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FORMULATION AND EVALUATION OF *FICUS BENGHALENSIS* LOADED CANDY FOR TOOTHACHE

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Keywords:

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ABSTRACT: People utilise plants regularly all around the world for the treatment and prevention of a wide range of illnesses. One abundant plant found in India is the banyan tree, *Ficus benghalensis Linn*. Oral and dental hygiene is the primary factor of a human being to lead a healthy life. The aim of this study is to design *Ficus benghalensis Linn.* candy to improve patient oral health, toothache, and acceptability. *Ficus benghalensis* latex was collected from market for preparation of candy for toothache. There were nine different *Ficus benghalensis* preparations made. *Ficus benghalenis*, latex, citric acid, methyl cellulose, glycerin, β-cyclodextrin, and isomalt were used in varying concentrations to create the candy. Formulation F1, F3, F6, & F8 depicted better result as compared to other formulation as they were flexible. The hardness, friability, weight fluctuation, and solubility of all of the formulations were within acceptable ranges. Due to its lack of major adverse effects and promising medicinal applications, the genus Ficus assumed to be safe for long-term pharmacotherapeutic use in humans.

INTRODUCTION: In Indian medicine, as well as other traditional medical systems across the globe, plants have long been a significant source of medications. The Rig-Veda, Charaka Samhita, and Sushrusha Samhita are the earliest sources of information on the curative and preventative characteristics of medicinal plants, and they include significant data on a variety of medicinal herbs. India has a long history of using traditional medical practises, and the Materia Medica, which contains a wealth of knowledge on the traditional uses of medicinally significant natural products derived from plants, gives a wealth of information on these practises [1].

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The roots of Indian traditional medicine may be found in a number of medical systems, including Ayurveda, Siddha, Unani, and Homeopathy. Banyan tree, Vata tree, and Vada tree are all popular names for the Moraceae species *Ficus benghalensis* (FB) [1]. Most Ficus species are endemic to the old world tropics, where there are more than 800 species and 2000 variations. Bangladesh, India, and Sri Lanka are its native habitats [2].

The Brits gave this tree its English name, Banyan, since it was a common meeting place for Hindu traders (known as "banias") at the time. It is a very tall tree, reaching heights of up to 30 metres, and it blooms all year long. Except in very arid regions, when it becomes temporarily leafless, it prefers a perpetually leafy setting to flourish in. It can endure dry periods and even some cold because of its resilience. While young, it takes an epiphytic position. It grows from seeds that birds have dropped on crumbling walls or other trees, and it is

harmful to forests, houses, and walls. It's numerous, far-flung branches are supported by a network of aerial roots. The bark has a bluish-green colour, and the leaves are simple, alternating, and arranged in groups at the tips of the branches. Their length is 10-20 centimetres, and their width is 5-12.5 centimetres [3]. Leaves are ovate to elliptic in form and are extensively ribbed from the base three to seven times. The fruiting reaches are paired and sessile; they are globose in form and become a brick red colour when mature; they hold male, female, and gall flowers; and the fruits are tiny and contained inside the same fleshy receptacles. There is a wealth of information regarding the pharmacological effects of several *Ficus benghalensis* parts included inside the drug.

All around the world, people look to trees as a symbol of tranquilly and unity. Locals utilise the black pepal of the Accasia catechu tree and the gum of the *Ficus benghalensis* tree to treat toothaches, pyria, and other dental issues. For many years, it has been understood that oral medication delivery is the most popular method of systemic drug administration. Because to its natural, simple, practical simplicity of administration, self-medication, exact dose, pain avoidance, and most importantly patient compliance, it has a broad acceptance and popularity of up to 50-60% of solid dosage forms [4].

