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PREPARATION AND EVALUATION OF MOUTH DISSOLVING FILM OF FEXOFINADINE HYDROCHLORIDE

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ABSTRACT

Mouth dissolving films are at the forefront of oral solid dosage forms, offering enhanced comfort and versatility. They outperform fast-dissolving tablets by rapidly dissolving in the mouth with reduced saliva, hence enhancing the effectiveness of the active pharmaceutical ingredient (API). These films are a popular choice among consumers compared to traditional tablets or capsules because they do not require chewing or water for administration. The emerging technology of oral mouth dissolving films demonstrates significant potential due to its capacity to meet diverse requirements. The objective of the study is to create and evaluate a mouth dissolving film containing fexofenadine hydrochloride. Children have a higher likelihood of experiencing acute rhinitis, hence fexofenadine has a synergistic effect in their treatment. The evaluation criteria include the assessment of organoleptic features, surface characteristics, tensile strength, folding endurance, thickness, drug solubility, percentage of elongation, and drug content determined using estimation techniques.

KEY WORDS: Mouth dissolving film , fexofenadine, solid casting technique, HPMC, oral cavity, anti-histaminics, dysphagia , acute rhinitis, polyethylene glycol (PEG), thin strips,manufacturing.

1. BACKGROUND

In modern pharmaceutical practice, it is required that medications possess aesthetically pleasing shapes. Medications are delivered to the body through various dose forms such as tablets, syrups, suspensions, suppositories, injections, and transdermal patches. [1] Traditional methods of administering drugs orally often result in rapid and complete release of the medication, which may not be desired due to factors such as the presence of food, stomach acidity, enzymatic breakdown, or changes in gastrointestinal movement, which can limit absorption time. [2-3] Currently, there is significant emphasis on developing drug delivery methods that prioritize sensory appeal and maximize patient acceptance, especially in pediatric and geriatric populations. [4-6]

Initially designed as alternatives to tablets, capsules, and syrups, quick dissolving medicine delivery systems were initially created specifically for pediatric and geriatric patients who have a higher risk of choking. An important benefit of these devices is their capacity to rapidly dissolve or disintegrate in saliva without the need for additional

liquids.[7] Among the various methods to enhance the absorption of hydrophobic pharmaceuticals through the mouth, self-emulsifying drug delivery devices (SEDDs) hold enormous potential. Upon ingestion, these systems disperse in the fluid of the gastrointestinal tract to form drug particles that are either in the form of nano-emulsions or micro-emulsions. By facilitating easier absorption through the lymphatic system, this bypasses the initial metabolism that occurs in the liver. [8-9]

1.1 MOUTH DISSOLVING FILM

Mouth dissolving films (MDFs) are thin polymeric films in the shape of stamps that dissolve quickly in the mouth when placed on the tongue.[10] These films show potential as a dose form, especially for geriatric and pediatric patients who have difficulty swallowing oral medication.[11] Various studies have explored their pharmacological development, including optimizing the formulation, characterizing their properties, assessing their mechanical properties, and successfully masking the taste of the drug incorporated into the film.[12-16]

In September 2003, Prestige International Brands introduced Chloraseptic® Relief StripsTM, the first oro-dispersible film product designed to provide relief for sore throats, in the United States. [17] In July 2010, Strativa Pharmaceuticals launched Zuplenz (ondansetron), a film that dissolves in the mouth. Initially approved by the US FDA for prescription use in the prevention of nausea and vomiting caused by cancer chemotherapy and radiation, this drug holds the distinction of being the first of its kind.[18]

1.2 CHARACTERISTICS OF MOUTH DISSOLVING FILM

Mouth dissolving films (MDFs) are small, aesthetically pleasing films that are specifically designed for medication distribution. They are approximately the size of a postage stamp. Similar to cotton candy, these films dissolve on the tongue and provide a pleasing texture and satisfactory flavour. These oral films dissolve quickly and smoothly; the film melts within seconds when it comes into touch with the top of the tongue. Unlike pills and other types of oral medication that are released immediately, this method bypasses the initial metabolism in the liver, perhaps enhancing the drug's bioavailability. One of the most significant characteristics of MDFs is their ability to leave either a minimal or no residue in the mouth after oral treatment. Moreover, these films must have a low vulnerability to external conditions such as humidity and temperature [19].

1.3 IDEAL REQUIREMENTS

The optimal requirements for Mouth Dissolving Films (MDF) can be summarized as follows:

- MDF should be thin, flexible and stable for efficient manufacturing, packing and handling.
- The film should be portable , non tacky , and stay flat without rolling up.
- Suitable for mentally disabled patient.
- Should have good taste and comfortable texture.
- No need of water for administration.
- Short disintegration time.
- Low sensitivity to temperature and humidity.
- Offer the benefit of liquid medication in solid form.

- Have smooth and consistent surface.
- Cost effective and easy to create. [20-22]

1.4 APPLICATIONS OF MDF IN DRUG DELIVERY SYSTEMS

1) **Oro-mucosal drug application:** Oral thin-film distribution via buccal, mucosal, and sublingual routes may eventually replace other delivery methods when treating conditions requiring quick drug absorption. This covers treating conditions relating to the central nervous system, pain, allergies, and sleep problems.[23].

