International Journal of Pharmaceutical Research and Applications
Volume 7, Issue 3 May-June 2022, pp: 235-247www.ijprajournal.com ISSN: 2456-4494

"Design, Development, and Evaluation of Fast Dissolving Tablet of Piroxicam by Employing Natural Super Disintegrant and Calorie Free Natural Sweetener"

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Submitted: 01-05-2022 Accepted: 10-05-2022

ABSTRACT
We have conducted research to prepare fast dissolving tablets of Piroxicam by Hole Technology, employing Hibiscus rosasinensis and Gum karaya as super disintegrants and stevia rebaudiana as a natural sweetener. Once these fast-dissolving tablets come into contact with saliva or gastrointestinal fluids, the fluid can enter the hole in the tablet and the tablet will disintegrate immediately. The formation of the large absolute space also influenced this rapid disintegration of tablets. The finished FDT have subjected to various pre-formulation and post-formulation studies. Piroxicam is the NSAIDs (non-steroidal anti-inflammatory drug) classified in the Biopharmaceutics Drug Classification system as a Class II drug with low solubility & high permeability. It demonstrates a slow & gradual absorption via the oral route & has a long half-life of elimination, rendering a prolonged therapeutic action & a delayed onset of analgesic & anti-inflammatory effects. Preparing tablet by hole technology favors high bioavailability and rapid onset of action. The main objective of this research was to prepare FDT by natural super disintegrant & calorie free sweetener deemed safe for consumption of diabetic patients. And also to study the drug release pattern. We evaluated formulation for hardness, weight variation, friability, in vitro disintegration time, in vitro dissolution test, wetting time. We found all the observations within the limit.

KEYWORDS: Hole technology, fast dissolving tablet, Piroxicam, Gum karaya, Sublimation, Stevia, Super disintegrant, Hibiscus rosasinensis.

I. INTRODUCTION:

Recently**,** a variety of research has been conducted to designnew dosage forms. Among the various dosage forms developed to facilitate ease of medication, the fast dissolving tablets (FDT) are one of the most widely employed commercial products. As our societyhas aged, the development of fast dissolvingtablets have been increased. Definition of fast dissolving tablets (FDT) by US FDA as "A solid dosage form having medicinal substance or active ingredients when placed upon the tongue should disintegrate rapidly within a matter of seconds"[1]. The disintegration time for FDT generally ranges from several seconds to about a minute. The bioavailability of some drugs may be increased due to absorption of drugs in the oral cavity &also due to pre gastric absorption of saliva containing dispersed drug that pass down into the stomach. Recently, immediate-release tablets have begun to acquire popularity and acceptance as a drug delivery system, primarily because they are easy to administer, have a rapid onset of action**,** are inexpensive and lead to better patient compliance. They are also a tool for extending product life cycles, expanding markets, and generating opportunities. In the formulation of FDT, super disintegrants are added to facilitate the breakup or disintegration of tablet content into smaller particles that can dissolve more rapidly than in the absence of disintegrants[2].Direct compression is the simplest**,** most convenient, and easiest way to obtain a rapidly disintegrating tablet with reasonable structural integrity. In the direct compression process**,** the most important thing is the selection of suitable excipient with good disintegration and compatibility properties. Several factors should be considered in selecting

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the superdisintegrants because these agents do not affect the rate of disintegration only, but they also affect friability, hardness, and how the tablet feels in the mouth. The disintegration & dissolution properties of the direct compressible FDTs are based on the single or combined action of disintegrants and water-soluble excipients. However, disintegrants have a major role. Choosing of a suitable disintegrant type and in optimal concentration is essential for ensuring high disintegration rate[3]

Ideal Characteristics on Mouth Disintegration Tablet[4]

Fast disintegration tablet should following characteristics:

1) They should not require water at the time of administration.
2) Should easily disintegrate and dissolve.
3) Overcome or mask unacceptable taste of drug.
4) They should have high drug loading.
5) They should have a pleasant or smoothing feel in mouth.
6) They should have negligible or no residue in the oral cavity after administration.
7) They should have low sensitivity against environmental conditions such as moisture and temp.
8) Ease of administration for patients who are disabled, uncooperative and mentally ill.
9) Should be portable without fragility concern.
10) They should be manufactured using conventional tablet processing &packing equipment at a low cost.

