



Formulation, Development and In-Vitro Evaluation of Loratadine Fast-Dissolving Films

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ABSTRACT

The present work describes the Formulation and in-vitro Evaluation of Loratidine Fast Dissolving Films. Fast dissolving films have been played an important role in the current pharmaceutical research. They have convenience and ease of use over other dosage forms such as orally disintegrating tablets and immediate release tablets. It improves the efficacy of APIs by dissolving within a minute in oral cavity after the contact with less saliva as compared to fast dissolving tablets, without chewing and no need of water for administration. Loratidine is a second generation orally administered non-sedative antihistamine used in the symptomatic relief of allergy such as hay fever (allergic rhinitis), urticarial(hives) and other skin allergies. In the work undertaken, an attempt was made to prepare quick release films of Loratidine with the purpose of developing a dosage form for very quick onset of action, which will be beneficial in managing severe condition of allergies, aiding in enhancement of bio availability and very convenient for administration, without the problem of swallowing & without using water. Thirteen (F1 – F13) fast dissolving films of Loratidine were developed using different viscosity grades of HPMC (E3 & E15) and Sodium CMC as film forming polymers and Poly ethylene glycol 400 as plasticizer. HPMC is a water-soluble synthetic polymer which was used as film former form many years. The films of Loratidine were prepared by solvent casting method using di-chloromethane and methanol as solvents. The prepared 2 cm X 2 cm films were evaluated for drug content, folding endurance, thickness, in-vitro disintegration time and in-vitro drug release time. Among all the 13 Formulations, A film formed of F1 formulation was transparent, smooth and homogenous with best film forming property among all the film forming agents. Films in formulation F1 showed its in-vitro disintegration time was 2 Min 10 Sec.

Keywords: Fast dissolving films (FDFs), HPMC E3 & HPMC E15, Sodium CMC, PEG 400, solvent casting Method, in-vitro.

1. INTRODUCTION

Fast-dissolving oral films:

Fast-dissolving oral films (FDOFs) are a novel drug delivery system designed to dissolve or disintegrate rapidly when placed on the tongue or in the buccal cavity. These films provide a faster onset of action compared to many conventional oral dosage forms. They are primarily prepared using hydrophilic polymers that readily dissolve in the presence of saliva. This rapid dissolution enhances patient convenience and improves the overall drug administration process.

Fast-dissolving oral films effectively overcome several limitations associated with conventional fast-dissolving or dispersible intraoral tablets, particularly the risk of choking. They are easy to handle and administer, making them suitable for patients of all age groups. In addition, these films help mask the unpleasant taste of drugs while ensuring accurate dose delivery. They are also simple to manufacture and can be conveniently packaged, contributing to improved patient compliance and product stability¹.

Certain bioactive compounds can be absorbed directly through the oral mucosa before the saliva reaches the stomach. This route of absorption helps bypass a portion of the first-pass metabolism. As a result, the bioavailability of such drugs is often higher than that achieved with conventional oral dosage forms. This enhanced absorption can improve the therapeutic effectiveness of the medication.

Fast-dissolving oral films are particularly beneficial for patients who experience difficulty swallowing conventional dosage forms. They are well suited for developmentally disabled individuals and patients suffering from persistent nausea or sudden episodes of allergic reactions. These films can be administered easily without the need for water, making them highly convenient in emergency situations. Their ease of administration also improves patient compliance, especially for individuals with limited access to drinking water².

The oral route is one of the most widely used methods of drug administration. However, it presents challenges for certain patient groups who experience difficulty in swallowing conventional dosage forms. Geriatric, pediatric, and psychiatric patients often face problems while taking tablets or capsules. Patients suffering from dysphagia also encounter significant discomfort and inconvenience with traditional oral medications.

In recent years, orally disintegrating films have gained considerable acceptance among healthcare professionals and patients. Their popularity is mainly due to their rapid disintegration or dissolution in the oral cavity. These films can be administered easily without the need for water, making them highly convenient for patients. Their ease of use and improved patient compliance make them an attractive alternative to conventional oral dosage forms³. Fast-dissolving films are an advanced oral dosage form designed to dissolve rapidly in the oral cavity. Compared with fast-dissolving tablets, these films exhibit greater mechanical stability and are less brittle or fragile during handling and storage. Their flexibility and durability make them more convenient for packaging, transportation, and administration. These characteristics contribute to improved patient acceptance and product reliability.

The successful design of fast-dissolving films requires a thorough understanding of the pharmaceutical and pharmacological properties of both the drug and the film-forming polymers. It also depends on selecting an appropriate manufacturing process to ensure the desired quality and performance of the final product. Fast-dissolving films are generally prepared as thin, flexible polymeric layers containing suitable plasticizers to enhance flexibility and strength. These films promote a faster onset of therapeutic action, improve drug efficiency, reduce the frequency of dosing, and thereby help minimize the risk of dose-related side effects.

