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Formulation and Evaluation of Herbal Gel for Gingivitis Disease

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ABSTRACT:

Gingivitis is a common and mild form of periodontal disease characterized by inflammation of the gingival tissues (gums). It is primarily caused by the accumulation of dental plaque—a biofilm of bacteria—on the surfaces of the teeth and gums.

Gingivitis is a non-destructive disease that causes inflammation of the gums. The most common form of gingivitis, and the most common form of periodontal disease overall, is in response to bacterial plaque that is attached to tooth surfaces, termed plaque-induced gingivitis.

If left untreated, gingivitis can progress to periodontitis, leading to irreversible damage to the supporting structures of the teeth. Clinical signs of gingivitis include redness, swelling, bleeding during brushing or flossing, and halitosis.

The condition is largely preventable and reversible with proper oral hygiene, including regular brushing, flossing, and professional dental cleanings. Risk factors such as poor oral hygiene, smoking, diabetes, hormonal changes, and certain medications can increase susceptibility to the disease.

Early diagnosis and management are crucial to preventing progression to more severe periodontal conditions.

Keywords: Periodontal disease, inflammation, bleeding, bacterial, gingivitis etc.

Introduction

Many people experience inflamed gums from time to time. Gingivitis, a form of gum inflammation, typically starts without major symptoms initially but can progress to affect other parts of the periodontium the soft tissue and bone that support and anchor our teeth causing damage. Good oral hygiene plays a crucial role in preventing gingivitis. It is an inflammatory condition of the gingival tissue, commonly caused by bacterial infection.

Unlike periodontitis, gingivitis does not involve attachment loss or migration of the junctional epithelium; it is confined to the gingival epithelium and connective tissue. Gingivitis is the most common among all periodontal conditions. It presents in various forms based on clinical appearance, duration, severity, and cause, with the most common form attributed to plaque.

Clinically, inflamed gums are characterized by swelling, redness, tenderness, a shiny appearance, and bleeding upon gentle probing.[2] Gingivitis seldom causes spontaneous bleeding and is generally painless, which may lead many cases to go unnoticed and untreated. Microbial plaque deposits in or near the gingival sulcus are responsible for gingivitis.

The bacteria most commonly associated with its development include Streptococcus, Fusobacterium, Actinomyces, Veillonella, and Treponema species. Other bacteria such as Bacteroides, Capnocytophaga, and Eikenella may also contribute to its etiology.

Additionally, other local or systemic factors can enhance plaque formation or increase the vulnerability of the tissues to microbial attack.

- **Gingivitis disease**

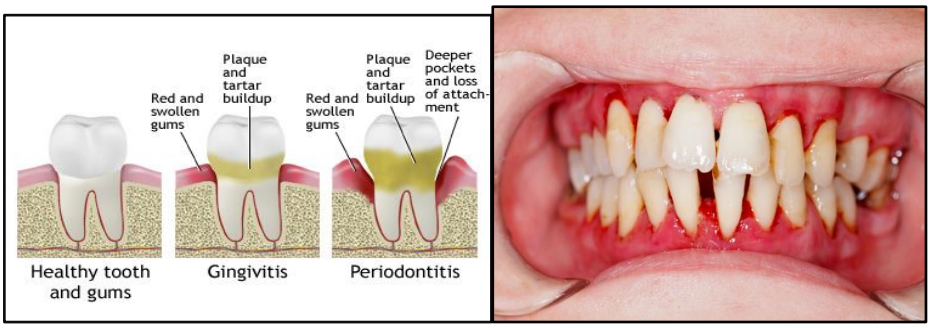

Fig . 1 Gingivitis disease

- **Symptoms of gingivitis include:**

1. Swollen or puffy gums.
2. Bright red or dark red gums, or gums that are darker than usual.
3. Gums that bleed easily when you brush or floss.
4. Tender gums.
5. Bad breath.

