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ORIGINAL ARTICLE

Formulation, optimization, and evaluation of herbal mouth freshener chewable tablets

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ABSTRACT

For those people who have bad breath, it significantly affects their regular social lives. People throughout the world commonly suffer from this problem. The goal of the current study was to develop herbal chewable mouth freshener tablets using natural ingredients. Herbs include Emblica officinalis (amla), Areca catechu (arecanut), Elettaria cardamomum (cardamom), Foeniculum vulgare (fennel), Syzygium aromaticum (clove), and Trachyspermum ammi (parsley). For the successful formulation, mannitol, acacia, talc, and magnesium stearate were used as excipients. In this study, the direct compression method was used to develop oral chewable tablets containing these plants. The pre and post-compressions ion characteristics for the manufactured tablet were assessed. The tablets' general appearance, weight variation, hardness, friability, and release of drugs were all analyzed. According to the above study, chewable tablets were produced using the direct compression method, which produced a satisfactory and acceptable outcome. The F5 batch shows better results than all prior batches, according to results from all the batches. The present study provides a method for modernizing traditional folklore formulations while maintaining their medicinal benefits, which are essential for industrial applications and satisfying the needs of customers. Therefore, the recently formulated chewable tablets might be a better option than the herbs used in traditional ways.

Keywords: *Herbal chewable tablets, Emblica officinalis, Areca catechu, Elettaria cardamomum, Foeniculum vulgare, Syzygium aromaticum, Trachyspermum ammi.*

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INTRODUCTION

As pharmaceutical scientists gain greater knowledge of the physicochemical and biochemical characteristics and their evaluation using innovative methods, herbal medicines are growing in acceptance and reliability on the global market. As more people become aware that plant-based therapeutics are natural, easily biodegradable, non-addictive, with no side effects, and widely accessible at reasonable costs, demand for these products is growing in developed as well as developing countries [1]. Bad breath, also known as halitosis or Oral malodor, is a significant social and psychological concern that impacts more than half of common people worldwide. Unpleasant breath from any cause, oral or non-oral, is referred to as halitosis. The word "oral malodor" is specifically used to describe the odor coming from the mouth. A large percentage of the population suffers from this, and those who are affected might suffer serious social or psychological problems. Our everyday social lives are significantly impacted by bad breath. This is a condition where a person's breath is changed in an unpleasant manner, which in turn makes the affected person and those around them feel extremely uncomfortable [2]. It is a

