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Article

FORMULATION AND EVALUATION OF VITAMIN C MEDICATED CHEWING GUM

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ABSTRACT

Objectives: The objective of the present research work was to formulate and evaluate vitamin C chewing gum.

Methods: Medicated chewing gum is formulated using a natural gum base (Prolamin) extracted from wheat. The gum base is extracted by mixing *Triticum aestivum* flour with 70% ethanol, stirring for 2 h, filtering, and then evaporating the filtrate. The concentrated solution is further treated to form a gum base. The formulation of the chewing gum, the gum base, and calcium carbonate are mixed in a mortar, while polyvinyl acetate, ethanol, glycerin, and other excipients are combined in another. The two mixtures are combined and thoroughly mixed to form the final chewing gum. Six formulations were prepared by varying the gum base and soya lecithin quantities. The chewing gum was evaluated for several parameters, including swelling index, water retention capacity, loss on drying, solubility, content uniformity, weight variation, drug release, and stability.

Results: The results of different evaluation parameters of prepared vitamin C chewing gum were within the standard range. Among all the formulations from F2 to F5 was good enough to meet the general characteristics of ideal chewing gum as all the evaluation parameters meet the standard values of chewing gum.

Conclusion: The natural gum base obtained from wheat (prolamin) was used, and vitamin C was used as a drug. The formulation was optimized by altering soya lecithin and the gum base. All the evaluation parameters were determined, and F2 and F5 were the best formulations obtained.

Keywords: Medicated chewing gum, Biodegradable, Prolamin gum base, Vitamin C.

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INTRODUCTION

As a delightful and entertaining candy, chewing gum has demonstrated in recent years that it can be a useful delivery system for pharmaceutical and nutraceutical ingredients. Chewing gum is discrete and encourages higher compliance when administered without water, both of which contribute to patient convenience. For various reasons, chewing gum is a desirable method of drug delivery. It tastes nice, is eco-friendly, and is simple to administer without the need for water. As the active ingredients enter the bloodstream directly through the jugular veins and the blood-rich, permeable oral mucosa, the drug takes effect quickly [1].

Chewing gum containing vitamin C is a dietary supplement that offers an enjoyable and convenient way to get a boost of this important nutrient. Ascorbic acid, or vitamin C-containing chewing gum, is an antioxidant medication. Many active ingredients in chewing gum formulations are sold commercially. Vitamin C neutralizes free radicals, shielding cells from oxidative stress and damage [2].

The European pharmacopoeia now describes medicated chewing gum as a well-established dosage form. It has several benefits, such as the quick onset of action, avoiding hepatic first-pass metabolism for drugs absorbed by the buccal route, and potentially lowering dosage requirements and fewer side effects [3].

The purpose of this study was to determine how much of a specific subset of fat- and water-soluble vitamins are released into the saliva during a typical chew from the gum matrix. Further research aimed to determine how chewing these vitamin-supplemented gums affected the acute plasma levels of the component vitamins in a cohort of healthy people. For acute medication, a chewable formulation is a fantastic choice. Dr. Stephen De Felice first used the term "nutraceutical" in 1989 to describe foods or food-related items that not only increase salivary flow and raise plaque pH but also offer health benefits and disease prevention. Research has indicated that even chewing gum without medication raises the pH of plaque and increases saliva flow [2,4].

In general, nutraceuticals can be divided into:

1. Prospective supplements
2. Well-known nutraceuticals.

Potential nutraceuticals

These process the ability to cure an illness or provide health or medicinal advantages. Established nutraceuticals have accumulated sufficient clinical data or use to imply any potential medical or health advantages.

Vitamins, minerals, amino acids, and other nutrients can all be found in nutritional supplements. Herbal medicines, phytochemical processes, and food-based supplements such as antioxidants, probiotics, and prebiotics represent various potential nutraceuticals. In both human and animal bodies, vitamin C is an essential nutrient that plays a role in the enzymatic synthesis of certain neurotransmitters, collagen creation, and tissue repair. It is essential to the body's healthy operation [2,4].