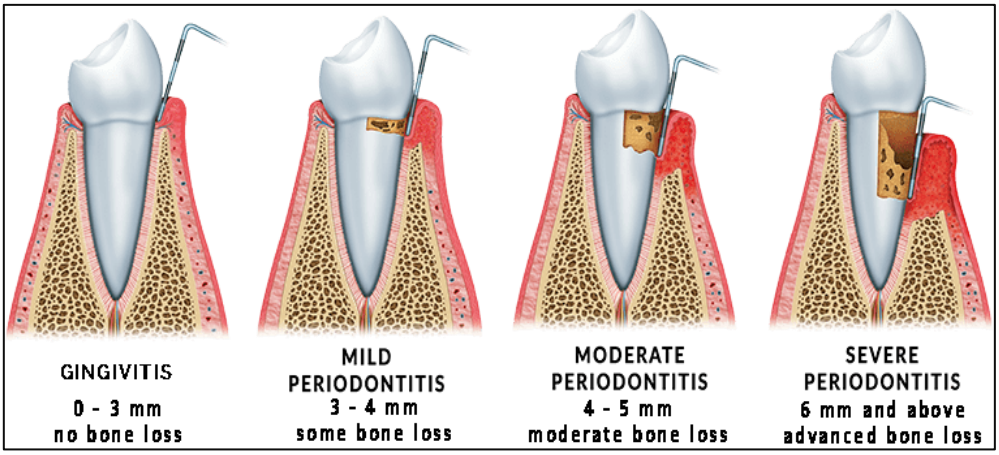

Fig .2 Stages of gingivitis disease (bone loss)

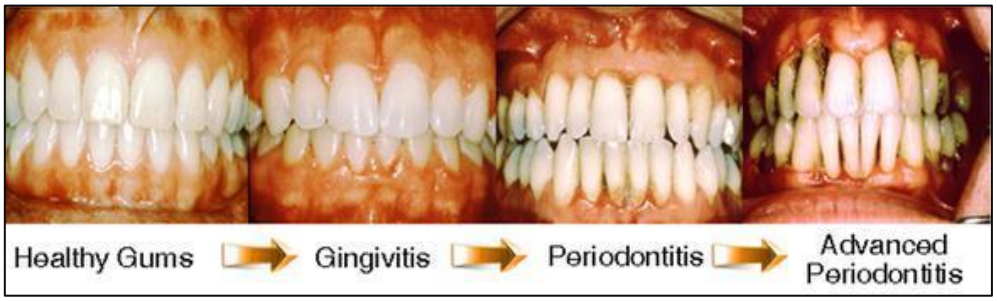

Fig .3 Stages tof gingivitis disease (healthy gums to periodontitis)

- **Causes of Gingivitis**

The primary cause is plaque—a sticky, colorless film of bacteria that forms on your teeth. If not removed by daily brushing and flossing, plaque can harden into tartar, which further irritates the gums.

Other contributing factors include:

- Poor oral hygiene
- Smoking or chewing tobacco
- Diabetes

- Hormonal changes (e.g., pregnancy, puberty)
- Certain medications (that reduce saliva or cause gum overgrowth)
- Poor nutrition, especially vitamin C deficiency
- Illnesses that affect the immune system (e.g., HIV/AIDS, cancer)

Types of Gingivitis

- **Plaque-Induced Gingivitis** : Most common, caused by plaque.
- **Non-Plaque-Induced Gingivitis** : Due to systemic disease, medication, or allergic reaction.
- **Hormonal Gingivitis**: Common in pregnancy or puberty.

The gingival lump can be graded into four types:

• **Grade 0** No signs of gingival lump.

• **Grade I** Swelling that's confined to the interdental papilla region.

• **Grade II** Swelling involving both the interdental papilla and the borderline gingiva.

• **Grade III** Swelling that covers three- fourths or further of the crown structure.

The flavonoids and tannins present in these plant are potent anti-inflammatoryy and tangy phytochemicals. thus, they can resolve both gingival bleeding and inflammation.

Some studies proved that there's a synergistic effect when the herbal shops are specified along with conventional mechanical procedures of shrine junking, similar as scaling.

- **Complications If Untreated**
- **Periodontitis**: A severe gum infection damaging soft tissue and bone.
- **Tooth loss**
- **Abscesses**: Pus-filled infections.
- **Systemic health issues**: Linked to heart disease, stroke, diabetes complications, and respiratory issues.

Fig .4 Acute periodontitis

Objective.

Many people experience inflamed gums from time to time. Gingivitis, a form of gum inflammation, typically starts without major symptoms initially but can progress to affect other parts of the periodontium the soft tissue and bone that support and anchor our teeth causing damage. Good oral hygiene plays a crucial role in preventing gingivitis. It is an inflammatory condition of the gingival tissue, commonly caused by bacterial infection.

