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COMPARATIVE STUDY ON MOUTH DISSOLVING FILM AND MOUTH DISSOLVING TABLET FOR ETORICOXIB DRUG

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Abstract
The objective of present study is investigated formulation development and evaluated of etoricoxib mouth dissolving tablet by using direct compression method and mouth dissolving film by solvent casting method, in different concentrations to enhance the disintegration profile. Etoricoxib is an anti-rheumatoid arthritis drug, which is commonly prescribed for treatment of rheumatoid arthritis, osteoarthritis and gout. It is a slightly soluble in water and it is cox-2 inhibitor. Etoricoxib has long biological halflife (22hrs). In the present study, MDTs and MDFs of etoricoxib were prepared by for better patient compliance and immediate action in rheumatoid arthritis, and osteoarthritis. The tablets were prepared by using superdisintegrants such as croscarmellose, sodium starch glycolate, In the MDFs film forming polymer meltodextrin, PVA, HPMC are used and increase the disintegration profile.

Keyword: Etoricoxib, Superdisintegrants, Mouth dissolving tablet, Mouth dissolving film.

1. INTRODUCTION:

Quick dissolving measurements structures have acquired prominence and acknowledgment as new medication conveyance frameworks because of their exceptional properties as they rapidly break down and disintegrate in the mouth and can be managed without water, making them especially reasonable for patients. Quick dissolving dose structures incorporate tablets, films and microspheres. Tablets are the most generally utilized among them. Orally crumbling drug conveyance frameworks were initially concocted by researchers at Wyeth Labs in the UK during the 1970s and their exploration lead to the result of Zydis, a protected definition innovation. Quick dissolving measurement structures are alluded by various names like quick dissolving, permeable tablet, soften in-mouth, oro-dispersible, speedy dissolving, orally deteriorating or quickly crumbling dose forms.[1] The film or tablet is essentially put on persistent's tongue or any oral mucosal tissue where because of moment wetting by spit, the film quickly hydrates and may stick onto the site of utilization. It then, at that point, quickly breaks down and disintegrates to deliver the medicament. These details can be utilized for both nearby and fundamental activity.

2. Mouth dissolving tablets

Mouth dissolving tablets (MDTs) are otherwise called quick deteriorating/softening tablets, Oro-dispersible tablets, rapimelts, and permeable tablets. They break up or crumble in no less than 60

seconds when put in the mouth without drinking or chewing.[2] The dynamic fixings are retained through mucous films in the mouth and GIT and enter the circulation system. In any case, because of specific burdens of quick dissolving tablets like: their actual strong structure, some of the time hard to convey, store and handle, leave disagreeable taste/lumpiness in mouth in the event that not figured out properly.[3] Mental apprehension about gulping, biting or gagging, low tension formed tablets created by various assembling strategies and their costly bundling cost. Also MDTs generally have inadequate mechanical strength, so cautious taking care of is required. To safeguard the dose structure and to conquer such issues, another innovation was created as quick dissolving oral movies.

Fig.1 mouth dissolving tablet

- **Benefits of MDTs:**

1. Ease of administration to patients who refuse to swallow a tablet, such as pediatric, geriatric, mentally ill, disabled and uncooperative patients.
2. Rapid dissolution of drug and absorption may produce rapid onset of action.
3. Pregastric absorption can result in improved bioavailability, and as a result of reduced dosage, improved clinical performance by reducing side effects.
4. No need of water to swallow the dosage form, which is highly convenient feature for patients who are travelling and do not have immediate access to water.
5. Convenience of administration and accurate dose as compared to liquids.
6. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach; in such cases bioavailability of drugs is increases.
7. Good mouth feel property of MDTS helps to change the psychology of medication as “bitter pill” particularly in pediatrics patients.

