

Fabrication and Quality Evaluation of a Poly-Herbal Dentifrice for Pediatric Oral Care.

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ABSTRACT

The present study aimed to develop and evaluate a herbal toothpaste formulation specifically designed for pediatric oral care, focusing on safety, efficacy, and child-friendly characteristics. The formulation incorporated natural ingredients such as calcium carbonate (mild abrasive), glycerin (humectant), guava extract (flavoring and antibacterial agents), coconut oil (antibacterial and anti-inflammatory agents), and black pepper (natural preservative). The prepared toothpaste was assessed for key physicochemical parameters, including pH, spreadability, homogeneity, and stability under various storage conditions. The optimized formulation exhibited a pH 7.9, within the acceptable range for pediatric oral care, along with smooth texture, fine consistency, and excellent spreadability. Stability evaluations confirmed that the formulation remained uniform and effective over time without significant alterations in texture or performance. The inclusion of guava extract and coconut oil contributed to notable anti-microbial activity, suggesting preventive benefits against common pediatric dental problems such as caries, plaque formation, and gingivitis. Overall, the developed herbal toothpaste provides a safe, effective, and natural alternative to conventional pediatric formulations, supporting a holistic and chemical-free approach to improving children's oral health care.

Keywords: Herbal toothpaste, Pediatric oral care, Guava extract, Coconut oil, antimicrobial activity, Natural formulation, Dental health.

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INTRODUCTION

Primary teeth are not merely a 'temporary teeth,' and their proper care is essential for both oral health habits and long-term dental outcomes. These teeth are markedly different from the fully developed teeth of adults, necessitating specialized care. This difference highlights the need for toothpaste formulations that are specifically designed to meet the unique oral care requirements of children as their teeth develop [1].

While past research has primarily focused on fluoride content in children's toothpaste emphasizing the importance of both avoiding excessive fluoride to prevent fluorosis and ensuring an adequate dose for caries prevention less attention has been given to other components of toothpaste[2]. Most studies have concentrated on fluoride levels, given its crucial role in preventing tooth decay, especially in high-risk populations. However, the issue of fluoride intake in children is a delicate balance, as excessive ingestion, often linked to appealing child-specific flavors or designs, may elevate the likelihood of fluorosis. Conversely, an insufficient dose may not provide enough protection against cavities, particularly in children who are

at higher risk of dental decay like gingivitis, plaque, cavities etc [3].



Children aged 0-4 yrs are particularly vulnerable to developing dental fluorosis, especially on the permanent incisors and first molars, as these teeth undergo crucial phases of calcification and maturation during this time. Research including the longitudinal Iowa fluoride study [4], has identified the first three years of life as a critical window during which fluoride exposure significantly influences the risk of fluorosis, particularly affecting maxillary incisors. Therefore, fluoride use in this age group requires careful regulation, balancing the need for caries prevention with the

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risk of excess systemic fluoride intake. This is especially important due to the immature swallowing reflex in young children which increases the likelihood of toothpaste ingestion during brushing [5].

Aside from fluoride, there are other factors such as toothpaste flavor and design that significantly influence child use of toothpaste. Research indicates that favorable child-friendly flavors and packaging can enhance use, but in doing so, enhance swallowing behavior and thus excessive fluoride intake. Hence, it is essential to take into account how flavor affects both user compliance and efficiency of fluoride delivery and retention in the oral cavity [6]. A Brazilian study comparing peppermint vs tutti-frutti flavored pastes in children aged 2-6 found that age and toothpaste type both affected the amount ingested; notably; flavor influenced ingestion rates-tutti-frutti flavored dentifrice resulted in higher ingestion compared to peppermint, especially with larger amounts loaded [7].

Although children may be able to utilize adult toothpaste with care, such as the use of a pea-sized portion, child-specific toothpaste is a more specialized approach. These toothpastes can take into consideration the unique characteristics of children's developing teeth, providing a more balanced quantity of fluoride and other ingredients to promote oral health without the danger of an inappropriate amount of fluoride [8].

Some research supports evaluation of fluoride free versus low fluoride children's dentifrices in an agar diffusion assay against *Streptococcus mutans*. They found no significant differences in antimicrobial activity between fluoride free and certain low fluoride pastes. For very young children who are at risk of developing fluorosis, fluoride-free toothpaste formulations may serve as safer alternatives to fluoride-containing products [9]. A systemic review of herbal dentifrices in children and adolescents concluded that herbal toothpastes were as effective as non-herbal ones in reducing bacterial plaques and *S. mutans* levels-though the evidence for caries prevention remains inconclusive and further high quality RCTs are recommended [10].

The overall philosophy of developing children's toothpaste must consider everything, including how much fluoride, flavoring, ingredients, and the different steps of the dentition development among children. Well-balanced composition optimizes benefits of oral well-being among children and minimizes risks with long-term dentistry advantages.

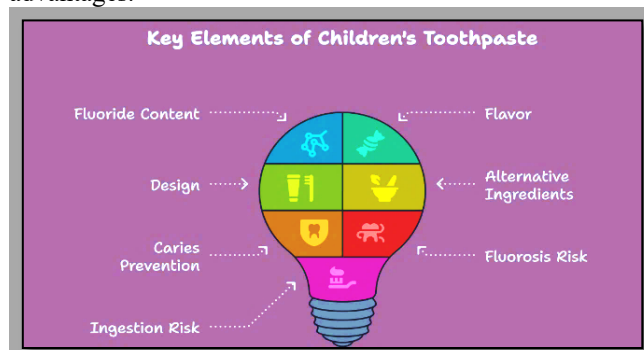


Figure 2.0 – Essential formulation consideration for children's toothpaste. This figure highlights the critical

elements involved in designing toothpaste for children, such as appropriate fluoride concentration, palatable flavors, appealing product design and the use of safe alternative ingredients. Additional considerations include caries prevention efficacy, minimizing fluorosis risk, and ensuring low ingestion-related harm due to accidental swallowing.

1.1 PAEDIATRIC DENTAL ISSUES:

1.1.1 DENTAL CARIES: Dental caries represents a prevalent chronic infectious disease that commonly manifests following the eruption of primary teeth, typically around six months of age. The etiopathogenesis involves the colonization of cariogenic microorganisms particularly *Streptococcus mutans* and *Lactobacilli*, which ferment dietary sugars to produce acids, resulting in progressive demineralization of the enamel surface [11]. The application of topical fluoride remains a cornerstone in the prevention of early childhood caries (ECC). Fluoride facilitates the formation of fluorapatite from hydroxyapatite, thereby enhancing enamel resistance to acid dissolution, inhibiting bacterial metabolism and aiding in the remineralization of incipient lesions. Clinical studies and meta-analysis have consistently supported the effectiveness of professionally applied fluoride varnishes (e.g., 5%NaF) in reducing ECC prevalence, particularly in high-risk pediatric populations [12]. In parallel, behavioral intervention, including supervised brushing with age-appropriate toothpaste, caregiver oral health education, and motivational interviewing, have demonstrated measurable reductions in plaque accumulation and gingival Inflammation, ultimately lowering caries incidence when consistently applied [13]. Additionally, the use of biomimetic non fluoride alternatives such as hydroxyapatite nanoparticles and calcium phosphate complexes has gained prominence as safer options for very young children, particularly where fluoride ingestion is a concern [14][15]. Emerging evidence from randomized controlled trials indicates that these agents provide comparable remineralization benefits and antimicrobial activity without the associated risk of fluorosis [16].

