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AN OPEN LABEL, SINGLE ARM, CLINICAL STUDY TO EVALUATE EFFICACY AND SAFETY OF MNDV TOOTHPASTE IN DENTAL CARE OF HEALTHY ADULTS

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1. ABSTRACT

Introduction: Oral disorders have remained the most prevalent disease group in India over the past three decades affecting almost 66.7 cr. (49.2% in comparison to 43.2 cr; 50.2%) people in 2019. Mouthwashes can be unpleasant and induce burning feelings in the oral cavity if they are not suited or used frequently. Mouth lozenges are ineffective in cases of malodour. MNDV toothpaste is a herbal toothpaste with natural ingredients that has the ability to treat dental plaque, gingivitis, and bad breath, among other things. It's supposed to help with general dental and oral health. **Aim:** The aim of the study is to clinically validate efficacy and safety of MNDV toothpaste in Dental Care of Healthy Adults. **Methods:** The study included four different visits to the study. Visit 1: Screening visit: The subject were selected for plaque index (between 2 and 4), gingivitis index (between 0.1 and 3.0), and halitosis with the use of Halimeter following the evaluation of trained staff. Visit 2: Registration [Visit 2 Day 1, Day 1, Basic Evaluation] (Before Brushing) Halitosis, gingival bleeding, plaque index and gingivitis (gingival index modified should be 0.1-3.0), etc. have been evaluated. The plaque Index should be 2-4. Adverse events and concurrent medications were recorded in Visit 3: Evaluation Phase [Visit 3 (Day 15 ± 2 days)] Visit 4: Evaluation/end of study [Visit 4 (Day 30 ± 2 days)] After the brushes, the study staff requested test product efficacy and tolerance questionnaires. **Results & Conclusion:** MNDV toothpaste dramatically improvement in gingivitis (gum inflammation), halimeter assessment, plaque reduction, and improved mouth feel compared

to their previous toothpaste. The population began to improve from gingivitis (gum inflammation), plaque reduction after only 15 days of consumption and continued to improve for the next 30 days. The quality of life was improved as measured by various questionnaires. There were no adverse events (AEs) reported neither by the Investigator and Dentist nor self-reported by the subjects during the conduct of the study.

Background and information

Oral hygiene is the practice of keeping one's mouth clean and free of disease and other problems by regular brushing of the teeth and cleaning between the teeth. It is important that oral hygiene be carried out on a regular basis to enable prevention of dental disease. Oral disorders have remained the most prevalent disease group in India over the past three decades affecting almost 66.7 crore (49.2% in comparison to 43.2 crore; 50.2%) people in 2019. Different oral conditions such as untreated caries of permanent teeth, untreated caries of deciduous teeth and severe periodontitis have a significant burden affecting 43.2 crores (32%), 11.2 crores (8.3%) and 18.1 crores (13.3%) people in India. Though the dental problems may seem to be small or not of much attention. They can be dental caries, dental plague, Bad breath, gingivitis, gingival bleeding, tooth sensitivity, etc. Dental caries is the localized destruction of susceptible dental hard tissues by acidic by-products from bacterial fermentation of dietary carbohydrates.[1] It is caused due to bacteria present in oral cavity which combine with food remnants and acid and forms plaque. This tartar than forms small size hole into the teeth which further increases and forms cavities.[2] Dental caries may be associated with several complications like pain, tooth abscess, swelling or pus around teeth, damage or broken teeth, chewing problems, tooth loss, weight loss or nutrition problems.[3] Dental plaque is a sticky film of bacteria which is produced constantly on teeth. The main causes of formation of dental plaque is avoiding oral hygiene and not brushing teeth properly. The dental plaque may lead to cavities, gingivitis and periodontal gum disease. It may also cause tooth infection, decay or loss.[4] Bad dental hygiene is caused by poor dental hygiene, smoking, chewing tobacco, following crash diets and consuming strong food and beverages, due to sinus mouth or threat conditions. It may rarely be caused due to ketoacidosis, bowel obstruction, bronchiectasis, etc.[5] Gingivitis is a major dental disorder. It is the earliest stage of gum disease; it is inflammation of the tissues surrounding and supporting the teeth and is most commonly a result of poor dental hygiene. The causes of gingivitis include plaque, smoking, chewing tobacco, crooked or rotated teeth, metabolic diseases, stress, poor saliva production, etc.[6,7] Gingival bleeding is defined as bleeding from gums spontaneously or on