Advantages of Mouth Dissolving Systems[5]

- Ease of administration to pediatric, geriatric,bed-ridden and mentally disabled patients who have difficulty in swallowing the tablet.
- Unlike conventional dosage forms, the FDTs do not need water for swallowing. This is simple for patients who are traveling or do not have immediate access to water, and thus, provide better patient compliance.
- Being unit solid dosage form provides the advantage of accurate dosing, easy portability and manufacturing, good physical and chemical stability, and an ideal alternative for pediatric and geriatric patients.
- It improved bioavailability of drugs because of absorption from the mouth, pharynx, and esophagus.
- Pre-gastric absorption can cause improved bioavailability and, because of reduced dose, improved clinical performance through a reduction of unwanted effects.
- Rapid onset of pharmacological action as the tablet is breakdown rapidly along with quick dissolution and absorption in the oral cavity.
- Good mouthfeel, especially for pediatric patients as a taste-masking technique issued to avoid the bitter taste of drugs.
- Minimum risk of suffocation in airways because of physical obstruction when FDTs are swallowed; thus, they provide improved safety and compliance with their administrations.
- Rapid drug therapy intervention is possible.
- Conventional processing and packaging equipment allow the manufacturing of tablets at a low cost.
- No specific packaging is required. It can be packaged in push through blisters.
- Provide new business opportunities as lifecycle management, product differentiation, uniqueness, patent-life extension, line extension, and exclusivity of product promotion.

Selection Criteria for Superdisintegrants[6]

a. Particle size should be small.
b. Should be non-toxic.
c. Compatible with other excipients and drug.
d. Good hydration capacity.
e. Good flow property.
f. Good mouthfeel.
g. Effective in less quantity.

As the superdisintegrants are readily available, cost effective, and can directlycompress, the use of superdisintegrants is a more desirable and profitable method of making fast-dissolving tablets compared to other proprietary technologies. The particles of the super disintegrants are small and porous, which facilitates the rapid disintegration of the tablets without creating an unpleasant mouthfeel. The ideal superdisintegrants should give good flowability, compressibility, and compatibility without affecting the mechanical strength of tablets.

Advantages of Superdisintegrant[7]

- Required in less concentration.
- Compatible with a huge variety of drug and excipients.
- Does not affect compressibility and flowability.

Need

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- The conventional tablet dosage form is inconvenient to swallow for theyoung or the elderly patient. It has been reported that dysphagia is common among all age groups of the patient but is more specific to pediatrics, geriatrics along with the institutionalized patient, and patients with motion sickness, vomiting and nausea complications, geriatric and pediatric patients may encounter inconvenience in swallowing it.
- Alternatively, the use of reliable and user-friendly water-dispersible forms is one of the best suggestions.
- Over the past decade, there has been an enhanced demand for more patient friendly and compliant dosage forms. As a result, there is an increase in demand for developing new technologies. Since, the development cost of the new drug molecule is high, efforts are now being made to focus on the development of new drug dosage forms for existing drugs with modified efficacy andsafety, bioavailability together with less dosing frequency, & the production of more cost-effective dosage forms.
- To fulfill these medical needs pharmaceutical technology is develop, a novel oral dosage form known as a fast disintegrating tablet, which disintegrates rapidly in a small amount of water, usually in a matter of a few seconds. Drug dissolution and absorption, as well as the onset of clinical effect and drug bioavailability, can be significantly greater than those observed in the conventional dosage form. Fast dissolving tablet offer an advantage for patients who have difficulty in swallowing dispersible tablets with good taste and flavor, increased the acceptability of bitter drugs by various groups of the population.
- As synthetic super-disintegrants had several disadvantages over natural super disintergrants such as high price, side effects, and toxicity. Therefore, there was a need to develop FDT by employing natural super disintegrants.
- Another factor is solubility isone of the most important physicochemical properties of the drug. Solubility and the way to alter it isan essential part of the pharmaceutical development program
- Piroxicam belongs to BCS Class II drug,i.e. low solubility, high permeability. It is practically insoluble in water. Hence, there is a strong need to enhance the aqueous solubility of piroxicam and to prepare a novel form possessing enhanced solubility and dissolution rate novel hole technology was used to prepare a fast dissolving tablet. It is a technique in which tablet contact with saliva or gastrointestinal fluids, the fluid will enter the hole present in the tablet and immediate breaking of the tablet is going to occur. The formation of a new absolute area also influenced the fast disintegration of tablets.
- Hence, the development of fast disintegrating tablets by novel hole technology by employing natural super disintegrates like hibiscus rosasinensis and gum karaya and calorie-free natural sweeteners stevia can improve the solubility and bioavailability of poorly aqueous soluble drug and also decreases the disintegration time which will provide quick onset of action.

II. OBJECTIVES

- The basic approach used in the development of FDT is the use of super disintegrants.
- The main aim of this research was to prepare tablets by using natural super disintegrants and calorie free natural sweeteners deemed safe for consumption by diabetic patients.
- To extract the mucilage from the leaves of Hibiscus rosasinensis and prepare a modified gum.
- Examine the disintegrant property of the dried mucilage and modified gum karaya to assess its functionality.
- To study their effect on drug release to enhance drug dissolution, which will further increase absorption and bioavailability of the drug.
- To enhance the solubility of poorly aqueous soluble drugs.

Rationale :

1. Pain often affects older people because of several reasons. As people age, they are at risk of developing side effects of medication. And they cannot tolerate pain for more duration so, there was a need to develop fast disintegrating tablets by employing natural super disintegrants.
2. The recent trend toward the use of vegetative and nontoxic products demands the replacement of synthetic additives with natural ones.
3. Natural materials like gums and mucilage have extensivelyused in drug delivery for their readily accessible, rapid biodegradability, excellent bioavailability, and no side effects.