Unlike periodontitis, gingivitis does not involve attachment loss or migration of the junctional epithelium; it is confined to the gingival epithelium and connective tissue. Gingivitis is the most common among all periodontal conditions. It presents in various forms based on clinical appearance, duration, severity, and cause, with the most common form attributed to plaque.

Clinically, inflamed gums are characterized by swelling, redness, tenderness, a shiny appearance, and bleeding upon gentle probing.[2] Gingivitis seldom causes spontaneous bleeding and is generally painless, which may lead many cases to go unnoticed and untreated. Microbial plaque deposits in or near the gingival sulcus are responsible for gingivitis.

The bacteria most commonly associated with its development include Streptococcus, Fusobacterium, Actinomyces, Veillonella, and Treponema species. Other bacteria such as Bacteroides, Capnocytophaga, and Eikenella may also contribute to its etiology.

Additionally, other local or systemic factors can enhance plaque formation or increase the vulnerability of the tissues to microbial attack.

Plan of work :

Literature Review

- Study the pathophysiology of gingivitis.
- Review conventional treatments and their limitations.
- Explore the pharmacological properties of selected herbal ingredients (e.g., aloe vera, turmeric, pomegranate, ginger, beetroot).
- Review existing herbal formulations and their outcomes.

Selection of Herbal Ingredients and Excipients

- Choose herbs with anti-inflammatory, antimicrobial, antioxidant, and wound-healing properties.
- Finalize excipients (e.g., Carbopol, Glycerin, Triethanolamine, Sodium benzoate) for gel formulation.
- Determine suitable natural preservatives and flavoring agents (e.g., Peppermint oil).

Preparation of Herbal Extracts

- Collect and authenticate plant materials.
- Use appropriate extraction methods (e.g., maceration, Soxhlet).
- Standardize and store extracts under suitable conditions.

Formulation of Herbal Gel (Batch Development)

- Prepare multiple batches (e.g., Batch 1, 2, and 3) with varying concentrations of herbal extracts.
- Incorporate excipients and adjust physical parameters (pH, viscosity, spreadability).

Evaluation of Formulations

A. Physical Parameters

- Color, odor, appearance, pH, viscosity, spreadability, homogeneity.

B. Chemical Stability

- Evaluate pH and physical stability over time (accelerated stability testing).

C. Antimicrobial Testing

DRUG PROFILE:

Collection and authentication of herbal plants:

The plant materials of Alovera, ginger, neem, pomegranate,turmeric were collected from college and home premises. The collected leaves of neem , rhizome of turmeric and ginger , peels of pomegranate were washed and dried under shade, glycerin, carbapol 934, sodium benzoate, peppermint oil ,triethanolamine are taken from the college lab and used as smoothing agent.

After proper drying, all materials were grinded using mixer and the powders were passed through sieve no.80 and 60 to get a fine powder.

This study was performed to expedite a new formulation and evaluation of formulated herbal gel for gingivitis disease to know their effectiveness against the minor gums problems**.**

Fig no. 1 All collected herbal ingredients

Aloe vera **(aloe barbadensis mill) –**

Fig .no. 2 Aloe vera

Synonyms of Aloe vera:

- Common Names: Aloe, Ghrita-kumari (Sanskrit), Kumari (Hindi)
- Scientific Synonyms: *Aloe barbadensis Mill, Aloe indica Royle.*

Family: Asphodelaceae (previously classified under Liliaceae)

Biological Source: Aloe vera is the dried juice or gel obtained from the leaves of *Aloe barbadensis* Miller, a succulent plant

Chemical Constituents:

- Polysaccharides: Acemannan (main bioactive mucopolysaccharide)
- Anthraquinones: Aloin, Emodin, Aloe-emodin (mostly in latex)

Medicinal Uses:

- Wound healing – Promotes skin repair and regeneration..
- Anti-inflammatory – Reduces inflammation in conditions like arthritis and burns.
- Antiseptic – Helps prevent infection in wounds and burns.

Health Benefits: Enhances immunity due to antioxidants, Supports oral health

(used in mouthwash and toothpaste).

Neem (azadirachta indica) –

Fig. no. 2 Neem

Synonyms : Scientific Name: *Azadirachta indica*

Common Names: Neem, Margosa tree

Family: Meliaceae (Mahogany family)

Biological Source:

Neem comes from the leaves, bark, seeds, and oil of the tree *Azadirachta indica*, which grows mainly in India and other tropical countries

Chemical Constituents of Neem:

Neem is rich in bioactive compounds, mainly limonoids, terpenoids, flavonoids, alkaloids, and tannins.

