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Original Article

Efficient Fabrication and Assessment of Telmisartan Fast-Dissolving Films Using Solvent Casting Approach

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ABSTRACT

Introduction: Telmisartan (TLM) is a common angiotensin II receptor antagonist used to treat hypertension. However, the drug's limited bioavailability and delayed onset duration diminish its efficacy. To address these concerns, fast-dissolving TLM films were fabricated in this investigation using the solvent-casting method. **Objectives:** This investigation aimed to create a film formulation of TLM, a widely prescribed antihypertensive medication. The objectives were to optimize the formulation parameters and assess the physicochemical properties, drug release profile and dissolution behavior of the rapidly dissolving TLM film. **Materials and Methods:** The solvent casting method efficiently produces homogeneous, flexible films with desirable properties, such as high drug dosage and rapid dissolution. The Box-Behnken design was utilized to investigate the effect of three distinct, independent variables on the physicochemical properties of FDFs to determine the optimal conditions for FDF production. The films' physicochemical properties, drug release characteristics and pharmacokinetic parameters were evaluated. **Results and Discussion:** The results demonstrated that the films had superior dissolution properties and improved bioavailability compared to conventional TLM tablets, suggesting their potential use as a TLM delivery system. **Conclusion:** The rapidly dissolving film comprising TLM, which exhibits promising drug release

Keywords: Fast dissolving film, Solvent casting Method, Pectin, PVP, TLM.

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INTRODUCTION

The global prevalence of hypertension, sometimes high blood pressure, is staggering. The risk of cardiovascular disease, stroke and other conditions rises with persistent blood pressure against the arterial walls.[1,2] Reducing medicines, such as diuretics, ACE inhibitors and calcium channel blockers, decrease bodily fluid and relax blood arteries.[3-6] Some people find it challenging to chew tablets and hard Gelatine capsules; as a result, they may not take their medications as directed. Around 35% of the population suffers from dysphagia, sometimes known as swallowing difficulties. Solid dose forms may be challenging for patients with mental illness, intellectual impairment, stubbornness and liquid restriction regimens or illness.[7,8] Dysphasia, also known as swallowing difficulties, affects 35% of the general population and is connected with stroke, vascular dementia, AIDS, radiation therapy to the head and neck and additional neurodegenerative problems.[9] To overcome these problems, scientists have created innovative pharmaceutical delivery methods using "melt in the mouth" or "mouth dissolve" tablets.[10] The European Pharmacopoeia defines Oro-dispersible tablets as those that dissolve in less than 3 min when put in the mouth before eating. A unique oral fast-dissolving dosage form has been created that combines the benefits of dosing ease and dosing without water.[11] They are especially beneficial for poorly absorbed medications in the gastrointestinal system, have a short half-life, or need a quick commencement of the action.[12]

Fast-dissolving dosage forms have become increasingly popular in the pharmaceutical industry due to their advantages, such as no need for water, exact dosing and fast onset of action, portability, ease of handling, a pleasing flavor and increased patient compliance.[13] The advantages of these dosage forms include no need for water for disintegration, exact dosing and fast onset of action, portability, ease of handling, a pleasing flavour and increased patient compliance. "Fast-Dissolving Films" (FDF) refer to thin, flexible films that quickly disintegrate in saliva and release drugs for local or systemic distribution. They have become more popular because of how simple it is to administer FDFs, how quickly they start working and how much better patient compliance is. They are used in several medical specialties, such as ophthalmology, neurology and pain treatment. When creating

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and choosing FDF drug delivery systems, it is essential to consider several variables, including the features of the medicine, the film and the patient's preferences. Fast-dissolving films are helpful for people who have problems swallowing standard medications, such as pediatric, elderly, bedridden, or developmentally impaired adults.[14] Solvent casting is a common technique for the Formulation of Fast dissolving films. The film-forming polymer and other excipients must be dissolved in a suitable solvent to create a uniform solution. This uniform solution is then cast onto a substrate and dried to form a thin film. For delivering various medications, including those with poor solubility or limited bioavailability, the solvent casting approach offers an easy-to-use, affordable and flexible tool.[15-17] To provide patients with the most convenient route of administration, it is required to develop a dosage form that dissolves rapidly, particularly one that disintegrates and dissolves/disperses in saliva and may be administered without water.[18]

This research aims to produce a fast-dissolving Telmisartan (TLM) film for providing rapid drug release properties. TLM is an angiotensin II receptor blocker used to treat hypertension and is essential for preventing cardiovascular disease.[19] Owing to significant first-pass hepatic metabolism, its bioavailability is around 45%. In order to enhance bioavailability and block rapid pass metabolism, solvent casting was utilized to produce FDFs loaded with TLM. The solvent casting method involves dissolving the active component and extra excipients in an appropriate solvent, casting the solution onto a flat surface and drying it to produce a thin film. *In vitro* evaluation is vital in making films with fast disintegration, as it determines the film's thickness, weight, disintegration time, drug content and drug release rate. This study seeks to produce and investigate fast-dissolving TLM using a variety of film formers, such as PVA, PVP and pectin. The tests for pharmacological excipient compatibility and *in vitro* disintegration and dissolution are carried out.