3. Mouth dissolving film:

A quick dissolving buccal film drug conveyance framework is a new ultra slender novel detailing of postage stamp size which contains dynamic drug fixings and excipients. Viability of Programming interface is improved as it breaks up or crumbles in the spit strikingly quick, inside a couple of moments without the requirement for water or chewing.[4] Most quick dissolving conveyance framework films should incorporate substances to cover the flavor of the dynamic fixing. Hydrophilic polymers are utilized to plan films, which quickly gets disintegrated when it interacts with spit. Notable highlights of quick dissolving films

These are slender and exquisite movies which can be made in different shapes and sizes, for the most part are of the size of a stamp. These strips are dainty so are unobstructive and can be handily managed by pediatric and geriatric patients. They are mucoadhesive so stick to the oral depression for quicker hydration which prompts quick breaking down of the film. Accordingly, the film is immediately disintegrated and delivers the medicament showing speedy beginning of action.[5]

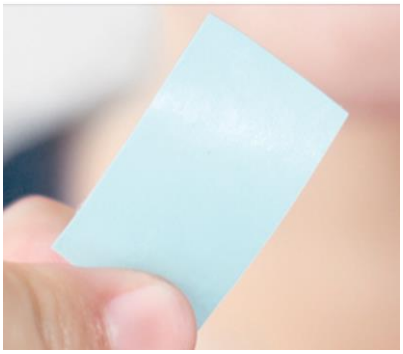


Fig.2 mouth dissolving film

- **Benefits**

1. Simplicity of organization and worked on quiet consistence.
2. Accommodating in more helpful dosing.
3. There is no gamble of gagging, as in the event of tablets and containers.
4. Improved security when contrasted with other measurement structures.
5. Taste covering of severe medications should be possible.
6. These movies have both site explicit and nearby activity.
7. Quick crumbling and disintegration of movies prompts fast medication discharge.
8. Drug enters foundational course with diminished first pass digestion.
9. Portion exactness in contrast with syrup.[6]

- **Rules for choice of medication**

1. It ought to stick to oral hole and ought to have the option to penetrate the oral mucosa.
2. Drug should shape slim and exquisite film
3. Having quick crumbling without water ought to be capable
4. Medication ought to have great dependability in water as well as in spit.
5. Medication ought to be somewhat unionized at pH of the oral pit for better ingestion
6. compelling in low portion up to 20mg just like the greatest portion for the arrangement of quick dissolving films
7. Drug with lovely taste and low to direct atomic weight are preferred.[7]

Table 1: Examination between Mouth Dissolving Tablets and film [8,9]

Mouth dissolving tablet	Mouth dissolving film
It is a tablet	It is a film
Lesser disintegration because of less surface region	More noteworthy disintegration because of bigger surface region
Less strong as contrasted and oral film	Preferred strong over oral tablets
Less understanding consistence than films High portion can be consolidated	More understanding consistence Low portion must be integrated
It has a feeling of dread toward chocking	No gamble of chocking

- **Technologies for preparation of MDTs**

1. Freeze drying or lyophilisation:

A process, in which water is sublimated from the product after freezing, is called freeze drying. Freeze dried forms offer more rapid dissolution than other available solid products. Lyophilization can be used to prepare tablets that have very porous open matrix network into which saliva rapidly moves to disintegrate lyophilized mass after it is placed in mouth. Apart from the matrix and active constituents, the final formulation may contain other excipients, which improve the process characteristics or enhance the quality of final product [10].

2. Sublimation:
This process involves addition of some inert volatile substances like urea, urethane, naphthalene, camphor, etc to other excipients and the compression of blend into tablet. Additionally several solvents like cyclohexane, benzene etc can also be used as pore forming agents. Orodispersable Tablets with highly porous structure and good mechanical strength have been developed by this method [11].

3. Spray drying:
A highly porous and fine powder is prepared by spray drying an aqueous composition containing support matrix and other components. This is then mixed with active ingredient and compressed into tablet. Disintegration and dissolution were further enhanced by adding an acid (e.g. citric acid) or an alkali (e.g., sodium bicarbonate). The suspension of above excipients was spray-dried to yield a porous powder which was compressed into tablets. Tablets manufactured by this method disintegrated in < 20 sec. in an aqueous medium [12].

4. Molding:
Molded tablets are prepared by using water soluble ingredients so that the tablets dissolve completely and rapidly. The powder blend is moistened with a hydro-alcoholic solvent and is molded into tablets under pressure lower than that used in conventional tablet compression. The solvent is then removed by air drying.[13]

5. Mass extrusion:
In this technique, a blend of active drug and other ingredients is softened using solve mixture of water soluble polyethylene glycol, using methanol and then the softened mass is extruded through the extruder or syringe to get a cylinder of product, which is finally cut into even segments with the help of heated blades to get tablets. The dried cylinder can be used to coat the granules of bitter tasting drugs and there by masking their bitter taste [14].

