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Authors' Affiliation:
Department of Pharmaceutics, Faculty of Pharmaceutical Sciences, Lahore University of Biological & Applied Sciences, Lahore, Pakistan

*Corresponding Author
Department of Pharmaceutics, Faculty of Pharmaceutical Sciences, Lahore University of Biological & Applied Sciences, Lahore, Pakistan

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DISCOVERY
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Design and fabrication of metoclopramide fast dissolving films by using combined natural and synthetic polymers, and *in vitro* evaluation

Muhammad Abid Mustafa*

ABSTRACT

Objective: Formulation aims to develop a film that dissolves quickly for advanced solid dosage forms in order to increase the drug's bioavailability and enhance its action. Natural gum and artificial polymers were combined to develop films with the desired properties. *Method:* Metoclopramide FDF was developed in nine different formulations (F1–F9) using the solvent casting process. The effect of varying formulation parameters on the physical and mechanical characteristics of metoclopramide films was investigated in vitro using phosphate buffer at 6.8 pH. Several techniques were used to evaluate the films' weight, thickness, tensile strength, folding durability, and oral dissolving time in order to determine the best possible formulation. *Results:* The findings showed that the materials were employed consistently throughout the whole film in terms of drug content. While all the formulations had acceptable testing features, formulation F7 was deemed the most promising due to its 99.12% in-vitro drug release and other characteristics. All the formulations are shown to obey first-order kinetics and fickian release. The formulation showed enhanced drug release rates over a 9-minute period, indicating its adaptability. It contained the ideal polymer concentrations of Cyamopsis tetragonoloba gum, HPMC, and PEG. *Conclusion:* The study suggests that metoclopramide fast-dissolving oral films are the most effective antiemetic option for quick onset of action and enhanced bioavailability.

Keywords: Fast dissolving films, oral mucosa, metoclopramide, anti-emetic, Cyamopsis tetragonoloba gum, improved bioavailability, Solvent casting, Film-forming polymers

1. INTRODUCTION

Recent advances in technology have made it possible for patients with nausea, noncompliant behavior, mobility problems, elderly age, or both to have efficient oral administration options (Arya et al., 2010). Fast-dissolving buccal films utilize a dissolving film to deliver drugs orally (buccally or sublingually) or enterically (via the small intestines). Mouth-dissolving films, a transdermal patch technology, facilitate rapid oral medication absorption by saliva, making them ideal for administering medications during emesis and nausea (Randale et al., 2010). An advanced substitute for the conventional tablets, capsules, and liquids frequently seen in prescription and over-the-counter medicine administration is fast dissolving buccal films. Thin film ribbons are similar in size, shape, and thickness to a postage stamp. They are usually intended for oral administration when the user places the ribbon on, beneath, or along the inside of the cheek. One main advantage of fast-dissolving medication delivery systems is improved patient compliance.

By introducing a novel and convenient method of drug administration, the fast-dissolving buccal film drug delivery system represents a significant advancement in drug administration (Thakur et al., 2013). In order to develop a film that dissolves or disintegrates on the tongue or in the buccal cavity in one-minute, hydrophilic polymers are employed. This allows the medicine to dissolve and enter the bloodstream when it comes into contact with fluids (Cilurzo et al., 2008). Various biological applications have been developed by incorporating various amounts of polymers, both novel and manufactured (Alipour et al., 2015; Andrews et al., 2009). Galactomannan polymers, which are employed as a swelling agent as they increase the viscosity of pharmaceuticals, are present in Cyamopsis tetragonoloba gum powder, which is made from Cyamopsis tetragonolobus embryos (Thombare et al., 2016). Metoclopramide, a 5-HT3 antagonist, was employed for its antiemetic properties due to its fast-dissolving film form and ability to absorb its active ingredient via the oral mucosa (Al-Mogherah et al., 2020).

Metoclopramide, a precursor of vitamin B10, has anti-emetic and gastro-prokinetic properties and is absorbed quickly with an oral bioavailability of 80-15.5%. Adults should take 5-10 mg daily, ensuring it can penetrate oral mucosal tissues (Ali et al., 2018). Since it is highly soluble in water, metoclopramide HCl falls under BCS Class III (Biopharmaceutical Classification System) (Stosik et al., 2008). The objective of the research was to develop a fast-dissolving film (FDF) that would increase the bioavailability of antiemetic drugs and their rapid effect. The oral mucosa absorbed the metoclopramide-containing dose form due to FDF. To achieve acceptable film properties, natural gum and polymers were combined, with Cyamopsis tetragonoloba gum used as a unique component and binding agent. This innovative approach addresses the market's main drawback of longer-lasting antiemetic dosages.