METHODS

The following materials of pharma grade or the best possible laboratory reagent were used as supplied by the manufacturer.

Materials

The materials used are as follows: Vitamin C, Glycerine, Peppermint Oil, Calcium Carbonate, Polyvinyl Acetate, Mannitol, Soy Lecithin, and Talc.

Equipment used

The instruments include an Electronic Balance, Homogenizer, Hot Air Oven, Ultrasonicator, Rectangular Water Bath, Vernier Calliper, UV Spectrophotometer, and Digital pH Meter.

Preparation of standard calibration curve of *vitamin* C

Principle

When examined in the range of 200–400 nm in a distilled water solvent, vitamin C shows an absorption maximum peak at 265 nm.

Instrument used

Shimadzu, ultraviolet (UV) spectrophotometer 1800, Japan.

Procedure: Preparation of stock solution

A standard curve was prepared by dissolving 100 mg of vitamin C in a distilled water solvent and making up a volume of 100 mL. It was further diluted to get the solution in the 0.5–20 µg/mL concentration range. The absorbance values were determined at 265 nm [5].

Preparation of working standard solutions

Further, from the above stock solution 5 mL of prepared stock solution was withdrawn into a 100ml volumetric flask and made up the volume to 100 mL using distilled water. Then 0.2, 0.4, 0.6, and 0.8 mL were pipetted out into 10 mL volumetric flasks. The volume was made up of distilled water to get the final concentrations of 1, 2, 3, and 4 µg/mL, respectively. The absorbance of each concentration was measured at 265 nm. The results obtained are compiled in Fig. 1.

λmax: 265 nm

Beer's range: 0.5–20 µg/mL

The concentration was calculated using the following formula with,

Table 1: List of chemicals used with their grade and names of suppliers/manufacturers

S. No.	Material	Supplier
1.	Vitamin C	Universal scientific works, Bangalore
2.	Glycerin	Mehta son's, Bangalore
3.	Calcium carbonate	Burgoyne burbidges, Mumbai
4.	Polyvinyl acetate	Burgoyne burbidges, Mumbai
5.	Mannitol	Burgoyne burbidges, Mumbai
6.	Soy lecithin	Burgoyne burbidges, Mumbai
7.	Talc	Burgoyne burbidges, Mumbai
8.	Peppermint oil	Mehta son's, Bangalore

Table 2: Details of equipment used

S. No.	Instrument	Manufacturer
1.	Electronic balance	The indosati instruments and chemicals
2.	Homogenizer	Remi elektrotechnik, vasai
3.	Hot air oven	Lawrence and Mayo
4.	Ultra-sonicator	The indosati instruments and chemicals
5.	Rectangular water bath	The indosati instruments and chemicals
6.	Vernier caliper	Mitutoyo, Japan
7.	UV spectrophotometer	Shimadzu-1800, Japan
8.	Digital pH meter	Elico. Model – LI 612.
9.	Hot air oven	Lawrence and Mayo

UV: Ultraviolet

Correlation coefficient (r^2)=0.9972

Absorbance=0.0662×+0.0005.

Isolation of the gum base process

The isolation of the gum base is done using a pure form of wheat flour obtained from pure wheat grains. Accurately, weigh 500 mg of *Triticum aestivum* flour, then add 1500 mL of 70% ethanol and blend the mixture for 2 h using a homogenizer. Further, filter the product obtained using a multilayer muslin cloth to remove the muck from the solution.

Then, further, the obtained filtrate was kept for vaporization till it got to 1/5th of the initial filtrate and add equal amount of water to it and heated at 70°C. The product acquired was dried using a hot air oven then after the complete drying of the product, it is triturated to get the extract in powder form [6].