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4. In this study, natural substances like Hibiscus rosasinensis mucilage and modified gum karaya use as a super disintegrant and Stevia rebaudiana is a calorie free natural sweetener that has good mouth feeling properties. Because of this property, it helps to change the perception of drugs as bitter pills, particularly in geriatric patients.
5. Fast disintegrating tablets by hole technology ensure complete solubilisation of tablets through surface erosion, leading to the elimination of lag time for disintegration, thereby offering quicker absorption and a speedy onset of action.
6. The disruption of the tablet occurs because of the swelling of this super disintegrant increasing its volume by various folds.
7. So, the hypothesis is that want to prepare such a tablet which can give rapid onset of action within 10 to 15 minutes with natural substance and safe for diabetic people also with disintegration time within a second.

III. MATERIALS AND METHODS:

Materials

Piroxicam receives as a gift sample from Arch Pharma Lab, Thane. Microcrystalline cellulose obtains from Maple Biotech, Pune. Magnesium Stearate and talc were received from the MLA Group of Industries, Kanpur. Stevia obtainsfrom Zindagi Pvt. Ltd. Punjab. All other chemicals used were of analytical grade.

Isolation and Characterization of Mucilage from Hibiscus rosa-sinensis[2]

The leaves of Hibiscus rosa-sinensislinn were collectedfrom local garden of Nashik. The fresh Hibiscus rosa- sinensislinn leaves were collected and washed with water to remove dirts and debris. Leaves were pulverized and immersed in water for 5-6 hrs, boiled for 30 minutes and allow to stand for 1hours to allow complete release of mucilage into water. The mucilage was extracted using various layer muslin cloth bags to remove the marc from the solution. Acetone (in the quantity of 3 times to the volume of filtrate) was added to precipitate the mucilage. The mucilage was isolated, dried in an oven at <50º C, collected, pulverized, passed through #80 sieve, and stored in desiccators at room temperature for later use. The dry powder mucilage was characterized for various physicochemical properties, like percentage yield, angle of repose, swelling index, particle size, etc.

Preparation of modified Gum karaya[8]

The gum powder was placed in a porcelain bowl and heated using a sand bath for different periods of time at different temperatures. The result of the swellability and viscosity showed that the modified gum has a similar property to karaya gum, but the viscosity decreased as a function of the heating temperature and time. However, GK samples are char when heated to 140 °C. When preparing the modified form of GK, no further change in the viscosity of GK was observed upon heating at 120 °C for over 2 h. Therefore, these heating conditions at 120 °C for 2 h were chosen to prepare the modified form of GK. The modified form of GK produced was finely sieved (100 mesh) and stored in an airtight container at 25 °C.

Preformulation Study

In the manufacturing of tablet formulations, the drug and polymer may interact as they are in close contact with each other, which can lead to the drug instability. Therefore, preformulation drug-polymer interaction studies are performed to select the appropriate polymers. FTIR spectroscopy was used to determine the compatibility between Piroxicam and selected polymers. Drug Polymer combinations and pure drug were subjected to FTIR studies. Potassium bromide, pure drug, and polymers were heated at 105°C for an hour to remove any moisture content in a hot air oven. Further, in the presence of an IR lamp, KBr was mixed with drug & polymer in a 1:1 ratio. The powder was ground with the help of a mortar and pestle. Then this mixture was placed on the sample holder of the instrument and the spectra were carried out. The spectra were run from the region of 4000 $cm^{-1}$to 400$cm^{-1.}$ The disappearance of the piroxicam peaks or the shift of the peak in one of the spectra was examined. FT-IR spectrum of Piroxicam was compared with the FT-IR spectrum of Piroxicam with a polymer. Pure drug & the drug with excipients were scanned separately. The disappearance of Piroxicam peaks or shifting of the peak in any of the spectra was studied.

Determination of λmax in Methanolic HCL and Phosphate Buffer pH 6.8

The absorption maxima of Piroxicam were determined in methanolic HCL and phosphate buffer pH 6.8 by scanning the drug between 400-200 nm using a UV spectrophotometer. Fig.2

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Figure 1 UV-visible spectrophotometer

Preparation of stock solution & calibration curve of Piroxicam

A standard stock solution of Piroxicam was prepared in phosphate buffer pH 6.8, from this stock solution of phosphate buffer pH 6.8 different aliquots of various concentration (5,10,15,20,25 µg/ml) were prepared. For phosphate buffer pH 6.8 absorbance was measured at 252 nm, against similarly treated blank[9]

Preparation of tablets by using novel hole technology

All ingredients were carefully weighed and another 100 mg of camphor granules pressed into a tablet. Piroxicam, Hibiscus rosasinensis, karaya gum and other excipients were added to the mortar. 6 were mixed and mixed with the pre-mixer in the mortar. Finally, natural flavors have been added to enhance the taste. Then this mixture is put into the mold cavity, and pre-compressed camphor tablets were stored in the center of the mold cavity, and then pressed into one tablet. These tablets contain tablet within tablet, i. e. Camphor tablet is available in Piroxicam tablet. After compression, these tablets were dried at 60 °C by keeping the tablets in a hot air oven until the camphor was completely removed to produce tablets with holes in the center, resulting in the formation of an additional absolute surface area.