Mouth Dissolving tablet formulation is growing and increasing popularity in the current trend of oral dose forms that emphasises the comfort of medicine since it is simple to give and improves patient compliance 8. These pills dissolve or scatter in the saliva in less than three minutes, leaving a residue that is simple to swallow. Water is not required for administration since the medication is released soon after coming in contact with saliva [5]. Tablets that dissolve in the tongue offer several additional benefits, including a good mouth feel and decent flavour masking ability. Patients with swallowing difficulties, such as infants, the elderly, the bedridden, the crippled, and those with renal failure, as well as paediatric, geriatric, and psychiatric patients, may benefit from having these tablets crushed and dissolved in water. This dose form has a high bioavailability because it is absorbed rapidly in the oral, pharyngeal, and oesophageal cavities before reaching the stomach. Tablets of Terbutaline Sulphate with a similar quick melting (mouth dissolving) formula have been produced by Mathew *et al*. for the treatment of bronchial asthma. Like with other oral dosage forms, such as candy, the fast-relief impact of candies is more durable since the medication is retained in the mouth for a lengthy amount of time and the drug slowly combines with the saliva, making the action of sweets last longer [6].

METHODOLOGY:

Collection of Plant Material: The *Ficus benghalensis* latex was collected from the local market, Morena (M. P).

Pre-formulation Studies: Laboratory studies to establish the features of active substances and excipients that may influence and process design and performance is thus described as Preformulation investigation. Sucrose, isomalt, glycerin, citric acid, menthol, peppermint, and β-Cyclodextrin were of used as an analytical grade. The shape and size of candy can be used to dimensionally represent, monitor, and control candy property [7].

Identification of Responsible Group of Analgesic Activity in *Ficus benghalensis* Latex by HPLC: Using HPLC, several phenol-containing chemicals were isolated from *Ficus benghalensis* fractions. 20 mg of plant extracts were combined with 12 mg of methanol, 5 mg of hydrochloric acid (HCl), and 18 mg of distilled water. The resulting mixture was incubated at 90 °C for 2 hours before being filtered through a 0.2 mm Millipore membrane strainer and injected into HPLC.

Identification of Responsible Group of Analgesic Activity in *Ficus benghalensis* Latexby IR: The extracts were centrifuged at 3000 rpm for 10 minutes in order to filter out impurities for IR spectrophotometer analysis. A high-pressure vacuum pump was then used to filter the filtrate through Whatmann No. 1 filter paper. The same solvent is used to dilute the sample to a ratio of 1:10. The distinctive peaks in the range of 400–4000 cm-1 and their functional groups were found *via* IR analysis utilising a Perkin Elmer Spectrophotometer instrument. Recordings of IR's peak values were made. For the spectrum confirmation, every single analysis was carried out twice.

Evaluation of Candy:

Thickness: The uniformity of the manufacturing process, including particle size, size distribution, mixing of powders, *etc*., is assessed by measuring thickness. During the process, tooling determines it [8].

Hardness: Tablet friability, dissolving, and disintegration are all impacted by hardness, making it a crucial quality. For handling, packing, and shipping, candy requires a certain degree of hardness and friability resistance to survive abrasion. The Monsanto and Pfizer hardness tester are used to measured hardness. The loading of round and conventional candy takes place across their diameter where breakage occurs therein plane. Crushing strength is measured by hardness (in kilogram, pound, or arbitrary units) which ought to be greater than 4kg [9].

Friability Test: A Friability Test was used to measure the candy's Friability (FR). Ten (10) candies were collected, de-dusting and the weight was recorded on a precision balance. The tablet was placed in the device clear drum and set to rotate at 100 revolutions. The difference in weight as a percentage of total initial weight of candy after the test was taken [10].

Friability (%) Initial weight (W1) – Final weight (W2) / Initial weight (W1) × 100

Mouth Dissolving Time: The duration it took for the lozenges to fully dissolve was determined using an USP disintegration equipment. Lozenges were inserted in each tube, and the duration was recorded using 900 cc of pH 6.8 phosphate buffer at 370 °C. Three duplicates of this experiment were performed.

Drug Content: In a 50 ml volumetric flask, lozenges were crushed and dissolved in 5 mL of methanol before being diluted with pH 6.8 phosphate buffer to the necessary volume of 50 ml. After being sonicated for 30 minutes with pH 6.8 phosphate buffer, 1 ml of this solution was transferred to a 50 ml volumetric flask and filtered through paper. The absorbance of this solution was determined at 280 nm using the proper blank [11].

Moisture Content Analysis: A mortar was used to weigh and smash the sample. One gram of the material was then weighed, dried for 24 hours in a desiccator. Weighing the sample after waiting 24 hours. By subtracting the end weight from the starting weight, we may calculate the moisture content [12].

