



IJPPR

INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals

ISSN 2349-7203



Human Journals

Research Article

March 2022 Vol.:23, Issue:4

© All rights are reserved by Mirza Prince et al.

Formulation and Evaluation of Effervescent Tooth Foaming Tablet



IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals



ISSN 2349-7203

Mirza Prince^{1*}, Gopinath E²

*¹Bachelor of pharmacy, T.john college of pharmacy,
Bangalore-560083 India*

*²M.Pharm, PhD, Department of pharmaceuticals, T.john
college of pharmacy, Bangalore-560083 India*

Submitted: 20 February 2022
Accepted: 25 February 2022
Published: 30 March 2022

Keywords: Toothpaste tablets, effervescence time, direct compression, oral hygiene.

ABSTRACT

Toothpaste tablets are small, bite-sized chewable tablets that can be chewed into a paste before brushing and they are showing a similar effect as traditional oral toothpaste. The research aimed to design, formulate and physico-chemically evaluate effervescent toothpaste tablets by direct compressible method since they are an eco-friendly alternative to traditional toothpaste. The tablets were prepared in a dosage of 200 mg by direct compression method. The powder blend was evaluated for various formulation characteristics such as angle of repose, compressibility index, Hausner's ratio, and % porosity. The post-compression characteristics including weight variation, hardness, friability, CO₂ content, effervescence time, pH, wettability, and foamability were evaluated. The best formulations were selected based on effervescence time and foamability with acceptable pre and post-compression properties that dissolved quickly in water. All the formulations were evaluated and F₅ formulations of 200 mg tablets were selected as the best formulation because of their physicochemical characteristics. The formulated effervescent toothpaste tablets were found to be a better alternative for toothpaste to improve oral hygiene.



HUMAN JOURNALS

www.ijppr.humanjournals.com

1. INTRODUCTION

1.1 Oral cavity:

The oral cavity, often known as the mouth or buccal cavity, is the first part of the digestive system to be reached. It is made up of several physically distinct elements that work together to accomplish multiple functions effectively and efficiently. Lips, tongue, palate, and teeth are among these features. The mouth cavity is a unique and complicated structure with multiple different nerves and blood arteries inside it, despite its modest size. Because of its unique and diverse significance in human life, this complicated network is required¹.

Structure and Function:

The oral cavity is neighboring the lips and is composed of two separate regions, the vestibule, the area between the cheeks, teeth, and lips, and the oral cavity proper¹. The lips, two flexible muscle folds that stretch from the corners of the mouth to the base of the nasal columella above and the mentolabial sulcus (fold over the chin) below surround the aperture of the oral cavity (Figure No. 1). There are three anatomic zones on the lip. The outer skin above and below the vermilion border has adnexal features including hair follicles, eccrine sweat glands, and sebaceous glands, and is identical to the skin at other sites. The vermilion is a transitional zone with a thin stratum corneum and an increase in dermal blood vessels, giving it a reddish-purple appearance².

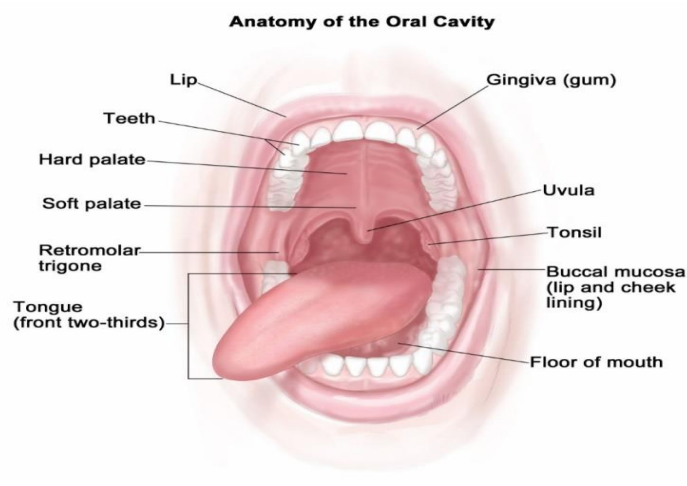


Figure No. 1: Structure of oral cavity

The oral cavity is the first and most important portion of the digestive system. The mouth cavity is where the digestive process begins. The mouth cavity is where our food is first broken down.

Food molecules are broken down and metabolized in the oral cavity at several distinct locations. Even in a healthy state, the mouth cavity contains a colony of bacteria that, when disturbed, might cause disease. Microbial flora can be found in many locations within the mouth cavity, providing them with a home. This flora is divided into several sections, each containing viruses, bacteria, yeasts, and, in rare cases, protozoa³. The microbial population in the human mouth is diverse, plentiful, and complex. The oral environment is perfect for the growth of oral bacteria because it is warm, nutrient-rich, has a constant flow of saliva, and has a pH that is close to neutral. The microbe is commonly found as a biofilm, which is a collection of bacteria embedded in an extracellular polymer matrix. This microbial community lives on a variety of surfaces in the human mouth⁴.

1.2 Tooth:

Teeth are white, hard structures that are present in the mouth. Teeth of different vertebrate species are occasionally specialized and employed for mastication. A crown and one or more roots make up each tooth. The crown is the visible, functional section of the tooth above the gum line. The root is the invisible component of the tooth that supports and anchors it to the jawbone. The crowns and roots of different animals have distinct forms in different areas of the mouth. The teeth on one side of the jaw are virtually identical to those on the opposite side. The upper teeth are distinct from the bottom teeth and work in tandem with them⁵.

Humans have two sets of teeth: primary teeth (twenty) and permanent teeth (thirty). The eruption of primary teeth usually begins at the age of 6 months and continues at a pace of one tooth per month until the age of 2 or 2.5 years. Subtract 6 from the child's age in months up to 2 years of age to get an approximation of the normal number of teeth for that age. The first molars normally occur at the age of six, signaling the start of permanent tooth eruption. Calcification of primary teeth occurs in the womb at 3–4 months, while calcification of permanent teeth begins at birth and lasts for 8–10 years. Dentin (hard tissue that makes up the bulk of teeth), cementin (a cement-like substance that anchors dentin to the periodontal ligament), and pulp are all made up of ectoderm (loose connective tissue containing blood vessels and nerves)².