6. Direct compression:
The disintegrant addition technology (direct compression) is the most preferred technique to manufacture the tablets. High doses can be accommodated and final weight of the tablet can exceed that of other methods. Easiest way to manufacture the MDTs tablets. Conventional equipment and commonly available excipients are used.A limited number of processing steps are involved cost-effectiveness. Tablet size and hardness strongly affect the disintegrant efficacy. Hard and large tablets have more disintegration time than normally required. Very soft and small tablets have lowmechanical strength. So, an optimum kind and concentration of disintegrant should be chosen to achieve quick disintegration and high dissolution rates. Above the critical concentration level, however, disintegration time remains approximately constant or even increases [15].

7. Cotton-candy process:
In this process Shear form technology is used in the preparation of a matrix known as FLOSS, made from the combination of the recipients either alone or with the drugs. The fibrous nature of the floss is similar to the cotton-candy fibers. The floss is commonly made of saccharides such as sucrose, dextrose, lactose and fructose at temperatures ranging between 180- 266 °F. [16].

- **Technologies for preparation of MDFs**

1. Solvent Casting Method
In solvent casting method water soluble are dissolved in water and the drug along with other. Excipients are dissolved in suitable solvent then both the solutions are mixed and stirred and finally casted into the petri plate and dried.

2. Semisolid casting

In semisolid casting method firstly a solution of water soluble film forming polymer is prepared. The resulting solution is added to a solution of acid insoluble polymer (e.g cellulose acetate phthalate, cellulose acetate butyrate), which was prepared in ammonium or sodium hydroxide. Then appropriate amount of plasticizer is added so toast a gel mass is obtained. Finally the gel mass is casted into the films or ribbons using heat controlled drums. The thickness of the film is about 0.15-0.5 inches. The ratio of the acid insoluble polymer to film forming polymer should be 1:4. Both mixtures are mixed to form homogenous viscous solution degassed under vaccum. Bubble free solution is coated on non-treated casting film coated film is sent to aeration drying oven. Film is cutting into desired shape and size.[17]

3. Hot melt extrusion

In hot melt extrusion method firstly the drug is mixed with carriers in solid form. Then the extruder having heaters melts the mixture. Finally the melt is shaped into films by the dies. There are certain benefits of the hot melt extrusion. Fewer operation units. Better content uniformity. An anhydrous process.[18]

4. Solid dispersion extrusion

In this method immiscible components are extruded with drug and then solid dispersions were prepared. Finally the solid dispersions are shaped into films by means of dies.[19]

5. Rolling method

In rolling method a solution or suspension containing drug is rolled on a carrier. The solvent is mainly water and mixture of water and alcohol. The film is dried on the rollers and cut into desired shapes and sizes. [20,21]

- **Excipient used in preparation of mouth dissolving films**

Ingredients	Example	% (W/W)
Water soluble polymers	Cellulose ethers (HPMC, HEC,HPC, and MC), PVC, PVA, gelatin, pullulan, kollicoat IR, tragacanth gum, guar gum, chitin, etc.,	40-50
Plasticizers	Glycerol, PG, PEG	0-20
Disintegrants	Pre gelatinised starch, MCC, crosspovidone, soluble starch	0-40
Preservatives	Salts of edetate (di sodium EDTA	0.01-1
Saliva stimulating agent	Citric acid, lactic, malic, succinic, ascorbic, adipic, fumaric and tartaric acid	2.5-6
Cooling agent	Mono methyl succinate	0.2-0.4
Surfactants	Mono& di glycerides of FA, poly oxy ethylene sorbitol esters	0.5-15
Stabilizing agents	Xanthan gum, locust bean gum and carrageenan	0.1-2
Emulsifying agents	Triethanolamine stearate, Qt.ammonium compounds, acacia, gelatin	0.01-0.7
Thickening agents	MC, CMC	0.01-5
Binding agents	Starch	0.01-2
Sweetening agents	Sucralose, aspartame, acesulfame K, neotame	0-2

Table 2: List of excipients

4. Evaluation of mouth dissolving tablet

- **Weight variation test:** Twenty tablets were selected randomly and the average weight was determined using an electronic balance. Tablets were weighed individually and compared with the average weight.

