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Formulation and Evaluation of Oral Gummies for Teeth Whitening for Pediatric Purposes.

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ABSTRACT:

Background: Pediatric dental health often suffers due to poor oral hygiene, leading to issues like tooth discoloration, plaque, and early caries. Also faces challenges due to children's reluctance towards traditional oral hygiene methods necessitating safer alternatives. Clove oil, rich in eugenol, is known for its antimicrobial, analgesic, and whitening properties, making it an ideal herbal candidate for pediatric oral care formulations.

Objective: The study aimed to develop and evaluate oral gummies enriched with clove oil for teeth whitening in children, focusing on their formulation, stability, and efficacy.

Methods: The gummies were formulated using gelatin as the primary gelling agent, along with guar gum, mannitol, citric acid, and clove oil. The formulation underwent trials to optimize texture, taste, and stability. Evaluated for pH, dispersion time , weight variation, syneresis, moisture content, and the phytochemical screening. Organoleptic properties, texture, and microbial stability were also assessed.

Results: The optimized formulation displayed desirable color, flavor, and chewiness suitable for children. The pH was within safe limits (6.74–6.98 acidic but non-irritant), and average dispersion time was 2.3 minutes. Syneresis and weight variation tests are conducted to confirm the physical stability and uniformity. Phytochemical tests confirmed the presence of eugenol . Texture analysis indicated acceptable hardness and chewiness. Stability testing confirmed no microbial growth or physical degradation over the test period.

Conclusion: The formulated clove oil-based oral gummies demonstrated effective teeth-whitening potential, along with antimicrobial properties . Their palatable form and favorable evaluation parameters make them a promising and safe alternative for pediatric dental care.

Keywords: Clove oil, pediatric dental care, oral gummies, teeth whitening, eugenol, herbal formulation, Clove based gummies, oral hygiene gummies.

1. Introduction:

1.1 General Background

Creating and assessing the effectiveness of oral pediatric teeth whitening gummies require an integrated method that emphasizes chewing adherence, safety, efficacy, enjoyment, and compliance due to tenderness associated with children's health. Oral health has implication on the overall health of a child and the well being. Children may suffer from discoloration of teeth due to dietary practices, use of some medication, and inadequate oral care. Some of the effective methods of teeth whitening, for instance, bleaching agents or abrasive toothpastes, are not suitable for children, hence the rise of gentler approaches. Syzygium aromaticum (clove) from the Myrtaceae family is well known for its fragrance and important medicinal attributes owing to the active ingredient eugenol. Clove, which has antioxidant properties, was used by many cultures for pain and infection treatment. It is well known in dentistry as a remedy for tooth ache, reduction of bacteria in the mouth and aiding in gum health. Clove oil is widely used in pediatric oral care although it is important to use diluted forms due to its strong nature.

1.2 Syzygium aromaticum

Syzygium aromaticum Linn. is a tropical evergreen tree of the family Myrtaceae and it has small, reddish-brown flower buds.This is commonly called Laung in Hindi lavang in marathi.

Fig. 1 Clove

Taxonomically classified as follows:

Table 1 – Taxonomic Classification of *Syzygium Arimaticum*

Taxonomic Rank	Classification
Kingdom	Plantae
Family	Myrtaceae
Subfamily/Subclass	Myrtoideae
Genus	Syzygium
Species	Syzygium Aromaticum
Common Name	Clove

In India,Syzygium aromaticum is known by a variety of colloquial names.Sanskrit: *Lavanga, Devakusuma, Hindi*: *Laung, Lavang, Tamil*: *Kirambu, Telugu*: *Lavangam, Lavangalu, Kannada*: *Lavanga, Gujarati*: *Lavang, Malayalam*: *Grambu, Lavangam, Bengali*: *Labango, Marathi*: *Lavang, Punjabi*: *Laung.(* The Editors of Encyclopaedia Britannica, 2025)

Botanical Description of SyzygiumArimaticum

The clove is a reddish-brown, aromatic dried flower bud harvested from the evergreen tree Syzygium aromaticum. Each bud consists of a long calyx that terminates in a ball-like unopened corolla. The buds are typically 1.5–2 cm in length and have a hard, woody texture with a strong, pungent aroma. The clove tree can grow up to 10–12 meters tall and begins flowering in 5 to 7 years, with optimal yield occurring after 15–20 years. Flower buds are harvested when they turn from green to bright crimson, just before blooming, and are then sun-dried for preservation (Sharma A, Verma RK, Iqbal M, 2023).

