

# Oral Dissolving Films of Chlorpheniramine Maleate: Formulation and Evaluation

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## ABSTRACT

**Background:** The primary purpose of this research was to carry out the study of the Orally Dissolving Films (ODFs) of Chlorpheniramine Maleate (CM). The films were formulated by solvent casting method. This research was also performed to evaluate the characteristics of the film and to examine the release kinetics of CM from the polymeric film. **Materials and Methods:** The oral films were formulated utilizing polymers that include Hydroxypropyl methylcellulose E 15, and polyvinyl acetate. The combination of two polymers with Polyvinyl Pyrrolidone K-30 (PVP K-30) was used to optimize the drug release. The study utilized Citric acid as a saliva-stimulating factor, Mannitol as a sweetening factor and Polyethylene Glycol 400 (PEG 400) as a plasticizer. Water and methanol were used as solvents. The effect of film-forming polymers, film thickness on the physicochemical characteristics, and drug release from ODFs was determined. The CM ODFs were evaluated for specific quality control factors. **Results and Discussion:** The ODFs passed all the tests. Among different batches, the F8 batch was found suitable which contains Hydroxypropyl methylcellulose E15 with a combination of polyvinyl pyrrolidone K-30 to achieve low disintegration time along with good physicochemical properties. Formulation F8 releases 99% of the drug in 8 min. Stability studies revealed that formulations were stable. **Conclusion:** These results suggested that the disintegration and drug release of Chlorpheniramine maleate could be controlled to a greater degree by optimizing the formulation variables in the formulation of CM ODFs.

**Keywords:** Oral Dissolving Films (ODFs), Chlorpheniramine Maleate, Hydroxypropyl methyl cellulose E15 (HPMC E15), Polyvinyl Acetate (PVA), Solvent casting method.

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## INTRODUCTION

The oral route is the most desired one for systemic effect which is attributed to its ease of administration, adaptability, non-invasiveness, patient compliance, and acceptability.<sup>1</sup> Tablet is the most recommended dosage because of ease in manufacturing, transporting, and higher patient compliance.<sup>2</sup> Generally, geriatric, nauseous, pediatric, bedridden, and noncompliant patients have trouble swallowing the traditional oral dosage form and do not take medicines as directed.<sup>3</sup> Hence therapy becomes noncompliant and ineffective. Therefore, ODFs were developed that dissolve or disintegrate fast (within three minutes) in mouth, without requiring water.<sup>4</sup> ODFs resemble postage stamps in their shape, thickness, and size, that dissolve or disintegrate quickly in the oral cavity when contact with saliva, and form solution

or suspension which helps in rapid absorption.<sup>5</sup> ODFs are very suited for the drugs with high first-pass metabolism. These are used for improving bio-availability, minimizing adverse or side effects and, also making it cost-effective.<sup>6</sup>

Chlorpheniramine maleate, an anti-histamine drug is indicated in the management of allergic reactions related to skin and mucous membranes.<sup>7</sup> According to the Biopharmaceutical Classification System (BCS), CM belongs to Class I. CM was especially designed to provide a fast onset of action, increase patient compliance for pediatrics, elderly and patients who find difficulty in swallowing.<sup>8</sup> The present study was an attempt to give pleasant taste, along with good bioavailability.

## MATERIALS AND METHODS

### Materials

CM is given as a gift sample by JSN Chemicals Ltd. HPMC E15, Polyvinyl Alcohol, Polyvinyl pyrrolidone K-30, Citric Acid, Mannitol and methanol were bought from Asian Scientific, Hyderabad.



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## Methods

### Fourier Transform Infrared Spectroscopy (FTIR)

The compatibility between the pure CM and excipients was determined by FTIR spectra.<sup>9</sup> The solid powder sample was placed directly on a yellow crystal made up of ZnSe. Then the spectra were recorded over the wave number of 4000 cm<sup>-1</sup> to 400 cm<sup>-1</sup>.

### Analytical methods

#### Determination of Chlorpheniramine maleate UV Absorption maxima

10 µg/mL solution prepared using pH 6.8 phosphate buffer was scanned between 200 to 400 nm using Elico double-beam UV-visible spectrophotometer.

#### Preparation of standard curve

A series of dilutions 10, 20, 30, 40, and 50 µg/mL was measured for absorbance against a blank phosphate buffer pH 6.8 at the  $\lambda_{\max}$  of 262 nm.

#### Dose calculation

The dose of CM is 4 mg. Hence the amount of CM required in 2 cm x 2 cm square film is 4 mg. The diameter of petriplate is 9 cm.<sup>10</sup>

$$\begin{aligned} \text{Area of Petriplate} &= \pi r^2 \\ &= 3.14 \times 4.5 \times 4.5 \\ &= 63.58 \text{ cm}^2 \end{aligned}$$

$$\begin{aligned} \text{Number of patches} &= \text{Area of Petriplate} / \text{size of the square film} \\ &= 63.58 / 4 \\ &= 15.9 \text{ (app. 16)} \end{aligned}$$

$$\begin{aligned} \text{Total amount of the CM} &= \text{Number of patches} \times \text{Dose} \\ &= 15.9 \times 4 = 63.6 \text{ mg (app. 64)} \end{aligned}$$

Therefore, 63.58 cm<sup>2</sup> of petri plate should contain 63.6 mg of the CM which is fixed for all the formulations.