MATERIALS AND METHODS

Materials

TLM was a gift sample from Azakem labs Pvt. Ltd., Hyderabad. Polyvinyl alcohol, pectin, polyvinyl Pyrrolidone (PVP), glycerol and potassium hydroxide were purchased from Sisco Research Laboratories Pvt. Ltd., Maharashtra, India. Double distilled water was also used.

Methods

Experimental factorial design

The systematic application of Design of Experiments (DoE) in formulation development involves strategically arranging tests to achieve predetermined objectives with sound justification. The availability of Design-Expert version 11.0, software developed by Stat-Ease Inc. in Minnesota with a specific focus on its commercial aspect, has been confirmed. The Box-Behnken design is a response surface methodology that efficiently optimizes multiple variables while minimizing the required experimental runs. It is widely used in pharmaceutical research to maximize the Formulation of drug delivery systems. In this study, the Box-Behnken design was chosen to investigate the effects of three independent variables with the lowest to highest concentration (PVP concentration, pectin concentration and glycerin concentration) on the physicochemical properties of FDFs (Table 1). The design allows for generating a mathematical model that describes the relationship between the independent variables and the response variables (such as drug release rate, tensile Strength, etc.,), identifying optimal conditions for FDF fabrication (Table 1).

X- Factors, R- Response

Preparation by Solvent Casting Method

In accordance with the formulation table, 0.1 g of PVA was dissolved in 5 mL of water and heated to 80°C to produce a transparent solution (Table 2). Pectin was dissolved in water using a magnetic stirrer and subsequently incorporated into the PVP solution per the formula. The PVP solution is administered gradually through the application of individual droplets. Subsequently, glycerol was incorporated by the prescribed formulation table. The medication known as TLM (at a concentration of 160 mg) was solubilized in a solution of 0.1N potassium hydroxide. This solution was subsequently added to the previous solution and homogenized to ensure uniform distribution. After 15 min of sonication to eliminate air bubbles, the solution was dispensed onto Petri plates and subjected to a drying process at 45°C for 24 hr. The procedure involves peeling the object and cutting it into square shapes measuring 3.5x3.5 cm^2. Subsequently, the films underwent additional assessment. The process of formulating pectin through the solvent-casting method is depicted in Figure 1.

Fourier Transform IR-Analysis (FTIR)

The FT-IR spectra of TLM were acquired using the Potassium Bromide (KBr) palletization method. The medication was mixed with KBr and compressed into a compact, thin disc before FT-IR spectroscopic analysis. The spectra were examined for peaks that matched distinct functional groups in the medication.[20,21]

Physical Appearance Test

A fast-dissolving film is a thin, transparent, flat film that dissolves swiftly in the mouth when exposed to saliva. It should be aesthetically attractive, simple to manipulate and fast dissolving in the mouth, offering a convenient and efficient delivery method for various active chemicals. The film's colour, smell and physical quality containing drugs were evaluated.

Weight variation

Many variables, including Formulation, manufacturing process and storage circumstances, may influence the weight fluctuation of a fast-dissolving film. 3.5x3.5 cm^2 films carrying a pharmacological dose were sliced and weighed on an analytical balance to determine the weight difference (Shimadzu Corporation Japan AUX 220).[15,22]

Thickness

The thickness of the film was measured utilizing a calibrated Vernier caliper manufactured by Mitutoyo in Japan. The measurement on the dial was documented now when the film was positioned onto the anvil. The thickness was measured in three separate locations. As the mean thickness, the average of six measurements was used.[23]

Folding Endurance

Folding durability refers to the number of folds required to cause a specimen to break or develop visible fissures. This reflects the fragility of the film. It was carefully calibrated for the prepared film's 3.5×3.5 cm^2 surface area. This test was conducted on a film from a particular location by folding it in the same plane multiple times until observable fractures occurred.[24]

Tensile Strength

The property that causes a load to bend and collapse a film is its tensile Strength (psi). Film strips of a specific size, free of air bubbles or physical imperfections, during the measurement, the top clamp pulled the strips at a 100 mm/min rate and the force and elongation were calculated until the film separated. The following formula was used to quantify tensile Strength: Power in tensile the sample's initial cross-sectional area is damaged.[22,24]

Determination of % Elongation

The % elongation is determined when the film snaps with enough force to reach the elastic boundary. The following equation was used to calculate % elongation.[25]

$$\% \text{ Elongation} = \frac{\text{Length increase at breaking point (mm)}}{\text{Initial length (mm)}} \times 100$$

Determination of Surface pH

To determine the potential of adverse consequences *in vivo*, the surface pH of a film with fast disintegration was evaluated.

