

## Formulation, Evaluation and Characterization of Mouth Dissolving Film of Cisapride

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### Abstract

Mouth dissolving films offer an attractive route for systemic drug delivery. MDFs are an alternative to fast dissolving tablets, Chewable tablet, due to their faster dissolution rate. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. Fast mouth dissolving films have become popular as a new delivery system. They disintegrate or disintegrate in the oral cavity without the need to swallow or chew.

The objective of the present study was to develop mouth dissolving films (MDF) of Cisapride used to treat heartburn in patients with gastroesophageal reflux disease (GERD), with fast disintegration, optimum morphological properties, and mechanical strength. Lycoat RS 720, Hydroxypropylmethyl-cellulose 3cps were used as polymers and Glycerine as plasticizer. Films were prepared by solvent casting technique. Parameters like in-vitro disintegration time, tensile strength, content uniformity, folding endurance, swelling index, and in-vitro drug release were evaluated. *In-vitro* dissolution studies showed that 99% of Cisapride was released within 5 min with an average disintegration time of 60 sec. UV and FTIR spectrophotometry were used to identify drug-excipient interactions. Accelerated stability studies were performed as per ICH guidelines wherein the MDFs were stable for 2 months at  $40 \pm 2$  °C and  $75 \pm 5\%$  relative humidity.

**Keywords:** Cisapride, mouth-dissolving film, HPMC 3cps, Lycoat RS 720, Glycerine

### Introduction

The oral route of drug administration is the very commonly and conveniently use for patient. Tablets and capsules represent the most widely used solid oral dosage forms. It is estimated that 35% of the general population, 30–40% of elderly nursing home patients and 25–50% of patients hospitalized for acute neuromuscular disorders and head injuries have dysphagia. Oral solid dosage forms are not ideal for elderly patients or those who have had surgery or radiation therapy to the head and neck [1,2].

Fast-dissolving oral drug delivery system is a novel solid dosage form, which disintegrate or dissolve in a few seconds after placement in the mouth. Offers substantial advantage over ordinary oral dosage form such as ease of administration, lack of requirement for drinking water, and improved compliance [3].

Sublingual and buccal routes enhance the onset of action and improve the efficacy. They can be used for local and systemic delivery. Mouth dissolving films offer an attractive route for systemic drug delivery. There is a rising interest in the development of Mouth Dissolving film (MDFs). MDFs are an alternative to

fast dissolving tablets, Chewable tablet, due to their faster dissolution rate [4].

The oral mucosa (MDF) is an attractive and feasible site for drug delivery, with good permeability, easy ingestion and swallowing, pain avoidance and a wide surface area for absorption. Marketed MDF products have also become available, including Listerine, Chloraseptic and Triaminic [5].

Delivery system consist of a very thin oral strip, which is simply based on the patient's tongue. The film rapidly hydrates and adheres onto site of application. It then disintegrates and dissolves to release the medication [6].

A fast-dissolving drug delivery system is in the form of a solid tablet that disintegrates or disintegrates in the oral cavity without the need to swallow or chew. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. Fast mouth dissolving films have become popular as a new delivery system. Since the sublingual mucosa is relatively permeable due to thin membrane and is highly perfused, rapid drug absorption and instant bioavailability is possible. This is beneficial in patients with dysphagia or difficulty in swallowing [7].

The fast-dissolving drug delivery system offers a giant leap forward in drug administration by providing a new and easy way of taking medication. Fast dissolving film is a thin film alleviates the fear of swallowing and the risk of choking commonly associated with a tablet.

Fast dissolving film is a thin film, with an area of 5-10 cm<sup>2</sup>, containing an active ingredient. The immediate dissolution, in water or saliva respectively, is reached through a special matrix. Drugs can be incorporated up to a single dose of 15 mg [8].

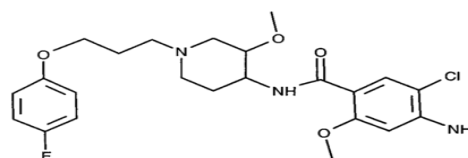
The faster the drug goes into the solution, quicker its absorption and onset of clinical effect. By altering the condition and formulation factors, it is possible to speed up dissolving rate

in the mouth. Normally these films are soluble in water at room temperature and will break up in 30 sec and dissolve in one minute [9].