Fast-dissolving films offer several advantages over conventional oral dosage forms. They provide enhanced bioavailability by facilitating rapid drug release and absorption. Their ease of administration significantly improves patient compliance, particularly among pediatric, geriatric, and dysphagic patients. These benefits make fast-dissolving films an attractive alternative to traditional tablets and capsules.

An ideal fast-dissolving film should possess adequate drug-loading capacity to deliver the required therapeutic dose effectively. It should exhibit a rapid dissolution rate or maintain an appropriate residence time at the site of administration to ensure optimal drug absorption. In addition, the formulation should demonstrate good physical and chemical stability throughout its shelf life. The film should also be non-toxic, biocompatible, and biodegradable to ensure its safety and suitability for pharmaceutical applications⁴.

Classification of Fast Dissolving Technology:¹³

Fast-dissolve technologies can be divided into three broad groups:

- Lyophilized systems
- Compressed tablet-based systems
- Thin film strips

Lyophilized systems: The technology used for these drug delivery systems involves preparing a suspension or solution containing the drug along with suitable structural excipients. This mixture is transferred into specially designed moulds or blister packs to produce tablet-shaped units. The moulding process ensures that the formulation attains the desired shape and uniformity. These prepared units are then subjected to further processing to achieve the required dosage form. After moulding, the tablet-shaped units are frozen and subsequently lyophilized within the mould or blister pack. The freeze-drying process creates a highly porous internal structure by removing the frozen solvent. This high porosity allows water or saliva to penetrate the dosage form rapidly after administration. Consequently, the tablets disintegrate quickly in the oral cavity, resulting in rapid drug release and improved patient convenience.

Compressed tablet-based systems: This drug delivery system is manufactured using conventional tablet production technology based on the direct compression method. In this process, the drug is blended with suitable excipients and compressed into tablets without the need for a granulation step. The direct compression technique is simple, cost-effective, and widely used in pharmaceutical manufacturing. The mechanical properties of the tablets, such as hardness and friability, vary depending on the formulation and manufacturing process employed. Fast-dissolving tablets are formulated to disintegrate much more rapidly than conventional tablets. Their rapid disintegration is achieved by incorporating water-soluble excipients, super disintegrants, or effervescent agents into the formulation. These ingredients facilitate the quick penetration of water into the tablet core after administration. As a result, the tablets disintegrate rapidly, leading to faster drug release and improved patient convenience.

Thin film strips:

Oral films, commonly referred to as oral wafers, have evolved significantly over the past few years. They were initially introduced in the confectionery and oral care industries as breath-freshening strips. Their convenience and ease of use gradually increased consumer acceptance. As a result, oral films emerged as a novel dosage form for delivering vitamins and personal care products.

Fast-dissolving films (FDFs) are now recognized as an effective technology for the systemic delivery of active pharmaceutical ingredients (APIs). They are widely used in over-the-counter (OTC) medications because of their rapid dissolution and ease of administration. In addition, several prescription drug formulations based on this technology are currently in the early to mid-stages of development. The growing popularity of FDFs has been driven by their ability to improve patient convenience and compliance.

The commercial success of breath-freshening products, such as Listerine PocketPaks, has played a significant role in promoting the acceptance of oral film technology. These films are typically prepared using a variety of hydrophilic polymers that produce thin films with a thickness ranging from approximately 50 to 200 μm . During manufacturing, the films are initially produced as large continuous sheets. They are subsequently cut into individual dosage units and packaged using pharmaceutically acceptable packaging materials for convenient handling and storage.

Ideal Properties of Fast Dissolving Films: ⁸

- It should have an acceptable taste.
- It should give a pleasing mouth feel.
- It should be less friable and have good mechanical strength to withstand the post manufacturing handling.
- It should be stable in environmental conditions.
- Subsequent to oral administration, it should leave least or no residue in mouth.
- It should quickly dissolve to release drug instantaneously in mouth.
- It should be compatible with the other ingredients.

Drug Selection Criteria for Fast Dissolving Films:

- The drug should have pleasant taste.
- The drug to be incorporated should have low dose upto 40 mg.
- The drugs with smaller and moderate molecular weight are preferable.
- Good solubility in water as well as in saliva and also good stability.

Benefits of Fast Dissolving Oral film over Fast Disintegrating Tablets:

- Provide a larger effective surface area for the disintegration.
- No friability loss
- Require less expensive processing and packaging materials
- No fear of choking
- Requires less excipients
- Less time-consuming process.
- More elegant
- More economical

Advantages of Fast dissolving films:

Fast dissolving films have several advantages over conventional dosage form and they are

- Pediatric, geriatric and psychiatric patients can easily administer fast dissolving films.
- It is desirable for patients suffering from motion sickness, dysphagia, repeated emesis, hypertension, paralysis and mental disorder.
- There is no need of water for administration of films hence no risk of choking.
- Fast dissolving films rapidly dissolved and disintegrated in the oral cavity because of large surface area which lowers dosing interval, improves onset of action, efficacy and safety profile of drug.
- Accuracy in the administered dose is assured
- The drug directly enters into the systemic circulation by avoiding hepatic first pass metabolism.
- Improved patient compliance.
- Fast dissolving films are more flexible, compliant and can be easily handled, storage and transported.
- Fast dissolving films tend to be flexible, portable and they are not fragile, whereas oral disintegrating tablet requires special package for transportation.
- As large surface area is accessible by the fast-dissolving film therefore this leads to quick disintegration and dissolution in the oral cavity within seconds.
- Fast dissolving films can be consumed at any time or place as per the convenience of the individual.

