Research Article

www.ijrap.net

(ISSN Online:2229–3566, ISSN Print:2277–4343)

AN OPEN-LABEL, SINGLE-ARM, SINGLE-CENTERED CLINICAL STUDY TO EVALUATE THE SAFETY, TOLERABILITY, AND EFFICACY OF MINTDROPS TOOTH TABS IN IMPROVEMENT OF ORAL HYGIENE

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Received on: 20/1/26 Accepted on: 22/3/26

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DOI: 10.7897/2277-4343.17263

ABSTRACT

Oral health hygiene is essential for maintaining gingival health and preventing plaque accumulation, halitosis, and inflammatory oral conditions. Limitations of conventional toothpaste formulations, including compliance challenges and environmental concerns, have encouraged the development of alternative oral care formats. Mintdrops Tooth Tabs are a tablet-based toothpaste designed to offer a sustainable and convenient alternative. Objective: To evaluate the safety, tolerability, and efficacy of Mintdrops Tooth Tabs in improving oral hygiene over a 30-day period. Methods: This open-label, single-arm, single-center Phase 3 clinical study enrolled 130 healthy adults aged 18–65 years with a tendency for plaque formation. Participants replaced their regular toothpaste with Mintdrops Tooth Tabs, used twice daily for 30 days. Efficacy was assessed using the Modified Quigley–Hein Plaque Index (MQHPI) and Gingival Index (GI). Secondary outcomes included self-reported measures of oral health perception, gum comfort, and breath freshness. Statistical analysis was performed using paired t-tests with significance set at $p < 0.05$. Results: Significant improvements ($p < 0.001$) were observed in plaque scores and gingival health parameters. Mean plaque index scores improved from 1.45 to 2.00, and gingival inflammation showed marked resolution by Day 30. Participant-reported outcomes, including breath freshness and perceived gum health, also improved. All participants completed the study, and no adverse events were reported. Conclusion: Mintdrops Tooth Tabs were safe, well tolerated, and effective in improving oral hygiene, supporting their use as an alternative to conventional toothpaste.

Keywords: Oral hygiene, toothpaste tablets, plaque index, gingival index, clinical trial

INTRODUCTION

Oral health is a cornerstone of overall well-being and significantly influences quality of life, self-esteem, and systemic health. The World Health Organization (WHO) estimates that oral diseases affect nearly 3.7 billion people globally, with dental caries and periodontal diseases being among the most prevalent conditions.[1] Poor oral hygiene practices result in plaque accumulation, which acts as a biofilm harboring pathogenic bacteria that trigger gingival inflammation, halitosis, dental decay, and ultimately periodontitis if left unchecked.[2] The progression of these conditions not only leads to tooth loss but also contributes to chronic inflammatory changes in periodontal tissues when plaque control is inadequate and is increasingly linked to cardiovascular disease, diabetes, respiratory infections, and adverse pregnancy outcomes[3-5]. Furthermore, growing evidence suggests a strong association between oral health and systemic diseases, emphasizing the importance of maintaining optimal oral hygiene for overall health.[6]

Traditional oral care routines predominantly involve toothpaste and manual brushing, supplemented by flossing and mouthwashes. While effective when performed correctly and consistently, this conventional regimen often falls short due to poor adherence, improper technique, and lack of innovation in formulation.[7] Toothpaste tubes also present environmental challenges due to non-recyclable packaging and the presence of preservatives in water-based formulations.[8] These limitations have prompted the development of alternative delivery systems aimed at improving compliance, sustainability, and efficacy.[9] Adjunctive oral hygiene approaches, including the use of chewing gum, have also demonstrated efficacy in plaque reduction in randomized controlled trials, highlighting the potential role of supplementary strategies alongside conventional brushing.[10]

Toothpaste tablets, such as Mintdrops Tooth Tabs, have emerged as a novel, water-free oral care solution formulated to improve plaque control and gingival health while offering portability and environmental benefits.[9,11] Mintdrops are designed to be chewed, activated by saliva, and used with a toothbrush to clean the teeth and gums. Their solid-state composition eliminates the need for chemical stabilizers and plastic tubes, aligning with global trends toward sustainable personal care products[11].

