



DEVELOPMENT AND EVALUATION OF TOOTHPASTE TABLETS FOR DENTAL CARIES

¹Jincy V Varghese, ²Rishikesh P, ³Sreelakshmi S, ⁴Ajay W, ⁵Rathul M A, ⁶Alwyn S Kumar

¹ Assistant Professor, Department of Pharmaceutics, Nehru College of Pharmacy, Pampady,
Thiruwilvamala, Thrissur, Kerala,

² Student, Nehru College of Pharmacy, Pampady, Thiruwilvamala, Thrissur, Kerala.

³ Student, Nehru College of Pharmacy, Pampady, Thiruwilvamala, Thrissur, Kerala.

⁴ Student, Nehru College of Pharmacy, Pampady, Thiruwilvamala, Thrissur, Kerala.

⁵ Student, Nehru College of Pharmacy, Pampady, Thiruwilvamala, Thrissur, Kerala.

⁶ Student, Nehru College of Pharmacy, Pampady, Thiruwilvamala, Thrissur, Kerala.

Abstract: Toothpaste is an essential component in keeping teeth healthy and preventing dental disorders. These days, people are becoming more interested in natural and herbal formulations as substitutes for conventional ones. Toothpaste tablets are chewable, tiny, bite-sized tablets that have a comparable effect to regular oral toothpaste when chewed into a paste before brushing. One of the common bacteria present in the human oral cavity is *Streptococcus mutans*. Bad breath odor and tooth cavities have been caused by these particular bacteria. The purpose of the study was to develop and evaluate the guava extract toothpaste tablets using the direct compression method against *S. mutans* ATCC 25175. Also we maximized the use of natural excipient like Stevia, Sodium cocoyl isethionate, Xylitol etc decreasing amount of artificial chemicals. The pills were prepared using the direct compression process in a 500 mg dosage form. The powder blend was assessed for a number of pre-formulation properties including porosity percentage, Hausner's ratio, compressibility index, and angle of repose. Evaluations were conducted on the post-compression properties such as weight variation, hardness, friability, pH, wettability, and foamability. Foamability and disintegration time were used to determine which formulas were the best. For better oral hygiene, the developed toothpaste tablets proved to be a superior substitute for toothpaste.

Keywords: - Dental plaque, Toothpaste Tablets, Direct compression, Oral hygiene.

I. INTRODUCTION

Toothpaste tablets are round, little pills that can be chewed like mints. To use them, just drop a tablet into your mouth, bite down, and then brush with a moist toothbrush. With only a little time, the tablet turns into a frothy paste that offers all the teeth-cleaning power you require for a clean, healthy smile. Put an end to squeezing and wasting of toothpaste.^[1]

Tooth decay is most generally referred to as dental caries. This happens as a result of the oral bacterium *Streptococcus mutans* breaking down carbs into acid.^[2, 3] It is a complicated, progressive disorder where the surface structure of a tooth gradually deteriorates. By using oral care products like toothpaste, mouthwashes, gargles, etc., dental cavities can be avoided.

Eco-friendly toothpaste substitutes are called tablets. Portability and tolerance to temperature variations are two advantages of these items. Users no longer need to worry about the toothpaste drying up if they forget to close the cap, nor do they have to carry around bulky tubes of toothpaste. To keep your teeth healthy when traveling, chewable toothpaste tablets are a wonderful choice. Users may use them for a quick clean even without a toothbrush, and the containers are conveniently sized to fit into little bags.^[4,5]

Toothpaste pills include the same chemicals as toothpaste, including sodium bicarbonate, calcium carbonate, and xylitol. They also contain natural chemicals like Stevia, Sodium cocoyl isethionate, etc.^[6] Like pharmaceutical tablets, they are packed securely. If stored correctly, these can last for a very long period. One plant that is advised against dental caries is guava (*P. guajava*), whose sensitive leaves are used to make toothpaste tablets that is utilized in traditional oral hygiene practices^[7]. Their aqueous extracts have an antibacterial effect on plaque bacterial growth. The extracts' possible application as anti-plaque agents is then suggested. Consequently, the goal of this research is to create toothpaste tablets that have ability to control dental caries.