2. MATERIAL AND METHOD

Materials

Metoclopramide HCl (MCP HCl) and Hydroxypropyl methyl cellulose 15 cp (HPMC 15 cp) were procured from Provider Pharma, India. Sigma Company supplies Cyamopsis tetragonoloba gum to pharmaceutical companies in Australia. PEG and glycerol were procured from Merck Specialties Ltd. The supplier of citric acid was Avonchim in Cheshire, UK. Sodium starch glycolate (SSG) and sucrose were purchased from Sigma-Aldrich, Inc. (Missori, USA). All the chemicals and their use in formulation are listed in (Table 1). Analytical-grade chemicals were all used exactly as provided.

Table 1 Chemicals and their uses in a formulation

Chemicals (Ingredients)	Use in a formulation as
HPMC	Thickening agent, film former
PEG-6000	plasticizers, surfactant
Metoclopramide HCl	Active ingredient
Glycerol	Smoothness
Sucrose	Sweetening Agent, Diluent
Cyamopsis tetragonoloba gum	Suspending Agent
Sodium Starch Glycolate	Disintegrating agent, Agent
Citric Acid	Saliva stimulating agent, Preservative
Peppermint oil	Flavoring agent

Method of preparation

Film-forming polymers are used in the solvent casting process to prepare the films. The study spanned eight months, from December 2, 2022, to July 3, 2023. Ethical approval for the study was obtained from the Lahore Pharmacy College, Lahore, Pakistan, with reference number (ref: RMEC/ZA/04723), ensuring compliance with ethical standards and guidelines. 10milliliters of water were used to dissolve the precisely weighed polymers. The polymer was allowed to swell in the beaker containing the water and polymer for five minutes, during which the mixture was continuously stirred with a magnetic stirrer. Concurrently, metoclopramide was carefully measured and dispersed in 10 ml of water in a separate beaker; subsequently. Once a homogenous viscous solution had been formed, the drug solution was transferred to the polymer solution and stirred. Glycerol and propylene glycol were then added to the resultant solution.

To attain a homogeneous dispersion of the insoluble constituents, the drug solution was subjected to sonication for a duration of 20 minutes. The polymer solution was incorporated after sonication and stirred constantly for seven to eight hours using a magnetic stirrer. An hour before filming, color and flavor were added to the drug polymer solution. Following thorough mixing and dispersion, the drug-polymer solution was then poured onto a glass petri dish with a diameter of four cm. Casted films were dried in a vacuum oven at 40 °C for 24 hours. The schematic diagram of the solvent casting technique is shown in (Figure 1). After drying, the cast film was gently removed from the petri dish and cut into 2 × 2 cm films. These were then wrapped in laboratory-prepared aliminium foil packaging (Reddy et al., 2018).