Class of Compound	**Example Compounds**	**Main Effects**
Limonoids (Triterpenoids)	Azadirachtin, Nimbin, Nimbinin, Salannin, Gedunin	Insecticidal, antimicrobial, anti-inflammatory

Medicinal Uses:

- neem has strong antibacterial and antifungal properties.
- Tooth and Gum Care: Neem sticks (twigs) are used to brush teeth and fight gum diseases.
- Digestive Health: Neem juice or tablets can improve digestion and help with worms and ulcers.
- Diabetes: Neem may help lower blood sugar levels.

***Turmeric* (curcuma longa) -**

Fig.no. 3 Turmeric

Synonyms:

- **Scientific Name**: *Curcuma longa*
- **Common Names**: Turmeric, Haldi

Family: Zingiberaceae (Ginger family)

Biological Source:

- Turmeric is obtained from the dried rhizomes (underground stems) of the plant *Curcuma longa*.

Chemical Constituents:

- Curcumin – the main active ingredient (gives turmeric its yellow color)
- Volatile oils – such as turmerone, atlantone, and zingiberene

Medical Uses :

- Turmeric is widely used in traditional and modern medicine because it has many health benefits:
- Anti-inflammatory – Helps reduce swelling and pain in conditions like arthritis.
- Antioxidant – Protects the body from harmful free radicals.

Ginger (zingiber officinale) –

Fig. no. 4 Ginger

Synonyms:

- **Scientific Name**: *Zingiber officinale*
- **Common Names**: Ginger

Family: Zingiberaceae (Ginger family)

Biological Source:

Ginger is the underground rhizome (stem) of the plant *Zingiber officinale*, used both fresh and dried.

Chemical Constituents:

- Gingerols – main active compound in fresh ginger (anti-inflammatory)
- Shogaols – formed when ginger is dried or cooked (stronger than gingerols)

Medicinal Uses;

- Relieves Nausea – Great for motion sickness, morning sickness, and upset stomach.
- Aids Digestion – Helps reduce bloating, gas, and indigestion.
- Reduces Inflammation – Useful in arthritis and joint pain.

Pomegranate(punica granatum)

Fig.no 5 Pomegranate

Synonyms:

- **Scientific Name**: *Punica granatum*
- **Common Names**: Pomegranate

Family: Lythraceae (formerly placed in the Punicaceae family)

Biological Source:

- The biological source of pomegranate is the fresh or dried fruit of the plant *Punica granatum*.
- Parts used: Fruit (arils, peel, seeds), rind, and sometimes the leaves and bark.

Chemical Constituents:

- Punicalagins – Powerful antioxidants found in the peel and juice
- Ellagic Acid – Antioxidant with anti-cancer properties

Medical Uses:

Pomegranate has a wide range of medicinal uses, both traditionally and in modern times:

- Antioxidant – The high levels of antioxidants protect the body from oxidative stress and free radical damage.
- Anti-inflammatory – Helps reduce inflammation, making it useful for arthritis and other inflammatory conditions.

Beet root (beta vulgaris) –

Fig.no. 6 Beet root

Synonyms (Other Names):

- **Scientific Name**: *Beta vulgaris*

- **Common Names**: Beet, Beetroot
- **Family**:Amaranthaceae
  (Previously classified under Chenopodiaceae)

Biological Source:

- Part Used: Fleshy root (taproot), and sometimes the leaves (beet greens)

Chemical Constituents:

- Betalains – Natural pigments (mainly betacyanins like betanin) that give beetroot its deep red color and antioxidant power.
- Nitrates – Convert to nitric oxide in the body, improving blood flow and reducing blood pressure.
- Flavonoids – Antioxidants like kaempferol.

Medicinal Uses:

- Anemia Treatment – Due to high iron and folate content, it helps increase red blood cell production.
- Blood Pressure Control – Dietary nitrates help lower high blood pressure by improving blood vessel dilation.
- Anti-inflammatory – Helps reduce inflammation in the body.

EXCIPIENTS PROFILE:

- ***CARBAPOL 934 :***

Fig no. 1 carbapol 934

Carbopol 937 is a synthetic high-molecular-weight polymer of acrylic acid,

crosslinked with polyalkenyl ethers or divinyl glycol.