***In-vitro* Buoyancy Studies:** The speed at which the medication dissolved from the lozenges was used to calculate the rate of drug absorption. Hence, the bioavailability and rate of dissolution may be directly connected to the lozenge's effectiveness. The dissolving media pH 6.8 phosphate buffers, 100mL, was added to the beaker holding the lozenges, and stirred at 100rpm using the magnetic stirrers. At 5-minute intervals, 5mL aliquot samples were removed and promptly reintroduced with an equivalent amount of fresh fluid, simulating salivary fluid. Each aliquot was diluted before being examined using a UV-visible spectrophotometer at 280 nm.

Dissolution: The containers of the USP dissolving apparatus were filled with 900ml of the dissolution medium (phosphate buffer, pH 6.8) for the dissolution research (type II). With the paddle speed set to 50 rotations per minute, the dissolution media was equilibrated to 37 0.5°C. Lozenges were put in each of the dissolving apparatus's vessels and worked at the designated rate. 5ml samples of the dissolving media were removed from the beaker at intervals of 5, 10, 15, 20, 25, and 30 minutes, and 5ml of new dissolution medium was added.

The medium's temperature was continuously maintained at 37 0.5°C during the test, and the vessel was covered. Filtered and diluted to a final concentration of 10ml of phosphate buffer with a pH of 6.8, the removed samples were then added to a volumetric flask. The diluted filtrates were analysed using a UV spectrophotometer at a wavelength of 219 nm using a phosphate buffer solution with a pH of 6.8 as a blank solution. The percentage drug release was determined from the latex concentration in samples collected at time intervals of 5, 10, 15, 20, 25, and 30 min using the equation derived from the calibration curve. The proportion of medication release versus time was shown [13].

Stability Studies: Stability tests were performed on each of the produced formulations for a month

at 400°C and 75% RH. Drug content, weight fluctuation, colour, hardness, and moisture content were assessed after one month[14].

RESULTS:

HPLC of Collected Latex: Separation and identification by HPLC A preliminary experiment using standard aloin was conducted in the present investigation to evaluate the best chromatographic conditions for aloin detection. **Fig. 7** depicts the chromatograms produced for the friedelin standard, liquid latex, and FG samples, as well as the ideal conditions for latex separation in all samples (dry gel, dry latex, FG, FL, and commercial items). After an average of eight injections, the peak for friedelin was seen after 7.93 0.02 min. Friedelin was discovered by comparing its retention time to the reference and utilising DAD characteristic spectra. An LC-MS analysis of commercial items was undertaken to corroborate the identification of the peaks. To begin, a reference solution of 7.44 g/mL of L of friedelin was analysed in negative ionisation dual ESI mode, with the drying gas temperature set between 300-350 °C, the nebulizing gas set between 30 and 60 psig, and the fragment or set between 100-170 V. The best results were achieved at a drying temperature of 300°C, a nebulizing gas pressure of 30 psig, and a fragment or voltage of 170 volt.

TABLE 1: HPLC METHOD FOR LATEX

Phenoliccompounds	Sample (mg)
Leukocyanidin	--
Anthocyanin	--
cyanidin3-glucosideequivalent(CGE)	0.012
cyanidin3-glucoside(Cy-3-Glu)	0.132
Chlorogenicacid	0.355
Friedelin	0.344
Queretin	--
Ferulicacid	--
B sistoerols	--
Glycosides	2.500
Rutin	1.536
Tanins	1.164

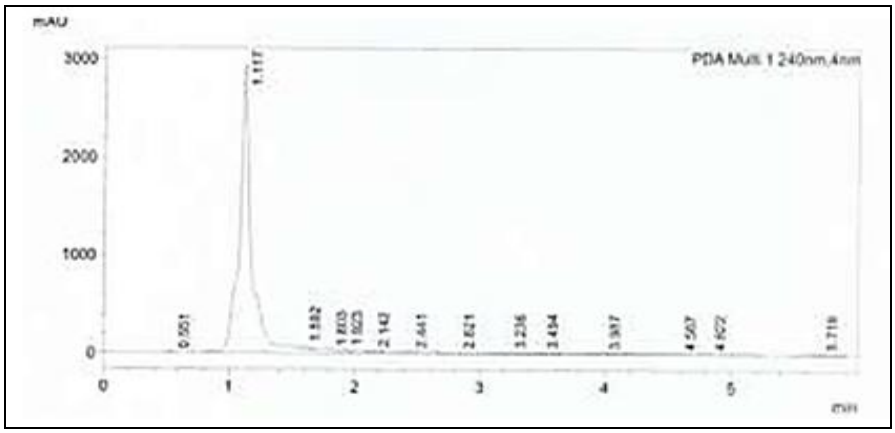

FIG. 1: HPLC GRAPH FOR LATEX

IR Spectroscoy Study of Latex:

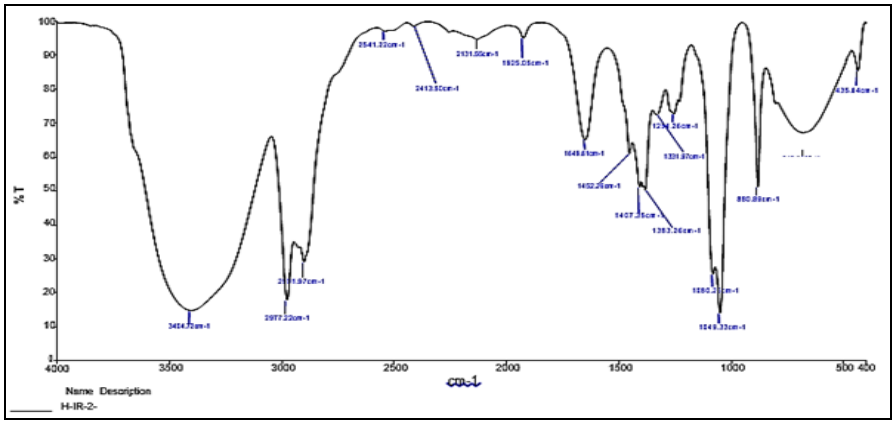

FIG. 2: IR PEAK VALUES OF LATEX

As infrared light travels through a sample of an organic molecule, certain frequencies are absorbed while others are transmitted through the sample undetected. A molecule's internal vibrations alter

when it is exposed to infrared light, and these changes are connected to infrared absorption. In light of this, vibrational spectroscopy may be used to explain infrared spectroscopy in general. Several bonds (C-C, C-O, C=C, C-C, C=O, O-H, and N-H) have various vibrational frequencies. By spotting the distinctive frequency absorption band in the infrared spectrum, it is possible to determine whether these sorts of bonds are present in an organic molecule. To identify the chemical components and clarify the structural compounds, infrared spectroscopy (IR) is a high-resolution analytical method. Latex fingerprinting may be done quickly and without any damage using IR. The latex's IR spectra were clearly visible, and absorbance measurements were made in the range of 4000 and 400 cm^1 **Fig. 2** and **Table 2**. The peak 3404.72 denotes phenolic and alcoholic groups, 2977.22 denotes alkenes (C-H stretch), 2131.55 denotes alkenes (- C=C- stretch), 2901.97 denotes alkenes (C-H stretch), 2541.22 denotes carboxylic acids (O-H strech), 1649.61 denotes alkynes (C=C- stretch), and 1452.26 denotes aromatics 1407.35 denotes aromatics (C-C stretch (in-ring), 1254.26 denotes aromatic amines (C-N stretch), 1331.97 denotes nitro compounds (N-O symmetric stretch), 1080.25 denotes alkynes (C-O stretch and C-N stretch), and 1049.33 denotes aliphatic amines (C-N stretch), and 880.89 denotes 1, o 2o amines (N-H wag).

TABLE 2: IR PEAK VALUES OF EXTRACT OF *FICUS BENGHALENSIS* LATEX

Peak Value	Bond	Functional group
3404.72	O-H stretch, free hydroxyl	Alcohols, phenols
2977.22	C-H stretch	Alkenes
2901.97	C-H stretch	Alkenes
2541.22	O-H stretch	Carboxylic acids
2131.55	-C=C- strech	Alkynes
1649.61	-C=C- strech	Alkenes
1452.26	C-C stretch (in-ring)C-H bend	Aromatics, Alkanes
1407.35	C-C stretch (in-ring)	Aromatics
1254.26	C-N stretch	Aromatic amines
1331.97	N-O symmetric stretch	Nitro compounds
1080.25	C-O stretch, C-N stretch	Alcohols, Carboxylic acids, esters, Aliphatic amines
1049.33	C-N stretch	Aliphatic amines
880.89	N-H wag	1^o, 2^o amines

Formulation of Candy: After confirming the antioxidant effects of the plant components indicated above, we employed powders of these constituents in varied quantities to optimise formulations. The exact number of components was measured and crushed into a powder form. Then, for dried granules mixing, all of the constituents was geometrically combined used the technique. F1 through F6 was six separate compositions with differing concentrations of all components.

