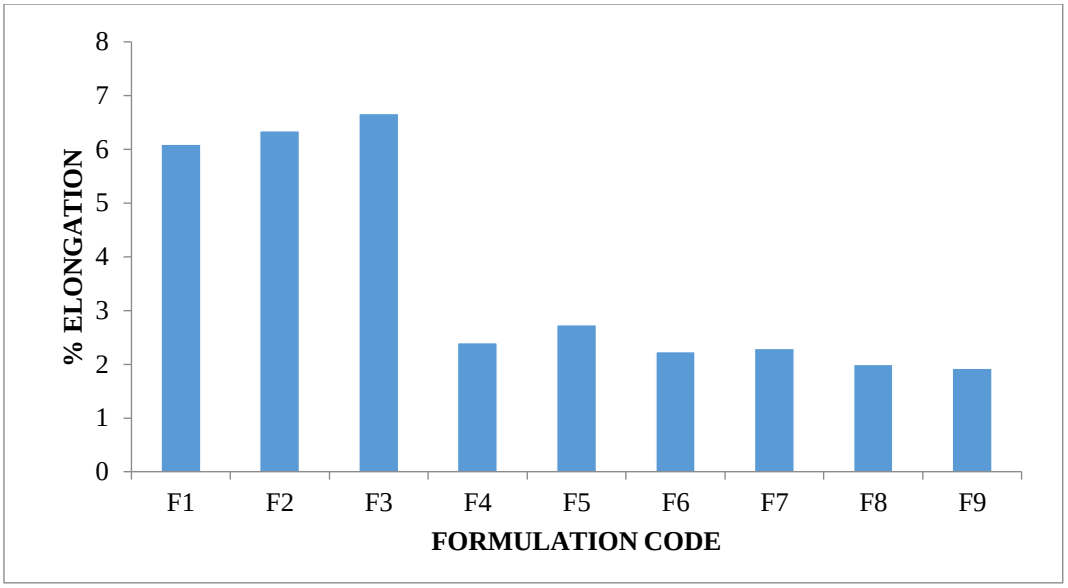


**Figure 3 % Elongation**

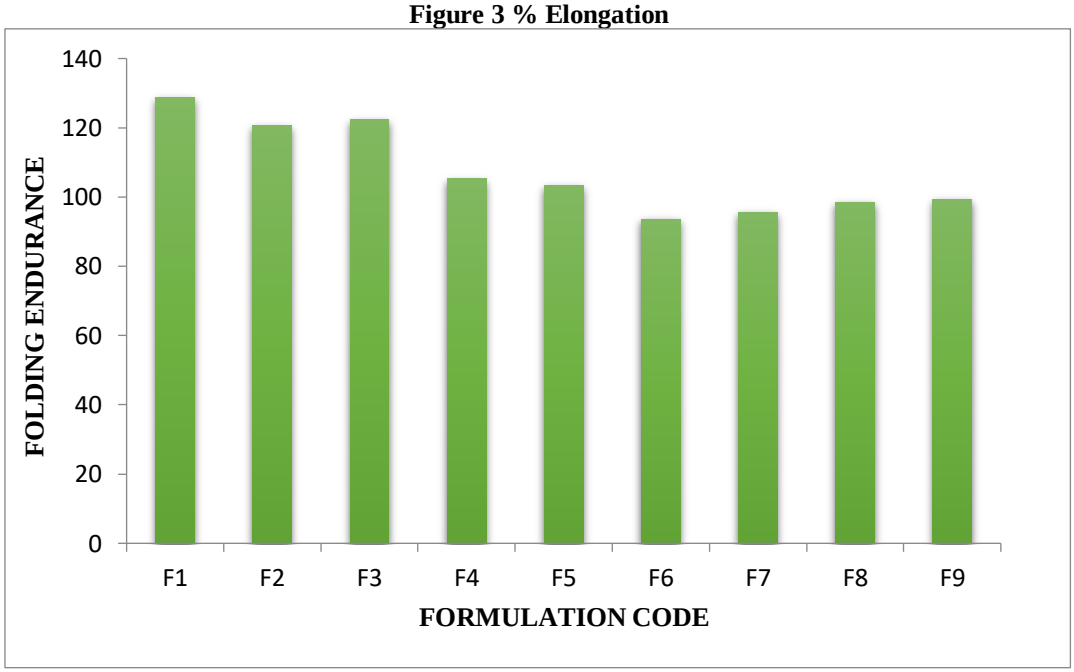


**Figure 4 Folding Endurance**

***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.

***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.

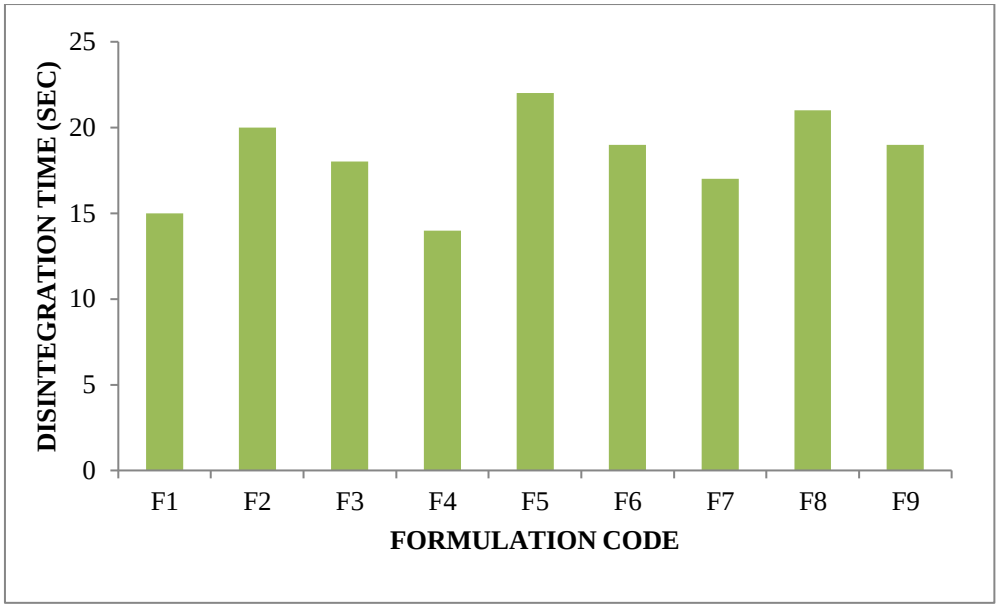