### Formulation of ODS Of Chlorpheniramine maleate

Chlorpheniramine maleate was selected as a drug based on its physicochemical and biological properties and also based on its suitability for Oral dissolving films. HPMC E15, PVA, and PVP K-30 were selected as film-forming polymers. PEG 400 was selected as a permeation enhancer and plasticizer. Citric acid was selected as saliva-stimulating agent. Mannitol was selected as a sweetening agent. ODFs were prepared using solvent-casting method. Eight Formulations (F1-F8) were created, the compositions of which are listed in Table 1. The Drug CM, citric

acid, and mannitol were suitably dissolved in water and methanol. An aqueous preparation of polymer was separately prepared by dissolving in suitable quantity of water and methanol. Aqueous solution of polymers was then added to the previously prepared solution, thereafter PEG 400 (Plasticizer) was added to the mixture to make a transparent solution with constant stirring for 1 hour until a uniformly viscous solution was obtained. Thereafter kept in a sonicator for degassing for 10 min. The finished product was cast onto a Petri dish and dried in a hot air oven at 50°C for 24 hr. The dried ODFs were cut into square-shaped films. Each film had approximate surface area of about 4 cm<sup>2</sup> (2 cm x 2 cm) with a dose of 4 mg of chlorpheniramine maleate.<sup>11,12</sup>

### Evaluation of the Oral film

#### Physical appearance

The homogeneity, smoothness, transparency, color, flexibility were inspected for all the ODFs.<sup>13</sup>

#### Thickness

The films of about 2×2 cm<sup>2</sup> dimension (3 films each from 3 different polymeric films) were used to determine the thickness using Vernier caliper at three different positions.<sup>14</sup>

#### Average Weight

The average weight of prepared ODFs was determined by taking three 2×2 cm<sup>2</sup> dimension films from each formulated batch and weighing them on a digital balance. Thereafter average weight was calculated.<sup>14</sup>

#### Folding endurance

Three ODFs of about 2×2 cm<sup>2</sup> from each batch were taken. Each ODF was folded at the same place repeatedly until cracks were visible. The folding endurance was calculated for ODFs of each formulation.<sup>15</sup>

#### Moisture content

This parameter was determined by initially weighing the ODF and, then putting this ODF in a desiccator (containing calcium carbonate) for about three days. Later, strips were taken out of the desiccator and reweighed. Moisture content was estimated using the below formula.<sup>16</sup>

$$\% \text{ Moisture absorbed} = \frac{(\text{Final weight} - \text{Initial weight})}{\text{Initial weight}} \times 100$$

#### Surface pH

Three ODFs of about 2×2 cm<sup>2</sup> from each batch were taken. Each ODF was moistened with 2 mL of pH 6.8 phosphate buffer in a Petri plate for 30 sec. The pH was noted after equilibrating the solution for 1 min using pH meter.<sup>17</sup>

## Drug content determination

The Limit of content uniformity should be 85-115%.<sup>18</sup> The ODFs of about 2×2 cm<sup>2</sup> from each batch was placed in a beaker containing 50 mL of pH 6.8 phosphate buffer. The contents were stirred to dissolve the film and then filtered. The absorbance of the solution was measured against the corresponding blank solution at 262 nm wavelength using UV-visible spectrophotometer. The average drug content was calculated.

$$\% \text{ drug content} = (\text{amount of drug in 50 mL}) / (\text{theoretical amount}) \times 100$$

## In vitro Disintegration Test

Disintegration time is the time when an oral film starts breaking when brought in contact with water or saliva. For a fast-dissolving film, the time of disintegration should be in the range of 5-30 sec. The test was performed using USP disintegration test apparatus, using 250 mL phosphate buffer pH 6.8 at 37±0.5°C as a medium, 2 cm<sup>2</sup>×2 cm<sup>2</sup> strips was placed in the tube, and the disks were placed over it. Three oral films of each formulation were kept in the disintegration apparatus and the average of three disintegration time was calculated.<sup>19</sup> Every formulated oral dissolving film was cut into 2×2 cm<sup>2</sup> dimension and its *in vitro* disintegration times was determined visually in a beaker of 20 mL containing distilled water with swirling every 10 sec. The mean of three readings was determined.<sup>20</sup>

## In vitro dissolution test

The dissolution time is the time when the film completely dissolves. The *in vitro* dissolution test was carried out in a USP-I rotating basket dissolution apparatus. Drug-loaded films were cut into 2 cm diameter and placed in the basket of the dissolution apparatus. The volume of dissolution medium (simulated saliva fluid i.e., phosphate buffer pH 6.8) was 500 mL and was maintained at the temperature of 37±4°C and the basket was rotated at 50 revolutions per min (rpm). Samples of 5 mL were withdrawn at predetermined time intervals and replaced with 5 mL of fresh medium. The absorbance was recorded at the wavelength of 262 nm against blank using a UV-visible spectrophotometer.<sup>21</sup>

## Evaluation of oral film by permeation studies (in vitro Diffusion cell)

An *in vitro* diffusion study through a cellophane membrane was carried out using a modified Franz diffusion cell with internal diameter 2.5 cm. The cellophane membrane was mounted between the donor and the receptor compartments. The donor compartment was filled with the drug dissolved in 20 mL of simulated salivary fluid of pH 6.8, which was maintained at 37±0.2°C, and hydrodynamics were maintained using a magnetic stirrer. Samples (1 mL) were withdrawn from the receptor compartment (phosphate buffer pH 6.8) at suitable time intervals of 2 min and replaced with an equal amount in the receptor compartment with phosphate buffer. The percentage amount of drug presence (diffused from the donor to the receptor compartment) in the receptor compartment was determined by measuring the absorbance in UV-visible spectrophotometer at  $\lambda_{\text{max}}$  of 262 nm.<sup>18,22</sup>

