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Research Article

Formulation and Evaluation of Novel Fast Dissolving Tablet Using *Aegle marmelos* Gum

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ABSTRACT

There are many different natural polymers that are utilized in FDT, but some of them have better disintegration properties than others. For instance, *Aegle marmelos* gum includes a significant amount of mucilage, a substance used in pharmaceutical formulations as a component. In the current study, a novel fast-dissolving tablet containing ketorolac tromethamine is developed and evaluated. Its effectiveness is contrasted with that of synthetic superdisintegrants like crosspovidone. *Aegle marmelos* mucilage is separated and characterized for chemical testing and micrometric parameters to enable its identification. Ketorolac Tromethamine fast-dissolving tablets will be made utilizing the direct compression method and *Aegle marmelos*. The tablet's hardness, thickness, percentage of friability, and soaking time, as well as other pre- and post-compression factors, should be within acceptable ranges. We are going to prepare FDT of ketorolac because of the high disintegration property of *Aegle marmelos*, which plays a major part in disintegration and provides fast relief from mild to moderate pain. Since it is well known that ketorolac Tromethamine treats mild to moderate discomfort, patients can easily obtain fast-dissolving tablets. Studies have shown that certain polymers, such as *Aegle marmelos* gum, have good disintegrating properties, which is why we used them in this formulation because they are inexpensive, readily available, and have good disintegrating properties.

Keywords: *Aegle marmelos*, Pain, Disintegration, fast dissolving tablet.

INTRODUCTION

Oral techniques, which are widely used, are used to provide up to 50 to 60 percent of all dosage forms. Solid dose forms are favored because they are straightforward to use, accurate in their dosage, allow for self-medication, lessen suffering, and—most crucially — increase patient adherence. Among solid dosage forms, tablets and capsules are the two most often utilized., although some people find them to be difficult to swallow. To successfully digest oral dose forms, water intake is essential. When water is present, many people find it challenging to consume traditional dosage forms like pills. Not available, when they get motion sickness (kinetics), or when they suddenly start coughing due to a cold, an allergy, or bronchitis[1].

Due to due to these factors, pills that swiftly in the oral cavity, disintegrate or dissolve drawn attention a lot of interest. For those who are physically active as well as those who have problems swallowing, dispersible pills are advised. Melt-in-your-mouth pills, Orodispersible pills, rapimelts, porous pills, rapid dissolution, etc. are other names for fast dissolving medications. Fast-dissolving tablets rapidly dissolve relieving the tension when pressed against the tongue drug, which subsequently dissolves or disperses inside saliva.[2]Saliva enters the stomach as it flows, several medicines are taken in through the mouth, throat, oesophagus, too. The faster the medicine enters solution, the faster it will be absorbed and start to have a therapeutic impact. In these circumstances, the Bioavailability of a medication is substantially greater than what is often seen with dosage forms of regular tablets. Academics and industry are increasingly recognizing the benefits of mouth-dispersing dose formulations.[3]

Recent the adoption of phrase "Orally disintegrating tablet " According to the pharmacopoeia of Europe, a pill should be put in the mouth, where it will quickly disperse prior to being ingested, serves to highlight their expanding significance. Less than three minutes should pass before the ODT disperses or breaks up, per European Pharmacopoeia. The fundamental strategy in the creation of FDT is the employment with Superdisintegrants, such as Polyvinylpyrrolidone, sodium starch glycolate, cross-linked carboxymethyl cellulose., which, when tablets are placed on the surface, offer instantaneous disintegration the drug is released onto the tongue, causing salivation. Some medications' bioavailability may be enhanced both by medication absorption in the oral cavity and pregastric absorption. medications that enter the stomach through saliva. More significantly, when compared to a typical pill, less drug travels through first pass metabolism. tablet compression, vaporization, Additionally, tablet molding, sugar-based excipients, freeze-drying, spray-drying, and to disintegration used to make tablets that dissolve quickly. The elderly now make up a sizable segment of the world's population as a result of longer life expectancies. These people's physiological and physical capabilities will gradually deteriorate.

