

# Clinical Study to Evaluate Efficacy and Tolerance of Test Toothpaste (Herbs & More Herbal Dental Paste) In Dental Care of Healthy Adults

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## Abstract

**Background:** Test product “Herbs and More Herbal Dental Paste (HM-DP)” manufactured by Netsurf Communications Pvt. Ltd. for dental care.

**Objective:** The main objective of the study was to evaluate efficacy and tolerance of test product in dental care of healthy adults via questionnaire.

**Materials and Methods:** Open label, single center, single arm, clinical study. Subjects were asked to brush their teeth with the test product for a period of 30 days. Their efficacy and tolerance report was prepared based on the perception of subjects to the questionnaire.

**Results:** The test product showed no adverse events (AEs) during the conduct of the study. The efficacy and tolerance assessment report proved that the test product was appealing in taste, giving long lasting effect of freshness and cooling sensation till 60 mins post brushing. Also, the test product was found to be better than the current toothpaste used by the subjects.

**Conclusion:** Test product was efficacious and had no tolerance effect on subjects for dental care.

**Keywords:** Test Product, Dental Care, Tolerance, Efficacy

## INTRODUCTION

Dental diseases are the chronic diseases worldwide, and an expensive affair to health care services, accounting around 5% to 10% of total health care expenditures. The predominance rate of dental caries in low-income countries is high and about 90% of caries is untreated. All over the world, estimated 5 billion people endure from dental caries. Dental diseases embrace dental caries, developmental defects of enamel, dental erosion and periodontal disease. Oral diseases resembling all other diseases allocate a wide range of risk factors such as age, sex and hereditary conditions while others are subjected to behavior and lifestyle, in particular high sugar intake – tobacco use, alcohol consumption. [1-3]

Treatment includes exclusion of decay by operative measures and renovation with suitable materials such as silver fillings, gold inlays, composite resin, glass ionomer cement, full metal or porcelain crowns, etc. Adopting use of sugar substitutes like saccharine, xylitol, mannitol, aspartame, etc. in paediatric medicinal syrups, bakery products, jams, marmalade, etc and regular use of fluoridated toothpaste helps to diminishing 30% occurrence of dental caries. [4-7]

The test product “Herbs and More Herbal Dental Paste (HM-DP)” was manufactured by Netsurf Communications Pvt. Ltd. This herbal toothpaste was evaluated for its efficacy and tolerance against dental caries in healthy adults [8-10]. Thus, the study for test product efficacy and tolerance was carried out via questionnaires.

## MATERIAL AND METHODS

### Study Design

This was an open label, single center, single arm, 4 weeks clinical study to evaluate the efficacy and tolerance of

Herbs and More Herbal Dental Paste in dental care of healthy adults.

### Study Objective

The objective of the study was to evaluate the test product efficacy and tolerance in dental care of healthy adults via questionnaires.

### Subject Selection

A total of 117 subjects were screened and signed the informed consent document for the study. Out of the 117 subjects, 60 subjects who met the study criteria were enrolled and randomized in the study. Subjects having T-VSC reading of >160 ppb, plaque index 2-4, modified gingival index 0.1-3.0 were selected for the study. Subjects with periodontal disease, carious lesions, dental prophylaxis and partial removable dentures were excluded from the study. A total of 60 subjects (34 females, 26 males) completed all the phases of the study.

### Test Product

The Test product was received by Clantha Research and the details mentioned in Table No.1.

### Study Procedures

The study comprised of five different study execution visits. The study was conducted in multiple groups. There were four test products in the study evaluated for their efficacy with enrolled subjects during the study period. Subject's teeth were assessed clinically by the study dentist as well as instrumentally, before application of toothpaste and were 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 and were informed about their next visit.

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 acclimatized at room temperature for at least 15 minutes prior to having any assessments.

