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TOPIC NAME -SPIRULINA LOZENGES: FOR OVERALL ORAL HYGIENE & ITS CARE

Girish Pratap Patil[1], Mohit Dipak Borse[2], Swapnil D Deo[3]
Dr. Uttamrao Mahajan College of B Pharmacy, Chalisgaon

1.ABSTRACT

Spirulina, a nutrient-dense blue-green algae, has gained increasing attention in the field of natural health products due to its rich content of proteins, vitamins, minerals, and antioxidants. This study explores the formulation and potential benefits of Spirulina-based lozenges as a novel approach to support oral hygiene. The lozenges are designed not only to deliver the nutritional benefits of Spirulina but also to promote oral health by inhibiting the growth of harmful bacteria, reducing inflammation, and supporting fresh breath. Their slow dissolution in the oral cavity ensures prolonged contact with the mucosa, maximizing local therapeutic effects. Preliminary findings suggest that Spirulina lozenges may help in reducing plaque formation, soothing gum inflammation, and maintaining oral microbial balance. This natural, non-invasive oral care solution offers a promising complementary strategy for improving oral hygiene and overall oral care, especially in populations seeking plant-based or holistic health alternatives. Spirulina, a nutrient-rich blue-green algae, is recognized for its high content of proteins, vitamins, minerals, and antioxidants, making it a valuable component in natural health products. This study investigates the development and oral health benefits of Spirulina-based lozenges as a novel, plant-based approach to oral hygiene. Designed for slow dissolution in the mouth, these lozenges enhance mucosal contact time, facilitating the localized therapeutic effects of Spirulina. Key benefits include antibacterial action, reduction of oral inflammation, prevention of plaque buildup, and promotion of fresh breath. Preliminary observations indicate that Spirulina lozenges may contribute to maintaining oral microbial balance and improving overall oral care. This natural, non-invasive formulation offers a promising alternative for individuals seeking holistic and sustainable oral hygiene solutions.

KEYWORDS: *Spirulina, Natural Health Products, Phycocyanin, Sustainable Nutrition, Immune Support, Holistic Care, Lozenges, Antioxidants, Antimicrobial, Anti-Inflammatory, Oral Health.*

2. INTRODUCTION

2.1. Lozenges :- Lozenges are the flavourized medicated dosage form intended to be sucked and held in the mouth or pharynx containing one or more medicaments usually in the sweetened base. Lozenges are intended to relieve oropharyngeal symptoms, which are commonly caused by local infections and also it provides systemic effect, the drug is well absorbed through the buccal linings or when it is swallowed. They are usually used for throat pain as well as irritation into throat extensively used to deliver the drug having topical anesthetic effect and also antibacterial effect[1]

Definition: "**Lozenges are solid dosage form containing the flavoring and sweetening agents that are intended to dissolve or disintegrate slowly in the mouth or oral cavity".** They are most often used for localized effect into oral cavity and can also show systemic effect if it is well absorbed in the buccal lining and phar Most lozenges can be bought over-the-counter and work by dissolving in the mouth gradually as you suck them, greasing up the throat coating, and decreasing the dryness and irritation and inflammation of the throat. Various brands of lozenges have different combinations of ingredients and various blends of fixings. They are used either for local or systematic action through the oral cavity. Lozenges are utilized for the delivery of analgesics, sedatives, antimicrobials, antihistamines, cleaning agents, antitussives, aromatics, astringents, corticosteroids, decongestants, demulcents and different classes, and combinations of medications [2] .

2.2. Mouth Ulcer :- Oral/mouth ulcers are painful lesions that are open sores or Îcanker sores. Gum, lip, inner cheek, and palate ulcers can develop in the mouth. A mouth ulcer is the loss or erosion of the mucosal membrane, the fragile tissue that lines the mouth. Keep in mind that mouth sores are distinct from cold sores, which are brought on by a virus that manifests itself in the lips. Canker sores, cold sores, leukoplakia (a thick white or grey area), and candidiasis or thrush (a fungal infection) are the most prevalent types of mouth sores. The erosion or loss of some of the fragile tissue lining inside of the mouth in mouth ulcers. Mouth ulcer The oral area is where ulcers are most frequently found, and patients typically seek medical or dental attention for these conditions. Common symptoms include discomfort, a burning feeling, and/or redness. They can appear anywhere in the oral cavity, but if they do so in the moveable area, they could be uncomfortable.[3] An ulcer that develops on the mucous membrane of the oral cavity is known as a mouth ulcer, also known as an oral ulcer or a mucosal ulcer. Usually, on the

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Fig. No 1 – Mouth Ulcer

inside of the cheeks or lips, these are painful round or oval sores that develop in the mouth. Mouth ulcers are fairly frequent and can be brought on by a variety of diseases and procedures, although most of the time they have no major underlying causes. Nutritional deficiencies, such as iron deficiency, vitamin deficiencies, particularly B12 and C, poor dental hygiene, infections, stress, indigestion, mechanical damage, food allergies, hormonal imbalance, skin conditions, etc. are common causes of mouth ulcers. Mouth ulcers often referred to as aphthousulcers, might hurt when drinking, eating, or cleaning your teeth. [4]Ulcer is a break in continuity of the epithelium by molecular necrosis. Ulcers are most common in the oral region, for which the patient consults physician/dental surgeon. The chief complaints are usually redness, burning sensation and pain.

2.3. Causes of oral / mouth ulcer [7] **:-** Causes of mouth ulcers Most single mouth ulcers are caused by things you can try to avoid, such as

1.**Biting** the inside of your cheek badly fitting dentures, braces, rough fillings or a sharp tooth cuts or burns while eating or drinking – for example, hard food or hot drinks a food intolerance or allergy damaging your gums with a toothbrush or irritating toothpaste feeling tired, stressed or anxious Sometimes they're triggered by things you cannot always control, such as:

2.**Hormonal changes** – such as during pregnancy your genes – some families get mouth ulcers more often a vitamin deficiency, such as iron, zinc, folic acid, vitamin B or vitamin D medicines – including some NSAIDs, beta blockers or nicorandil stopping smoking – people may develop mouth ulcers when they first stop smoking.

3.**Injuries**: Biting your cheek, tongue, or lip, or cutting or burning your mouth while eating or drinking Ill-fitting teeth: Dentures, braces, or sharp or broken teeth that rub against your mouth.