Table 1 Composition of a different batches of fast dissolving tablets of Piroxicam by hole technology involving sublimation method

Sr. No.	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
1.	Piroxicam	20	20	20	20	20	20	20	20	20
2.	HBS	5	2	2	8	2	5	8	5	8
3.	GK	6	8	6	8	10	10	6	8	10
4.	Mannitol	159	160	162	154	158	155	156	157	152
5.	MCC	100	100	100	100	100	100	100	100	100
6.	Stevia	2	2	2	2	2	2	2	2	2
7.	Magnesium Stearate	4	4	4	4	4	4	4	4	4
8.	Talc	4	4	4	4	4	4	4	4	4
9.	Flavour	qs	qs	qs	qs	qs	qs	qs	qs	qs
10.	Camphor	100	100	100	100	100	100	100	100	100

HBS – hibiscus rosasinensis, Gk- Gum karaya, MCC – microcrystalline cellulose.



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Figure 2 Powder blend Figure 3 Tablets prepare by Hole technology Figure 4 TLC of Piroxicam

To finalize the best formula, 3^2 Factorial design applied to this formula to get the best result. Two factors were chosen ,i.e. the amount of Hibiscus rosasinensis mucilage and the amount of Gum karaya. Three levels were high, medium, and low.

Evaluation of fast dissolving tablets[10]

a) Appearance

Tablets from every formulation were randomly picked and organoleptic properties, such as colour, odour, taste, and shape, were evaluated.

b) Swelling index

Swelling index is the volume in ml that is occupied by 1 gm of active ingredient or any adhering mucilage after it has swollen in awatery liquid for 4 h. [6]

c) Hardness:

It measured the crushing force of the tablets using a Monsanto hardness tester. Three tablets from every formulation batch were tested randomly and the mean reading was noted. The hardness was measured in terms of kg/cm.2 The hardness of all batches is described in (Table 4) [11]

d) Weight variation:

Randomly twenty tablets pickedand weighed individually. Compared the individual weights with the mean weight for determination of weight variation. The % deviation was determined and then compared with the USP specifications. Table 4. describes the weight variation of fast dissolving tablets.

e) Thickness:

Thickness and diameter were determined using a verniercaliper. Three tablets of each formulation were selected randomly, and the thickness was measured individually. The thickness of all batches is described in (Table 4)

f) **Friability:**Twenty tablets were weighed and placed in a Roche friabilator and the equipment was rotated at 25 rpm for 4 min. The tablets were removed out, dedusted and reweighed. Friability of all batches described in table 4. The % friability of the tablets was measured as stated by the following formula. [12]

Percentage Friability (%) = Initial weight−Final weight/Initial weightX 100

g) **Wetting time:** A piece of tissue paper (10.75×12 mm) folded twice was placed in a petridish (d=6.5 cm) containing 6 ml of water. A tablet was put on the paper and the time required for the upper surface of the tablet to become wet was noted as the wetting time of the tablet. Wetting time of all formulation is described in table 4.

h) **Water absorption ratio:**The test was done with the same procedure as that of wetting time. In this test initial weight of tablet was taken prior to placing on petri dish. After entire wetting the wetted tablet was then weighed. Water absorption ratio, R was determined using the equation,

Water absorption ratio(R) = $Wa-Wb/Wa$X 100

Where Wa is the weight of the before test and Wb is the weight of the tablet after water absorption. The water absorption ratio of all batches described in Table no.4.[13]

i) **In -Vitro disintegration time:** The disintegration time for all formulations was carried out using a USP tablet disintegration test apparatus (ED 21, Electro lab, Mumbai). Six tablets were kept individually in each tube of disintegration test apparatus and discs were put down. The water was kept at a temperature of 37° ± 2°C and the time taken for the complete tablet to disintegrate entirely was noted. The disintegration time of all batches is described in table 4.

j) **In -Vitro Dispersion time:** Tablet was added to 10 ml of phosphate buffer solution (pH 6.8) at 37±0.5°C. Time required for the entire dispersion of a tablet was measured.

k) **Drug (Active Ingredient) Content:** Twenty tablets were powdered and an equivalent weight of 20mg piroxicam tablet powder was accurately weighed and transferred to a 100ml volumetric flask. First, 5 ml of methanol was added, and the mixture was stirred for 10 minutes. The volume was made upto 100 ml with phosphate buffer pH 6.8. The solution in the volumetric flask was filtered, diluted appropriately, and analysed spectrophotometrically at 252 nm.