Concept of fast dissolving drug delivery system:

conventional techniques for drug administration. Due to physiological changes associated with aging and paediatric children in particular, dysphasia, or trouble swallowing, is a prevalent problem among patients of all ages. dose forms that are solid and can broke up, Saliva in

the mouth dissolves or suspends food are extremely beneficial for geriatrics and paediatrics populations, as well as those who prefer A fast-acting medication delivery system was designed as a way to give patients access to the easy swallowable with ease dose forms. These tablets rapidly dissolve when pressed against the tongue, dissolving or dispersing saliva containing the medication.[4]

Recently, research into pharmaceutical therapies for older patients has focused on improving their treatment compliance and quality of life. Tablets that dissolve easily in saliva are an appealing dose form and endurance - focused medication preparation.[5]

The dissolving mouthwash pills have drawn the attention of attention of several researchers. Many older people find it challenging to swallow pills, pills, and powders. To address this issue, these pills are designed to breakdown or dissolve without the use of water, in the mouth. Saliva aids. the dissolved material travel down the oesophagus smoothly so that even those with swallowing or chewing issues can easily absorb it.[6]

Two categories of dispersible exist pills that need being distinctive. The alternative tablet composition may readily dissolve in water to create a dispersion that the patient can easily drink, whilst one dose form dissolves immediately in the mouth so that it consumed lacking the need for water.[7]

Criteria for a Drug Delivery System with Fast Dissolving:

Without the need for water to be swallowed, the within a split second, tablets should evaporate or disintegrate in the tongue. accept taste masking with grace. Be flexible and unafraid to break. Feel pleasing in your mouth. little to no aftertaste should remain after oral delivery. low awareness of environmental elements like Thermodynamics and humidity Let the tablet be to be produced at a low cost using common processing and packaging equipment.

The Benefits of the Fast-Acting Drug Delivery Method Key Aspect.

Administration is simple for individuals who are unable to ingest, for example, the elderly, those who have had a stroke, those who are bedridden, those who have renal failure, and those who won't swallow, including those in psychiatric, geriatric, and pediatric care. Neither the dosage form nor require swallowing water, which is an extremely useful feature for folks who are on the road and might lack easy Water is available. Some medications are taken in through the mouth, throat, and the oesophagus when saliva flows-up the gullet. This quick breakdown and absorption results in a quick start to the drug's activity. When this happens, the medication's bioavailability is increased. By reducing adverse effects as a result of a dosage reduction, pregastric absorption can increase bioavailability and improve clinical performance. A good tongue feel quality, especially in paediatric kids, helps to alter the idea that taking medicine is like taking a bitter pill. The standard formulation can be administered orally without physical blockage, which lowers the chance of choking or asphyxia and increases safety. For conditions like motion sickness, unexpected allergic reactions reaction, or coughing that require a higher bioavailability, new commercial potential for patent extensions, product promotion, product differentiation, as well as life cycle management are beneficial due to the tablets' rapid disintegration and dissolving, especially for drugs that are insoluble and hydrophobic. because the medication is kept in solid dosage form until it is administered, it has longer-lasting stability. Thus, it combines the benefits of granular dosage forms for stability with dosing forms for liquids for bioavailability.

Fast-Acting Tablet Benefits:

- Tablets that dissolve quickly are solid. dose forms with high drug loading and precision dosing. They are a terrific alternative to conventional tablets and a perfect dose option for people who are elderly or young.
- As soon as it comes into exposure to saliva, it begins to melt. It is swiftly absorbed in the oral cavity, melts quickly, and begins to act quickly as soon as the patient takes it.
- Pregastric absorption alters the medications' bioavailability and dosage requirements, which affects patient compliance and changes clinical reports.
- Fast-dissolving pills can be taken anytime, anywhere, and are a practical option for people who are conscientious but are on the go and do not always be able to access water. As a result, Patient adherence is improved.
- Due to their solid unit dosage form, they are exceedingly simple and practical to administer, making them especially useful for elderly, juvenile, recalcitrant, and dysphasic patients.
- Fast dissolving tablets pose no threat of asphyxia due to a physical impediment while swallowing, in the airways, making them extremely safe and simple to take.
- Tablets that dissolve quickly have few leaves and completely dissolve in the tongue without leaving any trace, giving the tablet a pleasing mouthfeel and enhancing its palatability.
- Because they are less vulnerable to external variables, fast-dissolving tablets are very stable.
- Fast-dissolving pills are less expensive since they come in standard blister packaging as opposed to fancy, expensive packaging.
- Fast dissolving tablets offer budding company opportunities such line expansion, product diversification, product promotion, uniqueness, and life cycle management.
- Because they don't require pricey components, fast-dissolving tablets are less expensive. Simple blister packs can be used to package natural polymers because they are

readily available, affordable, and don't need special packaging materials when used as excipients.