4.**Toothbrush or toothpaste**: Damaging your gums with a toothbrush or using toothpaste with sodium lauryl sulfate.

5.**Stress and anxiety**: Feeling stressed or anxious can make mouth ulcers worse.

6.**Hormonal changes**: Some women develop mouth ulcers during their menstrual period..

Medications: A reaction to certain medications

- Vitamin deficiencies: A deficiency in vitamin B2, folate, or iron.
- Gastrointestinal disease: Crohn's disease or celiac disease.
- Autoimmune diseases: Such as Behçet's disease.
- Weakened immune system: A weakened immune system can make mouth ulcers more likely Mouth ulcers may be benign, but they can also be a sign of something more serious, like cancer. If an ulcer persists for more than a couple of weeks, it's important to get it checked out by a doctor.
- Burns: From hot food or drinks
- Food: Eating certain foods, such as chocolate, spicy foods, coffee, peanuts, almonds, strawberries, cheese, tomatoes, and wheat flour
- Stress: Feeling tired, stressed, or anxious
- Hormonal changes: Some women develop mouth ulcers during their monthly period

2.4. Classification of oral ulcerative agents :[7]

Traumatic Ulcers: The most common ulcer is traumatic ulcer, and it is acute in nature. The ulcers are usually caused by physical, thermal, or chemicalrauma to the oral mucosa. Physical trauma can be caused during regular activities like tooth brushing or flossing and even the sharp edges of denture or tooth and sometimes it can be selfinflicted by the patient when he/she is under local anesthesia during a dental procedure [8]The commonly encountered thermal burns are from hot food substances or beverages like pizza, coffee or tea or from a heated dental instrument during a dental procedure. Oral mucosal damage can be from the unintentional use of therapeutic agents during dental procedures such as eugenol, formocresol, sodium hypochlorite, and monomer. Chemical burns due to aspirin are seen in patients who keep the aspirin tablet sublingual to relieve pain [8] Mucosal alterations can also be from mouthwashes or oral hygiene products with high alcohol content. Lips are the common site for electrical burns. Burn injuries from food are small and localized to the hard palate and lips. These present with pain and an area of erythema that develop into ulcers which may take several days to heal depending on the extent of trauma. The ulcers have a yellowish-white necrotic pseudomembrane with raised and erythematous borders. Ulcers in the lip are usually crusted [9]The traumatic ulcers usually heal within 7-10 days if the cause is removed. It is important to distinguish traumatic ulcers from squamous

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cell carcinoma. If the ulcer does not heal within two weeks, a biopsy is recommended to rule out a deep fungal infection or malignancy [8] These ulcers are usually single, but syphilis may present as single ulcers in primary and tertiary stages. Necrotizing Sialometaplasia:

Necrotizing Sialometaplasia (NS) is acute and also chronic in nature. It is a self-limiting, benign, non-neoplastic, inflammatory disease of the salivary glands mimicking a malignancy both clinically and histopathologically
It is more commonly seen in men of middle-age. The most common location of involvement is the palate, followed by the lower lip, retromolar area, sublingual region, tongue The lesion initially starts as a non-ulcerated swelling presenting with pain, and later the necrotic tissue sloughs leave a crater-like ulcer. The ulcer is indurated with well-delineated borders. Lesion ranges from 1 cm to 5cm in size 6 and the ulcer regresses on its own within 5 to 7 weeks 8.

Primary Herpetic Gingivostomatitis: Primary herpetic gingivostomatitis is the frequent oral manifestation of symptomatic herpes simplex virus (HSV) infection. More than 90% of the cases are caused by HSV-1, which occurs above the waist. HSV-2 occurs below the waist. With the fluctuating sexual practices, it is not unusual to culture HSV-2 from oral lesions [10]Usually, the age of occurrence is between 6 months to 5 years, with a peak incidence of occurrence between 2 and 3 years. Prodromal symptoms include fever, nausea, anorexia, and irritability [11] . The initial contact with the virus is acquired by inoculating infected secretions into the mucosa, skin, and eye resulting in primary infection. The virus then establishes a chronic latent infection in the sensory ganglion, such as the trigeminal ganglion migrating along the sensory nerve axons [8]. Clusters of vesicles and/or ulcers appear on both the hard and soft palate. Other sites are attached gingival, tongue, buccal and labial mucosa. The vesicles break down to ulcers that range from 1 to 5 mm and coalesce to form large ulcers. The borders are erythematous and scalloped. The mouth is tender, red and often causes difficulty in swallowing and eating. Reactivation of HSV may cause asymptomatic shedding of HSV in the saliva, and oral secretions, which may cause ulcers at the site of innervations, usually in the vermillion border of lips and perioral skin, and they are called as herpes labialis/cold sores/fever blisters [12] . Recrudescent HSV in immune-compromised patients occurs mainly on the keratinized mucosa with oral ulcers similar to primary HSV infection [13] Recurrent HSV ulcers may also look like traumatic ulcers seen on the palate. Primary herpetic gingivostomatitis might show ulcers similar to coxsackievirus infections, but the latter does not present ulceration on the gingiva and are not clustered. Viral culture or a cytology smear distinguishes the two. A cytological smear or viral culture is necessary to eliminate aphthous ulcers, necrotizing ulcerative gingivitis, an [8].

Varicella-Zoster Virus Infection: Primary VZV infection or chickenpox occurs in the first two decades of life. The disease started with a lowgrade fever, malaise, and the development of an intensely pruritic, maculopapular rash 13 and is followed by "dewdrop-like" vesicles. Some patients present with involvement of the trigeminal nerve, and the condition is painful if the maxillary branch is involved. Some patients have tenderness and burning sensation [7] After the prodromal symptoms, clusters of ulcers are seen unilaterally on the gingiva or hard palate. These ulcerations coalesce to form larger ulcers with a scalloped border. These ulcers heal within 10 to 14 days [14]. The pain that is experienced before the onset of vesicles and ulcerations may mislead to the diagnosis of pulpitis, leading to unnecessary dental treatment. HSV and herpes zoster infection can be differentiated by culture. Autoimmune diseases like pemphigus and pemphigoid also present with skin and oral ulcerations, but these lesions are chronic and are not unilateral. If the patient is immunecompromised, acute necrotizing ulcerative periodontitis should be considered, which can be eliminated with appropriate tests.[9]

Erythema Multiforme: Clinically, erythema multiforme can be classified into major, minor, and persistent variations. The condition can be present with typical or atypical skin lesions. Target lesions located on the extensor surfaces of the acral extremities are the pathognomic presentation for this disorder. These lesions consist of a dusky central blister, a dark red inflammatory zone surrounded by a pale ring of edema, and an erythematous halo on the periphery of the lesion. Lesions may also manifest in the mucous membranes of the oral, ocular, or genital mucosa and can occur with or without cutaneous lesions [15] Oral involvement occurs with 25%-60% of patients with erythema multiform.