Structure of the teeth:

Four dental tissues make up your teeth. Enamel, dentin, and cementum are the three hard tissues. Pulp, or the soft, non-calcified tissue in the center of the tooth that contains nerves, blood vessels, and connective tissue, is the fourth tissue. (Figure No. 2)

Enamel: In the crown of the tooth, calcified tissue covers the dentin. Tooth enamel is unable to repair damage caused by decay or wear because it lacks active cells. These problems can only be fixed by a dentist.

Anatomical Crown. The section of your tooth that is visible. Enamel covers it in most cases.

Gums are a type of gum that is used to (also called gingiva.) Soft tissues that cover and protect your teeth's roots, as well as teeth that haven't yet erupted.

Pulp Chamber is an acronym for “pulp chamber”. The pulp—the soft tissue at the middle of your teeth that contains nerves, blood arteries, and connective tissue—takes up this space.

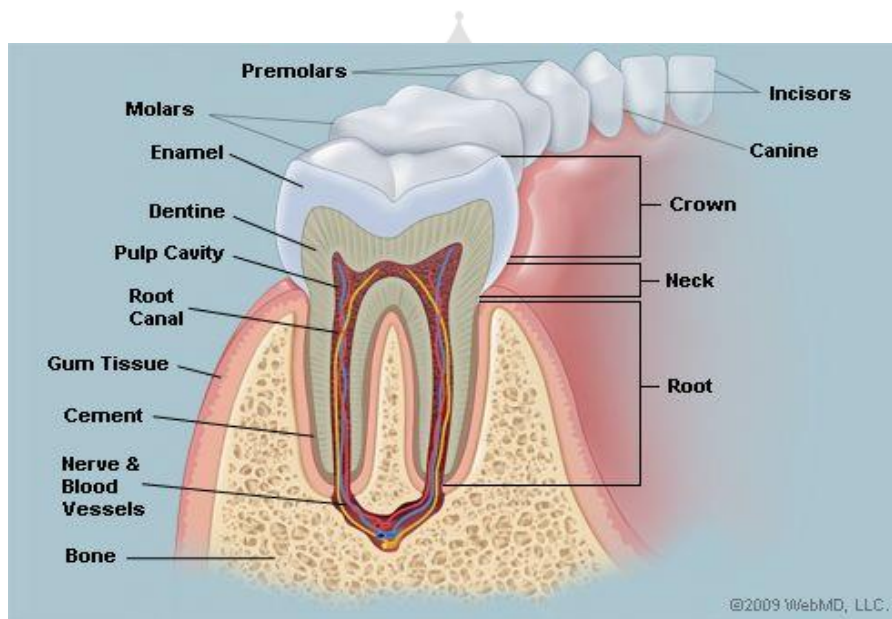


Figure No. 2: Structure of teeth

- Neck. The point at which the crown meets the root.
- Dentin. Underneath the enamel and cementum is the pulp of the tooth. It has minute tubules in it (small hollow tubes or canals). When the protective layer (enamel) on the dentin wears away, the tubules allow heat and cold, acidic, or sticky foods to activate the nerves and cells inside the tooth, resulting in insensitivity.

- Bone-in the jaw (Alveolar Bone.) The portion of the jaw that protects the tooth roots.
- A root canal is a procedure that removes the roots of the chamber within the root of a tooth that contains the pulp; a section of the pulp cavity inside the root of a tooth.
- The cementum, the periodontal ligament is attached to the hard connective tissue that covers the tooth root⁶.

Function:

Teeth provide a variety of roles in addition to mastication, such as shaping phonation kinetics, breathing, preserving a patent airway, and serving as a basis for the face's vertical dimensions. Different teeth have different roles in different types of chewing, and the entire group functions as a dynamic entity. It is because of these crucial responsibilities that tooth loss can be so traumatic⁷.

1.3 Oral health:

Oral health is defined by the World Health Organization as “the state of not having chronic mouth and facial pain, oral and throat cancer, oral infection and sores, periodontal (gum) disease, tooth decay, tooth loss, and other diseases and disorders that limit an individual's capacity in biting, chewing, smiling, speaking, and psychosocial wellbeing.”

Importance of Oral hygiene:

Oral hygiene is the practice of brushing (dental hygiene) and cleaning between the teeth regularly to maintain one's mouth clean and free of disease and other problems (such as foul breath)⁸. Oral hygiene should be practiced regularly to avoid tooth disease and poor breath. Tooth decay (cavities, dental caries) and gum disorders, such as gingivitis and periodontitis, are the most frequent types of dental disease⁹. Brushing twice a day is recommended, but ideally, the mouth should be cleaned after each meal. Interdental cleaning is just as important as tooth brushing when it comes to cleaning between the teeth. This is because a toothbrush cannot reach between the teeth and hence only removes around half of the plaque on the surface. Floss, fossette, and interdental brushes are some of the instruments available for cleaning between the teeth; it is up to the person to decide which tool is best for him or her. Oral hygiene is sometimes associated with white or straight teeth; however, a hygienic mouth

might contain stained teeth and/or crooked teeth. People may choose tooth whitening and orthodontics for cosmetic purposes^{8,9}.

1.4 Oral care products:

Oral care items are those that are used to clean the mouth, freshen the breath, and keep oral hygiene in good shape. Because the dentistry sector is growing at a rapid pace.

There are many different types of oral care products accessible in the market. The selection procedure is made more complicated by the market. Various techniques influence the decision of oral hygiene products. A personalized approach is at the top of the list and should be utilized by people to find the ideal formulation of oral care that meets their needs, as proper selection of an appropriate oral health care product can play a vital role in enhancing oral health and preventing dental problems. As a result, the current study was done to learn more about the various aspects that influence oral care product selection, particularly about the individualized approach to oral care product selection¹⁰.

For many years, oral hygiene products have been widely utilized by humans. Toothpaste and mouthwashes are the most common health and beauty goods, and demand for these dental items is considerable. Chemical and botanical goods are included in this category.