- As the first pass effect is avoided so a dose of a drug can be reduced which leads to reduction in side effects associated to molecule.
- From marketing perspective this new Fast dissolving film technology offers the opportunity to extend revenue life cycles for pharmaceutical companies whose drug patents are about to expire and soon be vulnerable for generic competition.

Disadvantages of Fast dissolving films:⁷

Fast dissolving films have some limitations they are.

- High dose cannot be incorporated into strip.
- Packaging of fast dissolving films requires special equipment's and it is difficult to pack.
- The drugs which cause irritation to mucosa cannot be administered.
- Fast dissolving films are usually hygroscopic in nature; therefore, special precaution should be taken for longer preparation.
- Combining more than two drugs are is very difficult because both the dissolution rate and disintegration time are obstructed by the co administration of a drug in films.

MATERIAL AND METHODS:-

Loratadine was obtained as a gift sample from Hetero labs ,HPMC E3 and sodium CMC was Purchased from Loba chemicals ,Mumbai ,HPMC E15 was Purchased from Gravite Pharmaceuticals. PEG 400 was Purchased from merck ,Mumbai. hydrochloric acid and dichloromethane was purchased from Pinark chemicals.Methanol was purchased from Fisher Scientific Private Limited.

Methods:-

Various methods used in the study are discussed below

Analytical Method in the Determination of Drug:³⁵

Drug content can be determined using the UV Spectrophotometry method. Spectrophotometry is a quantitative analytical technique used to determine the amount of a chemical substance present in a sample. It is based on measuring the amount of light absorbed by the substance at a specific wavelength. The absorption of light is related to the concentration of the substance in the sample.

In UV Spectrophotometry, the intensity of light passing through the sample is measured. This intensity is compared with the intensity of light passing through a reference solution or blank. The difference in light intensity provides information about the amount of substance present. Therefore, UV Spectrophotometry can be used to quantitatively determine the drug content in a formulation.

Loratadine solutions having different concentrations (5, 10, 15, 20, 25, 30, 35, 40 µg/ml) were prepared and absorbance was measured at 262.4 nm.

Preparation of fast dissolving film: ³³

Various film-forming polymers were investigated for the preparation of Loratadine fast-dissolving films. The polymers selected for the study included Xanthan gum, Polyvinyl pyrrolidone, Guar gum, and Pullulan gum. Sodium alginate, Maltodextrin, Polyvinyl alcohol, and Hydroxypropyl methylcellulose were also evaluated. These polymers were selected based on their potential film-forming properties.

The selected polymers were converted into films using the solvent casting technique. Each polymer was cast separately to evaluate its ability to form a suitable film. The prepared films were assessed for their physical and film-forming characteristics. Based on the evaluation, the most suitable polymer was selected for the preparation of Loratadine fast-dissolving films. Suitable film forming polymer selected, then polymer dissolved in solvents like methanol and dichloromethane, prepared polymeric solution kept a side for about 5 – 6 hours for swelling of polymer.

The drug was dissolved in methanol along with other excipients, such as a plasticizer, sweetening agent, and saliva-stimulating agent. The resulting drug–excipient solution was then added to the previously prepared polymeric solution. The mixture was sonicated for 10 minutes to ensure uniform distribution of the drug throughout the formulation. The resulting homogeneous solution was then ready for casting.

The prepared solution was carefully cast onto a Petri dish to form a uniform film. The Petri dish was kept aside to allow controlled evaporation of the solvent. After sufficient drying, the formed films were carefully peeled from the Petri dish. The films were then cut into the required dimensions for further evaluation.

Evaluation of fast dissolving film: ³⁴

The prepared fast-dissolving films were evaluated to determine their physical and chemical properties. Various evaluation tests were performed to assess the quality and performance of the prepared films. The thickness and other physical characteristics of the films were examined using suitable instruments. These evaluations helped to determine the uniformity and suitability of the films.

The disintegration behavior of the films was evaluated using a disintegration apparatus. The drug release characteristics were studied using a dissolution apparatus. Drug content and related chemical properties were analyzed using a UV-Visible spectrophotometer. The results obtained from these evaluations were used to assess the overall quality and performance of the fast-dissolving films. Preparation of Loratidine fast dissolving films using HPMCE3.

Required quantity of film forming polymer HPMC E3 was added to the solvents methanol and dichloromethane in the ratio 1:1 and kept a side for about 5 to 6 hours for swelling of polymer.