Fast dissolving films should be water soluble and disintegrate when in contact with saliva. Polymers selected for the study are Lycoat and HPMC-3 cps. Fast release film type of dosage form for Cisapride was thought worth to formulate.

The MDF is a thin, printable, low-moisture, non-tacky film that is convenient for labeling and flexible for easy packing, handling and application. The rapid hydration rate facilitates an almost immediate softening of the MDF upon application in the oral cavity [10].

Oral routes of drug administration have wide acceptance up to 50-60% of total dosage forms due to ease of ingestion and pain avoidance. Fast-dissolving films which dissolve/disintegrate in the mouth within a few seconds without additional water and the need to swallow are gaining interest as an alternative [11, 12].



### Cisapride

Figure 1: Structure of Cisapride

**Molecular formula:** C<sub>23</sub>H<sub>29</sub>ClFN<sub>3</sub>O<sub>4</sub>

**IUPAC Name:** 4-amino-5-chloro-N-[(3S,4R)-1-[3-(4-fluorophenoxy)propyl]-3-methoxypiperidin-4-yl]-2-methoxybenzamide

### Material and Method

Cisapride was received as a gift sample from Healthy Life Pharma, Mumbai. HPMC was re-

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ceived from Colorcon Asia Pvt. Ltd., Mumbai. Lycoat RS 720 was procured from Roquette Pharma, Mumbai. PEG 400 was received as a gift sample from PEG 400 (Central Drug House, Mumbai). All other excipients were purchased from local vendor and were of analytical grade.

**UV-spectrophotometric calibration curve**

The UV calibration curve of Cisapride was constructed in phosphate-buffered saline (PBS) at pH 6.8 (2.38 g Na<sub>2</sub>HPO<sub>4</sub>, 0.19 g KH<sub>2</sub>PO<sub>4</sub>, and 8.00 g NaCl/1 L of distilled water)[13].

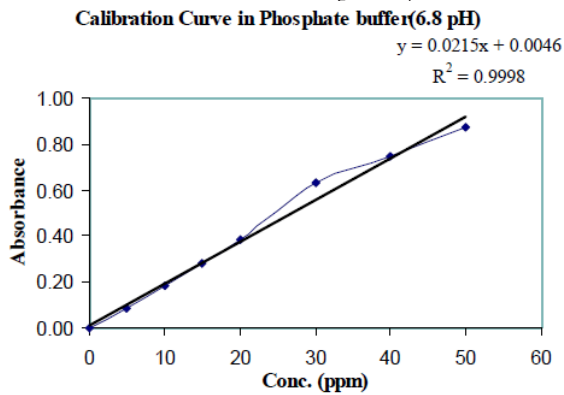


Figure2: Calibration curve of Cisapride in 6.8 buffer solution

**Drug-excipients compatibility studies**

Drug – Excipients studies were done to confirm the compatibility of Cisapride and other excipients used in the formulation. The drug

alone and along with different excipients was mixed, sealed in clear glass vials, which were then charged into stability chambers[14].

**Saturated solubility**

The saturated solubility of Cisapride has been determined. A known amount of Cisapride (100 mg) was mixed with 10ml of distilled water in glass vials. The suspension was filtered through 0.45-µm membrane filter before analysis[15].

**Formulation of fast dissolving films**

Fast dissolving films of Cisapride were prepared by solvent casting technique. A flat square shaped, TLC applicator having surface area of 25 cm<sup>2</sup> was fabricated for casting the films.

**HPMC casting solution**

The weighed quantities of polymer were preserved in distilled water in the HPMC casting solution. With distilled water, the volume was increased to 10 mL. Vacuum was used to release trapped air bubbles.