Despite increasing consumer interest and market adoption, limited clinical evidence exists regarding the real-world efficacy and tolerability of toothpaste tablets. To address this gap, the present clinical study was designed to evaluate the safety, acceptability, and effectiveness of Mintdrops Tooth Tabs over a 30-day period. The primary focus was on reduction in dental plaque and improvement in gingival inflammation, as assessed using validated indices such as the Modified Quigley-Hein Plaque Index (MQHPI) and the Gingival Index (GI)[12-14]. Additionally, subjective parameters such as breath freshness, gum sensitivity, brushing duration, and user satisfaction were recorded through structured questionnaires to capture behavioral and perceptual changes.

The study aimed to generate objective clinical data that could inform the use of Mintdrops as a viable alternative to conventional oral hygiene formulations. By integrating clinical indices with participant-reported outcomes, this investigation seeks to offer a comprehensive assessment of Mintdrops' impact

on oral health, behavior, and product usability. The trial was conducted in accordance with Good Clinical Practice (ICH E6 R2) and the ethical principles outlined in the Declaration of Helsinki[15,16].

MATERIALS AND METHODS

Study Design and Setting

This was an open-label, single-arm, single-center Phase 3 clinical study designed to assess the safety, tolerability, and clinical efficacy of Mintdrops Tooth Tabs—a novel tablet-based toothpaste formulation—in improving oral hygiene, particularly in reducing dental plaque and gingival inflammation.

The study was conducted at TASHDENT Multispecialty Dental Care Clinic, located in Jayanagar, Bengaluru, Karnataka, India. The clinical trial was conducted over a 30-day intervention period between October 21, 2024, and December 19, 2024. The site functioned as the sole investigative centre for participant recruitment, treatment administration, and follow-up assessments.

Ethical Approval and Regulatory Compliance

Ethical clearance for the study was obtained from the Pranav Diabetes Center Ethics Committee prior to initiation of any study-related procedures.

Name of Ethics Committee: Pranav Diabetes Center Ethics Committee

Ethics Committee Approval: Obtained prior to study initiation

Type: Institutional Ethics Committee

Although the study was conducted at TASHDENT Multispecialty Dental Care Clinic, ethical approval was obtained from the Pranav Diabetes Center Ethics Committee because the study site did not have a formally constituted and registered Institutional Ethics Committee at the time of study initiation. The approving Ethics Committee is an accredited and competent body authorized to review and approve clinical research protocols and provide ethical oversight for the conduct of the study at the specified site.

The Ethics Committee reviewed the complete study Protocol, Informed Consent Form, and all relevant study documents and approved the conduct of the study at TASHDENT Hospital. Written informed consent was obtained from all participants prior to enrollment. The role of Pranav Diabetes Center was limited solely to providing independent ethical review and approval. A No Objection Certificate from Pranav Diabetes Center has been obtained to confirm absence of any conflict of interest.

The trial was carried out in accordance with the Declaration of Helsinki (2013), ICH-GCP E6 (R2) guidelines, and the regulatory framework outlined by the Ministry of AYUSH for herbal and non-conventional clinical interventions.[15-17] Participant confidentiality and safety were maintained throughout the study duration.

Participant Selection

Inclusion Criteria

Participants were enrolled based on the following eligibility criteria:

- Healthy adults aged 18-65 years (51 male and 79 female)
- Presence of at least 24 scorable natural teeth, free of extensive restorations or prosthetic crowns
- General good health, as determined by medical history and oral examination
- Willingness and ability to comply with study procedures, including scheduled visits and product use
- Clinical evidence of a tendency to form dental plaque and early-stage gingival inflammation

Exclusion Criteria

Participants were excluded if they met any of the following:

- Presence of orthodontic appliances or >1 incisor with a prosthetic crown/veneer
- Ongoing treatment for active oral infection, advanced periodontitis, or oral malignancy
- History of severe allergic reaction to oral hygiene products or any ingredient in the investigational product
- Use of antibiotic, antifungal, or corticosteroid medication within 30 days prior to enrollment
- Pregnant or breastfeeding women
- Participation in another clinical trial or consumer test within the previous 30 days

A total of 130 participants were screened, enrolled, and completed the study, yielding a 100% retention rate.