Loratidine was dissolved in 4 ml of dichloromethane and this drug solution was added to the above polymeric solution. This step was followed by the addition of plasticizers. Uniformity of drug content is achieved by sonication for 10 minutes. The solution was cast on a petri dish and dried at room temperature. The film was carefully removed from the petri dish, then checked for imperfections and cut to the required size to deliver the equivalent dose (2×2 cm²) per strip.

Table 1 Formula for Loratidine FDF using HPMC E3

S. No.	Content	Category	Formulations					
			F1	F2	F3	F4	F5	F6
1	Loratidine	API	100 mg	100 mg	100 mg	100 mg	100 mg	100 mg
2	HPMC E3	Polymer	300 mg	400 mg	500 mg	600 mg	700 mg	800 mg
3	Talc	Solvent	12 ml	12 ml	12 ml	12 ml	12 ml	12 ml
4	Methanol	Solvent	8 ml	8 ml	8 ml	8 ml	8 ml	8 ml
5	Magnesium carbonate	Plasticizer	1 drop	1 drop	1 drop	1 drop	1 drop	1drop

Preparation of Loratidine Fast dissolving films using Sodium CMC

The required quantity of Sodium CMC, used as the film-forming polymer, was accurately weighed and transferred into a mortar. Loratidine was dissolved in 2 mL of methanol and added to the polymer in the mortar. About 20 mL of water was gradually added to the mixture. The contents were triturated thoroughly to obtain a uniform solution without the formation of lumps.

Two drops of , used as a plasticizer, were added to the prepared mixture. The contents were triturated again to ensure uniform mixing of the plasticizer throughout the formulation. The resulting homogeneous solution was then carefully transferred into a Petri dish. The solution was spread uniformly in the Petri dish to facilitate the formation of a consistent film.

The Petri dish was dried at 70°C for 12 hours to obtain the prepared film. After drying, the film was carefully peeled from the Petri dish. The film was examined for visible imperfections and defects before further processing. Finally, it was cut into 2×2 cm² strips, with each strip designed to deliver the required equivalent dose of Loratidine.

Table 2 Formula for Loratidine FDF using Sodium CMC

S.No	Content	Category	Formulations			
			F7	F8	F9	F10
1	Loratidine	API	100 mg	100 mg	100 mg	100 mg
2	Sodium CMC	Polymer	300 mg	400 mg	500 mg	600 mg
3	Methanol	Solvent	2 ml	2 ml	2 ml	2 ml
4	Water	Solvent	20 ml	20 ml	20 ml	20 ml
5	PEG 400	Plasticizer	2 drops	2 drops	2 drops	2 drops

Preparation of Loratidine fast dissolving films using HPMC E15

The required quantity of HPMC E15, used as the film-forming polymer, was added to a solvent mixture of methanol and dichloromethane (DCM) in a 1:1 ratio. The polymeric solution was kept aside for approximately 5–6 hours to allow adequate swelling of the polymer. Loratidine was separately dissolved in 4 mL of dichloromethane.

The prepared drug solution was then added to the polymeric solution with continuous mixing. PEG 400 was added to the mixture as a plasticizer. The resulting formulation was mixed thoroughly to ensure uniform distribution of the drug and excipients. The solution was then subjected to sonication for 10 minutes to achieve uniform drug content.

The resulting homogeneous solution was used for film casting. The prepared solution was carefully cast onto a Petri dish and dried at room temperature. After drying, the film was carefully peeled from the Petri dish and examined for visible imperfections. The film was then cut into the required dimensions to obtain uniform strips. Each 2×2 cm² strip was designed to deliver the required equivalent dose of Loratidine.

Table 3 Formula for Loratidine FDF using HPMC E15

S.No.	Content	Category	Formulations		
			F11	F12	F13
1	Loratidine	API	100 mg	100 mg	100 mg
2	HPMC E15	Polymer	100 mg	200 mg	300 mg
3	Dichloro methane	Solvent	12 ml	12 ml	12 ml
4	Methanol	Solvent	8 ml	8 ml	8 ml
6	Magenisium streate	Plasticizer	1 drop	1 drop	1 drop



FIG 1 Loratidine films made up of HPMC E3

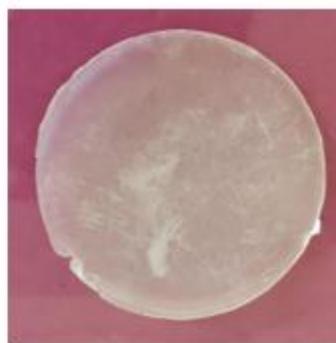


FIG 2 Loratidine films made up of sodium CMC

Construction of standard graph of Loratidine using Spectrophotometry method:

i. Preparation of 0.1N HCl solution:

To prepare 0.1N HCl 8.3 ml of HCl added to 1000 ml volumetric flask, and make up with distilled water upto 1000ml.

ii. Preparation of standard stock solution of Loratidine:

Weigh 10 mg of Loratidine and taken into a 100 ml volumetric flask add 75 ml of prepared 0.1N HCl. Dissolve the Loratidine with continuous shaking and make upto 100 ml. label as stock solution From the stock solution prepare series of Loratidine solutions having different concentrations (5, 10, 15, 20, 25, 30, 35, 40 µg/ml).

iii. Determination of λ max for Loratidine:

From the above prepared stock solution was diluted to get different concentrations of loratidine, This solution was scanned between 400 nm to 200nm in UV spectrophotometer to get λ max for Loratidine.

iv. Construction of standard graph:

The absorbance of solution was measured spectrophotometrically at 262.4 nm using methanol as blank. The absorbance values were plotted against concentration to obtain the standard graph..