2) **Topical Applications:** Topical applications, such as wound care and other therapies, may benefit from the use of soluble films to deliver active chemicals like analgesics or antibacterial agents.

3) **Gastroretentive Delivery System:** An inquiry is now being conducted on dissolvable films as a dosage form for compounds with varied molecular weights, including both water-soluble and poorly soluble substances. These films are designed to be retained in the gastrointestinal tract. The film has the potential to be beneficial in the treatment of gastrointestinal diseases because to its ability to be broken down by the pH levels or enzyme synthesis in the gastrointestinal tract (GIT).

4) **Diagnostic Devices:** Dissolvable films can be loaded with sensitive reagents for controlled release when exposed to biological fluids. They can also form isolation barriers to separate various reagents, allowing a timed reaction within a diagnostic equipment. [24].

2. MATERIALS AND METHODS

TABLE:1 MATERIAL AND EQUIPMENT USED

S. NO.	MATERIAL USED	EQUIPMENT USED
1	Fexofinadine Hydrochloride (API)	Weighing balance
2	Hydroxy propyl methyl cellulose (HPMC)	Magnetic stirrer
3	Ethylene cellulose (EC)	Water bath
4	Citric acid (CA)	Vernier caliper
5	Mannitol	Dissolution appratus

6	Polyethylene glycol (PEG)	UV-spectrophotometer
7	Dichloromethane (MDC)	pH meter
8	Ethanol	FTIR

3. METHOD OF PREPARATION AND EVALUATION

3.1 Preparation of MDF by Solid Dispersion Method

1. Solid dispersion method

By using the fusion process, fexofenadine hydrochloride solid dispersion were created. In short, PEG 4000 (drug:polymer ratio: 1:2) and the hydrophilic carriers are physically mixed and heated until the medication melts. After that, this melt is continuously stirred as it cools. To obtain a uniformly sized solid dispersion, the resulting solid mass is crushed and sieved.

2. Preparation of MDF

The method which practice to formulate the mouth dissolving film of fexofenadine hydrochloride is Solvent Casting Method . In the mixture of MDC and ethanol, the film-forming components (HPMC E15) were dissolved. The polymeric solution was continuously stirred while ethyl cellulose was added. A dosage of 15 mg was dissolved in phosphate buffer to create the medication solution. At an appropriate RPM, the drug solution and polymers were combined and continuously agitated. A glass Petri dish was filled with the mixture, and it was left to dry at room temperature. Tested on the created films were surface quality, ability to fold or break, and detach from the Petri dish with ease.

TABLE: 2. FORMULATION CONSIDERATION

Material	**F1**	**F2**	**F3**	**F4**	**F5**
Fexofenadine HCL (mg)	15	15	15	15	15
HPMC (mg)	400	450	500	400	450
EC (mg)	300	350	250	300	350
PEG (ml)	5	5	5	5	5
Citric acid (mg)	20	20	20	20	20
Mannitol	20	20	20	20	20

MDC (ml)	30	30	30	30	30
Ethanol (ml)	30	30	30	30	30

3.2 EVALUATION PARAMETERS:

3.2.1Thickness Test

A calibrated digital micrometre is used to measure the thickness of a film, and then the mean average is determined. Typically, three readings are calculated for each batch and then averaged.

3.2.2 Weight variation

The weight variation of a film is assessed by cutting the film into three separate pieces and measuring the weight of each individual piece. Consistency in thickness is crucial, as it has a direct correlation with the precision of the film's dosage.[25]

3.2.3 Tack test

Tack refers to the level of persistence with which the movie adheres to the auxiliary that is brought into contact with the strip. This test also measures the level of dryness. [26].

3.2.4 Tensile strength

Tensile strength is the maximum amount of tension that a film can withstand before breaking. This test is primarily employed to ascertain the mechanical robustness of film. The value is determined by dividing the applied load at rupture by the cross-sectional area of the strip, as indicated in equation [27].

The formula for tensile strength is calculated by dividing the load at breakage by the product of the strip thickness and strip width.

3.2.5 Percentage Elongation

The measurement of the increase in length expressed as a percentage, known as percentage elongation.

When sample films experience tensile stress, they undergo deformation, resulting in the stretching or elongation of the sample. The ductility of polymers is determined by utilizing a texture analyzer. The calculation is performed using a formula:

The percentage elongation is calculated by multiplying the increase in length by 100 and dividing it by the original length.

3.2.6 Measurement of pH of surface

The pH of a film is ascertained by immersing it in a Petri dish, saturating it with distilled water, and gauging the pH with a pH meter electrode. Measuring surface pH is crucial because an acidic or basic pH might cause oral mucosal irritation. [28-29].

3.2.7 Content Uniformity

Various pharmacopoeias provide standardized test procedures to precisely determine the composition of a drug. Twenty samples undergo analytical methods. According to the Japanese Pharmacopoeia, the acceptability value of the test must be lower than 15%. The USP27 specifies that the contents should fall between the range of 85% to 115%, with a standard deviation that is equal to or less than 6%. The content homogeneity is a measure used to assess the drug concentration in specific films.[30-31].