As the dental industry develops by day, there are several oral care products available in the market which includes,

- Toothpaste
- Mouth wash
- Floss
- Toothpowder
- Whitening agent
- Tooth tablet¹¹

Toothpaste:

Toothpaste is a gel or paste-based oral hygiene solution that is used in conjunction with a toothbrush to clean and maintain oral hygiene. It is a widely used dental care product in the community^{12,13}. Kinds of toothpaste have been around since the beginning of time and are an essential part of oral health care. The development of toothpaste formulas dates back to 300-500 BC in China and India. During that time, abrasives such as squashed bone, crumbled eggs, and clamshells were used to clean teeth. In the nineteenth century, modern toothpaste compositions were created¹³. Although brushing the teeth twice a day is recommended by most dentists and is highly effective for plaque removal, it is not possible to prevent bacterial infection. Plaque removal helps to reduce the risk of periodontal inflammation, which is mostly caused by bacteria or oral flora. To address this issue, it is suggested that the patient use toothpaste with increased antibacterial activity¹².

Tooth powder:

To maintain oral hygiene, tooth powder is a light powder that is used in conjunction with a toothbrush. Tooth powder is made in a relatively straightforward manner. The main goal is to ensure that all of the ingredients are distributed evenly and that no alien elements are introduced.

Tooth Powder Types:

Whitening Tooth Powder - This powder is used to freshen breath, support gum health, and minimize mouth inflammation. It's used to whiten and polish a person's teeth.

Natural toothpowder - Ingredients such as sea salt, which acts as an abrasive, natural chalk, and essential fragrances such as peppermint and eucalyptus are utilized in the natural toothpowder.

Herbal Tooth Powder - Herbal tooth powder can help with aching or bleeding gums. It's possible to use a range of substances. Baking soda, powdered chalk, and white clay are all common ingredients. Herbal tooth powder has been used for ages, and many people consider it to be a necessary component of any Teeth Cleaning practice.

Homemade Tooth Powder - You may make these powders at home as well. Homemade herbal tooth powder can be advantageous because it costs less and the person creating it knows exactly what components he is putting in his or his children's mouths¹⁴.

Mouthwash:

They are meant to supplement, not to replace, oral hygiene procedures. They fall into three categories: antiseptic, plaque-inhibiting, and preventative. Plaque-inhibiting mouthwashes contain a variety of active ingredients, ranging from antimicrobials (e.g., cetylpyridinium chloride) and antibacterial agents (e.g., amine alcohol delmopinol hydrochloride) to essential oils (e.g., thymol, eucalyptol, and menthol combined with methyl salicylate) and preventive mouthwashes. Antiseptic mouthwash has several advantages, but it also has a few drawbacks, according to certain studies. In their clinical study, Bescos R, et.al., Mouthwash containing chlorhexidine was found to cause a substantial shift in the salivary microbiome, increasing the abundance of Firmicutes and Proteobacteria while decreasing the amount of Bacteroidetes, TM7, SR1, and Fusobacteria in 36 healthy adults. As a result, more acidic conditions and decreased nitrite availability are seen in healthy people¹⁰.

Flossing:

Brushing is important but it won't remove the plaque and particles of food between the teeth, under the gum line, or braces. Although dental floss is more effective than a manual toothbrush at removing interdental plaque, dental floss as an auxiliary oral hygiene device is not widely used over the world. According to various statistics, just a small percentage of the population uses dental floss on a daily basis¹⁵.

The following are the major benefits expected over the original linear floss:

- (i) increased user compliance
- (ii) Easier handling
- (iii) Reduced raw material and string waste
- (iv) Increased string length use
- (v) Improved string hygiene

(vi) improved plaque removal efficacy and periodontal condition. As a result, the gadget investigated in this article¹⁶.

Tooth-Whitening Products:

Tooth whitening (bleaching) is one of the most prevalent and cost-effective ways to cure tooth discoloration. The majority of individuals value dental aesthetics, particularly tooth color, and the discoloration of even a single tooth can have a detrimental impact on one's quality of life. As a result, a study of the literature (limited to aesthetic teeth whitening) was conducted to offer a wide overview of the efficacy and side effects of various tooth whitening solutions on soft and hard oral tissues¹⁷.

Toothpaste tablets:

Toothpaste tablets are chewable versions of the paste we've all used since we were children. That's not entirely true. Simply place one in your mouth, chew it to break it up, then brush as usual. There are all-natural and vegan-friendly alternatives available, and the tablets crumble and foam as you brush (no water required)¹⁸.

For personal care items in their purchases, consumers place a high value on sustainability and clean label attributes. Retailers' shelves are stocked with reusable and environmentally friendly products. Traditional toothpaste tubes, on the other hand, are harmful to the environment, owing to the packaging materials used. The tubes are constructed of aluminum and plastic, and they take a lot of time, labor, and recycling to produce. Toothpaste tubes break down into microplastics over time, posing a risk to the environment as well as human and animal health. As a result, toothpaste tablets are emerging as a practical solution. Toothpaste tablets are small, bite-sized chewable that can be chewed into a paste before brushing, and they're showing a similar effect as traditional toothpaste.

Toothpaste tablets make use of toothpaste formulations, including xylitol, calcium carbonate, sodium bicarbonate, and tartaric acid derivatives, without the addition of water. They are packed in a close manner to medicinal pills. Toothpaste tablets are available in both fluoride and non-fluoride formulations, also are free of preservatives such as parabens, and can have a long shelf life inadequate storage conditions. The product can be popular among users looking for natural products¹⁹.

Toothpaste tablets are an eco-friendly alternative to toothpaste. These products are beneficial in terms of portability and resistance to temperature changes. Therefore, users don't have to carry around bulky toothpaste tubes, and need not worry about the paste going dry when they forget to close the cap. Chewable toothpaste tablets are a good option for maintaining oral hygiene levels while traveling. The containers can be easily stored in small bags, and users can use them even without a toothbrush for a fast cleansing.