On Day 0, General health (well-being) and concomitant medication record if any were recorded. Urine pregnancy test was performed for females of childbearing potential only. Subjects were enrolled and received subject number. Dental examination was performed by Dentist. Dinner was served before 10 pm on Day 0. Subjects were asked to brush their teeth before going to bed at facility on day 0. Subjects were confined at clinical facility on Day 0.

On Day 1: Baseline Assessments (Before Brushing) of halitosis were performed by trained study personnel. Subject's carious teeth 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. Test product efficacy and tolerance questionnaires were asked by study staff after brushing at 0mins (+5 mins), 30 mins, 60 mins ( $\pm 5$  mins), 4, 8 and 12 hours ( $\pm 15$  mins) (before having meals at each time point). Study restrictions and instructions were provided to subjects and asked to follow study instructions. Subjects were provided meals i.e. breakfast, lunch, snacks and dinner at appropriate time interval. Subjects exit the facility after brushing their teeth in the evening and were 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  $\pm 2$  days)] Subject arrived to the facility on Day 15. Adverse event and concomitant medication record if any 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. Subject's carious teeth were evaluated by visual assessment by dentist. Test product efficacy and tolerance questionnaires were asked by study staff after brushing. Study restrictions and instructions were provided to subject and asked to follow study instructions. Subject 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  $\pm 2$  days)] Subject arrived to the facility on Day 30. Adverse event and concomitant medication record if any were recorded. Subjects were acclimatized at room temperature for at least 15 minutes prior to having any assessments (clinical or instrumental). Urine pregnancy test was performed for females of childbearing potential only. Dental examination was performed by Dentist. Subjects were asked to brush their teeth under supervision of the study staff. Subject's carious teeth were evaluated by visual assessment by dentist. Study 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. Subject were received the compensation and their participation in the study was considered completed.

#### Statistics

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. If required appropriate analysis using non parametric test was done. All statistical tests were done using SAS software of 5% level of significance (Version: 9.4, SAS Institute Inc., USA).

### RESULT AND DISCUSSION

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 (Table No.2).

#### Efficacy Questionnaire Assessments

##### 1. Do you find that the taste of the toothpaste is appealing?

The efficacy assessment shows that 3(5.00%) subjects agree that toothpaste was appealing and 57 (95.00%) subjects were strongly agree that toothpaste was appealing at visit (Day 1:0 mins) shown in Figure No.1.

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

(Day 1: 0 Mins): Efficacy assessment shows that 6 (10.00%) subjects agree that the product gives a cooling effect which was appealing and 54 (90.00%) subjects were strongly agreeing with product giving a cooling effect which was appealing at visit.

(Day 1: 30 Mins): Efficacy assessment shows that 6 (10.00%) subjects agree that the product gives a cooling effect which was appealing and 54 (90.00%) subjects were strongly agreeing with product giving a cooling effect which was appealing at visit.

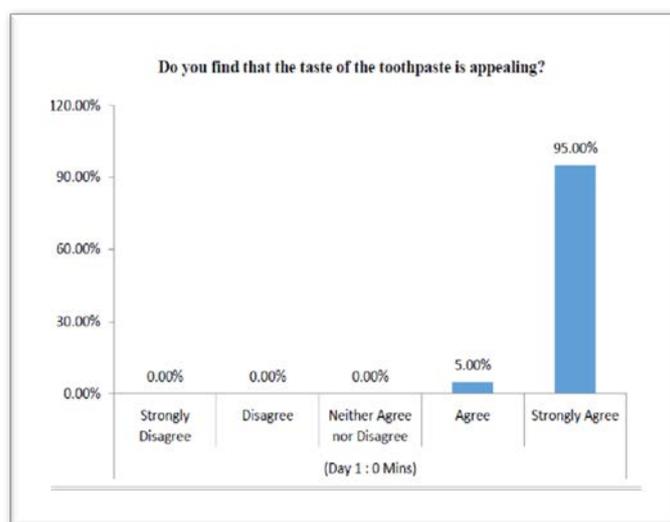
(Day 1: 60 Mins): Efficacy assessment shows that 6 (10.00%) subjects agree that the product gives a cooling effect which was appealing and 54 (90.00%) subjects were strongly agreeing with product giving a cooling effect which was appealing at visit. (Figure No.2)