any mild trauma. It is caused due to plaque accumulation, consumption of tobacco, deficiency of Vitamin K or vitamin C, Stress. Gingival bleeding may lead to abscesses or infection in the gingiva or jawbone, periodontitis, mouth trench, recurrent gingivitis, etc.[8] Tooth sensitivity is a common dental problem that involves discomfort or pain in teeth when encountering certain substances and temperatures. It can be caused due to brushing too hard or using hard-bristled toothbrushes. It may also occur due to gum recession, cracked teeth, plaque build-up and acidic food consumptions.[9,10] Dental issues due to oral causes can be cured by practicing oral hygiene like daily brushing, flossing. Normal utilization of antimicrobial agents when embedded in personal care formulations like toothpastes, oral mouth cleansers and mouthwashes are helpful in the treating various dental issues. These formulations are found to be effective in reducing the bacterial count, enhancing the freshness of mouth and maintaining the pH of oral cavity. Same it case with brushing and flossing, though they are important to maintain oral hygiene they are not much effective in treating malodour. Thus, after long term use of these conventional medicines, people often trust upon alternative treatments such as herbal or Ayurveda therapies. Over the globe, the estimates of people noticing dental problems corresponds to about 8-50 %.[11]

Dosage and Administration

The subjects were asked to brush their teeth using toothpaste along brush head of test product twice a day for 2 minutes by moving brush up-down and side wise movement fashion followed by scrapping their tongue with Colgate soft bristle toothbrush and rinsing mouth with water after any meal. Subjects were instructed to bring back the tube of test product in next visit.

Storage and Disposition

Test products were stored in a temperature controlled (15°C to 30°C), secure, limited access location under the supervision of the investigator.

Sample size

A total of 110 subjects were screened and signed the informed consent document for the study. Out of the 110 subjects, 60 subjects who met the study criteria were enrolled and randomized in the study. A total of 60 subjects (34 females, 26 males) completed all the phases of the study.

Study schedule

The duration of the study was 30 days. First visit -Screening visit: Within 30 days prior to Day 1; the second visit- Day 0: Prior to enrolment Day 1; Third visit- Day 1: Enrolment day; Fourth Visit-Day 15: Evaluation day; Fifth Visit-Day 30: Evaluation + end of the study day.

2. MATERIALS AND METHODS

2.1 Study design

The present study is an Open Label, Single Arm, Clinical Study to Evaluate Efficacy and Safety of MNDV toothpaste in Dental Care of Healthy Adults. MNDV toothpaste is herbal toothpaste with a formula having natural ingredients with potential to manage dental plaque, gingivitis, malodour etc. It is thought to promote overall oral and dental health.

2.2 Inclusion criteria

Subjects in age range from 18 to 55 years old (both males and females) were chosen. Healthy male and non-pregnant/non-breastfeeding female were included in the study. Females of Childbearing potential must have a negative urine pregnancy test performed on screening and enrolment visit. The subjects who were in good health were included in the study. Subjects having T-VSC reading (total volatile sulphur compounds) more than 160 ppb (parts per billion) were included in the study. The subject who were having mild, moderate and severe plaque and gingivitis (plaque index 2-4 and gingival index 0.1-0.3) were eligible for the study. Subjects who were willing to come to the test site without brushing their teeth in the morning without consumption of anything except water after meal of previous night were selected. Those subjects who were willing to provide consent and follow up for the duration of the study were included in the study.

2.3 Exclusion criteria

Subjects with soft and/or hard fabric of the cavity of the tumour, periodontal disorders (exudate pure, tooth motility and/or substantial loss of periodontal attachment), carious lesions, a plaque index of 0, 1 and 5 partial detachable teeth were deemed ineligible for the study. Subjects who have already participated in other dental clinical trials over the past two weeks before they entered the trial were not allow to enter for the study. Subjects with dental prophylaxis and allergy history to oral care or a history that may lead to oral malodour (e.g. diabetes mellitus, bronchitis, tonsillitis, sinusitis etc.) were not suitable for the study. Subjects using or drinking alcohol or smoke cigarette or consume any other form of tobacco was excluded from the study.

3. METHODOLOGY

The study comprised of four different study execution visits. Subject teeth were assessed clinically by the dentist as well as instrumentally, before application of toothpaste and will considered as baseline value.