Toothpaste tablets are still not well known among purchasers and they're not easily available at large retailers. Also, toothpaste tablets have not yet been approved by organizations such as the American Dental Association due to a lack of adequate clinical trial data. Fluoride-free products do not have a very good reputation in the oral care sector due to the potential for an increased risk of cavities and also, consumers may not be comfortable making the change from toothpaste to tablets^{18,19}.

1.5 Effervescent tablets:

Effervescent tablets are uncoated tablets that when coming into contact with water, emit carbon dioxide, which aids in their dissolution. The tablets entirely disintegrate in a few minutes, and the medicine is available in solution. The chemical interaction between a carbonate or bicarbonate salt (e.g., sodium bicarbonate) and a weak organic acid (e.g., citric or tartaric acid) in the presence of water results in the production of carbon dioxide. The gastric pH is momentarily raised after intake of the medication solution due to the high carbonate salt concentration, resulting in rapid gastric emptying²⁰.

Effervescent pill compositions typically include a CO₂ releaser (sodium carbonate or sodium bicarbonate) and a CO₂ inducer (adipic acid, malic acid, tartaric acid, ascorbic acid, fumaric acid, maleic acid, succinic acid, or citric acid). API is either present in the effervescent granule combination or is transformed to the salt form during the dissolution process if it has a low solubility. These agents are combined with binders, diluents, and lubricants to make effervescent tablets, which are then compressed into tablets. Sodium benzoate, polyethylene glycol, and adipic acid are examples of water-soluble lubricants. The most often used lubricant, magnesium stearate, is insoluble in water and consequently interferes with the effervescence process. Disintegrants are not required in the formulation of effervescent tablets because the disintegration process is aided by in situ CO₂²¹.

A plasticizer can be used to change the rate of effervescence. Increasing the number of plasticizers slows down the rate of effervescence. Effervescence can also be modified by altering the hydrophobicity and hydrophilicity of binders used in the hot-melt extrusion process. The rate of effervescence is reduced as the amount of hydrophobic binder is increased. In addition, if a tiny excess of either acidic or alkaline agents is employed, the effervescence rate will be increased compared to when both agents are used in the same amount. Furthermore, these effervescent tablets can be coated to deliver drugs to the desired location in the gastrointestinal tract²².

In comparison to ordinary tablets, effervescent tablets enable a larger dose to be administered. Because swallowing is not required, patient compliance is improved in both elderly and pediatric patients. They also allow for better dosing, and because of the evolution of CO₂, all substances self-mix. Effervescent tablets are examined for carbon dioxide concentration, water content, effervescence period, and pH, in addition to the characterization techniques used for conventional tablets²¹.

Uses of effervescent tablets: ^{23,24}

- Rapid drug action.
- Facilitate the intake of the drug.
- Optimal compatibility
- Enhanced absorption
- Increase in liquid intake.



1.6 Direct compression technique:

Direct compression is the simplest and most economical method for the manufacturing of tablets because it requires fewer processing steps of spray-dried had changed the tablet manufacturing process and opened avenues of direct compression tableting compression is used to define the process by which tablets are compressed directly from powder blends of the active ingredient and flow uniformly in the dies & forms a film compact^{25,26}.

The phrase "direct compression" was coined to describe a select group of granular compounds that have all of the physical properties necessary to be compressed directly into

tablets without the need for an intermediary granulating phase. As a result, potassium salts (chlorate, chloride, bromide, iodide, nitrate, and permanganate), ammonium chloride, and methenamine were the only substances it was utilized for.

The availability of novel excipients, modified forms of old excipients, and the design and use of new tablet machines have all contributed to the success of the direct compression technique in tablet manufacturing, particularly for low and medium dosage medications.

Techniques in direct compression:

The procedures involved in the direct compression method of tablet production can be broken down into three parts.

1. Direct compression technique using induced die feeders
2. Direct compression technique using dry binders and
3. Direct compression technique using direct compression excipients²⁷.

Application of direct compression:

1. In the manufacture of orodispersible/mouth dissolving tablets: Due to the availability of improved tablet excipients, particularly tablet disintegrates and sugar-based excipients, this technique can now be applied to mouth dissolving tablets.
2. For hygroscopic API: Due to the presence of water and heat, wet granulation and dry granulation techniques cannot be used to manufacture hygroscopic API tablets. As a result, it is an appropriate technique for this type of API.
3. Low-dose API tablets are also produced using the direct compression method and a direct compression filler to maintain compatibility.
4. Tablets with a high loading API and low compatibility are also made using the direct compression method. By using a direct compression binder, you can get a high level of compatibility. MCC or Lactose with super disintegrant, for example.²⁸

2. METHODOLOGY

2.1 MATERIALS AND METHODS

2.1.1 Chemicals and reagents:

Table No. 1: Chemicals and reagents

SR. NO.	MATERIALS	USE
01.	Calcium Carbonate	Abrasive
02.	Sodium bicarbonate	Penetrates the plaque layer
03.	Citric acid	Effervescent agent
04.	Tartaric acid	Effervescent agent
05.	Sorbitol	Humectant
06.	Sodium saccharine	Sweetening agent
07.	Sodium lauryl sulfate	Surfactant
08.	Sodium starch glycolate	Disintegrant
09.	Talc	Lubricant

2.1.2 Instruments and apparatus:

Table No. 2: Instruments and apparatus

SR. NO.	INSTRUMENTS	MANUFACTURER
01.	Electronic balance	Citizen scales Pvt. Ltd, Mumbai
02.	Hot air oven	Servewell Instruments Pvt. Ltd.
03.	pH meter	
04.	Tablet punching machine	
05.	Monsanto hardness tester	
06.	Roche friabilator	

2.2 FORMULATION OF EFFERVESCENT TOOTHPASTE TABLET:

2.2.1 Composition of effervescent toothpaste tablets:

Table No. 3: Composition of effervescent toothpaste tablets

Ingredients	F ₁	F ₂	F ₃	F ₄	F ₅
CaCO ₃	42	42	42	42	42
NaHCO ₃	52	39	20	15	10
Citric acid	2	4	10	10	10
Tartaric acid	2	4	10	10	10
Sodium saccharin	4	4	4	4	4
Sorbitol	80	80	80	85	90
SLS	10	15	20	20	20
Sodium starch glycolate	8	10	12	12	12
Talc	-	2	2	2	2
Peppermint oil	QS	QS	QS	QS	QS

2.2.2 Procedure:

- Accurately weighed the required quantity of all the ingredients.
- The above-weighed ingredients were blended using the mortar and pestle to form a homogeneous powder.
- Then sufficient quantity of peppermint oil (1 drop) is added into the homogeneous powder and again blended to form granules.
- The granules were dried at 50° C for 15 - 20 minutes using a hot air oven.
- Accurately weighed lubricant (talc) was added into the dried granules and mixed.
- By direct compression method; the above-dried granules were punched using punch size numbers and shallow convex-shaped effervescent toothpaste tablets were formed.