Table 1: Box-Behnken Design fast Dissolving Film factor and Response table.

Factor	Name	Units	Type	Subtype	Minimum	Maximum
X1	Pectin	g	Numeric	Continuous	0.3000	0.5000
X2	PVP	g	Numeric	Continuous	0.1000	0.2000
X3	Glycerol	g	Numeric	Continuous	0.2000	0.4000

R1=Wt. variation (mg); R2=Thickness(µm); R3=% elongation; R4=Tensile Strength; R5=*In vitro* disintegration (sec); R6=% CDR.

Table 2: Formula variation of fast dissolving film in accordance to box Behnken Factorial design.

Run	Pectin (g)	PVP (g)	Glycerol (g)	PVA (g)	DRUG (mg)	KOH Sol. (mL)	Distil Water
1	0.3	0.2	0.3	0.1	160	5	q.s
2	0.5	0.1	0.3	0.1	160	5	q.s
3	0.4	0.2	0.2	0.1	160	5	q.s
4	0.5	0.15	0.2	0.1	160	5	q.s
5	0.4	0.15	0.3	0.1	160	5	q.s
6	0.5	0.15	0.4	0.1	160	5	q.s
7	0.4	0.2	0.3	0.1	160	5	q.s
8	0.4	0.1	0.4	0.1	160	5	q.s
9	0.4	0.1	0.4	0.1	160	5	q.s
10	0.3	0.10	0.3	0.1	160	5	q.s
11	0.4	0.15	0.3	0.1	160	5	q.s
12	0.5	0.2	0.3	0.1	160	5	q.s
13	0.3	0.15	0.2	0.1	160	5	q.s
14	0.3	0.15	0.4	0.1	160	5	q.s
15	0.4	0.1	0.2	0.1	160	5	q.s

This was accomplished using a pH electrode. The film was allowed to expand for 30 min in a closed petri dish. The pH was evaluated by placing an electrode on the surface of the sublingual film. The mean and standard deviation were provided for each experiment.[25,26]

In vitro disintegration/dissolution

In vitro disintegration or dissolution testing for films is a typical method for determining the efficacy of Fast-Dissolving Films (FDFs) in pharmaceutical and medical applications. A film measuring 3.5×3.5 cm^2 was placed in a glass Petri dish holding 20 mL of PBS (pH 6.8) to conduct a disintegration test with mild shaking. The time necessary for the film to decompose was recorded and the findings are presented as the average of six separate measurements.[16,27]

In vitro Drug release assay

The dissolution test for rapidly dissolving films comprises producing a dissolution medium, inserting a film sample in the medium and measuring the drug release at predetermined time intervals using a UV spectrophotometer. The dissolving testing device was of basket construction. The dissolving media was prepared as a solvent consisting of Phosphate buffer (pH 6.8, adjusted with sodium hydroxide) at 37.5ºC. The fast-dissolving film was sliced into tiny, equal-sized pieces and one was put in the dissolution liquid. 5 mL aliquots of samples and the equal amount of buffer were drawn at specified intervals. Absorption was calculated at 295 nm after suitable dilutions. The findings are calculated using the mean of three determinations and calculated the concentration of drug using the calibration curve.[28-30]

RESULTS

Preparation of fast-dissolving film

A fast-dissolving film drug delivery system is a popular choice for drug delivery due to its advantages over traditional oral dosage forms. This system is designed to dissolve or disintegrate quickly in the mouth without water, making it an attractive option for patients with difficulty swallowing tablets or capsules.[31] In this study, the preparation of a solution involved dissolving 0.1 g of PVA in 5 mL of water and then heating the mixture to a temperature of 80ºC until a transparent solution was achieved, as per the formulation table. Several pectin fragments were rendered soluble in an aqueous medium with the assistance of a magnetic stir bar and subsequently integrated into the PVP solution. A solution containing TLM at a concentration of 160 mg was prepared by diluting it in a 0.1N solution of potassium hydroxide. This solution was then combined with glycerol to achieve a standard distribution. A translucent solution containing TLM was prepared by incorporating PVA, pectin and potassium hydroxide. Subsequently, the solution was transferred into Petri dishes and subjected to a drying process for one night at 45vC. Subsequently, an analysis was conducted to evaluate the physicochemical properties, drug content, *in vitro* drug release and stability of the film. A section measuring 3.5×3.5 cm^2 was excised from the desiccated film and exposed to diverse experimental conditions. 15 formulations were generated in accordance with the formulas outlined in Table 1. Figure 2 illustrates the Formulation of the fast-dissolving film by the Design Expert software, utilizing all 15 runs.