prevalent condition that affects people of all ages, genders, and ethnicities, and its intra- and/or extra-oral causes can be identified. People who are trying to get rid of bad breath are advised to keep brushing their teeth, use chewing gum, consume chocolate, use mouth fresheners, and mouthwashes, and keep their distance while speaking. Patients frequently use chewing tablets to freshen their breath and eliminate bad odour. The most suitable kind of substance for medications that are taken orally is in the form of solid oral dosage forms. Chewable tablets are those that need to be split down and chewed in between the teeth before use. They are an oral immediate-release dosage type that should be chewed by the patient before being swallowed, compared to being swallowed whole. The advantages of unit dosage types include ease of handling, adaptability, convenience, and safety. This dosage form was chosen due to its convenience, ease of administration, and ability to mask up the unpleasant flavors and odors of plants [3]. Technologies for dealing with unpleasant odour include flavors to cover bad breath and antimicrobial substances to lower halitosis bacteria levels. A palatable chewable tablet is one that can be consumed with little or no water after being swallowed. They enable the tablet to dissolve completely quickly, resulting in an immediate drug impact after swallowing. Tablets that are designed to be chewed have a smooth texture when they dissolve and an appealing flavor without any bitterness or off flavors. A suitable option for synthetic chemicals is traditional medicine. For mouth fresheners for unpleasant breath, natural components like amla, arecanut, cardamom, fennel, clove, and parsley are used. A significant herbal plant with a long tradition of use is Emblica officinalis, also called amla or Indian gooseberry, which belongs to the family of Euphorbiaceous family. Amla is a nutrient-rich fruit that is an excellent source of vitamin C, amino acids, minerals, and other minor nutrients. The pulp of this fruit, which is utilized as a strong rasayana as well as for medicinal purposes in Ayurveda to treat diarrhea, jaundice, inflammation, and several other conditions, has medicinal qualities in almost all its parts. It aids in preventing bad breath, and digestive issues, strengthening cardiovascular functions, building a strong immune system, enhancing eyesight, and making our hair strong and shiny [4]. Areca catechu, also referred to as areca nuts or Betel nuts, belongs to the Palmeae family. The use of this nut as chewing gum gives it significance. It held a significant position as a pharmaceutical in both Chinese and ancient Indian medical systems, including Ayurveda. It can cure a wide range of disorders, particularly parasitic conditions, and problems with digestive function, depression, and mouth odour [5]. The Zingiberaceae family consists of Elettaria cardamomum, also referred to as green cardamon. It is used as a flavoring agent (spice) in a range of foods and is known as the "Queen of Spices" in India and "Hel" in Iran. Its seed powder is frequently employed as a digestive aid, stomachic, breath freshener, anti-emetic, and carminative as well as in the therapy of gastrointestinal disorders. They have been employed for conventional medical purposes, such as the treatment of gum, tooth, and asthma diseases [6]. Fennel seed is the typical name for Foeniculum vulgare. It has been widely used in traditional treatment for a wide variety of illnesses. It is used all over the world to treat a variety of illnesses, including gingival wounds, carminative disorders of the gums, mouth ulcers, stomachaches, abdominal pains, antiemetics, arthritis, cancer, colic in young children, conjunctivitis, constipation, fever, gastritis, kidney problems, laxative, liver pain, mouth ulcers, and decreasing stress [7]. Syzygium aromaticum, commonly referred to as clove, is a dried floral bud from the Myrtaceae family. It has historically been used to treat burns and wounds, as a mouth freshener, as a dental pain reliever, and to treat teeth infections and toothaches. Additionally, it has been used for thousands of years as a nerve stimulant and to treat liver, bowel, and stomach problems as well as vomiting, flatulence, and nausea [8]. The plant Trachyspermum ammi, also known as "Ajwain," is a member of the umbellifereae family. The fruit has gastroprotective, antihypertensive, hepatoprotective, antispasmodic, broncho-dilating, antimicrobial, and digestive stimulant properties. The seeds of T. ammi are used medicinally for amoebiasis, antiseptic, stomachic, carminative, and expectorant purposes [9]. The primary goals of these tablets are to easily dissolve in our mouths during a period of an average amount of time or to be ingested by chewing the tablet. The main features are a smooth texture and no bitterness or other unpleasant tastes. The present research is intended to develop a mouth-freshening herbal chewable tablet formulation using *Emblica officinalis, Areca catechu, Elleteria cardamom, Foeniculum vulgare, Syzygium aromaticum, Trachyspermum ammi* in accordance with all available data and knowledge.

MATERIAL AND METHODS

Materials: The powder of Emblica officinalis, Areca catechu, Elleteria cardamomum, Foeniculum vulgare, Syzygium aromaticum, *Trachyspermum ammi* was purchase from local store. The coarse powder was then stored in a polythene bag and stored in a cool, dark, and dry place for further analysis. The Acacia, mannitol, magnesium stearate, sodium hydroxide, potassium dihydrogen phosphate, and talc all these ingredients used in the study were procured from Modern Industries, Nashik.

Methods

Preformulation Studies: Preformulation is the research of the chemical and physical characteristics of the medicinal substance both on its own and in combination with excipients. The appropriate development of dosage forms starts with this step [10].

Organoleptic properties: An analysis was done of the API's organoleptic characteristics, including colour, odor and taste. In a brightly lit location, the colour of a small amount of all API placed on butter paper was observed. The tongue was used to evaluate the taste using just a little of each API, while the sense of smell was used for identifying odour [11].