2.3 EVALUATION OF EFFERVESCENT TOOTH FOAMING TABLET:

2.3.1 Pre-compression Parameters:

Before compression the flowability properties of granules and powders were characterized by the angle of repose, flow rate, bulk density tap density, compressibility index also called carr's index, percentage porosity, and Hausner's ratio.

The angle of repose:

The angle of repose is defined as the maximum angle possible between the surface of a pile of powder and the horizontal plane. The frictional force in a loose powder or granules can be measured by the angle of repose is an indicator of the powder flow property.

$$\tan \theta = H / R$$

$$\theta = \tan^{-1} (H/R)$$

Where,

θ is the angle of repose

H is the height of the pile

R is the radius of the base of the pile



Procedure:

At definite height (H) the funnel was fixed to a stand through which the powder was allowed to flow. The angle of repose was then calculated by measuring the height and radius of the heap of the powder which was formed. Care was taken to see that the powder particles slip and roll over each other through the sides of the funnel.

Table No. 4: Angle of repose as an indication of powder flow

The angle of repose or degrees	Flow
< 25	Excellent
25 - 30	Good
30 - 40	Passable
> 40	Very poor

Flow Rate:

The flow rate of a powder is defined as the rate at which the particular mass emerges through the orifice of the funnel of a suitable diameter. By pouring accurately weighed quantities of granules in a funnel with an orifice of 8 mm diameter, the flow rate of granules of each formulation was determined. Using the stopwatch record the time required for complete granule mass to emerge out of the orifice. The flow rate was calculated by the below-mentioned equation.

$$Flow\ rate = \frac{Weight\ of\ granules}{Time\ in\ seconds}$$

Bulk Density:

The bulk density is defined as the ratio of the mass of the powder by the bulk volume in cm³. The sample was carefully introduced into a 100 ml graduated measuring cylinder. This cylinder was dropped at 2 seconds intervals onto a hardwood surface 3 times from a height of 1 inch. The bulk density of each formulation was then obtained by dividing the weight of the sample in grams by the final volume in cm³ of the sample which is contained in the measuring cylinder. It was calculated by using the following equation.

$$Bulk\ density = \frac{Mass}{Bulk\ volume}$$

Tap Density:

The tap density is defined as the ratio of the mass of the powder by the tapped volume in cm³. The sample was carefully introduced into a 100 ml graduated measuring cylinder. This cylinder was dropped at 2 seconds intervals onto a hardwood surface 100 times from a height

of 1inch. The tapped density of each formulation was then obtained by dividing the weight of the sample in grams by the final tapped volume in cm³ of the sample which is contained in the measuring cylinder. It was calculated by using the following given equation.

$$\text{Tap density} = \frac{\text{Mass}}{\text{Tap volume}}$$

Carr’s index:

Carr’s index which is also called as % compressibility index is an indirect method of measuring the flow of granules using the bulk densities. It was developed by Carr. The % compressibility of a powder was a direct measure of the potential powder or bridge strength and the stability of the granules. Carr’s index of each formulation was calculated by using the following equation⁵¹.

$$\% \text{ Compressibility} = \frac{\text{Tap density} - \text{Bulk density}}{\text{Tap density}} \times 100$$

Table No. 5: Carr’s Index as an indication of powder flow

Compressibility index	Flow
5 - 15	Excellent
12 - 16	Good
18 - 21	Fair to passable
23 - 35	Poor
33 - 38	Very poor
> 40	Very very poor

2.3.2 Post compression evaluation:

Weight variation:

Weight variation was done to check whether different batches of tablets have uniformity. Weighed 20 tablets individually, calculated the average weight, and compared the individual tablet weight to average. If not more than two tablets are outside the percentage limit and

none of the tablets differ by more than two times the Percentage limit, the tablets meet the test.

Table No. 6: Weight variation specification as per I.P.

Average weight (mg)	Maximum % difference
130 or less	10%
130 - 324	7.5%
> 324	5%

Hardness:

The hardness of the tablet was evaluated by using a Monsanto hardness tester. It consists of a barrel containing a compressible spring held between two plungers. A lower plunger was placed in close contact with the tablet and a zero reading was taken. By turning a threaded bolt, the upper plunger was forced against a spring until the tablet fractures. The force of fracture was recorded. Ten tablets of each formulation were evaluated⁵⁹.

Friability:

Roche friability is used to evaluate the friability of 20 tablets from each formulation. Pre weighed tablets were placed in the friabilator plastic chamber and the friabilator was run for 4 minutes at 25 rpm. All the tablets were dedusted and weighed by the following Formulas³⁹.

$$\% \text{ friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

Measurement of effervescence time:

One tablet is kept in a beaker having 200 ml of purified water at 20 °C ± 1. If a clear and transparent solution without any trace of particles is obtained, effervescence time has finished.

The average measurement of three formulations was recorded and reported.

Measurement of CO₂ content:

Three effervescent tablets were randomly taken where each one is separately added into a beaker containing 100 ml of 1N H₂SO₄ solution and the weight change was determined after the completion of dissolution. The obtained weight difference showed the amount of CO₂ released per tablet. The average of all the three tablets was determined and reported⁴⁰.