Chemical Constituents

Major Bioactive Components*:*

Eugenol (70–85%) – The primary component responsible for its medicinal and aromatic properties, Eugenyl acetate, Beta-caryophyllene, Tannins, Flavonoids, Terpenoids, and Gallic acid.

Nutritional Composition (per 100g of dried buds):

Carbohydrates: 30 g, Dietary Fiber: 34 g, Protein: 6 g, Fat: 20 g (mostly essential oils), Calcium: 632 mg, Iron: 11.83 mg, Magnesium: 259 mg,Vitamin C: 0.2 mg (USDA Database; Ayurvedic sources)

Pharmacological and Therapeutic Activities

Clove and its main component eugenol exhibit a wide range of biological activities:

Analgesic – Local anesthetic effect useful in dental applications.

Antimicrobial – Effective against bacteria, fungi, and some viruses.

Antioxidant – Protects against oxidative damage.

Anti-inflammatory – Inhibits pro-inflammatory mediators.

Antiseptic – Promotes wound healing and prevents infection.

Anticancer – Shown to induce apoptosis in certain cancer cells (in vitro).

Anthelmintic – Effective against certain intestinal parasites.

Mechanism of Action

Clove's biological effects are primarily due to *eugenol*, which:

Inhibits prostaglandin synthesis, reducing inflammation and pain.

Disrupts microbial cell walls, leading to antimicrobial action.

Scavenges free radicals, reducing oxidative stress.

Modulates ion channels and nerve transmission, contributing to its analgesic effects.

1.3 Tasting Notes

Cloves are one of the most intensely flavored spices: high quality cloves contain 15-20% essential oil. The characteristic flavor of cloves mainly comes from the aromatic compound "eugenol" which comprises upwards of 85% of the essential oil composition. Cloves can also cause a numbing sensation in the mouth. This is because the eugenol found in cloves is a natural anesthetic such that it was traditionally used to numb and reduce toothache pain.

(McCormick Science Institute.)