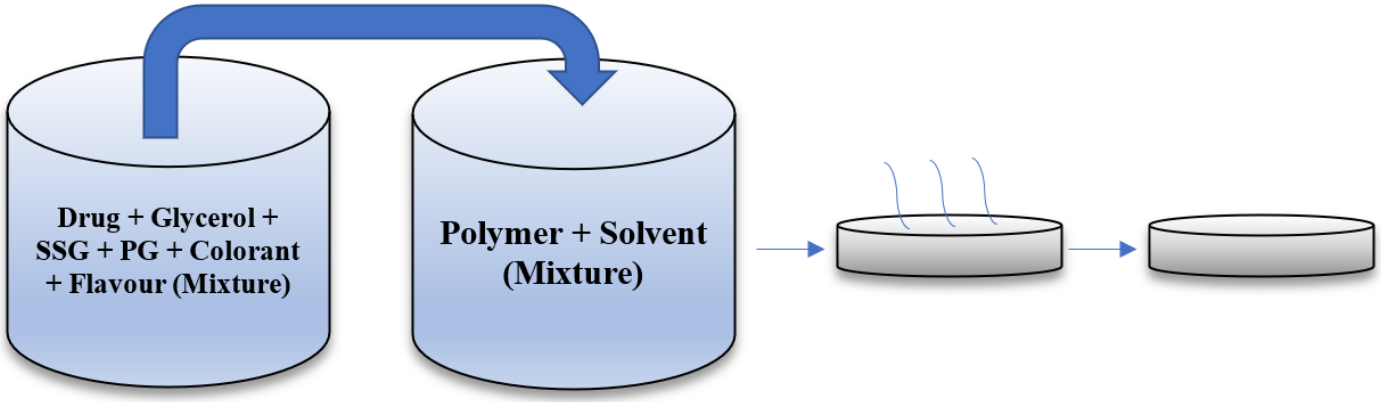

Figure 1 Schematic diagram of solvent casting technique

Formulation Quantitative Analysis

Characterization

The characterization of the formulation consists of the following testing:

Table 2 The formulation of nine different batches contains specific quantities of chemicals.

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Metoclopramide HCL	150	150	150	150	150	150	150	150	150
PEG-6000	-	-	-	100	150	200	100	200	300
HPMC	100	150	200	-	-	-	100	200	300
Cyamopsis tetragonoloba gum	100	150	200	100	150	200	100	200	300
Glycerol	5ml	5ml	5ml	5ml	5ml	5ml	5ml	5ml	5ml
Citric acid	150	150	150	150	150	150	150	150	150
Sucrose	500	500	500	500	500	500	500	500	500
Sodium Starch	250	250	250	250	250	250	250	250	250

Glycolate									
Peppermint oil	5	5	5	5	5	5	5	5	5
Colorant	5	5	5	5	5	5	5	5	5
Solvent (Ethanol: water)	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1

Pre-formulation studies

Melting point

Computerized melting point equipment was used to determine the M.P. after the powdered drug was placed into a glass tube with one side open and the remainder sealed (Khunteta et al., 2019).

Solubility studies

Solubility was determined using the shake-flask method. The solubility was assessed using several kinds of buffers and solvents (Khunteta et al., 2019).

Preparation for calibration curve in Phosphate Buffer solution 6.8

Twelve milligrams of metoclopramide HCl and a pH 6.8 phosphate buffer solution were added to a 25-mL volumetric flask. The remaining volume was added once the solution was transferred to a 100-mL volumetric flask. The concentration was 100 g/mL. After dilution of 1–10 mL of the stock solution in a series of 10 mL volumetric flasks, phosphate buffer solution (PBS) was added to the volume to mark. The dilutions have been analyzed with a UV spectrophotometer with a maximum wavelength range of 272 nm (Agterdenbos, 1979).

Post Formulation studies

Visual study

For such films, the surface morphology, homogeneity, color, and opacity of the product formulation were examined (Tizkam et al., 2020).

Weight variation

Films sized 2.25 cm2 were cut from the caste film at five different points. The weight of each filmstrip was determined, and the weight variation was calculated (Verma et al., 2015).

Thickness Test

Using a Vernier calliper, the thickness of five randomly selected films from each group was determined. The thickness of the film was measured at several points along its length, and mean values were computed.

Folding endurance

After a strip has been evaluated, folding endurance measures the film's fragility by reporting the values and repeatedly folding the film in the same spot until a break is evident (Jaafar, 2017).

Tensile Strength

The study focuses on determining the tensile strength of films to prevent load deformation or failure. Exact film strips were clamped three centimeters apart, dragged at a speed of 100 mm per minute, and the point at which the film fractured was recorded. The calculations did not take into account the results of films that broke at the clamps. Measurements were performed three times for each film (Mahajan et al., 2011).

The following equation provides another definition for tensile strength:

Tensile strength (N/mm2) = Breaking force (N) /Cross-sectional area of the sample (mm2)

Surface pH

The standard approach for assessing the pH of a film is to place it in a petri dish, wet it with distilled water, and then measure the pH by placing a pH meter electrode in direct contact with the film's surface. Because an acidic or basic pH might irritate the surfaces of the epithelial cells, the surface pH must be determined (Irfan et al., 2016).

Percentage elongation

The elastic modulus that is produced as the film expands is calculated using the following equation (Irfan et al., 2016).
Elongation at break % = increase in length at breaking (mm)× 100% original length (mm)

Mouth dissolving time

The films were placed in a glass container holding 50 milliliters of pH 7.4 phosphate buffer to determine the oral disintegration time. The length of time it took for the film to disintegrate was measured (Deepthi et al., 2014).