- **Hardness test:** Hardness or tablet crushing strength (fc), the force required to break a tablet in a diametric compression was measured using Monsanto tablet hardness tester. It is expressed in Kg/cm^2
- **Thickness test:** Ten tablets were selected randomly and thickness was assessed using a Vernier caliper/screw gauge.
- **Friability test**: Friability is the loss of weight of tablet in the container due to removal of fine particles from the surface. Friability test is carried out to access the ability of the tablet to withstand abrasion in packaging, handling and transport. Friability of the tablets was determined using Roche friabilitor at 25 rpm/min for 4 min[22,23]

% Friability = [(W1-W2)100]/W1

Where, W1= Weight of tablet before test, W2 = Weight of tablet after test

- **Tablet Hardness: -** Tablet hardness is termed as crushing strength and resistance to friability to withstand mechanical shocks of handling in manufacture, packaging and shipping. This can be tested by using one of the following hardness testers i.e. Monsanto hardness tester, Pfizer tester[24].
- **Disintegration time**: - The disintegration time of the tablet is the time taken for the tablet to break into small particles and was determined by using USP disintegration test apparatus. The limit for disintegration is not more than 3 times at 37˚c. Procedure:-Six tablets were placed individually in each tube of disintegration test apparatus in which bath temperature was maintained at 37±0.5˚c and disc were placed on each tablets. The disintegration time of each tablet was noted.[25]

5. Evaluation of mouth dissolving film

- ✓ **Thickness:** To ensure uniformity in the thickness of the film, it is important to measure it accurately. The thickness can be measured at various strategic locations using a micrometer screw gauge or calibrated digital Vernier calipers.
- ✓ **Weight variation:** Weight variation study entails weighing each of the ten films that were chosen at random and figuring out their average weight. A measure of the film's flexibility and physical stability during production, packaging, and usage, Average weight and average folding endurance shouldn't deviate too much from one another. It was discovered by physically folding a film across the middle several times until a crack emerged. The folding endurance was calculated as how many folds on a single crease were necessary to cause a crack[26,27].
- ✓ **Folding endurance:** The film's flexibility and physical stability throughout production, packaging, and usage are gauged by its folding endurance. It was discovered by continuously physically folding a film across the center until a crack emerged. The folding number describes how many folds on a single crease are required to result in a fracture.
- ✓ **Ph surface:** To assess possible side effects in vivo, the surface pH of oral thin films containing etoricoxib that dissolve quickly was measured. Using a portable pH value, a mildly moist oral strip was utilized to test the pH by placing the electrode in connection with the film surface.[28]
- ✓ **In vitro Disintegration Time**

  A glass Petri dish with 10 cc of pH 6.8 phosphate buffer (0.1N HCl) was placed on top of the film size needed for dosage administration (4 cm^2). In vitro disintegration time was recorded as the length of time needed for the film to shatter.[29,30]
- ✓ **Scanning electron microscopy (SEM**) is well suited for morphological analysis, as it can provide high-quality, nanometer-scale images of powders and particles. SEM can be used to assess raw materials from different suppliers or compare one batch to another. The finished product can also be analyzed using an SEM, which can help analysts discover the root cause of quality issues[31]

✓ **Uniformity of drug content**

All batches of thin films medication content were determined using UV spectrophotometry. For this, a single 4-cm^2 strip was dissolved in 100ml of a pH 6.8 buffer. The solution was adequately diluted before measuring the absorbance at 234 nm. Five films were selected at random from each batch of formulation, and each film was weighed individually. Methanol was added to each film and swirled for 24 hours before being properly diluted for spectrophotometric assessments of absorbance at 234 nm. It was discovered what drugs typically included. The uniformity of dosage units for the oral film preparation was tested using 10 preparations, and the concentration of etoricoxib in each preparation was determined using UV spectrophotometry.