- They are a multifaceted field of technology since they are used to create veterinary, over-the-counter (OTC), and prescription (Rx) medications.
- They require no water to be swallowed and are easily portable because They are a more resistant to environmental changes solid dosage forms.[8,9]

Restrictions on Orally Disintegrating Tablets: The pills frequently don't have enough mechanical toughness. Therefore, prudent handling is necessary. The incorrect manufacturing of the tablets could result in unpleasant aftertaste and/or grittiness.

Prerequisites for fast-acting tablets include:

There are several requirements for tablets to fast erode, including, the tablet must dissolve and distribute throughout the oral cavity in the absence of water intake. It holds a lot of drugs. In addition to being compatible with excipients and taste masking agents, it should have the greatest dramatic effect. After administration, there shouldn't be much leftover. It should be able to maintain its integrity during formulation processes to the best extent possible. At the range of humidity and temperature, it should be steady. It ought to be adaptable and work with current equipment for processing and packing. It ought to be inexpensive to create.[10,11]

Suitability of drugs for fast disintegrating tablets:-

When choosing the medicine, excipients, and formulation process for a certain drug, numerous criteria ought to be taken into account in order to develop FDT. These are listed below: Dugs intended for long-term use are not good candidates for FDT. Drugs like Clopidogrel that have a particularly unpleasant taste are inappropriate. Patients with Jorgen's syndrome, those who produce less saliva, and those who are not fit for the dose form in FDT.

A drug use a minimal half-life and those that must be dosed often are not suitable candidates. Patients who are using anticholinergic medication should avoid FDT. Drugs like selegiline, apomorphine, and buspirone that exhibit changed pharmacokinetic behavior when synthesized in this dosage form compared to their regular dosage form are not appropriate. Drugs that are well absorbed in the oral and pregastric regions Ideal possibilities include and that, during first pass metabolism and in the GIT, produce high levels of hazardous metabolites. FDT is believed to work well with medication that is absorbed through the upper digestive system and oral mucosal epithelial cells.[12]

Polymers that used in fast dissolving tablet:

Disintegrants are compounds that are added to tablet formulations as well as a few capsulated ones to induce the fragmentation fragmentation of tablet and capsule "slugs" when submerged in water. This expands the accessible surface area and quickens the release of the medicinal component. They encourage the tablet matrix's internal moisture absorption and dispersion. There has been a lot of interest in the tablet disintegration process, which is necessary for enabling quick medicine release. Given the emphasis on drug accessibility, it is crucial to take into account a tablet's rate of dissolution as a criterion for figuring out unrestrained drug dissolving behavior. Numerous factors affect the use of disintegrates instead of tablets, although their primary purpose is to counteract the effects of the tablet binder.as well as the physical forces at work when compressing a tablet. The disintegration agents need to be more effective the stronger the binder is for the tablet's release of its medicament. It should ideally cause the tablet to crumble into the granules and the powder used to form the granulation used to compact it. The production of tablets depends on disintegrates.

Function disintegration requires a significant affinity for water. Swelling, wicking, deformation, as well as distortion all possible mechanisms of disintegration action. Disintegrants used in formulations with granules techniques may be more efficient in breaking up tablets granules, furthering the granules' disintegration to release the therapeutic material into solution when used both "intragranularly" and "extragranularly." But because of conventional knowledge,

In wet granulation techniques, the fraction of disintegrants integrated intragranularly is less effective than the component integrated extra granularly. Because of the drying and wetting it experiences (for the purpose of granulation), which lessens the Disintegrants' action.

Because a compaction technique does not expose the disintegrants to wetting and drying, they tend to preserve good disintegration activity.[13,14]

Spontaneous inchoation yields more dependable and efficient polymers. According They are preferred over synthetic polymers because they are easily accessible, according to Journal of Pharmaceutics from Hindawi Publishing Corporation in natural settings all over the world. The majority of preparations use natural polymers, which are more cost-effective, simple to produce in sufficient numbers, and cheaper than synthetic ones. Natural polymers are nontoxic and have no negative effects on the body. Since natural polymers are biodegradable and do not harm the environment, they are pollution-free. Natural polymers are free of side effects because they are derived from a natural source. Since natural polymers are more effective, safe, and have higher patient compliance than synthetic ones, patients tend to prefer them. Since they are utilized repeatedly in numerous processes and act as a nutritional supplement, natural polymers are renewable.[15]