1.1.2 PLAQUE FORMATION: Dental plaque is initiated when oral bacteria permeate salivary glycoproteins and residual food particles to form a microbial biofilm on tooth surfaces. In children, especially those with limited manual dexterity, inadequate removal of this biofilm allows rapid maturation into calcified dental calculus, resulting in increased susceptibility to gingivitis and dental caries [17]. Inadequate brushing frequency and poor technique significantly contribute to plaque accumulation. Longitudinal studies demonstrate that high caries risk children benefit substantially from supervised daily toothbrushing, leading to marked reduction in visible plaque and gingival bleeding over multiyear follow up [18]. Interproximal plaque removal is equally critical yet often overlooked in pediatric oral hygiene. Evidence from clinical evaluations shows that dental flossing effectively reduces interproximal plaque and may decrease interproximal caries risk by approximately 40% when performed professionally in children aged 4-13 years [19].

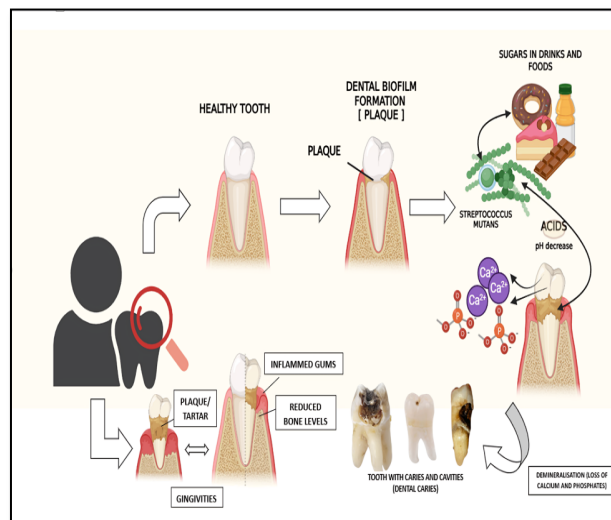
1.1.3 GINGIVITIS: Gingivitis in children arises from microbial biofilm accumulation adjacent to the gingival sulcus, with pathogenic species including *Streptococcus sanguinis*, *Fusobacterium nucleatum*, *actinomyces*, *Veillonella*, and *Treponema*, and occasionally *Capnocytophaga* and *Eikenella*, which collectively alter the microbial ecology over time and increase tissue inflammation [20]. The disease progresses through the initial, early and established stages- beginning with neutrophil-mediated acute inflammation, advancing to a T-lymphocyte dominated infiltrate, and culminating in a chronic lesion characterized by B-lymphocytes and plasma cells, as described in classic pathogenesis models [21]. Pediatric studies indicate that gingivitis in younger children remains largely lymphocyte-dominated and rarely progresses to periodontitis, emphasizing the potential for reversal with effective plaque control [22]. Recent research further demonstrates that the severity of bleeding-on-probing correlates with microbial diversity and pathogen burden in subgingival biofilms among children, with more severe inflammation associated with increased prevalence of periodontal pathogens such as *Prevotella intermedia*, *Peptostreptococcus micros*, and *Capnocytophaga gingivalis* [23]. Therefore timely mechanical removal of plaque and interventions that modulate biofilm ecology are crucial to prevent progression of gingival inflammation in pediatric patients.

In summary, plaque control in pediatric populations demands formulations that combine mechanical efficacy with safety and acceptability. The development of edible, fluoride and SLS-free herbal toothpaste featuring calcium carbonate as mild abrasive, coconut oil for its antimicrobial and plaque repellent fatty acids, glycerin for moisture retention, and guava extract for potent antibacterial action-provides a clinically supported approach to pediatric oral hygiene. Guava extract has demonstrated in vitro inhibition of *Streptococcus mutans* and *S. sanguinis* as well as significant reductions in plaque scores in adolescent cohorts ($p < 0.05$) [24]. Additionally, virgin coconut oil has shown potential in enamel remineralization and fostering on oral environment less permissive to microbial adhesion [25]. These findings reinforce the rationale for selecting these botanical and edible ingredients in a pediatric toothpaste formulation: enabling consistent daily usage, minimizing irritation or fluorosis risk, and effectively managing plaque biofilm. Further clinical trials are warranted to validate long term efficacy and real-world outcomes, but current evidence supports our formulation as a promising age-appropriate oral care solution.

Figure 3.0 – Dental caries and periodontal Disease Progression. This figure illustrates the pathological process leading to dental caries and gingivitis due to dental biofilm formation.

1.2 DESIGN AND DEVELOPMENT:

The selection of ingredients is pivotal in the formulation and functional optimization of pediatric toothpaste. Each component is chosen based on its specific physiochemical or biological properties, contributing synergistically to the



overall efficacy, safety and acceptability of the final product. The following sections outline the key ingredients incorporated in the formulation, along with their respective therapeutic or functional roles.

1.2.1 THICKENER:

Thickeners are essential for achieving the optimal rheological properties of pediatric toothpaste, ensuring that the product can be squeezed from its tube while retaining sufficient body to remain on the brush without dripping highlighting and especially crucial attribute for young users with developing manual dexterity, who require consistency conducive to careful dispensing and brushing. In our formulation, inclusion of calcium carbonate renders dual function: it acts not only as a gentle abrasive to support effective mechanical plaque removal but also a, mild thickening agent that contributes to the pastes structure and viscosity. Importantly, calcium carbonate exhibits acid-buffering capacity and releases calcium ions under acidic conditions, thereby supporting enamel remineralization and neutralizing plaque acidity- mechanisms confirmed by in vitro and clinical studies showing improvements in enamel microhardness and reductions in lesion depth when used either alone or in combination with other calcium-based actives [26]. These clinically documented benefits reinforce the rationale for leveraging calcium carbonate in pediatric herbal toothpaste, enabling a formulation that is both functional in plaque removal and structurally stable without reliance on fluoride or surfactants like SLS.