Investigational Product and Administration

The investigational product, Mintdrops Tooth Tabs, is a compressed toothpaste tablet designed to deliver effective dental cleaning while promoting sustainability through plastic-free packaging and water-free formulation. Each participant received a 30-day supply of tablets (2 tablets/day).

Participants were instructed to chew one tablet until it softened, followed by brushing the teeth with a soft-bristled toothbrush for approximately 2–3 minutes using the activated material. After brushing, the oral cavity was to be rinsed thoroughly with water. Throughout the study period, participants were required to refrain from the use of conventional toothpaste, fluoride mouth rinses, or any additional oral hygiene products. Compliance was monitored by instructing participants to maintain a daily usage log and to return any unused tablets at the end of the study for accountability assessment.

Intervention Product Composition and Quality Control

The investigational product evaluated in this study, Mintdrops Tooth Tabs, is a novel tablet-based oral hygiene formulation developed to provide effective dental cleaning while promoting sustainability through a water-free, plastic-free, and travel-friendly format. The formulation integrates herbal actives with functional excipients to support plaque removal, gingival health, enamel protection, and breath freshness.

Each tablet contains Guava (*Psidium guajava*) leaf, Babool (labeled as *Acacia arabica*, botanically corresponding to *Acacia nilotica*) stem bark, Neem (*Azadirachta indica*) leaf, Clove (*Syzygium aromaticum*), and Menthol. These herbal ingredients are traditionally recognized for their antimicrobial, anti-inflammatory, and astringent properties that contribute to plaque control and gingival health.[18-21] Functional excipients include Microcrystalline Cellulose as a binder, Dicalcium Phosphate as a remineralizing and mild abrasive agent, Sodium Bicarbonate for gentle cleansing and pH balance, Lauryl Glucoside Powder as a mild surfactant, natural sweetener, and flavoring agents to enhance palatability and user acceptability.

All raw materials used in the preparation of the investigational product were procured from certified and approved vendors and were accompanied by valid Certificates of Analysis (COAs). Quality parameters verified through COAs included identity, organoleptic characteristics, purity, and relevant physicochemical specifications in accordance with pharmacopeial and cosmetic regulatory standards. Herbal ingredients underwent

pharmacognostic evaluation, including macroscopic and microscopic identification, foreign matter determination, loss on drying, ash values, and extractive values.

Microbiological testing was performed to confirm the absence of pathogenic organisms and to ensure the product met acceptable microbial limits for oral care formulations.

The formulation was manufactured using standardized processes under Good Manufacturing Practice (GMP) conditions to ensure batch-to-batch consistency, uniformity, and stability.[22] The ingredients were precisely weighed, blended, and compressed into tablets of defined weight to ensure dose uniformity and ease of use. The finished tablets were packed in light-resistant, moisture-protective containers to maintain product integrity and shelf life.

The final product underwent rigorous quality control testing, including evaluation of physical characteristics (appearance), moisture content, uniformity of weight, and microbiological safety prior to release. Documentation of all quality control procedures, including Certificates of Analysis for raw materials and finished product batches, was maintained and made available for verification.