It is commonly used in pharmaceutical and cosmetic formulations as a gel-forming agent, thickener, suspending agent, or stabilizer.

Carbopol 937 as an Excipient in Gels

Key Characteristics:

- **Appearance:** White, fluffy, hygroscopic powder
- **pH Range for Gel Formation:** 6.0–7.0 (neutralized with a base like triethanolamine or sodium hydroxide)
- **Viscosity:** High; suitable for creating clear gels
- **Swelling Behavior:** Swells in water to form colloidal dispersions

Role as an Excipient in Gels:

1. **Thickening Agent:** Provides the desired consistency and texture in topical or transdermal gels.
2. **Suspending Agent:** Helps suspend insoluble ingredients (e.g., APIs, colorants).
3. **Stabilizer:** Improves the stability of emulsions or gel-based formulations.

4. **Controlled Release:** Can modulate the release profile of active pharmaceutical ingredients (APIs).

➢ ***Sodium benzoate :***

Fig no.2 sodium benzoate

sodium benzoate is widely used as an excipient functioning as a preservative agent in gel formulations, particularly water-based gels such as topical pharmaceutical or cosmetic gels.

 Sodium Benzoate as a Preservative Excipient in Gel Formulations

✅ **Excipient Role:**

- **Function:** Antimicrobial preservative
- **Type:** Synthetic, generally recognized as safe (GRAS)
- **Classification:** Pharmacopoeial excipient (found in USP, Ph. Eur.)

📋 **Technical Summary:**

Property	**Details**
Effective concentration	0.1% – 0.3% (typical use: 0.1–0.2%)
Solubility	Freely soluble in water
Antimicrobial spectrum	Primarily antifungal; mild antibacterial
Optimal pH range	**4.0–5.5** (less effective at pH > 6.5)
Form	White crystalline powder or granules
Stability	Stable under normal conditions

➢ ***Glycerin :***

Fig no. 3 glycerin

Glycerin is not the active treatment for gingivitis but plays an important supportive role as an excipient in formulations for conditions like gingivitis.

✅ **Functions of Glycerin in Gingivitis Gels:**

Function	Explanation
Humectant	Attracts and retains moisture, keeping the gel from drying out and maintaining hydration in the oral mucosa.
Solvent	Helps dissolve certain active ingredients or preservatives.
Texture Enhancer	Improves spreadability and smoothness of the gel.
Stabilizer	Contributes to physical and chemical stability of the gel.
Mild sweetener	Provides a slight sweet taste, enhancing patient acceptability.
Soothing effect	Gentle on irritated or inflamed mucosal tissues.

💊 **Typical Actives in Gingivitis Gels:**

Glycerin is commonly used in gels that include actives such as:

- Chlorhexidine gluconate (antibacterial)
- Triclosan
- Aloe vera extract
- Curcumin or herbal extracts

➢ ***TRIETHYLAMINE :***

Triethylamine (TEA) is used in gels—including those for gingivitis treatment—primarily as a pH adjuster or neutralizing agent, not as an active or therapeutic component.

 Role of Triethylamine in Gels for Gingivitis

Function	Description
pH Adjuster / Neutralizer	TEA is used to neutralize acidic gelling agents like Carbopol (carbomer), enabling the gel to thicken and form a stable matrix.
Gel Structure Builder	Helps in forming a smooth, clear gel by activating the thickening properties of Carbopol polymers.
Non-active excipient	TEA itself does not provide antimicrobial or therapeutic benefits for gingivitis.

➢ ***Peppermint oil :***

Using peppermint oil in an herbal gel for gingivitis can be a beneficial natural approach, thanks to peppermint's antibacterial, anti-inflammatory, and cooling properties. When formulated correctly, such a gel can help reduce gum inflammation, kill harmful oral bacteria, and provide soothing relief from pain and swelling.

How Peppermint Oil Helps with Gingivitis ?

- Menthol (the active component in peppermint oil) has antimicrobial effects, helping to kill bacteria that cause plaque and gum disease.
- Reduces gum swelling and irritation
- Provides a cool, numbing sensation, which can ease discomfort
- Helps with bad breath, a common symptom of gum infections .