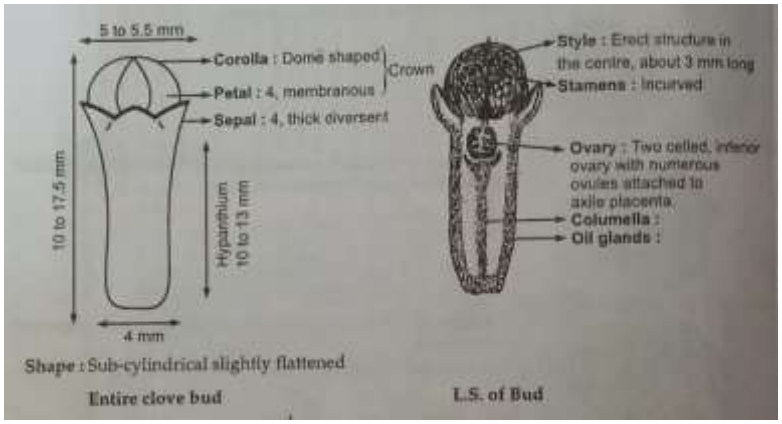

Fig 2.Entire clpve bud and L.S. of bud

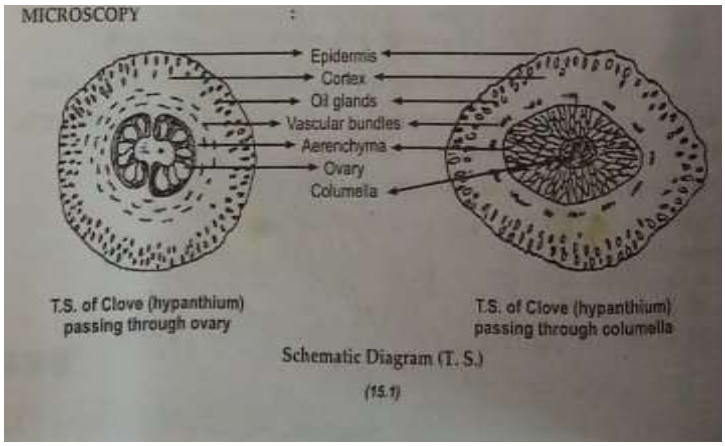

Fig 3. T.S of clove

1.4 Teeth Whitening gummies

Tooth discoloration in children, although less discussed than in adults, is a growing concern due to factors such as poor oral hygiene, dietary habits (consumption of colored beverages, sweets, cold drinks, etc.), use of certain medications, and even genetics. Traditional teeth whitening methods are not suitable for pediatric use, as they often contain strong bleaching agents like hydrogen peroxide or carbamide peroxide, which may damage developing enamel and cause tooth sensitivity or irritation.

There is a need for a gentle, child-friendly solution that promotes oral hygiene and gradually improves tooth appearance without causing harm. Teeth whitening gummies for children present an innovative and non-invasive approach to address this need.

This project aims to formulate and evaluate a teeth whitening gummy specifically designed for children, with a focus on safety, palatability, efficacy, and acceptance.The product will also aim to reinforce daily oral hygiene habits in a fun and appealing way.

By developing a scientifically evaluated and child-appropriate gummy for gentle teeth whitening, this project bridges the gap between oral health and functional confectionery, aligning with current trends in pediatric nutraceuticals and preventive dentistry.(Nathan, D., 2020)(Rani, K. C., Hasanah, T. U., Ilmiah, B., & Jayani, N. I. E., 2022)(Marcin, A., 2021)

1.5 Novelty Clove Gummies

Oral Buddies (clove gummies) designed for kids combine the natural oral health benefits of clove with the convenience and appeal of chewable, kid-friendly gummies. Clove is a well-known natural ingredient with antimicrobial, anti-inflammatory, mild analgesic properties, and teeth whitening property, making it effective in promoting dental hygiene.(Hole, A. V., Wagh, S. A., & Pabale, M. S., 2024)

Key Benefits:

Natural Whitening: Clove contains eugenol, which helps reduce stains and discoloration on teeth over time, contributing to a brighter smile.

Cavity Prevention: The antibacterial properties of clove help fight harmful oral bacteria that cause cavities and plaque buildup.

Gum Health Support: Clove may soothe minor gum irritations and support healthy gum tissue.

Kid-Friendly Format: Gummies are a convenient and fun way for kids to maintain oral health, especially for those who may not enjoy traditional brushing or mouth rinses.

2. Materials and Methodology:

2.1 Materials

Table 2 – Ingredients

Sr. No.	Ingredients	Percentage (%)	Function
1	Gelatin	20%	Gelling agent; provides the structure and chewiness to gummies
2	Gaur Gum	0.5%	Thickening agent; improves texture of gummies.
3	Talc	0.5%	Anti-sticking agents prevent gummies from sticking to packaging and mould.
4	NaCl (Salt)	0.9%	Flavour enhancer, balances taste of gummies.
5	PVP	2%	Binder and stabilizer; improve texture and solubility.
6	Citric Acid	5%	pH regulator and flavouring agent; gives a sour taste and also helps to preserve the gummies.
7	Mannitol	20%	Sugar alcohol; provides sweetness and a cooling effect, anti-cariogenic.
8	Sorbitol	10%	Sugar substitute; adds sweetness and retains moisture in gummies.
9	Clove oil	1-2 drops	Teeth whitening agent.
10	Liquorice	1%	Natural foaming agent and sweetner; reduces plaque and has antibacterial effects.
11	Starch Paste	5%	Thickener and stabilizer; improves gummy consistency.
12	Dextrose	5%	Simple sugar improves taste and provides quick energy.
13	Sodium Benzoate	1%	Preservative; inhibit taste and provide quick energy.
14	Yellow Pigment	1%	Colouring agent; gives an appealing yellow color to gummies
15	Peppermint Oil	q.s.	Flavouring agent provides a refreshing taste.
16	Water	q.s. to 100	Solvents; helps dissolve ingredients and form the gummy base.