1.2.2 ABRASIVE:

Abrasives serve as critical components in toothpaste formulations, primarily contributing to the mechanical removal of plaque, food particles, and extrinsic stains through frictional action during brushing. While toothbrushes and adjunct tools plays a significant role in oral hygiene, the abrasivity of toothpaste enhances the overall cleaning process by disrupting the dental biofilm. In pediatric formulations, the concentrations of abrasive

particles is typically lower than in adult counterparts to minimize the risk of enamel and dentin wear in developing primary teeth, which have thinner enamel and are more susceptible to damage [27]. The type, particle size distribution, hardness and morphology of abrasives directly influence their cleaning efficacy and polishing performance. Materials with irregular particle shapes or higher hardness may demonstrate enhanced stain removal but pose a higher risk for dental tissue abrasion. Conversely softer abrasives such as precipitated or ground calcium carbonate offer gentler action making them suitable for pediatric use. Calcium carbonate not only provides mild abrasivity but also contributes buffering capacity, helping to neutralize acidic byproducts from bacterial metabolism [28]. Two internationally recognized measures Relative Dentine Abrassivity (RDA) and Relative Enamel Abrassivity (REA) are employed to evaluate and regulate toothpaste abrasivity. According to ISO 11609 standards, RDA values below 250 are considered safe, but pediatric formulations generally aim for much lower scores often between 30-70, to preserve dental issues while ensuring effective cleaning. Toothpastes with excessively low abrasivity, however, may fail to adequately remove plaque or prevent staining, highlighting the need to balance safety with efficacy [29]. In fluoride free pediatric formulations such as those containing herbal components abrasives like calcium carbonate play an even more significant role in plaque control due to the absence of chemical remineralizing agents. Their function is not merely mechanical but also supportive in maintain a clean oral environment conducive to enamel integrity. Optimizing particle size (typically <math><10\mu\text{m}</math>) and uniform dispersion ensures non-damaging yet effective physical cleansing, a critical consideration in the formulation of safe, natural toothpaste products for children [27].

1.2.3 FLAVOURING AND SWEETENING AGENTS:

Flavors and sweetness are critical considerations in pediatric toothpaste formulation, as children's sensory preferences significantly influence brushing compliance and acceptability. In this formulation, guava (*Psidium guajava*) pulp extract has been incorporated as a natural flavoring agent owing to its pleasant fruity aroma, sweet sour taste and bioactive profile [24][30]. The pulp contains essential volatile compounds such as aldehydes, esters and terpenoids which not only contribute to flavor and fragrance but also offer antimicrobial and antioxidant properties beneficial to oral health. Guava pulp is particularly rich in vitamin C, flavonoids and carotenoids which have been shown to exhibit mild antibacterial effects against oral pathogens and help in neutralizing oral malodor. Its fruity flavor also effectively masks the bitterness of herbal or chemical components, making the product more palatable to children. Furthermore, non-cariogenic sweeteners such as xylitol, sodium saccharin and sucralose are added to enhance taste without promoting plaque formation or acid production. Xylitol in particular has been well documented for reducing *Streptococcus mutans* adhesion and biofilm formation contributing to caries prevention in pediatric

population [31]. The combined action of guava pulp extract and safe sweeteners thus supports both sensory satisfaction and functional oral health benefits making it a strategic component in fluoride and SLS free pediatric toothpaste formulations.

1.2.4 HUMECTANT:

Humectants are essential excipients in toothpaste formulations, primarily responsible for maintaining moisture content and ensuring product stability over time. They prevent desiccation by attracting and retaining water molecules, thereby preserving the semi-solid consistency and enhancing the shelf life of the formulation. In pediatric toothpaste, humectants also contribute to smoother texture, improved spreadability and visually appealing glossy appearance, all of which influence user compliance and product acceptability. Common humectants such as glycerin, sorbitol and polyethylene glycol (PEG) are widely used due to their non-toxic nature, biocompatibility and multifunctional roles. Glycerin in particular is recognized for its hydrating properties, ability to improve mouthfeel and compatibility with a wide range of active and inactive ingredients. These compounds not only maintain physical stability but also enhance flavor perception and support even dispersion of therapeutic agents, making them vital in both adult and pediatric oral care formulation [32].

1.2.5 PRESERVATIVE:

Preservatives are indispensable in toothpaste formulations, particularly when natural plant extract like guava pulp and black pepper are incorporated as these may support microbial growth over time. In pediatric preparations that may be ingested, selection of preservatives must combine effective antimicrobial action with minimal toxicity. Black pepper (*Piper nigrum*) rich in piperine and phenolic compounds demonstrates significant broad-spectrum antimicrobial efficacy including activity against oral microbes and periodontal pathogens such as *P. gingivalis*, *S. aureus* and *S. mutans* at inhibitory concentrations around 3-6 mg/ml [33][34]. Clinical evaluation of a herbal dentifrice containing Piper nigrum for twelve weeks showed marked reductions in gingival bleeding, salivary anaerobic bacterial load and plaque scores in children confirming in vivo safety and efficacy. Toxicological assessments further support its safety: piperine the main bioactive constituent is considered non-genotoxic and non-toxic at low exposure levels with NOAEL established by EFSA at ~5mg/kg body weight per day. Including black pepper thus offers dual functionality- serving as natural preservative to inhibit microbial contamination while adding to antimicrobial action in a fluoride and SLS free pediatric toothpaste [35]. Its favorable safety profile and traditional use support its suitability in formulations intended for children who may swallow small quantities during brushing.

2.0 MATERIALS AND METHODS:

Materials: Calcium Carbonate, Coconut oil, Glycerin, Guava, Black Pepper

Equipment: Beaker, Spatula, Glass Rod, Hot air oven, Mortar Pestle, Petre Plate, Glass Slide.

2.1 INGREDIENTS:

2.1.1 CALCIUM CARBONATE:

Calcium carbonate is naturally derived inorganic salt widely employed as a primary abrasive's agent in toothpaste formulation. Its inclusion in paediatric dentifrices is particularly justified due to its low to moderate abrasivity, biocompatible, chemical inertness, cost effectiveness and buffering capacity. As developing primary teeth have thinner enamel than permanent teeth, the abrasive system must be carefully calibrated to ensure cleaning efficacy while minimizing enamel and dentin wear. Calcium carbonate, a naturally occurring mineral provides gentle mechanical action that helps dislodge dental plaques and extrinsic stains without compromising enamel integrity. The morphology and particle size of calcium carbonate critically affect its performance. Studies suggest that irregularly shaped or large particles increase cleaning efficacy but may pose higher abrasion risk, whereas finely ground (<10µm) or precipitated forms ensure safer use in paediatric formulations. Calcium carbonate also contributes to neutralizing bacterial acid byproducts, due to its buffering properties helping maintain oral pH and protect against enamel demineralisation. In the formulation referenced, calcium carbonate was used at 35% w/w, which falls within the acceptable upper limit for herbal dentifrices formulations as per Bureau of Indian Standards (BIS IS 6356:1993) and is considered safe for daily paediatric use. The Relative Dentine Abrassivity (RDA) for paediatric pastes containing calcium carbonate typically ranges from 30-70, which is below the ISO safety threshold of RDA 250, making it a suitable choice for children. Furthermore, when fluoride and chemical surfactants like SLS are omitted from formulation like in case of our formulation abrasives like calcium carbonates play even more critical role in mechanical plaque disruption and supporting oral cleanliness, filling the functional gap left by the absence of fluoride-based remineralisation agents [36].