**Lycoat as a casting solution**

Lycoat was used as a casting solution, and it was made by dissolving weighed amounts of polymers in water and heating it on a water bath. The medication and flavour were dissolved in distilled water before being added to the aforementioned polymer solution, along with

Table 1: Formulation of Cisapride Mouth Dissolving film

Sr. No.	Ingredient (mg)	FC1	FC2	FC3	FC4	FC5	FC6	FC7	FC8	FC9
1	Cisapride	5	5	5	5	5	5	5	5	5
2	Lycoat RS 720	--	--	2	4	4	6	6	6	6
3	Glycerine	1	1.5	2.0	2.5	2.0	1.5	2.0	2.5	1
4	HPMC 3 cps	14.24	14.24	12.24	10.24	10.24	10.24	10.24	10.24	14.24
5	Ferric oxide red	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03
6	PEG-400	--	0.03	--	--	2	2.4	2.4	2.4	2.4
7	Masking Agent (ml)	2	2	2	2	2	2	2	2	2
8	Purified water (ml)	19.23	19.23	17.23	17.23	17.23	19.23	19.23	19.23	19.23

the plasticizer propylene glycol, and well mixed to make a homogeneous mixture. HPMC and Lycoat combination casting solution, the casting solutions were made by dissolving weighed amounts of polymers in distilled water [16].

**Preparation of fast dissolving films:** The casting solution (10 ml) was poured into a glass mould and dried in a vacuum oven at 50°C for 24 hours to allow the solvent to evaporate. The patches were peeled off and cut into squares of 2.5 cm by 2.5 cm (6.25 cm<sup>2</sup>). These patch-

Table 2: Physical and mechanical properties of Cisapride mouth dissolving films

Formulation code	Visual Appearance	Tack Test	Tensile strength (kg/mm <sup>2</sup> )	Folding endurance	Disintegration time
FC1	Transparent	Non-tacky	0.465±0.95	>100	78sec ±2.12
FC2	Semi-Transparent	Non-tacky	0.455±0.78	<100	191sec ±1.89
FC3	Non-Transparent	Non-tacky	0.412±0.11	<100	172sec ±1.45
FC4	Transparent	Non-tacky	0.423±0.18	<50	245sec ±1.50
FC5	Transparent	Non-tacky	0.430±0.48	<100	133sec ±1.30
FC6	Transparent	Non-tacky	0.405±0.50	<100	145sec ±3.60
FC7	Transparent	Non-tacky	0.490±0.45	<50	115sec ±2.90
FC8	Transparent	Non-tacky	0.480±0.40	<100	105sec ±1.50
FC9	Transparent	Slightly-tacky	0.376±0.75	<100	135sec ±2.15

es were dried for two days in a desiccator before being wrapped in aluminium foil and put in self-sealing covers. Fast-dissolving films were made with various polymer ratios while keeping the plasticizer and sweetener concentrations constant [17,18]. Table 1 shows the formulation components used in preparation of Cisapride mouth dissolving film and physical and mechanical properties including tack test, tensile strength, folding endurance and disintegration time is shown in table 2.

**Physical and chemical evaluation of film [19, 20]**

**Tack test**

Tack refers to how well the film sticks to the attachment that has been pressed against the strip. The dryness is also determined by this test.

**Tensile strength**

Tensile strength is defined as maximum stress applied at which the film breaks. Basi-

cally, this test is performed to measure the mechanical strength of films. It can be calculated from applied load at rupture divided by the strip cross-sectional area given in the equation below:

$$\text{Tensile strength} = \text{Load at breakage} / \text{Strip thickness} \times \text{Strip Width}$$

**Folding endurance**

A piece of film is cut and repeatedly folded at the same location until it breaks to measure folding endurance. The folding endurance value is determined by the number of times the film could be folded at the same point without breaking. A film's typical folding endurance ranges from 100 to 150 folds.

**Disintegration time**

The disintegration time of a film is determined using disintegration apparatus stated in official pharmacopoeias. The disintegration time is usually a function of the film composition, as it changes with the formulation, and it typically

spans from 5 to 30 seconds. This test is commonly performed using the USP disintegration device. For estimating the disintegration period of orally rapid disintegrating films, there are no established recommendations available. There are two ways for determining the time it takes for a film to disintegrate.

#### **Characterization of mouth dissolving films**

##### **Morphological Properties of Prepared Films**

MDF homogeneity, colour, transparency, and surface were visually assessed. All of the formulas were wrapped in butter paper and subsequently aluminium foil, kept at room temperature (25°C) with a relative humidity of 65 ±5% RH, and were tested periodically for 3 months.