Types of Mouth Ulcer :-[33].

- **Canker sores -** Canker sore is the most common type of moth ulcer it's a minor trauma that is bitting your chicks the canker sores are usually white or red.
- **Leukoplekia –** The leukoplekia is develope because of excess of cell growth they are usually white or grey in colour . the chronic irritation cause from the smoking and chewing tobacco**.**
- **Erythroplakia** – They are develope behind thir lower front teeth under their tongue they are red patches inside the mouth **.**
- **Oral trush –** The overgrowth of yeast candida albicans it cause fungal infections inside the mouth red or creamy white sores patches.

2.5. Oral submucous fibrosis (OSF) :is a chronic, progressive, and potentially malignant oral disorder characterized by scarring and fibrosis of the oral mucosa, often leading to difficulty in opening the mouth and potentially increasing the risk of oral cancer.

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Oral submucous fibrosis (OSMF) is a precancerous disorder of the submucosa that causes inflammation andprogressive fibrosis, leading to pronounced stiffness and trismus. Chewing betel nuts is a significant riskfactor for OSMF in India. Arecoline from betel nuts and copper, which causes fibroblast dysfunction and thedevelopment of fibrotic bands, are the main components of betel quid. OSMF is distinguished by fibrosis inthe submucosal region, which affects the majority of the oral cavity and results in advanced lockjaw due torigidity in the lips, pharynx, cheeks, and upper third of the oesophageal canal, which progresses todysphagia.

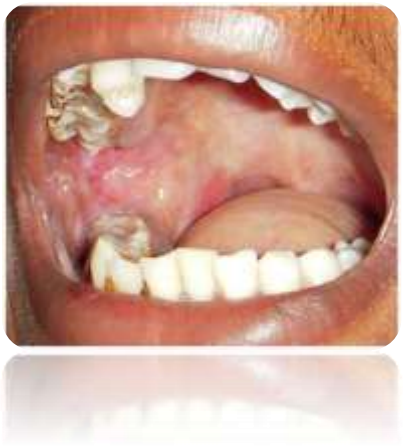

Fig. No – 2 Oral Submucous Fibrosis

Symptoms:-

- Limited mouth opening (Trismus)
- Burning sensation
- Dry mouth
- Difficulty swallowing (Dysphagia)
- Alter taste
- Tongue mobility issues
- Mouth ulcer

Progression and Risk :

1. Precancerous condition : OSF is consider as a precancerous condition meaning it increase the risk of oral squamous cells carcinoma it's a type of oral cancer.
2. Malignant transformation : The WHO lists OSF as one of the oral potentially malignant disorder (OPMDS).
3. Morbidity : OSF can significantly impact on a person quality of life due to the symptoms and potential for cancer development

Importance of Oral Hygiene

- Prevents **tooth decay** and **gum disease**
- Avoids **bad breath** (halitosis)
- Helps maintain **strong teeth and fresh breath**
- Reduces the risk of **systemic diseases** like heart disease and diabetes
- Essential for **overall well-being**

1. Antibacterial Agents

Used to control plaque and gingivitis.

- **Chlorhexidine Gluconate (e.g., Peridex, Periogard)**
  - Prescription mouthwash
  - Kills bacteria that cause gum disease
  - Used short-term (can cause staining with long use)
- **Cetylpyridinium Chloride (e.g., found in many OTC mouthwashes like Crest Pro-Health)**
  - Mild antibacterial
  - Helps reduce plaque and freshen breath
- **Essential Oils (e.g., Listerine)**
  - OTC mouthwash with antimicrobial effects
  - Reduces plaque and gingivitis

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2. Fluoride Products
Strengthen enamel and prevent tooth decay.

- **Sodium Fluoride Mouthwash (e.g., ACT, Fluorigard)**
  - OTC or prescription
  - Daily use recommended, especially in people with high caries risk
- **Prescription-Strength Fluoride Toothpaste (e.g., Prevident 5000 Plus)**
  - Higher fluoride concentration than regular toothpaste
  - Used for preventing cavities in high-risk patients

3. Desensitizing Agents
Used to reduce tooth sensitivity.

- **Potassium Nitrate (e.g., Sensodyne toothpaste)**
  - Blocks pain signals from reaching the tooth nerve
  - For daily use
- **Strontium Chloride**
  - Less common than potassium nitrate
  - Helps with sensitivity by blocking dentin tubules

- **Topical Corticosteroids (e.g., triamcinolone acetonide dental paste)**
  - Used in oral ulcers or inflammation like lichen planus
  - Prescription onl

5. Antifungal Medications
Used to treat oral fungal infections like **oral thrush**.

- **Nystatin Oral Suspension**
  - Prescription rinse
  - Effective for Candida infections
- **Clotrimazole Troches**
  - Dissolve in the mouth to treat fungal infections

2.7. Spirulina:

a blue-green algae, shows promise for promoting dental health due to its antimicrobial and anti-inflammatory properties, potentially reducing plaque and gingivitis. Some studies even suggest it can help manage oral submucous fibrosis and might be a natural adjunct in periodontal therapy. Spirulina is 100% natural and a highly nutritious micro salt water plant. It was discovered in South American and Africa in natural alkaline lakes. This spiral shaped algae is a rich food source. For a long time (centuries) this algae has constituted a significant part of the diet of many communities. Since the 1970's, Spirulina has been well known and widely used as a dietary supplement in some countries.Spirulina contains rich vegetable protein (60~ 63 %, 3~4 times higher than fish or beef), multi Vitamins (Vitamin B 12 is 3~4 times higher than animal liver), which is particularly lacking in a vegetarian diet. It contains a wide range of minerals (including Iron, Potassium, Magnesium Sodium, Phosphorus, Calcium etc.), a high volume of Beta- carotene which protects cells (5 time more than carrots, 40 time more than spinach), high volumes of gamma-Linolein acid (which can reduce cholesterol and prevent heart disease). Further, Spirulina contains Phycocyanin which can only be found in Spirulina.