l) **In vitro disintegration test:** The disintegration time was measured with a disintegration test apparatus. One tablet was put down in each tube of the basket. The basket with the bottom surface of stainless steel mesh (#10 mesh) was immersed in water at a temperature of 37 ± 2°C. The time required for complete tablet disintegration in each tube was determined using a stopwatch. In accordance with pharmacological standards, dispersible tablets should disintegrate within 3 minutes when tested with the tablet disintegration test.

m) **In vitro dissolution study:** The release rate of piroxicam from rapidly dissolving tablets is

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determined using the United States Pharmacopeia (USP) Dissolution Test Apparatus II (paddle method). The dissolution test was carried out with 900 ml phosphate buffer (pH 6.8) at 37 ± 0.50 °C & 50 rpm. A sample of 5 ml solution is withdrawn from the dissolution apparatus at regular intervals for 5 min. Samples are replaced with an equal volume of fresh dissolution medium. The samples are filtered through filter paper. Absorbance of these solutions is measured at 252 nm using a Shimadzu UV/Vis dual-beam spectrophotometer. The cumulative percentage of drug release is calculated using an equation derived from a standard curve [14]

Figure 5 Dissolution TestApparatus

n) Accelerated stability study

Accelerated stability study was performed as per ICH guidelines on best batch F8 to determine the change in physical characteristics, dissolution study and disintegration time of tablets on storage at 45 °C and 75% relative humidity for 3 months. Every month the sample was taken out and to evaluated for change in friability, hardness, weight of tablets, in vitro disintegration time, uniformity of drug content and dissolution. The accelerated stability studies of fast dissolving tablets were shown in table 7.

IV. RESULT AND DISCUSSION:

Characterization of Mucilage from Hibiscus rosa-sinensis and modified gum from Gum karaya.

Mucilage isolated from Hibiscus rosa-sinensis and modified gum was characterized for its physical and chemical properties the results of which are given in.

Table 2 Characterization of Mucilage and Modified Gum

Sr No.	Physical parameters	Observation HBS	Observation Gum karaya
1	Appearance	Greenish Powder	White to light brown(Grade l)
2	Odour	Characteristic	Characteristic like acetic acid
3	Percentage Yield	25%	45%
4	Weight loss on drying	29.65±0.47	28.42±0.61
5	Solubility	Slowly soluble in water to form viscous solution	Slowly soluble in water to produce a viscous solution
6	pH	7 (Neutral)	4
7	Chemical Characterization • Molisch's test(for carbohydrates) • Mounted in ruthenium red	Positive Particles stained red	Powder+water= viscous solution. Produces pink color

Pre-formulation parameters

Piroxicam was observed for organoleptic properties like physical appearance, odor, and melting point. The drug was identified with the help of UV and FTIR and exhibited absorption maxima at 334nm when 0.01 N Methanolic HCL was used as a solvent and at 252nm when phosphate buffer pH 6.8 was used as a solvent as shown in fig 7 & fig 8.

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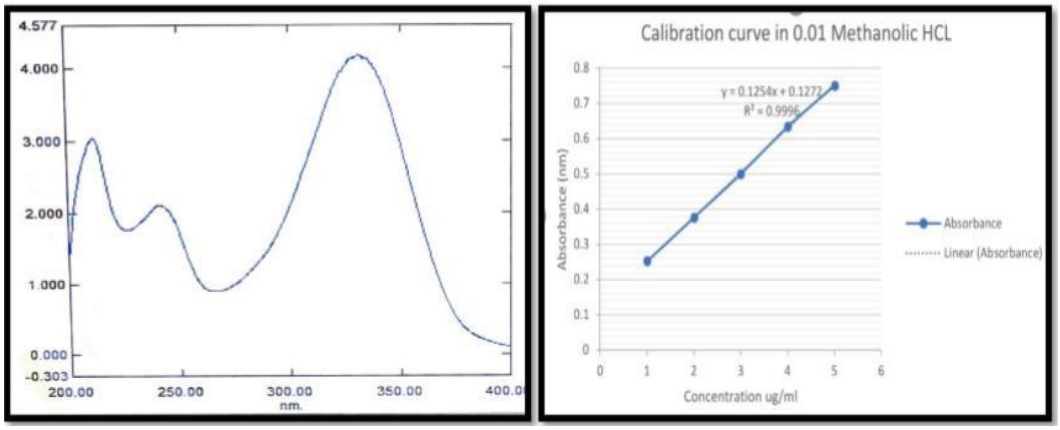