The formulation process of vitamin C chewing gum

Take two mortars and a pestle. In the first mortar, add gum base, calcium carbonate, mannitol, ascorbic acid, soya lecithin, glycerin, peppermint oil, rose pink, and triturate it Table 3. In the second

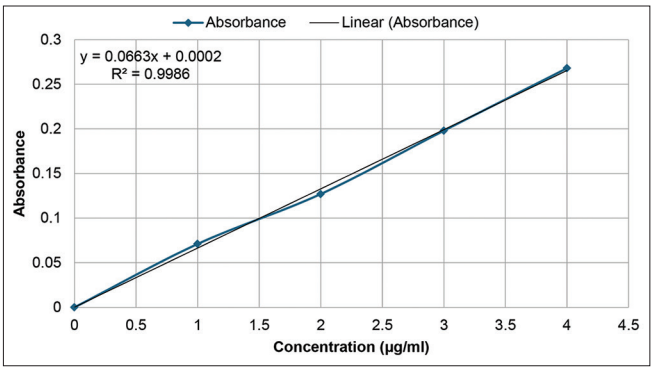

Fig. 1: Standard calibration curve of vitamin C

Table 3: Formulation for the preparation of vitamin C medicated chewing gum

Ingredients	F1	F2	F3	F4	F5	F6
Vitamin c (mg)	80	80	80	80	80	80
Gum base (mg)	1000	1200	1300	1200	1200	1200
Soya lecithin (mg)	-	-	-	5	10	15
Calcium carbonate	90	90	90	90	90	90
Polyvinyl acetate	50	50	50	50	50	50
Peppermint oil (mL)	0.02	0.02	0.02	0.02	0.02	0.02
Mannitol (mg)	1	1	1	1	1	1
Glycerol (mL)	0.05	0.05	0.05	0.05	0.05	0.05
Coloring agent	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S

Table 4: Solubility of prolamin in various solvents

Solvents	Solubility (moL/L)
Water	Insoluble
Methanol	Soluble
Ethanol	Soluble
Dil. HCL	Soluble
NaOH	Soluble

Table 5: Solubility of vitamin C in various solvents

Solvents	Solubility(moL/L)
Water	Highly soluble
Methanol	Moderately soluble
Benzene	Least soluble

mortar, add polyvinyl acetate which is previously dissolved in the pure form of ethanol. Further, add all the mixed ingredients from the first mortar to the second mortar and continue triturating till chewing gum formulation is obtained [7,8].

Characterization of isolated gum base

1. Swelling index (SI): To figure out the SI, prior weighed gum base extract (1 g) was migrated to a 10 mL measuring cylinder, the initial volume was quantified, and distilled water was incorporated. After gently agitating, the measuring cylinder was kept aside for 24 h at ambient temperature and humidity. The volume engaged by the powder sediment was noted [9] Fig. 2.
2. Water retention capacity (WRC): To assess the WRC, the content that remained in the measuring cylinder during the study of the SI was filtered using a muslin cloth. The water was permitted to drain and the volume was assessed. The difference between the initial volume and the final volume of the drained water was referred as WRC [9].
3. Loss on drying (LOD): Precisely weighted gum base (1 g) was carried in the petri plate and was heated in a hot air oven at 105°C. The gum mass was reweighted and was calculated. LOD was the difference between the initial weight and the final weight of the sample expressed as a percentage [10].

Evaluation parameter of vitamin C medicated chewing gum

Medicated chewing gum was evaluated by performing the following tests:

1. Physical appearance: All the formulations were visually evaluated for physical appearance, color, odor, and taste. The texture study was carried out manually by pressing the gum between the thumb and the finger. The texture feel was described as sticky and good [7].
2. Determination of content uniformity: Three chewing gums were withdrawn randomly. Each chewing gum was degraded in 100 mL phosphate buffer of 6.8 Ph. The amount of vitamin was analyzed by evaluating the drug absorbance at 265 nm using a UV spectrophotometer (UV-1800, Shimadzu) [11].
3. Drug release study: *In vitro* dissolution study in phosphate buffer. The dissolution study of chewing gum is relatively different than the conventional dosage form Fig. 3. The mechanical force is essential to discharge the drug from chewing gum. Because of these justifications, an apparatus composed of the following parameters was considered for the release of gum formulation which stimulated human chewing behaviors. *In vitro* drug release of Vitamin C chewing gum was performed using the basket and bead method in which 70 mL of the dissolution media is a phosphate buffer of 6.8 Ph was taken in a container and in that the basket was added as the basket containing the magnetic bead and the formulated chewing. The container was placed on a magnetic stirrer at 310–320 rpm during the dissolution study. 0.5 mL of the aliquots was withdrawn at periodic time intervals and replaced with fresh dissolution media. Further, the absorbance was determined using a UV-spectrophotometer. Moreover, a graph was plotted on time versus % cumulative drug release (CDR) [7] Fig. 4.
4. Weight variation test: Weight variation plays a major role in evaluation parameters; it ensures the amount of drug present in each formulation. The weight of vitamin C chewing gum was analyzed using analytical balance. Then, calculate the average weight of the chewing gums and compare the individual medicated chewing gum to the average [12].
5. Stickiness: On the plain surface, medicated chewing gum was placed, and it was hammered using a Teflon hammer with a mass of 250 g for a period of 10 min at which time the stickiness observed was noted down [12,13].
6. Stability study: Stability study was studied according to the ICH guidelines. To ensure the safety and efficacy of the product. It was conducted for a period of 4 weeks [11].

Table 6: Swelling index study of prolamin

Swelling	In mL
Before	1 mL
After	2 mL

Table 7: Water retention capacity

Parameter	Prolamin
Water retention capacity	1.3±0.1 mL

Table 8: Loss of drying

Before drying	After drying
1.	0.96

Table 9: Evaluation of chewing gum containing vitamin C

S. No.	Parameter	Results (%)
1.	Physical appearance	Rose pink
2.	Content uniformity	78
3.	Weight variation	0.76
4.	Stickiness	Observed between 30 s and 1 min

RESULTS

Standard calibration curve of vitamin C

Various concentrations of vitamin C were taken, the absorbance was checked, and a linear graph was observed. The R^2 was found to be 0.9986.

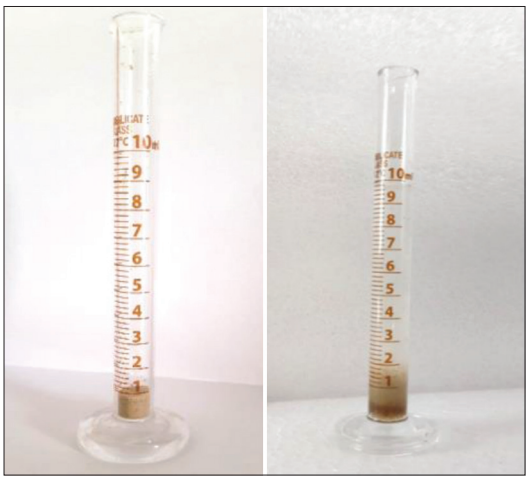

Fig. 2: Swelling index

Table 10: Stability study data

Time	Physical appearance	Weight variation (%)	Drug content uniformity (%)	% CDR
0 week	Rose pink	0.07±0.1	78±0.1	92±0.12
1 week	Rose pink	0.07±0.12	78±0.1	92±0.13
2 weeks	Rose pink	0.07±0.13	78±0.13	92.8±0.2
3 weeks	Rose pink	0.07±0.2	77.8±0.12	92.6±0.1
4 weeks	Rose pink	0.07±0.1	77.78±0.1	92.3±0.13

CDR: Cumulative drug release. *n*=3

Solubility of prolamin in various solvents

The solubility behavior of the wheat gum base (prolamin) and vitamin C in different solvents can provide useful insights into their chemical properties. Here is a breakdown:

Wheat gum base (prolamin):

1. Insolubility in water: Prolamins are hydrophobic due to their high content of non-polar amino acids. This makes them water-insoluble but soluble in alcohol-based solvents Table 4 and Fig. 5.
2. Solubility in methanol and ethanol: Prolamins dissolve in alcohols such as methanol and ethanol due to their polar characteristics, which can interact with the hydrophobic amino acids Fig. 6.
3. Solubility in dilute HCl and NaOH: The acidic and basic conditions can cause partial denaturation of prolamin, exposing polar groups, which increases solubility.