At Visit 1, screening Phase - (within 30 days from Day 1)

Potential subjects were screened as per the inclusion and exclusion criteria after obtaining written informed consent from the subject. The subjects underwent physical examination, dental examination, demography (age and gender), concomitant medication and medical history. Urine pregnancy test was performed for females of childbearing potential only. Subjects were selected after assessment for plaque index (plaque index between 2 to 4), gingivitis index (GI 0.1 to 3.0), and halitosis by trained staff using Halimeter. Subjects were instructed to follow the study restrictions and instructions provided.

Enrolment [Visit 2 (Day 1)]

Subject was reported to the study site on day 0 i.e., prior to enrolment Day 1 and their inclusion and exclusion criteria reviewed to determine continued eligibility. Subjects were being acclimatized at room temperature for at least 15 minutes prior to having any assessments.

On Day 1: Baseline Assessments (Before Brushing)

Assessment of halitosis were performed by trained study personnel. Plaque index (plaque index should be 2-4), gingival bleeding and gingivitis index (modified gingival index should be 0.1-3.0) were evaluated by dentist. Subjects were evaluated by visual assessment by dentist. After baseline assessments, eligible subjects were given one colgate soft bristle toothbrush each and test product as per subject number. They were instructed to use the same product for brushing their teeth throughout the study period. After brushing below mentioned assessments was performed: subjects were asked to brush their teeth under supervision of the study staff. halimeter readings was performed at 0 hour (+15 mins) before brushing and at 4, 8 and 12 hours (±15 mins) after brushing but before having meals at each time point. Plaque index was evaluated by dentist. Test product efficacy and tolerance questionnaires were asked by study staff after brushing at 0 mins (+5 mins), 30 mins, 60 mins (±5 mins). Study restrictions and instructions was provided to subject and asked to follow. Subjects were provided meals i.e., breakfast, lunch, snacks and dinner at appropriate time interval. Subjects

were exiting the facility after brushing their teeth in the evening and was asked to return to the facility along with colgate soft bristle toothbrush for assessing its integrity on Day 15.

Evaluation Phase [Visit 3 (Day 15 ± 2 days)]

Subject was arriving to the facility on Day 15. Adverse event and concomitant medication record were recorded. Subjects were acclimatized at room temperature for at least 15 minutes prior to having any assessments. Dental examination was performed by dentist. Subjects were asked to brush their teeth under supervision of the study staff. Plaque index, gingivitis index and gingival bleeding was evaluated by dentist. Subjects were evaluated by visual assessment by dentist. Test product efficacy and tolerance questionnaires were asked by study staff. Subjects exit the facility and were asked to return to the facility along with Colgate soft bristle toothbrush for assessing its integrity on Day 30.

Evaluation / End of the Study [Visit 4 (Day 30 ± 2 days)]

Subject was arriving to the facility on Day 30. Adverse event and concomitant medication were recorded. Subjects were acclimatized at room temperature for at least 15 minutes prior to having any assessments (clinical or instrumental). Dental examination was performed by dentist. Subjects were asked to brush their teeth under supervision of the study staff. Plaque index, gingivitis index and gingival bleeding were evaluated by dentist. Improvement in gum tightening and carious teeth was evaluated by dental examination by dentist. Test product was collected from subject. Test product accountability and compliance were performed. Test product efficacy and tolerance questionnaires were asked by study staff after brushing.

4. METHOD OF STATISTICAL ANALYSIS

For continuous variables, within-treatment differences for the change from baseline mean was analyzed utilizing Paired t test. For categorical variables, the frequency and percentage of each category was provided. Appropriate analysis using nonparametric test was done. All statistical tests were done using SAS software of 5% level of significance.

5. RESULTS AND DISCUSSION

Demographic and Other baseline characteristics

Table 1: Demographical data.

Summary of Demographic Characteristics		
Variables		**(N=60)**
Gender, n (%)	Female	26 (43%)
	Male	34 (57%)

Race, n (%)	Asian	60 (100%)
Age (years)	N	60
	Mean (SD)	36.5 (6.27)
	Median	36.5
	Min, Max	19, 52

In this study, there were 34 females and 26 males; age of the subjects ranged from 19 to 52 years with an average being 36.5 years.

Efficacy Results and Tabulations

Gingivitis index assessment

Table 2: Within-treatment t-test results of Gingivitis Index Assessment - Change from Baseline.