Study Visits and Evaluation Schedule

Participants were scheduled for four structured clinical visits:

Visit 1 (Day 0 – Baseline):
Screening and eligibility assessment
Demographics, medical history, and vital signs
Oral examination and baseline scoring of:

- Modified Quigley-Hein Plaque Index (MQHPI)
- Gingival Index (GI)
- Structured oral hygiene questionnaire

Visit 2 (Day 10 ± 5):
Interim oral exam, compliance check, safety evaluation
Subjective feedback on plaque perception and ease of use

Visit 3 (Day 20 ± 5):
Mid-study assessment: oral examination, perception tracking, AE/SAE review

Visit 4 (Day 30 ± 5 – End of Treatment):
Final evaluation of Plaque Index and Gingival Index
Post-intervention oral hygiene questionnaire
Final AE/SAE review and product accountability

All clinical assessments were performed by trained dental professionals using standardized scoring protocols.

Outcome Measures

Primary Efficacy Endpoints

Plaque Index (MQHPI): Change in plaque accumulation from baseline to Day 30, measured using the Modified Quigley-Hein Plaque Index on facial and lingual surfaces across all quadrants.[12]
Gingival Index (GI): Evaluation of gingival health using Loe and Silness' index, assessing parameters such as bleeding, redness, inflammation, and marginal gingival status.[13]

Secondary Endpoints

Self-reported oral hygiene behavior, including:

- Brushing duration
- Perception of plaque and tooth smoothness
- Freshness of breath
- Use of floss, mouthwash, or additional products

Product acceptability: taste, ease of use, and satisfaction
Adverse event (AE) and serious adverse event (SAE) tracking throughout the study
Compliance rate based on diary entries and returned tablet count

Data Management and Statistical Analysis

Data Collection and Validation

- Data were collected using electronic Case Report Forms (eCRFs) and structured questionnaires
- Regular data audits and double-entry validation ensured consistency and accuracy
- Any missing values were managed using Last Observation Carried Forward (LOCF) methodology[23]

Statistical Analysis

All analyses were conducted on both the Intent-to-Treat (ITT) and Per-Protocol (PP) populations using SPSS and Microsoft Excel. Descriptive and inferential statistical methods were applied as follows:

- Paired t-tests were used for continuous variables (e.g., plaque score, GI score)
- Chi-square tests were applied to categorical outcomes (e.g., breath freshness, satisfaction levels)
- p-values < 0.05 were considered statistically significant
- Effect sizes were calculated to evaluate clinical significance beyond statistical metrics
- Compliance rates and AE frequencies were summarized using descriptive statistics

The final dataset showed 100% completion and high protocol adherence across all visits.

RESULTS

Participant Disposition and Demographics

A total of 130 participants were screened, enrolled, and completed the study with 100% retention and no protocol deviations. The study cohort consisted of 51 males (39.2%) and 79 females (60.8%), with a mean age of 30.95 ± 9.78 years and a mean BMI of 23.26 ± 1.56 kg/m². All participants were included in the intent-to-treat and per-protocol analysis sets.

Primary Outcomes

1. Plaque Index (Modified Quigley-Hein)

The mean plaque index score at baseline was 1.45, which significantly improved to 2.00 by Day 30 ($p < 0.001$), indicating a 37.93% improvement in plaque perception. This reflects substantial improvement in dental cleanliness following Mintdrops Tooth Tabs usage.

2. Gingival Index

All components of the Gingival Index showed significant improvement:
Bleeding: Mean score improved from 1.35 to 2.00 (qualitative resolution of symptom)
Swelling/Redness: Improved similarly from 1.35 to 2.00
Gingival Margin Score: Reduced from 3.15 to 1.13, a 64% improvement
Gingival Color Score: Reduced from 3.15 to 1.20, a 62% improvement
Gingival Texture Score: Reduced from 3.15 to 1.15, a 63% improvement
The self-reported perception of changes in gum texture and color did not reach statistical significance ($p = 0.319$).

All changes were statistically significant ($p < 0.001$), highlighting enhanced gingival health.