Types of Polymers Found in Fast-Dissolving Tablets:

Organic Polymer:

These come in a variety of plant-based forms. For the reasons listed below, plant-based materials are an alternative to synthetic ones:

- Accessibility in your area.
- Ecological friendliness.
- Inherent bio acceptability.
- Being more affordable and made from renewable resources than synthetic alternatives

Natural Polymers Are Used in Tablets That Dissolve Quickly:

Examples:- Chitin and Chitosan, Gum acacia, Karaya Gum, Treated Agar and Agar, Fenugreek Seed Mucilage, Soy Polysaccharide, *Aegle marmelos* Gum, Gellan Gum, Gellan Gum, Pectin from mango peel, Lepidium sativum Mucilage, Mucilage in Plantago ovata Seeds, Lucerne legume gum, Fruit Mucilage from Ficus Indica, Mangifera indica Gum (MIG), Mucilage from *Rosasinensis hibiscus* and prepared agar.

***Aegle marmelos* Gum:**

It is produced more quickly and consistently than croscarmellose sodium from *Aegle marmelos* fruits that are a part of International Journal of Pharmaceutics 5. The scarlet pulp of the ripe fruit has a mucilaginous, astringent taste. The pulp contains a variety of nutrients, including carbohydrates, proteins, vitamins C and A, dictamine, Omethylfordinol, marmeline, and isopentyl halfordinol. Heat treatment is used to produce AMG. It enhances the solubility of less soluble medications. As a result, there is a large change in the amount of the liver, kidney, stomach, and intestine all contain GSH (glutathione). It also increases glycosylated hemoglobin and blood glucose levels in diabetics. It decreases hepatic glycogen and plasma insulin in diabetic patients. Purified bee contains D-galactose (71.1%), D-galactose (6.5%), L-rhamnose (6.5%), and L-arabinose (12.5%).[16]

MATERIALS AND METHODS

Ketoroac was obtained as a gift sample from Synokem Pvt. Ltd. Haridwar. *Aegle marmelos* Gum Mucilage is Separated by Extraction Process, Crospovidone from Kayel medichem pvt ltd Delhi and Fenugreek gum, Orange flavour from Rama gum industries, Local market and all other excipients from sigma Aldrich.

Extraction, purification and characterization of *Aegle marmelos* Gum:

Initial Phytochemical Examinations: It consists of many chemical assessments and testing. By quantitatively estimating the amount of active chemical ingredients present, one can determine the purity of crude pharmaceuticals. The technique may be helpful in identifying a single active ingredient or a collection of related ingredients that are present in a single medication.

Extraction by Continuous hot percolation (Soxhlet extraction): In a pastel mortar and mixer, the plant material was ground. The powder was run through mesh number 10 before being retained on mesh number 60 for extraction. The substance was contained in a paper cylinder composed of filter paper and put inside the Soxhlet extractor's body. The flask was filled with the solvent. After that, the device was properly fitted.

Marmelosin Separation from Extract: Chromatography using Thin layer chromatography was used to analyze the extract. The Stahl (1965) methods for column chromatography solvent optimization were applied in the TLC method.

Table 1: Every ingredient in the formulation of Fast Dissolving tablet fexofenadine

S.No.	Ingredients (mg)	No. of Formulation					
1.	fexofenadine (mg)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**
		10	10	10	10	10	10
2.	*Aegle marmelos* Gum	-	-	-	-	15	24
3.	Fenugreek Gum	-	-	15	24	-	-
4.	Crospovidone	16	24	-	-		
5	MCC	66	58	67	68	67	58
6.	Orange flavour	2	2	2	2	2	2
7.	Aspartame	2	2	2	2	2	2
8.	Talc	4	4	4	4	4	4
9.	Magnesium Stearate	QS	QS	QS	QS	QS	QS
10.	Mannitol	50	50	50	50	50	50
	Total weight	150	150	150	150	150	150

Note -Excipients Quantity in Mg

Ketorolac Fast Dissolving Tablets Manufacturing:

Ketorolac-containing fast-dissolving tablets were created using the in-line compression approach by Using a mortar and pestle, a compound containing 10 mg of ketorolac and polymers such as *Aegle marmelos* gum, crospovidone, and fenugreek gum was well blended. The Superdisintegrants were used in various ratios and combinations. With the exception of magnesium stearate. The components were measured and combined well according to the specification. The mixture was then run through sieve number 60, which was used to assess the flow qualities. Magnesium stearate is then added to the powder and excipient mixture after it has been blended for 5 minutes Making use of 9.5 mm flat punches and a break line and an eight-station tablet punching machine, the blended blend was compressed. Compressor for the 9.5 mm station's four punches is secured with Dummy punches are used to fix the die cavity and residual material.