Drug content

Three equal-sized sections of film were cut, and each was put in a different container with 100 milliliters of pH 6.8 phosphate buffer. The containers were then violently shaken for ten minutes. The solutions were filtered, appropriately diluted, and subjected to a UV spectrometer analysis at 272. The final reading was based on the three films' combined average drug content (Reddy et al., 2018).

FTIR

Using a Fourier transformed infrared (FT-IR) spectrophotometer, a film drug and excipient incompatibility study was conducted to confirm that there was no possibility of complex formation between the medications and excipients. The sample was analyzed with a spectrophotometer between 400 and 400 (Patel et al., 2016).

Disintegration study

Oral disintegrating film breakdown needs to be done using USP disintegration tools. Place a piece of film in a petri dish with 2 mL of distilled water. The time it took for the films to disintegrate was the disintegration time (Irfan et al., 2016).

Dissolution study

In-vitro dissolution studies in 0.1N HCl were carried out for 9 minutes utilizing USP class II (paddle) dissolution equipment. The dissolution medium for the triplicate dissolution studies was a 0.1N HCl solution. The rotation speed was maintained at 50 rpm, and the temperature of the 6.8-pH phosphate buffer was maintained at 37 °C. Drug samples that had been dissolved and collected at predefined intervals were analyzed using a UV spectrometer (Irfan et al., 2016).

Release kinetics

Several kinetic models, including the Korsmeyer-Peppas model, the zero-order Higuchi model, and the first-order Higuchi model, were taken into consideration in order to determine drug kinetics. The drug release mechanism and formulation type—controlled-release or sustained-release—were confirmed using these models. The decision has been made using the values of n and R2 (Irfan et al., 2016).

3. RESULTS AND DISCUSSION

Pre formulation studies

Melting point

Within the permitted range of 183°C to 185°C, the melting point test result of 184°C was obtained (Mishra and Soni, 2019).

Solubility analysis

A solubility test was performed using a variety of solvents. Table 3 displays the results of the solubility test (Mishra and Soni, 2019).

Table 3 Solubility studies of metoclopramide

Solvent used	Solubility
Methanol	Soluble
Ethanol	Soluble
Water	Sparingly soluble
0.1 N HCL	Sparingly soluble
0.1 N NaOH	Sparingly soluble
Phosphate buffer saline (pH 6.8)	Sparingly soluble

Construction of Calibration Curves

Plotting the drug concentration against absorbance on a graph revealed a straight line for metoclopramide. The outcome of linear regression analysis was employed to develop (Figure 2). The drug complied with the Beer-Lambert rule, as evidenced by the value being higher than 0.99.

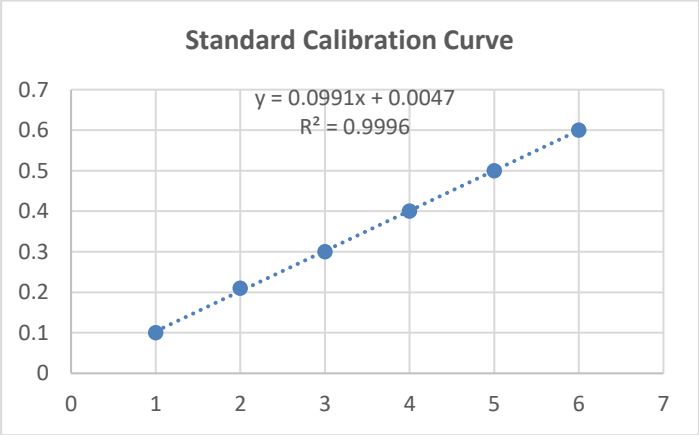

Figure 2 Standard calibration curve of metoclopramide

Post formulation studies

Visual studies

The surfaces of the films formed were smooth, transparent, and homogenous. The results obtained from the films are acceptable and show uniform drug distribution in Table 4 without any asymmetry or air entrapment (Jaafar, 2017).

Weight variations

Table 4 displays the official limit for the weight variation test results that falls within the specified range. The number of components utilized was found to increase the weight of the films (Deepthi et al., 2014).