➢ MATERIAL AND METHOD

Etoricoxib was politely provided by Yarrow Chemical Goods in MUMBAI Central Drug. The CMC, lactose, starch, magnesium stearate, PVA, SLS, maltodextrin, citric acid, twee, menthol. Was supplied by SD Fine-Chem.

Mouth dissolving tablet formulation:

The method used for preparation of mouth dissolving tablets of etrocoxib was direct tablet compression method. It is the simplest and least expensive tableting process. From the term "direct compression" this method have steps- milling, weighing, sieving, blending, then compression into tablet punching machine. The tablets are obtained directly from the powder API or other excipient. Etoricoxib mouth dissolving tablets were formulated using direct compression method.

Table 3 Mouth dissolving tablet of Etoricoxib different formulations

Ingredient	F1	F2	F3	F4	F5
Etoricoxib	60	60	60	60	60
Croscarmellose sodium	10	20	30	-	15
Sodiumstarch glycolate	20	10	-	30	15
Magnesium stearate	50	50	50	50	50
Lactose	40	40	40	40	40
Sodium lauryl sulfate	30	30	30	30	30
Starch	20	20	20	20	20
Sucrose	20	20	20	20	20

6. Mouth dissolving film formulation

The water soluble polymers and plasticizers were dissolved in distilled water. The solution is stirred up for 2 hrs in the magnetic stirrer and kept aside to remove all air bubbles entrapped. Meanwhile, the excipients and drug were dissolved and stirred well for 30 min, after the completion of stirring both the solutions are mixed together. Finally the solution is casted on a suitable petriplate to form a film. The plates were kept in a hot air oven at 60° c for 1 hour. The dried film was gently separated from glass plate and cut into a desired sizes.

Table 4 Mouth dissolving films of Etoricoxib different formulations

INGREDIENT	F1	F2	F3	F4	F5
ETORICOXIB(mg)	60	60	60	60	60
PVA(mg)	-	20	40	40	20
HPMC(mg)	40	40	40	-	20
MELTODEXTRIN(mg)	40	20	-	40	40
TWEEN 80(ml)	0.5	0.5	0.5	0.5	0.5
SUCROSE(mg)	10	10	10	10	10
GLYCEROL(ml)	0.5	1	0.5	1	1
MENTHOL	qs	qs	qs	qs	qs
TIO2(mg)	5	5	5	5	5
CITRIC ACID(mg)	5	5	5	5	5
WATER	qs	qs	qs	qs	qs

- **RESULT AND DISSCUSSION**
- **Weight variation Test:** The weight variation average values for MDT made with different formulations are shown in Table. It was discovered that the weight variance ranged from 301 to 304 mg.

Table 5 weight variation

s.no	Formulation	Weight variation (mg) (Mean±SEM)
1	**F1**	**301±0.96**
2	**F2**	**304±0.55**
3	**F3**	**303±0.32**
4	**F4**	**302±0.62**
5	**F5**	**302±0.71**