Figure 6Uv Scan spectrum of piroxicam in 0.01 N Methanolic HCL

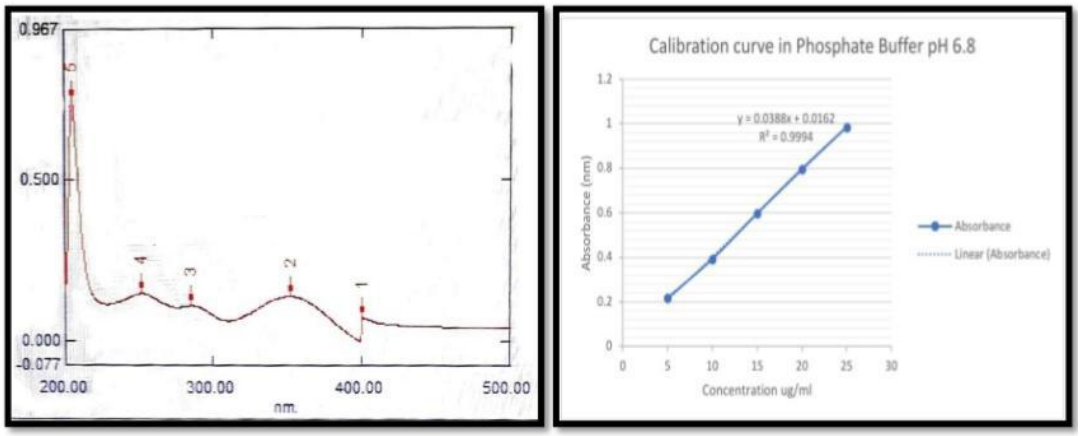

Figure 7UvScan of Piroxicam in Phosphate buffer pH 6.8

FTIR

IR spectra of the drug and mucilage were carried out to study the compatibility of the drug with various polymers. The FTIR spectra of drug, mucilage, and physical mixture of drug and mucilage (1:1) were shown in the figure. No major differences in the FTIR patterns of pure drug and mucilage were observed. Therefore, the FTIR studies determine the possibilities of any drug excipient interaction during the preparation of dosage form.

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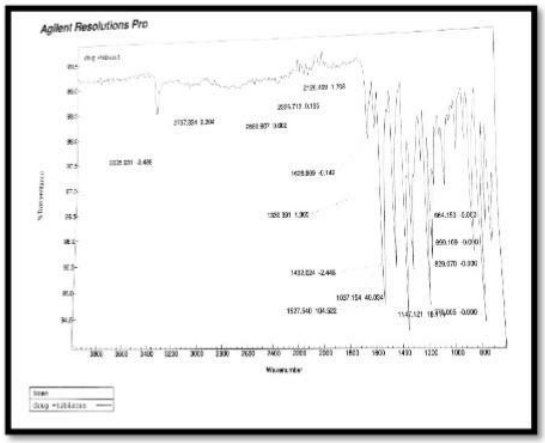

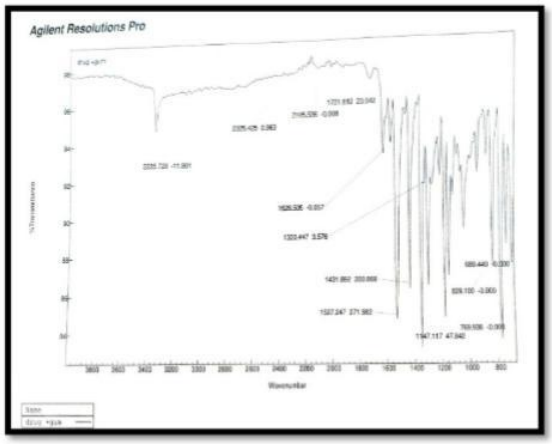

Figure 8 FTIR spectra of Drug and hibiscus Figure 9 FTIR spectra of Drug and Gum karaya

Pre compression parameters

The values were found to be within prescribed limits of pre-compression parameters and indicated good free-flowing property data are tabulated in the table.

Table 3 Pre-compression parameter of powder blend

Formulation	Angle of repose ()	Bulk Density (g/ml)	Tap density (g/ml)	Carr's Index (%)	Hausner's ratio
F1	33±0.643	0.37±0.005	0.44±0.003	14.7±0.569	1.16±0.005
F2	31.31±0.516	0.34±0.004	0.40±0.004	14.8±0.363	1.17±0.003
F3	33.17±0.274	0.44±0.007	0.52±0.008	14.7±0.457	1.17±0.002
F4	30.55±0.431	0.47±0.003	0.55±0.005	14.3±0.623	1.16±0.005
F5	27±0.457	0.41±0.006	0.49±0.004	16.4±0.763	1.19±0.003
F6	27.88±0.325	0.37±0.002	0.43±0.003	13.9±0.342	1.16±0.002
F7	26.8±0.564	0.43±0.008	0.49±0.006	12.2±0.412	1.13±0.006
F8	28.8±0.211	0.31±0.001	0.39±0.002	13.70±0.231	1.15±0.001
F9	25.41±0.354	0.34±0.005	0.40±0.005	14.86±0.352	1.17±0.004

Mean ± SD (n = 3)

Post Compression Parameters

Post-compression parameters of all the formulations were carried out successfully & data were tabulated in the table.