Visit	N	Mean	Std. Dev.	% change
Baseline	60	2.48	0.278	-
Day 15	60	2.215	0.345	10.16
)ay 30	60	1.871	0.333	24

The p-value is <0.05. The result is significant.

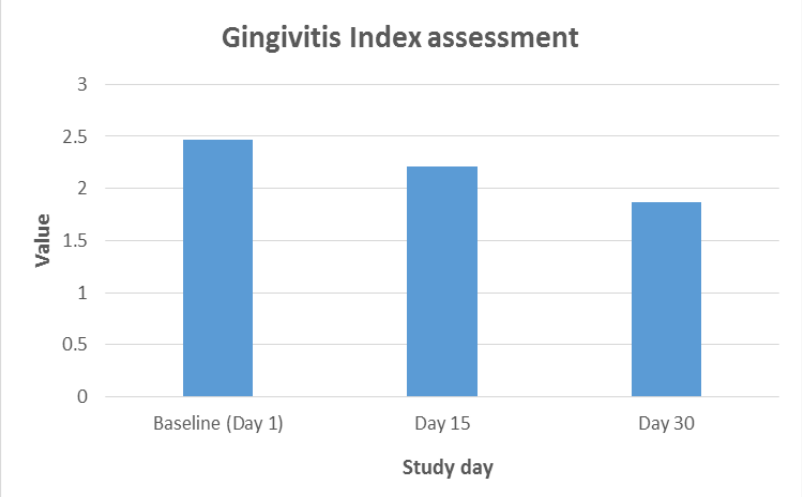


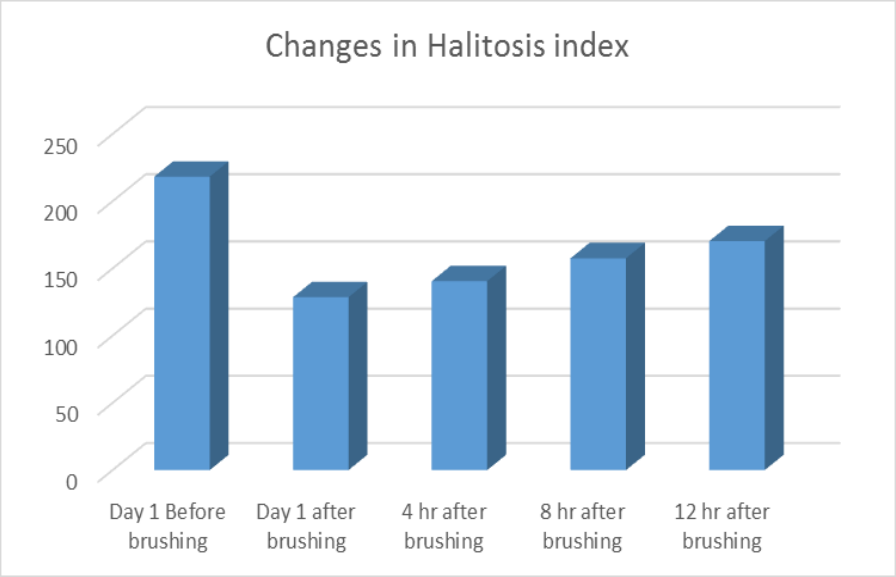
Figure 1: Graphical representation of gingivites index assessment.

Halimeter assessment (Halitosis index)

Table 3: Listing of halimeter assessment - Change from baseline.

Visit	N	Mean	StdDev	% change
Day 1 (Baseline) Before brushing	60	218.23	16.12	
Day 1 (0 hr. ± 15 mins) after brushing	60	128.51	19.23	41.11
Day 1 (4 hr. ± 15 mins) after brushing	60	140.5	16.72	35.62
Day 1 (8 hr. ± 15 mins) after brushing	60	157.55	21.50	27.81
Day 1 (12 hr. ± 15 mins) after brushing	60	170.3	20.01	21.96

The p-value is <0.05. The result is significant.