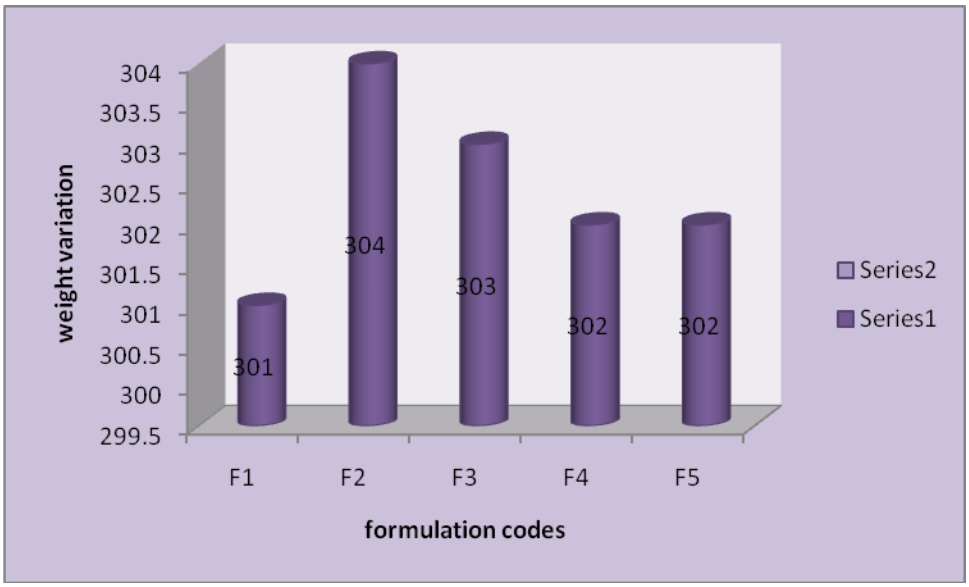


Fig.3 weight variation

- **Thickness:** The average MDT thickness values for all formulations are shown in Table. It was discovered that the thickness ranged from 3.5 to 4.0 mm

Table 6 Thickness test

S. No.	Formulation	Average Thickness (mm)	Mean ± SEM
1	F1	3.5	± 0.09
2	F2	3.7	± 0.012
3	F3	4	± 0.09
4	F4	4.2	± 0.09
5	F5	3.9	± 0.010

- **Hardness:** According to these testing, the hardness ranges from 3.9 to 4.3 kg/cm2.

Table 7 Hardness

s.no	Formulation	Average hardness (kg/cm2)
1	F1	3.9
2	F2	4.2
3	F3	3.7
4	F4	4.3
5	F5	4.2

- **Friability:** friability is a test designed to assess the physical strength of a tablet. According to the specified formula, the friability test should not exceed 1.0%. The result indicates a friability of less than 1%.

Table 8 Friability

s.no	Formulation	Friability
1	**F1**	0.5%
2	**F2**	0.7%
3	**F3**	0.6%
4	**F4**	0.8%
5	**F5**	0.9%

Disintegration time: The disintegration time of the tablet is the time taken for the tablet to break into small particles and was determined by using USP disintegration test apparatus. The limit for disintegration is not more than 3 times at 37˚C. It shows good disintegration time.

Table 9 Disintegration time

s.no	Formulation	Disintegration time: Second
1	**F1**	58
2	**F2**	56
3	**F3**	59
4	**F4**	51
5	**F5**	50