The following ingredients were carefully selected and used in the formulation of the teeth whitening gummies, considering both functional and therapeutic properties:

Gelatin

Gelatin is a fundamental component of gummy products. It is the principal gelling agent responsible for the chewy, elastic feel typical of gummies. Gelatin, which is derived from animal collagen, melts in hot water and gels when cooled. The network of gel retains moisture and other components, resulting in the shape and texture of gummies. Gelatin can aslo improve mouthfeel.(Rather JA, Akhter N, Ashraf QS, Mir SA, Makroo HA, Majid D, et al,2022)

Fig. 4 Gelatin

Guar gum

Guar gum is obtained from guar beans and it is natural polysaccharide. In gummy formulation it is used as thickening and stabilizer. By enhancing the mixture's viscosity, it improves the gummy texture and avoids phase separation. Guar gum work synergistically in combination with gelatin, enhancing chewiness and also decrease stickiness. Guar gum is also appreciated as being biodegradable and ingestible. (Mudgil D, Barak S, Khatkar BS, 2011)

Fig. 5 Guar Gum

Talc

Talc is employed in pharmaceutical and food-grade products as an anti-stick material. Talc is applied lightly to avoid sticking in gummies. This enhances manufacturing effectiveness and appearance of the product. Talc makes demolding smooth and prevents gummies from clumping while in storage. Purified, non-toxic forms are employed in food use. (Flament MP, Leterme P, Bizi M, Baudet G, Gayot A, 2002)

NaCl (Salt)

Sodium chloride (NaCl), or salt, added in small amount to boost the flavor taste of gummies. It balances the total sweetness and contributes a depth of flavor that boosts fruity or tangy flavors. Salt also possesses mild antimicrobial effects and oral hygiene benefits. Its addition is strictly controlled so that it will not be perceivable as saltiness but will still benefit the product. (Henney JE, Taylor CL, Boon CS 2010)

PVP

Polyvinylpyrrolidone (PVP) is a polymer used in gummy formulation for binding and solubilizing purposes. It increases the mechanical strength and integrity of the final product. PVP stabilizes the formula, providing for uniform dispersion of active ingredients, and improves solubility. It is particularly beneficial in those formulas needing transparent gels or containing activities such as vitamins or minerals (Kurakula M, Rao GSN, 2020).

Citric acid

Citric acid is a natural organic acid commonly employed in gummies for its dual function as a flavoring and pH-adjusting agent. It provides a tart, fruity flavor that adds flavor appeal, particularly in citrus-flavored gummies. By reducing the pH, citric acid prevents microbial growth, adding to preservation. It also assists in gelation when combined with pectin or other gelling agents, providing a firm but pleasant texture. (Lambros M, Tran T, Fei Q, Nicolaou M, 2022)

Mannitol

Mannitol is a sugar alcohol that serves as a sweetener and texturizer in sugar-free or lower-sugar gummies. It leaves a cooling effect when it dissolves and does not promote tooth decay, so it's perfect for children's products. Mannitol also increases the shelf life. Its low glycemic index is another plus for health-focused formulations. (Msomi NZ, Erukainure OL, Islam MdS,2021)

Sorbitol

Sorbitol is a sweetner , stabilizing agent and also humectant and it is a sugar alcohol. It is used to maintain moisture in gummies so they do not dehydrate with age. Sorbitol also imparts smoothness and enhances the chewability of the product. It is non-cariogenic and has a lower caloric value than sugar, and therefore it promotes oral health and finds extensive application in dental-care confectionery products (Li CH, Wang CT, Lin YJ, Kuo HY, Wu JS, Hong TC, et al,2022)

Liquorice extract

Liquorice extract is a botanical ingredient with natural sweetness and health-promoting properties. It imparts a good flavor and also acts as a natural foaming agent, and promotes oral health by inhibiting plaque development and providing antibacterial activity. In dental health gummies, liquorice soothes the oral cavity and provides a herbal undertone to the flavor. It is rich in flavonoids and glycyrrhizin; they are also used as anti-inflammatory compounds. (Ibanoglu E,2000)