Fig. No 03 spirulina powder.

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Antioxidant Effects
Spirulina's antioxidant properties can help combat the oxidative stress and inflammation associated with chronic periodontitis. One study showed that spirulina lowered the risk of oral cancer in people who chew tobacco.

2.8. DRUG PROFILE
1. General Information
- **Name:** Spirulina
- **Scientific Name:** *Arthrospira platensis*, *Arthrospira maxima*
- **Type:** Natural nutraceutical / dietary supplement
- **Source:** Blue-green algae (cyanobacteria)
- **Formulations:** Powder, tablets, capsules, flakes, drinks

2. Composition
Spirulina is rich in:
- **Proteins:** ~60–70% by dry weight
- **Vitamins:** B1 (thiamine), B2 (riboflavin), B3 (niacin), B6, B12 (though biologically inactive), vitamin E, vitamin K
- **Minerals:** Iron, calcium, magnesium, potassium
- **Pigments:** Phycocyanin (a powerful antioxidant), chlorophyll, beta-carotene
- **Fatty Acids:** Gamma-linolenic acid (GLA)
- **Other:** Polysaccharides, phenolic compounds

3. Pharmacological Effects
Spirulina exhibits a wide range of bioactivities, including:
- **Antioxidant:** Scavenges free radicals (due to phycocyanin, beta-carotene)
- **Anti-inflammatory:** Inhibits pro-inflammatory cytokines
- **Immunomodulatory:** Stimulates macrophages, T cells, and antibody production
- **Antiviral:** Inhibits replication of certain viruses (e.g., HIV, herpes)
- **Anticancer:** Experimental effects on tumor cell inhibition
- **Lipid-lowering:** Reduces LDL cholesterol and triglycerides
- **Antidiabetic:** Helps reduce fasting blood glucose
- **Antiallergic:** Reduces histamine release in allergic rhinitis

4. Clinical Uses
While not an FDA-approved drug, Spirulina is used as a supplement in:
- Malnutrition treatment
- Immune support
- Cholesterol and blood sugar management
- Fatigue and energy enhancement
- Allergic rhinitis (some supportive evidence)
- Adjunct in weight loss and detox programs

5. Dosage
- **Typical dose:** 1–10 grams/day
- **For lipid/glucose control:** 2–8 grams/day
- **Athletic performance:** ~3 grams/day
- **Pediatric malnutrition (WHO/UNICEF programs):** Variable based on formulation

12. Classification
- **Drug Class (Theoretical):**
  - *Biological response modifier*
  - *Antioxidant and immunostimulant agent*
  - *Metabolic modulator*
- **Nature:** Natural biologic from cyanobacteria (*Arthrospira* spp.)

13 . Mechanism of Action (MOA)
- **Phycocyanin** – Inhibits COX-2 and iNOS → ↓ Pro-inflammatory cytokines (e.g., TNF-α, IL-6)

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- **Antioxidant action** – Scavenging of reactive oxygen species (ROS) via enzymatic (e.g., SOD mimicry) and non-enzymatic pathways
- **Lipid modulation** – Regulation of lipoprotein metabolism via inhibition of lipid peroxidation and enhancement of HDL synthesis
- **Immune modulation** – Stimulates T-cell proliferation, macrophage activity, and NK cell function via polysaccharide content
- **Hypoglycemic effect** – Enhances insulin sensitivity, possibly via GLUT-4 translocation and reduced oxidative stress in pancreatic β-cells
- **Hepatoprotective** – Stabilizes hepatocyte membranes and promotes regeneration through antioxidant mechanisms

14. Therapeutic Potential (Theoretical Indications)
- **Chronic inflammatory diseases:** Rheumatoid arthritis, IBD, asthma
- **Metabolic syndrome:** Hyperlipidemia, Type 2 diabetes
- **Neuroprotection:** Parkinson's, Alzheimer's (via anti-oxidative stress mechanisms)
- **Cancer adjunct therapy:** Due to immune stimulation and anti-proliferative effects
- **Viral infections:** As adjunct in viral suppression (e.g., HIV, herpes, hepatitis B/C)

15. Adverse Effects (Theoretical Risk)
- **Immune overactivation:** Theoretical risk in autoimmune conditions
- **Gastrointestinal irritation:** Nausea, bloating due to high protein content
- **Contaminant toxicity:** Heavy metals, microcystins if not sourced properly

2.9. Medicinal Uses of Spirulina

Spirulina is a blue-green algae (cyanobacteria) that is rich in protein, vitamins, minerals, and antioxidants. It has been used for centuries as a **nutritional supplement** and is now recognized for its wide range of **medicinal benefits**.

1. Antioxidant and Anti-inflammatory Effects
- Spirulina is rich in **phycocyanin**, a powerful antioxidant that fights free radicals and inhibits inflammation.
- This helps reduce oxidative stress and may protect against chronic diseases like cancer and heart disease.

2. Boosts Immune System
- Spirulina enhances the activity of various immune cells, including macrophages, natural killer (NK) cells, and antibodies.
- It may help strengthen the immune system, especially in immunocompromised individuals.

3. Lowers Cholesterol and Improves Heart Health
- Spirulina has been shown to reduce **LDL (bad cholesterol)** and **triglycerides** while increasing **HDL (good cholesterol)**.
- This contributes to better cardiovascular health and reduced risk of atherosclerosis.

4. Antiviral and Antibacterial Properties
- Contains compounds that may inhibit the replication of viruses such as **herpes simplex**, **influenza**, and even **HIV** in preliminary studies.
- Also exhibits antibacterial activity against harmful gut bacteria.

2.10.Geographical sources of spirulina:

1. **United States**
   - **Location**: Hawaii (Kona Coast), California
   - **Notable Producers**: Nutrex Hawaii (Hawaiian Spirulina), Earthrise Nutritionals
   - **Why Here**: Consistent sunlight, clean water, and advanced cultivation methods.

2. India
   - **States**: Tamil Nadu, Karnataka, Maharashtra, Andhra Pradesh
   - **Organizations**: CFTRI (Central Food Technological Research Institute) supports cultivation.
   - **Why Here**: Warm climate, low cost of production, and increasing demand for nutritional supplements.