Evaluation Parameters of Compressed Tablet:

Tablet Hardness:

It made use of the Monsanto hardness tester by the Ketorolac tablets' hardness was specifically chosen. 10 fast-dispersing Tablets from each group were evaluated for defeat strength in kg/cm2 with known weights and tablet hardness.

Tablet Thickness:

Fast-dissolving tablet thickness was designed to be thick. The average value was calculated using a Vernier caliper after using 5 pills

Friability:

Using a Roche Friability tester, the friability of the tablet served as a stand-in for estimating solidity. 20 tablets are first ingested, and then they are carefully weighed and placed in the Friability tester. The tester ran until 100. Times or for four minutes at 25 rpm. By using the formula below, % damage in bulk friability was deserved.

$$F = \text{Initial wt - Final wt/Initial wt} \times 100$$

Weight fluctuation:

This procedure uses a weight-based variant of tablets. Twenty tablets were weighed (grams) separately on a digital account. The average tablet weight was then determined, and the variance in weight of the tablet is observed. Percentage weight deviation calculation:

$$\% \text{ Variation} = \text{Individual wt - Average wt/Average wt} \times 100$$

Wetting Time:

A small Petridis measuring 6.5 cm in diameter and a tissue paper square folded twice, and 6 cc of water are contained within inside it. On top of tissue paper, a pre-weighed pill was put, and it was given time to soak up all the water. The amount of time needed for water to completely saturate. The wetting time refers to the top surface of the tablet. After that, the wet tablet was weighed. The following equation was used to compute the water absorption ratio. (R).

$$R = \text{Wa-Wa/ Wb } X \text{ 100}$$

Where,

Wb - Weight of tablet before wetting.

Wa - Weight of tablet after wetting.

Time of Dispersion:

In 10 ml of phosphate buffer solution with a pH of 6.8, the pill was dissolved. The time taken for the tablet to completely dissolve was recorded.

Studies on *in vitro* dissolution

Using a dissolve test device (electro lab) at 50 rpm, a research of *in-vitro* dissolution was conducted out. As a dissolving media, pH 6.8 phosphate buffer in 900 ml was utilized at a 2-minute time interval and was filtered. By measuring the sample's absorbance at Selegiline at 310 nm in a phosphate buffer with a pH of 7.4 the using UV spectroscopy, the amount of medicine that was dissolved was calculated using a Shimadzu 1800, a UV spectrophotometer from Japan. Quantity of the dissolving medium that is exact (5 ml) was removed while the temperature was kept at 37.50°C. The following method was employed to determine the in vitro dissolution rate for each formulation throughout the investigation.

Dissolution characteristics:

equipment used - Electro lab

Temperature - 37± 0.50C

RPM - 50 rpm

5 ml were withheld for 5 minutes

λ max - 310nm

Stability research

According to ICH guidelines, stability tests of the optimized formulation were conducted. For 90 days, the right formulation was tested for stability at 40°C and 75°RH. evaluated at predetermined times for their appearance and drug use.

The duration of the investigation Proper storage guidelines is provided by ICH

- Long-term investigation A year at 25°C, 2°C, 60% RH, and 5%.
- Six-month accelerated testing at 40°C, 2°C, and 75% relative humidity

Cooler temperatures 3 months at 5°C and 3°C. Accelerated testing for six months at 40°C and 2°C and 75% RH and 5%.

RESULTS AND DISCUSSION

Preformulation Study-

UV Spectroscopy-

Using the UV Spectroscopy Method, the wave length of the sample medication was measured to be approximately pH 7.4 phosphate buffers at 310 nm.