## Stability studies of F8 formulation

The final optimized formulation was subjected to aggravated conditions of temperature and relative humidity by wrapping it in aluminum foil and packaging it in a glass container. The films were kept in stability chamber, at 40±2°C temperature and 75±5% RH for 3 months. After 3 months the films were tested.<sup>23</sup>

## RESULTS AND DISCUSSION

### FTIR

The interpretation of FTIR spectra appertaining to Chlorpheniramine maleate (Figure 1) and optimized formulation (Figure 2) elicited no drug-excipients interaction.

### UV Absorption maxima

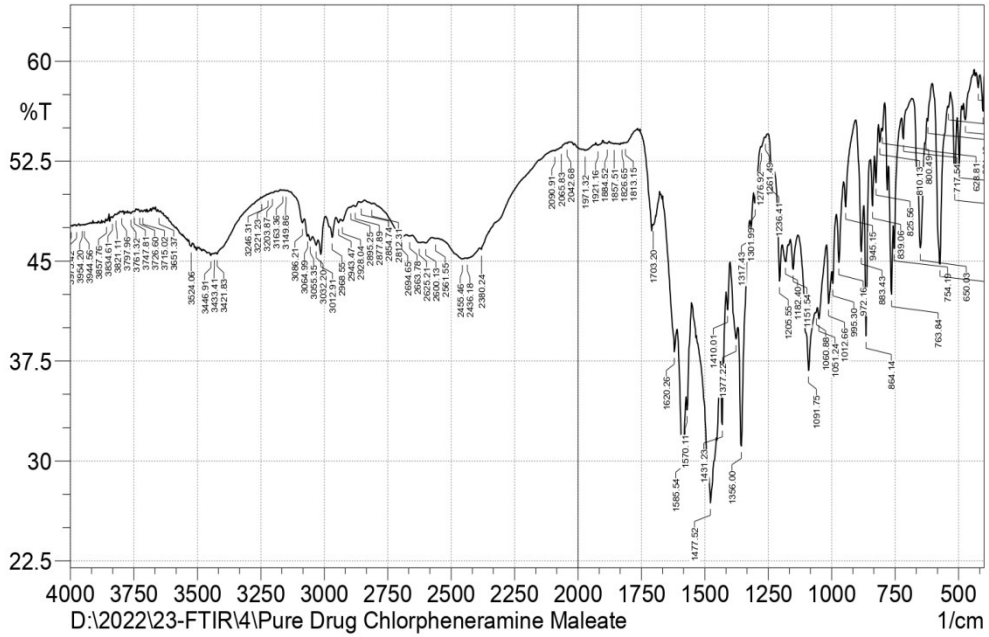
The prepared 10 µg/mL solution was found to have 262 nm absorption maxima (Figure 3).

### Standard Calibration Curve of Chlorpheniramine Maleate

The concentration range of 10-50 µg /mL obeyed the Beer's Lambert law. It was observed from the Figure 4 that it had good reproducibility with R<sup>2</sup> value of 0.9998.

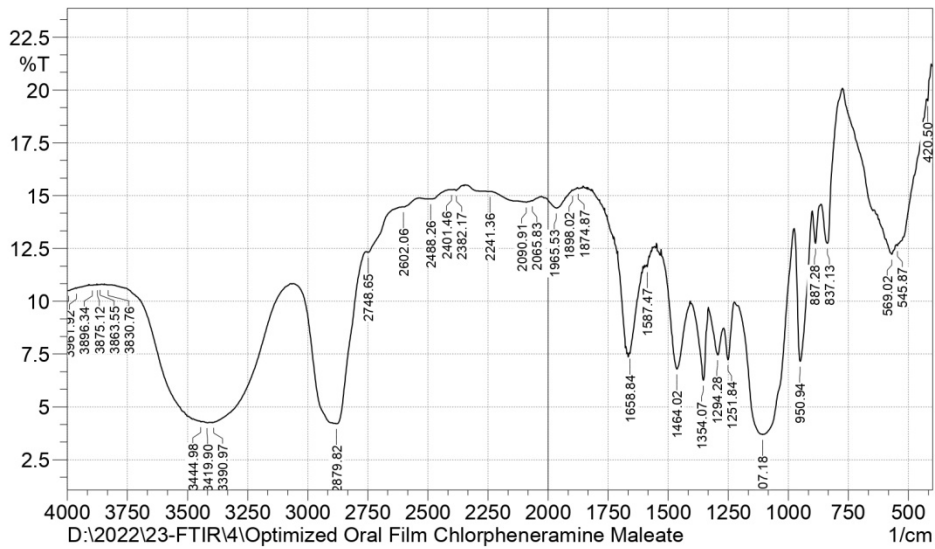
**Table 1: Formulation table of CM oral dissolving Film.**

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8
Drug	64	64	64	64	64	64	64	64
HPMC E15	200	300	400	-	-	-	-	200
PVA	-	-	-	200	300	400	200	-
PVP K 30	-	-	-	-	-	-	100	100
PEG 400	1	1	1	1	1	1	1	1
Citric acid	12	12	12	12	12	12	12	12
Mannitol	12	12	12	12	12	12	12	12



Comment: D:\2022\23-FTIR\4\Pure Drug Chlorpheniramine Maleate  
 No. of Scans: 10  
 Resolution: 4 [1/cm]  
 Apodization: SqrTriangle  
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 User: Administrator

Figure 1: FTIR Spectra of Chlorpheniramine Maleate.