Film thickness

All the formulations F1 and F9 had a thickness value within an official range. The thickness test results are shown in Table 4, given below. Every batch of films had a fragile layer of film and improved flexibility.

Folding endurance

The test of folding endurance was carried out. The findings showed that formulations (F1–F6) were folded more than 140 times, and the figures are shown in Table 5 below. All formulations folded approximately 150 times and fell within the recommended limit. The best formulation, F7, had better film endurance than other formulations (198 ± 0.08) (Jassim et al., 2018).

Measurement of tensile strength

The maximum tensile strength was obtained by Formulation F7; the results are displayed in (Table 4). The findings showed that the tensile strengths of formulations F1 through F9 were within the official limitations (Verma et al., 2015).

Surface pH

The pH levels of all films were within the acceptable buccal pH range and had a surface pH of between 5.55 and 6.49. Table 4 presents the figures. Findings showed that the formulation's pH was almost neutral and could be used safely (Alipour et al., 2015).

Percentage elongation

The percentage elongation of all the formulations F1–F9 was determined to be within the official limits as a consequence. Table 4 presents the figures. F7 had the greatest percentage of elongation, 2.37±1.83% (Zhang et al., 2019).

Mouth dissolving time

The results demonstrated that fast-dissolving films (F1–F9) disintegrated quickly in less than 60 seconds. Table 4 presents the figures. F7 was the best formulation and disintegrated after 32 seconds (Deepthi et al., 2014).

Drug content

The results given in Table 5 showed that the drug content of formulation F7 was between 96.68±0.53, falling within the content uniformity limit of 85% to 110%. It was found that the drug was dispersed uniformly across the entire film as a result (Jassim et al., 2018).

Table 4 Results of Surface pH, Weight Variation, % Elongation, Thickness, Tensile Strength, Mouth Dissolving Time, Drug Content, and Folding Endurance of Fast Dissolving Films

Formulations	F1	F2	F3	F4	F5	F6	F7	F8	F9
Surface pH	5.55	5.58	5.62	5.21	6.32	6.49	6.25	6.19	6.33
Weight variation(***mg***)	0.95 ±0.01	0.91 ±0.03	0.98 ±0.01	0.94 ± 0.06	0.96 ±0.05	0.91 ±0.02	0.93 ±0.04	0.91 ±0.05	0.94 ±0.04
%Elongation (***mm***)	0.12 ±0.19	0.23 ±0.10	0.24 ±0.43	0.69 ±0.49	1.19 ±0.94	1.28 ±0.61	2.37 ±1.83	2.22 ±0.40	2.04 ±0.30
Thickness (***mm***)	0.33 ±0.06	0.36 ±0.006	0.34 ±0.01	0.35 ±0.02	0.37 ±0.07	0.34 ±0.06	0.32 ±0.05	0.35 ±0.02	0.36 ±0.02
Tensile strength (***MPa***)	0.616 ±0.62	0.628 ±0.58	0.670 ±0.53	0.616 ±0.64	0.910 ±0.51	1.760 ±0.46	2.19 ±0.071	2.11 ±0.15	1.98 ±0.187
Mouth dissolving time (***sec***)	42	60	57	37	52	38	30	40	37
Drug content(%)	93.00 ±0.25	95.67 ±0.13	93.69 ±1.23	92.14 ±0.39	98.3 ±1.1	91.0 ±1.3	96.68 ±0.53	93.83 ±0.87	94.0 ±1.7
Folding Endurance	120 ±0.67	115 ± 0.46	148 ± 0.53	136 ±0.62	136 ±0.73	141 ± 0.24	150 ±0.08	110.33 ±0.32	143 ±0.41

FTIR

According to an FT-IR spectroscopy analysis, the drug and excipients utilized in the development of fast-dissolving films of metoclopramide HCl were shown to be compatible. Drugs, polymers, and a physical mixture of drugs and polymers were all subjected to FT-IR investigation. Below are the FT-IR spectroscopy spectra that were obtained at wave number (-). As a preformulation research, the IR characteristics of Metoclopramide hydrochloride with the polymer correspond to almost the IR structural features of the pure drug, indicating the drug's compatibility with polymers. The drug spectra have strong peaks at (3280.1) cm-1, (2929.7) cm-1, (1593.4) cm-1, and (848.0) cm-1, which correlate to the -NH, -OH, C=O, and C-Cl stretching's, respectively.