2.1.2 GLYCERIN:

Glycerin a polyhydric alcohol, is an essential component in paediatric toothpaste formulations due to its multifunctional role as a humectant, solvent and texture enhancer. In the context of fluoride and SLS free herbal formulation it ensures the retention of moisture, thereby preventing desiccation and phase separation over the products shelf life. Its humectant property functions by attracting and holding water molecules which helps maintain the semi solid consistency of the paste and contributes to smooth, glossy texture that enhances product aesthetics and ease of application. Beyond its physicochemical role, glycerin improves palatability and mouthfeel, both critical factors in paediatric oral care products where compliance is often behaviourally driven. It also facilitates the uniform dispersion of herbal bioactives like guava pulp extract and black pepper thus ensuring consistent therapeutic delivery in each case. Importantly glycerin is non-toxic non irritating

and generally recognised safe GRAS by the USFDA and other international regulatory agencies making it suitable for paediatric formulations that may be accidentally ingested. Furthermore, glycerin has been shown to exert mild antimicrobial properties by lowering water activity indirectly supporting preservation when used alongside natural antimicrobial agents like Piper nigrum. Its compatibility with herbal ingredients, excellent safety profile and multifunctional benefits make glycerin a critical excipient in the formulation of fluoride and SLS free herbal toothpaste for children [37][38].

2.1.3 GUAVA EXTRACT:

Guava (*Psidium guajava*) pulp extract serves as a multifunctional agent in paediatric herbal toothpaste, offering benefits in flavouring, antimicrobial protection, antioxidant, anti-inflammatory, cariostatic and oral tissue health [39]. It is particularly valuable in paediatric herbal toothpaste formulations due to its combination of flavour enhancing and functional bioactive properties. The pulp is rich in vitamin C, carotenoids, polyphenols and flavonoids such as quercetin and Kaempferol all known for its antioxidant and mild antibacterial effects that supports oral health without harsh chemical action. Comprehensive phytochemical analyses reveals that guava pulp contains substantial levels of quercetin (~122mg/kg) and kaempferol (~38 mg/kg), which have demonstrated efficacy in inhibiting the adhesion, biofilm formation and virulence of key oral pathogens like *S.mutans*, *S.sanguinis*, *Actinomyces*, *P.gingivalis* via mechanisms such as membrane disruption and inhibition of quorum sensing [40]. Additionally the high vitamin C and antioxidant content of guava pulp helps neutralise oral malodour and reduce gingival inflammation through free radical scavenging and tissue toning properties [41][42]. Given its edible and non-toxic profile, guava pulp extract is particularly suited to paediatric toothpaste, where incidental ingestion is a consideration. Its fragrance and mild sweetness enhance palatability while its ability to moderate microbial activity provides a supportive antibiofilm mechanism, especially in fluoride and surfactant free formulations.

2.1.4 COCONUT OIL:

Coconut oil, predominantly rich in medium chain fatty acids most notably lauric acid, has demonstrated potent antimicrobial and anti-biofilm properties against key oral pathogens, including *Streptococcus mutans*, *Porphyromonas gingivalis* and *Candida albicans* [43]. In a randomized cross-over clinical trial, oil pulling with coconut oil inhibited plaque regrowth similarly to 0.2% chlorhexidine mouthwash, with significantly less tooth staining and comparable reductions in gingival inflammation and bleeding on probing indices over a four-day period [44]. Similarly, a 30-day intervention involving oil-pulling in adolescents showed approximately a 50% reduction in plaque and gingival index scores, with improvements beginning as early as day 7, confirming the efficacy of coconut oil as a adjunctive oral hygiene measure [45]. A 2024 in vivo study in children demonstrated that coconut oil pulling yielded a significant reduction in S.

mutans colony counts, comparable to a fluoridated mouthwash group [46]. While oil pulling is not practical for children under 5 due to swallowing risk and compliance issues, formulating coconut oil into toothpaste offers a safer delivery route, allowing its antimicrobial benefits to be leveraged without requiring mouth rinsing or retention. Given its non-toxic, edible nature, natural origin and low risk of adverse reactions, coconut oil is especially well-suited for fluoride and SLS free paediatric toothpaste formulations. Its incorporation provides a natural antimicrobial agent that supports plaque inhibition, calms gingival inflammation and refreshes breath without relying on synthetic preservatives or surfactants aligning with our formulation's overarching safety and efficacy objectives.

2.1.5 BLACK PEPPER:

Piper nigrum, commonly known as black pepper and often called as king of spices is a climbing perennial in the Piperaceae family with its botanical origin in India's western ghats and Malabar coast, particularly Kerala where it has been cultivated for millennia. The dried unripe fruit peppercorn is rich in piperine the primary alkaloid responsible for its pungency, along with essential oils,

flavonoids and phenolic compounds that confer bioactive benefits. Comprehensive phytochemical and pharmacological reviews affirm that black pepper exhibits antioxidant, anti-inflammatory, antimicrobial and bio enhancing properties. Specifically, piperine and related compounds significantly inhibit biofilm formation and growth of pathogens such as *Streptococcus mutans*, *S. aureus*, *E. coli* and *P. gingivalis* at concentrations ranging from 50-500 ppm [47]. Black pepper offers natural preservative efficacy through phenolics that disrupt microbial cell membranes and inhibit bacterial motility and quorum sensing, contributing to product microbiological stability [48]. Enhance bioavailability enhancement as piperine is known to improve absorption and therapeutic potential of co-administered botanicals such as guava extracts and other herbal actives. Alongside it provides a favourable safety profile with traditional dietary use and limited toxicity at low concentrations. These data support the potential use of black pepper extract as a natural preservative and antimicrobial agent in herbal dentifrices.