3.2.8 Disintegration time

The disintegration time of a film is determined using the equipment described in reliable pharmacopoeias. Typically, the disintegration time varies based on the composition and might range from five to thirty seconds. Typically, the USP disintegration equipment is used to do this test. Currently, there are no established rules that dictate the disintegration time of orally fast-disintegrating films. There are two methods available for determining the disintegration time:

(a) Slide frame method

A drop of distilled water is applied over the film, which is securely attached to slide frames placed on a Petri plate. The film's disintegration is observed to occur over a period of time. [32-33].

(b)Petri Dish Method

The film is immersed in 2 millilitres of distilled water within a Petri dish. The disintegration time of the film refers to the duration it takes for the film to completely dissolve. [34].

3.2.9 In vitro dissolution test

Studies on the dissolution of films are conducted using the standard approved basket or paddle apparatus. Maintain sink conditions consistently during the dissolving process. Two media, namely a 0.1 N hydrochloric acid solution with a volume of 900 ml and a phosphate buffer with a pH of 6.8 and a volume of 300 ml, are utilized. The temperature is regulated at a precise range of 37 ± 0.5°C, while the spinning speed of 50 rpm is carefully monitored and adjusted. The dissolved pharmaceutical samples are analyzed using a UV-spectrophotometer at regular intervals. Despite its widespread use, the dissolving test remains susceptible to significant errors and test failure. [35-36].

4. RESULT AND DISCUSSION

4.1 PREFORMULATION STUDIES

1. **FTIR spectra of fexofenadine hydrochloride**

Identification of the drug sample Fexofenadine HCL was confirmed from the FTIR spectrophotometer. The FTIR spectrum of drug is shown in Figure.

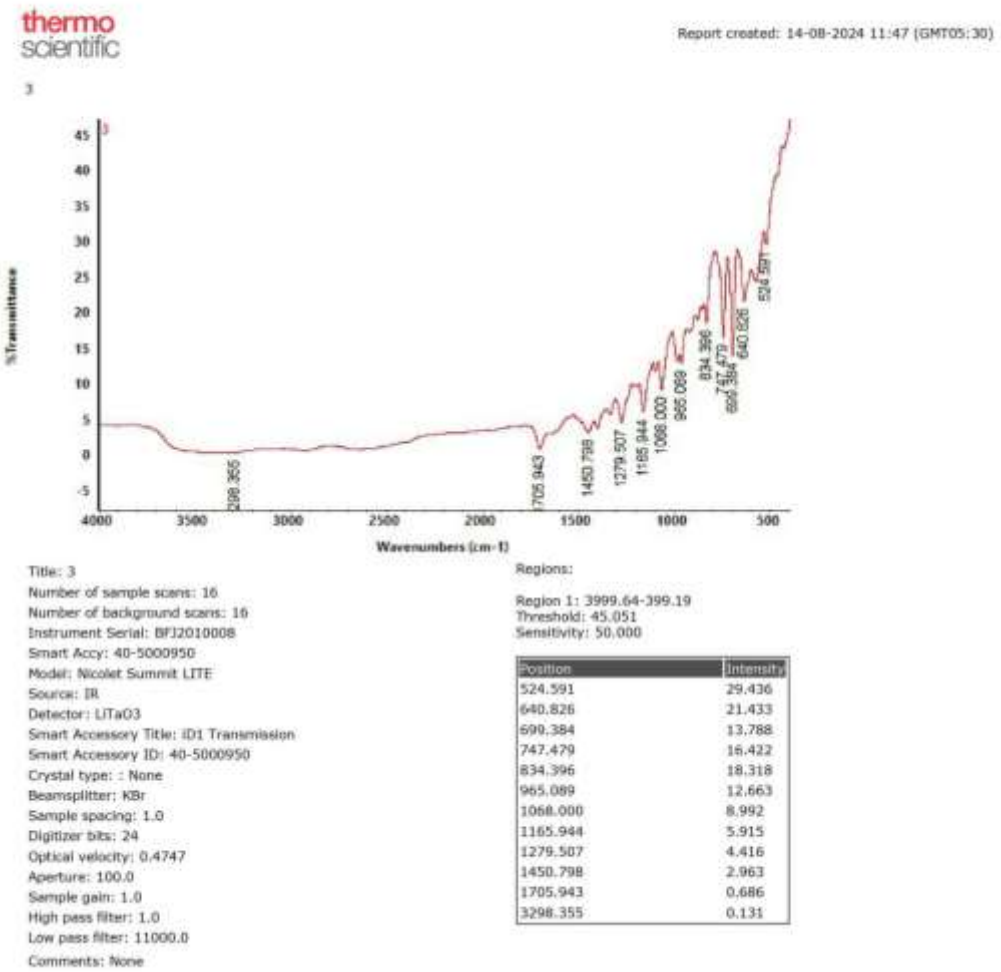
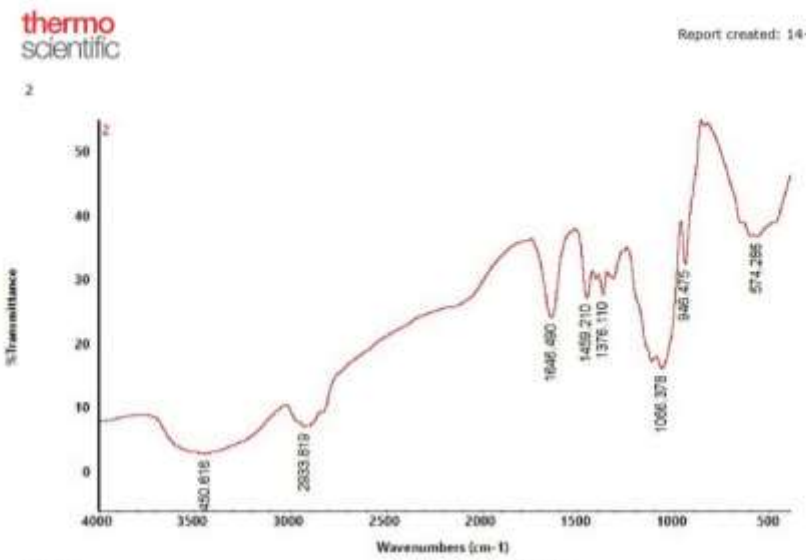