Phytochemical Screening and evaluation: The API powder was tested for cardiac glycosides, terpenoids, flavonoids, alkaloids, steroids, tannins, terpenoids, saponins, amino acids, carbohydrates, and vitamins. In physicochemical evaluation, loss on drying, ash value, and swelling index of crude powder helps in understanding the pharmacopeia standards of the medicine according to Khandelwal book [12].

FT-IR studies: Studies using Fourier Transform Infrared Spectroscopy were carried out to investigate whether the active compounds interacted with one another. Specifically, all API powder and excipients are included in the chewable tablets [13].

Pre-compression Parameters: The pre-compression investigation is the initial stage in the manufacturing of novel dosage forms for medications. The angle of repose, bulk density, tapped density, and compressibility index were some of the pre-formulation properties that were examined [14].

Angle of repose: The funnel method was used to determine the powder blend's angle of repose. The powder mixture was poured into a glass funnel along with a specified quantity. The funnel's height was adjusted such that the tip of the funnel was barely touching the top of the powder mixture. The powder mixture may easily pass through the funnel. The powder pile's diameter was measured, and the following equation was used to determine the angle of repose.

Angle of repose (θ) = tan-1 h/r

Where,

Tanθ = angle of repose; h = height; r = radius of the powder mass.

Bulk density: It is the ratio of the powder's bulk volume to mass. ρb denotes it. To determine homogeneity, bulk density is employed.

$$\text{Bulk density } (\rho b) = \frac{\text{Mass of the sample}}{\text{bulk volume}}$$

Tapped density: It is the ratio of the powder's weight to the measuring cylinder's minimum volume of occupied space. A graduated cylinder with a specified mass of medicine or formulation is placed on mechanical tapper equipment, which is operated at a given number of taps (100) until the powdered substance reaches a minimum volume, in order to measure the tapped density.

$$\text{Tapped density } (\rho t) = \frac{\text{Weight of powder blend}}{\text{Minimum volume occupied by cylinder}}$$

Compressibility indices:

Carr's index: The following formula was used to calculate the % compressibility of the powder mixture based on the apparent bulk density and the tapped density.

$$\text{Carr's index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped Density}} \times 100$$

Hausner's ratio: It serves as a proximate indicator of how simple it is to determine powder flow. Better flow characteristics are indicated by a lower Hausner's ratio (>1.25) than by a greater one (>1.25").

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Formulation of chewable tablet:

Direct compression method: In this compression method, each ingredient was weighed individually. The powder of amla, arecanut, cardamom, fennel, clove, parsley, acacia, and mannitol were mixed for 10 min in a mortar pestle. After that, talc and magnesium stearate was used as a glidant to lubricate the mixture for two minutes. When the powder blend's flow characteristics were examined and they were found to be favorable [15]. Using a Karnavati Rimek machine, the evaluated blend was compressed into 250 mg tablets. Each batch was manufactured with a minimum of 30 tablets. In Table 1, the tablet manufacturing formula is listed.

Formulation of chewable tablet by using 3^2 Full Factorial Design: Chewable tablet formulation using a 3^2 full factorial design. As shown in the above table, nine formulations were created using equal quantities of all API powder and varying excipient concentrations. In 3^2 full factorial designs, 2 factors were taken which are observed as independent variables such as Acacia(X1) and Magnesium

stearate(X2). Three responses (Dependent variables) were considered Y1 as %CDR and Y2 as hardness. Three levels were considered as low, medium, and high and all possible combinations of all formulations were shown in Tables 2 and 3.

Evaluation of post-compression parameters: After considering pre-formulation evaluation, the tablets were tested for several standards in order to prevent formulation preparation failures. They are like General appearance, Thickness, Hardness, Weight variation, Friability, and in vitro drug release studies [16].

General appearance: The tablets should not have any cracks, depressions, or other defects. The tablets should have a smooth surface. The shape, color, texture, and odor of the tablet's general appearance were observed visually.

Weight variation: By using a Wensar weighing balance, it is determined. The weight variation test is carried out by weighing each of the 20 tablets individually, determining the average weight, and comparing the average weight to the weight of each tablet. The weight variation test would provide a reliable way to evaluate the uniformity of tablets' drug contents [17].