##### **Drug-Excipient Interaction Studies**

To guarantee that there was no contact between the drug and the polymer or due to circumstances in the formulation process, the following interactions were investigated.

##### **Tack Test**

Tackiness was determined by gently pushing the film between fingertips and noting whether it was tacky or non-tacky.

##### **Thickness Evaluation**

The consistency of the film thickness is critical since it is directly related to the accuracy of dosage distribution in the film. The thickness of the film was measured using digital Vernier Calliper that were calibrated. At five different locations, the thickness was measured (four corners and one at centre).

##### **Weight Variation**

This test was carried out by cutting 6.25 cm<sup>2</sup> of film from the casted film at three separate locations. Weight of each film was determined using an electronic balance. For the weight variation research, three values were averaged.

#### **Folding Endurance**

The folding endurance of a film, which is related to its flexibility, was measured manually by strongly holding and folding the films through the centre multiple times. The value of folding endurance was defined as the number of folds on the same crease required to develop a crack in the film.

#### **pH Evaluation**

An acidic or alkaline pH might irritate the oral mucosa, the surface pH of the MDFs was evaluated to study possible side effects caused by a change in pH in vivo. The pH of the surface was measured with a pH metre.

The film was allowed to swell for 1 h at room temperature after being in contact with 1ml of distilled water. The pH was measured by placing the electrode on the film's surface, allowing it to equilibrate for 1 minute, and then recording the result.

#### **Tensile Strength**

The tensile strength of the films was determined using Universal Tensile Strength Tester (Dual Column) GT-C01-1 tiny tensile grips, as stated below: On the texture analyser, a 6.25 cm<sup>2</sup> sheet free of air bubbles or physical flaws was held longitudinally in the tensile grasp. The test was carried out using a crosshead speed of 2 mm/sec and a 6 mm initial grip separation from both sides until the film broke. For each film, all measurements were made in triplicate. The setting of texture analyser is done as follow:

##### **Pre- test speed**

1.50 mm/sec., Test speed: 2.00 mm/sec., Post-test speed: 10.00 mm/sec., Trigger force: 5.00 kg, Data acquisition rate: 200 pps.

#### **In-vitro Disintegration of Films**

In a petri dish containing 25 ml of phosphate buffer pH 6.8 at 37±0.5°C, the in-vitro disintegration time of 6.25 cm<sup>2</sup> films was visually evaluated. The time the film began to shatter or

disintegrate was recorded, and this is the film's disintegration time.

### **Percentage Moisture Loss**

To check the integrity of films in the dry state, percentage moisture loss was computed. Films were cut into 6.25 cm<sup>2</sup>, weighed precisely, and stored in desiccators with fused anhydrous calcium chloride. The films were removed and weighed again after 72 hours. The amount of moisture loss was determined by the decrease in the weight of the films. The percentage loss in moisture was calculated by using the following formula:

percentage moisture loss = (Initial weight - final weight) / (Initial weight) × 100

### **Percentage Moisture Absorption**

By slicing the films into 6.25 cm<sup>2</sup> patches, the moisture uptake could be evaluated. These films were dehydrated for one day at room temperature in a desiccator containing a saturated potassium sulphate solution (relative humidity: 75%). It was discovered that the weight of the films had increased due to moisture absorption. The percentage gain in the moisture by the films was calculated using the following formula:

percentage moisture loss = (Initial weight - final weight) / (Initial weight) × 100

**Swelling Index:** On a 2% agar plate, a pre-weighed drug-loaded film was inserted. The weight of the film gradually increased until it reached a stable weight.

**Drug Content Uniformity:** The film (6.25 cm<sup>2</sup>) was transferred into a graduated flask containing 100 ml of distilled water. The flask was shaken for 4 h in a mechanical shaker. Then the solution was filtered and after suitable dilutions with distilled water, the absorbance value was measured at 281 nm using the placebo patch solution as blank and the drug content was calculated.