Fig : 1. FTIR of Fexofenadine HCL

2. **FTIR of drug polymer interaction**



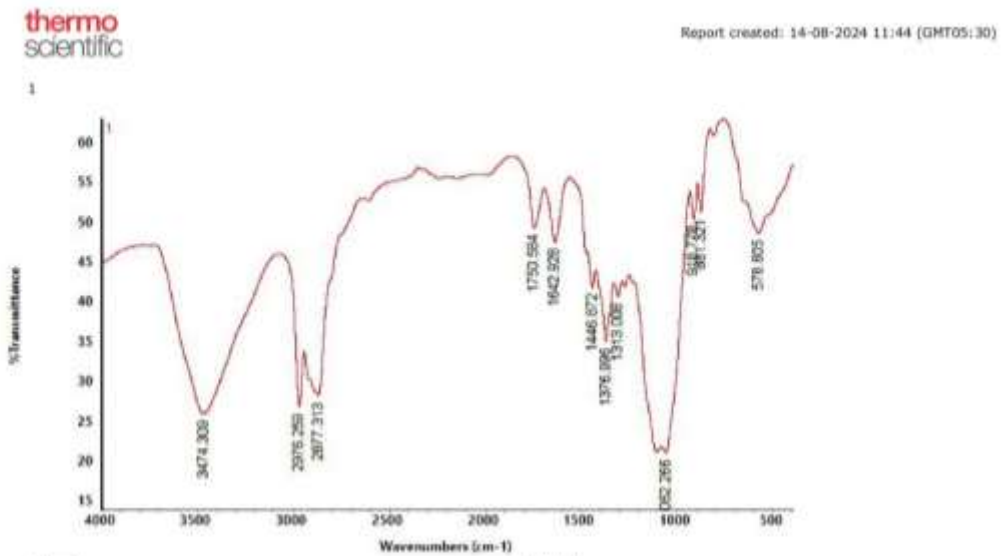
Title: 2
Number of sample scans: 16
Number of background scans: 16
Instrument Serial: BFJ2010008
Smart Accy: 40-5000950
Model: Nicolet Summit LITE
Source: IR
Detector: LiTaO3
Smart Accessory Title: iD1 Transmission
Smart Accessory ID: 40-5000950
Crystal type: : None
Beamsplitter: KBr
Sample spacing: 1.0
Digitizer bits: 24
Optical velocity: 0.4747
Aperture: 100.0
Sample gain: 1.0
High pass filter: 1.0
Low pass filter: 11000.0
Comments: None

Regions:

Region 1: 3999.64-399.19
Threshold: 50.619
Sensitivity: 50.000

Position	Intensity
574.286	36.575
946.475	32.300
1066.378	15.902
1376.110	27.493
1459.210	26.959
1646.490	23.824
2933.819	6.777
3450.616	2.591

Fig : 2 FTIR of HPMC



Title: 1
Number of sample scans: 16
Number of background scans: 16
Instrument Serial: BFJ2010008
Smart Accy: 40-5000950
Model: Nicolet Summit LITE
Source: IR
Detector: LiTaO3
Smart Accessory Title: ID1 Transmission
Smart Accessory ID: 40-5000950
Crystal type: : None
Beamsplitter: KBr
Sample spacing: 1.0
Digitizer bits: 24
Optical velocity: 0.4747
Aperture: 100.0
Sample gain: 1.0
High pass filter: 1.0
Low pass filter: 11000.0
Comments: None

Regions:

Region 1: 3999.64-399.19
Threshold: 58.946
Sensitivity: 50.000

Position	Intensity
578.805	48.503
881.321	51.075
918.778	50.234
1062.266	20.892
1313.008	40.452
1376.996	34.865
1446.872	41.649
1642.928	47.353
1750.584	49.154
2877.313	28.033
2976.259	26.612
3474.309	25.736

Fig : 3 FTIR of Ethyl cellulose

3. Calibration curve

Fexofenadine HCL calibration curve in phosphate buffer pH 6.8. Accurately weighed 10mg Fexofenadine HCL was dissolved in 100 ml of Phosphate buffer pH 6.8to obtain a solution of 100 µg/ml. From the above prepared stock solution, aliquot were taken and appropriately diluted to obtain 10,20,30,40,50, 60,70,80 and 90 µg/ml concentrations of Fexofenadine HCL. Absorbance of each solution was measured in triplicate at 259 nm. against 6.8 pH phosphate buffer as blank at that specific λ max. The absorbance of each concentration is shown in table 7.5 and the calibration curve is shown in figure 4.