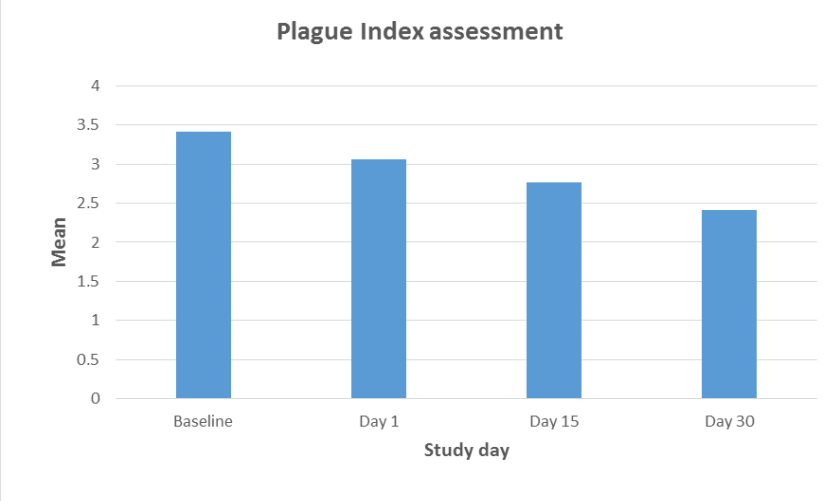
Graph 2: Graphical representation of halimeter assessment.

Plaque assessment

Table 4: Listing of plaque index assessment - Change from baseline.

Visit	N	Mean	Std. Dev.	% change
Baseline	60	3.406	0.389	
Day 1	60	3.055	0.391	10.31
Day 15	60	2.762	0.393	18.91
Day 30	60	2.417	0.420	29.04

The p-value is <0.05. The result is significant.



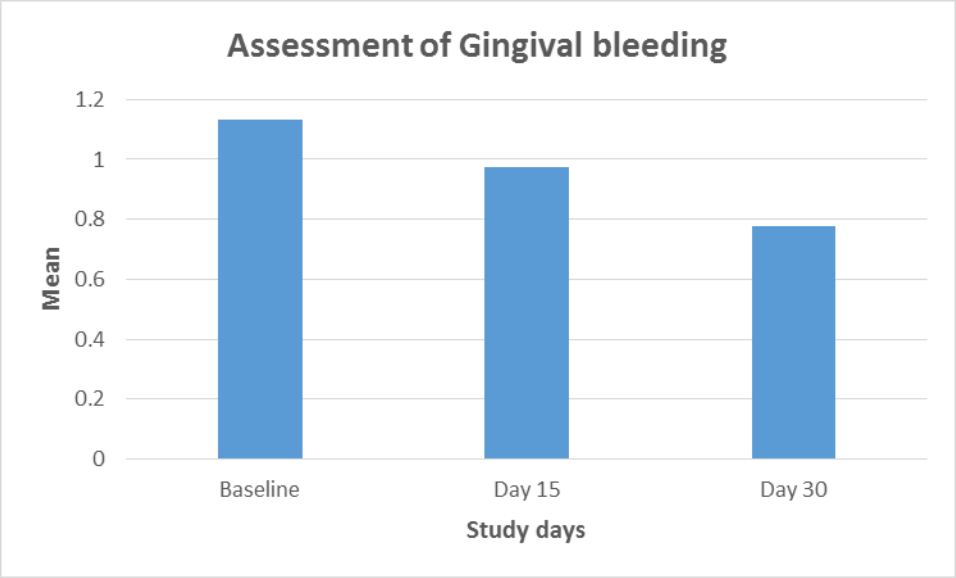
Graph 3: Graphical representation of plague index assessment.

Gingival bleeding assessment

Table 5: Listing of gingival bleeding assessment - Change from baseline.

Visit	N	Mean	Std. Dev.	% change
Baseline	60	3.406	0.389	
Day 1	60	3.055	0.391	10.31
Day 15	60	2.762	0.393	18.91
Day 30	60	2.417	0.420	29.04

The p-value is <0.05. The result is significant.



Graph 4: Graphical representation of assessment of gingival bleeding.

Carious teeth assessment

Table 6: Listing of carious teeth assessment - Change from baseline.

Visit	N	Mean	Std.Dev.
Baseline	60	2.11	0.865
ay 30	60	2.23	0.934

The p-value is >0.05. The result is non-significant

Efficacy questionnaire assessments

Table 7: Frequency table of efficacy questionnaire.

Do you find that the taste of the toothpaste is appealing?