2.11. Chemical Constituets

Spirulina Chemical Constituents Table (per 100g Dry Weight)

Chemical constituents	Amount
Protein	50-70g
Carbohydrates	10-20g
Lipids (total fat)	6-8g
Gamma linolenic acid (GLA)	1-2g
Fibre	8g
Chlorophyll	1-1.5g

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Phycocyanin	10-15g
Carotenoids	0.3-0.6g
Vitamin E	5-6mg
Vitamin B1,B2,B3,B12	1.5-2g
Calcium	100-150mg
Magnesium	200-300mg

3.Material and method :

Cultivation Methods

1. Mud Pot Cultivation (Small-Scale, Rural-Friendly)

This low-cost method is ideal for rural areas:

- **Setup**: Three 35–40 liter mud pots are partially buried in the ground.
- **Medium**: A mixture of biogas slurry, sea salt, or chemical nutrients.
- **Inoculation**: Pure spirulina culture is added.
- **Maintenance**: The medium is stirred 3–4 times daily; pots are exposed to sunlight.
- **Harvesting**: Once the medium turns dark green (after 3–4 days), spirulina is filtered using cloth, washed, and dried in the shade.
- **Yield**: Sufficient to meet daily vitamin A and B12 requirements for one person.

2.Open Raceway Ponds (Commercial Scale)

Common in commercial production due to lower costs:

- **Design**: Shallow, rectangular ponds with paddle wheels to circulate water.
- **Advantages**: Cost-effective and scalable.
- **Challenges**: Susceptible to contamination and evaporation

3. Greenhouse Systems

Offers better environmental control:

- **Structure**: Shallow ponds within greenhouses, often with netted cladding for ventilation.
- **Control**: Enhanced regulation of temperature, light, and humidity.
- **Efficiency**: Improved yield compared to open ponds.

4. Closed Photobioreactors (Advanced, High-Yield)

Provides optimal conditions for spirulina growth:

- **Design**: Enclosed systems like tubes or bags.
- **Control**: Precise regulation of light, temperature, and nutrients.
- **Benefits**: Higher productivity and reduced contamination risk.
- **Considerations**: Higher initial and operational costs.

Environmental Requirements

- **Temperature**: Optimal growth occurs between 30–35°C; temperatures above 35°C can cause culture bleaching.
- **pH**: Maintain between 8 and 11 for healthy growth.
- **Light Intensity**: 20–30 K lux is ideal; specific light wavelengths can enhance protein content.

Harvesting Techniques

- **Mechanical Filtration**: Water is passed through sieves and mesh filters to collect spirulina biomass.
- **Washing**: The harvested spirulina is washed to remove contaminants.
- **Drying**: Dried in the shade to preserve nutritional quality.

7.2 Collection of spirulina :

Harvesting Spirulina: Step-by-Step Guide

1. Determine Harvest Time

- Harvest spirulina when the culture appears thick and dark green, indicating high biomass concentration.
- Morning is the optimal time, as spirulina has higher protein content at sunrise.

2. Prepare Harvesting Equipment

- Ensure all equipment, including harvesting funnels, filter cloths, and tubes, are clean and free from contaminants.
- Avoid using hot water with 3D printed parts, as PLA warps at temperatures above 60–65°C.

3. Collect the Biomass

- **Manual Method**: Use a fine mesh (30–50 microns) to filter the culture.
  - Place the mesh above the cultivation tank and pass the liquid through it until a thick paste forms on top.
  - Rake the wet biomass to the center of the mesh, then squeeze out the excess water.
  - Repeat the process with fresh water to remove excess nutrients.
- **Mechanical Method**: Utilize a pump and filter system.
  - Pump the culture medium through a filter, collecting the spirulina biomass.

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- Press the collected spirulina to remove excess liquid, then weigh it to determine the amount harvested

4. **Post-Harvest Handling**
   - Store the harvested spirulina in a cool place or refrigerate it to maintain freshness.
   - Rinse all harvesting equipment with water after use to prevent contamination.
5. **Replenish Nutrients**
   - After each harvest, add nutrients back into the cultivation medium to support continued growth.
     - For mineral nutrients, add 200 ml per 100 grams of freshly pressed spirulina.
     - For organic nutrients, add 200 ml of urine plus 10 ml of iron solution per 100 grams of fresh pressed spirulina.

7.3 Formulation Table :

Batch I (jaggery syrup):-

Ingredients	Function	Quantity per lozenges	Quantity for 10 lozenges
Spirulina (Powder)	API	100mg	10g
Jaggery Syrup	Base& Sweetner	500mg	50g
Honey	Preservative	50mg	5g
Menthol	Flavor Masking Agent	5mg	0.5g
Citric Acid	Flavor Masking Agent	10mg	1g

Fig.04.Jiggery syrup

Batch II (sugar syrup):-

Ingredients	Function	Quantity per lozenges	Quantity for 10 lozenges
Spirulina (powder)	API	100mg	10g
Sugar syrup	Base& sweetner	500mg	50g
Honey	Preservative	50mg	5g
Menthol	Flavor masking agent	5mg	0.5g
Citric acid	Flavor masking agent	10mg	1g

Batch III (sugar syrup with starch and sucrose):-

Ingredients	Function	Quantity per lozenges	Quantity for 10 lozenges
Spirulina (powder)	Api	100mg	10g
Sugar syrup	Base& Sweetner	500mg	50g
Honey	Preservative	50mg	5g
Menthol	Flavor Masking Agent	5mg	0.5g
Citric acid	Flavor Masking Agent	10mg	1g
Starch	Binder, Diluent	Quantity sufficient	Small amount
Sucrose	Stabilizer	25mg	2.5g

Final Batch IV (sugar syrup with starch and sucrose):

Ingredients	Function	Quantity per lozenges	Quantity for 10 lozenges
Spirulina (powder)	API	100mg	10g
Sugar syrup	Base& sweetner	500mg	50g
Honey	Preservative	50mg	5g
Menthol	Flavor masking agent	5mg	0.5g
Citric acid	Flavor masking agent	10mg	1g
Starch	Binder, diluent	Quantity sufficient	Small amount
Sucrose	Stabilizer	25mg	2.5g

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7.4.Formulation of lozenges: To prepare **hard candy** for **oral administration** (commonly used in pharmaceutical or medicinal formulations for drugs, lozenges, or supplements), you need to follow a controlled method that ensures **dose accuracy**, **stability**, and **palatability**. Here's a general method used in **pharmaceutical compounding** or **nutraceutical manufacturing**:

Ingredients (Typical)

- **Active Pharmaceutical Ingredient (API)** or supplement (e.g., vitamin C, menthol, zinc)
- **Sucrose (sugar)** – primary base
- **Corn syrup** – prevents crystallization, improves texture
- **Water** – to dissolve sugar
- **Flavoring agents** – mint, fruit, etc.
- **Coloring agents** – optional
- **Acidulants (optional)** – like citric acid, for taste and pH adjustment

Equipment Needed

- Candy thermometer
- Stainless steel pot or pan
- Molds (non-stick or silicone)
- Stirring utensil
- Cooling surface (greased slab or tray)

7.5.Procedure

1. **Prepare the sugar base:**
   - In a stainless-steel pan, combine:
     - 70% **sucrose**
     - 30% **corn syrup**
     - Enough **water** to dissolve the sugar (typically 15–25% w/w of sugar)
   - Heat the mixture slowly with **constant stirring**.
2. **Heat to Hard Crack Stage:**
   - Use a **candy thermometer** to monitor temperature.
   - Heat until the mixture reaches **148–154°C (298–310°F)** – known as the **hard crack stage**.
   - Do **not stir** once boiling begins to avoid crystallization.
3. **Add API and excipients:**
   - Remove the mixture from heat.
   - Allow it to **cool slightly** (to about 130°C / 266°F).
   - Add the **active drug**, **flavor**, **color**, and any **acidulants**.
   - Stir quickly and evenly to ensure uniform distribution.

API should be stable at elevated temperatures. Thermolabile drugs are not suitable for this method.

4. **Pour into molds:**
   - Quickly pour the mixture into **pre-greased molds** or onto a greased slab to cut once cooled.
   - Allow to cool and solidify completely at **room temperature**

Fig .05.Pouring in Moulds

5. **Packaging**
   - Once solid, remove from molds.
   - **Individually wrap** or store in **airtight containers** with desiccants if needed.

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- Label properly.

Precautions

- Use protective gloves and tools – hot syrup can cause severe burns.
- Ensure API is uniformly distributed for dose consistency.
- Avoid introducing moisture, as it may lead to stickiness or microbial growth.
- Quality control for hardness, weight uniformity, and dissolution is important in regulated production.

Fig.06.Lozenges

Types of lozenges

- Medicated lozenges.
- Non-medicated lozenges.

Classification of lozenges

- I. According to its site of action:
- a. Local Effect-
- e.g Antiseptics, Decongestant.
- b. Systemic Effect-
- e.g Vitamins, Nicotine.
- II. According to its texture and composition:
- a. Chewable
- e.g Vitamins.
- b. Hard-
- e.g Lollipops.
- c. Soft-
- e.g Bentasil.
- d. Compressed-
- e.g Troches.

- **A. CHEWABLE LOZENGES**

The medicaments in chewable lozenges are incorporated into caramel base, hence instead of dissolving it into mouth it is chewed. These lozenges are prepared or formulated by using Glycerin, Gelatin, and Water. They are highly flavourized by fruits and also having somewhat acidic taste which is intentionally provided to mask the acrid taste of glycerin. These kinds of lozenges are especially for the pediatric use so that the medication meant for GIT absorption and systemic effect can be acquired. The Glycerin base used for chewable lozenges are totally similar with base used in glycerin suppositories or glycerin gelatinized suppositories. Which consists of 70% glycerin, 20% gelatin and 10% purified water.

- **B. HARD LOZENGES**

These types of lozenges are the mixture of sugar and carbohydrates. They are in noncrystalline forms usually in amorphous or glassy state. They are also called as “syrups of sugar”. The weight of hard candy lozenges are between 1.5-4.5gm. Moisture content of those are 0.5-1.5% these lozenges must undergo directly into dissolution instead of disintegration, but these lozenges preparation requires high temperature hence heat liable substance or ingredient cannot be formulated. Hard lozenges are widely used to treat the sore throat pain or to treat the various throat infection and also to get the relief from irritation by delivering the drug having the category of topical anesthetic or antibiotic activity.

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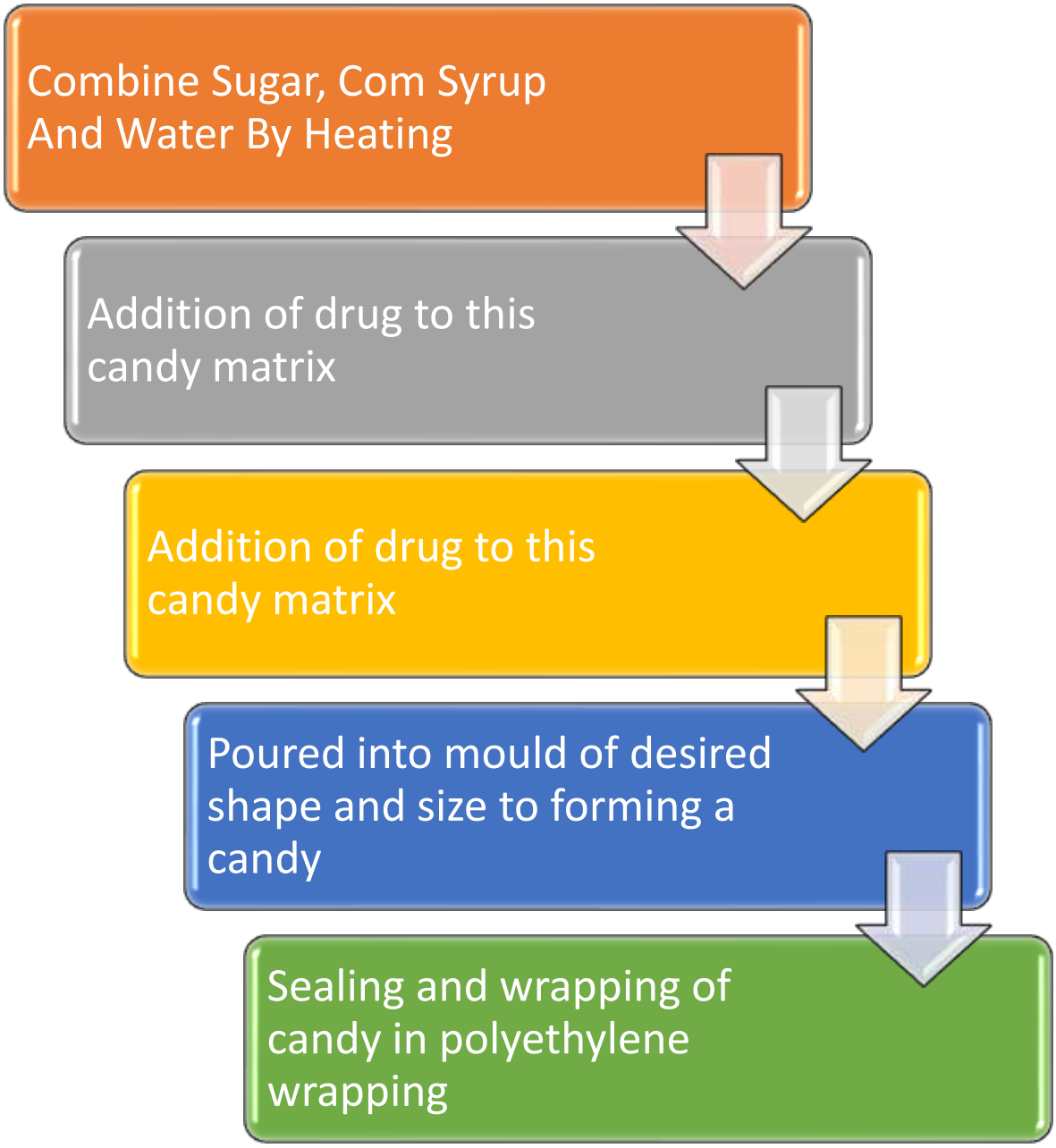
- **C. SOFT LOZENGES**

