RESEARCH PAPER

FORMULATION AND EVALUATION OF MORINGA CHEWABLE GUMMIES

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Introduction:

Moringa oleifera, a deciduous tree from the Moringaceae family, originated in India and is now widely farmed in Asia, Africa, and tropical Central America. M. oleifera, often known as the "horseradish tree" or "drumstick tree," has been used for nutritional and therapeutic purposes for centuries. Moringa oleifera, often referred to as the "miracle tree," is renowned for its rich nutrient profile, including vitamins, minerals, and antioxidants[3]. Traditionally consumed in its leaf or powder form, moringa is now being incorporated into more convenient and palatable products, such as chewable gummies[2,4]. This plant's leaves, roots, seeds, fruits, and flowers have anti-inflammatory, antiparasitic, antidiabetic, antioxidant, immunomodulatory, anticancer, antihypertensive, and antimicrobial properties that are beneficial to humans and animals. It has been cultivated in subtropical and tropical regions in many countries of the world for its many uses as an important nutraceutical and medicinal herb[2,4,5,6]. It contained huge quantity of phenolic compounds, principally flavonoids, phenolic acids, and their glycosides.

Alkaloids, tannins, saponins, isothiocyanate, and glucosinolate were also found in moringa leaf. *M. oleifera* can grow up to 12 m in tropical and subtropical environments. Although it is native to South Asia, the cultivation itself has already spread to the Middle East, Africa, Asia, and other areas. Traditionally, *M. oleifera* has been used in medicine, skincare, breastmilk production, and even food.[1,3] Almost all parts of *M. oleifera* can be useful. Nowadays, *M. oleifera* is also used for water purification, animal feed, as a bio-stimulant, bio-pesticide, and biomass as biodiesel production in industrial and agricultural process[1,4]

Moringa oleifera leaf powder contains recommended daily allowances for protein (42%), calcium (125%), magnesium (61%), potassium (41%), iron (71%), vitamin A (272%), and vitamin D. *Moringa oleifera* leaves contain seven times the vitamin C in oranges, four times the calcium in milk, four times the -carotene in carrots, twice the protein in milk, and three times the iron[2,3].

Beetroot (Beta vulgaris) is a nutrient-rich vegetable with several key constituents that contribute to its health benefits. The main constituents of beetroot include: Betalains which include Betanin and Vulgaxanthin, responsible for the deep red and purple color of beets. These pigments have strong antioxidant, anti-inflammatory, and detoxification properties. Nitrates, Vitamins and Minerals, Folate (Vitamin B9), Potassium, Iron, Magnesium and Calcium, Antioxidants, Fiber. Beetroot is chosen as a coloring agent in gummies for several key reasons: Natural Pigment (Betalains): Beetroot contains betalains, particularly betanin, which provides a vibrant red to purple color. These pigments are water-soluble and easily extracted, making them suitable for use in food products like gummies[14,15]. Health Benefits: Being a natural food colorant, beetroot is a healthier alternative to synthetic dyes (like Red 40 or carmine), which some consumers prefer to avoid due to potential health concerns. Natural Ingredients: Using beetroot as a coloring agent appeals to this trend of avoiding artificial additives in favor of plant-based alternatives[14]. Safe for a Wide Audience: Beetroot-derived colors are generally considered safe for consumption by children, adults, and individuals with dietary restrictions, such as vegetarians and vegans, making it a versatile choice for gummy products[14,15]. Food Applications: while betalains are sensitive to light and heat, they still offer reasonable stability in low-processing conditions like gummy production, where lower temperatures are often used. Neutral Flavor Contribution: The flavor of beetroot is mild enough that it doesn't overpower the taste of gummies[2,4,5,6,7,8,11,12]. For these reasons, beetroot is an attractive natural coloring agent in gummies, providing both aesthetic and health-conscious benefits. This study explores the potential of chewable moringa gummies as an alternative health supplement, focusing on their efficacy, consumer acceptance, and market potential product[2,4,5,6,9,10,11].

Stevia is often used in gummies as a natural sweetener, reasons why it's commonly chosen are because of its Low Calorie: Stevia has little to no calories, making it ideal for creating low-calorie

gummies, which appeal to health-conscious consumers[16]. Natural Origin: Stevia comes from the leaves of the Stevia rebaudiana plant, making it a natural alternative to artificial sweeteners like aspartame or sucralose[2,3]. High Sweetness Intensity: Stevia is much sweeter than sugar (about 200-300 times sweeter), meaning a small amount can be used to achieve the desired sweetness, reducing the overall sugar content in the product. Suitable for Diabetics: Stevia doesn't raise blood sugar levels, making it a good option for people with diabetes or those looking to manage their blood sugar[1,2,4,5,11].