Fig.6 Liquorice Extract

Starch paste

Starch paste serves as a binder, thickener, and texturizer in gummy products. It stabilizes the network of gel and improve texture and density uniformity. The paste enhances molding and prevents the gummies from being overly soft and sticky. Made from corn or potato starch, it imparts a smooth, elastic texture that is appropriate for use in children's confectionery applications. (Tian Y, Qu J, Zhou Q, Ding L, Cui Y, Blennow A, et al,2022)

Fig. 7 Starch Paste

Dextrose

Dextrose is a basic sugar that adds sweetness to gummies. Dextrose has a rapid solubility to provide an even flavor throughout the gummy. Dextrose also serves as a functional ingredient in formulation by affecting the crystallization behavior and increasing chewiness. Dextrose is particularly well-suited for children's products because of its quick absorption and natural flavor profile. (ScienceDirect Topics)

Sodium benzoate

Sodium benzoate is a preservative that guards against microbial spoilage of gummies, particularly yeasts and fungi. It operates effectively at low levels and at acidic pH and is thus highly suitable for use in citric acid-based gummies. Including it guarantees shelf life extension as well as the safety of the product without considerable influence on texture or flavor. (McCulloch M, 2023)

Clove oil

Clove oil is an essential oil . It is a pale yellow to colorless liquid with a pungent, spicy fragrance, consisting mostly of eugenol, but also containing trace amounts of eugenyl acetate and beta-caryophyllene. It is famed for its intense antimicrobial, analgesic, antioxidant, and anti-inflammatory activity and has been used in traditional oral medicine to inhibit bacteria and maintain healthy teeth. In gummies, clove oil plays a two-fold role: it promotes oral hygiene by combating dangerous microbes and has a gentle anesthetic effect on the gums. Also, its unique spicy-sweet taste enhances the overall taste quality of the gummies. Clove oil has to be used in well-measured amounts, as high doses can lead to irritation. It is recognized as safe (GRAS) under proper use and should be placed in tight, airtight containers and should be shielded from light and heat to retain its stability and potency. (Seladi-Schulman J, 2019)

Fig.8 Clove oil

Yellow pigment

Yellow color is added to enhance the appearance of gummies. It adds to the color and makes the product look more appealing, especially for kids. Only food-grade pigments, which are not toxic, are utilized in order to meet safety regulations. The color also assists in flavor perception by visually connecting color with a taste expectation (e.g., lemon). (Yin S, Niu L, Zhang J, Liu Y, 2024)

Peppermint oil

Peppermint oil contributes a revitalizing, minty taste and scent to gummies. It gives a cooling mouthfeel to the gummies. The oil contributes to the perception of the product and assists in covering any nasty aftertastes from functional ingredients. It is particularly valued in oral care products for its deodorizing effect. (Zhao H, Ren S, Yang H, Tang S, Guo C, Liu M, et al,2022)

Water

Water is the major solvent in gummy formulation. It is used to dissolve the gelatin, sweeteners, and other ingredients to create a uniform solution. Water dictates the texture and also firmness of the final gummies. Proper heat control and evaporation during the manufacturing process guarantee the correct consistency and inhibit microbial growth. (Kasaai MR, 2014)

2.3 Methodology/ Procedure

Step 1: Preparation and Pre-weighing

- Calibrate the weighing balance.
- Weigh each raw material accurately according to the specified formulation batch size.

Step 2: Formation of solution A

- Soak gelatin in 10 ml of water.
- Heat it at 50°c make an uniform solution.

Step 3: Formation of solution B

- Take required amount of starch.
- Mix with q.s. amount of water heat at 50°c make an slurry of starch solution.

Step 4: Powder Dispersion Preparation

- In a mortar, combine: Guar gum, talc, NaCl, PVP, citric acid, mannitol, Liqurice extract, dextrose, sodium benzoate
- Triturate manually until a fine, uniform dry blend is achieved (approximately 3–5 minutes).