TABLE 1.0 – COMPOSITION AND THEIR FUNCTIONAL ATTRIBUTES OF FINAL FORMULATION

S no.	Ingredient	Uses	References
1	Calcium carbonate	-Mild abrasives for mechanical plaque removal without damaging primary enamel. -Buffers acidic byproducts to maintain oral pH. -Provides structure and safe RDA value for pediatric use (30-70).	[36]
2	Coconut oil	-Anti-microbial against <i>S. mutans</i> , <i>P. gingivalis</i> , <i>C. albicans</i> and Anti-cavity. -Reduces plaque, gingival inflammation and bleeding indices. -Edible, safe and supports biofilm disruption. -Natural alternative to synthetic surfactants.	[43][44][45][46]
3	Glycerin	-Humectant maintain moisture content and paste consistency. -Improves mouthfeel and palatability. -Aids uniform dispersion of herbal actives. -Safe and non-toxic (GRAS certified by USFDA).	[37][38]
4	Guava pulp extract	-Natural flavoring and sweet fruity taste. -Antibacterial and antioxidant activity via flavonoids (quercetin and kaempferol) -Helps reduce gingival inflammation and oral malodor -Safe for ingestion by children.	[39][40][41][42]

5	Black pepper	-Natural preservative action inhibition of microbial growth and quorum sensing. -Piperine improves absorption of other botanical actives. -Antibacterial and antioxidant -Enhances product shelf stability.	[47][48]
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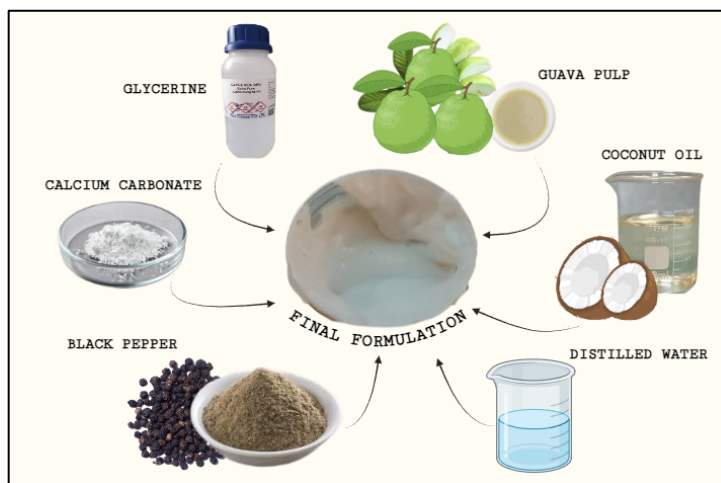


Figure 4.0 – Formulation blueprint of polyherbal toothpaste formulation

2.2 METHOD OF PREPARATION OF PEDIATRIC TOOTHPASTE (10gm):

Weighing Ingredients Began by weighing 5 grams of calcium carbonate and 2.5 grams of glycerin. These ingredients serve as the primary abrasive and humectant, respectively.

Mixing Base Ingredients Using a mortar and pestle, triturated the calcium carbonate and glycerin until a uniform mixture was achieved.

Adding Flavor Incorporated 1 gram of coconut oil and 1 gram of guava extract into the mixture. These ingredients not only enhance the flavor but also contribute to the overall appeal of the toothpaste for children. Mixed thoroughly to ensure even distribution.

Adjusting Consistency To achieve the desired consistency, added 2-3 drops of water or additional glycerin as needed. This step is crucial for ensuring that the toothpaste is neither too runny nor too thick.

Preservation Added 0.05 grams of black pepper to the mixture. This ingredient acts as a natural preservative, helping to extend the shelf life of the toothpaste

Storage Transferred the prepared mixture into a clean container. Stored the container in a cool and dry place for a duration of 1 month to allow the flavors to meld and the toothpaste to stabilize.

Stability Studies Conducted stability studies to assess the quality and effectiveness of the toothpaste over time. This step is essential to ensure that the product remains safe and effective for use. The paste was tested after one week of storage.

TABLE 2.0 – COMPOSITION OF FOUR FORMULATION PREPARED (F1-F4). *F3 FOUND TO BE SUITABLE FOR FURTHER EVALUATION

3.0 EVALUATION PARAMETERS:

3.1 SPREADIBILITY TEST:

Spreadability of the herbal toothpaste was evaluated to determine the ease of application, a key attribute for paediatric use. Approximately 1gm of the prepared toothpaste was placed between two clean glass slides (7cm × 7cm). A standard weight of 1 kg was gently placed on the top slide to simulate mild compressive force. After 2 minutes, the diameter of spread was measured in centimetres using vernier scale. The test was conducted in triplicate and the average spreadability was recorded. This method simulates real -life brushing pressure and helps evaluate texture consistency [36].

3.2 pH DETERMINATION:

To ensure compatibility with the oral environment and minimize mucosal irritation, the pH of the toothpaste was assessed. One gram of the formulation was dispersed in 10ml of distilled water in a 100ml beaker and stirred for 5 minutes at room temperature. The pH was measured using a calibrated digital pH meter. Ideal pH for paediatric toothpaste should be near neutral to prevent enamel erosion and irritation to oral tissues. Research conducted an in vitro comparison of commercially available toothpastes, including herbal formulations and reported a mean pH range from 7.262 ± 0.414 to 7.729 ± 0.534 , all safely above the enamel critical threshold (~5.5) [49].

3.3 HOMOGENEITY:

The prepared toothpaste was visually and tactilely examined for uniformity. Absence of lumps, phase separation, and graininess was confirmed through manual inspection and spreading on a clean glass slide. The smooth consistency and even distribution of ingredients confirmed the homogeneity of the formulation, essential for accurate dosing and pleasant mouthfeel [36].

viscometer was used to measure viscosity at 100rpm at 30°C with spindle number 61. The viscosity value helps ensure ease of dispensing and retention on the toothbrush. Higher viscosity formulations are preferred for paediatric use to avoid dripping and enhance brushing compliance [36].

3.4 VISCOCITY TEST:

Viscosity was determined to evaluate the flow behaviour and physical stability of herbal toothpaste. A Brookfield

TABLE 3.0 – EVALUATION PARAMETERS (+++ Excellent ++ Good + Fair)

S. No	Parameters	Observation			
		F1	F2	F3*	F4
1	Homogeneity	++	+ +	++ +	+
2	pH	5.5	6.8	7.9	9.9
3	Spreadability (cm/sec)	6	4	5	3

4.0 RESULT:

4.1 MORPHOLOGICAL EVALUATION: All the morphological parameters were evaluated and reported.

S. No	Parameter	Observation
1	Color	White
2	Odor	Characteristic
3	Appearance	Smooth, fine
4	Texture	Fine
5	Smoothness	Smooth

4.2 PHYSICOCHEMICAL EVALUATION: All the physicochemical parameters for the pediatric toothpaste were evaluated and reported