Advantage:

- Toothpaste tablets are easier to use.
- Toothpaste tablets are made with the same excipients as regular toothpaste; no additional excipients are required.
- No water is required for their formation.
- It masks the unpleasant taste and smell of the medications, increasing patient tolerance by a pleasing flavor; it can be used as a substitute for traditional toothpaste.
- Cut down on product waste.
- Simple to use when traveling.
- Eco-friendly.^[8]

Application:

- It is an affordable product; unlike traditional toothpaste, it doesn't require pricey machinery or a drawn-out production process.
- Lower the water content of toothpaste tubes to minimize logistics and supply chain management.
- To provide glass jars or reusable containers for easy transport dry or tablet items (like toothpaste tablets) in locations where the transportation of liquid or gel is forbidden.
- Instead of using paper for massive packaging, we might use refillable containers to conserve a huge number of trees each year.
- To motivate people living in both rural and urban areas to spread the idea of a healthy environment.^[8]

Botanical classification:Table no 1: Botanical classification of *Psidium guajava*

Kingdom	Plantae
Sub kingdom	Tracheobionta vascular plants
Divison	Mangnoliophyta flower plants
Class	MangnolipsidaDicotyledonus
Subclass	Rosidae
Order	Myrtales
Family	Myrtaceae
Subfamily	Myrtoideae
Genus	Psidium
Species	<i>Psidium guajava</i>

Guava leaves have many potential benefits for teeth, including:

- Preventing plaque: Guava leaves have antibacterial properties that can help prevent plaque buildup on teeth. Plaque can lead to gingivitis and periodontitis if left untreated.
- Relieving pain: Chewing a raw guava leaf can provide short-term pain relief from toothaches. The natural juice from the leaf can help soothe a sore tooth.
- Reducing inflammation: Guava leaves can help reduce gum inflammation and gingivitis.
- Freshening breath: Guava leaves can help eliminate bad breath.

II. METHODOLOGY

2.1 MATERIALS AND METHODS:

2.1.1 Chemicals and reagents

Table no 2: Chemicals and reagents

MATERIALS	USE	PERCENTAGE
Guava leaf extract	Therapeutic agent	40%
Calcium carbonate	Polishing agent	10%
Sodium bicarbonate	Penetrates the plaque layer	10%
Xylitol	Humectant	16%
Stevia	Sweetening agent	2%
Starch	Disintegrant and binding agent	10%
Sodium cocoyl isethionate	Surfactant	7%
Menthol	Cooling/Breath freshening agent	0.2%
Peppermint oil	Remineralizes tooth enamel Helps fight sensitivity	One drop
Magnesium stearate	Glidant	2%
Talc	Lubricant	2.8%

2.1.2 Instruments and apparatus:

Table no 3: Instruments and apparatus

SR. NO.	INSTRUMENTS
1.	Electronic balance
2.	Hot air oven
3.	pH meter
4.	Tablet punching machine
5.	Monsanto hardness tester
6.	Roche friabilator

2.2 FORMULATION OF TOOTHPASTE TABLETS:

2.2.1 Preparation of Extract

After being washed, *Psidium guajava L.* (Myrteceae) leaves were dried in an oven set at 60°C for 48 hours. Following the pulverization of the dried leaves, the plant powder (1 g) was extracted by adding it to 10 ml of deionized water, and the mixture was boiled for 15 minutes to make tea. The extract was allowed to cool and centrifuged. The supernatant was lyophilized and kept in refrigerator.

2.2.2 Composition of toothpaste tablets

Table no 4: Composition of toothpaste tablets

INGREDIENTS	F ₁	F ₂	F ₃
Guava leaf extract	230	200	170
Calcium carbonate	50	50	50
Sodium bicarbonate	45	50	55
Xylitol	80	80	80
Stevia	10	10	10
Starch	30	50	70
Sodium cocoyl isethionate	30	35	40
Menthol	1	1	1
Peppermint oil	One drop	One drop	One drop
Magnesium Stearate	10	10	10
Talc	14	14	14

2.2.3 Procedure:

- weighed all the components to the exact amount required.
- a homogenous powder was created by blending the previously weighed materials with a mortar and pestle.
- after that, enough peppermint oil (one drop) is added to the powder mixture and it is combined once more to create granules.
- using a hot air oven, the granules were dried at 50° C for 15 to 20 minutes.

- then, precisely weighed talc was added to the dry granules and combined.
- By using the direct compression method; toothpaste tablets were produced by punching the above-dried granules with punch size numbers.^[9,11]

2.3 EVALUATION OF TOOTHPASTE TABLETS

2.3.1 Pre-compression Parameters:

Prior to compression, the following factors were used to describe the flowability characteristics of powders and granules: Hausner's ratio, bulk density, tap density, compressibility index (also known as Carr's index), percentage porosity, and angle of repose.

Angle of repose:

The maximum angle that can exist between the surface of a pile of powder and the horizontal plane is known as the angle of repose. The angle of repose, which is a measure of the powder flow property, can be used to calculate the frictional force in loose powder or granules.^[10]

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

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

Where,

θ is the angle of repose

H is the height of the pile

R represents the pile's base radius.