Comment: D:\2022\23-FTIR\4\Optimized Oral Film Chlorpheniramine Maleate  
 No. of Scans: 10  
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Figure 2: FTIR Spectra of Optimized Batch.

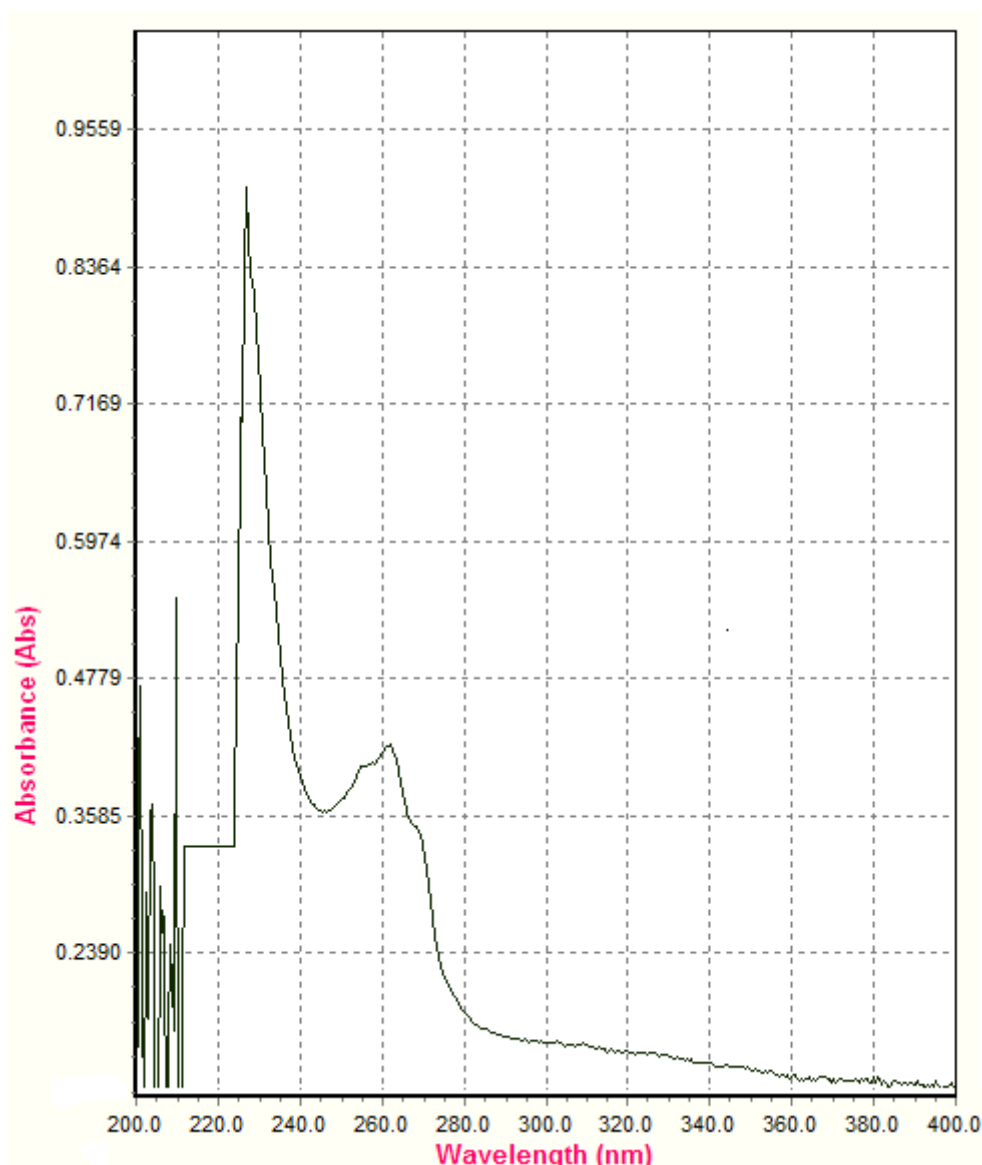


Figure 3: Spectrum showing absorption maxima.

### Evaluation of ODFs of Chlorpheniramine Maleate

The results of the physical appearance, average weight, thickness, and folding endurance of oral dissolving films are tabulated in Table 2. The results of the drug content, percentage moisture content, surface pH, and *in vitro* disintegration time of ODFs is given in Table 3.

#### Physical appearance

The orally disintegrating films F1, F2, F3 prepared by HPMC E15 were transparent. The F4, F5, F6 prepared by PVA were semi-transparent. The films prepared with a combination of PVA and PVP K-30 was opaque whereas HPMC and PVP were transparent. The ODFs were smooth no bubbles and cracks.

#### Average weight

From the results, it was observed that weight variations were not significant, which revealed uniformity of drug distribution.