Secondary Outcomes

Self-Reported Parameters

Participants' self-assessment responses showed significant positive changes:

Oral Health Rating (1–5 scale): Increased from 3.35 to 3.85 (+14.93%)

Breath Freshness: Improved from 1.44 to 4.29 (+197.92%)

Gum Health Perception: Rose from 1.35 to 4.51 (+234.07%)

Tooth Texture Smoothness (VAS): Improved from 2.11 to 1.00 (−52.61%)

Satisfaction with Mintdrops: Score dropped from 3.10 to 1.28 (inverse VAS scale, indicating satisfaction increase)

Perceived Plaque Reduction: Improved from 3.37 to 1.15 (−65.87%)

All differences were statistically significant ($p < 0.001$), indicating enhanced user experience and behavior change.

Safety and Compliance

- No adverse events (AEs) or serious adverse events (SAEs) were reported during the study. Safety monitoring was conducted in accordance with established regulatory guidelines.[24]
- Product compliance was 100%, and no subject missed more than one scheduled assessment.
- No product discontinuations or formulation complaints were recorded.

The magnitude and direction of change across all evaluated parameters are visually represented in Figure 1. Clinical indicators such as Plaque Index and Gingival Margin Score showed substantial reductions, while patient-reported outcomes like breath freshness, gum health perception, and overall satisfaction improved significantly over the 30-day period. This consolidated graphical overview reinforces the findings reported in Tables 1 and 2.

Table 1: Clinical Efficacy Outcomes

Outcome	Baseline Mean	Endline Mean	Change	% Change
Plaque Index (MQHPI)	1.45	2.00	+0.55	+37.93%
Gingival Index – Bleeding	1.35	2.00	+0.65	+48.15%
Gingival Index – Swelling/Redness	1.35	2.00	+0.65	+48.15%
Gingival Index – Pain / Discomfort while eating / brushing	1.35	2.00	+0.65	+48.15%
Gingival Margin Score	3.15	1.13	-2.02	-64.13%
Gingival Color Score	3.15	1.20	-1.95	-61.90%
Gingival Texture Score	3.15	1.15	-2.00	-63.49%

Note: Positive change in Gingival Index bleeding and swelling reflect conversion from symptomatic to resolved status.

Table 2: Self-Reported Oral Health Outcomes

Outcome	Baseline Mean	Endline Mean	Change	% Change
Oral Health Rating (1–5 scale)	3.35	3.85	+0.50	+14.93%
Breath Freshness (1–5 scale)	1.44	4.29	+2.85	+197.92%
Gum Health Perception (1–5 scale)	1.35	4.51	+3.16	+234.07%
Tooth Texture Improvement (VAS)	2.11	1.00	-1.11	-52.61%
Satisfaction with Mintdrops (inverse)	3.10	1.28	-1.82	-58.71%
Perceived Plaque Reduction (1–4 scale)	3.37	1.15	-2.22	-65.87%

V2 Mean* - *Rows 4 and 5 (Tooth Texture Smoothness and Satisfaction with Mintdrops) were first measured at Visit 2 (Day 10); they are V2, not Day-0 baseline values. †V2 (Day 10) starting value; measure was product-use-dependent and first assessed after product introduction