TABLE 3: ORGANOLEPTIC EXAMINATION OF PREPARED CANDY LOZENGES

Parameters	Result
Shape	Spherical
Colour	Red
Texture	Smooth
Taste	Sweet

Table shows the quantity of each element. Hardness was observed to vary from 10.18 to 11.21 kg/cm^2, as reported in **Table 2.**

TABLE 4: RESULTS OF CANDY LOZENGES

Formulation	Hardness Kg/cm^2	Weight variation	Friability	*In-vitro* mouth dissolving time (min)	Drug content	Moisture content analysis
F1	10.16±0.002	2.91±0.002	0.90±0.008	21±0.003	98.5±0.005	0.6±0.100
F2	11.16±0.005	2.90±0.005	0.87±0.005	22±0.005	98.8±0.006	0.7±0.002
F3	11.83±0.008	2.98±0.009	0.85±0.006	24±0.004	97.9±0.004	0.6±0.003
F4	10.14±0.006	2.87±0.005	0.87±0.004	21±0.008	98.9±0.005	0.6±0.005
F5	11.16±0.003	2.67±0.003	0.66±0.12	21±0.005	99.5±0.009	0.8±0.005
F6	11.16±0.005	2.99±0.004	0.92±0.15	24±0.002	96.3±0.004	0.6±0.006
F7	10.16±0.005	2.69±0.003	0.76±0.14	22±0.002	97.3±0.005	0.6±0.003
F8	11.21±0.004	2.89±0.007	0.83±0.152	21±0.006	98.5±0.008	0.7±0.008
F9	10.18±0.005	2.73±0.004	0.72±0.032	24±0.004	99.2±0.004	0.8±0.004

Friability varies from 0.66 to 0.92 while weight variation ranges from 2.67 to 2.98. Friability was highest in F1 (0.90) and lowest in F5 (0.66). The in vitro oral dissolving time ranges from 21 to 24 minutes. Every sample has a drug content that varies from 96 to 99. Moisture content study showed that F9 and F5 had the highest values (0.8), whereas F1, F3, F4, F6, F7 had the lowest values (0.6).

Results of Candy Lozenge:

Hardness: The disintegration and solubility of a tablet are all affected by its hardness. The hardness and friability of candy must be just right so that it doesn't crumble apart during packing, shipping, and handling. In order to determine a substance's hardness, a device called a "Monsanto and Pfizer hardness tester" is used. Round and regular candies are loaded across their diameter "as a diametrical loading," with breaking happening in the plane of the candy's shape [USP 40NF 35, 2017].

Crushing strength, expressed as "in kilogram, pound, or arbitrary units," should be larger than 4kg. **Fig. 3** represents the highest hardness of candy in F6 and lowest in F5.

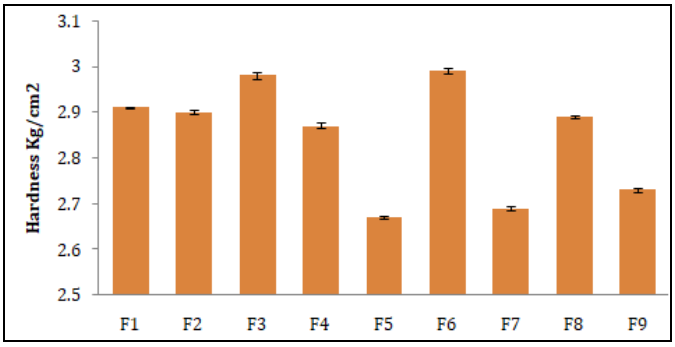

FIG. 3: HARDNESS

Weight Variation: The average weight of 10 candies is then determined, and the weights of the individual candies are compared to the average.