**Accelerated Stability Studies for Optimized Formulation:** The ICH Q1A (R2) rules were followed for the accelerated stability studies. For the expedited stability research, the formulations FC7 and FC8 were chosen. Each film (6.25cm<sup>2</sup>) was wrapped with butter paper, then aluminium foil, before being placed in an aluminium pouch and heat-sealed. For two months, a stability study was conducted at 40±2°C and 75±5% RH. After a 15-day period, samples were taken out and analysed for physicochemical qualities. After two months of storage at 40±2°C and 75±5% RH, the similarity factor was used to investigate the influence of storage on physical appearance, in-vitro disintegration time, tensile strength, and drug content[21].

### **Results and Discussion:**

**Morphological Properties of Prepared MDFs:** After three months of storage at room temperature (25°C) with a relative humidity of around 65±5%RH, the formulations showed no change in characteristics, including no crystallisation of the medication.

**Drug-Excipient Interaction Studies:** UV and FTIR studies were conducted to examine if there was any interaction between the drug and the excipients. A UV and FTIR scan of a physical mixture of drug and excipients exhibited peaks that were comparable to those of the pure drug, indicating that there was no interaction between the drug and the excipients, as shown in figure 3 and 4.

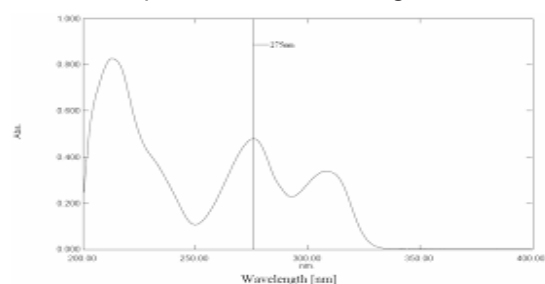


Figure 3: UV spectrum of drug and excipients in phosphate buffer pH 6.8

Table 3: Physico-chemical evaluation of Cisapride mouth dissolving film

Formulation code	Thickness (mm) ±SD	Weight variation (mg)	pH	% Moisture loss	% Moisture absorption
FC1	0.06±0.011	24.50±1.11	6.5±0.20	8.50± 0.55	7.75±0.30
FC2	0.07±0.014	26.50±1.60	6.4±0.30	8.73±0.45	8.11±0.35
FC3	0.08±0.013	28.75±1.25	6.5±0.20	8.24±0.31	9.56±0.45
FC4	0.09±0.009	29.25±1.57	6.4±0.25	8.11±0.25	10.90±0.26
FC5	0.08±0.008	31.50±1.80	6.9±0.30	6.55±0.23	11.98±0.40
FC6	0.07±0.013	30.25±1.55	7.1±0.15	5.85±0.19	12.18±0.35
FC7	0.08±0.011	32.75±1.71	7.3±0.25	4.45±0.21	13.11±0.30
FC8	0.09±0.007	31.50±1.55	7.4±0.30	4.15±0.19	14.15±0.25
FC9	0.09±0.013	29.25±1.61	7.4±0.20	5.27±0.20	14.23±0.40

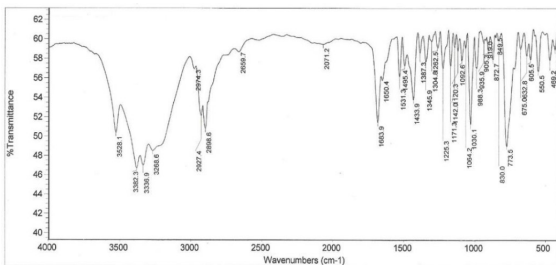


Figure 4: FTIR of drug and excipients

Surface Morphology Study by SEM: Cisapride showed crystalline structure while MDFs showed smooth surface without any scratches and transverse striations indicating that the drug is uniformly distributed. No crystals of the drug were observed in the prepared films Fig. 5 shows the results of SEM studies which were performed to assess the surface morphology of a drug and its preparation (MDFs).

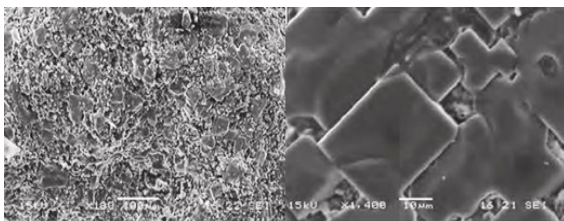


Figure 5: SEM image of drug and prepared film

#### Tack Test

Films F1 to F8 were non-tacky. The F9 was slightly tacky. This may be due to a lesser amount of glycerine. The results are shown in table 2.