Vitamin C (ascorbic acid): Vitamin C solubility in different solvents typically depends on its polarity and hydrogen bonding capabilities.

1. Soluble in water: Vitamin C is highly polar and can form hydrogen bonds with water molecules Table 5
2. Solubility in alcohols: Moderately soluble in ethanol and methanol due to hydrogen bonding, though less so than in water
3. Reactions with dilute HCl and NaOH: Vitamin C remains stable in slightly acidic conditions (dilute HCl). In basic conditions (NaOH), it can degrade, forming dehydroascorbic acid and further breakdown products.

SI

The SI is the volume occupied by 1 g of prolamin and the adhering mucilage after it has solen in water for 24 h, the swelling was found to be 2 mL Table 6.

The SI is typically expressed as the ratio of the final volume of the material (including any swelling or adhered mucilage) to the initial weight of the sample.

Given: Initial weight of prolamin: 1 g

Final volume after swelling: 2 mL

The SI is calculated as:

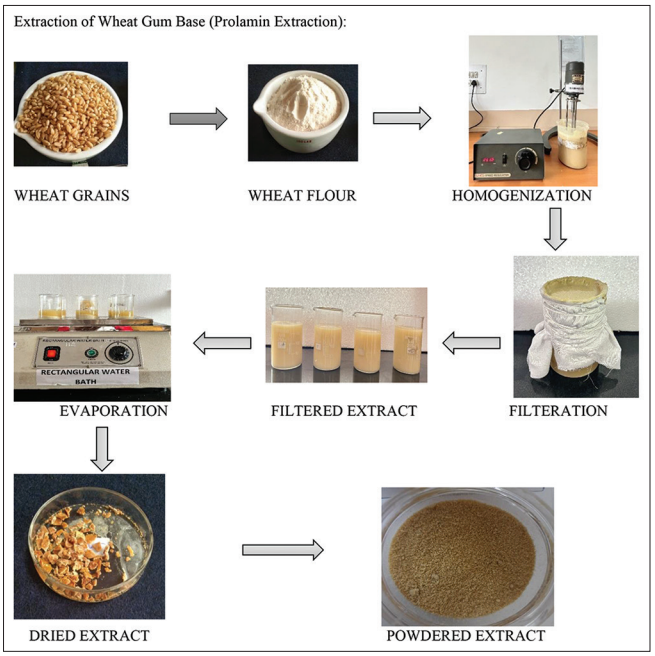

Fig. 3: Extraction of wheat gum base (prolamin extraction)

$$\text{Swelling Index (SI)} = \frac{\text{Final Volume (mL)}}{\text{Initial Weight (g)}}$$

$$\text{SI} = \frac{1\text{ g}}{2\text{ mL}}$$

$$= 2\text{ mL/g}$$

SI=2 mL/g indicates that 1 g of prolamin swelled to occupy 2 mL of volume in water over 24 h. This low SI suggests limited water uptake, consistent with the hydrophobic nature of prolamins. The adherence of mucilage likely contributes to the observed swelling, as mucilage tends to absorb water Table 7.

WRC

The water retained after the filtration of the SI, the difference between the initial and final volume of the drained water was referred as WRC.

The WRC being reported as 1.3±0.1 mL means that the material can retain 1.3 mL of water on average, with a margin of error or variability of ±0.1 mL.

1.3 mL is the mean value of water retained in the material after drainage. ±0.1 mL represents the standard deviation or experimental error, indicating the variability across repeated measurements.

If this data comes from a SI experiment:

Initial water volume: Total water added initially to the material.

Drained water volume: Water that flows out after the material has reached equilibrium.