#### Thickness

Mean thickness of formulated ODFs ranges from  $0.11 \pm 0.01$  mm to  $0.6 \pm 0.05$  mm.

#### Folding endurance

The results indicate (Table 2) that the folding endurance increased on increasing polymer concentration in the ODF. The folding endurance of all the ODFs ranged  $112 \pm 2.03$  to  $<300$ .

### Drug content determination

Percentage drug content ranged  $91.23 \pm 0.0329\%$  to  $103.5 \pm 0.153\%$  in the ODFs that ensured good uniformity of drug content.

### Percentage Moisture content

The moisture content (%) of all the ODFs ranged from  $0.95 \pm 0.035$  to  $2.53 \pm 0.025$  which indicates that the ODFs has very small amount of moisture due to which films exhibited good physical integrity and stability.

### Surface pH

The ODFs had surface pH ranging from  $6.5 \pm 0.24$  to  $6.9 \pm 0.323$  which is around neutral pH.

### In vitro Disintegration Test

The results showed optimized ODFs containing the combination of the polymers were undergoing disintegration in less time than the films containing single polymer. Most of the ODFs were disintegrating within 2 min. The ODFs containing HPMC E15 disintegrate faster than formulations containing PVA.

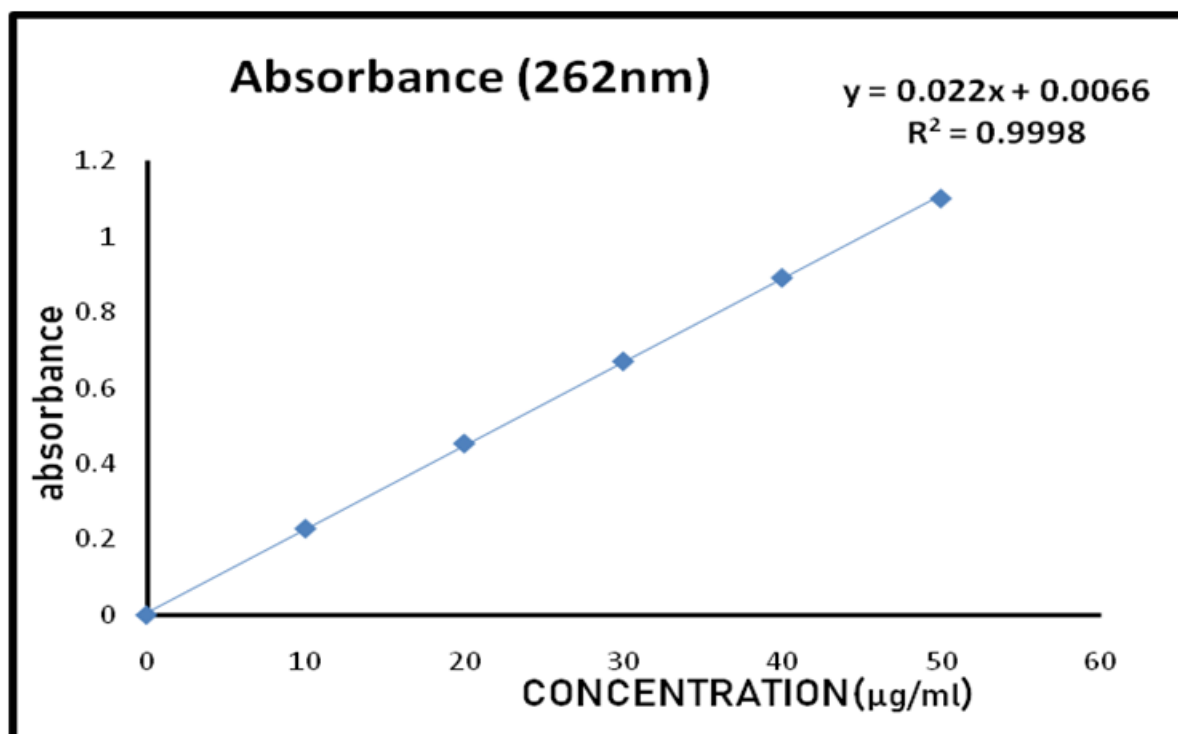
### In vitro release studies

At different time intervals, the *in vitro* dissolution profile of ODFs was recorded up to 12 min. It confirmed that the drug Chlorpheniramine Maleate get rapidly released from all the ODFs. To study the effect of film thickness and polymer concentration on drug release, formulations F1, F2, F3 were prepared using HPMC E15 as a polymer and ODFs F4, F5, F6 were prepared using PVA

**Table 2: Evaluation of ODFs of Chlorpheniramine Maleate.**

Formulation Code*	Physical Appearance*	Average weight (mg)*	Thickness (mm)*	Folding Endurance*
F1	Transparent	$60 \pm 1.73$	$0.35 \pm 0.045$	$112 \pm 2.03$
F2	Transparent	$67.3 \pm 2.12$	$0.5 \pm 0.001$	$122 \pm 1.48$
F3	Transparent	$111.3 \pm 2.35$	$0.52 \pm 0.011$	$200 \pm 0.10$
F4	Semi-Transparent	$82 \pm 2.02$	$0.11 \pm 0.028$	$249 \pm 2.96$
F5	Semi-Transparent	$89 \pm 3.64$	$0.13 \pm 0.003$	>250
F6	Semi-Transparent	$97 \pm 1.89$	$0.14 \pm 0.048$	>250
F7	Opaque	$76.3 \pm 2.32$	$0.6 \pm 0.053$	$144 \pm 2.56$
F8	Transparent	$70.6 \pm 3.65$	$0.3 \pm 0.021$	$100 \pm 3.54$

\*Mean  $\pm$  Standard deviation (SD),  $n=3$ .