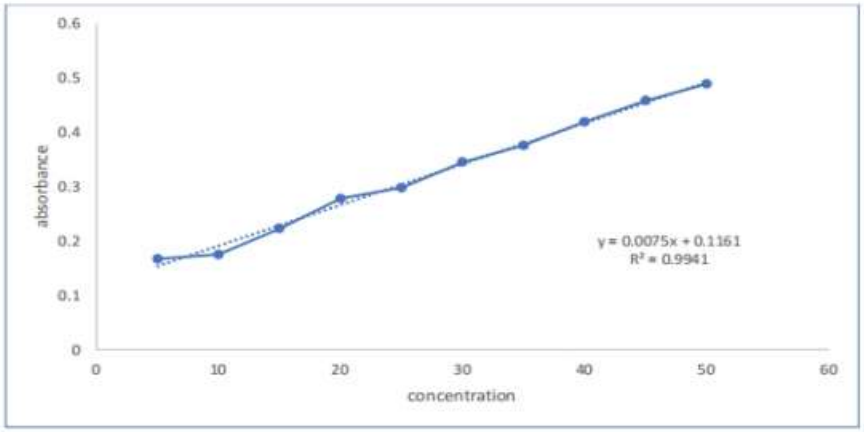


Fig:4. Calibration curve of fexofenadine HCL

TABLE:3. Showing absorbance of sample at given concentration

S No.	Concentration (µg/ml)	Absorbance ±SD
1.	0	0
2.	10	0.015
3.	20	0.005
4.	30	0.053
5.	40	0.068
6.	50	0.038
7.	60	0.018
8.	70	0.024
9.	80	0.022
10.	90	0.045