Drug and excipients interaction study

Fourier Transform Infrared Spectroscopy (FTIR) can be utilized to identify the Drug excipients interaction present in a rapidly dissolving film of TLM. The film's FTIR spectrum is expected to exhibit characteristic peaks corresponding to the various

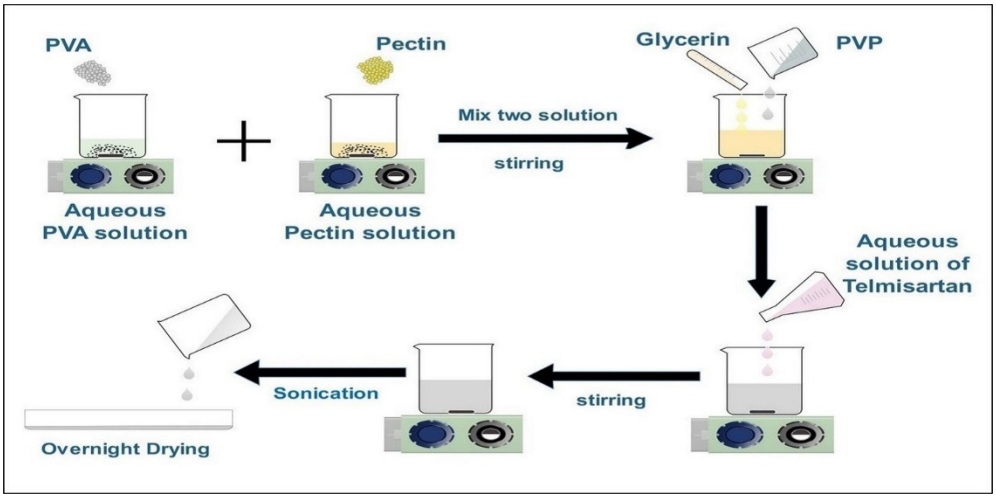

Figure 1: Schematic representation of the Development of the fast-disintegrating film having TLM as an Active Ingredient.

functional groups present in the polymers and the drug. In Figure 3, The distinctive peak observed in the PVP and pectin spectrum are similar with the previously reported FTIR.[32,33] TLM exhibits characteristic spectral peaks at a maximum wavenumber of 2952 cm^{-1}, which correspond to the C-H stretching vibration, the C-O stretching vibration at 1266 cm^{-1}, the C=O stretching vibration at 1691 cm^{-1} and the vibration stretching of O-H 1342 cm^{-1}. The drug-loaded films exhibit similar peaks and no other peaks are obtains, suggesting the absence of any chemical interaction between the polymer and the pure drug and confirming the drug's existence in the film.

Physical characterization of Fast dissolving film

The mean weight was calculated by determining the individual weights of 15 samples from each formulation class and subsequently computing their average. Except for runs 2, 4, 6 and 12, which had slightly elevated pectin concentrations resulting in increased film thickness and weight, the weight of the films produced in each formulation run remained consistent. The thickness of the film was measured using a calibrated Vernier caliper. The sample for the dose equivalent of the drug was collected based on measurements ranging from 100 to 200 cm. The films exhibited a uniform thickness throughout. The thickness of the film exhibited a slight increase with the rise in polymer concentration (Table 3). To evaluate the folding endurance of the film, a singular specimen was subjected to repetitive folding at a precise location until it reached a point of failure, with a total of 300 folds being performed. This methodology was deemed adequate for discerning favorable film characteristics. The film's folding endurance is ascertained by the number of times it can be folded without experiencing any tearing at the precise location. Numerous formulations exhibit a folding endurance of no less

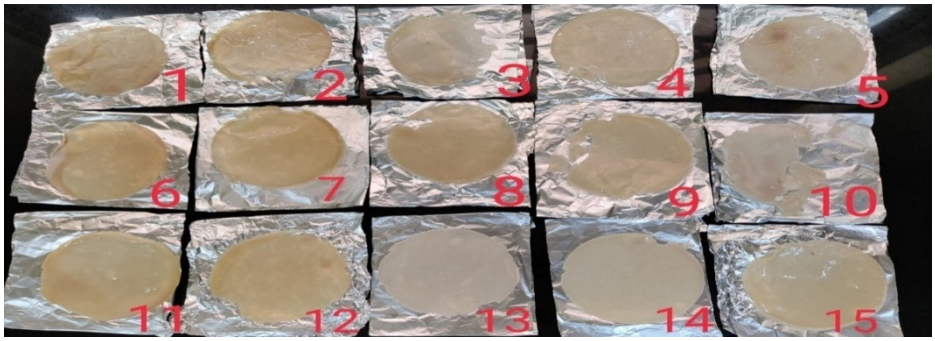

Figure 2: The fast-dissolving film formulation was developed using the Design Expert program, using all 15 experimental runs.