**Table No.1:** Test Product Details

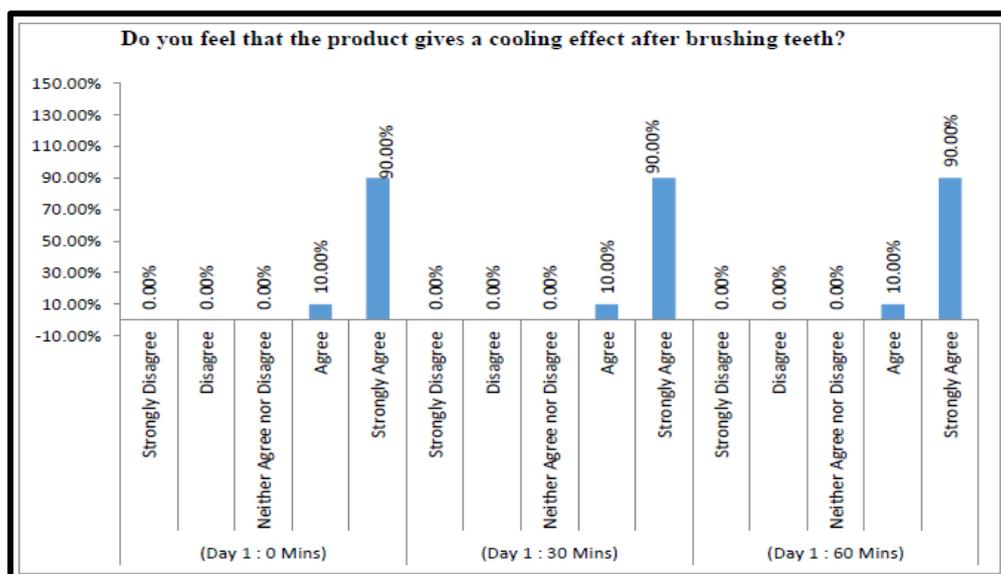
<b>Formulation</b>	Herbs and More Herbal Dental Paste
<b>Sponsor Code</b>	HM-DP
<b>Manufactured by</b>	Netsurf Communications Pvt. Ltd.
<b>Storage</b>	At room temperature 15°C to 30°C.
<b>Quantity</b>	75

**Table No. 2:** Demographical data

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



**Figure No.1:** Graphical Representation for toothpaste was appealing



**Figure No. 2:** Graphical Representation for cooling effect

**3. Do you feel fresh sensation after brushing your teeth?**

Efficacy assessment shows that 6 (10.00%) subjects agree that the product gives a fresh sensation and 54 (90.00%) subjects were strongly agreeing with product giving a fresh sensation at visit (Day 1 : 0 Mins)

Efficacy assessment shows that 6 (10.00%) subjects agree that the product gives a fresh sensation and 54 (90.00%) subjects were strongly agreeing with product giving a fresh sensation at visit (Day 1 : 30 Mins)

Efficacy assessment shows that 6 (10.00%) subjects were agree that the product gives a fresh sensation and 54 (90.00%) subjects were strongly agreeing with product giving a fresh sensation at visit (Day 1 : 60 Mins) (Figure No.3)

**4. Do you find any reduction in bad breath after brushing your teeth?**

Efficacy assessment shows that 5 (8.33%) subjects agree that product gives reduction in bad breath and 55(91.67%) subjects were strongly agreeing with product giving a reduction in bad breath at visit (Day 1 : 0 Mins)

Efficacy assessment shows that 5 (8.33%) subjects were agree that product gives reduction in bad breath and 55(91.67%) subjects were strongly agreeing with product giving a reduction in bad breath at visit (Day 1 : 30 Mins)