4. **Scanning Electron Microscopy of formulation**

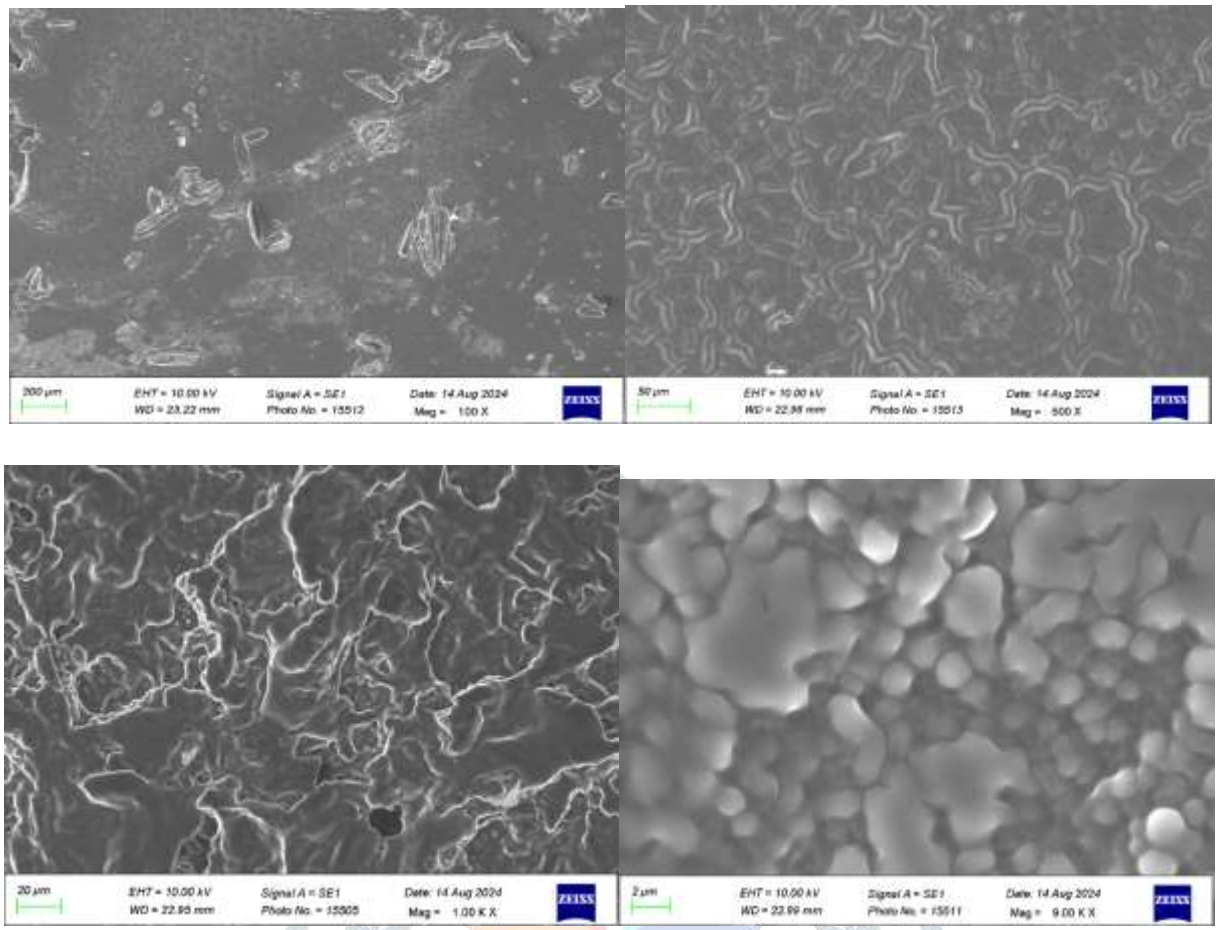


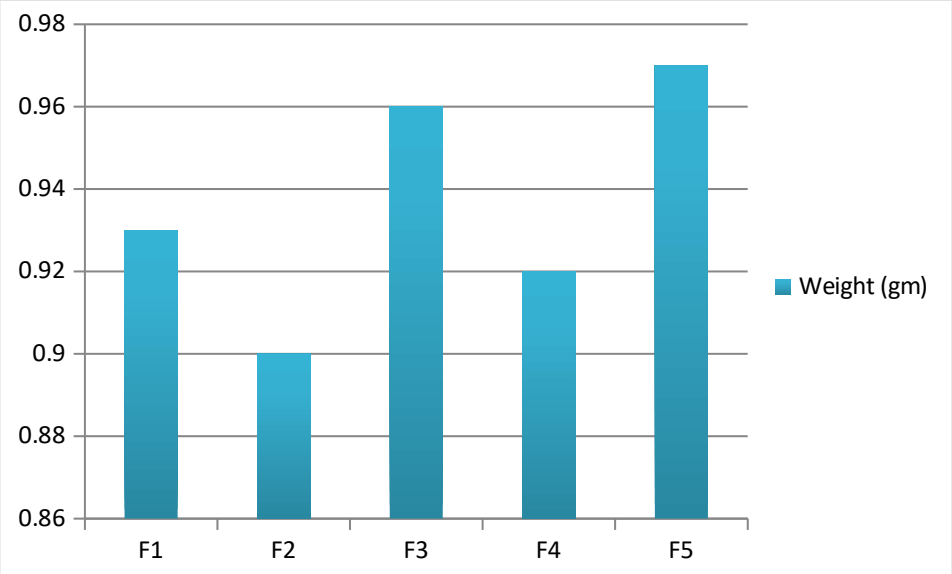
Fig : 5 SEM of the formulated film of Fexofenadine Hydrochloride

5. EVALUTION OF MDF

1. **Appearance:** Transparent, non-sticky and flexible

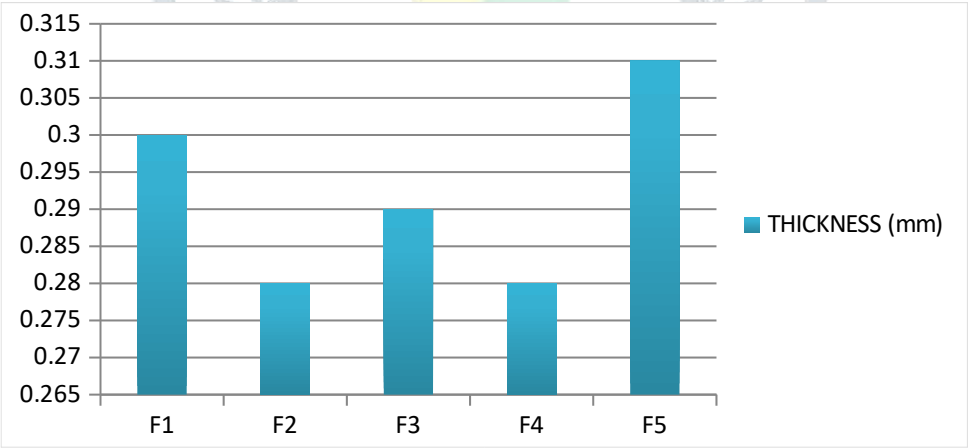
2. **Weight variation**

S.No.	Formulation	Weight (gm)
1.	F1	0.93
2.	F2	0.90
3.	F3	0.96
4.	F4	0.92
5.	F5	0.97