METHODOLOGY

The Moringa gummy formulation was developed by incorporating standardized *Moringa oleifera* extract with suitable gummy-forming ingredients to achieve optimum compatibility, stability, and consumer acceptability. The standardized Moringa extract, containing known concentrations of bioactive constituents such as vitamins and antioxidants, was used for formulation development.

All ingredients, including Moringa extract, gelatin, sweeteners, acidulants, flavoring agents, colorants, and purified water, were accurately weighed according to the optimized formulation to ensure batch-to-batch consistency in texture, taste, and therapeutic efficacy.

Gelatin was dispersed in purified water and allowed to bloom for 10–15 minutes to ensure complete hydration and the formation of a uniform gel matrix. Separately, water and the selected sweetener (stevia) were heated under continuous stirring until complete dissolution was achieved. The hydrated gelatin was then incorporated into the heated solution with constant stirring to obtain a homogeneous gummy base. The processing temperature was carefully maintained to prevent gelatin degradation.

Following the preparation of the gummy base, the standardized Moringa extract was gradually added under continuous stirring to ensure uniform dispersion and to prevent agglomeration. The temperature was carefully monitored throughout the process to minimize degradation of the thermolabile bioactive compounds present in the extract. Subsequently, citric acid, flavoring agents, and approved colorants were incorporated to improve the organoleptic properties of the formulation while ensuring compatibility with the active ingredient.

The gummy mixture was maintained at a controlled temperature of 70–80°C, which is considered optimal for gelatin-based formulations, until the desired viscosity and consistency were achieved. Continuous stirring was maintained throughout the heating process to prevent localized overheating, sticking, or burning of the formulation.

The prepared gummy mass was then carefully transferred into clean, lightly lubricated silicone moulds to facilitate easy demoulding after setting. Any entrapped air bubbles formed during mixing were removed by allowing the mixture to stand briefly prior to moulding.

The filled moulds were allowed to cool and set at room temperature for 4–6 hours, or until the gummies attained the desired firmness and chewable texture. After complete setting, the gummies were carefully demoulded and lightly coated with a thin layer of edible oil to prevent adhesion during storage and packaging.

Finally, the prepared gummies were packaged in airtight containers and stored in a cool, dry place, protected from direct sunlight and moisture until further characterization and evaluation.

Preformulation Studies

The powder mixture was analyzed prior to the gummy synthesis. The quality of the powder used to produce high-grade gummies was assessed using a variety of parameters, such as hygroscopicity, bulk density and solubility.

1. **Hygroscopicity**

The amount of water present in the material was determined using the quantitative reaction of water with iodine and sulphur dioxide in the presence of a low molecular weight alcohol and an organic base.

2. **Bulk density**

Fill the graduated cylinder or container with gummies up to a specific volume mark. Avoid shaking or tapping during this step to prevent unnatural settling. Place the cylinder or container with the gummies on the scale and record the total weight. Subtract the weight of the empty container from the total weight to get the weight of the gummies.

3. **Solubility:**

To evaluate the solubility of Moringa in water. This is critical for ensuring that the active ingredient is evenly distributed in the gummy matrix.

FORMULATION TABLE

Sl.no	Ingredients	F1	F2	F3	F4
01.	Moringa leaf extract(ml)	2	2	2	2
02.	Gelatin(gm)	10	10	10	10
03.	Stevia(gm)	30	10	30	30
04.	Citric acid(gm)	2	2	2	2
05.	Propylene Glycol(gm)	2	2	2	10
06.	Sodium benzoate(gm)	0.5	0.5	0.5	2
07.	Beetroot flavor(gm)	5	10	10	0.5
08.	Aqua purificata(ml)	20	40	40	20

Table1: Formulation Table

QUALITY CONTROL TESTS:

1. **Organoleptic evaluation**

The four chewable gummy formulas for Moringa leaf extract were subjected to physical observations, including color, taste, shape,

texture, and smell. Observation of the texture of the preparation was carried out qualitatively by gently pressing the surface of the chewable gummy using both fingers. When pressed using both fingers, the chewable gummy's elasticity and stickiness were recorded as the texture of the chewable gummy. [3]

2. Weight variation

Weight variation of the CGTs was measured to determine the content homogeneity of each tablet. In the initial stage, not less than 20 individual tablets were weighed, and then the average weight was calculated. The tablet is concluded as meeting the predefined requirement if its weight does not deviate more than 7.5% from the average. If one tablet fell outside this range, the test continued to the second stage with an additional set of not less than 20 gummies the test continued to the second stage with an additional set of not less than 20 gummies , in which the tablet is concluded as meeting the requirement if its weight does not deviate more than 10% from the average weight.