Foamability:

The foamability of the formulated product was estimated by adding a tablet into a 100 ml graduated measuring cylinder containing the required amount of distilled water. The initial volume of the measuring cylinder was recorded. Then the measuring cylinder was shaken 10 times. The final volume was recorded after the production of foam³⁶.

$$\text{Foam expansion} = \frac{\text{Volume of foam}}{\text{Volume of solution}}$$

pH:

The pH of the solution was measured using a pH meter by dissolving 3 tablets in 3 beakers containing 200 ml of water⁵¹.

Wetting ability:

The wettability of the formulated tablet was evaluated by folding the Whatman filter paper and placing diametrically in a petri dish of 8.5 cm in diameter. 8 ml of water containing the water-soluble dye amaranth was added to the filter paper on the petri dish. Carefully placed the tablet on the filter paper at time $t = 0$ and time for complete wetting was measured.

3. RESULT:

3.1 Pre-formulation studies:

Table No. 7: Pre-formulation studies

Trail number	Bulk density (g/ml)	Tapped density (g/ml)	Angle of repose	Hausner's ratio (g/ml)	Compressibility index (%)	Percentage porosity
F ₁	0.591	0.633	37.83°	1.071	6.63	5.97
F ₂	0.502	0.572	36.71°	1.139	12.23	12.02
F ₃	0.525	0.573	31.50°	1.091	6.631	6.025
F ₄	0.571	0.607	31.86°	1.063	5.93	5.53
F ₅	0.565	0.597	29.62°	1.056	5.36	4.97

3.2 Post evaluation studies:

Table No. 8: Post evaluation studies

Trial No	Weight Variation (g)	Hardness (kg)	Friability (%)	pH	Effervescence time	CO ₂ Content (mg)	Foaming ability (cm)	Wettability (sec)
F ₁			0.51		10min16sec	0.04		
F ₂			0.75		7min 35sec	0.15		
F ₃			0.45		5min 25sec	0.16		
F ₄			0.92		3min 40sec	0.25		
F ₅			0.63		2min 33sec	0.29		

4. DISCUSSION

4.1 Pre-formulation tests:

- **The angle of repose:**

The angle of repose of the powder blend was determined by the fixing funnel method.

The formulations F₁ to F₅ showed passable flow.

F₅ is having the minimum angle of repose with good flow property.

- **Hausner's ratio:**

Hausner's ratio was found to be between 1-1.1 for all the formulations and is shown the excellent flow property.

- **Carr's index:**

Carr's index for the formulation F₂ is found to be good.

The formulations F₁, F₃, F₄, F₅ are having a carr's index range of less than 10 and were found to have excellent flow property.

4.2 Post formulation:

- **Weight variation:**

All the formulations that are from F₁ to F₅ have passed the weight variation test as the percentage weight variation was within the I.P limit of ± 5.0 % of the weight. All the tablet weights were found to be consistent with the minimal standard deviation values. The prepared formulations obey the standards of the weight variation test.

- **Friability:**

The maximum friability of the formulation was found to be 0.96 for F₄.

The minimum friability was found to be 0.51% for F₃. The percentage friability was less than 1% for all the formulations (F₁-F₅) ensuring that all the tablets were mechanically stable.

- **pH:**

The pH of all the formulations was tested using a pH meter and it was found to be within the limit.

- **Effervescence time:** The effervescence time for the formulations F₁, F₂, F₃, F₄ exceeded the standard effervescence time (< 3minutes) whereas the formulation F₅ showed the effervescence time of 2 minutes 33 seconds which is less than the standard effervescence time.

- **CO₂ content:**

The Carbon dioxide content was determined for all the formulations.

- **Foaming ability:**

The foaming ability for the formulation F₁ was found to be fair whereas, for the formation F₂, F₃, F₄, F₅ have a good foaming property.

- **Hardness:**

The hardness of all the formulations was tested using the Monsanto hardness tester and all the formulations were within the standard limit.

5. CONCLUSION AND SUMMARY

The present research work entitled "FORMULATION AND EVALUATION OF EFFERVESCENT TOOTHPASTE TABLETS" was carried out to replace the traditional toothpaste that we have used from the early years. Toothpaste tablets are chewable versions of toothpaste that can be chewed into a paste before brushing. The effervescent toothpaste tablets were prepared in a dosage of 200 mg by direct compression method.

Pre-compression studies like the angle of repose, bulk density, tap density, compressibility index, Hausner's ratio, flow rate, and percentage porosity were conducted on the powder blend. The formulated tablets were evaluated for post-compression tests like weight variation, hardness, friability, wettability, pH, effervescence time, carbon dioxide content, and foaming ability.

The results obtained at each stage of the formulation were utilized and the best formulations were selected.

Finally, the F₅ formulation of 200 mg tablets was selected as the best formulation because of their physicochemical characteristics. We concluded that the formulated effervescent toothpaste tablets can be significantly used as an eco-friendly alternative for traditional toothpaste.