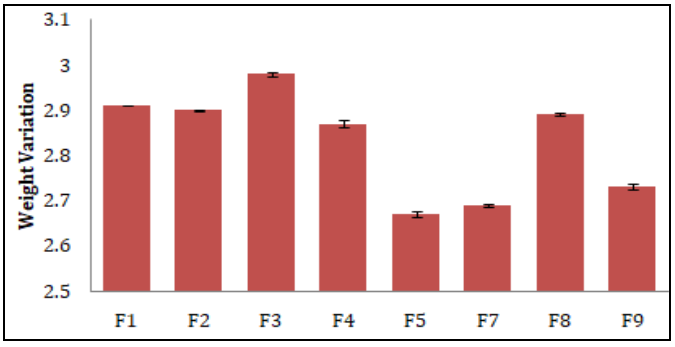

FIG. 4: WEIGHT VARIATION

The result of a weight variation test is reported as a percentage. The candy weight variance seen in **Fig. 4** is greatest for F3 and least for F5.

Friability: A friability Test was used to measure the candy's Friability (FR). Ten (10) candy were collected, dedusting and the weight was recorded on a precision balance. The tablet was placed in the device clear drum and set to rotate at 100 revolutions. The difference in weight as a percentage of total initial weight of candy after the test was taken. **Fig. 5** represents the friability level highest in F6 and lowest in F5.

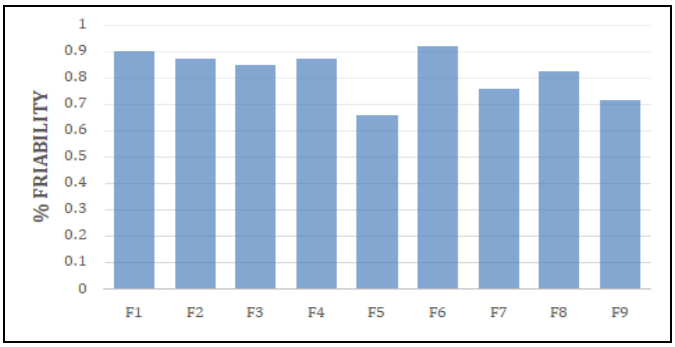

FIG. 5: FRIABILITY

Mouth Dissolving Time: The time it took for the lozenges to completely dissolve was ascertained using a USP disintegration apparatus, in which lozenges were placed in each tube and the time it took for the lozenges to completely dissolve was noted down using 900ml phosphate buffer of pH 6.8 at 37°C. This experiment was carried out in triplicate. **Fig. 6** shows that the time required to dissolve candy in the mouth was longer in F3, F6, F9 and shorter in F1, F4, F5, F8.

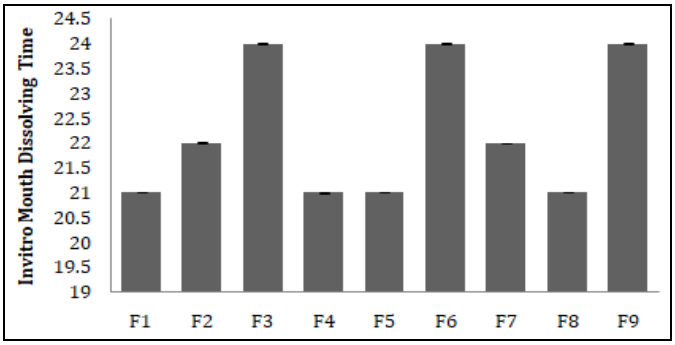

FIG. 6: *IN-VITRO* MOUTH DISSOLVING

Drug Content: The lozenges were ground into a powder and dissolved in 5mL of methanol in a 50 mL volumetric flask; the remaining volume was adjusted to 50 mL using a pH 6.8 phosphate buffer. We diluted 1 ml of this solution with pH 6.8

Phosphate buffer in a 50 ml volumetric flask, sonicated it for 30 minutes, and then filtered it through filter paper. Using a suitable blank, the absorbance of this solution was determined to be 280 nm. **Fig. 7** represents the highest drug content in candy was observed in F5 and lowest in F6.