Table 3: The table comprises wt. Variation, thickness, % elongation, Tensile Strength, *in vitro* disintegration, folding endurance, % drug release and surface pH.

Run	Wt. variation (mg)	Thickness (µm)	% elongation	Tensile Strength	*In vitro* disintegration (sec)	Folding endurance	% CDR	Surface pH
1	46±1.5	384±2	15.2	16.56±0.89	60±5	312±3	95	6.3
2	65±2.6	465±3	17.2	25.2±0.56	78±3	317±5	88	7.1
3	52±2.7	402±5	16.3	20.7±1.2	62±4	316±4	93	6.4
4	68±2.4	457±4	15.7	25.78±1.15	74±2	309±2	89	6.5
5	41±1.9	398±6	16.5	19.5±0.97	70±4	303±6	90	6.7
6	66±1.7	450±2	17.6	24.8±1.12	78±3	335±4	90	7.2
7	54±2.4	412±6	16.8	21.8±1.09	68±5	345±5	95.4	7.3
8	52±1.98	405±7	15.9	21.66±0.96	69±4	321±3	90	6.5
9	56±2.12	396±8	16.2	22.65±1.56	79±5	331±5	93	7.4
10	45±2.2	390±6	14.8	15.7±0.68	62±3	313±4	94	6.2
11	50±1.5	415±5	16.8	23.12±1.12	72±3	326±2	93.05	6.8
12	64±2.3	455±3	16.9	25.98±1.23	76±4	355±7	91	7.3
13	44±1.6	388±2	15.8	14.2	60±4	342±6	91.78	6.5
14	41±1.8	382±5	16.7	14.7	64±3	316±4	90.5	6.7
15	50±5.9	390±8	15.7	22.8	66±2	329±5	90	6.9

than 300 folds. Table 3 indicates that the 7th and 9th formulations have superior Strength and flexibility. A film's tensile Strength indicates its Strength and flexibility, as defined by its inherent properties. The tensile strength was found in different variation due to the changes of the polymer concentration. The parameters of interest are the Elongation at failure (E/B) and the tensile Strength.

Low Tensile strength and E/B values define fragile and delicate polymers. In contrast, moderate Tensile Strength and low E/B values define robust and brittle polymers and high Tensile Strength and E/B values define soft and resilient polymers. When polymer quantity increases, the fraction of elongation grows.[34,35] The pH values of each Formulation's surface were evaluated. The results ranged from 6.2 to 7.4, like a neutral pH and less irritating to the sublingual mucosa. The peel ability and adaptability of the film were unaffected by KOH (Table 3). The variability of TLM fast-dissolving film's disintegration time is depending upon its formulation and manufacturing process. Fast-dissolving films are formulated to disintegrate quickly in the buccal cavity, usually within a period ranging from 30 sec to 2 min. It is crucial to recognize that multiple variables, including the temperature of the buccal cavity, the amount of saliva and the pH level, can impact the disintegration time of fast-dissolving films. The result indicates the *in vitro* disintegration time varies from 68 to 127 sec, depending on the variance in polymer concentrations. The *in vitro* disintegration/dissolved into the simulated mouth pH, which helps to understand the breakdown of polymer which helps to release of the drug at earliest.

In vitro drug release study

The cumulative drug release of a fast-dissolving film containing TLM is determined by the Formulation of the film, the kind and concentration of polymers used the manufacturing process and the testing conditions. The cumulative drug release is calculated by performing dissolve experiments using the USP type II Dissolution Apparatus.[36] Generally, the drug release from a fast-dissolving film follows a specific pattern, with a rapid initial release followed by a gradual release over time. The cumulative drug release may be monitored at several intervals upto 30 min. A UV spectrometer calculates the total quantity of medicine released during each interval. Figure 4 depicts the cumulative drug release profiles of the different formulations, highlighting the efficacy of Formulation 7 in achieving rapid drug release, with 95.4% of the drug released within 30 min, meeting the criteria for Fast-Dissolving Films (FDFs). The graph illustrates that variation in polymer concentrations influence the release of the drug from the films. The kinetic model analysis of Formulation 7, as presented in Figure 4, reveals that the drug release follows zero-order kinetics (R^2=0.9966), indicating a consistent release