Table 4 Post compression parameter of tablet

Formulation	Weight variation	Thickness(mm)	Hardness(kg/cm3)	Friability(%)	Water abs	Drug Content(%)
F1	Pass	2.59±0.03	2.8±0.54	0.73±0.52	78±0.34	101.4±0.5
F2	Pass	2.6±0.024	2.6±0.37	0.69±0.64	73±0.15	98.4±0.43
F3	Pass	2.58±0.045	2.7±0.73	0.63±0.43	79±0.46	102±0.36
F4	Pass	2.56±0.036	2.8±0.56	0.69±0.54	82±0.63	100.4±0.2
F5	Pass	2.5±0.054	2.7±0.27	0.63±0.36	86±0.25	98.4±0.43
F6	Pass	2.6±0.065	2.8±0.63	0.73±0.32	91±0.23	98.8±0.61
F7	Pass	2.55±0.035	2.8±0.35	0.72±0.21	83±0.47	99.2±0.24
F8	Pass	2.52±0.042	2.8±0.43	0.62±0.24	94±0.14	100.05±0.12
F9	Pass	2.53±0.045	2.7±0.45	0.70±0.67	89±0.56	99.9±0.3

Mean±SD (n=3)

Formulation	Disintegration time (sec)	Water Absorption	Wetting time(sec)

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		Ratio	
F1	28±0.56	90.67±0.54	19±0.35
F2	23±0.64	87.95±0.43	15±0.52
F3	29±0.76	91.56±0.56	23±0.43
F4	18±0.58	90.23±0.24	12±0.52
F5	22±0.67	91.44±0.52	14±0.49
F6	16±0.43	94.7±0.26	11±0.75
F7	19±0.54	92.36±0.32	13±0.45
F8	15±0.37	94.98±0.15	10±0.34
F9	18±0.45	91.32±0.54	12±0.64

Mean±SD(n=3)

Dissolution Studies

Dissolution studies were conducted for all formulations via USP dissolution apparatus to paddle-type using phosphate buffer pH 6.8 as dissolution medium. It has been observed from the drug release profile more than 90% was released within 15 minutes. Formulation 8 contain 5 mg of Hibiscus rosasinensis mucilage and 8% of gum karaya which shows 100% drug release within 15 minutes which was formulated by whole technology yeah cumulative percent re drug release of all the formulation is tabulated below comparative drug release of all the formulation where shown in the figure

In vitro dissolution study of tablet was conducted using USP apparatus II Paddle apparatus 900 ml of phosphate buffer pH 6.8 as dissolution media. The speed of the paddle was kept at 50 rpm throughout the study. A sample of 5 ml was removed at a time interval of 0,5,10,15,20,25 minutes and the volume was replaced with the fresh medium. The samples were filtered and the concentration in each sample was determined by UV at 252 nm with a spectrophotometer and reported as an average of three determinations.

Table 5 Dissolution Studies of Different Batches

Time(min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
5	30.85	31.31	26.09	32.59	21.45	42.68	47.20	61 .81	54..62
10	40.76	41.34	40.73	41.35	35.02	72.02	74.48	90.34	87.40
15	64.76	64.53	77.96	67.44	63.40	94.92	84.52	100	94.49
20	91.21	93.19	86.16	93.79	80.22	97.30	97.75		100
25	96.12	94.86	94.87	95.93	94.23	98.30	100		
30	97.00	97.12	97.01	99.82	99.27	100			

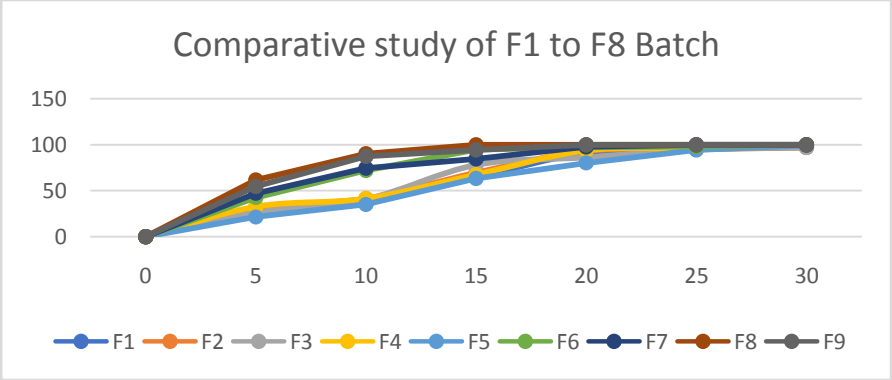

Figure 10 Comparative study of F1 to F8 Batch

Table 6 Comparison of a dissolution profile of Batch F8 and marketed formulation tablet.