Literature survey:

1] Manu Rathee et al.,(2022)

Highlights the Describe the etiology and pathogenesis of gingivitis. Identify the clinical signs and symptoms of gingivitis. Review the treatment options for patients with gingivitis. Outline the importance of improving care coordination among the interprofessional team to enhance the delivery of care for patients affected by gingivitis

2] Rakesh K. Sindhu et al., (2022)

This study examined the most recent advancements in nanogel production and drug delivery. Phytochemistry is a discipline of chemistry that studies herbal compounds. Herbal substances have aided in the development of innovative remedies for a wide range of illnesses. Several of these compounds are forbidden from being used in medications due to broad medical characteristics and pharmacokinetics

4] Aparna C et al., (2022)

Nanogels have been helpful in providing the better action or potenc-y of the drug due to their small particle size, as the less the particle size the more the surface area and hence more the action. So far studies over nanogels have collected enough evidence to prove nanogels as potential targeting carriers that can deliver bioactive substances by topical delivery of skin for conditions like skin cancer, wounds, inflammation, local anesthesia, etc

5] Pallavi M. Chaudhari et al., (2020)

This review will focus on the nanogel for herbal medicines with high delivery rate, patient compliance and efficiency. A nanoparticles contained hydrogel with cross linked polymer networks called as ‘Nanogel’. Nanogel preferred for herbal medicines due to stability and for the ease. Nanogels in terms of herbal drugs are promising and novel approach which also can be called as future generation drug delivery systems owing to high drug encapsulation capacity, uniformity, minimum toxicity and greater stability.

6] Sharma s et al., (2020)

They've reported ayurveda is one of the world’s oldest systems of drug. It began in India andhas evolved there over thousands of times. The term “ Ayurveda ” combines also Sanskrit words ayur(life) andveda(wisdom or knowledge). Some herbal products, including numerous Date 2023-06- 15 Words 1000 Characters 7245 Page 1 of 3 traditional drug phrasings, also include beast products and minerals. Herbal products are vended as either raw shops or excerpts of portions of the factory or in the form expression i.e. tablet, capsule, saccharinity, cream and ointment etc.

MATERIAL AND METHODS :

Fig no. 1 Material / Ingredients used

NO.	Equipment	Ingredients/Excipients Processed
1	Grinder / Pulverizer	Neem, Ginger, Turmeric, Pomegranate Peel, Beetroot juice
2	Hot Plate / Water Bath	All ingredients requiring heat processing
3	Beaker (Borosilicate)	All ingredients
4	Magnetic Stirrer with Hot Plate	Carbopol 937, Ethylamine, Glycerin,Peppermint oil sodium benzoate Herbal Extracts
5	Mortar and Pestle	Ginger, Neem, Turmeric, etc.
6	Soxhlet Apparatus / Maceration Jar	Neem, Ginger, Pomegranate, Turmeric, Beetroot
7	Filtration Unit (Whatman Filter)	All herbal extracts
8	pH Meter	Final gel formulation
9	Weighing Balance (Digital)	All ingredients and excipients
10	Gel Filling Machine (Manual/Semi-auto)	Final gel formulation
11	Storage Containers (Amber Glass)	Extracts, Finished Gel
12	Measuring Cylinder	Glycerin, Aloe Vera Juice, Extracts
13	Spatula / Stirring Rod	All components

Table no. 1 Ingredients and Equipments Table Of Herbal Gel For Gingivitis

- **Herbal Extraction by Boiling Method (Decoction):**

Fig no. 2 Extraction processes

- **Purpose:**

To extract water-soluble active constituents from plant materials for use in a gingivitis treatment gel.

- **Ingredients & Raw Materials:**

Plant Material	Suggested Form	Approx. Quantity (for 100 mL decoction each)
Aloe vera	Fresh gel/pulp	25–30 g (peeled inner gel)
Neem leaves	Fresh/dried	20 g fresh or 10 g dried
Ginger	Fresh root	15 g sliced
Turmeric	Fresh/dried	10 g fresh or 5 g dried powder
Pomegranate peel	Dried peel	10–15 g
Beetroot	Fresh root	25–30 g sliced
Purified Water	-	200–300 mL per batch (top-up as needed)

Table no. 2 Raw material quantity

- **Extraction Procedure**:

Step 1: Preparation of Raw Materials

- Wash all plant materials thoroughly under running water.
- Chop or slice fresh ingredients (Aloe vera, ginger, turmeric, beetroot) into small pieces.
- If using dried materials (like neem leaves or pomegranate peel), crush lightly.