**Figure 4:** Standard Curve of Chlorpheniramine maleate.

as a polymer. The order of *in vitro* drug release for HPMC E15 ODFs was F3>F2>F1 (Figure 5) and for PVA ODFs was F4>F5>F6 (Figure 6). The cumulative percent of Chlorpheniramine Maleate at the end of 8 min was 74±0.11, 68±1.45 and 60±0.97 for F1, F2 and F3 respectively. The cumulative percent of Chlorpheniramine Maleate at the end of 8 min was 84±0.88, 72±1.23 and 68±0.87 for F4, F5 and F6 respectively.

To study the effect of wetting or solubilizing agent, ODFs containing HPMC and PVA were selected. PVP K-30 was added to the formulation. The cumulative percent of Chlorpheniramine Maleate at the end of 8 min was 95±1.67 and 99±1.86 respectively as reflected in Figure 7.

## Evaluation of oral film by permeation studies

### Diffusion studies

The diffusion profile of optimized ODFs F8 was recorded using Franz diffusion cell. It was observed that in 8 min the entire Chlorpheniramine from the optimized ODF diffused completely (Figure 8). Thereby it showed a good diffusion coefficient, which was required for faster onset of action.

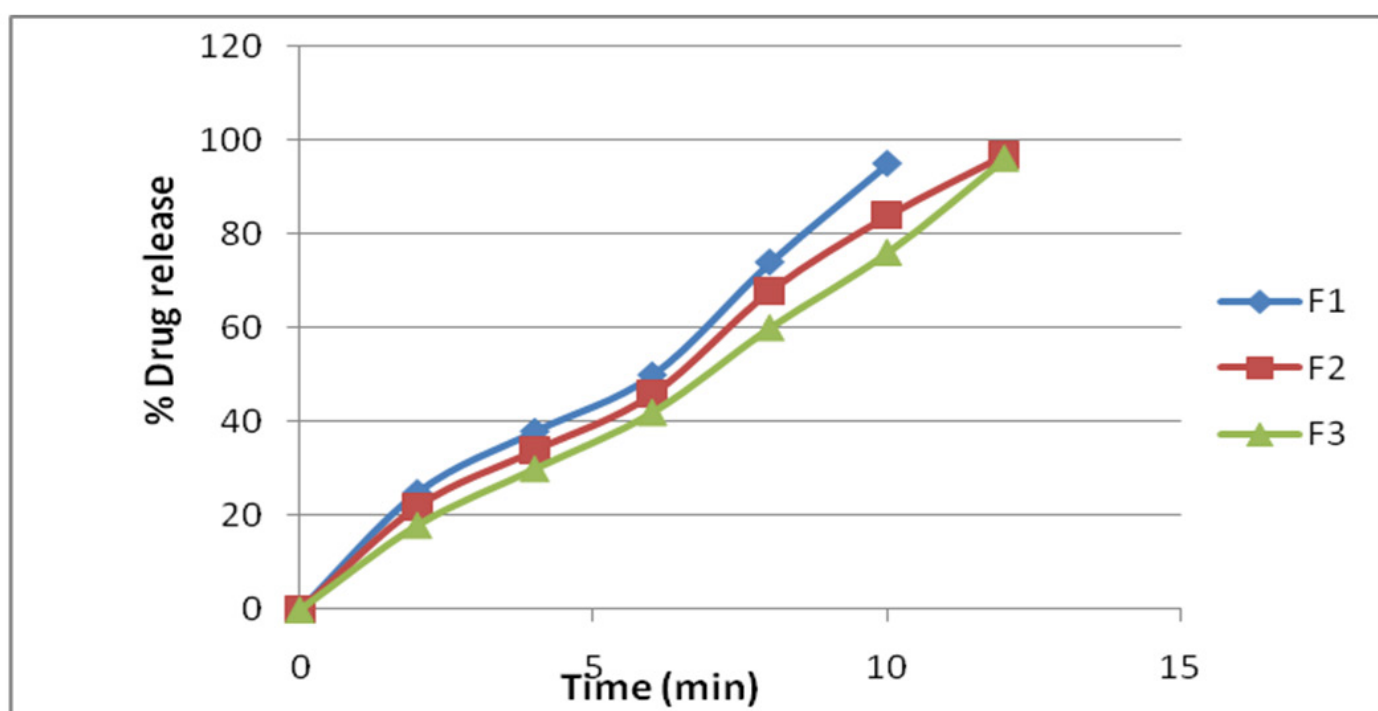
### Stability studies of optimized formulation

The appearance of the ODFs remains unchanged throughout the studies. There was no statistically significant change observed in weight, surface pH, drug content, and disintegration time and *in vitro* dissolution after 3 months (Table 4).