Procedure: The funnel was mounted to a stand through which the powder could flow at a specific height (H). The height and radius of the powder heap that formed were then measured in order to determine the angle of repose. We kept an eye on the powder particles to make sure they didn't slide and cover one another through the funnel's walls.

Table No. 5: Angle of repose as an indication of powder flow

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

Flow Rate:

The rate at which a specific mass passes through a funnel's appropriate diameter aperture is known as the powder's flow rate. The flow rate of granules of each formulation was measured by carefully pouring precisely weighed amounts of granules into a funnel with an 8 mm diameter aperture. The time taken for the entire granule mass to come out of the orifice is noted using a stopwatch. The equation that follows was used to determine the flow rate.

Flow rate = Weight of the granules / Times 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 three times from a height of one inch onto a hardwood surface at intervals of two seconds. 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. The following equation was used to calculate it.

Bulk density = 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 1 inch. 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 computed with the aid of the provided equation.

Tap density = Mass / Tap volume

Carr's index:

The % compressibility index, commonly known as Carr's index, is a technique that indirectly measures flow of granules by utilizing bulk densities. It was developed by Carr. A powder's % compressibility served as a direct indicator of its granule stability and bridge strength. Carr's index of each formulation was calculated by using the following equation^[11]

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

Table No. 6: 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.^[12]

Table No. 7: Weight variation specification as per I.P.

Average weight	Maximum percentage 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. The upper plunger was pushed up against a spring until the tablet broke by rotating a threaded bolt.^[13] The force of fracture was recorded. For each formulation, ten tablets were evaluated.

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 4minutes at 25 rpm. All the tablets were dedusted and weighed by the following Formula.

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

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. The measurement cylinder was then shaken ten times. The final volume was recorded after the production of foam.^[11,12]

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

pH:

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

Disintegration test

The USP disintegration apparatus contains six glass tubes that are 3 inches long, open at the top, and held against 10 mesh screens at the bottom end of the basket rack assembly. Each tube holds one tablet, and the basket rack is set up in a one-liter beaker of distilled water that is $37 \pm 2^\circ\text{C}$. The tablets are arranged so that, when they rise, they stay below the liquid's surface and don't descend any closer than 2.5 cm from the beaker's bottom. It was noticed how long it took for the tablet to disintegrate entirely.^[14,15,16]

III. RESULTS AND DISCUSSION

3.1 RESULT

3.1.1 Pre-formulation studies:

Table No. 8: Pre-formulation studies

Trial No	Bulk Density(g/ml)	Tapped Density(g/ml)	Angle of Repose	Hausner's Ratio(g/ml)	Compressibility index (%)	Percentage Porosity
F ₁	0.596	0.634	37.73°	1.090	6.43	5.95
F ₂	0.509	0.571	29.59°	1.058	12.19	12.01
F ₃	0.568	0.613	31.47°	1.051	5.35	6.023

3.1.2 Post evaluation studies:

Table No. 9: Post evaluation studies

Trial No	Weight Variation(g)	Hardness(kg)	Friability (%)	pH	Disintegration time	Foaming ability(cm)
F ₁	508	1.8	0.75	8.13	10min 35sec	35
F ₂	515	2.7	0.63	8.78	7min 35sec	55
F ₃	503	3.5	0.91	9.01	5min 43sec	60

3.2 DISCUSSION

3.2.1 Pre-formulation tests:

- The angle of repose:

Using the fixed funnel method, the powder blend's angle of repose was determined.

The flow of the formulations F1 through F3 was passable.

The best flow characteristic and the lowest angle of repose are found in F2.

- Hausner's ratio:

For every formulation, Hausner's ratio was found to range from 1 to 1.1, demonstrating the outstanding flow characteristic.

- Carr's index:

It is discovered that Carr's index for formulation F2 is good.

The formulations F1, F3 were found to have excellent flow properties and carr's index in the range of less than 10.

3.2.2 Post formulation:

- Weight variation:

All the formulations that are from F1 to F3 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:

For F3, the formulation's maximum friability was determined to be 0.91.

For F2, the lowest friability was discovered to be 0.63%. For every formulation (F1-F3), the percentage friability was less than 1%, guaranteeing the mechanical stability of every tablet.

- pH:

Using a pH meter, the pH of each formulation was checked, and it was discovered to be within the acceptable range.

- Foaming ability:

It was discovered that the formulation F1 had a fair foaming capacity, whereas the formulations F2 and F3 had good foaming properties.

- Hardness:

Using the Monsanto hardness tester, the hardness of each formulation was examined; all of the formulations tested within the standard limit.