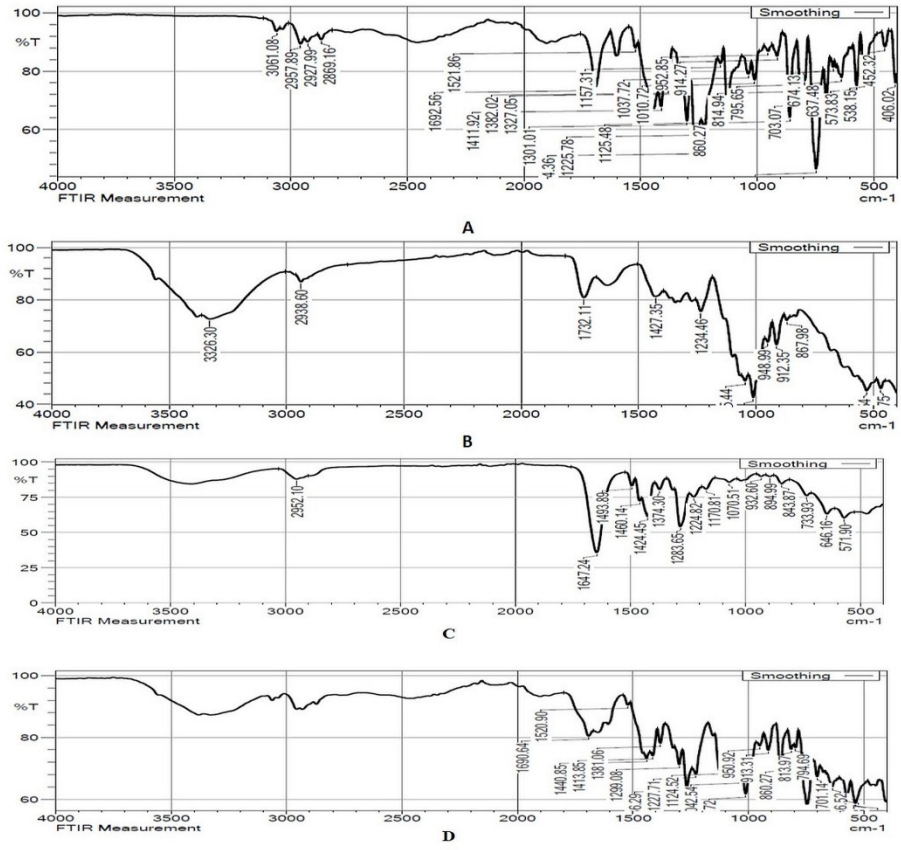

Figure 3: FT-IR Overlay of A. FT-IR for the spectrum of PVP B. FT-IR for the spectrum of Pectin C. FT-IR for the spectrum of TLM D. FT-IR for the spectrum of drug excipient mixture.