The absence of distinctive drug peaks at (3280.1) cm1 is visible in the drug-polymer combination spectrum (Figure 4). In the subtraction spectrum, the drug's distinctive peak at (3280.1) cm-1, due to NH stretching, was absent. Metoclopramide HCL absorption peaks were all preserved in physical combinations of metoclopramide HCL with various excipients. The physical combination spectra did not demonstrate a change in the vibration bands of metoclopramide HCL. FTIR studies on pure drugs and mixtures of drugs and excipients showed that the distinctive bands were not significantly changed, suggesting that there was no interaction between the drug and the excipients as shown in (Figure 3). The resulting graphs show that the drug and excipients are compatible (Kshirsagar et al., 2021).

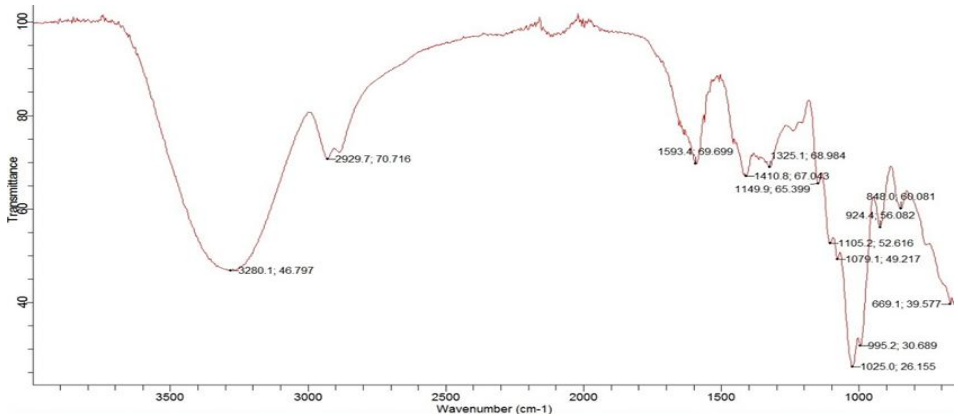

Figure 3 FTIR spectra of Metoclopramide HCl FDF

In-vitro disintegration studies

According to the results listed in Table 5, all formulations (F1–F9) disintegrated within a few seconds, indicating that the films dispersed quickly. Within 32 seconds, F7 revealed the fastest disintegration ability (Tizkam et al., 2020).

Table 5 Disintegration time of fast-dissolving films

Formulation code	Disintegration time (***sec***)
F 1	36±1.5
F 2	38±1.0
F 3	39±1.3
F 4	42±1.6
F 5	36±2.0
F 6	35±1.5
F 7	32 ±1.5
F 8	37±1.4
F 9	40±1.6

In-vitro dissolution

The film is rapidly disintegrated in the mouth by a low concentration of Cyamopsis tetragonoloba gum and super disintegrant, and the oral mucosa subsequently absorbs it. Salivary enzymes further promote the release of drugs by disintegrating Cyamopsis tetragonoloba gum. When a drug has high permeability or blood flow, it becomes more bioavailable. Because of salivary enzyme enzymatic breakdown, we observed in our studies that 15.5% of the drug had been released at 0.5 minutes and that this amount increased over time. The percentage of drug release over time is shown in (Figure 4). After 9 minutes, 99.12% of drug was released from the film (Deepthi et al., 2014).