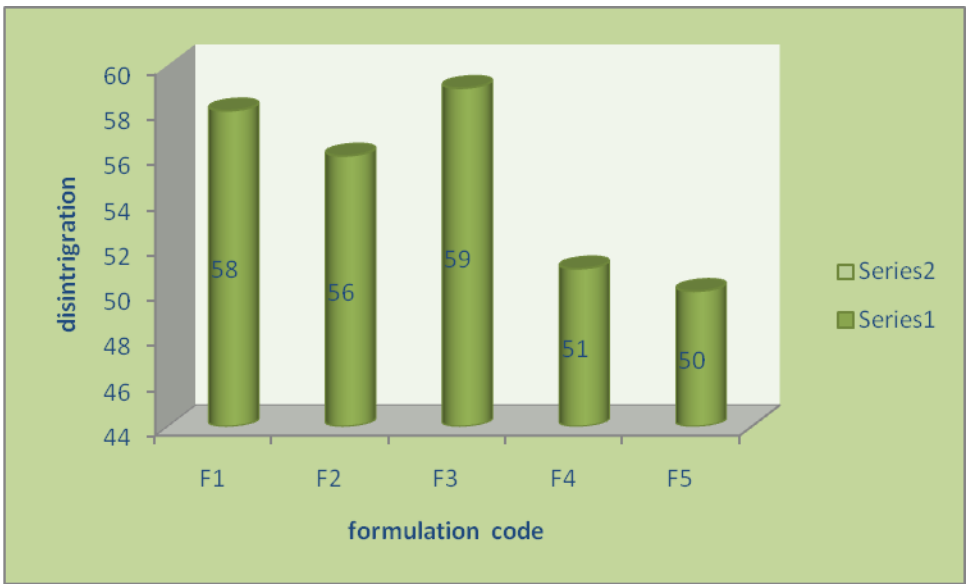


Fig 4 disintegration

- **Mouth dissolving film**

Table 10 Evaluation

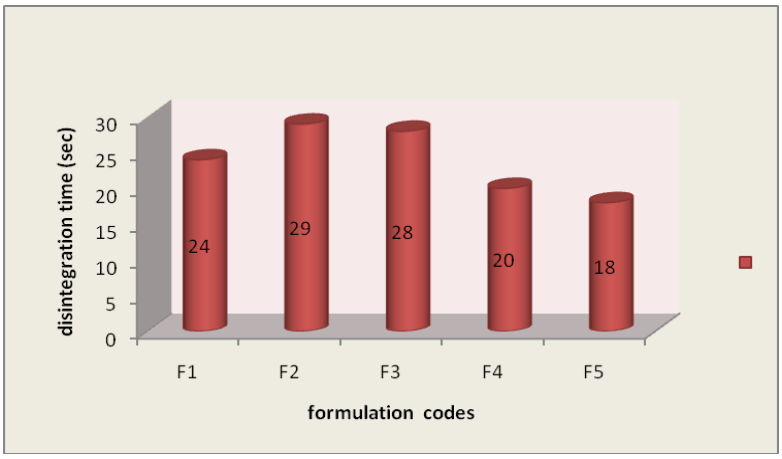
Respective formulation	Weight Variation (mg)	Folding endurance	Surface pH	thickness in um	Swelling property	% drug content	Disintegration in vivo(Sec)
F1	117±4	168±2	6.54±0.03	64±3	1.31±0.03	97.80±0.20	24±1
F2	130±10	193±1	7.00±0.02	58±1	1.36±0.02	98.00±0.15	29±2
F3	126±8	167±4	6.92±0.04	77±2	1.43±0.23	96.33±0.30	28±1
F4	155±5	156±2	6.39±0.01	83±2	1.12±0.2	99.16±0.15	20±1
F5	118±6	178±3	6.50±0.02	61±4	1.04±0.40	99.46±0.22	18±2

- **Thickness:** The average film thickness values for all formulations are. It was discovered that the thickness ranged from 58 to 83 mm.

- **Weight variation:** The weight variation average values for films made with different formulations are shown in Table. It was discovered that the weight variance ranged from 117 to 155 mg.
- **Folding endurance**

  The folding endurance values for films made from all formulations are shown in table . It was discovered that the folding endurance ranged from 156 to 193. Folding endurance reveals a product's packing state. These both show the items' plasticity and enable the product to be transported securely without breaking. In the average folding resistance of all films is displayed.
- **PH Surface**

  To assess the potential for any adverse effects in vivo, the surface pH of the Etoricoxib fast-dissolving oral thin films was evaluated and is shown in table . The pH of the surface should be kept as neutral as possible since an acidic or alkaline pH may irritate the oral mucosa. A Ph of 6.39 to 7.0.
- **In vivo Disintegration test:** The average results of the in vivo disintegration test for all films are shown in Table .The disintegration test in vivo varied, taking between 18 and 29 seconds. The formulations' in-vivo disintegration tests show how soon the films separate the particles from the solution. An extremely low standard deviation score suggests that the process for creating films can be repeated.



Disintegration time comparison

- **SEM**- Fluorescence microscopy evaluations are conducted on all Etoricoxib oral thin formulations. We can assess the formulation's particle size in this investigation. Set to 3010, the fluorescence microscope was used.

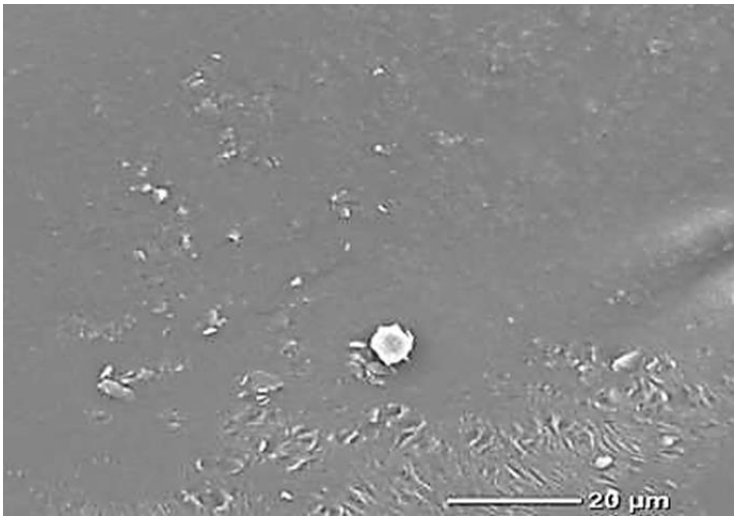


Fig 5 SEM

- **Content of drugs%:** All the formulations are compliant with USP standards, although only F2, F4, and F3 exhibit noteworthy outcomes. These formulations provide the full dose of the medicine in 12–28 seconds.