Step 2: Boiling Process (Decoction)

Combine the plant materials in a stainless steel pot.

- Add water (200–300 mL total or enough to submerge materials).
- Bring the mixture to a boil over medium heat.
- Simmer gently for 30–45 minutes with the lid partially on, stirring occasionally.
- Top up water during boiling to maintain volume if needed.
- Stop heating when the volume reduces to half and the extract appears rich in color and aroma.

Step 3: Filtration

- While warm, filter the extract using muslin cloth or fine mesh to remove solids.
- Press or squeeze the plant residue gently to extract more liquid.

Step 4: Cooling & Storage

- Let the filtrate cool to room temperature.
- Store in a clean amber bottle in the refrigerator.
- Use within 3–5 days unless preserved with sodium benzoate or similar agent.

METHODS OF PREPARATION:

FORMULATION TABLE:

Ingredient	Function	Formula 1 (g)	Formula 2 (g)	Formula 3 (g)
Aloe vera extract	Healing, soothing	5.0	5.0	5.0
Turmeric extract	Anti-inflammatory	1.5	1.5	1.5
Ginger extract	Antimicrobial	1.0	1.0	1.0
Neem extract	Antibacterial	2.0	2.0	2.0
Pomegranate extract	Antioxidant	2.0	2.0	2.0
Beetroot extract	Anti-inflammatory	1.0	1.0	1.0
Peppermint oil	Flavor, antimicrobial	0.2	0.3	0.25
Carbopol 937	Gelling agent	1.0	0.8	1.2
Sodium benzoate	Preservative	0.1	0.15	0.2
Glycerin	Humectant	3.0	4.0	2.5
Triethanolamine (TEA)	pH adjuster (q.s.)	q.s.	q.s.	q.s.
Purified Water	Vehicle (q.s.)	to 50 g	to 50 g	to 50 g

Table .no. 3 Formulation Table For Herbal Gel For Gingivitis Disease

PROCEDURE:

1. **Weighing :** Accurately weigh all the raw materials (active ingredients and excipients) using a digital weighing balance.
2. **Grinding :**Dry the raw herbal materials (Neem leaves, Turmeric, Ginger, and Pomegranate peel), then grind them into a fine powder using a grinder or pulverizer.
3. **Shifting :** Pass the herbal powders through a sieve (e.g., mesh #60) to ensure uniform particle size and remove coarse particles.
4. **Preparation of Gel Base :** Disperse Carbopol 937 in distilled water and allow it to swell and hydrate for at least 1–2 hours. Stir gently to avoid air bubbles.
5. **Addition of Glycerin :**Add Glycerin to the hydrated Carbopol mixture. Mix well to obtain a smooth gel-like base.
6. **Incorporation of Herbal Actives :** Add the Aloe Vera gel, followed by the finely powdered herbal ingredients (Neem, Turmeric, Ginger, and Pomegranate). Stir thoroughly to ensure even distribution.
7. **Addition of Preservative and Flavor :** Add Sodium Benzoate (preservative) and Peppermint Oil (for flavor and soothing effect) into the gel mixture. Mix well.
8. **pH Adjustment:** Adjust the pH of the gel to around 6.5–7.0 by slowly adding Triethanolamine. Stir continuously until the gel becomes clear and uniform.
9. **Consistency Checking:** Visually check and manually test the consistency of the gel to ensure it is smooth, non-gritty, and of appropriate viscosity.
10. **Pouring:** Pour the finished gel into pre-cleaned and sterilized containers or tubes while slightly warm or at room temperature.

11. **Cooling :** Allow the gel to cool completely to room temperature, if not already done.
12. **Storage:** Store the containers in a cool, dry place away from direct light to maintain stability.
13. **Packing and Dispensing :** Label the gel containers properly with the formulation details, manufacturing and expiry date, and usage instructions. Dispense as per requirement.