Step 5: Mix solution A and B

- We mix both solutions A and B

Step 6: Mix excipients in solution A+B

- Mix the triturated excipients with mixture of solution A and B.

Step7: Mixing of API and other remaining ingredients

- Then add clove oil and mix it.
- Next we will add sorbitol, peppermint oil.
- Then mix the solution properly.

Step 8: Moulding and Solidification

- Then we oil the moulds and pour the mixture in moulds.
- Then we allow it refrigerate for 24 hrs.

Step 9: Demoulding and Finishing

- Take out moulds from refrigerator and demould the gummies.
- Then we pavk individual gummy separately.
- Then we put in bigger container so that we can use one gummy at a time without getting other gummies damaged.
- Store in clean, airtight containers to prevent from oxidation and fragrance loss in refrigerator.

FIG. 9 TEETH WHITENING GUMMIES (CLOVE GUMMIES)

2.4 Evaluation parameters

1. Organoleptic Properties-

The direct examination of the formulation's sensory qualities through sight, touch, and smell is known as organoleptic evaluation. For cosmetic acceptability, it is a crucial factor.

The qualities listed below were assessed:

Physical Appearance: The formulation's homogeneity, the existence of any phase separation, and the lack of air bubbles or granules were examined visually. The ideal stick appearance was thought to be smooth, homogeneous, and free of bumps or splits.

Colour: The stick's consistency and suitability for the desired shade were examined. Any colour instability, patchiness, or discolouration suggested possible formulation problems.

Texture: The stick's texture was evaluated by lightly touching its surface and applying it to the skin. When applied, a good stick formulation should feel non-greasy, non-gritty, and smooth. Any stickiness or roughness was viewed as undesirable. (Hole AV, Wagh SA, Pabale MS, 2024) (Gupta L, Patil S, Kable R, Sharma D, Shivani Pawar M, 2024) (C. Rani K, U. Hasanah T, Ilmiah B, I. E. Jayani N, 2022) (Jchr.org, 2025)

2. Dimensional Analysis

A Vernier Calliper was used to measure the dimension of ten gummies in ordering to vouch size consistency and choose appropriate elemental promotional material. To square up size homogeneity, the distance, width, and thickness were measured.

Criteria for Acceptance - If the gummies' dimensions' standard departure is less than 5%, they satisfy the necessity. This warrant uniform gummy sizing, which is essential for quality control and publicity.

The modeling's measure, measured with a vernier calliper, are 1 cm by 1 cm. (Hole AV, Wagh SA, Pabale MS, 2024) (Gupta L, Patil S, Kable R, Sharma D, Shivani Pawar M, 2024) (C. Rani K, U. Hasanah T, Ilmiah B, I. E. Jayani N, 2022) (Jchr.org, 2025)

3. pH - The gummies were dissolved in distilled water. Then the pH was determined by using litmus paper. The solution turns blue litmus red. This shows that the gummies have an acidic nature. (Hole AV, Wagh SA, Pabale MS, 2024) (Gupta L, Patil S, Kable R, Sharma D, Shivani Pawar M, 2024) (C. Rani K, U. Hasanah T, Ilmiah B, I. E. Jayani N, 2022) (Jchr.org, 2025)

4. Syneresis Test

Syneresis is a phenomenon where liquid separates from a gel or solid structure, potentially affecting the quality of the product. To evaluate syneresis, the following test was conducted:

1. Test conditions: The test was performed at room temperature (25 ± 5°C).

2. Methodology: An absorbent paper was placed on the surface of each gummy tablet, and the weights were recorded before and after the test.This test helps assess the stability and quality of the gummies by measuring the amount of liquid separation.

Find the difference of avg initial wt – avg of final wt

Percentage (%) syneresis = 0.0006

A significant difference between the initial and final weights indicates the occurrence of syneresis. (Hole AV, Wagh SA, Pabale MS, 2024) (Gupta L, Patil S, Kable R, Sharma D, Shivani Pawar M, 2024) (C. Rani K, U. Hasanah T, Ilmiah B, I. E. Jayani N, 2022) (Jchr.org, 2025)

5. Weight Variation Test - To ensure content homogeneity, the weight variation of gummies was evaluated in two stages:

Stage 1

1. Sample size of it: Not less than 20 individual gummies were weighed.

2. Average weight calculation: The mean weightiness was calculated.

3. Acceptance standard: Gummies meet the requirement if their weight does not deviate more than 7. 5% from the average weight.