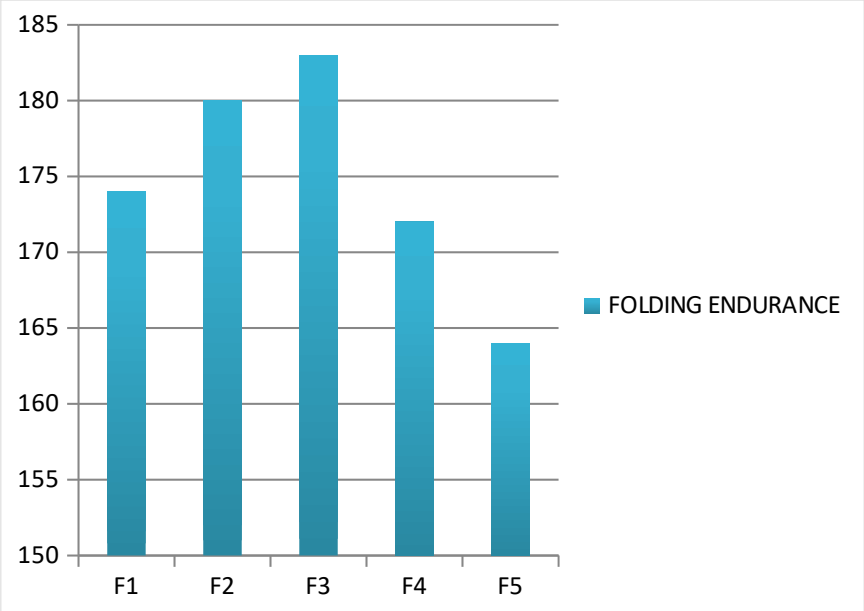
3. **Thickness of film**

S.No.	Formulation	Observation (mm)
1.	F1	0.30 ±0.04
2.	F2	0.28 ±0.08
3.	F3	0.29 ±0.01
4.	F4	0.28 ±0.05
5.	F5	0.31 ± 0.07



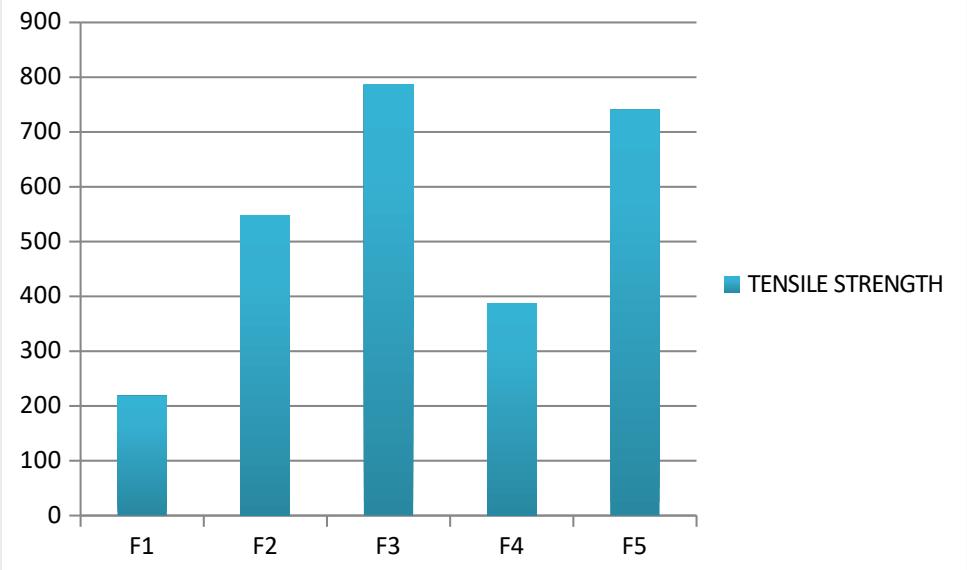
4. Folding endurance

S.No.	Formulation	Observation
1.	F1	174 ± 9
2.	F2	180 ± 7
3.	F3	183 ± 5
4.	F4	175 ± 8
5.	F5	164 ± 4



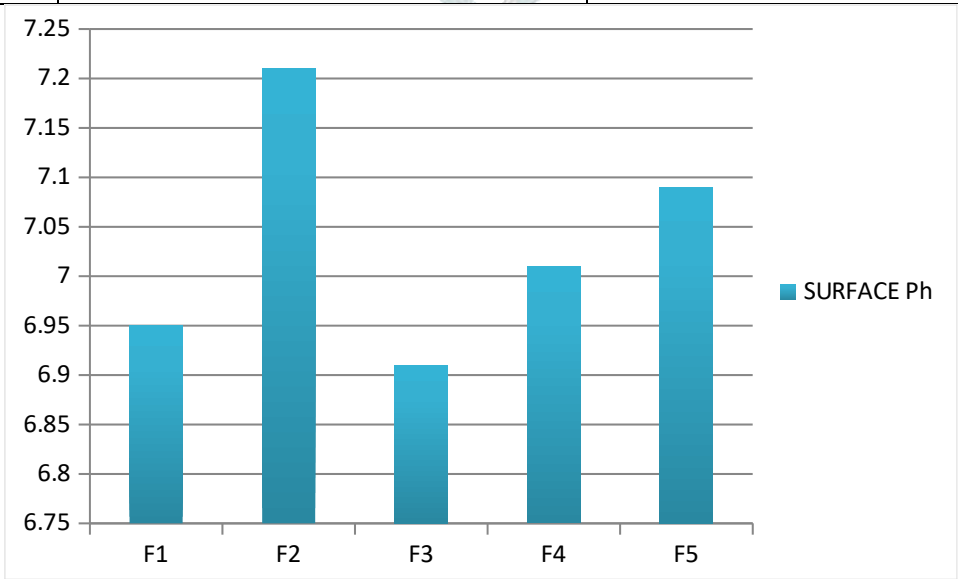
5. Tensile strength

S.No	Formulation	Observation
1.	F1	218.5
2.	F2	547.5
3.	F3	786.6
4.	F4	387.2
5.	F5	740.4