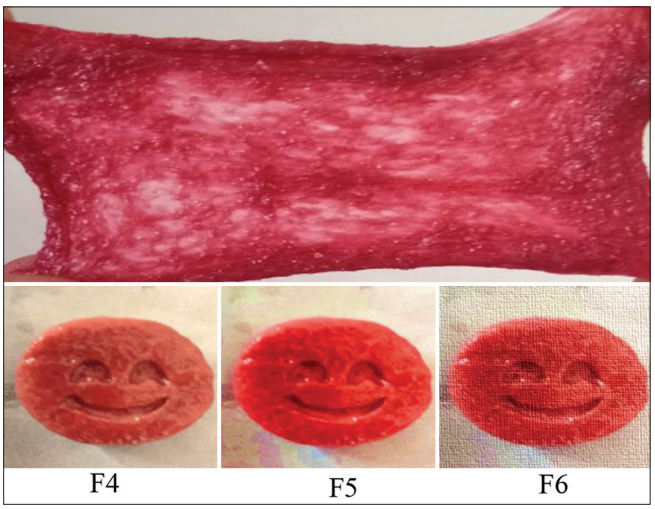

Fig. 4: Chewing gum formulations and its elasticity

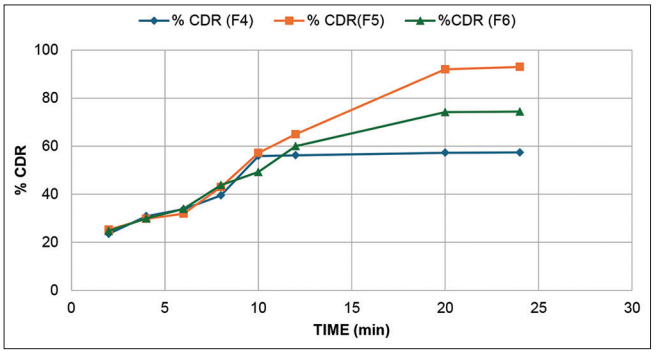

Fig. 5: *In vitro* drug release profile (%cumulative drug release vs. time)

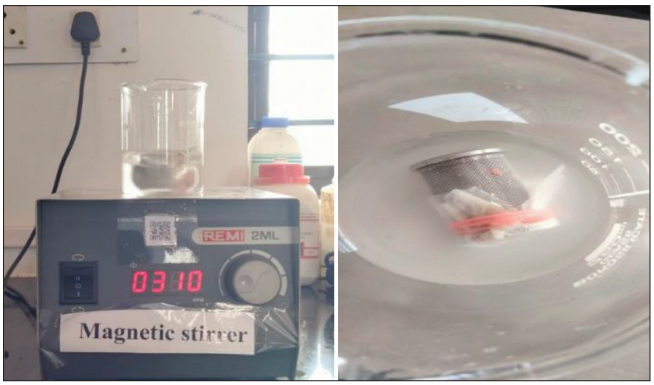

Fig. 6: *In vitro* dissolution studies

WRC is the difference between these values, and the mean is calculated over multiple trials, yielding 1.3±0.1 mL Table 9.

LOD

The loss was analyzed by accurately measuring 1 g of the gum base in a petri plate and heating it using a hot air oven at 105°C drying temperature.

The analysis described corresponds to determining the gum base's LOD. LOD measures the amount of moisture (or volatile substances) removed from a material when heated under specified conditions. Here is how it works based on your data:

The formula for LOD:

$$\text{LOD}\ (\%) = \frac{\text{Weight Before Drying} - \text{Weight After Drying}}{\text{Weight Before Drying}} \times 100$$

$$\text{LOD}\ (\%) = \frac{1 - 0.96 \times 100}{1}$$

=4%

The LOD=4%, which falls within the acceptable range for chewing gum.

The weight loss is primarily due to the evaporation of water, glycerine, and possibly some volatile flavoring agents.

Evaluation of chewing gum containing vitamin C

1. Appearance and texture: The chewing gums were uniformly rose pink and round, with a smooth texture and a shiny surface. This indicates a good esthetic appeal and uniform processing during manufacturing.
2. Average weight: Each gum weighs 1.2 g on average, ensuring consistency in size and mass among the formulations. Weight uniformity is critical for dosage consistency, especially for functional or medicated chewing gums.
3. Drug content uniformity: The formulations exhibited a drug content uniformity of 78%. While this is a reasonable result, higher uniformity (closer to 75–100%) is typically desired for pharmaceuticals. The value suggests that the Vitamin C is evenly distributed.