Stage 2 (if necessary)

1. Additional sample distribution: If one gummy outmatches the 7. 5% diversion limit, an additional set of not less than 20 gummies is weighed. 2. Toleration criteria: Gummies meet the essential if their weight does not deviate more than 10% from the median weight. This test ensures that gummies have consistent weight, which indicates uniform content distribution.

Gummies meet the predefined requirement if its weight does not deviate more than 7.5% from the average range.

Gummies lie within the defined range. Thus, gummies comply with the test. (Hole AV, Wagh SA, Pabale MS, 2024) (Gupta L, Patil S, Kable R, Sharma D, Shivani Pawar M, 2024) (C. Rani K, U. Hasanah T, Ilmiah B, I. E. Jayani N, 2022) (Jchr.org, 2025)

6. Dispersion time test:

The dispersion time test evaluates how quickly chewable gummies dissolve in aqueous media, simulating the release of active pharmaceutical ingredients (APIs) upon contact with saliva. Significance - A faster dispersion time indicates faster API release i.e quicker dissolution of gummies in saliva can lead to faster absorption and onset of action and rapid dispersion can enhance the bioavailability of APIs. Gummies disperse primarily due to the gelling agent, which is the main ingredient that provides the characteristic chewy texture and allows them to dissolve in the mouth. Here the gelling agent is gelatin. Gummies were dispersed in 10ml phosphate buffer IP at 37°C.Gummies should disperse within 10 mins. (Hole AV, Wagh SA, Pabale MS, 2024) (Gupta L, Patil S, Kable R, Sharma D, Shivani Pawar M, 2024) (C. Rani K, U. Hasanah T, Ilmiah B, I. E. Jayani N, 2022) (Jchr.org, 2025)

7. **Desiccation –**

One gummy was weighed and then crushed in a mortar and pestle. 1g of this sample was weighed and dried for 24hrs in a desiccator. The sample is weighed after 24hrs.

% moisture = initial wet weight – dry weight / dry weight × 100 (Gupta L, Patil S, Kable R, Sharma D, Shivani Pawar M, 2024)

8. **Identification of drug by phytochemical screening**

Phytochemical tests are performed to detect the presence of a component in the plant extract and plant parts.

i. When lead acetate solution is added to aqueous extract the reaction there is occurrence of white precipitate, which indicates the presence of tannins.

ii. On addition of 5% ferric chloride solution to clove oil and alcohol give blue colouration indicating the presence of eugenol.

iii. Mixing of aqueous extract with ferric chloride 5%solution gives a dark colour which infers tannins in clove.

iv. Needle shaped eugenate crystals are obtained due to the reaction of eugenol in the volatile oil and strong KOH.

(Dr. K. R. Khandelwal, 2008)

9. Texture analysis –

Fig. 10 Texture analyzer

The gummies were placed in the texture analyser and the texture was analysed by using a conical probe. Texture analysis test is conducted to evaluate the texture of gummies. (Hole AV, Wagh SA, Pabale MS, 2024) (Gupta L, Patil S, Kable R, Sharma D, Shivani Pawar M, 2024) (C. Rani K, U. Hasanah T, Ilmiah B, I. E. Jayani N, 2022) (Jchr.org, 2025)

10. Stability Studies

The following criteria were used to evaluate the teeth whitening gummies -

A batch of 20 gummies was prepared. 10 gummies were kept in the refrigerator at 2-8 degree Celsius. Other 10 gummies were kept at room temperature. The formulation was kept in the mould in the refrigerator for 15 days to check the stability. Changes in colour, odour, hardness and texture were evaluated.

3.Results

3.1 Gummies exhibited yellow colour, mint odour, soft texture, sweet taste and a cubic shape. This indicates a successful formulation with appropriate ingredients.