6. REFERENCES

1. Dotiwala AK, Samra NS. StatPearls [Internet]. StatPearls Publishing; Treasure Island (FL): April 19, 2021. Anatomy, Head and Neck, Tongue.
2. Editor(s): Bernad A Cohen, Pediatric Dermatology (Fourth Edition), W.B.Saunders,2013, Page viii,<https://doi.org/10.1016/B978-0-7234-3655-3.00014-X>.
3. Chaturvedi, Manav & Punj, Anahita. (2018). Human oral microflora. International Journal of Current Advanced Research. 7. 14065-14070. 10.24327/ijcar.2018.14070.2539.
4. Wi, Wan & Fathilah, Abdul & Abdul razak, Fathilah & Rahim, Zubaidah & Rahim, Abdul. (2013). oral microbes and its environment: a review article. Esteem academic journal. 9. 67-75.
5. Britannica, the Editors of Encyclopedia. "Tooth". Encyclopedia Britannica, 19 Feb. 2021, <https://www.britannica.com/science/tooth-anatomy>. Accessed 1 October 2021.
6. American Dental Association: <https://www.mouthhealthy.org/en/az-topics/t/tooth>.
7. Fabbri G, Cannistraro G, Pulcini C, Sorrentino R. The full-mouth mock-up: a dynamic diagnostic approach (DDA) to test function and esthetics in complex rehabilitations with the increased vertical dimension of occlusion. Int J Esthet Dent. 2018; 13(4):460-474.
8. Dhage, Varsha & Chougule, Pratibha. (2019). Importance of Oral Hygiene in Oro-Dental Diseases: A Review Study. E-ISSN: 2349-9788; P-ISSN: 12.
9. Naseem, Sajida & Fatima, Syeda & Ghazanfar, Haider & Haq, Sana & Khan, Najeeb & Mehmood, Moez & Ghazanfar, Ali. (2017). Oral Hygiene Practices and Teeth Cleaning Techniques Among Medical Students. Cureus. 9. 10.7759/cureus.1487.
10. Agrawal A, Gupta A (2020) Exploring the Factors Influencing the Choice of Oral Care Products: A Review on Personalized Approach. Int J Oral Dent Health 6:109. doi.org/10.23937/2469-5734/1510109
11. Zare, P. & Saeedi, Majid & Akbari, Jafar & Morteza-Semnani, Katayoun. (2017). A review on herbal oral care products. Journal of Mazandaran University of Medical Sciences. 26. 394-410.
12. Sekar, Mahendran. (2016). Formulation, Evaluation and Antibacterial Properties of Novel Polyherbal Toothpaste for Oral Care. International Journal of Pharmaceutical and Clinical Research. 8. 1155-1158.
13. Mude, Gaurav & Thombare, Ganesh. (2020). Formulation and evaluation of polyherbal toothpaste and comparative study with marketed formulations. 3796.
14. Shilpa PD, Priya VM, Prachi M. Preparation and evaluation of herbal tooth powder: World Journal of Pharmaceutical Research. 8(10):944-948.
15. Madan, Charu & Arora, Kapil & Chadha, Vandana & Manjunath, Bhadravathi & Chandra shekar, B R & Rani, Vatchala. (2014). A knowledge, attitude, and practices study regarding dental floss among dentists in India. Journal of Indian Society of Periodontology. 18. 361-8. 10.4103/0972-124X.134578.
16. Azcarate-Velázquez, Francisco & Garrido-Serrano, Roberto & Castillo-Dalí, Gabriel & Serrera-Figallo, Ma & Gañán-Calvo, Alfonso & Torres-Lagares, Daniel. (2017). Effectiveness of flossing loops in the control of the gingival health. Journal of Clinical and Experimental Dentistry. 9. 10.4317/jced.53858.
17. Majeed, Abdul & Farooq, Imran & Grobler, Sias & Rossouw, RJ. (2015). Tooth-Bleaching: A Review of the Efficacy and Adverse Effects of Various Tooth Whitening Products. Journal of the College of Physicians and Surgeons--Pakistan: JCPSP. 25.
18. Toothpaste Tablets: A New Way to Brush Your Teeth By: Jim Marion | Mar 29, 2019 <https://health.howstuffworks.com/wellness/oral-care/products/toothpaste-tablets-new-way-to-brush-teeth.htm>
19. Toothpaste tablets: Your next big thing by: Sudip Saha | May 25, 2021 <https://www.dentistryiq.com/dentistry/products/hygiene/article/14203936/toothpaste-tablets-your-next-big-thing>
20. Atheer Awad, Sarah J. Trenfield, Abdul W. Basit, Chapter 19 - Solid oral dosage forms, Editor(s): Adeboye Adejare, Remington (Twenty-third Edition), Academic Press, 2021, Pages 333-358.
21. Ashika Advankar, Rahul Maheshwari, Vishakha Tambe, Pooja Todke, Nidhi Raval, Devesh Kapoor, Rakesh K. Tekade, Chapter 13 - Specialized tablets: ancient history to modern developments, Editor(s): Rakesh K. Tekade, In Advances in Pharmaceutical Product Development and Research, Drug Delivery Systems, Academic Press, 2019, Pages 615-664.