Folding Endurance: As demonstrated in Table 2, the folding endurance of several MDFs ranged from 50 to 100.

#### Thickness evaluation

The consistency of the film thickness is critical since it is directly related to the accuracy of dosage distribution in the film. The thickness of the films rose as the amount of polymer increased, and was determined to be in the range of 0.06 to 0.09 mm, as shown in table 3.

#### Weight variation

The weight of the individual formulations was not significantly different from the average value in any of the batches. Weight variation as shown in table 3 for prepared film was found to be in the range of 24 to 32 mg.

#### pH evaluation

The pH of the surface was measured with a pH metre. The surface pH of prepared MDFs was found to be in the range of 6.1 to 7.5 in Table 3, indicating that they were in the neutral pH range and would not cause irritation when placed in the oral cavity.

#### Percentage moisture loss

To check the integrity of films in the dry state, percentage moisture loss was computed. Films were cut into 6.25 cm<sup>2</sup>, weighed, and stored in desiccators with fused anhydrous calcium chloride. The films were removed and

reweighed after 72 hours, as shown in Table 3.

**Percentage Moisture Absorption**

The % moisture absorption test was used to determine the film's physical stability or integrity in a humid environment. The moisture uptake of the films (n=3) was measured by exposing them to a 75%RH environment (saturated calcium chloride solution) at room temperature for one day, table 3 shows the results.

**Swelling Index**

The swelling index is used to measure the ability of hydrophilic polymers to absorb water after being hydrated. Drug release from a film is also affected by the rate and extent of film hydration and swelling. The amount of swelling was found to be directly proportional to the concentration of polymer and plasticizer in the current investigation, as shown in table 4.

**Drug Content Uniformity:** The content uniformity test was carried out to ensure that the medicine was distributed evenly. All of the formulas were tested for content homogeneity. The results showed that there was good homogeneity in drug content across all formulations, ranging from 91.50 to 99.05%. The drug concentration of the formulations is shown in Table 4.

Table 4: Swelling index and drug content of Cisapride mouth dissolving film

Formulation code	Swelling index	Drug content
FC1	41.50%±2.08	83.40±1.01

FC2	45.50%±1.50	93.30±1.14
FC3	52.45%±2.11	91.40±1.25
FC4	63.42%±1.45	78.20±1.75
FC5	69.42%±1.75	87.90±1.03
FC6	70.42%±2.10	92.30±1.19
FC7	83.22%±1.50	97.79±1.13
FC8	86.25%±1.25	99.15±1.11
FC9	80.25%±2.14	90.11±1.42

**In-vitro Dissolution Study:** The data reveals that the percentage of drug release at the end of 5th minute was between 65.10 to 96.2% for formulations F1 to F9. All formulations had a nearly identical release pattern, with rapid release in the first few minutes, followed by a steady release, and finally reaching a plateau level in around 5 minutes. Due to the various concentrations of polymer in each formulation, the rate of release during the early rapid release phase varied slightly between formulations. The greatest percentage drug release for Formulation F8 was 96.2 percent as shown in figure 6 and cumulative percent drug release from formulations FC1 to FC9 is shown in table 5.

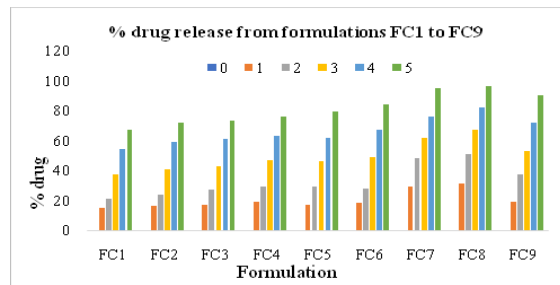


Figure 6: In-vitro percent drug release from formulations FC1 to FC9

Table 5: In-vitro percent drug release from formulations FC1 to FC9

Time (min.)	% Cumulative drug release								
	FC1	FC2	FC3	FC4	FC5	FC6	FC7	FC8	FC9
0	0	0	0	0	0	0	0	0	0
1	19.4	25.2	29.6	13.8	20.3	24.4	12.8	16.2	18.3
2	53.6	59.4	65.2	47.2	49.5	58.6	33.4	41.6	50.7
3	62.2	67.6	77.4	58.3	60.4	69.4	50.8	52.9	62.2
4	76.6	85.4	88.3	69.4	78.2	82.2	58.9	70.8	73.8
5	83.4	93.3	91.4	78.2	87.9	92.3	97.79	99.15	90.11