Properties	**Inference**
Colour	Yellow
Odour	Mint
Texture	Soft
Taste	Sweet
Shape	Cube

3.2. Dimensional Analysis

The modeling's measure, measured with a vernier calliper, are 1 cm by 1 cm.

The gummies meet the requirement as they do not deviate from the standard.

3.3 pH

Normal pH range: 6.74 to 6.98. Gummies are acidic due to the presence of citric acid.

3.4 Syneresis test

Percentage (%) syneresis was found out to be 0.0006. A significant difference between the initial and final weights indicates the occurrence of syneresis.

3.5 Weight variation

Gummies meet the predefined requirement if its weight does not deviate more than 7.5% from the average range. Gummies lie within the defined range. Thus, gummies comply with the test.

3.6 Dispersion time

Average dispersion time of 3 gummies was found out to be 2.3 mins. Thus, gummies meet the specifications.

3.7 Desiccation

The calculation of percent moisture content was 0.91%.

3.8. Identification of drug by phytochemical screening

The tests for tannins and eugenol were performed and the results are-

Sr no	Tests	Observation	Inference
1	Aqueous extract + Lead acetate solution	White ppt	Tannins
2	Clove oil + alcohol + ferric chloride 5%solution	Blue colorations	Eugenol
3	Aqueous extract + ferric chloride 5%solution	Dark colour	Tannins
4	Strong KOH solution	Needle shaped eugenate crystals	Eugenol in volatile oil

3.9 Texture analysis

By performing the texture analysis test following observations were noted.

1. Hardness of gummies – 15.30 g
2. Springiness – 0.76 mm
3. Stringiness length – 2.93 mm

3.10 Stability Studies

Evaluation Parameter	**Initially**	**After 15 days**
Physical Appearance	Opaque	Opaque
Colour	Yellow	Yellow
pH	Acidic	Acidic
Odour	Pleasant	Pleasant
Texture	Soft	Soft
Hardness	15.30 g	15.30 g

4. Conclusion

The gummies containing *Syzygium aromaticum* (Clove) shows great potential as a cosmetic preparation due to its teeth whitening properties. The batch exhibits favourable organoleptic properties such as soft texture, pleasant odour, acidic pH making it suitable for paediatric use for the purpose of teeth whitening. The stability testing at 2-8 °C, this shows that gummies remain stable. Chewability and hardness were guaranteed by texture analysis that showed hardness of 15. 30g.Phytochemical analysis revealed the presence of eugenol suggesting effective teeth whitening properties in clove. Overall the teeth whitening gummies for paediatric purpose offer safe and effective alternative to conventional synthetic based products.

5. Discussion

The present study focused on the formulation and evaluation of toothpaste gummies using ingredients such as gelatin, mannitol, citric acid, guar gum, clove oil, and starch. The formulation aimed to create a convenient, palatable, and effective alternative to traditional toothpaste, especially suitable for pediatric and geriatric populations.The choice of gelatin as a gelling agent provided desirable texture and chewability, which contributed to the stability and shape retention of the gummies. Guar gum and starch were incorporated as additional binders and thickeners to enhance the structural integrity and control the release of active ingredients during chewing. Mannitol served a dual purpose as a sweetener and humectant, improving taste while maintaining moisture content and preventing crystallization. The presence of citric acid contributed to flavor enhancement and pH regulation, supporting oral hygiene by mildly reducing bacterial growth.The inclusion of clove oil, known for its antimicrobial and analgesic properties, added therapeutic value to the formulation. It not only provided a natural defense against oral pathogens but also contributed to the characteristic flavor profile.Upon evaluation, the formulated toothpaste gummies exhibited satisfactory organoleptic properties, appropriate pH, uniformity of weight, and acceptable mechanical strength. These findings suggest that the formulation is both functional and user-friendly. However, the study also identified areas for improvement, such as optimizing the concentration of gelling agents to achieve a balance between firmness and chewability. Additionally, further microbiological studies are recommended to assess the long-term antimicrobial efficacy and stability of the gummies under various storage conditions.Overall, the research supports the feasibility of developing toothpaste gummies as an innovative and effective alternative for oral care, particularly in populations with difficulty using conventional toothpaste.

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