Table 11 *In vitro* drug release Studies of film Formulation F-1 to F-5

Time [min]	Formulation code				
	F1	**F2**	**F3**	**F4**	**F5**
1	3.99 ±0.34	4.12±0.40	5.64±0.36	6.78±0.39	1.8±0.10
2	35.41 ±0.32	49.99±0.45	42.16±0.39	42.09±0.36	31.99±0.30
3	47.09±0.41	62.14±0.46	50.89±0.30	55.89±0.42	45.16±0.40
4	55.64±0.43	70.74±0.53	61.89±0.52	66.18±0.52	51.09±0.43
5	57.92±0.51	67.65±0.56	62.18±0.57	63.92±0.51	56.89±0.51

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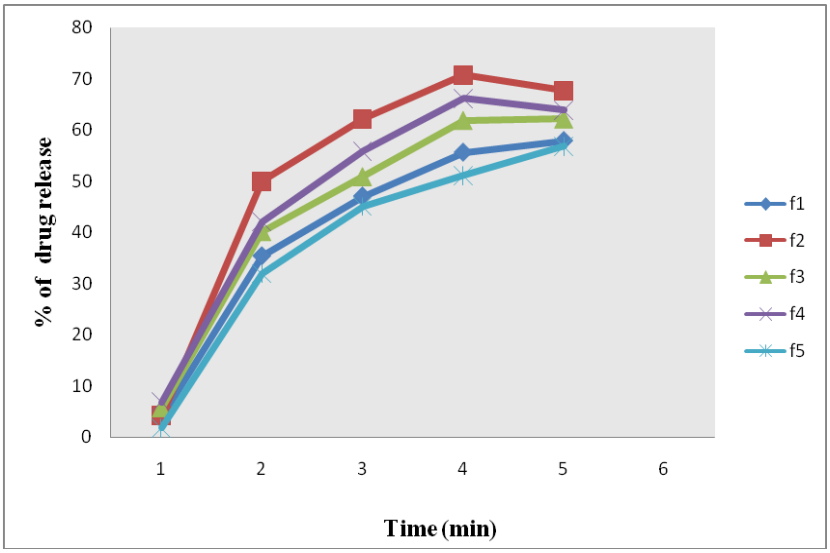

Fig.6 drug release

✓ CONCLUSION:

Etoricoxib MDTs (mouth dissolving tablets) and MDFs (mouth dissolving films) were evaluated from various batches. There was no interaction between the medication and the polymer, according to the FT-IR analysis. The tablets were made using the direct compression method with super disintegrants like CMC and SSG, as well as lubricants like magnesium stearate, diluents like lactose, surfactants like SLS, binding materials like starch, and sweeteners. The tablets were tested for hardness, thickness, weight fluctuation, friability, drug content, disintegration time, and dissolution research, among other characteristics. Five formulations in total were created in MDTs, and produced successful outcomes.

The solvent casting approach was used to make etoricoxib mouth dissolving films and was successful. Mouth-dissolving films were made using polymers such meltodextrin, PVA, and HPMC. Tween 80 as an emulsifier, and glycerol as a plasticizer. The amount of polymer, plasticizer, and emulsifier in the formulation, as well as its stability when folded and in vitro dissolution, were found to have an impact on the films' thickness, folding resistance, and in vitro dissolution. Prepared films were noted to be rapid and thin. These formulae meet all USP requirements. These films have the potential to be used as quick-dissolving films, and the excipients indicated above will help to improve diffusion. The thickness, weight variation, pH, folding durability, drug content, disintegration time, and dissolution study of the mouth dissolving films (MDFs) were all evaluated. Five formulations were created, and the findings from formulations 4 (f4) were satisfactory.

In the comparative study the mouth dissolving film is better then the mouth dissolving tablet because its manufacturing cost is low and the, better disintegration time and drug content is also good.

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