Visit	Response	N (%)
(Day 1: 0 Mins)	Strongly Disagree	0
	Disagree	0
	Neither Agree nor Disagree	0
	Agree	4(6.66%)
	Strongly Agree	56 (93.33%)

Interpretation: Efficacy assessment shows that 4(6.66%) subjects were agreeing with toothpaste was appealing and 56 (93.33%) subjects were strongly agreed with toothpaste was appealing at visit (Day 1:0 Mins).

Table 8: Frequency table of efficacy questionnaire.

Do you feel that the product gives a cooling effect after brushing teeth?

Visit	Response	N (%)
(Day 1 : 0 Mins)	Strongly Disagree	0
	Disagree	0
	Neither Agree nor Disagree	30 (50.00 %)
	Agree	30 (50.00 %)
	Strongly Agree	0
(Day 1 : 30 Mins)	Strongly Disagree	0
	Disagree	0
	Neither Agree nor Disagree	30 (50.00 %)
	Agree	30 (50.00 %)
	Strongly Agree	0
(Day 1 : 60 Mins)	Strongly Disagree	0
	Disagree	0
	Neither Agree nor Disagree	30 (50.00 %)
	Agree	30 (50.00 %)
	Strongly Agree	0

Interpretation

- **(Day 1: 0 Mins):** Efficacy assessment shows that 30 (50.00 %) subjects were neither agree nor disagree with product gives a cooling effect was appealing and 30 (50.00 %) subjects were agreeing with product gives a cooling effect was appealing at visit.
- **(Day 1: 30 Mins):** Efficacy assessment shows that 30 (50.00 %) subjects were neither agree nor disagree with product gives a cooling effect was appealing and neither agree nor disagree subjects were agreeing with product gives a cooling effect was appealing at visit.
- **(Day 1: 60 Mins):** Efficacy assessment shows that 30 (50.00 %) subjects were neither agree nor disagree with product gives a cooling effect was appealing and neither agree nor disagree subjects were 30 (50.00 %) agree with product gives a cooling effect was appealing at visit.

Table 9: Frequency table of efficacy questionnaire.

Do you feel fresh sensation after brushing your teeth?

Visit	Response	N (%)
(Day 1 : 0 Mins)	Strongly Disagree	0
	Disagree	0
	Neither Agree nor Disagree	0
	Agree	5 (8.33%)
	Strongly Agree	55 (91.66%)
(Day 1 : 30 Mins)	Strongly Disagree	0
	Disagree	0
	Neither Agree nor Disagree	0
	Agree	5 (8.33%)
	Strongly Agree	55 (91.66%)
(Day 1 : 60 Mins)	Strongly Disagree	0
	Disagree	0
	Neither Agree nor Disagree	0
	Agree	5 (8.33%)
	Strongly Agree	55 (91.66%)

Interpretation

- Efficacy assessment shows that 5 (8.33%) subjects were agree with product gives a fresh sensation and 55 (91.66%) subjects were strongly agreeing with product gives a fresh sensationat visit (Day 1: 0 Mins)
- Efficacy assessment shows that 5 (8.33%) subjects were agreeing with product gives a fresh sensation and 55 (91.66%) subjects were strongly agreeing with product gives a fresh sensationat visit (Day 1: 30 Mins)
- Efficacy assessment shows that 5 (8.33%) subjects were agree with product gives a fresh sensation and 55 (91.66%) subjects were strongly agreeing with product gives a fresh sensationat visit (Day 1: 60 Mins)

Table 10: Frequency table of efficacy questionnaire.

You find any reduction in bad breath after brushing your teeth?

Visit	Response	N (%)
(Day 1: 0 Mins)	Strongly Disagree	0
	Disagree	0
	Neither Agree nor Disagree	0
	Agree	6 (10%)
	Strongly Agree	54 (90%)
(Day 1 : 30 Mins)	Strongly Disagree	0
	Disagree	0
	Neither Agree nor Disagree	0