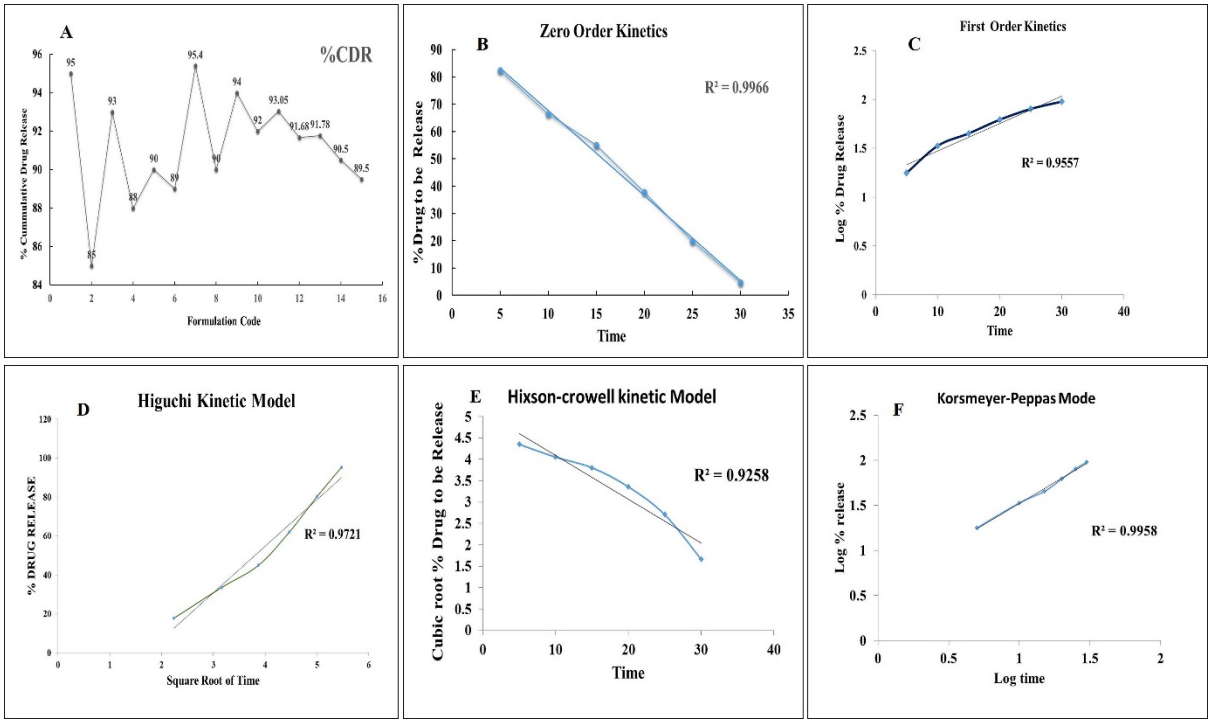

Figure 4: Overlay of Dissolution kinetics for A. Zero order Reaction; B. First order Reaction; C. Higuchi model; D. Hixson model; E. Kosemeyar Peppas model for all the 15 formulations

rate over time. These findings underscore the importance of polymer concentration in modulating drug release kinetics and emphasize the suitability of Formulation 7 for rapid and controlled drug delivery.

Experimental Design and Data Analysis

The application of Response Surface Methodology (RSM) for analyzing various characterizing parameters is illustrated in Figure 5. This method delves into the intricate interplay between concentrations of pectin and PVP. Through this analysis, six responses (R1: weight variation, R2: thickness, R3: percentage elongation, R4: tensile strength, R5: *in vitro* disintegration and R6: percentage Cumulative Drug Release [%CDR]) were subjected to statistical analysis and optimization. 15 experimental runs were conducted and the responses were simultaneously fitted to linear models using Design-Expert software. The software determined the highest-order polynomial model as the most suitable, considering coefficients of determination (R^2), predicted residual sum of squares values and the significance of additional terms. ANOVA was then employed to assess the suggested model's significance for the responses. In-depth analysis was facilitated through 3D surface graphs, integrating experimental design and insights, as depicted in Figure 5. The optimization process utilized desirability plots, providing optimal values for independent variables. Higher desirability values indicated more favorable formulations. The optimized formula derived from this process consisted of 0.404 g of pectin (X1), 0.122g of PVP (X2) and 0.390g of glycerol (X3). The model theoretically predicts the optimized formula's performance, as illustrated in the overlay plot. Consequently, the optimized formulation is anticipated to yield a weight variation of 53 mg, a thickness of 413.3 µm, a percentage elongation of 16.55%, a tensile strength of 21.09, disintegration in 73 sec and 90% drug release, achieving a desirability score of 1. The formulation resulting from this Design of Experiments (DoE) approach holds promise for the development of optimized FDFs for onset drug delivery, offering potential applications in future endeavours.

DISCUSSION

Developments in pharmaceutical manufacturing are evident through the creation of Fast-Dissolving Films (FDFs) made with polymers like pectin, PVA and PVP and the incorporation of TLM. Selecting pectin, PVA (Polyvinyl Alcohol) and PVP (Polyvinylpyrrolidone) as film-forming polymers in the present investigation provides numerous benefits.[37] Initially, pectin was a natural polysaccharide obtained from plants and recognized for its biocompatibility and biodegradability, which makes it ideal for pharmaceutical applications. Pectin is known for its exceptional film-forming properties, which help create smooth, flexible and transparent films.[38,39] Additionally, PVA is a synthetic polymer commonly utilized in the pharmaceutical industry for its impressive film-forming capability, strong mechanical properties and stability. PVA films have excellent adhesion to mucosal surfaces, which helps in quick dissolution and drug release. Finally, PVP is a flexible polymer recognized for its ability to dissolve in various solvents and improve the dissolution rate and bioavailability of drugs with low solubility. These polymers have outstanding film-forming capabilities, essential for creating thin,