Evaluation of Loratidine Fast Dissolving films

Loratidine fast dissolving films were evaluated for different properties such as

Folding endurance is determined by repeated folding of the Loratidine film at the same place till the film breaks. This gives the indication of brittleness of Loratidine film. The number of times the Loratidine film is folded without breaking is calculated as the folding endurance value.

Thickness:

As the thickness of film is directly concern with Loratidine content uniformity so it is necessary to ascertain uniformity in the thickness of the film. It can bemeasured by micrometer screw gauge

Thickness = Main Scale Reading + Circular Scale Reading X Least Count

Drug content uniformity (Assay):

The films were tested for drug content uniformity by UV Spectrophotometric method. Films of 2 cm x 2 cm square size were cut from films. Film was placed in 100 ml volumetric flask and dissolved in 0.1N HCl solution and the volume was made up with 0.1N HCl solution. The absorbance of the solution was measured at 262.4 nm using UV-visible spectrophotometer after suitable dilution.

In-vitro Disintegration test:

The in-vitro disintegration time of Loratidine fast dissolving films was determined visually in a glass dish of 8 ml 0.1N HCl with swirling action. The disintegration time is the time when a film starts to break or disintegrate. The in vitro disintegration time for the film was recorded.

In-vitro Dissolution study:

The dissolution study of the film was carried out using dissolution apparatus (Electrolab, Mumbai) at $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ using 900 ml of 0.1N HCl as dissolution media. The agitation speed of paddle was 50 rpm. At predetermined time intervals, 5 ml of sample was withdrawn and replaced with fresh medium. The sample was filtered through Whatmann filter paper and analyzed at 262.4 nm.

RESULTS AND DISCUSSION

Construction of Standard graph of Loratidine:

The absorbance of series of solutions is given below. The absorbance was plotted against the concentrations of Loratidine. Calibration curve was used to determine the amount of loratidine in unknown solutions.

Table 4 Calibration data of Loratidine

S.No.	Concentration ($\mu\text{g/ml}$)	Absorbance
1.	0	0
2.	5	0.112
3.	10	0.229
4.	15	0.32
5.	20	0.408
6.	25	0.511
7.	30	0.597
8.	35	0.735
9.	40	0.794

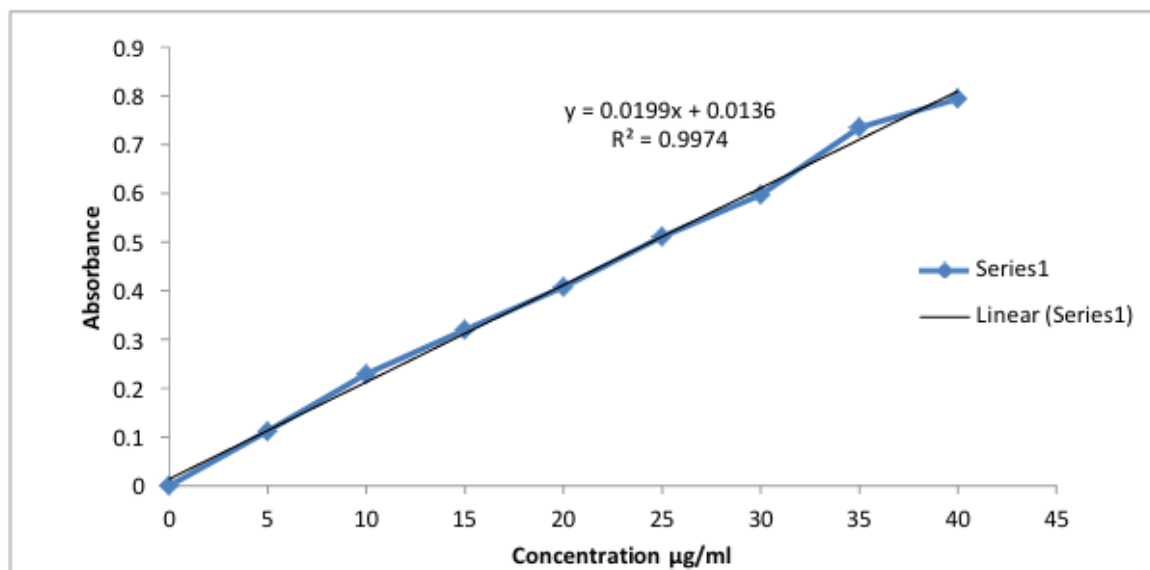


Fig 3 : Standard graph of Loratidine

Discussion: • Graph was constructed by taking absorbance on y axis and concentration on x axis.

