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FORMULATIONS AND EVALUATION OF EFFERVESCENT MOUTHWASH TABLET

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ABSTRACT

The objective of this research was to identify and evaluate dental caries, which result from bacterial presence in the biofilm (dental plaque) on tooth surfaces, leading to localized degradation of hard tissues primarily due to acid production. These degradations are commonly referred to as dental caries.[1] To address the limitations of commercially available liquid mouthwashes that contain artificial active ingredients such as tooth staining, high alcohol content, unpleasant flavors, dry mouth, and stability concerns—a herbal effervescent mouthwash tablet was formulated using menthol and zinc oxide, both of which possess antimicrobial, antibacterial, antiplaque, and anti-inflammatory properties. This study emphasizes the formulation process and examines the effects of the natural extract on adherence, biofilm formation, and cellular substrate hydrolysis. The bacterial strains utilized in this research include Staphylococcus aureus, Bacillus pumilus, Bacillus subtilis, Acinetobacter baumannii, Micrococcus luteus, and Pseudomonas aeruginosa.[2]

KEYWORDS: Zinc oxide, effervescent mouthwash tablet, dental care, antimicrobial, oral hygiene, halitosis, cytotoxic effect, eco-friendly, gingivitis, etc.[3]

INTRODUCTION

History of Herbal Mouthwash

Throughout the ages, individuals have prioritized cleanliness and fresh breath. In ancient Egypt, people utilized mixtures of honey, water, and spices to enhance their breath. They even created chewable tablets made from plants and honey. A Greek physician recommended the use of olive leaves and other natural ingredients for mouthwash. The Romans also valued dental hygiene, employing toothpaste and mouthwash that contained an unusual ingredient: urine.

This practice persisted until the 18th century, with mouthwash being recognized for its potential to aid in disease prevention for many years.[4]

Mouthwash serves as a medicinal solid dentifrice that is retained in the mouth and swished around by the perioral muscles to eliminate oral bacteria, with its primary purpose being oral hygiene.

Mouthwashes can be formulated in three distinct ways

1) Antibacterial mouthwashes;
2) Fluoride-containing mouthwashes;
3) Mineral-based mouthwashes.

There are various types of mouthwashes, including cosmetic and therapeutic options. Cosmetic mouthwash temporarily masks bad breath using flavoring agents, providing a fleeting sense of freshness. Mouthwash tablets represent an innovative approach to oral care, offering a convenient and portable alternative to traditional liquid mouthwashes, which may enhance oral health and cater to specific hygiene requirements.[5]

Dental caries arise from the localized dissolution of tooth enamel, primarily due to acids produced by microorganisms in the biofilm (dental plaque) on tooth surfaces, leading to cavities. Commercially available liquid mouthwashes containing synthetic active ingredients have certain drawbacks, such as tooth staining, high alcohol content, taste alterations, dry mouth, and stability concerns.

Mouthwash Overview

Definition

Mouthwashes, often referred to as mouth rinses or oral washes, are liquid formulations designed primarily to prevent, alleviate, and treat oral health issues while promoting overall oral hygiene.

Fresh Breath

Numerous mouthwashes include components that eliminate bad breath by targeting and killing the bacteria responsible for it.

Cavity and Gum Disease Prevention

Certain mouthwashes are fortified with fluoride, which aids in reinforcing tooth enamel and reducing the risk of cavities.

Oral Cavity and Hygiene

Mouthwash plays a vital role in removing food particles and bacteria from the mouth, thereby fostering a cleaner and healthier oral environment.

Mouthwash is beneficial in the following situations

1. Gum disease
2. Mucositis
3. Halitosis
4. Periodontal disease

5. Xerostomia[6]

Ideal Characteristics of Mouthwash Tablets

1. Quick dissolution
2. Breath freshening properties
3. Plaque reduction
4. Antibacterial benefits
5. User-friendly
6. Travel-friendly and available in various flavors.

Advantages of Mouthwash Tablets

1. Freshens breath
2. Assists in removing food particles and debris lodged between teeth
3. Prevents the accumulation of plaque
4. Aids in combating cavities
5. Whitens teeth
6. Treats canker sores.