**Figure 5 Disintegration Time (Sec)**

**Table 5 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 |

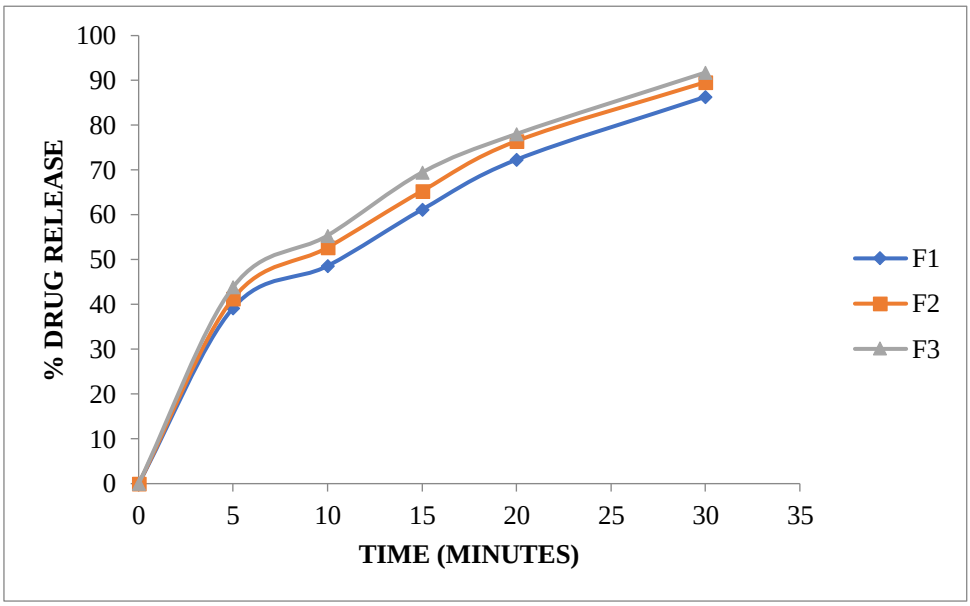


**Figure 6 a Comparison curve of *Invitro* drug release for F1- F3 formulations**

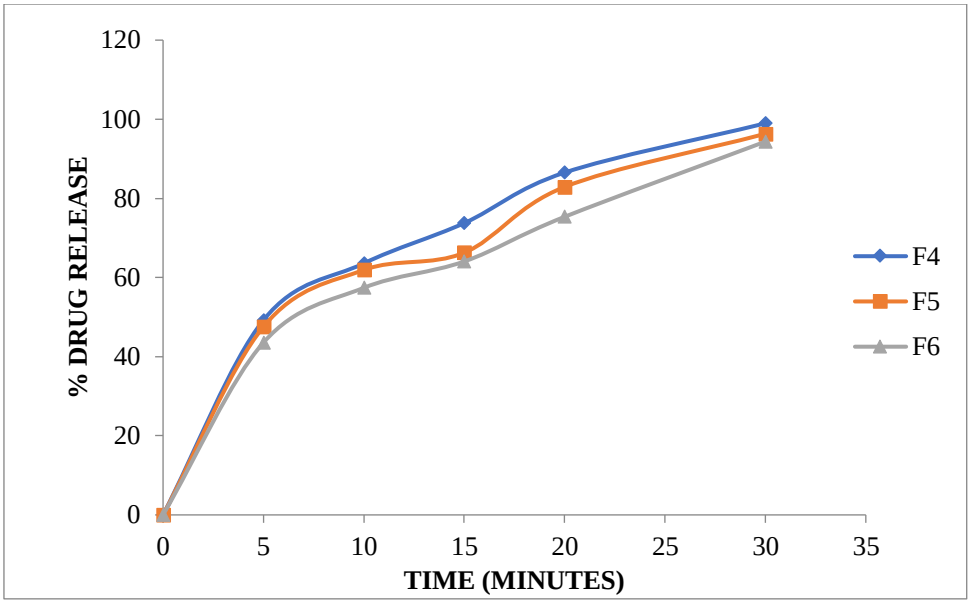


**Figure 6b Comparison curve of *Invitro* drug release for F4- F6 formulations**

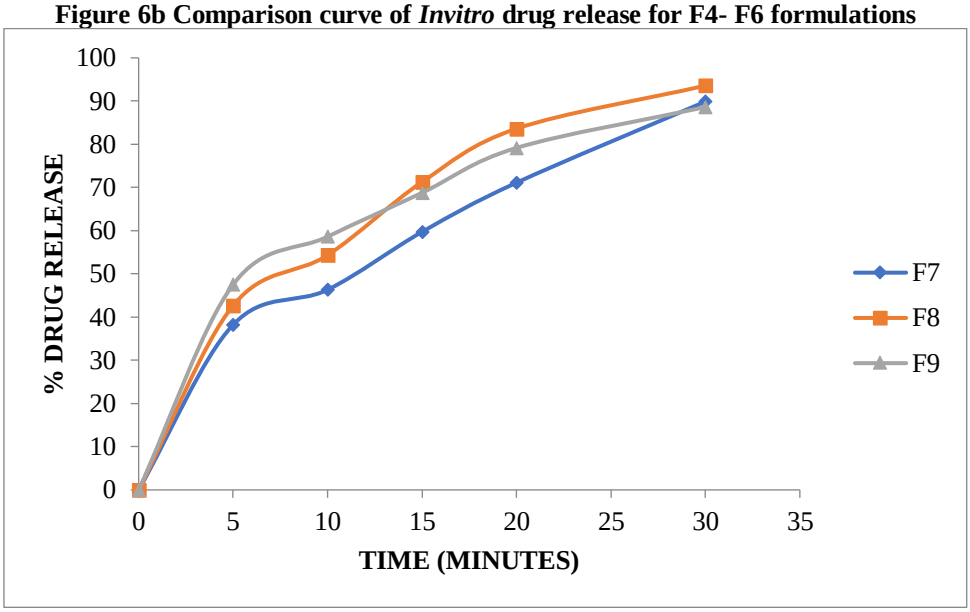


**Figure 6c Comparison curve of *Invitro* drug release for F7- F9 formulations**

*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.

***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 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 acceptable 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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