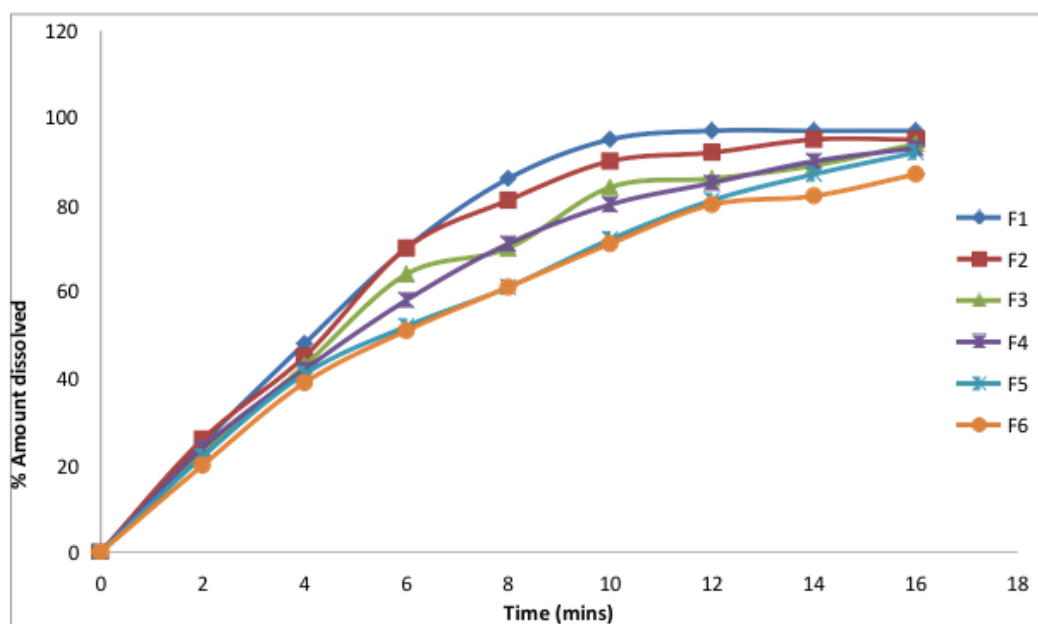
• Graph of absorbance vs concentration given a straight line ($y=mx+c$) with slope 0.0199

Table 5 Evaluation of Loratidine Fast Dissolving Films

S.No	Formulation Code	Thickness (mm)	Disintegration Time (mm:sec)	Assay (mg)	Folding Endurance	Dissolving Time (mm:sec)
1.	F1	0.16	2:10	10.2	96	3:00
2.	F2	0.16	2:30	10.2	80	3:31
3.	F3	0.17	2:49	10.36	76	3:49
4.	F4	0.17	3:18	10.7	62	4:00
5.	F5	0.18	4:20	10	59	5:00
6.	F6	0.18	4:26	10.3	57	5:20
7.	F7	0.17	2:00	10.15	74	2:35
8.	F8	0.19	2:45	10.15	72	3:00
9.	F9	0.20	4:28	10.05	69	5:00
10.	F10	0.22	4:30	10	68	5:10
11.	F11	0.14	1:40	10.36	127	1:40
12.	F12	0.15	2:28	10.52	121	3:00
13.	F13	0.19	3:35	10.89	107	4:00

Table 6 Dissolution profile for Formulations made up of HPMC E3

S.No.	Time (mins)	F1	F2	F3	F4	F5	F6
1.	0	0	0	0	0	0	0
2.	2	25	26	23	24	22	20
3.	4	48	45	43	42	41	39
4.	6	70	70	64	58	52	51
5.	8	86	81	70	71	61	61
6.	10	95	90	84	80	72	71
7.	12	97	92	86	85	81	80
8.	14	97	95	89	90	87	82
9.	16	97	95	94	93	92	87

**Fig 4 :Drug Release Profiles of various Formulations of Loratadine &HPMC E3 (F1-F6)****Discussion:**

The above results show that, among the formulations made of HPMC E3 Formulation F1 releases drug rapidly than the remaining formulations.