Hardness: Tablet-crushing strength is another name for hardness. The Monsanto hardness tester was used to measure the tablet's hardness. The tablet's hardness was tested in Kg/cm2 by putting it longitudinally between the upper and lower plungers and applying pressure with a threaded screw until it breaks [18].

Friability: It has been demonstrated by the Roche friability which has a plastic chamber that rotates at 25 revolutions per minute while falling tablets from 6 inches apart while spinning for 100 revolutions to place several tablets to the combined effects of abrasion and shock. In accordance with the specified limit, friability should be less than 1%. Pre-weighed tablets were dusted and reweighed. The formula is used to calculate it [18].

$$\%\ \text{Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}}$$

In vitro dissolution studies: Using a dissolution equipment USP Type II (paddle), herbal chewable tablet in-vitro dissolution investigations were carried out. The dissolution medium (phosphate buffer 6.8) has been used in a volume of 900 ml, and the temperature was kept constant at 37 +/- 0.5 °C. The paddle was rotated at a speed of 50 rpm. Every jar of the dissolution apparatus was filled with one tablet. At every five minutes for the first 30 minutes, 5ml of the sample from each jar was removed, and an equal amount of the dissolution medium was added to each jar to keep the total volume of the dissolution medium at 900ml. The sample was filtered using Whatman filter paper and diluted with dissolution medium and taken absorbance in a UV spectrophotometer and using a calibration curve [19].

The Indian Pharmacopoeia and the United States Pharmacopoeia were both followed for all evaluation [20, 21].

RESULT AND DISCUSSION

This study was an attempt to develop a formulation of chewable tablets by direct compression method using *Emblica officinalis, Areca catechu, Elleteria cardamomum, Foeniculum vulgare, Syzygium aromaticum, Trachyspermum ammi* powder.

Preformulation studies: All API was individually characterized for the organoleptic properties and the observed properties were correlated with the reported standards where the observed characteristic of chewable tablets complies with that of reported standards.

ATR studies: The ATR spectra of the chewable tablet powder blend and All API powder are presented in Figure 2, respectively. Using IR spectroscopy (Bruker optic alpha II), an FT-IR investigation was carried out. It should be noted that the characteristic peaks in the ATR spectra of the excipients used to make chewable tablet powder or tablets were not changed, showing that there are no interactions between the active ingredient and the excipients. The peaks were in the same frequency range even though the sharpness and wavelength were found to differ. According to ATR spectral analyses, all the excipients and the drugs are compatible. The ATR spectrum of the physical mixture revealed all the distinctive peaks of the API, confirming that there was no drug-to-formulation interaction.

Phytochemical screening of powders: Phytochemical screening of the individual drugs has been done to evaluate the chemical constituents present in powder as shown in Tables 5.

Physiochemical analysis: To determine the standard and purity of the conformation, a physicochemical examination of every drug and formulation was performed as shown in Table 6.

Pre-compression parameters: The powder blends were examined for the angle of repose, bulk density, tapped density, compressibility index, and Hausner's ratio, among other factors. Tables 7 and 8 below show the results.

All formulations' angles of repose were determined to be between 23°.9' and 27°.4', which is well within the 23°-27° specification limit and suggests that the flow type of the powder blend was good. The flow properties of Formulation F5 were better. Between 0.43 and 0.47 g/cm^3 was determined to be the bulk density, and 0.47 to 0.52 g/cm^3 was found to be the tapped density. The range of the compressibility index, which shows the flow type of the powder blend was fair, was 9.30 to 13.95%. The range of Hausner's ratio is 1.06 to 1.13. The precompression parameter results showed that all formulations' flow properties were better and within acceptable limits.

Post-compression parameters:

General appearance: We investigated the general appearance of all batches (F1-F9). The tablet was discovered to be round and beige in color. The surface was discovered to be perfect, without any pinholes, depressions, or cracks.