Table 2: Calibration of Ketorolac Tromethamine

S.No.	Concentration µg/ml	Absorbance 310nm
1.	0	0
2.	2	0.1151
3.	4	0.2149
4.	6	0.2411
5.	8	0.4714
6.	10	0.4812
7.	12	0.6812
8.	14	0.9232
9.	16	0.8828

Evaluation of Powders for Tablets with Rapid Dissolving:

The combined batch powder ranged from having excellent to weak compressibility and flow ability. The physical combinations for fast dissolving tablets where Angle of repose was taken into consideration, and it was discovered to be between 26.361.06 and 30.860.48 and Carr's index values, which were found to be 19.500.8 to 28.680.8%. It was discovered that the Hausner ratio ranged from 1.19 to 1.40. All of the batches' bulk density ratios ranged from 0.58 to 0.64 to 0.68 and their tapped density ratios from 0.69 to 0.78 to indicate that probable and poor flow characteristics.

Discussion of all tablet specifications:

The physical conditions Tablets ranged in hardness from 4.0 to 5.0 kg/cm^2. The friability ranged from 0.32% to 0.63% for all produced tablets. The thickness was discovered to be between 4.07 mm and 4.17 mm. All tablets' weight variations were determined to be 292306 to 295309mg. Disintegration time was discovered to range from 31 and 31 seconds, dispersion time was found to be between 36 and 87 seconds.

Drug Release Studies *in Vitro*:

The proportion of medication released from formulations F1, 2, and 3 was discovered to be 52.12 to 77.22, 49.3 to 77.98, and 51.04 to 73.11, respectively. It was discovered that the percentage from formulas F4, 5, and 6 released of medication was 51.650.24 to 80.120.91, 53.40.72 to 70.981.29, and F6, 57.851.30 to 98.110.94 for accordingly. The formulation F6 was shown to contain the highest concentration of Superdisintegrants compared to the other formulations, giving the greatest release within 15 minutes.

Studies on stability:

While the color has not changed during the course of stability tests on Formulation 6, there has been a slight difference in Hardness, time till breakdown, and drug release in vitro. all information was reviewed for 90 days according to at 40 °C and 75% RH ICH norms.

Compatibility studies for physical medication excipients include:

FTIR: -

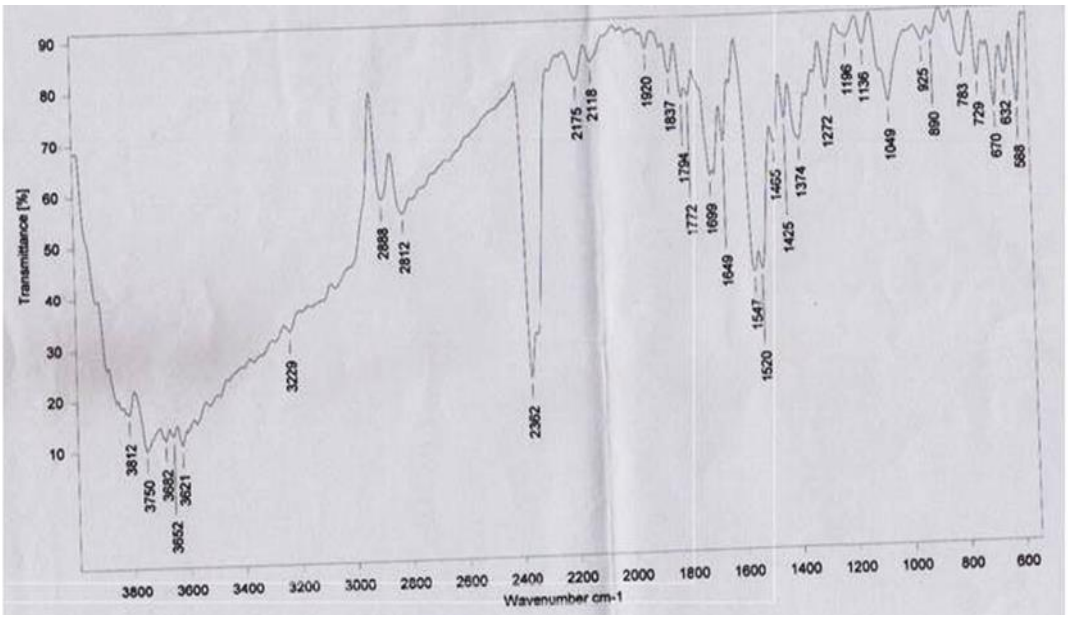

Figure 1: The Ketorolac Tromethamine FTIR spectrum

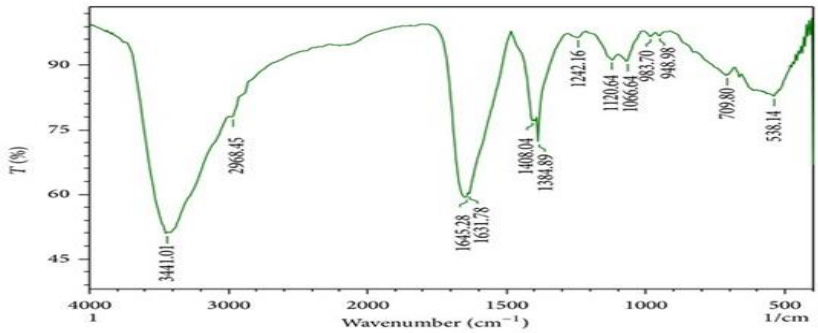

Figure 2: Ketorolac Tromethamine FTIR spectrum with *Aegle marmelos* Gum

DSC Studies Ketorolac Tromethamine**:**

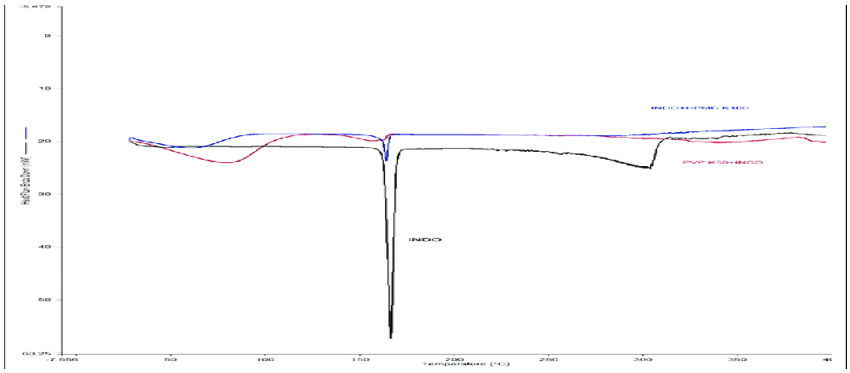

Figure 3: Calorimetric Differential Scanning of Ketorolac Tromethamine with Excipients

Table 3: Assessment of Powders for Tablets with Fast Dissolving Ketorolac Tromethamine

Formulation Code	Angle of Repose	Bulk density (gm/ml)	Carr's index (%)	Tapped density (gm/cc)	Hausner's ratio
F1	27.20±0.52	0.64±0.69	24.15±1.9	0.79±0.54	1.23±0.14
F2	29.34±1.06	0.62±0.51	21.36±0.6	0.76±1.06	1.20±0.18
F3	30.86±0.48	0.59±0.44	20.50±1.2	0.75±0.99	1.26±0.23
F4	28.25±1.10	0.62±1.23	28.68±0.8	0.69±1.05	1.40±0.20
F5	28.54±0.12	0.59±0.78	26.09±0.7	0.69±0.02	1.30±0.18
F6	26.74±0.64	0.60±0.55	19.50±0.8	0.75±0.89	1.31±0.13

Values are expressed as mean ±SD (n=3)

Table 4: A review of compressed tablets that dissolve quickly Ketorolac Tromethamine

Formulation Code	Weight variation Average wt in (mg)	Hardness (Kg/cm²)	Thickness in (mm)	Friability (%)	Drug content
F1	149 ±152	4.5±0.5	4.07±0.4	0.49%	99.18± 0.72
F2	145±153	4.5±0.5	4.09±0.3	0.43 %	92.53± 1.13
F3	148 ± 154	5.0±0.5	4.08±0.4	0.29 %	90.52± 1.16
F4	147±153	5.0±0.5	4.13±0.3	0.35%	100.03± 1.03
F5	149±158	4.0±0.5	4.23±0.4	0.43%	98.05± 0.91
F6	149 ±159	4.5±0.5	4.2±0.4	0.32%	99.08 ±0.72
Formulation Code	**Wetting Time (sec)**	**Dispersion Time**	**Disintegration time (Sec)**		
F1	47±1	69±1	57±1		
F2	39±1	63±1	45±1		
F3	62±1	87±1	69±1		
F4	50±1	68±1	58±1		
F5	35±1	50±1	44±1		
F6	23±1	36±1	31±1		