Disadvantages of Mouthwash Tablets

1. Mouthwash poses a risk to children under the age of six.
2. The high alcohol content in some mouthwashes can aggravate canker sores.
3. Mouthwash may lead to staining and darkening of teeth.
4. Certain formulations can cause damage to various areas of the mouth.
5. Many mouthwashes contain alcohol, which can increase tooth sensitivity.

Limitations of Effervescent Mouthwash Tablets

1. Effervescent tablets must be stored in a dry environment due to their hygroscopic properties, and occasionally, improperly manufactured tablets may leave an unpleasant aftertaste.
2. Achieving consistent dosage in effervescent tablets can be challenging, necessitating specialized packaging to ensure their stability.[7]

Excipient Profile

Excipient used in Mouthwash tablet formulation

Sr. No	Excipient	Category
1	Zinc oxide	Antibacterial,anti-inflammatory
2	Sodium Bicarbonate	pH balancer, effervescent
3	Citric acid	Effervescent, flavour enhancers
4	Sucrose/Sorbitol	Sweetener, prevents bacterial growth
5	Magnesium stearate	Lubricants, prevents sticking
6	Menthol	Flavoring agent, fresh breath
7	Methyl Cellulose	Binder, tablet str.

Procedure for Mouthwash Tablets

Direct Compression Method

The direct compression method, which involves only mixing and compressing, represents the most advanced technology available. This approach allows for quicker production due to reduced unit operations, fewer machines, less labor, shorter processing times, and enhanced product stability. The effervescent tablets were produced using this direct compression technique. After weighing all the ingredients for the zinc oxide effervescent tablets, magnesium stearate and talc were incorporated as lubricants. The resulting 100 mg mixture was then compressed into tablets using a tablet punching machine equipped with a 12 mm punch, resulting in tablets each weighing 0.50 mg.[9]

Ingredients Used in Mouthwash Tablets

Sr. No	Name of Ingredients	F1(mg)	F2(mg)	F3(mg)	F4(mg)
1	Zinc oxide	0.14mg	0.14mg	0.14mg	0.14mg
2	Sodium Bicarbonate	0.10mg	0.11mg	0.10mg	0.11mg
3	Citric acid	0.07mg	0.07mg	0.07mg	0.07mg
4	Sucrose/Sorbitol	0.07mg	0.07mg	0.07mg	0.07mg
5	Magnesium stearate	0.03mg	0.03mg	0.03mg	0.03mg
6	Menthol	0.03mg	0.03mg	0.03mg	0.03mg
7	Methyl Cellulose	0.06mg	0.05mg	0.06mg	0.05mg

Evaluation of Tablet

Evaluation Parameters

PRE-FORMULATION STUDIES

In pre-formulation studies, the physicochemical properties of the drug substance are analyzed based on biopharmaceutical principles to develop an optimal drug delivery system. This study aims to utilize natural super disintegrants in the direct compression method to formulate effervescent zinc oxide tablets.[9]

1. Bulk Density (Db)

Bulk density is defined as the ratio of the total mass of the powder to its total volume. It is determined by placing a measured amount of pre-sieved powder (40-work) into a measuring container and recording the volume. This volume is referred to as the bulk volume. The bulk density is calculated using the following formula:

$$Db = M/Vb$$

Where M represents the mass of the powder and V denotes the bulk volume of the powder.[10]

2. Tapped Density (Dt)

To ascertain the final tapped volume (Vt), the powder with a known mass is subjected to 100 tapings in a bulk density apparatus. The resulting figures are then used to compute the tapped density.

$$Dt = M/Vt$$

Where M is the mass of the powder and Vt is the tapped volume of the powder.

3. Angle of Repose (Ɵ)

The powder mixture is poured through a wide-mouthed funnel attached to a stand. After forming a heap, the height (h) and the radius (r) of the base of the heap are measured. The angle of repose is calculated using the following formula:

$$\text{Tan } Ɵ = h/r$$

Where Ɵ is the angle of repose, h is the height of the pile in centimeters, and r is the radius of the pile in centimeters.[11]

Angel of repose Types of flow:

Angel of repose	Type of Flow
<25	Excellent
25-30	Good
30-40	Passable
>45	Very poor

4. Carr's Index

5. Hausner's Ratio

POST-FORMULATION STUDIES

In accordance with I.P. guidelines, all formulated tablets were evaluated based on the following criteria:[12]

1) Organoleptic Properties

a. Solubility:

- Water or inorganic solvent.

b. Weight Variation

The weight variation assessment involves individually weighing each of the 20 tablets, calculating the average weight, and comparing each tablet's weight to this average.