	Agree	6 (10%)
	Strongly Agree	54 (90%)
(Day 1 : 60 Mins)	Strongly Disagree	0
	Disagree	0
	Neither Agree nor Disagree	0
	Agree	6 (10%)
	Strongly Agree	54 (90%)
(Day 1 : 4 Hours)	Strongly Disagree	0
	Disagree	0
	Neither Agree nor Disagree	2 (3.33%)
	Agree	37 (61.66%)
	Strongly Agree	21 (35.00%)
(Day 1 : 8 Hours)	Strongly Disagree	0
	Disagree	1 (1.67%)
	Neither Agree nor Disagree	30 (50.00%)
	Agree	29 (48.33%)
	Strongly Agree	0
(Day 1 : 12 Hours)	Strongly Disagree	0
	Disagree	1 (1.67%)
	Neither Agree nor Disagree	59 (98.33%)
	Agree	0
	Strongly Agree	0
Visit 3 (Day 15)	Strongly Disagree	0
	Disagree	0
	Neither Agree nor Disagree	0
	Agree	0
	Strongly Agree	60 (100%)
Visit 4 (Day 30)	Strongly Disagree	0
	Disagree	0
	Neither Agree nor Disagree	0
	Agree	0
	Strongly Agree	60 (100%)

Interpretation

Efficacy assessment shows that 6 (10%) subjects were agree with product gives a reduction in bad breath and 54 (90%) subjects were strongly agree with product gives a reduction in bad breath at visit (Day 1: 0 Mins, 30 and 60 mins).

Efficacy assessment shows that 2 (3.8 %) subjects were neither agree nor disagree with the product gives a reduction in bad breath, 37 (61.66%) subjects were agree with product gives a reduction in bad breath and 21 (35.00 %) subjects were strongly agree with product gives are diction in bad breath at visit (Day 1: 4 Hours).

Efficacy assessment shows that 1(1.67%) subjects were disagree with product gives a reduction in bad breath, 30 (50.00%) subjects were neither agree nor disagree with the product gives a reduction in bad breath and 29(48.33%) subjects were agree with product gives a reduction in bad breath at visit (Day 1: 8 Hours).

Efficacy assessment shows that 1(1.67%) subjects were disagreeing with product gives a reduction in bad breath and 59(98.33%) subjects were neither agree nor disagree with the product gives a reduction in bad breath at visit (Day 1: 12 Hours).

Efficacy assessment shows that 60(100%) subjects were strongly agreeing with product gives a reduction in bad breath at visit 3(Day 15) and Visit 4(Day 30).

Table 11: Frequency table of efficacy questionnaire.

Do you find this test product better than your current toothpaste?

Visit	Response	N (%)
Visit 4 (Day 30) afterbrushing	Strongly Disagree	0
	Disagree	0
	Neither Agree nor Disagree	1 (1.66%)
	Agree	7 (11.66%)
	Strongly Agree	52 (86.67%)

Interpretation: Efficacy assessment shows that 1 (1.66%) subject was neither agree nor disagreewith the product was better than current toothpaste, 7 (11.66%) subjects were agreeing with product wasbetter than current toothpaste and 52(86.67%) subjects were strongly agree with product was betterthan current toothpaste at visit 4(Day 30).

Tolerance questionnaire assessments

Table 12: Frequency table of tolerance questionnaire.

Burning Sensation

Visit	Response	N (%)
0 hours (+ 15 mins) afterbrushing	None	3 (5.00%)
	Slight	57 (95%)
	Moderate	0
	Severe	0
4 hours (± 15 mins) afterbrushing	None	58 (96.6%)
	Slight	2 (3.33%)
	Moderate	0
	Severe	0
8 hours (± 15 mins) afterbrushing	None	60 (100%)
	Slight	0

	Moderate	0
	Severe	0
12 hours (± 15 mins) afterbrushing	None	60 (100%)
	Slight	0
	Moderate	0
	Severe	0
Visit 3 Day 15 afterbrushing	None	60 (100%)
	Slight	0
	Moderate	0
	Severe	0
Visit 4 Day 30 afterbrushing	None	60 (100%)
	Slight	0
	Moderate	0
	Severe	0

Interpretation

- 57(95.00%) subjects had slight burning and 3(5.00%) subjects had no burning sensation at0 Hours.
- 58(96.6%) subjects had no burning and 2(3.33%) subjects had slight burning sensation at 4 Hours.
- 60(100%) subjects had no burning sensation at 8 Hours, 12 Hours, Day 15 and Day 30.

Table 13: Frequency table of tolerance questionnaire.