**Table 3: Evaluation of ODFs of Chlorpheniramine Maleate.**

Formulation Code	Drug Content (%)	Moisture Content (%)	Surface pH	Disintegration Time (sec)
F1	91.23±0.0329	1.25±0.032	6.8±0.11	70±2.02
F2	96.880±0.045	1.08±0.014	6.5±0.24	60±3.05
F3	93.24±0.039	2.53±0.025	6.7±0.042	45±3.03
F4	94.08±0.045	1.76±0.035	6.8±0.022	90±2.51
F5	95.42±0.056	1.46±0.035	6.6±0.038	84±4.50
F6	103.5±0.153	1.55±0.025	6.8±0.78	56±5.03
F7	95.46±0.055	1.12±0.065	6.9±0.323	35±5.02
F8	93.76±0.050	0.95±0.035	6.8±0.66	30±3.45

Mean±Standard deviation (SD), n=3.



**Figure 5:** *In vitro* dissolution for F1-F3.

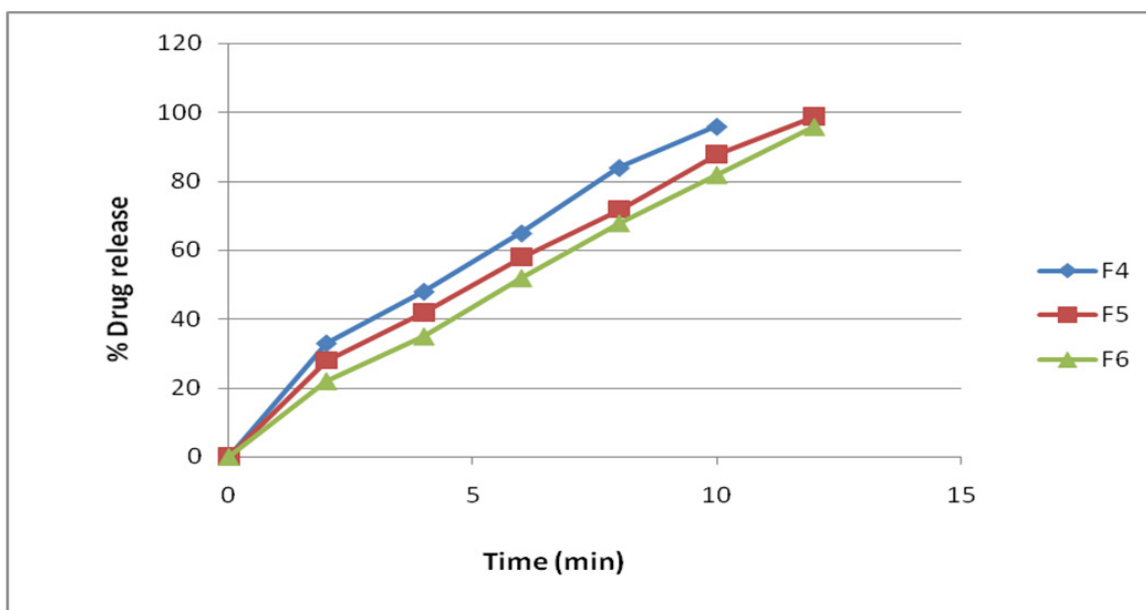


Figure 6: *In vitro* dissolution for F4-F6.

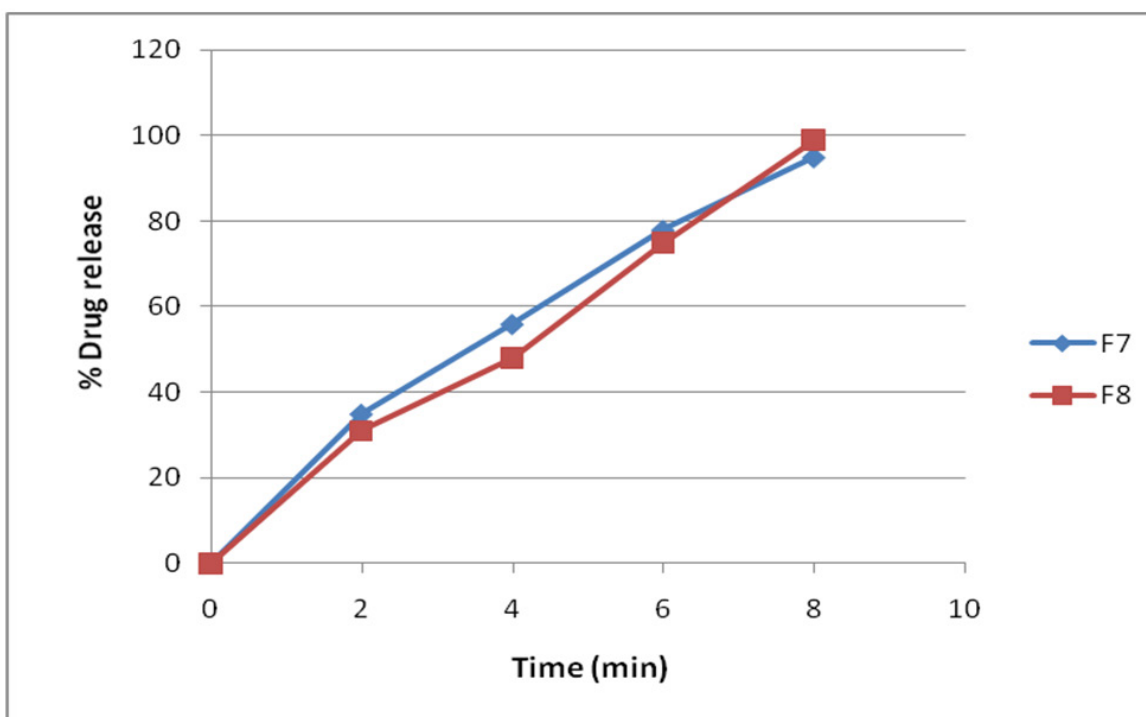


Figure 7: *In vitro* dissolution data F7-F8.