EVALUATION PARAMETERS:

On herbal gel for gingivitis, your evaluation should cover both scientific and product-development aspects. The parameters and tests should help determine:

- **Safety**
- **Efficacy**
- **Stability**
- **Patient acceptability**

1. Evaluation Tests for Herbal Gel (Scientific Parameters)

A. Physicochemical Parameters

1. **Appearance / Color / Odor / Texture** – Visual inspection
2. **pH** – Should be ~5.5 to 7 (compatible with oral mucosa)
3. **Viscosity** – Use Brookfield viscometer
4. **Spreadability** – To assess ease of application
5. **Homogeneity** – Uniform distribution of herbal content
6. **Extrudability** – How easily gel is expelled from the tube/jar

B. Microbiological Tests

1. Antibacterial activity – *In vitro* testing against *Porphyromonas gingivalis*, *Streptococcus mutans*, etc.
    - Agar well diffusion method
2. Preservative efficacy test – Check microbial contamination over time

C. Phytochemical Screening

- To confirm the presence of key active components (e.g., tannins, flavonoids, alkaloids)

D. Stability Studies (per ICH guidelines)

- Store gel at different temperatures (e.g., 4°C, room temp, 40°C)
- Monitor over 3 to 6 months for changes in pH, viscosity, color, etc.

E. In-Vivo / Clinical Evaluation

- Small volunteer group (ethical approval needed)
- Gingival Index and Plaque Index scoring before and after use (e.g., Loe and Silness Index)
- Duration: 1 to 4 weeks

2. Important Parameters

Parameter	**Method/Test**	**Ideal Range/Standard**
pH	Digital pH meter	5.5–7.0
Viscosity	Brookfield viscometer	Depends on formulation
Antibacterial activity	Agar diffusion method	Zone of inhibition (mm)
Gingival Index	Loe and Silness scoring	Reduction indicates efficacy

Plaque Index	Silness and Loe Index	Reduction post-treatment
Stability	ICH Q1A guidelines	No major change over time
Spreadability	Glass slide method	High spreadability desirable
Phytochemical content	TLC, HPTLC, or spectrophotometric analysis	Varies by herb used

3. Microbial Evaluation

Test	**Method**
Total Viable Count (TVC)	Plate the gel on nutrient agar to check for bacterial growth (CFU/mL). Should comply with pharmacopeial limits.
Fungal Count	Use Sabouraud dextrose agar to detect yeasts and molds.
Preservative Effectiveness (PET)	Challenge test (optional): Inoculate gel with known microbes and assess preservative activity over time.

❖ **RESULT REPORT – HERBA GEL FOR GENGIVITIS:**

Test Parameter	**Method Used**	**Observed Result**	**Standard/Limit**	**Conclusion**
Appearance	Visual observation	Smooth, reddish-pink gel	Uniform, smooth, colored gel	Pass
Odor	Organoleptic	Pleasant herbal, peppermint	Acceptable aroma	Pass
pH	Digital pH meter	6.5	6.0 – 7.0	Pass
Viscosity	Brookfield Viscometer	48,000 cps (Spindl4, 10 rpm)	30,000 – 60,000 cps	Pass
Spreadability	Glass slide method	e13.5 g·cm/sec	≥ 10 g·cm/sec	Pass
Grittiness	Touch and visual	None detected	Should be smooth	Pass
Homogeneity	Visual, glass slide method	No lumps or separation	Homogeneous	Pass
Total Microbial Count	Plate count (Nutrient agar)	<10 CFU/g	<1000 CFU/g	Pass
Total Fungal Count	Sabouraud agar	Nil detected	<100 CFU/g	Pass
Pathogens (E. coli, S. aureus)	Selective media	Absent	Absent	Pass
Stability – 25°C (2 weeks)	Observation	No change in pH, color	Stable	Pass
Stability – 40°C (2 weeks)	Observation	Slight viscosity drop, acceptable	Stable	Pass
Antibacterial Activity	Agar well diffusion (*S. mutans*)	15 mm zone of inhibition	≥10 mm zone	Pass

Discussion:

A herbal gel composed of Aloe vera, Turmeric (*Curcuma longa*), Ginger (*Zingiber officinale*), Pomegranate (*Punica granatum*), and Neem (*Azadirachta indica*) was developed to manage gingivitis. The gel was reddish in appearance, primarily due to pomegranate extract and turmeric, which contain anthocyanins and curcuminoids respectively—both known for their bioactive properties**.**

The reddish herbal gel demonstrated promising anti-inflammatory, antimicrobial, and antioxidant effects in the management of gingivitis. The synergistic combination of Aloe vera, Turmeric, Ginger, Pomegranate, and Neem contributed to the observed therapeutic outcomes.

Fig no. 1 Actual photograph of formulated herbal gel for gingivitis disease

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