All herbal chewable tablet formulations passed the weight variation test since the values were within the tablet's acceptable variation range (7.5%). The tablet was discovered to have a hardness between 4.2 kg/cm^2 and 5.8 kg/cm^2. The prepared tablets were sufficiently hard and had high mechanical strength. Likewise, the created herbal chewable tablets' percentage friability results indicated a weight loss of less than 1%, which is well within the allowed limits. All of the tablets, therefore, passed the friability test. The findings of a multi-parameter evaluation of herbal chewable tablets are shown in Table 9.

Table 1: Formulation of chewable tablet

Ingredients	Batches								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Amla (mg)	12.5	12.5	12.5	12.5	12.5	12.5	12.5	12.5	12.5
Areca nut (mg)	5	5	5	5	5	5	5	5	5
Cardamom (mg)	5	5	5	5	5	5	5	5	5
Fennel (mg)	12.5	12.5	12.5	12.5	12.5	12.5	12.5	12.5	12.5
Peppermint oil (ml)	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
Clove (mg)	5	5	5	5	5	5	5	5	5
Parsley (mg)	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5
Acacia (mg)	88	100	120	88	100	120	88	100	120
Mannitol (mg)	q. s	q. s	q. s	q. s	q. s	q. s	q. s	q. s	q. s
Magnesium stearate (mg)	1.9	1.9	1.9	2.5	2.5	2.5	3.1	3.1	3.1
Talc (mg)	5	5	5	5	5	5	5	5	5
Total (mg)	250	250	250	250	250	250	250	250	250

The drug release of formulation F1-F9 was found to be 69.89% to 98.48% at 30 minutes as shown in Table 10. Among the nine formulations, formulation F5 showed the highest dissolution rate at the end of 30 mins which is 98.48%. The dissolution profile of herbal chewable tablets was shown in Figure 3. Formulation F5 was taken as an optimized formulation based on hardness (5.1 kg/cm^2) and in vitro dissolution profiles (98.48 %).

Table 2: Variables in optimization study

Variables	Code	Factor
Independent	X1	Acacia (gm)
	X2	Magnesium stearate (gm)
Dependent	Y1	% CDR
	Y2	Hardness

Table 3: Experimental design as per 3^2 Full factorial Design

Formulation Code	Coded Values			
	X1	(mg)	X2	(mg)
F1	-1	88	-1	1.9
F2	0	100	-1	1.9
F3	1	120	-1	1.9
F4	-1	88	0	2.5
F5	0	100	0	2.5
F6	1	120	0	2.5
F7	-1	88	1	3.1
F8	0	100	1	3.1
F9	1	120	1	3.1

Table 4: organoleptic properties

API	Colour	Odour	Taste
Amla	Brownish green	Astringent	Sour
Areca nut	Reddish brown	Pungent	Salty
Cardamom	Light green	Sweet & spicy	Fruity
Fennel	Dark green	Aromatic	Sweet
Clove	Reddish Dark brown	Strong spicy	Pungent aromatic
Parsley	Greyish brown	Aromatic	Pungent

Table 5: phytochemical screening of powder

Test Plants	**Amla**	**Supari**	**Cardamom**	**Fennel**	**Clove**	**Parsley**
Alkaloids	+	+	+	-	+	-
Glycosides	+	-	+	+	-	+
Tannins	+	+	-	-	-	+
Saponins	+	+	+	-	-	+
Steroids	-	+	+	-	-	+
Flavonoids	+	+	+	+	+	+
Terpenoids	-	-	+	+	+	+
Amino acids	+	+	-	+	+	+
Carbohydrates	+	+	+	+	+	+
Vitamins	+	+	+	+	+	+

Table 6: Physiochemical analysis of the powders

API	Ash value % w/w	Water soluble ash value % w/w	Acid insoluble ash value % w/w	Loss on drying %w/w	Swelling index %w/w	Foreign matter %w/w
Amla	4.9	2.2	0.8	3.02	2.5	Nil
Arecanut	1.82	3.89	0.2	3.8	1.89	Nil
Cardamom	5.2	7.6	2.6	5.41	3.98	Nil
Fennel	8.46	9.03	4.49	5.25	1.23	Nil
Clove	5.57	4.9	0.26	9.97	0.12	Nil
Parsley	8.12	4.34	0.142	5.12	2.02	Nil