Soft lozenges are meant for slow release of drug into mouth, and are prepared by using ingredients like PEG (polyethylene glycol), chocolate or acacia base some of soft lozenges contain silica gel also in its base acacia is the hero ingredient into these lozenges to achieve the smoothness and texture. PEG based lozenges get soften at high temperature and are also hygroscopic hence must be advised to store in a cool and dry place.

- **D.COMPRESSED LOZENGES**

The heat liable ingredients i.e heat sensitive ingredients are not possible to formulate by procedure same as that of soft lozenges, hard lozenges. Simply the compression method is applicable for such type of ingredients, same as like compressed tablet. The only difference between them is non-disintegrating and slower dissolution profile. The granulation method is used in compressed lozenges

- **Method of preparation**



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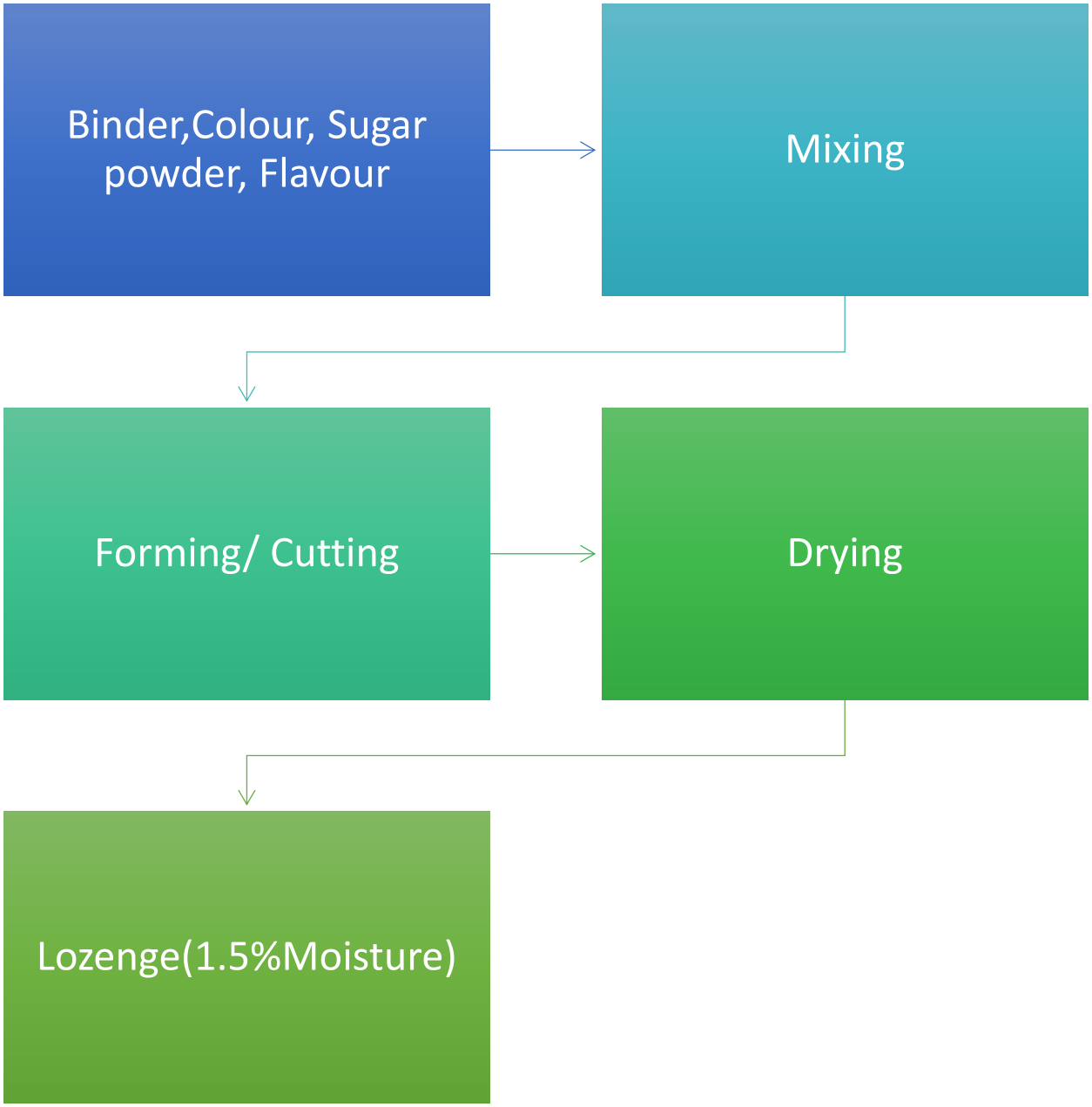

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4.Evaluation Parameters:

- **Weight variation:** Weight variation test: Twenty lozenges were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one lozenge was determined from the collective weight. The percent deviation was calculated using the following formula; % Deviation = (Individual weight – Average weight / Average weight) × 100otal

C1= 5.45, C2= 5.63, C3=5.41, C4 = 4.60, C5= 7.4 , C6= 4.74, , C7= 5.09 , C8= 5.03, C9= 4.78, C10=4.70

Total weight = 52.47

= 52.47/10

%Deviation = individual weight – average weight /average weight *100

Individual weight	Average weight	% deviation
5.45	5.24	4.00
5.63	5.24	7.44
5.41	5.24	3.24
4.60	5.24	12.21
7.4	5.24	41.22
4.74	5.24	9.54
5.09	5.24	2.86
5.03	5.24	4.00
4.78	5.24	8.77
4.70	5.24	10.30

This formula calculates the absolute difference between each weight and the average, divided by the average, then multiplied by 100 to express the result as a percentage. The resulting values indicate how close or far each measurement is from the average. For instance, weights like 5.41 and 5.09 show low deviations (around 3%), indicating good consistency. However, the value 7.40 has a high deviation of approximately 41%, suggesting it is an outlier or a possible error in measurement. Overall, this method allows for a clear understanding of the variation within a dataset. Smaller deviations suggest high consistency among measurements, while larger deviations may highlight anomalies. This type of analysis is particularly useful in scientific and industrial settings where precision and uniformity are essential.They are also called as “syrups of sugar”. The weight of hard candy lozenges are between 1.5-4.5gm.According to the United States Pharmacopeia (USP), British Pharmacopoeia (BP), and Indian Pharmacopoeia (IP), the acceptable limit for weight variation is ±5 [13, 14]. For each batch, a random selection of 10 tablets was made and individually weighed to determine any variation in weight. ...

- **Thickness:** Thicknessis an important characteristic in reproducing appearance. Thickness was measured using Vernier Caliper’s average thickness for Lozenges is calculated and presented with a standard deviation.

- **Hardness:** The force required to break the lozenge throughout its diameter is referred to as the lozenge's hardness. The hardness of the lozenge determines how resistant it is to chipping, abrasion, or breaking when stored, transported, and handled prior to use. For each formulation, the hardness of tablets was determined using a Monsanto hardness tester and the average was calculated and presented with standard deviation. It is expressed in kg/cm2 .

Fig.07.Monsanto Hardness Tester.

- **pH Determination Test :** By putting the lozenges in a petri dish, this test was assessed. After that, 2 ml of phosphate buffer were added to wet it, and it was left for 30 seconds. Following one minute of equilibration and contact between sample and the electrode of pH meter and the pH was measured. For each formulation, the mean of the three results was calculated. The acidity or alkalinity of lozenges was indicated by using a lab pH meter, a scale from 1.0 to 14.0. 1% W/Solution was prepared by dissolving 1 g candy in 100 ml distilled water and its pH was recorded.

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Fig.08. pH meter

- ❖ **Mouth Dissolving Time:** Place each lozenge in separate beakers with 100 ml phosphate buffer pH 6.8, stirring at 50 rpm using a mechanical stirrer at 37°C to record the time taken for complete dissolution.

- ❖ **Disintegration time :** General Disintegration Time for Lozenges.
- Lozenges are typically designed to dissolve slowly in the mouth, rather than disintegrate quickly like tablets.
- Standard disintegration for conventional oral tablets is around 15–30 minutes, but lozenges are meant to dissolve over 5 to 15 minutes in the mouth.

For Herbal Spirulina Lozenges Specifically

- No universal pharmacopeial standard exists specifically for Spirulina lozenges, but the lozenge form implies that:
  - The disintegration (dissolution) time in the mouth could be between 5 to 10 minutes.
  - In laboratory testing (using disintegration testers), some herbal lozenges may take up to 30 minutes in simulated saliva or neutral pH buffers.

What Affects Disintegration Time

1. Type and amount of binder/filler (e.g., mannitol, sorbitol, gum arabic).
2. Moisture content and compression force during manufacturing.
3. Presence of natural gums or mucilaginous herbs, which may slow dissolution.
4. pH and temperature of the dissolution medium.

- For nutraceuticals, especially herbal lozenges, there is no strict pharmacopeial disintegration requirement unless the product makes specific therapeutic claims.
- If tested (e.g., per USP <701> Disintegration), manufacturers might use modified methods tailored to lozenges.

5.RESULT

The prepared spirulina lozenges were subjected to various evaluation parameters to determine their suitability as an effective oral hygiene product. The weight variation test revealed an average lozenge weight of 5.24 grams, with most samples falling within the acceptable deviation range. However, one sample showed a higher deviation of 41.22%, indicating a need for improved uniformity in future batches. The thickness of the lozenges was measured using a Vernier caliper to ensure physical consistency, while the hardness was assessed using a Monsanto hardness tester. The lozenges demonstrated adequate hardness, confirming their ability to withstand handling and storage conditions without breaking.

The pH of the lozenges was found to be within an acceptable range when tested using a 1% solution (1 gram of lozenge in 100 ml of distilled water), ensuring compatibility with the oral environment. The dissolution time was evaluated by placing each lozenge in phosphate buffer at 37°C and stirring at 50 rpm. This test indicated that the lozenges dissolved appropriately in the mouth, releasing the active ingredients effectively. The dissolution behavior was influenced by factors such as lozenge size, shape, excipients used, and storage conditions. Overall, the results suggest that spirulina lozenges possess acceptable physical and chemical characteristics, supporting their potential as a natural and effective oral hygiene formulation.

6CONCLUSION

The present study successfully demonstrated the formulation and evaluation of spirulina-based lozenges intended for promoting oral hygiene. The lozenges were prepared using natural and palatable ingredients such as spirulina, honey, sugar, and starch, which contributed both to their therapeutic and organoleptic properties. Evaluation results confirmed that the lozenges had acceptable physical characteristics such as uniform weight, adequate hardness, proper pH, and suitable dissolution time. Moreover, preliminary antimicrobial testing indicated promising activity against common oral pathogens.

Overall, spirulina lozenges proved to be a viable, natural alternative to conventional synthetic oral hygiene products. Their formulation not only promotes oral health but also aligns with the growing consumer demand for herbal and plant-based remedies. Thus, spirulina lozenges may serve as an effective supplement for maintaining daily oral care in a holistic and sustainable manne

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