Values are intimate as design ±SD (n = 3)

Table 5: Release studies F1-F6

Time/Min	% Release drug					
Formulation	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**
0	0	0	0	0	0	0
3	52.12±2.4	49.3±0.28	51.04±0.96	51.65±0.24	49.4±0.71	57.85±1.30
6	57.18±2.2	54.51±0.99	60.52±1.31	54.46±0.47	54.85±0.87	68.71±1.22
9	62.10±2.3	57.04±0.90	61.12±1.27	60.12±0.76	58.14±1.24	72.87±1.10
12	70.25±0.9	71.14±0.21	70.44±1.12	64.22±0.82	59.14±1.15	84.80±1.17
15	77.22±0.5	77.98±1.21	73.11±0.98	80.12±0.91	70.98±1.29	98.11±0.94

Points are expressed as means and standard deviations (n = 3).

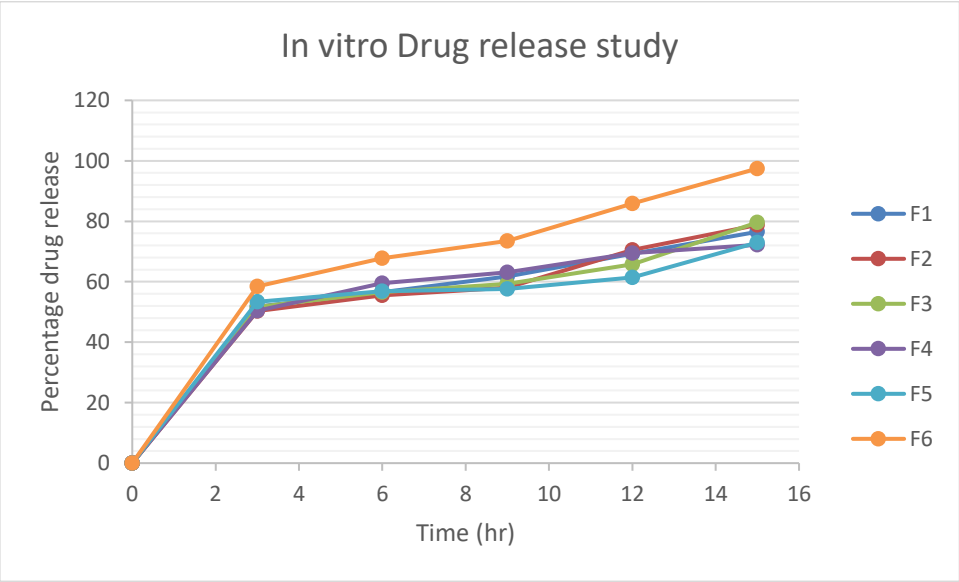

Figure 4: Cumulative Percentage drug release of Ketorolac Tromethamine

Table 6: Stability analysis of the ideal formulation F6

S.No.	Parameters	Initial	1 Month	2 Month	3 Month
1	Colour	White	No Change	No Change	No Change
2	Hardness	4.5±0.5	4.5±0.5	4.5±0.5	4.5±0.5
3	Disintegration time (sec)	31±1 (sec)	31±1 (sec)	31.5±1 (sec)	31.8±1 (sec)
4	Release of Drugs *in Vitro*	98.11±0.94	98.02±0.97	97.85±0.070	97±1.05

CONCLUSION

The Ketorolac Tromethamine Fast Disintegrating Tablets were made using the dry granulation method and a variety of Superdisintegrants, including *Aegle marmelos* Gum, Crospovidone, and Fenugreek gum, in varying concentrations. To increase the product's compatibility and stability, Mannitol and crospovidone co-ground mixes were also created. The results of the FTIR and DSC analyses showed that the polymer and ketorolac tromethamine employed were compatible. With an increase in Superdisintegrant concentration, the disintegration time decreases. *Aegle marmelos* Gum (the superdisintegrants (15, 24 mg in concentration) are the only formulation that satisfactorily satisfies all the criteria. Compared to other formulations, formulation F6 released over 98.11% of the medication within 15 minutes according to in vitro release experiments. Consequently, it was found that *Aegle marmelos* Gum played a crucial role in this study. Mannitol has a function in the quick release of drugs while also enhancing product stability and compatibility with other disintegrants. In the current work, quick-dissolving pills have created to address the problems with mild and moderate pain.

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