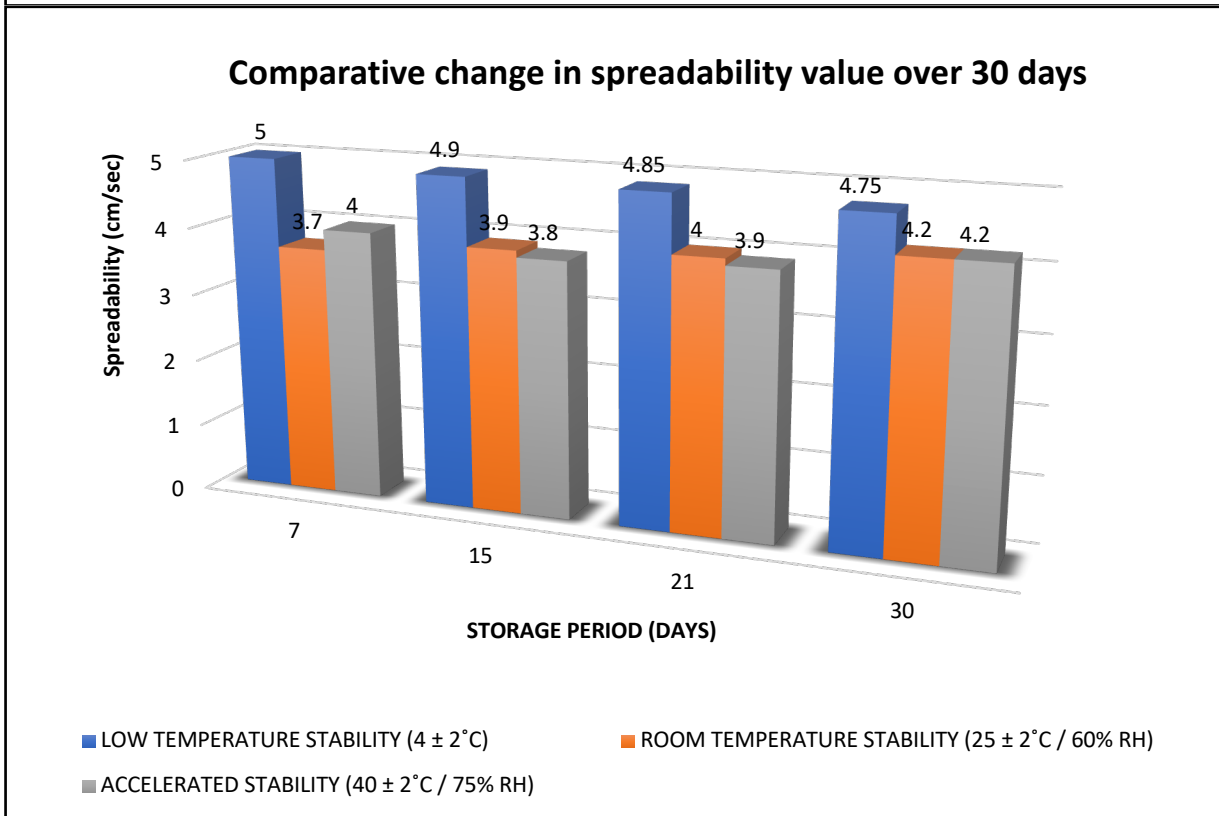
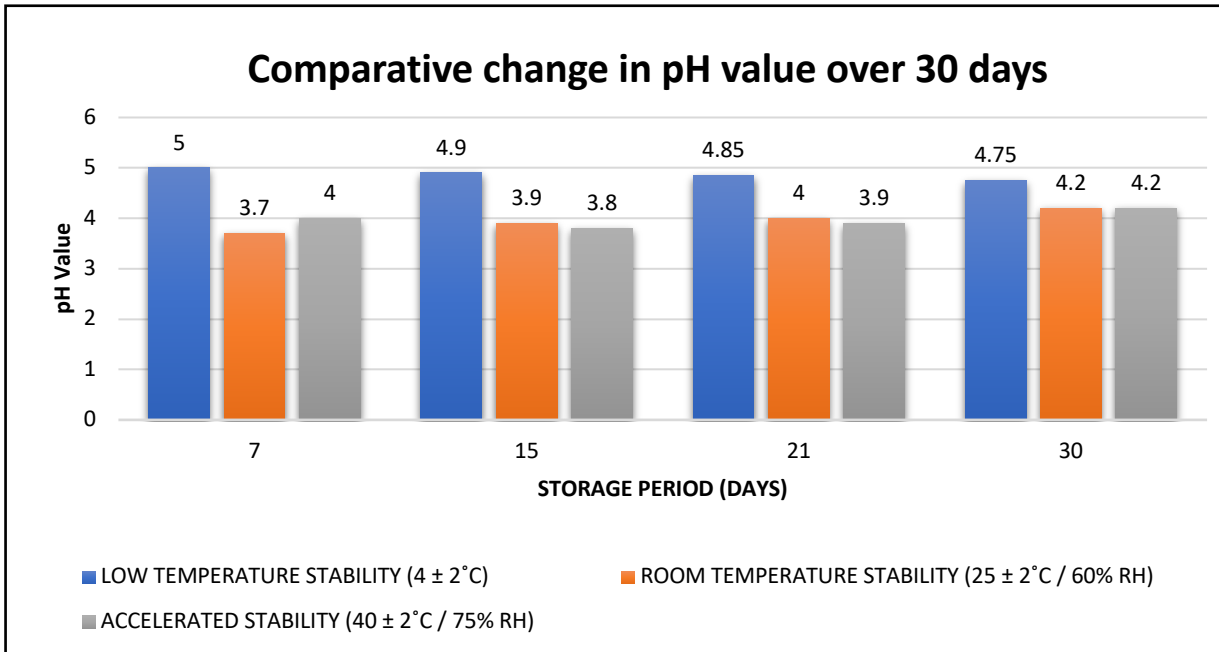
S. No	Parameter	Observation
1	pH	7.9
2	Spreadability	5cm
3	Homogeneity	+++
4	Viscosity	49,000 Cps