Efficacy assessment shows that 5 (8.33%) subjects were agree that product gives reduction in bad breath and 55(91.67%) subjects were strongly agreeing with product giving a reduction in bad breath at visit (Day 1 : 60 Mins)

Efficacy assessment shows that 3 (5.00%) subjects neither agree nor disagree that the product gives a reduction in bad breath, 36(60.00%) subjects were

agreeing with product giving a reduction in bad breath and 21(35.00%) subjects were strongly agreeing with product giving a reduction in bad breath at visit (Day 1 : 4 Hours)

Efficacy assessment shows that 1(1.67%) subjects disagree that the product gives a reduction in bad breath, 31(51.67%) subjects neither agree nor disagree that the product gives a reduction in bad breath and 28(46.67%) subjects were agreeing with product giving a reduction in bad breath at visit (Day 1 : 8 Hours)

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

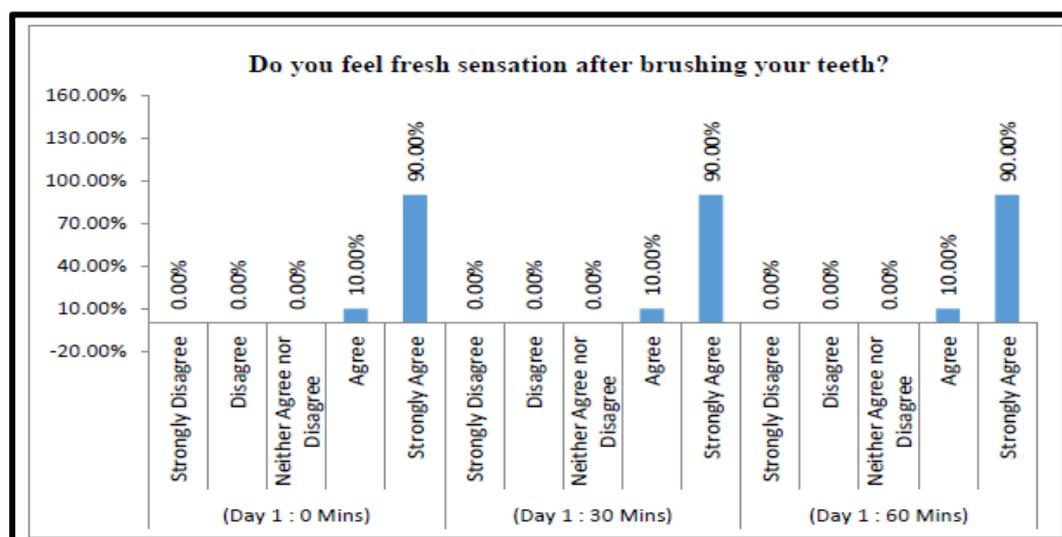
Efficacy assessment shows that 60(100%) subjects strongly agree that the product gives a reduction in bad breath at visit 3(Day 15) and Visit 4(Day 30). (Figure No.4)

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

Efficacy assessment shows that 2 (3.33%) subjects neither agree nor disagree that the product was better than current toothpaste, 6(10.00%) subjects agree that the product was better than current toothpaste and 52(86.67%) subjects were strongly agreeing that product was better than current toothpaste at visit 4(Day 30). (Figure No.5)

**6. Can you rate the mouth feel after using test product as compared to your current toothpaste?**

Efficacy assessment shows that 6(10.00%) subjects feel good in the mouth feel compare to current toothpaste and 54(90.00%) subjects feel better in the mouth feel compare to current toothpaste at visit 4 (Day 30). (Figure No.6)