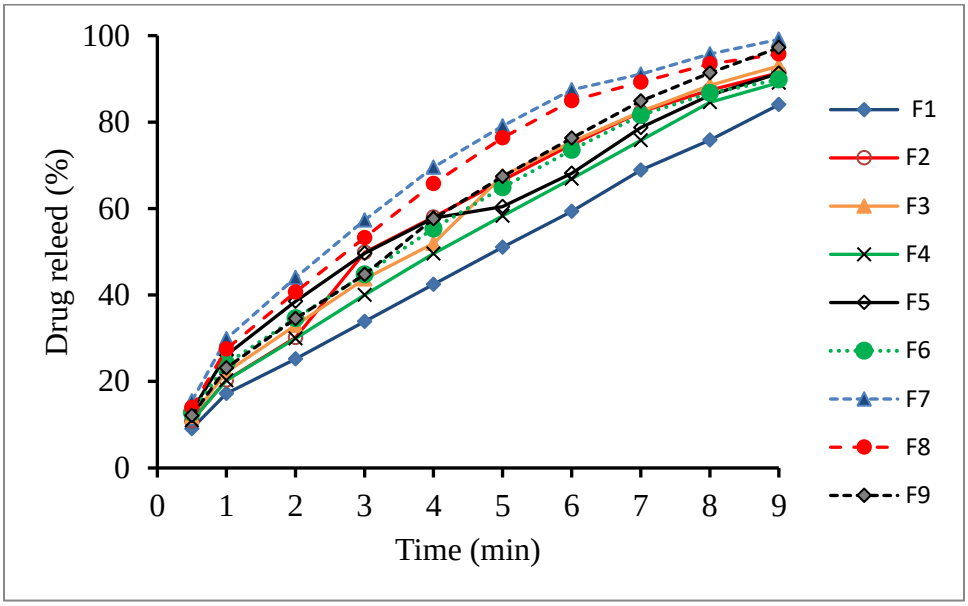

Figure 4 Percentage drug release over a time

Kinetic Released Studies

Understanding drug dissolution procedures and controlling release characteristics is crucial for meeting therapeutic requirements, as it helps relate data to a suitable representation. The in vitro dissolution rate pattern was calculated or represented using various mathematical model coefficients. The value of r2, which helps in understanding the nature of fast-dissolving film, is shown in the table below. As shown in Table 6, the value of R2 for first-order kinetics is 0.9889 and for zero-order kinetics is 0.7405. The first-order value of R square near 1 indicates of sustained release of the drug, which confirmed that the fast-dissolving films followed first-order kinetics and showed sustained release effects. In the Korsemeyer-Pappas model, all formulations showed a value of n between 0.266 and 0.44, demonstrating that all formulations followed fickian release and first-order kinetics. The Higuchi model was fitted with release data, and it was found that the metoclopramide release was sustained throughout time.

Table 6 Drug Release Kinetics

Formulation	Zero Order		First Order		Higuchi		Korsmeyer	
	K0	R2	K1	R2	kH	R2	kKP	N
F1	9.817	0.972	0.159	0.9743	24.424	0.9127	14.466	0.396
F2	11.734	0.8912	0.228	0.9885	29.543	0.9501	22.075	0.266
F3	11.728	0.9157	0.224	0.9763	29.453	0.947	21.085	0.39
F4	10.888	0.9426	0.193	0.9776	27.253	0.9396	18.358	0.424
F5	11.638	0.8033	0.232	0.9858	29.545	0.9814	25.55	0.283
F6	11.55	0.8746	0.222	0.9866	29.149	0.9665	22.826	0.44
F7	13.292	0.7405	0.317	0.9889	33.884	0.9808	30.919	0.353
F8	12.844	0.7874	0.288	0.9895	32.639	0.9735	28.377	0.38
F9	12.124	0.9172	0.239	0.9735	30.455	0.9522	21.947	0.287

Discussion

Metoclopramide HCL, a 5-HT3 antagonist with antiemetic properties and the ability to be absorbed through buccal, palatal, or gastrointestinal channels, is being developed as a promising new drug delivery technology through oral films. The selection and combination of film-forming polymers and pharmaceutical excipients are crucial in improving dissolution rate, buccal absorption,

bioavailability, and patient compliance. A solvent casting method and a variety of polymers are used to produce the films. We followed the method with slight modifications as Irfan et al., (2016) used this method to develop fast-dissolving films in their research, demonstrating the method's validity. The decision has been made using the values of n and R2 PEG was utilized as a plasticizer, while HPMC was used as a film-forming agent. By inserting its small molecules into the polymer matrix, glycerol was utilized as a plasticizer to improve the film's flexibility and reduce its brittleness. It also helps the film dissolve quickly while it is in the mouth cavity and leaves a pleasing mouthfeel.