Average weight (USP)	Percentage difference	Average weight (IP)
130 mg or less	10	80 or less
More than 130 mg through 324 mg	7.5	80 mg to 250mg
More than 324 mg	5	More than 250

Average weight = Total weight of tablet/20.

Limit = percentage deviation allowed/100 × Average weight.

Upper limit = Average weight + Limit

Lower limit = Average weight - Limit.

c. Wetting Time

A piece of tissue paper, folded in half, was placed in a petri dish with a diameter of 6.5 cm and filled with 6 ml of water. The time required for the tablet to become fully saturated was quickly assessed after the tablet was positioned on the paper. The procedure was modified to maintain a water temperature of 37°C. Six tablets were randomly chosen from a batch, and their wetting times were recorded, with a total of six tablets being evaluated for this parameter.[13]

d. Hardness

The hardness of the tablets was measured using a Monsanto/Pfizer tablet hardness tester, which evaluates the crushing strength, defined as the force necessary to fracture a tablet under diametric compression.[14]

e. Friability

The friability of the tablets was determined using a Roche friabilator (USP). Six pre-weighed tablets were placed in the friabilator and subjected to 100 revolutions at a speed of 25 rpm. The percentage of friability was calculated using the formula:

$$\% \text{ friability} = (\text{initial weight} - \text{final weight} / \text{initial weight}) \times 100.$$

f. Disintegration Test

Tablets were placed in a beaker containing water at a temperature ranging from 15°C to 25°C. They were expected to disintegrate within three minutes. This procedure was repeated for the remaining five tablets.

g. Dissolution Test

A tablet was positioned in a dissolution apparatus filled with a suitable medium. The apparatus was then operated at a predetermined temperature and speed. Over time, samples were taken and analyzed to determine the extent of drug dissolution. The medium used should be water-based with a pH of 5.7 at 37°C.(15)

Pre formulation test

1) Bulk Density

Batch	Mass(g)	Volume (cm3)	Bulk Density (g/cm3)
FT1	8	20	0.4
FT2	8	20	0.4
FT3	8	20	0.4
FT4	8	19.3	0.41

2) Tapped Density

Batch	Mass(g)	Volume (cm3)	Tapped Density (g/cm3)
FT1	8	17	0.47
FT3	8	17.3	0.462
FT3	8	16	0.5
FT4	8	16.8	0.476

3) Angel of repose

Batch	Height (cm)	Radius (cm)	Repose
FT1	1.86	3.5	27.3
FT2	1.9	3.6	27.4
FT3	1.63	3.5	24.9
FT4	2.0	3.3	30.9

Formulation (FT3) has excellent flow, whereas formulations (FT1, FT2) have good flow and formulation FT4 has passable flow property.

4) Carr's Index (or) % compressibility

Carr's Index of Formulation

Batch	Tapped Density (g/cm3)	Bulk Density (g/cm3)	Compressibility
FT1	0.48	0.4	16.6
FT2	0.48	0.4	16.6
FT3	0.45	0.4	11.1
FT4	0.49	0.41	16.3

Formulations FT3 have excellent flow description; whereas formulations (FT1, FT2, FT4) have good flow description.

5) Hausner ratio

Batch	Tapped Density (g/cm3)	Bulk Density (g/cm3)	Hausner ratio
FT1	0.48	0.4	1.2
FT2	0.48	0.4	1.2
FT3	0.45	0.4	1.125
FT4	0.49	0.41	1.225

All the formulations have good flow

1) Organoleptic Properties

Colour : White colour

Odour : odourless

Shape : Circular

Size : 12 mm

Taste : Batter

2) Weight variation

Tablet No	FT1	FT2	FT3	FT4
1	0.54	0.50	0.54	0.50
2	0.52	0.52	0.52	0.52
3	0.53	0.53	0.53	0.53
4	0.52	0.51	0.52	0.51
5	0.52	0.52	0.52	0.52
6	0.51	0.52	0.51	0.52
7	0.54	0.51	0.54	0.51
8	0.50	0.51	0.50	0.51
9	0.52	0.53	0.52	0.53
10	0.53	0.50	0.53	0.50
11	0.52	0.53	0.52	0.53
12	0.52	0.53	0.52	0.53
13	0.54	0.52	0.54	52
14	0.53	0.51	0.53	0.51
15	0.53	0.52	0.53	0.52
16	0.51	0.52	0.51	0.52
17	0.52	0.51	0.52	0.51
18	0.53	0.53	0.53	0.53
19	0.53	0.52	0.53	0.52
20.	0.54	0.51	0.54	0.51
Average wt.	0.525(g)	0.571(g)	0.525(g)	0.571(g)
S.D	5%	5%	5%	5%