**Figure No.3:** Graphical Representation for feel fresh sensation

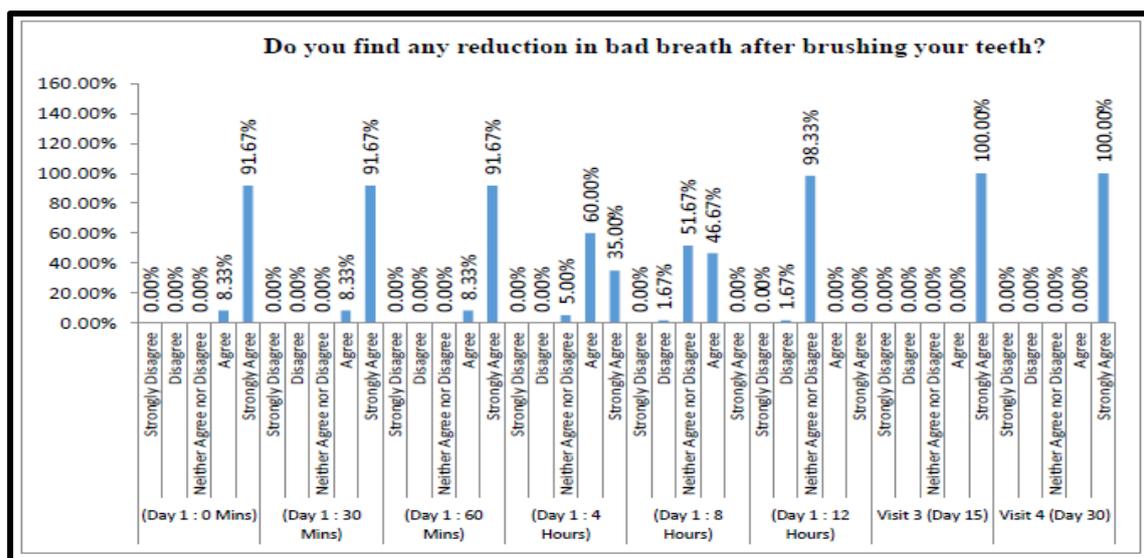


Figure No. 4: Graphical Representation for reduction in bad breath

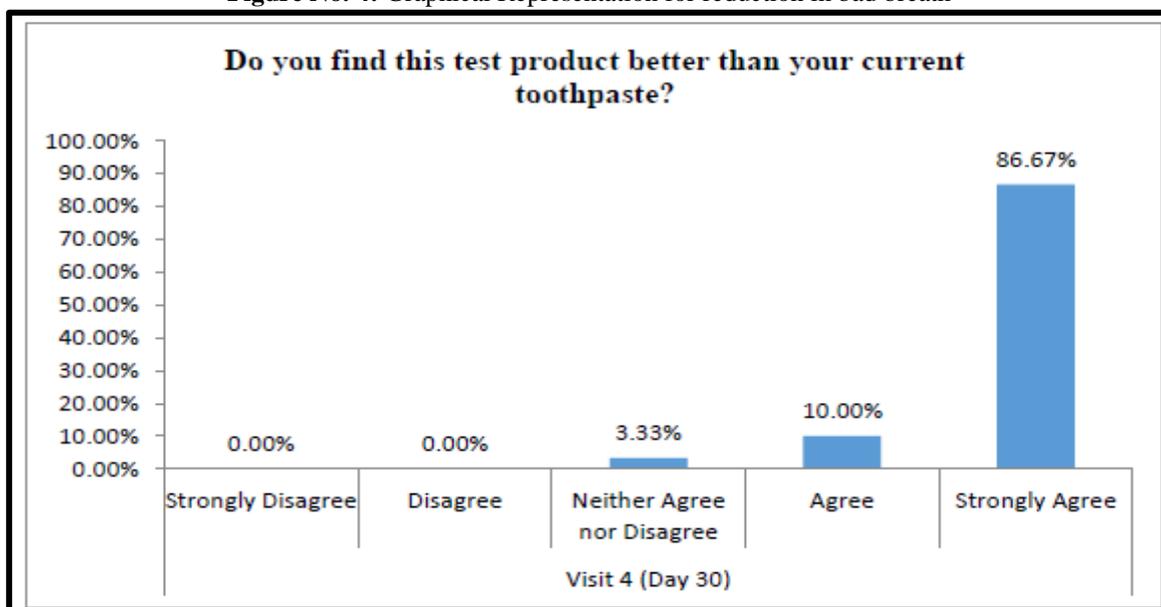


Figure No.5: Graphical Representation for test product better than your current toothpaste