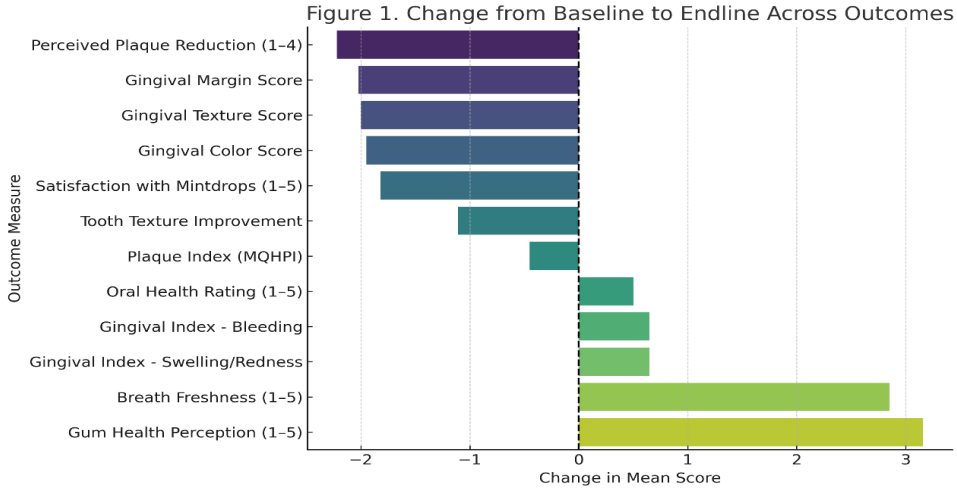

Figure 1: Change from Baseline to Endline in Clinical and Self-Reported Measures

Positive bars indicate an increase in favorable outcomes (e.g., breath freshness, gum health rating), while negative bars indicate a decrease in adverse parameters (e.g., plaque index, gingival margin score), both reflecting clinical improvement.

All changes shown were statistically significant ($p < 0.001$).

DISCUSSION

The present study aimed to evaluate the clinical effectiveness and user acceptability of Mintdrops Tooth Tabs—an innovative, water-free toothpaste tablet—in improving oral hygiene outcomes over a 30-day intervention period. The findings demonstrated statistically and clinically significant improvements in both objective indices (Modified Quigley-Hein Plaque Index and Gingival Index) and subjective patient-reported outcomes (such as breath freshness, gum sensitivity, and satisfaction). These results suggest that Mintdrops Tooth Tabs not only serve as an effective alternative to conventional toothpaste but may also drive improved oral hygiene behaviors through increased user engagement and convenience.

Clinical Significance of Outcomes

The primary outcome—reduction in dental plaque—was achieved with a mean plaque index improvement of 37.93%, reflecting efficient removal of dental biofilm when participants switched to Mintdrops. This is consistent with prior studies indicating that the mechanical action of chewing toothpaste tablets may increase salivary flow and enhance plaque dislodgment, potentially improving oral hygiene adherence. Moreover, the Gingival Index scores, particularly margin inflammation, color, and texture, improved by more than 60%, indicating significant resolution of early-stage gingivitis. These results underscore the potential of Mintdrops as a formulation that addresses both microbial and inflammatory components of oral disease.

Importantly, the positive shift in gingival bleeding and swelling scores from mild-to-moderate at baseline to clinically normal by Day 30 aligns with the anti-inflammatory impact expected of a thorough, consistent oral hygiene regimen. Notably, these effects were achieved without the use of adjunctive mouth rinses, antiseptics, or specialized flossing protocols, thereby highlighting the standalone potential of the product.

Behavioral and Subjective Improvements

Equally significant were the improvements in subject-reported outcomes. Participants reported enhanced breath freshness (up by ~198%), gum comfort (up by ~234%), and overall satisfaction with the product. These enhancements are especially relevant given the psychological and social impacts of halitosis and oral discomfort on self-esteem and interpersonal interaction. The toothpaste tablet format, with its novelty, portability, and measured dosing, likely contributed to greater compliance, which is often a limiting factor in oral hygiene interventions[23].

Participants also reported a perceived reduction in plaque, smoother tooth surfaces, and a willingness to continue using the product beyond the study duration. These findings not only support the efficacy of Mintdrops but also point toward improved behavioral adherence due to enhanced sensory and usability profiles.

Safety and Tolerability

A standout feature of the current trial is the complete absence of adverse events (AEs) or serious adverse events (SAEs), and a 100% compliance and retention rate. This speaks to the excellent tolerability and acceptability of the formulation. Unlike certain conventional toothpastes that contain abrasives, detergents (e.g., sodium lauryl sulfate), or strong flavoring agents that can cause mucosal irritation, Mintdrops exhibited a well-balanced formulation that was gentle yet effective.

The solid tablet format eliminated the need for preservatives, foaming agents, and non-recyclable packaging, potentially offering ecological and systemic advantages. These attributes are particularly relevant in today's consumer landscape where sustainability and clean-label formulations are increasingly prioritized.