Table 6: Accelerated stability studies of formulations FC7 and FC8

Parameter	Appearance	Tensile Strength (kg/mm <sup>2</sup> )		Disintegration Time (sec)		Drug Content (%)	
	FC7 and FC8	FC7	FC8	FC7	FC8	FC7	FC8
Initial	Transparent and both surfaces smooth	0.490 ±0.75	0.480 ±0.60	115sec ±1.15	105sec ±1.25	97.79	99.15
After 10 days	Transparent and both surfaces smooth	0.488 ±0.57	0.478 ±0.45	113 sec ±1.00	103 sec ±1.01	97.74	99.00
After 20 days	Transparent and both surfaces smooth	0.484 ±0.71	0.477 ±0.75	112 sec ±0.94	102 sec ±1.06	97.45	98.76
After 30 days	Transparent and both surfaces smooth	0.484 ±0.65	0.476 ±0.70	109 sec ±1.40	100 sec ±1.00	97.30	98.52
After 40 days	Transparent and both surfaces smooth	0.482 ±0.69	0.475 ±0.92	108 sec ±1.12	98 sec ±0.75	97.27	98.15
After 50 days	Transparent and both surfaces smooth	0.481 ±0.85	0.472 ±0.51	107 sec ±1.16	97 sec ±1.11	97.13	98.09
After 60 days	Transparent and both surfaces smooth	0.480 ±0.50	0.471 ±0.53	106 sec ±1.20	95 sec ±1.00	96.15	98.01

This could be due to the bigger proportion of the hydrophilic polymer expanding at a faster rate and to a greater extent. The drug release was minimal in Formulation F9. This could be owing to a higher polymer concentration but a lower plasticizer content.

Accelerated Stability Studies for Optimized Formulation: Stability studies of optimised formulations FC3 and FC6 were carried out at 40 ±2 °C and 75 ±5% RH for 2 months to detect the change in dosage form performance due to storage. After a 10-day period, samples were taken and physicochemical parameters were assessed. The batch's effect on storage was investigated using the similarity factor. It was inferred from the data in Table 6 that formulations F7 and F8 were stable and preserved their original qualities with slight modifications. Physically, there was no change in look or flexibility. Furthermore, there were no significant differences in disintegration time or drug content. As a result, the formulations were discovered to be stable.

**Conclusion** Cisapride is a gastro retentive agent; commonly a quick release dosage form will be highly suitable for having rapid onset of action. Water soluble polymers were chosen and films were formulated by solvent casting method. Some of these polymers individual not give films of desirable property. From the study, combination of two polymers i.e., HPMC 3 cps

and Lycoat gave best films with required physical characteristics.

Cisapride MDFs were tested for stability at 40°C / 75% RH for one month, did not show any change in morphology, content of the drug and dissolution. The mean thickness and weight of buccal polymeric patches increased with an increase in the amount of polymer weight.

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**Conflict of interest:** None

#### References

1. Shariff, Z. B., Dahmash, D. T., Kirby, D. J., Missaghi, S., Rajabi-Siahboomi, A., & Maidment, I. D. (2020). Does the Formulation of Oral Solid Dosage Forms Affect Acceptance and Adherence in Older Patients? A Mixed Methods Systematic Review. *Journal of the American Medical Directors Association*. 21(8), 1015-1023.
2. Pawar, R., Sharma, R., Sharma, P., & Darwhekar, G. N. (2019). A Review on Mouth Dissolving Film. *Journal of Drug Delivery and Therapeutics*, 9(6), 206-210.
3. Hannan, P. A., Khan, J. A., Khan, A., & Safiullah, S. (2016). Oral dispersible system: A new approach in drug delivery system. *Indian journal of pharmaceutical sciences*, 78(1), 2.
4. Uddin, M. N., Allon, A., Roni, M. A., & Kou-