3. Hardness

Hardness is the major factor that determines the chewiness of gummy jelly. The hardness of formulations F1 to F4 was tested using Monsanto hardness tester.

4.Friability

A sample of 10 gummies at random and placing them in the plastic chamber of the Rosch Friabilator, the friability of gummies was examined. For 4 min, the friabilator drum was circulated at 25 rpm. The formula given below was used to compute the percentage drop in gummies weight. Friability should be under 1%. It is calculated using formula:

$$\text{Friability } (\%) = \left(\frac{W_1 - W_2}{W_1} \right) \times 100$$

5. Moisture content

Drying finely ground samples (10 g) in an air oven at 105°C overnight to create a constant weight was carried out.

6.pH determination

A micro pH meter with a glass combination electrode was used to monitor the pH. The materials were divided into thin slices, added to boiling water (1:3, w: w), and mixed continuously until completely dissolved. The pH was measured after the heated solution was tempered at 25°C. Each measurement was taken thrice times. The acceptable pH range of chewable gummies is 5.69 to 6.34.

7.*In vitro* disintegration Test

The USP disintegration apparatus is made up of six glass tubes that are 3 inches long, open at the top, and positioned at the bottom end of the basket rack assembly against the 10-mesh screen. Plastic discs with perforations can also be utilized in the tests. These are put on top of the gummies and have a negative impact on them. Use the tool for a predetermined period of time. If all particles pass through the 10-mesh screen at the designated time while the gummies are unplugged, the gummies complies with the test. Any remaining material must have a soft bulk and no visible solid core. Gummies was found to disintegrate within 15 min with a standard deviation of ± 0.01

8.*In vitro* dissolution testing

Gummies are tested for dissolution to determine rate at which it produces a solution. British and US Pharmacopoeia dissolution apparatus (paddle/basket apparatus) are made of a cylindrical vessel. Using a water bath or heating apparatus, the test vessel's internal temperature can be maintained at 37 ± 0.5°C while maintaining a consistent bath fluid level. Withdraw a sample not less than 1 cm from the vessel wall, from the area centered between the dissolving medium's surface and the top of the spinning basket, within a certain time frame or at each interval provided. Most formulations in dissolution tests released 85% of the drug after 15 min with a standard deviation of ±0.01

9. Swelling Ratio

The chewable gummy development index was measured by weighing the initial weight of the chewable gummy (Wd). The swelling index determines the absorption capacity of the liquid in the chewable gummy structure. In the next stage, the chewable gummy preparation was soaked in 100 ml of aqua purificata for 10 seconds at controlled room temperature (25-30°C). A chewable gummy that has been soaked is then removed and cleaned using filter paper to absorb water adhering to the surface of the chewable gummy.

$$\text{Swelling Ratio} = \frac{Ws - Wd}{Wd} x100\%$$

Index:

Ws = weight of chewable gummy after soaking

Wd = weight of chewable gummy before soaking

10.Scanning Electron Microscopy:

Moringa gummies were prepared using a standard formulation, incorporating Moringa oleifera extract, gelatin, sweeteners, and flavorings. Samples were cut into small pieces (approximately 1 cm^3) to fit the SEM sample holder.

To enhance conductivity and prevent charging under the electron beam, the samples were coated with a thin layer of gold or palladium using a sputter coater. The coated samples were placed in the SEM chamber. The analysis was conducted using an electron microscope operated at varying voltages depending on the desired resolution and the material's conductivity. Images were captured at different magnifications to observe the surface morphology and texture.

RESULTS AND DISSCUSION:

1. Organoleptic Evaluation:

Observing the chewable gummy's shape, color, smell, taste, and texture. Physical observation test is one of the factors that must be considered in product development. The four formulations are gummy bear in shape, yellow in color, smell of beetroot, sweet in taste, have a chewy, elastic texture, and are not sticky when pressed with a finger.

Fig8:Gummies prepared by F1
Fig9:Gummies prepared by F2

Fig10: Gummies prepared by F3
Fig11: Gummies prepared by F4

2. Weight variation test:

The uniformity of mass was determined gravimetrically according to the European Pharmacopoeia 6.0. Each of the 20 randomly selected gummy bears were carefully placed and weighted using an analytical balance .The gummy bears were then left in an open packaging at room temperature and weighted after 7 and 14 days. The results are presented as mean ± standard deviation.

Formulation	Weight variation
F1	1.07±0.5
F2	1.98±0.4
F3	1.94±0.5
F4	1.85±0.6

Table 2: Weight variation test

3. Hardness:

The hardness testing of moringa chewable gummies demonstrated with all samples remaining within an acceptable range for consumer acceptance.

4.Friability:

The friability of formulations F1 to F4 was found to be less than 1%, which shows satisfactory results.