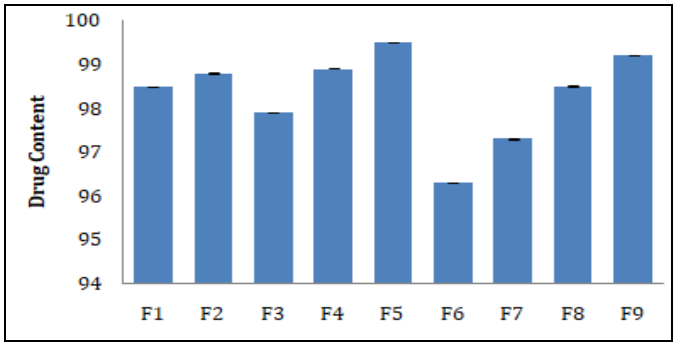

FIG. 7: DRUG CONTENT

Moisture Content Analysis: A mortar was used to smash the sample before it was weighed. This led to the collection of one gram of the sample, which was then dried out in a desiccator for a whole day. The sample is then weighed after 24 hours. Calculating the water content requires subtracting the total weight from the initial weight.

TABLE 5: *IN-VITRO* DISSOLUTION PROFILE OF CANDY LOZENGES

Time (min)	% Drug released								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
5	34.71	28.79	26.21	41.57	39.94	36.82	34.05	28.98	32.21
10	51.53	39.43	35.66	58.15	51.18	49.46	45.76	40.21	48.54
15	65.38	49.74	46.03	75.09	69.98	63.72	58.87	49.89	59.65
20	79.62	60.09	55.97	86.91	80.19	72.03	69.63	57.71	70.59
25	88.59	79.84	68.18	91.42	87.76	78.83	73.59	66.87	84.63
30	95.11	85.05	79.35	96.06	90.24	87.29	79.32	79.92	96.76
35	97.39	96.49	86.42	96.06	94.41	95.41	89.48	85.75	96.76

In-vitro dissolution profile of candy lozenges at various times (0-35min) is shown in **Table 4**. Most of the candy in F1 dissolves in 35 minutes, but in F9 it dissolves within five minutes **Fig. 8.**

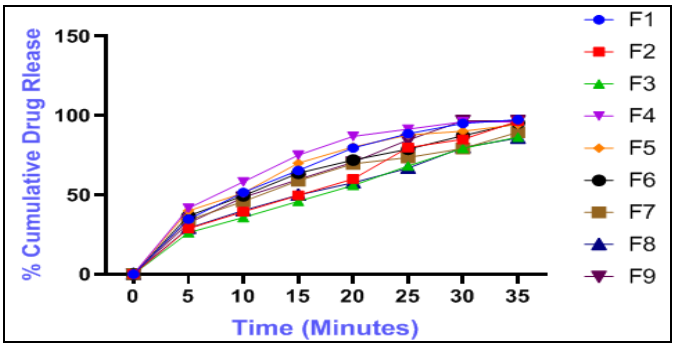

FIG. 8: COMPARATIVE DISSOLUTION RATES OF FORMULATED BATCH

DISCUSSION: Toothache is a widespread phenomenon that is classified as a primary cause of impairment in practically all areas of human quality of life, notably disrupting sleep, social interactions, everyday task performance, and affecting care-seeking behaviour. Extracted plants and materials are used to treat different diseases in human. Lozenges are flavor-infused pharmaceutical dosage forms designed to be retained in the mouth or throat while being delivered. They typically include one or more medications in a sweetened foundation.Candy are flavored medicated dosage form intended to be sucking and held in the mouth or pharynx containing one or more medicaments usually in the sweetened base. Medicated candy is designed to improve patient compliance, acceptability.

CONCLUSION: The total nine formulations of *Ficus benghalenis* were prepared. The candy prepared mainly consisted *Ficus benghalenis*, latex, citric acid, methyl cellulose, glycerin, β-cyclodextrin, isomalt in different ratios. The results were obtained during this project have inspired us to derive the conclusions. All the formulation that was prepared exhibited good physiochemical

characteristics such as hardness, friability, weight variation, dissolution. Thus, formulation F1, F3, F6, & F8 depicted better result as compared to other formulation as they were flexible.

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CONFLICTS OF INTEREST: No conflict of interests to declare.

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