c) Wetting Time

Batch	Wetting Time (In second)
FT1	15 second
FT2	10 second
FT3	12 second
FT4	13 second

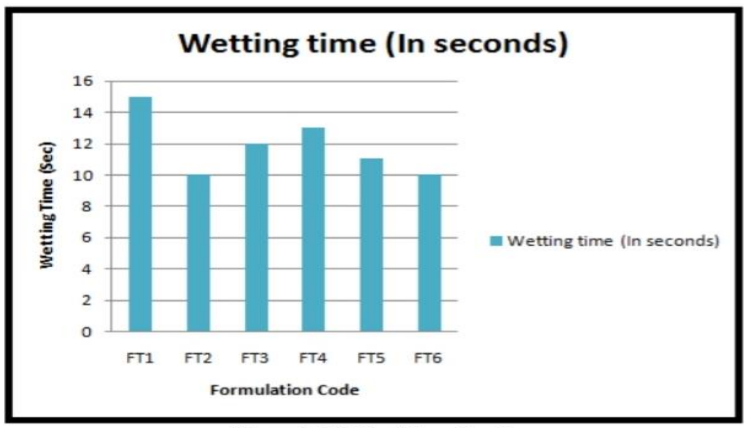

Figure 3: Wetting Time Graph

d) Hardness

Batch	Hardness (kg)
FT1	3.56±0.094
FT2	3.5±0
FT3	3±0
FT4	3.5±0

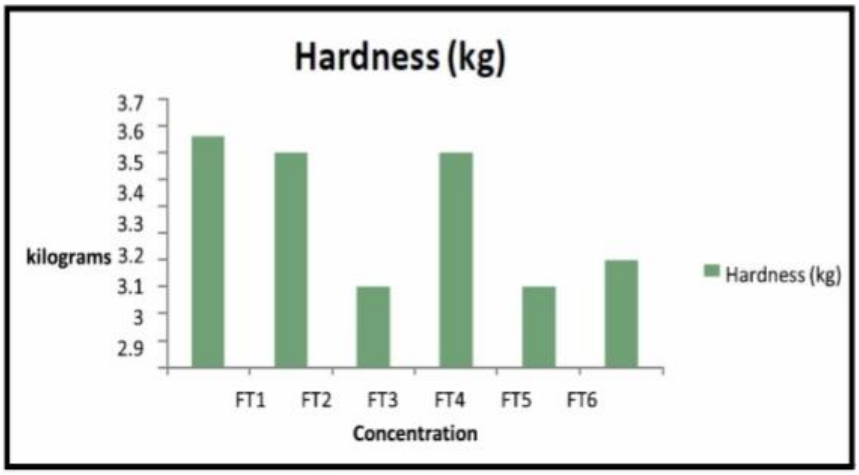

Figure 4: Hardness plot

e) Friability Test

Batch	Initial Weight	Final Weight	% Friability
FT1	0.54	0.53	1.8%
FT2	0.53	0.52	1.8%
FT3	0.55	0.54	1.8%
FT4	0.54	0.53	1.8%