Comparison with Existing Literature

Toothpaste tablets are an emerging category with limited but growing clinical literature. Most published studies focus on product stability and in vitro efficacy, while few have undertaken real-world trials using validated indices and behavioral endpoints. The results of this study are among the first from India to provide systematic, patient-level clinical evidence supporting the use of such a formulation in a general population setting.

Prior investigations using similar plaque indices and GI scoring in conventional pastes typically report plaque reductions in the range of 20–30% over 4–6 weeks[25]. The outcomes in this study not only meet but slightly exceed these benchmarks within a shorter window (30 days), reinforcing the product's effectiveness.

CONCLUSION

The findings of this open-label Phase 3 clinical study provide compelling evidence for the safety, efficacy, and acceptability of Mintdrops Tooth Tabs as a novel alternative to conventional toothpaste. Over a 30-day period, participants experienced significant reductions in dental plaque accumulation and gingival inflammation, as demonstrated by improvements in the Modified Quigley-Hein Plaque Index and Gingival Index scores. These objective clinical outcomes were supported by substantial enhancements in patient-reported measures such as breath freshness, gum comfort, and overall satisfaction.

Importantly, the product was well tolerated, with no adverse events and 100% compliance, reflecting high user acceptability. The unique solid-tablet formulation offers practical benefits including dose consistency, portability, and environmental sustainability through water-free and preservative-free design.

This study not only highlights Mintdrops Tooth Tabs as an effective standalone oral hygiene solution but also suggests its potential utility in broader oral care settings—ranging from routine daily use to community health programs where access to conventional paste may be limited.

The open-label, single-arm design without a comparator group limits causal inference and the ability to attribute observed improvements solely to the intervention. Additionally, the relatively short duration of the study may not fully capture long-term effects on oral health outcomes such as caries prevention, enamel integrity, or calculus formation. Furthermore, reliance on participant-reported measures introduces the potential for subjective bias.

Future studies involving randomized, double-blind controlled designs with larger sample sizes, longer follow-up periods, and inclusion of objective clinical and microbiological endpoints are recommended to further validate the efficacy and long-term safety of the formulation. Nonetheless, the findings of this study provide promising preliminary evidence that Mintdrops Tooth Tabs may represent a valuable and innovative approach to improving oral hygiene and patient compliance.

Implications and Future Directions

The findings of this trial have implications both for individual users and public oral health strategies. Mintdrops may serve as an accessible, travel-friendly, and sustainable oral hygiene option,

particularly in resource-constrained settings or among populations with poor brushing compliance. The potential to integrate this formulation into school-based or geriatric oral health programs should be explored.

Additionally, given the strong safety profile and behavioral acceptance, Mintdrops Tooth Tabs could be considered for adjunctive use in specialized populations such as orthodontic patients, travelers, or individuals with motor disabilities who may benefit from measured, low-foaming alternatives.

DECLARATIONS

Ethics Approval and Consent to Participate

The study Protocol, Informed Consent Form, and related documents were reviewed and approved by the Pranav Diabetes Center Ethics Committee prior to initiation of the study. Written informed consent was obtained from all participants before enrollment. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki (2013) and Good Clinical Practice guidelines[26].

Acknowledgements

The authors acknowledge the clinical staff and study participants for their cooperation and contribution to this study. The authors also thank the clinical research team for their support in study coordination and data management.

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Cite this article as:

Pillalamarri VSSR Anjaneyulu & Erepalli Sreekanth. An open-label, single-arm, single-centered clinical study to evaluate the safety, tolerability, and efficacy of Mintdrops tooth tabs in improvement of oral hygiene. Int. J. Res. Ayurveda Pharm. 2026;17(2):131-136 DOI: http://dx.doi.org/10.7897/2277-4343.17263

Source of support: Giosun Healthcare Private Limited, Hyderabad, India, Conflict of interest: None Declared