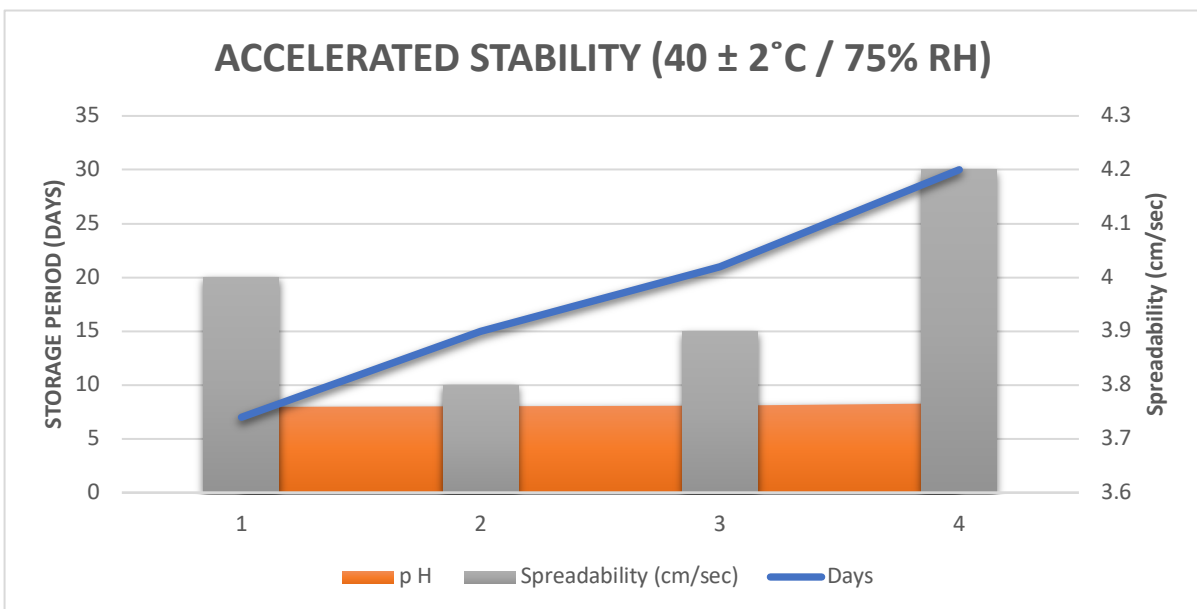
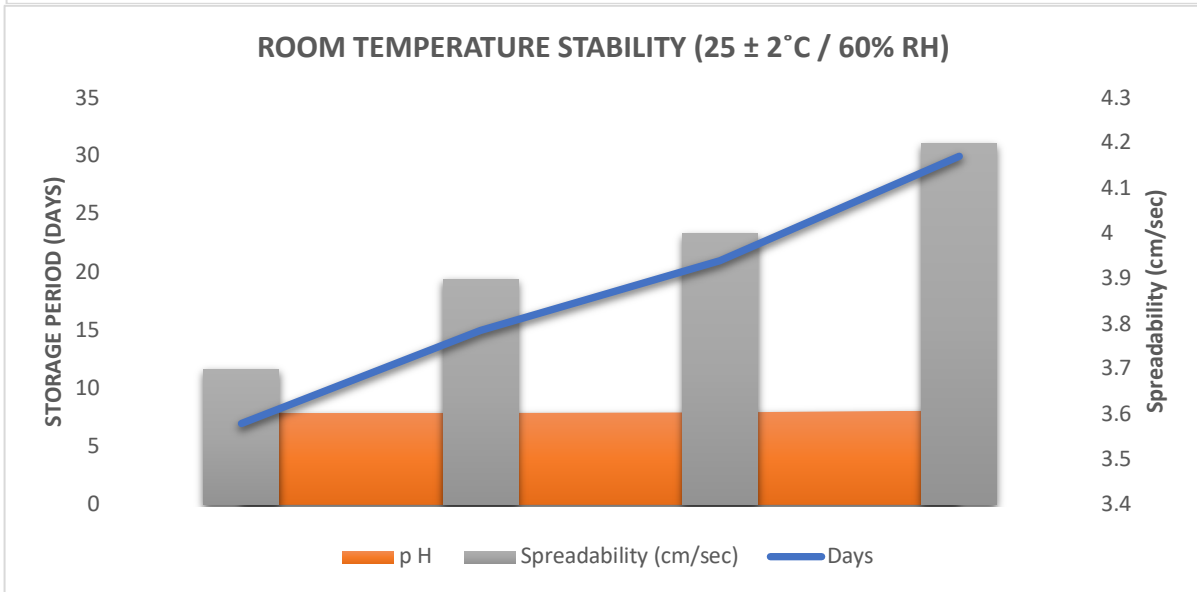
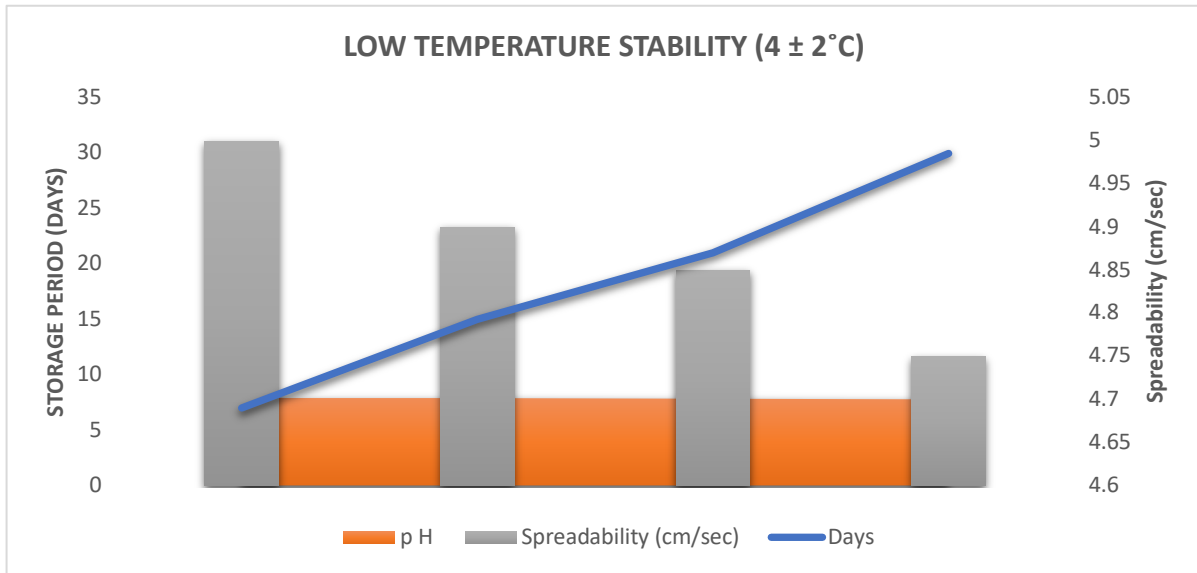
S. No	Ingredients	Quantity			
		F1	F2	F3*	F4
1	Calcium carbonate	4gm	4.8gm	5gm	5.1gm
2	Glycerin	3.5gm	2.6gm	2.5gm	2.6gm
3	Coconut oil	1gm	1.1gm	1gm	1gm
4	Guava extract	1gm	1gm	1gm	1gm
5	Black pepper	0.05gm	0.08gm	0.05gm	0.04
6	Water	q. s	q. s	q. s	q. s