Formulation	Friability%
F1	0.23
F2	0.21
F3	0.25
F4	0.22

Table 3: Friability testing

5.Moisture content:

All formulations had moisture content values that were less than 20%, which is the ideal level for this kind of product. Our findings were consistent with earlier studies, which found that jelly candies had moisture levels in the range of 18–21%.

Formulation	Moisture content %
F1	18
F2	18
F3	18
F4	18

Table 4: Moisture content

6.pH determination:

It was found that chewable gummies have a pH. All the formulations F1 to F4 showed satisfactory results, and their pH values reside within the recommended range (5.69 to 6.34).

Formulations	pH
F1	5.78
F2	5.9
F3	6.01
F4	6.12

Table 5: pH determination

7.*In vitro* disintegration:

All the gummies were found to disintegrate within 15 min, which was according to their specifications and previous studies. F1 to F4 formulations had disintegration times between 6:50 and 10:42 min with standard deviation of ±0.01

Formulations	*In vitro* disintegration(minutes)
F1	6:50
F2	6:05
F3	10:42
F4	6:55

Table 6 :*In vitro* disintegration

8. *In vitro* dissolution:

The percentage of drug release was observed for a period of 30 minutes, the kinetic investigation, the drug release percentage versus time graph plot was used to determine the order of release for all formulations. Most of the formulations tested in

dissolution tests released 85% of the drug after 25 min. At time 0, there is no drug release. The initial release of the drug was relatively slow. All the formulations except F4 have released 50% of the drug within 15 min. For F4, more than 50% of the drug was released earlier, within 10 min. At the end of 30 min, F1–F4 have released the maximum amount of the drug. The formulation F4 showed the highest drug release within 30 min; that's why it is considered to be the best formulation. [1]

Time(min)	Percentage Drug Release			
	F1	F2	F3	F4
0	0	0	0	0
5	35.4	33.8	30.9	22.1
10	45.5	43.1	45.4	39.6
15	55.9	55.7	59.5	58.5
20	75.7	72.9	70.1	80
25	83.0	80.4	85.5	89.9
30	91.8	95.4	94.8	93.2

Table 7: In vitro dissolution

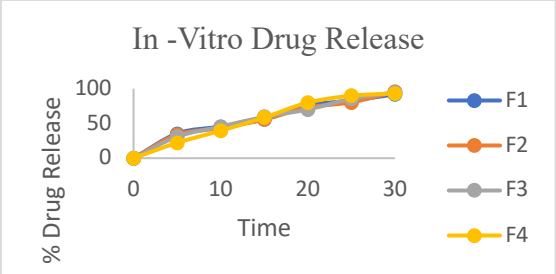

Fig 13: Graph of *in vitro* dissolution

9. Swelling ratio:

The swelling index was evaluated to determine the ability of the chewable gummy gel matrix to swell in water. The smallest development index was shown by formula 4, 0.43 ± 0.08%, while the largest development index was shown by formula 1, 0.75 ± 0.32%. [2]

Fig 14 : Before swelling **Fig15**: After swelling

10.SCANNING ELECTRON MICROSCOPY:

SEM of confections followed procedure with some modifications. Confection samples were cut into 7 mm small cubes leaving 1 naturally fractured surface, and then freeze-dried. After freeze-drying, samples were sputtered for 180 seconds. It was observed via a scanning electron microscopy with magnification of 500X.

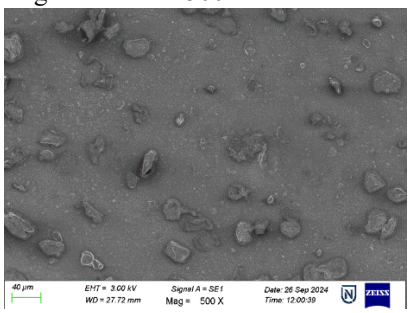

Fig16: SEM analysis with 500X magnification

CONCLUSION:

The type and concentration of gelling agents and interaction between these two factors significantly affect the hardness, gumminess, and chewiness of Moringa oleifera chewable-gummies. Gummies developed using 10% gelatin and 30% stevia are considered optimal formulations because these fulfill all the required physical characteristics and provide a better texture than the other formulations. The concentration of sucrose as a filler and propylene glycol as a plasticizer is essential in forming a chewable gummy structure. Based on the results of evaluation, increasing the concentration of stevia will impact increasing the average weight, disintegration time, and decreasing the swelling index.

Four formulations of gummies were made by adjusting the water and gelatin contents. The F4 formulation was found to be the best of all, with 10g of gelatin per gummy. Organoleptic evaluation revealed that the texture of gummy bears was elastic and chewy. All formulations revealed satisfactory percentage weight variation, hardness, moisture content and friability results.

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