f) Disintegration time

Disintegration time for Tablet

Batch	Disintegration time (in second
FT1	59sec
FT2	28sec
FT3	33sec
FT4	36sec

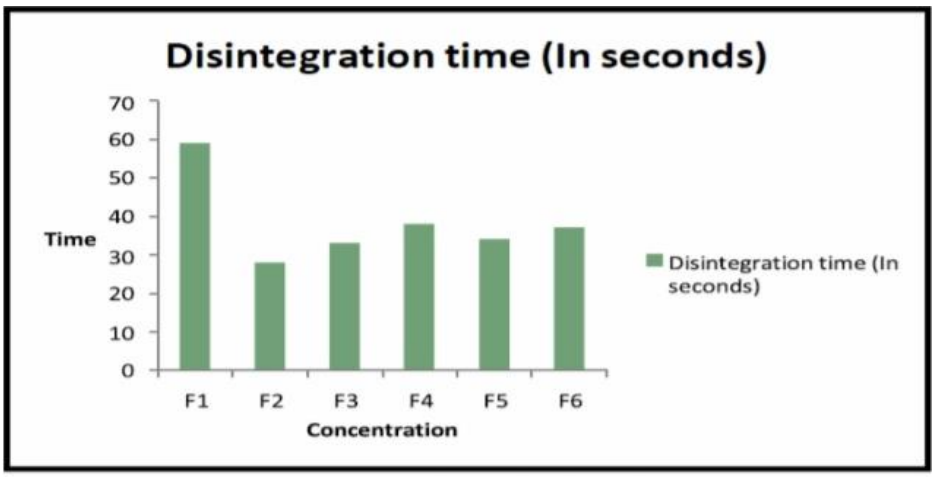

Figure 5: Disintegration Time plot

g) Content Uniformity test

Drug content Uniformity (%) in Tablet.

Batch	Absorbance (nm)	Content Uniformity (%)
FT1	0.2868	95.9
FT2	0.2848	98.9
FT3	0.2788	99.9
FT4	0.2686	90.9

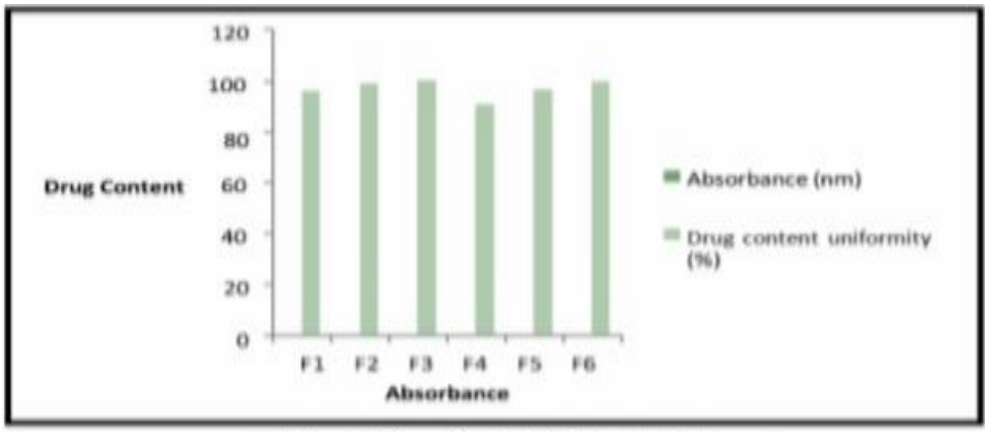

Figure 6: Drug Content Uniformity Plot

DISCUSSION

Maintaining oral health through regular tooth cleaning is essential for preventing diseases, bad breath, and other dental issues. According to the World Health Organization (WHO), dental caries affect individuals globally. In response to identified demographic risks, various campaigns have been initiated to promote dental health awareness. Regular removal of dental plaque is crucial in preventing cavities, gingivitis, and periodontal disease. Most microorganisms exist within "biofilms," which are communities of cells encased in an extracellular matrix that provide a habitat for these organisms, facilitating their growth on damaged tissues. Currently, the pharmaceutical industry lacks a herbal solution for denture care, with only allopathic treatments proving effective against biofilm and plaque infections on dentures. Nevertheless, researchers continue to seek remedies for these conditions, with studies indicating that certain medicinal plants exhibit stronger antibacterial properties.[16]

CONCLUSION

In summary, the development of zinc oxide and menthol mouthwash tablets offers a promising approach to enhancing oral hygiene and providing therapeutic benefits.[17] Our research indicates that this combination may function effectively as a drug delivery system, potentially yielding significant therapeutic outcomes with minimal adverse effects. Further investigation and long-term studies are necessary to thoroughly assess its advantages, optimize its efficacy, and confirm its safety for extended use. Raising awareness among healthcare providers and the general public regarding the benefits of these mouthwash tablets could facilitate their broader acceptance and use as a preferred option in oral care.[18]

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