## DISCUSSION

The interpretation of FTIR spectra appertaining to Chlorpheniramine Maleate (Figure 1) and optimized formulation (Figure 2) elicited no drug-excipients interaction. The appearance of all the prepared ODFs was homogenous, flexible and non-sticky in texture properties with elegant appearance. The thickness of films increased as the polymer concentration increased. All the ODFs exhibited good folding endurance that ensured good

flexibility. The neutral pH range of ODFs ensured no irritation to the mucosa of the oral cavity. The results indicate that the disintegration time decreased as the polymer concentration increased.

For the formulations F1, F2 and F3, it was obvious that formulation showed a significant decrease in cumulative percentage drug release with increase in concentration of polymer. This may be attributed to dense (thick) gel formed due to rapid water uptake by

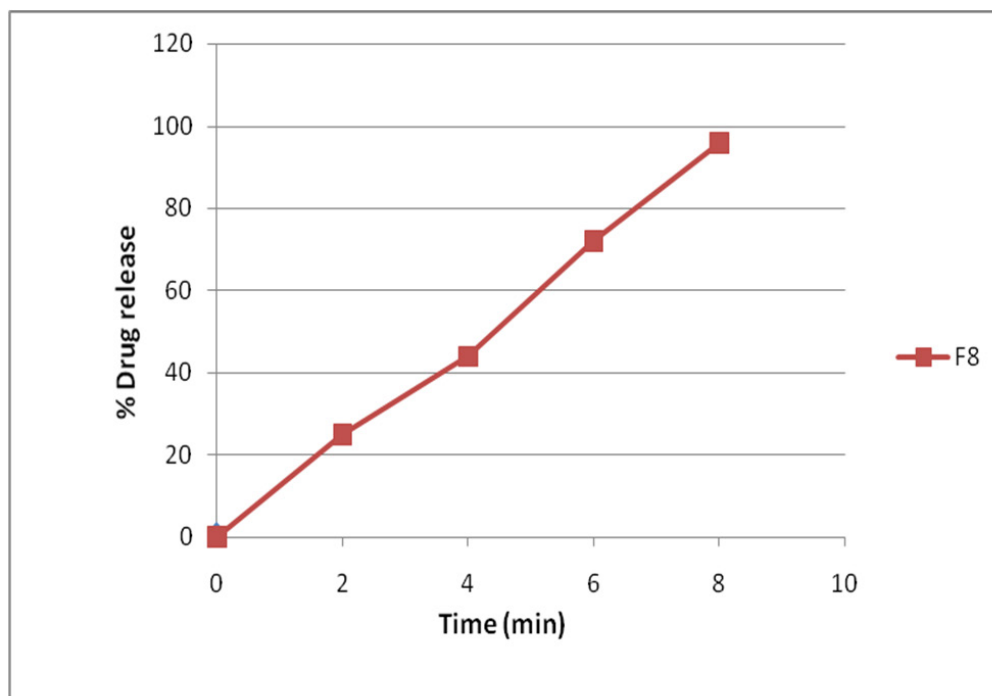


Figure 8: *In vitro* diffusion time data for F8.

Table 4: Stability Study for Formulation F8.

Parameter	Initial	After 3 months
Thickness (mg)	0.3±0.218	0.28±0.115
Average Weight (mg)	79±0.623	78±1.5
Folding endurance	103±0.232	105±0.766
Disintegration time (sec)	30±0.422	35±0.515
Percentage drug content (%)	102±0.331	107±0.188
Surface pH	6.9±0.07	6.9±0.2

Mean±Standard deviation (SD), n=3.

high concentration of polymer that further retards water uptake by the dissolution media thereby decreases the Chlorpheniramine release. The ODFs F4, F5, F6 containing PVA showed more drug release than formulations F1, F2 and F3 containing HPMC polymer. This resulted from the fact that PVA has high solubility in water. The ODFs with HPMC and PVP K-30 showed superior drug release profile when compared to PVA and PVP K-30. Overall, the Chlorpheniramine release from the ODF F8 showed good release profile as compared to that of other ODFs.

The percentage of drug released from the dissolution studies were similar to the drug diffused through the cellophane membrane. The results of stability studies indicated that the Chlorpheniramine was stable in ODFs.

## CONCLUSION

Chlorpheniramine Maleate was especially designed to increase the patient compliance that provides fast onset of action along with ease of swallowing especially for pediatrics, geriatrics and individuals who suffer from difficulty of swallowing. The present research was an attempt to mask the taste of CM with ODFs and also as to provide good bioavailability, pleasant taste along with improved patient compliance.

## ACKNOWLEDGEMENT

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## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

## ABBREVIATIONS

**ODF:** Orally dissolving films; **CM:** Chlorpheniramine Maleate, **PVP K-30:** Polyvinyl pyrrolidone K-30; **PEG 400:** Polyethylene glycol 400; **HPMC E15:** Hydroxypropyl methyl cellulose E15; **PVA:** Polyvinyl acetate; **BCS:** Biopharmaceutical Classification System; **FTIR:** Fourier transform infrared spectroscopy.

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