Table 7: Pre-compressional evaluation

Formulation code	Angle of repose (Θ)	Bulk density (g/cm3)	Tapped density (g/cm3)	Type of flow /Conclusion
F1	25.3	0.43	0.47	Good
F2	25.8	0.44	0.49	Good
F3	26.4	0.46	0.51	Good
F4	25.8	0.43	0.49	Good
F5	23.9	0.45	0.48	Good
F6	26.7	0.44	0.50	Good
F7	25.8	0.47	0.52	Good
F8	26.4	0.46	0.51	Good
F9	27.4	0.44	0.50	Good

Table 8: Pre-compressional evaluation

Formulation code	Compressibility index (%)	Hausner's ratio	Type of flow /Conclusion
F1	9.30	1.09	Excellent
F2	11.36	1.11	Excellent
F3	10.86	1.10	Excellent
F4	13.95	1.13	Excellent
F5	6.67	1.06	Excellent
F6	13.63	1.13	Excellent
F7	10.63	1.10	Excellent
F8	10.86	1.11	Excellent
F9	13.63	1.13	Excellent

Table 9: Post-compressional evaluation

Formulation code	Weight variation %	Hardness (kg/cm2)	Friability %
F1	1.07	4.2	0.87
F2	1.09	4.4	0.69
F3	1.15	4.7	0.54
F4	1.2	4.3	0.72
F5	1.04	5.1	0.41
F6	1.17	4.8	0.48
F7	1.23	4.9	0.59
F8	1.41	5.3	0.39
F9	1.18	5.8	0.31

Table 10: % Cumulative drug release of F1-F9 batch

Time (min)	% Cumulative Drug Release								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
5	8.54	22.22	27.56	31.17	38.75	32.89	34.04	24.87	14.53
10	15.89	29.31	35.97	40.21	50.05	43.51	46.37	33.74	28.79
15	20.13	51.87	59.85	65.02	77.45	68.24	71.45	54.52	34.33
20	45.76	60.07	69.42	75.48	88.09	79.64	83.57	67.75	57.65
25	60.31	78.05	86.05	87.89	95.56	90.12	91.55	83.25	69.62
30	69.89	80.94	89.25	90.67	98.48	92.44	94.29	87.13	71.66