International Journal of Pharmaceutical Research and Applications
Volume 7, Issue 3 May-June 2022, pp: 235-247www.ijprajournal.com ISSN: 2456-4494

Time in min	Batch F8	Marketed Batch
0	0	0
5	61.81	54.9
10	90.34	74.48
15	100	81.95
20	-	86.7
25	-	88.29
30	-	95.02

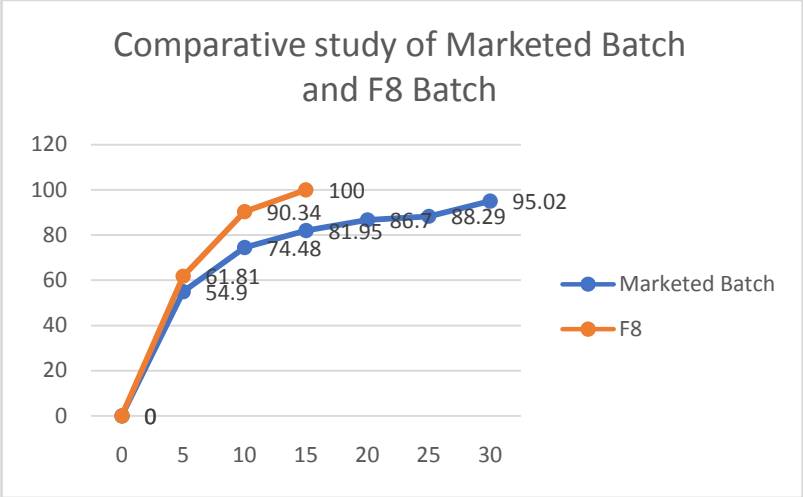

Figure 11 Comparative Study of Marketed Batch and F8 Batch

Stability studies:
Stability studiesperformon F8 formulation as per ICHguidelines for 60 days at 40°C±2°C / 75% RH±5%. They indicate no remarkable change in physical properties & release profile of the prepared tablets. Results of the stability studies given in Table 6.

Table 7 Stability studies of F8 formulation at 40°C±2°C/75% RH±5%

Parameters	Days			
	0	**15**	**30**	**60**
In vitro dissolution studies	100±0.2	99.68±0.31	99.87±0.27	99.92±0.38
Disintegration time	15 ±0.36	16±0.29	15±0.22	15±0.31
Hardness(kg/cm^3)	2.8±0.53	2.8±0.42	2.7±0.21	2.8±0.24
Wetting time	10±0.54	10±0.36	10±0.42	11±0.21

V. CONCLUSION:

From the present study, we concluded that natural super disintegrants like Hibiscus rosasinensis Linn mucilage powder and modified gum karaya indicated better-disintegrating properties than the most widely used synthetic super disintegrants like crosspovidone, sodium starch glycolate, or croscarmellose in the formulations of Fast dissolving tablets. We can use superdisintegrants like Hibiscus rosa-sinensis Linn mucilage powder and modified gum karaya in place of the currently marketed synthetic super disintegrating agent. We concluded it from the above study that natural superdisintegrants have better effects on fast dissolving tablets. Hole technology method is used to prepare fast dissolving tablets using natural super disintegrants in different combinations. From the observed parameters, we concluded that the formulations satisfied all the official requirements. Natural Polymers increased the drug release rate from the

International Journal of Pharmaceutical Research and Applications
Volume 7, Issue 3 May-June 2022, pp: 235-247www.ijprajournal.com ISSN: 2456-4494

tablet while decreasing the dissolution & disintegration time, disintegrants. We can also use it as a binder, super disintegrant, and diluent. Natural super disintegrantsfavorsover synthetic super disintegrants as they are easily available at low cost, non-toxic, excellent biodegradability, rapid bioavailability, use in low concentration, and as naturally extracted, provide a nutritional supplement. The goals behind the addition of super disintegrants were to expand the surface area of tablet fragments & to overcome cohesive forces which keep particles in powder together in a tablet. Releasing the active ingredients for absorption, disintegrants swell and tend to dissolve when the tablet comes in contact with a fluid. By using various kinds of super disintegrants, fast disintegrating tablets will successfully commercialize.

VI. FUTURE SCOPE:

- Novel Hole Technology will hold a promising opportunity in various pharmaceutical applications in the upcoming future because of its characteristics.
- Suitable selection of a polymer is one of the major challenging tasks in the formulation of pharmaceutical fast dissolving tablets with hole technology. For this, various knowledge-based approaches are being used. A combination of knowledge-based and experiment methods for the selection of polymer offers a new era in FDT hole technology.
- Despites off outstanding development in this field of FDT using natural polymers, commercial success is still awaited. We can also use other drug candidates in the future to formulate with hole technology. Further, these natural polymers can also replace with others, such as locust beans, dehydrated banana powder, Guar Gum.
- It is a novel approach to decrease the disintegration time and increase patient compliance. So, patients who cannot swallow, such as stroke victims, bedridden patients, or affected by renal failure, so formulation with this technology with natural polymers is supposed to be a better technique in pharmaceuticals.
- Industrial interest in pharmaceutical fast dissolving tablets is increasing because of the increased pharmaceutical benefits. They can use novel hole techniques for enhancing the physicochemical properties of drugs without affecting their pharmacological properties.

ACKNOWLEDGEMENT: Authors are thankful to Arch Pharma Lab, Thane, for providing the Piroxicam drug sample.

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