Citric acid was used as a saliva-stimulating ingredient, which increases saliva production and facilitates the film's rapid breakdown. Peppermint oil was employed as a flavoring agent and sodium saccharin as a sweetener to help mask the unpleasant taste of the drug and promote patient compliance. The pH 6.8 simulated salivary fluid was used as the dissolving medium. All films' pH levels were within the permissible buccal pH range, with a surface pH ranging from 5.55 to 6.49. A similar trend in surface pH was observed by Bala and Sharma, (2018) during their studies, Formulation optimization and evaluation of fast dissolving film of aprepitant by using design of experiment. The drug was dispersed equally across the film, with all formulations falling within the 85% to 110% content uniformity range. Comparable content uniformity that adheres to the specified limits was observed by Jassim et al., (2018) during their studies, Formulation and evaluation of Fast Dissolving Film of Lornoxicam.

The formulation's pH was almost neutral, according to the results, and its usage was safe. The formulation F7 had the highest percentage of elongation, at 2.37±1.83%. In their study on the, Formulation and assessment of fast-dissolving oral films of diazepam, Ali et al., (2016) noted similar patterns for percentage elongation. The aim of this study was to determine the optimal ratio of polymer combinations to develop a formulation with the best in vitro disintegration and dissolving characteristics. To improve organoleptic qualities, polymers have been employed alone and in combination. Because the HPMC used had a medium viscosity, which developed a tough film that delayed solubility and lowered drug release, films made entirely of HPMC did not show a desirable drug release profile. The formulation, which consists of the polymers PEG, HPMC, and Cyamopsis tetragonoloba gum in an equal ratio with a low concentration of gum, as well as the super disintegrant, rapidly dissolves the film in the mouth, which is then absorbed by the oral mucosa.

In their study, Formulation and Assessment of Mouth Dissolving Film of Ropinirole Hydrochloride by Employing Pullulan Polymers, Panchal et al., (2012) observed a comparable pattern of drug disintegration among nine formulations. By dissolving Cyamopsis tetragonoloba gum, salivary enzymes improve drug release even further. The formulation F7, which contained HPMC, PEG, and Cyamopsis tetragonoloba gum, had a superior release profile. Through our investigation, we found that at 0.5 minutes, 15.5% of the formulation was released; this amount then increased over time due to enzymatic breakdown (salivary enzyme). After nine minutes, 99.12% of the material was removed from the film. Over a specific amount of time, a comparable pattern of drug release was noted by Zhang et al., (2019) in their study, Self-microemulsifying oral fast dissolving films of vitamin D3 for infants: Preparation and characterization.

Two batches of formulations (F8 and F9) were developed in order to further investigate the ideal polymer combination ratio and the in vitro dissolving profile. Following this adjustment, all formulation batches provided a more pleasant and viscous solution while pouring into the mold, and the resultant film after drying was smooth and consistent. Metoclopramide HCl undergoes enzymatic metabolism in the liver via oxidation and glucuronide and sulfate conjugation processes; consequently, oral absorption bypasses first-pass metabolism and improves bioavailability. Increased permeability, or blood flow, promotes drug bioavailability. The results indicate that metoclopramide FDF is currently taken orally in order to obtain a rapid onset of action.

4. CONCLUSION

Developing metoclopramide-fast-dissolving films is the aim of the current endeavour. Metoclopramide fast-dissolving films were formed by the solvent-casting method using PEG-6000 as the plasticizer and HPMC as the film. The prepared films showed high folding endurance, were smooth, homogenous, free of particles, and dissolved entirely in less than 10 seconds. The thickness and weight of the films increased as the polymer content increased. According to a study of content homogeneity, the drug is dispersed consistently throughout the film. Although the testing qualities of all the formulations were considered acceptable, formulation F7 was selected as the most promising one based on its 99.12% in-vitro drug release rate and acceptable evaluation characteristics.

This formulation had higher polymer concentrations of HPMC and PEG and improved drug release rates over a nine-minute period. According to the FTIR tests, it would appear that there is no possibility of interaction between the metoclopramide HCL and the polymers of other excipients used in the strips. The findings suggest that metoclopramide fast-dissolving oral films are the most effective antiemetic option in clinical settings for their quick onset of action and enhanced bioavailability, leading to higher efficacy and patient compliance.

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Conflict of interest

The authors declare that there is no conflict of interests.

Ethical approval

Ethical approval for the study was obtained from the Lahore Pharmacy College, Lahore, Pakistan, with reference number (ref: RMEC/ZA/04723), ensuring compliance with ethical standards and guidelines.

Informed consent

Not applicable.

Data and materials availability

All data sets collected during this study are available upon reasonable request from the corresponding author.

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