22. Rothhäuser B, Kraus G, Schmidt PC. Optimization of an effervescent tablet formulation containing spray-dried L-leucine and polyethylene glycol 6000 as lubricants using a central composite design. *Eur J Pharm Biopharm.* 1998 Jul; 46(1):85-94. DOI: 10.1016/s0939-6411(97)00154-9. PMID: 9700026.
23. Payghan, Santosh. (2015). Formulation and Evaluation of New Effervescent Tablet of Famotidine for Peptic Ulcer Therapy. *Inventi Rapid: Pharm Tech.* 2015. 1-15.
24. Ipci, Kagan & Öktemer, Tuğba & Birdane, Leman & Altıntoprak, Niyazi & Bayar Muluk, Nuray & Passali, Desiderio & Lopatin, Andrey & Bellussi, Luisa & Mladina, Ranko & Pawankar, Ruby & Cingi, Cemal. (2016). Effervescent tablets: a safe and practical delivery system for drug administration. *ENT Updates.* 10.2399/jmu.2016001009.
25. Dokala GK, Pallavi C. Direct Compression - An Overview. *International Journal of Research in Pharmaceutical and Biomedical Sciences*, January– March 2013; Volume 4 (1): 155-158.
26. McCormick Douglas. Special Report on Evolutions in Direct Compression. *Pharmaceutical Technology*, www.Pharmtech.Com. April 2005; 52-62.
27. Manufacture of Tablets by Direct Compression Method by Pharm approach | March 26, 2020, in *Pharmaceutical Technology*. <https://www.pharmapproach.com/manufacture-of-tablets-by-direct-compression-method-2/>
28. Iqbal, Mohammad Kashif. (2018). Recent advances in direct compression technique for pharmaceutical tablet formulation.
29. Singh, Kuldeep & Singh, Pooja & Oberoi, Gurpreet. (2016). Comparative studies between herbal toothpaste (dantkanti) and non-herbal toothpaste. 4. 53-56. 10.14419/ijdr.v4i2.6633.
30. Patil, Sachinkumar & Dhanraj, Jadge & N., Purohit. (2008). Formulation of toothpaste from various forms and extracts of tender twigs of neem. *Journal of Pharmacy Research.* 1. 148-152.
31. Nwakanma, Chioma & Ejim, Justina & Unachukwu, Marian. (2014). Original Research Article The Effects of selected toothpaste on the microbial flora of the mouth of GOU Student. *International Journal of Current Microbiology and Applied Sciences.* 3. 785-792.
32. Grace, Fatima & C, Darsika & V, Sowmya & Afker, Azra & S, Shanmuganathan. (2015). Preparation and evaluation of herbal dentifrice. *International Research Journal of Pharmacy.* 6. 509-511. 10.7897/2230-8407.068102.
33. J Okpalugo, K Ibrahim, US Inyang Toothpaste formulation efficacy in reducing oral floral tropical *Journal of Pharmaceutical Research*, February 2009; 8 (1): 71-77.
34. Shukla, Kavita & Kumari, Deepika. (2019). Formulation Development and Evaluation of Herbal Toothpaste for Treatment of Oral Disease. *Journal of Drug Delivery and Therapeutics.* 9. 98-104. 10.22270/jddt.v9i4-s.3344.
35. Thoke, Sagar & Sharma, Yogesh & Rawat, swatirawat & Nangude, Satish. (2013). Formulation development & evaluation of effervescent tablet of alendronate sodium with Vitamin D3. *Journal of Drug Delivery & Therapeutics.* 3. 65-74. 10.22270/jddt.v3i5.623.
36. Payghan, Santosh. (2015). Formulation and Evaluation of New Effervescent Tablet of Famotidine for Peptic Ulcer Therapy. *Inventi Rapid: Pharm Tech.* 2015. 1-15.
37. Kareem Abu Bakr Mohammed, Howida Kamal Ibrahim & Mahmoud Mohammed Ghorab (2016) Effervescent tablet formulation for enhanced patient compliance and the therapeutic effect of risperidone, *Drug Delivery*, 23:1, 297-306, DOI: 10.3109/10717544.2014.912693
38. Aslani A, Jahangiri H. Formulation, characterization and physicochemical evaluation of ranitidine effervescent tablets. *Adv Pharm Bull.* 2013;3(2):315-22. doi: 10.5681/apb.2013.051. Epub 2013 Aug 20. PMID: 24312854; PMCID: PMC3848210.
39. Perth Appachetty, Palanisamy & Abhishekh, Rabi & Kumar, D. Yoganand. (2011). "Formulation And Evaluation Of Effervescent Tablets Of Aceclofenac". *International Research Journal Of Pharmacy.* 2. 185-190.
40. Khan MK. Evaluating the Clinical Efficacy of Tooth Powder on Plaque-Induced Gingivitis: A Randomized Controlled Trial. *Compend Contin Educ Dent.* 2017 Sep;38(8):e13-e16. PMID: 28862466.
41. Khan, Muhammad & Mudassar, Abdul & Kareem, Abdul & Mirza, Kamran & Khan, Ayyaz & Hosein, Tasleem & Ansari, Shazia. (2012). Does the use of toothpowder affect the oral health status of an individual *Journal of the Pakistan Dental Association?* 21. 153-156.

42. Bharathi M, Rajalingam D, Vinothkumar S, Artheeswari R, Kanimozhi R, & Kousalya V. (2020). Formulation and evaluation of herbal tooth powder for oral care. *International Journal of Pharmaceutical Research and Life Sciences*, 8(1), 1-5.
43. Agrawal, Dr. Ali, Dr. Gupta, Narinder. (2016). Evaluation of Clinical Efficacy of Unani Toothpowder (Payorin) on Plaque and Gingivitis- A Randomized Clinical Trial. *International Journal of Scientific Research*. 5. 1-4.
44. Shilpa Pandharinath Dakhurkar, Priya Vishwanath Mijgar, Snehal Dilip Wani and Prachi Madhukar Murkute (2019). Preparation and evaluation of herbal tooth powder. *World Journal of Pharmaceutical Research*. 8. 944-948.
45. Paul, Yunana & Tyagi, Sunayana & Singh, Bhupinder. (2011). Formulation and Evaluation Oral Dispersible Tablets of Zidovudine with Different Superdisintegrants. *International Journal of Pharmaceutical and Clinical Research*. 2. 81-91.
46. Vankadari, Rama Mohan Gupta & Gupta, V.R.M & Devanna, Nayakanti & M, Rama & Harish, Nanabala & Krishna, Vamsi & Koundinya, Raman & Prasad, Dr. (2012). Formulation and evaluation of ORO dispersible tablets of Stavudine by direct compression technique. *Asian Journal of Pharmaceutical and Clinical Research*. 5. 219-224.
47. Jadhav, Sudhakar & Kaudewar, D. & Kaminwar, G. & Jadhav, A & Vishwanathrao, Kshirsagar & Sakarkar, M. (2010). Formulation and Evaluation of Dispersible Tablets of Diltiazem Hydrochloride. 3.
48. Vankadari, Rama Mohan Gupta & Prasad, Dr & Devanna, Nayakanti & Subramanian, N. & Reddy, Ch & Kumar, Ch. (2013). Formulation and evaluation of orodispersible tablets of rizatriptan benzoate by direct compression technique. *International journal of pharmaceutical and chemical sciences*. 2. 1558-1568.
49. Chirag, Jadav & Asija, R. & Dhruv, Kaunil. (2012). Formulation and evaluation of orodispersible tablets of diazepam using different super disintegrants. *International Research Journal of Pharmacy*. 3. 298-301.
50. Raymond C Rowe, Paul J Sheskey, and Siân C Owen. *Handbook of Pharmaceutical Excipients*. Pharmaceutical Press and American Pharmacists Association 2006. 5.
51. Kashi, Srinath & Cherukuri, Pooja chowdary & Pethappachetty, Palanisamy & Krishna, A, Vamsy & Aparna, S. & Ali, Syed & Rakesh, P. & K. Swetha, (2011). Formulation and evaluation of effervescent tablets of paracetamol. *International journal of pharmaceutical research and development (IJPRD)*. 3. 76-104.

HUMAN