***In vitro* dissolution studies**

The rate of dissolution affects how quickly and how much a drug is absorbed and how well it works therapeutically. The type and concentration of the drug, surface area, diffusion distance, solubility of the formulation, manufacturing technique, and diluents can all impact the dissolution test.

Dissolution test results

F5: 92% drug release (best among the three formulations).

F4: 73.75% drug release (lowest release).

F6: 77.2% drug release (moderate release).

Factors influencing drug release

1. Type and concentration of drug: Higher drug solubility and proper dispersion can enhance release rates. If F5 has a better drug-to-excipient ratio or optimized Vitamin C concentration, it may explain the higher release.
2. Surface area of the gum: Greater surface area (e.g., thinner or smaller gum pieces) allows more drug to interact with the dissolution medium. Variations in size or shape among formulations could lead to different release rates.
3. Diffusion distance: The thickness of the gum matrix influences how far the drug must diffuse to reach the surface. F5 may have a more porous or less dense structure compared to F4 and F6, enabling faster diffusion.
4. Solubility of the formulation: Inclusion of solubilizers or hydrophilic excipients (e.g., sorbitol, mannitol) enhances drug release. F5 may include such excipients or have a better formulation balance.
5. Diluents/excipients: The choice and concentration of diluents (e.g., binders, plasticizers) impact the matrix's solubility and drug release. If F5 uses more water-soluble excipients, this could explain its superior release performance.

Stability studies

The best formulation F5 was checked for stability studies and was found to be stable for a month. Results indicate that the formulation (F5) is stable with not much variation in its physical and chemical properties.

Physical stability

Observation: The gum retained its rose-pink color throughout the study.

Inference: No noticeable changes in appearance or texture, suggesting stability of the excipients, pigments, and overall composition.

Weight variation: Range: 0.07±0.1% throughout the study.

Inference: Consistent weight indicates no moisture absorption, loss, or structural degradation, pointing to excellent physical stability.

Drug content uniformity: Initial value: 78±0.1%

Final value (week 4): 77.78±0.1%

Inference: Drug content remained nearly unchanged, with minor variations well within acceptable limits. This indicates the chemical stability of Vitamin C and compatibility with other components in the formulation.

% CDR: Initial value: 92±0.12%

Final value (week 4): 92.3±0.13%.

Inference: Drug release was stable over the 4 weeks, showing no adverse effects on the release mechanism or matrix integrity.

The stability study confirms that formulation F5 exhibits excellent physical and chemical stability over 1 month, with:

1. No significant changes in appearance or texture
2. Consistent weight variation
3. Stable drug content and release profile.

This makes F5 a robust candidate for further long-term stability testing and potential commercialization.

DISCUSSION

It is essential to maintain uniform standards for vitamin C chewing gum, keeping this view in mind, the formulated vitamin C chewing gum was evaluated for various parameters such as color and appearance, solubility test, stability, weight variation, and dissolution. Hence, based on the evaluation parameters, the F6 formulation has the problem of elasticity due to an increase in the quantity of softening agent and

the F4 formulation has a problem of higher hardness. Hence, among all the formulations F1 to F6, F5 was good enough to meet the general characteristics for ideal chewing gum as all the evaluation parameters meet the standard values of medicated chewing gum.

CONCLUSION

The natural gum base obtained from wheat (prolamin) was used, and vitamin C was used as a drug. The formulation was optimized by altering soya lecithin and the gum base. All the evaluation parameters were determined, and F2 and F5 were considered the best formulations.

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AUTHOR'S CONTRIBUTION

All authors contributed equally to the design, data collection, analysis, and writing of this study. All authors read and approved the final manuscript.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHORS FUNDING

The authors declare that no funding was received to conduct this study.

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