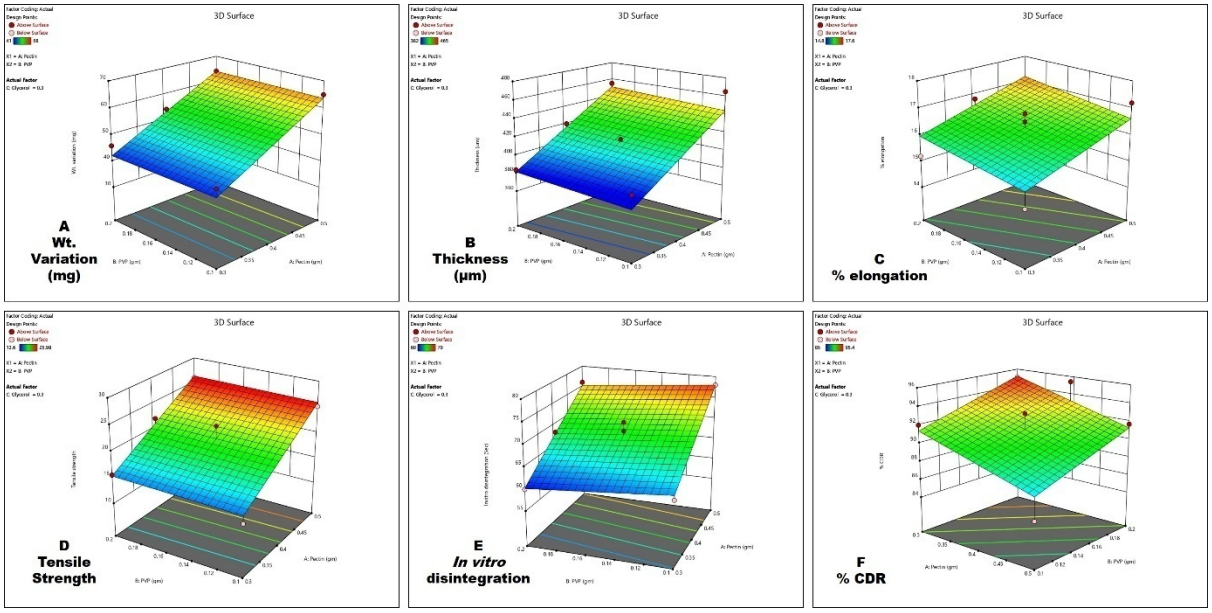

Figure 5: Response Surface curve of PVP and Pectin on % Cumulative drug release and Disintegration time A. Weight variation B. Thickness. % Elongation D. Tensile Strength E. *In vitro*-Disintegration F. % CDR.

flexible and uniform films.[40,41] When formulating Fast-Dissolving Films (FDFs) with TLM, the solvent casting method is favored for its capability to carefully control composition and thickness, resulting in even distribution of the Active Pharmaceutical Ingredient (API) in the polymer matrix. One of the main challenges in creating formulations for TLM is its low solubility within the normal pH levels of the body. Alkalizers such as potassium hydroxide are used to address this problem to enhance the solubility of TLM. Solvent casting provides flexibility in choosing polymers, scalability and cost efficiency, making it ideal for large-scale manufacturing.[36] Moreover, the straightforward nature of the procedure enables the effective production of FDFs with favorable physical and mechanical attributes, along with quick drug-release characteristics. Overall, the use of solvent casting allows for the creation of TLM-loaded FDFs that provide easy administration, increased bioavailability and better patient adherence, leading to advancements in drug delivery technology and therapeutic results.[37,42,43]

After analyzing the FDFs, it is evident that they show positive outcomes regarding their physical characteristics, disintegration time, durability, strength, flexibility and drug release behavior. Among all the formulations, Formulation 7 is remarkable for its exceptional folding endurance, tensile strength and drug-release properties. The material's impressive durability, along with its strong tensile strength and elongation, demonstrates outstanding mechanical characteristics. Moreover, it proves over 95.4% drug release within 30 min in simulated gastric fluid, indicating quick dissolution and bioavailability of TLM. The creation of TLM-loaded FDFs signifies a significant breakthrough in pharmaceutical technology. We successfully created FDFs with favorable physical and mechanical properties and fast drug release using polymers and the solvent casting technique. The FDFs can transform drug delivery, providing a convenient, effective and patient-friendly option compared to traditional dosage forms.

CONCLUSION

This study successfully developed a fast-dissolving film containing TLM using the solvent-casting approach. The film's quick breakdown and drug release made it an attractive alternate dosage form for TLM, with potential for future Development as a commercial dosage form. Various polymers, such as pectin, polyvinylpyrrolidone and poly (vinyl alcohol), were used to produce TLM films using design of experiment for rapid oral dissolution. From all the 15th formulation, the seventh Formulation with a pectin concentration of 0.4 g, a PVP concentration of 0.2 g, a PVA concentration of 0.1 g and a glycerol concentration of 0.3 g exhibited the highest drug release of all formulations, at 95%. The evaluation tests for TLM films indicate that they can be manufactured as fast-dissolving films using diffusion-enhancing excipients, which can affect the release and bioavailability of the drug. The study suggests the potential for fast-dissolving TLM films as an alternative dosage form.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

TLM: Telmisartan; **PVP:** Polyvinylpyrrolidone; **PVA:** Polyvinyl Alcohol; **FDF:** Fast-Dissolving Films; **%CDR:** percentage Cumulative Drug Release.

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