- Disintegration time:

Formulation F2's disintegration time fell between 7 and 9 minutes. The amount of time it takes for tablets to dissolve was found to decrease with an increase in the disintegrating agent concentration in the formulation.

V. SUMMARY AND CONCLUSION

The goal of the current research work entitled, "DEVELOPMENT AND EVALUATION OF TOOTHPASTE TABLETS FOR DENTAL CARIES," is to replace the conventional toothpaste that we have been using since we were young children. Chewable toothpaste in the form of tablets is designed to be chewed into a paste before brushing. The 500 mg dosage of toothpaste tablets was created using the direct compression method.

The powder blend was subjected to pre-compression evaluations for the angle of repose, bulk density, tap density, compressibility index, Hausner's ratio, flow rate, and percentage porosity. Post-compression tests including weight variation, hardness, friability, pH, foaming ability, and disintegration time were performed on the prepared tablets.

The best formulations were chosen by utilizing the outcomes at each stage of the formulation process.

Ultimately, due to its physicochemical properties, the 500 mg tablet formulation known as F2 was determined to be the optimal formulation. We came to the conclusion that the designed toothpaste tablets are a very useful and environmentally friendly substitute for conventional toothpaste.

REFERENCES

1. Mirza P, Gopinath E, Formulation and evaluation of effervescent tooth foaming tablet. *International Journal of Pharmacy and Pharmaceutical Research. Human.* 2022; 23 (4): 185-209.
2. Michalek SM, McGhee JR, Shiota T, et al. Low sucrose levels promote extensive *S.mutans*-induced dental caries. *Infect Immun* 1977; 16 :712-4.
3. Anuradha A, Priya H, Bhavana SB, Puneeth HK, Asif M. and Vijay Srinivas G. Guava leaf extract - a credible anticariogenic agent. *Ijcmpr* 2016; Vol. 2, Issue, 6, pp.375-378
4. Mohite MT, Mirani K. A Game-Changer in Oral Care: Unraveling the Formulation Secrets of Toothpaste Tablet. *Journal of Survey in Fisheries Sciences.* 2023 Aug 24:3463-71.
5. Suppipat S, Hu AH, Trinh LT, Kuo CH, Huang LH. A comparative life cycle assessment of toothpaste cream versus toothpaste tablets. *Sustainable Production and Consumption.* 2022 Jan 1;29:357-69.
6. Thakur K, Chopde M. A review article: Herbal tooth tablets formulation. *World Journal of Pharmaceutical Research.* 2022 Jun 1;11(10):648-54.
7. Nurhidayah Md. H, Shuhaila H, Muhammad S, Rabiatal J, Tengku N, Zaidatul S, Optimization of guava chewable toothpaste tablets, *International Jasin Multimedia and Computer Science Invention and Innovation Exhibition.* 2020; 148-150.
8. Deore Nisha N, Surawase RK. A Chewable Toothpaste Tablet: An Alternative approach to the Toothpaste. *Research Journal of Pharmaceutical Dosage Forms and Technology.* 2022;14(4):336-2.
9. Monika Sahebrao Tambe, Priyanka Pradeep Tandel, Manish Mukesh Vaishnav. A Review on Tooth Paste Tablet. *International Journal of Research Publication and Reviews,* 2023, Vol 4, no 4, pp 805-808
10. Patil PS, More AK, Kadam S, Vishwasrao V, Patel Y. Formulation and evaluation of orodispersible tablets of perindopril erbumine using natural superdisintegrant. *Journal of Drug Delivery and Therapeutics.* 2013 Sep 14;3(5):44-8.
11. G. Govinda Reddy, Naina R., N. Abhishek, Nasir M., Murugesh Roopashree a, Gopal Naik L. M. Formulation and evaluation of triclosan chewable toothpaste tablet. *World journal of pharmacy and pharmaceutical sciences.* Volume 12, Issue 11, 1189-1204
12. Brahmanekar M, Jaiswal B, *Biopharmaceutics and pharmacokinetics, A treatise.* 1st edition. New Delhi. Vallabh Prakashan. 1995
13. Naveen Nagar (2024) Formulation and Evaluation of Floating Tablet of Isradipine Educational Administration: Theory a Practice, 30(5), 9250-9259
14. Patidar VK, Sharma A. Design, Formulation and evaluation of Amiodarone HCl co-crystal tablet. *European Journal of Molecular & Clinical Medicine.* 2021;7(8):2020.
15. *Indian Pharmacopeia,* Government of India Ministry of Health and Family Welfare. The Controller of Publications. Delhi. 2007; 2: 550,746.
16. ICH Harmonized Tripartite Guidelines, Stability Testing of New Drug Substances and Products. ICH Committee; 2003.