Alteration in taste

Visit	Response	N (%)
0 hours (+ 15 mins) after brushing	None	60 (100%)
	Slight	0
	Moderate	0
	Severe	0
4 hours (± 15 mins) after brushing	None	60 (100%)
	Slight	0
	Moderate	0
	Severe	0
8 hours (± 15 mins) after brushing	None	60 (100%)
	Slight	0
	Moderate	0
	Severe	0
12 hours (± 15 mins) after brushing	None	60 (100%)
	Slight	0
	Moderate	0

	Severe	0
Visit 3 Day 15 afterbrushing	None	60 (100%)
	Slight	0
	Moderate	0
	Severe	0
Visit 4 Day 30 afterbrushing	None	60 (100%)
	Slight	0
	Moderate	0
	Severe	0

Interpretation: 60(100%) subjects had not felt alteration in taste for all the visits.

Table 14: Frequency table of tolerance questionnaire.

Redness around lips

Visit	Response	N (%)
0 hours (+ 15 mins) after brushing	None	60 (100%)
	Slight	0
	Moderate	0
	Severe	0
4 hours (± 15 mins) after brushing	None	60 (100%)
	Slight	0
	Moderate	0
	Severe	0
8 hours (± 15 mins) after brushing	None	60 (100%)
	Slight	0
	Moderate	0
	Severe	0
12 hours (± 15 mins) after brushing	None	60 (100%)
	Slight	0
	Moderate	0
	Severe	0
Visit 3 Day 15	None	60 (100%)
	Slight	0
	Moderate	0
	Severe	0
Visit 4 Day 30	None	60 (100%)
	Slight	0
	Moderate	0
	Severe	0

Interpretation: 60(100%) subjects had not feel redness around lips for all the visits.

6. CONCLUSION

Based on statistical analysis below are the study result,

- Test product showed statistically significant (P-value is <0.05) reduction in **Gingivitis** (inflammation of gums) as early as 15 days of use and continued to improve till 30 days.
- Test product showed statistically significant (P-value is <0.05) reduction in **Halimeter assessment** as early as 15 days of use and continued to improve till 30 days.
- Test product showed statistically significant (P-value is <0.05) reduction in **Plaque** (soft deposits that form the bio film adhering to the tooth surface) as early as 15 daysof use and continued to improve till 30 days.
- Test product showed statistically significant (P-value is <0.05) reduction in **Gingival bleeding** as early as 15 days of use and continued to improve till 30 days.
- There were no adverse events (AEs) reported neither by the Investigator and Dentist nor self-reported by the subjects during the conduct of the study.
- Basis subject perception, test product was appealing in taste, giving long lasting effect of freshness till 60 mins post brushing.

% population			
	0 mins	30 mins	60 mins
Agreement of Appealing Taste	93.33%	--	--
Agreement in Giving Cooling Effect	50%	50%	50%
Agreement in giving long lasting. freshness	91.66%	91.66%	91.66%

- 91.66% subjects agreed on the test product providing better mouth feel from their current toothpaste.
- 86.67 % subjects agreed that this test product is better than their current toothpaste.
- 100% subjects agreed on ‘NO’ redness around the lips, ‘NO’ alteration in taste and ‘NO’ burning sensation from baseline on day 30.

7. REFERENCES

1. Selwitz RH, Ismail AI, Pitts NB. Dental caries. The Lancet, 2007; 6, 369(9555): 51-9.
2. https://www.healthgrades.com/right-care/oral-health/dental-caries#:~:text=Dental%20caries%20are%20caused%20by,a%20sticky%20film%20called%20plaque

3. https://www.mayoclinic.org/diseases-conditions/cavities/symptoms-causes/syc-20352892#:~:text=As%20the%20decay%20gets%20larger,something%20sweet%2C%20hot%20or%20cold
4. https://my.clevelandclinic.org/health/diseases/-plaque#:~:text=Plaque%20is%20a%20sticky%20film,the%20bones%20that%20support%20teeth
5. https://www.medicalnewstoday.com/articles/166636#causes
6. https://www.medicinenet.com/gum_disease/article.html
7. https://www.hse.ie/eng/health/az/g/gingivitis-and-periodontitis/complications-of-gum-disease.html
8. Preethi D. Gingival Bleeding. European Journal of Molecular & Clinical Medicine, 2020; 13, 7(2): 6649-54.
9. https://www.livescience.com/44377-sensitive-teeth.html
10. https://www.healthgrades.com/right-care/oral-health/sensitive-teeth#:~:text=Erosion%20can%20also%20be%20caused,to%20cavities%20and%20their%20complications.
11. Pandharipande N, Rajput A, Kulkarni O. A clinical validation of efficacy and safety of test dental cream (herbs & more herbal dental paste) in dental care of healthy adults.