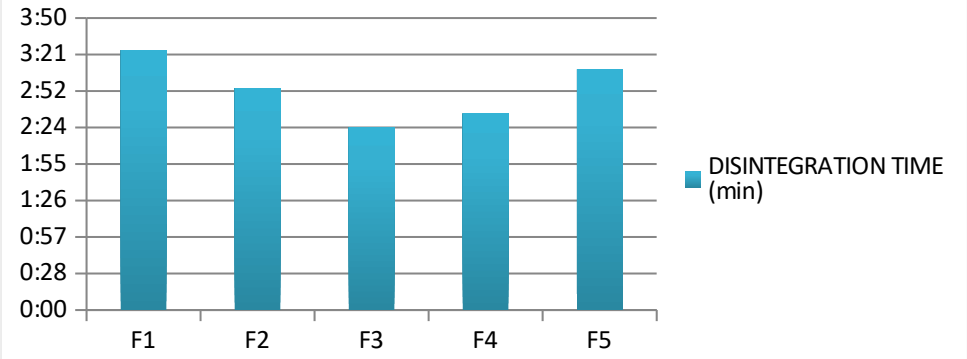
6. Surface pH

S.No	Formulation	Observation
1.	F1	6.95
2.	F2	7.21
3.	F3	6.91
4.	F4	7.01
5.	F5	7.09



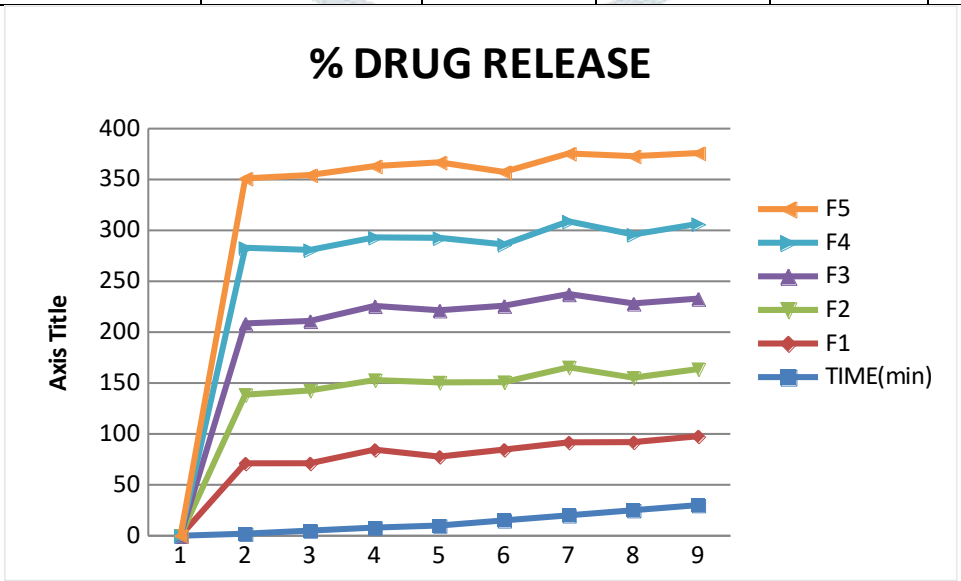
7. Disintegration time

S.No	Formulation	Observation
1.	F1	3min 25sec
2.	F2	2min 55sec
3.	F3	2min 24sec
4.	F4	2min 35sec
5.	F5	3min 10sec



8. % Drug release

TIME(min)	F1	F2	F3	F4	F5
0	0	0	0	0	0
2	69.06	67.48	70.02	74.39	68.09
5	66.13	71.54	68.31	69.82	73.54
8	76.53	68.35	72.87	67.34	69.99
10	67.73	72.84	70.85	71.22	74.19
15	69.60	66.32	75.05	60.12	71.27
20	71.73	73.68	71.98	71.48	66.72
25	66.93	63.24	73.05	67.66	77.00
30	67.73	65.95	69.24	73.43	69.61



CONCLUSION

In recent times, pharmaceutical companies have widely adopted Mouth Dissolving Films,a viable and readily acceptable dosage form..Orally dissolving mouth films are a type of medicine delivery technology that rapidly show dissolution in the oral cavity with instance of seconds, without the need for water. The oral dissolving films include unique properties that make them a beneficial delivery form for patients who have difficulty swallowing pills and capsules, such as geriatric, pediatric, or dysphasic individuals. These qualities may include rapid dissolution and disintegration, preferential by patients ease to administer and the rapid onset of action.Present research work focuses on preparation and evaluation of MDF of Fexofenadine Hydrochloride.Throughout,all the formulated preparations of MDFs resulting to improved physical and mechanical properties such as thickness ,tensile strength ,weight uniformity etc. F3 was best prepared MDF on the basis of various characterization parameters such as folding endurance, thickness, weight uniformity, disintegration and dissolution parameters. Moreover, this technology serves as a valuable instrument for pharmaceutical enterprises to enhance the longevity of existing goods and manage product life cycles.As a result Mouth Dissolving Films shows as an promising and beneficial dosage form for every kind and age group of consumer.Our study tries to compile and consolidate the existing knowledge of MDF Formulations.

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