Table 7 Dissolution profile for Formulations made up of Sodium CMC

S.No.	Time (mins)	F7	F8	F9	F10
1.	0	0	0	0	0
2.	2	55	51	50	46
3.	4	67	61	59	56
4.	6	75	67	66	67
5.	8	79	74	74	70
6.	10	87	83	81	76
7.	12	92	89		83
8.	14	96	94		89
9.	16	97	96		91
10.	18				96
11.	20				97

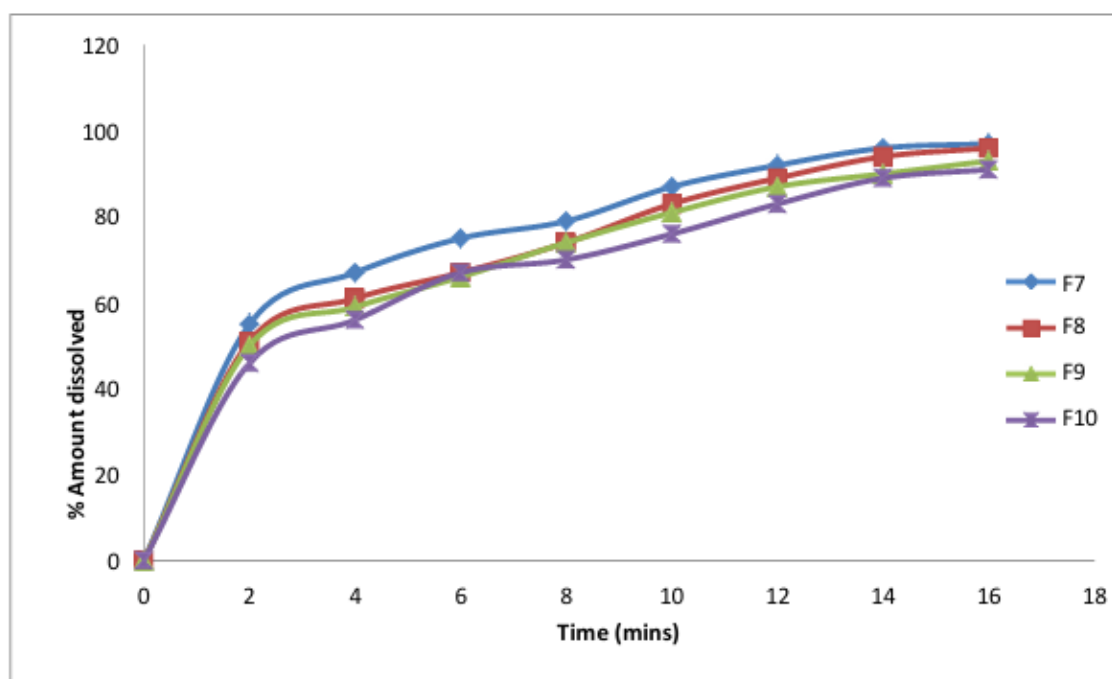


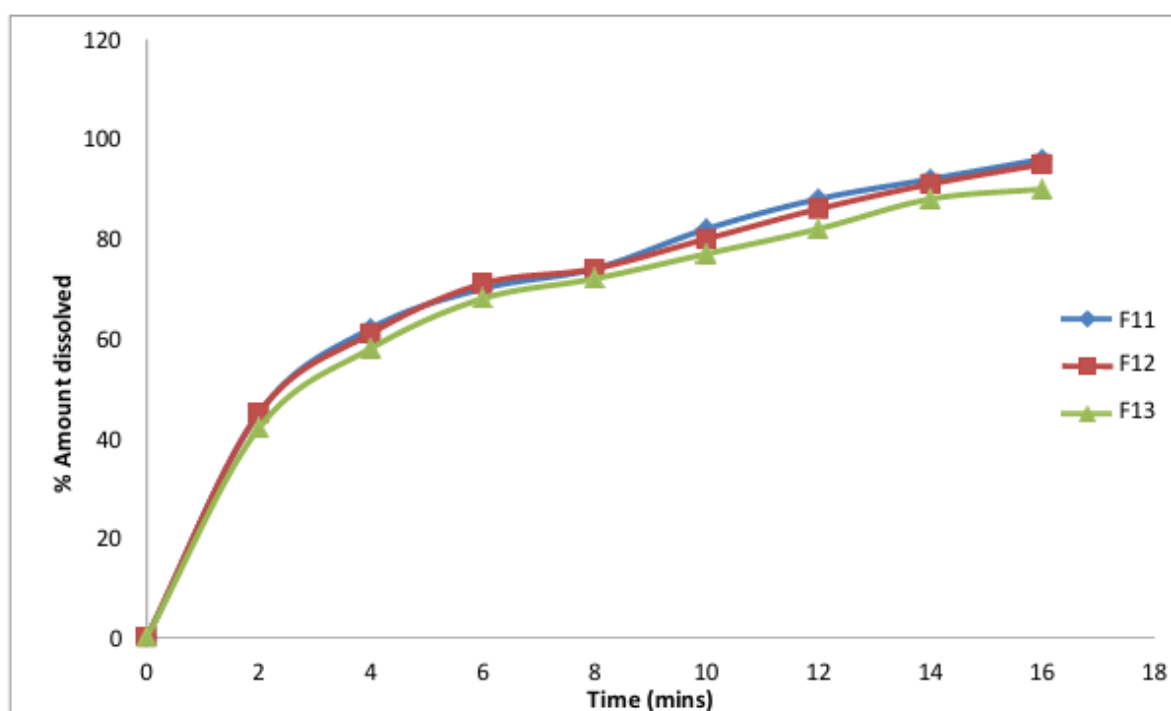
Fig 5 :Drug Release Profiles of various Formulations of Loratadine & Sodium CMC (F7-F10)

Discussion:

The above results show that, among the formulations made of Sodium CMC Formulations F7 releases drug rapidly than the remaining formulations.