Figure 1; Optimized batches of F1 – F9 chewable tablet

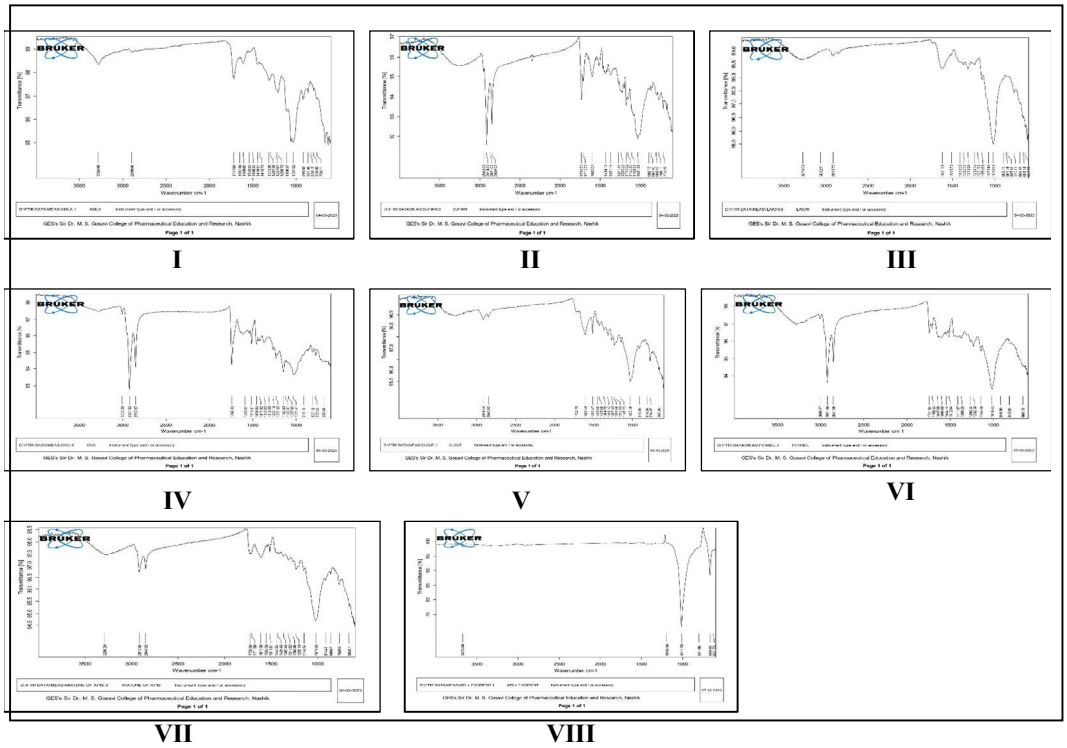

Figure 2; IR spectrum: (I) Amla (II) Arecanut (III) Cardamom (IV) Parsley (V) Clove (VI) Fennel (VII) Mixture of all drugs (VIII) Mixture of drug+ Excipients.

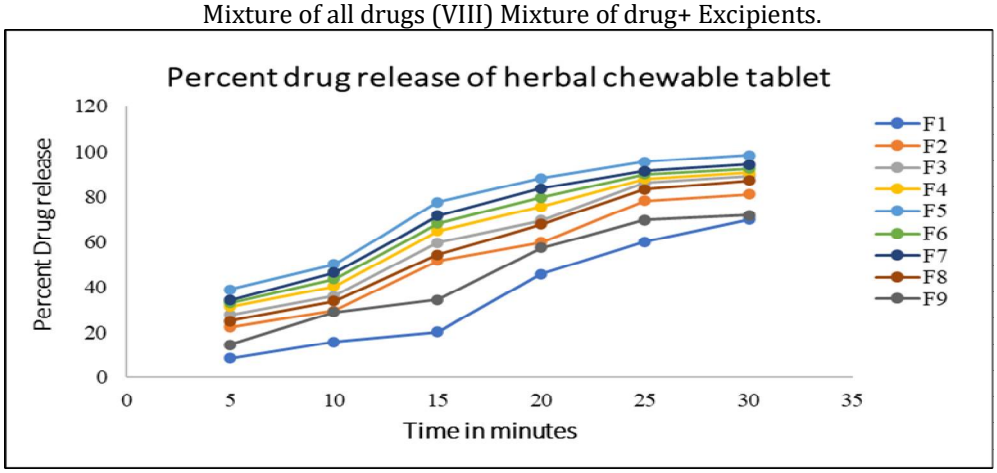

Figure 3; In vitro drug release profile of formulation F1-F9 of herbal chewable tablet

CONCLUSION AND FUTURE SCOPE

The chewable tablet made from powdered parsley, fennel, clove, cardamom, amla, and arecanut is intended to be consumed as a mouth freshener. We conclude from the study that the chewable tablets were produced using the direct compression technique which gave outcomes that were acceptable and satisfactory. It was determined that herbal chewable tablets made in a cost-effective tablet influence may decrease patients' compliance while reducing side effects and increasing beneficial effects on the body. To improve the composition of the tablet powder blend, pre-formulation experiments were conducted. The results of the FTIR analyses showed that there is no interaction between the powder and the excipients used in the formulation of the tablet. Results from all nine batches indicate that formulation F5 had better flowability than other batches for Carr's index, Hausner's ratio, and angle of repose. Batch F5 was selected for further development of the commercially applicable product based on the obtained results and our requirements because it provided a uniform release of more than 98% over a period of 30 minutes, showed good powder flow ability, hardness, and met the pharmacopeia requirements for tablet properties. The proper use of this herb in various conventional mouth fresheners can be researched in the future. The developed chewable tablets may therefore be an improved choice for the herbs' traditional uses.

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