4.3 STABILITY TESTING:

Days	Temperature	p H	Spreadability (cm/sec)	Homogeneity
LOW TEMPERATURE STABILITY (4 ± 2 °C)				
7	4 ± 2 °C	7.90	5.00	+++
15	4 ± 2 °C	7.88	4.90	+++
21	4 ± 2 °C	7.82	4.85	+++
30	4 ± 2 °C	7.75	4.75	+++
ROOM TEMPERATURE STABILITY (25 ± 2 °C / 60% RH)				
7	25°C ± 2 °C	7.90	3.70	++
15	25°C ± 2 °C	7.90	3.90	++
21	25°C ± 2 °C	7.98	4.00	++
30	25°C ± 2 °C	8.12	4.20	++
ACCELERATED STABILITY (40 ± 2 °C / 75% RH)				
7	40 ± 2 °C	7.95	4.00	++
15	40 ± 2 °C	8.02	3.80	++
21	40 ± 2 °C	8.10	3.90	+
30	40 ± 2 °C	8.30	4.20	+

COMPARATIVE ANALYSIS:





5.0 DISCUSSION:

This study focused on the development and assessment of a poly herbal toothpaste for children- as a natural, safe, and effective alternative to conventional synthetic formulations. Given the unique oral care requirements of children, this research emphasizes the necessity for a specialized dental product that addresses pediatric concerns such as dental caries, plaque formation and gingivitis while also ensuring minimal toxicity and maximum patient compliance. The creation of pediatric oral care products, including herbal toothpaste should ensure a balance between effectiveness, safety, sensory attractiveness and compatibility with the physiological development of teeth. The research conducted in this study addresses a significant gap in the oral hygiene market by formulating a toothpaste that is fluoride free and composed of natural ingredients specifically chosen for their mildness, antimicrobial properties and suitability for children.

Pediatric patients differ significantly from adults in terms of dental anatomy, physiology and behavioral patterns. Primary teeth, characterized by thinner enamel and greater susceptibility to demineralization, require gentler abrasives and ingredients that promote remineralization and antimicrobial protection. Furthermore, since children are more prone to swallowing toothpaste during brushing, the inclusion of fluoride or synthetic chemical in high concentrations poses potential for fluorosis and other negative consequences. The formulation developed in this study intentionally avoids fluoride, opting instead for plant-derived ingredients with known antimicrobial and anti-inflammatory properties.

Each ingredient in the polyherbal formulation serves a purposeful function which collectively create a balanced formulation that supports both cleanliness and health of pediatric teeth. The physiochemical evaluation of the selected formulation (F3) satisfactory parameters for pediatric use. The pH value of 7.9 is within the optimal range, ensuring compatibility with oral environment and preventing mucosal irritation aligning well with safe range for children's oral health avoiding both acidity which could harm enamel and high alkalinity which could irritate gums. The spreadability and homogeneity results suggests that the formulation is easy to apply and consistent throughout, crucial for ensuring even dosage during brushing. Morphological analysis confirmed the products fine texture, smooth appearance and pleasant odor-characteristics that enhance user acceptance, particularly in younger children.

The **Stability Evaluation** of the pediatric herbal, fluoride-free and SLS-free toothpaste demonstrated consistent physiochemical robustness under low 4°C, ambient 25°C, and accelerated 40°C, conditions over the study period. The pH remained close to neutral across all temperatures. Showing only minor fluctuations attributable to temperature-dependent ionization of herbal constituents, thereby confirming chemical stability and ensuring pediatric safety. Spreadability patterns revealed a

characteristic pseudoplastic profile: reduced spreadability at low temperatures indicated increased viscosity at rest, while the progressive rise in spreadability at room and elevated temperatures reflected shear-thinning behavior, supporting the formulations non-Newtonian flow nature that allows it to remain stable on the toothbrush yet spread smoothly during brushing. Homogeneity remained acceptable throughout, with no phase separation observed even under thermal stress, indicating a stable semi-solid matrix and effective integration of herbal excipients. Collectively, these results confirm that the formulation maintains structural, chemical, and rheological integrity under varying storage conditions, validating its suitability for pediatric use and supporting the conclusion of a pseudoplastic, shear-thinning flow profile.

The measured viscosity of the formulation was 49000 centipoises (cP), which falls within the typical acceptable range for commercial pediatric toothpaste products (30000-70000 cP), as reported in literature for semi-solid oral care formulations [50]. Thus, level of viscosity ensures that the product remains stable and cohesive within the tube, resisting phase separation and dripping, while still allowing for easy extrusion and application under brushing force. The shear thinning behavior common among denitrifies was supported by glycerin which modulates viscosity and improves spreadability, and calcium carbonate which contributes to the internal structural network of the paste.

The incorporation of guava extract, coconut oil, and black pepper didn't adversely affect the viscosity profile, confirming good excipient compatibility. The balance between structural firmness and spreadability provided by this rheology is crucial for the pediatric formulations, which must be easy to dispense and spread yet remain stable when stored. Overall, the measured viscosity of 49000 cP confirms the formulation suitability for children aged 0-5 years, supporting both functional performance and user compliance in the absence of fluoride and SLS.

This formulation directly addresses the most prevalent oral health issues in pediatric population. Dental caries, commonly induced by acidogenic bacterial activity on fermentable carbohydrates, is mitigated through the combined antibacterial effects of guava extract and coconut oil. Plaque formation and gingivitis, which result from bacterial biofilms on the tooth surface and gingival margin, are targeted by the toothpastes cleansing and antimicrobial properties. Moreover, the incorporation of natural flavoring agents not only improves palatability but also encourages regular brushing behavior. Literature indicates that pleasant flavor perception is positively associated with brushing duration and technique, thereby enhancing the therapeutic efficacy of oral care products in children.

This shift away from chemical preservatives, synthetic flavors, and fluorides reflects a growing trend towards holistic, herbal solutions in modern pharmaceuticals, this study aligns with that movement, providing a viable option for parents seeking natural products for their children's health. Importantly, it also encourages sustainable

ingredient sourcing and leverages local botanicals like guava which are commonly available and culturally accepted.

6.0 CONCLUSION:

In summary the polyherbal toothpaste is a thoughtful and evidence-based formulation tailored to the unique needs of children. Its development involved careful selection of safe, functional and natural ingredients that synergistically provide cleaning, antimicrobial protection and aesthetic appeal. Evaluation of the formulation confirmed its effectiveness, safety and user friendliness supporting its potential as an alternative to synthetic pediatric toothpaste. This work underscores the importance of targeted formulation science in pediatric care and opens pathways for further development of herbal based dental products. Further in vivo studies may provide additional evidence of its clinical efficacy and broaden its potential for commercialization in pediatric dental care.

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