- zi, S. (2019). Overview and future potential of fast dissolving buccal films as drug delivery system for vaccines. *Journal of Pharmacy & Pharmaceutical Sciences*, 22, 388-406.
5. Wertz, P. W. (2021). Roles of Lipids in the Permeability Barriers of Skin and Oral Mucosa. *International Journal of Molecular Sciences*, 22(10), 5229.
6. Patel, N. A., Shah, D. P., & Patel, T. J. (2016). A novel approach for buccal drug delivery system-buccal film. *Pharma Science Monitor*, 7(2).
7. Pingale, P. L., Rajput, A. P., & Bagade, S. B. (2020). Use of natural superdisintegrants in formulation of fast disintegrating tablet of atenolol. *European Journal of Molecular & Clinical Medicine*, 7(09), 3743-3752.
8. Pingale, P.L., Boraste, S. S., & Amrutkar, S. V. (2021). Formulation and evaluation of pravastatin fast disintegrating tablets using natural superdisintegrant. *Journal of Medical Pharmaceutical & Allied Science*, 10(3), 2977-2981.
9. Bala, R., Pawar, P., Khanna, S., & Arora, S. (2013). Orally dissolving strips: A new approach to oral drug delivery system. *International journal of pharmaceutical investigation*, 3(2), 67-76.
10. Alqahtani, M. S. (2021). Advances in oral drug delivery. *Frontiers in Pharmacology*, 12, 62.
11. Rada, S. K., & Kumari, A. (2019). Fast dissolving tablets: waterless patient compliance dosage forms. *Journal of Drug Delivery and Therapeutics*, 9(1), 303-317.
12. Kumar, R. S., & Ghosh, A. (2019). Fast dissolving tablets: patient compliance dosage forms. *World Journal of Pharmacy and Pharmaceutical Sciences*, 8(3), 280-300.
13. Prasad, N., Issarani, R., & Nagori, B. P. (2013). Ultraviolet spectrophotometric method for determination of glipizide in presence of liposomal/proliposomal turbidity. *Journal of Spectroscopy*, 836372, 1-5.
14. Pingale Prashant, L., & Nikhilita, P. (2021). Effect of Natural Polymer on Release Retarding Rate of Glimepiride Sustained Release Tablet. *Journal of Advanced Scientific Research*, 12(1), 145-150.
15. Aghrbi, I., Fülöp, V., Jakab, G., Kállai-Szabó, N., Balogh, E., & Antal, I. (2021). Nanosuspension with improved saturated solubility and dissolution rate of cilostazol and effect of solidification on stability. *Journal of Drug Delivery Science and Technology*, 61, 102165.
16. Kathpalia, H., & Patil, A. (2017). Formulation and evaluation of orally disintegrating films of levocetirizine dihydrochloride. *Indian Journal of Pharmaceutical Sciences*, 79(2), 204-211. Alkahtani, M. E., Aodah, A. H., Abu Asab, O. A., Basit, A. W., Orlu, M., & Tawfik, E. A. (2021). Fabrication and Characterization of Fast-Dissolving Films Containing Escitalopram/Quetiapine for the Treatment of Major Depressive Disorder. *Pharmaceutics*, 13(6), 891.
17. Bala, R., & Sharma, S. (2018). Formulation optimization and evaluation of fast dissolving film of aprepitant by using design of experiment. *Bulletin of Faculty of Pharmacy, Cairo University*, 56(2), 159-168.
18. Raza, S. N., Kar, A. H., Wani, T. U., & Khan, N. A. (2019). Formulation and evaluation of mouth dissolving films of losartan potassium using 32 factorial design. *International Journal of Pharmaceutical Sciences and Research*, 10(3), 1402-1411.
19. Patel, M. A., & Pingale, P. L. (2014). Comparative effect of different high functionality excipients on various characteristics of vardenafil HCl tablets (BCS II drug). *International Journal of Pharmaceutical Sciences and Research*, 5(12), 5447-5551.
20. Chennuri, A., & Prasanthi, D. (2018). Solubility enhancement of aripiprazole by solid-self emulsifying drug delivery systems. *International Journal of Pharmaceutical Sciences and Drug Research*, 10(4), 233-245.

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