Table 8 Dissolution profile for Formulations made up of HPMC E15:-

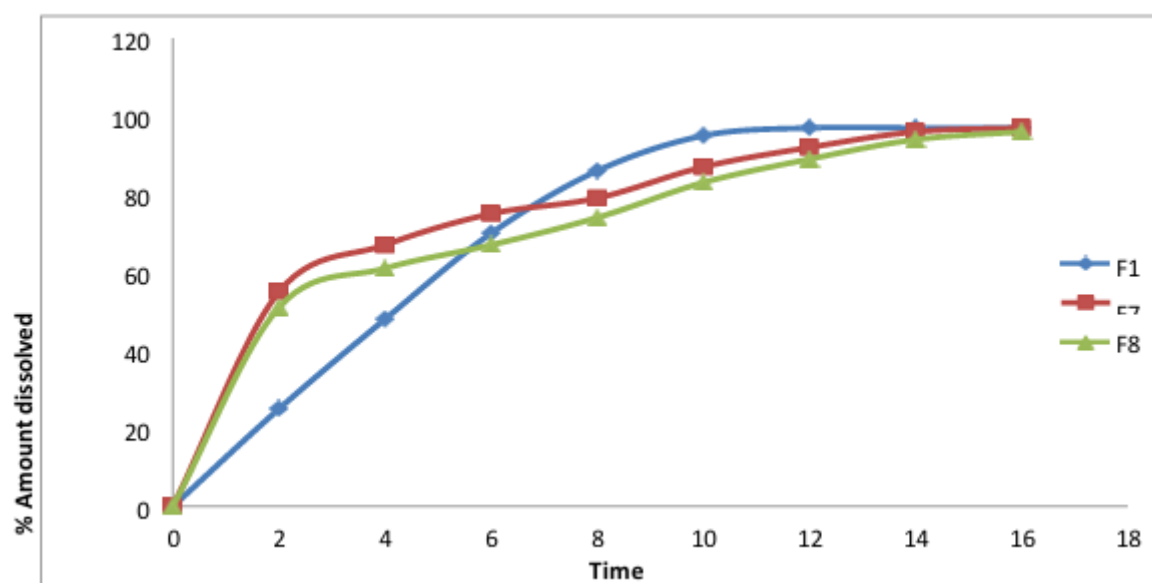
S.No.	Time (mins)	F11	F12	F13
1.	0	0	0	0
2.	2	45	45	42
3.	4	62	61	58
4.	6	70	71	68
5.	8	74	74	72
6.	10	82	80	77
7.	12	88	86	82
8.	14	92	91	88
9.	16	96	95	90

**Fig 6 :Drug Release Profiles of various Formulations of Loratadine &HPMC E15(F11-F13)****Discussion:**

The above results show that, among the formulations made of HPMCE 15 Formulations F11 releases drug rapidly than the remaining formulations.

Table 9 Comparative dissolution profile of best three formulations:-

S.No.	Time (mins)	F1	F7	F8
1.	0	0	0	0
2.	2	25	55	51
3.	4	48	67	61
4.	6	70	75	67
5.	8	86	79	74
6.	10	95	87	83
7.	12	97	92	89
8.	14	97	96	94
9.	16	97	97	96

**Fig 7 :Drug Release Profiles of various Formulations of Loratadine & HPMC E3 & SODIUM CMC E3 (F1,F7,F8)****Discussion:**

Considering the physical and chemical properties of formulations best three formulations have been chosen, among them F1 releases drug rapidly.

CONCLUSION

In the present study, Fast dissolving films of Loratadine was successfully developed in the form of mouth dissolving films which offered a suitable and practical approach in serving desired objective of faster disintegration and dissolution characteristics with increased bioavailability. Loratadine mouth dissolving films were prepared using HPMC E3, HPMC E15, Sodium CMC as polymers using solvent casting technique. From the findings obtained, it was concluded that:

- The Prepared films contain Loratadine was clear and elegant.

- Formulated films gave satisfactory results for various Physic – chemical evaluation of films like physical appearance, thickness, drug content, in-vitro disintegration time and in vitro drug release.
- Among 13 formulations Formulation F1 in-vitro disintegration time was found to be 2min 10seconds and the in-vitro drug release studies showed complete drug release in 10mins which was desired.
- From the present study, it could be concluded that the mouth dissolving films of Loratidine can be prepared by solvent casting technique using HPMC E3 as polymer with a dissolution time of 10 minutes for the complete release of drug from film.

Based upon the dissolution performance, F1 was selected from various trails of developed formulations. Therefore, it was finally concluded that F1 is a satisfactory formulation that could perform therapeutically, with improved efficacy and better patient compliance.

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