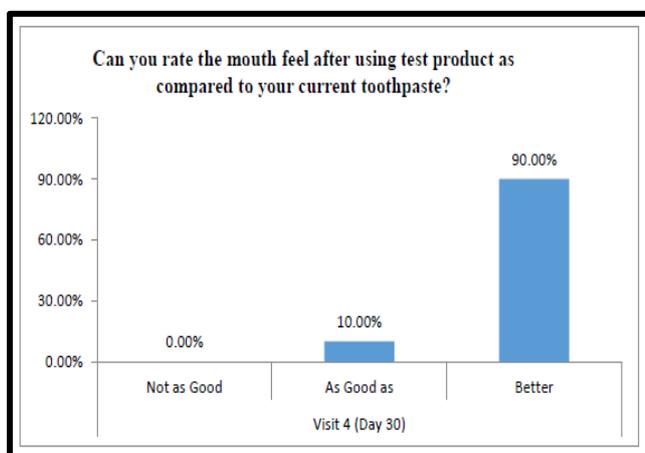


Figure No. 6: Graphical Representation for rate the mouth feel

**Tolerance Questionnaire Assessments**

- Burning Sensation**  
 58(96.67%) subjects had no burning sensation and 2(3.33%) subjects had slight burning sensation at 0 Hours.  
 59(98.33%) subjects had no burning sensation and 1(1.67%) subjects had slight burning sensation at 4 Hours.  
 60(100%) subjects had no burning sensation at 8 Hours, 12 Hours, Visit 3 and Visit 4. (Figure No.7)
- Alteration in Taste**  
 60(100%) subjects had not felt alteration in taste for all the visits.(Figure No.8)
- Redness around lips**  
 60(100%) subjects had not felt redness around lips for all the visits. (Figure No.9)

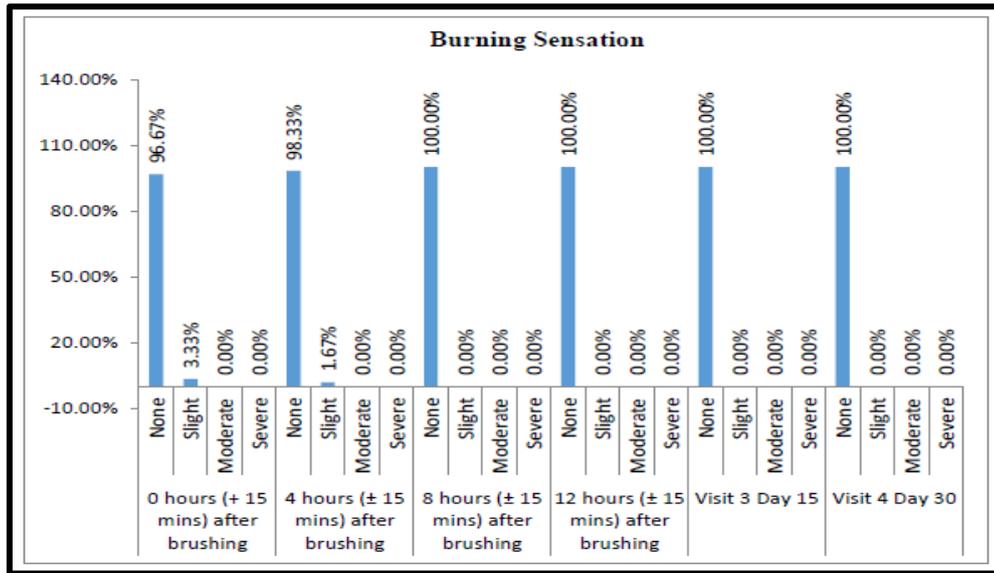


Figure No. 7: Graphical Representation for Burning Sensation

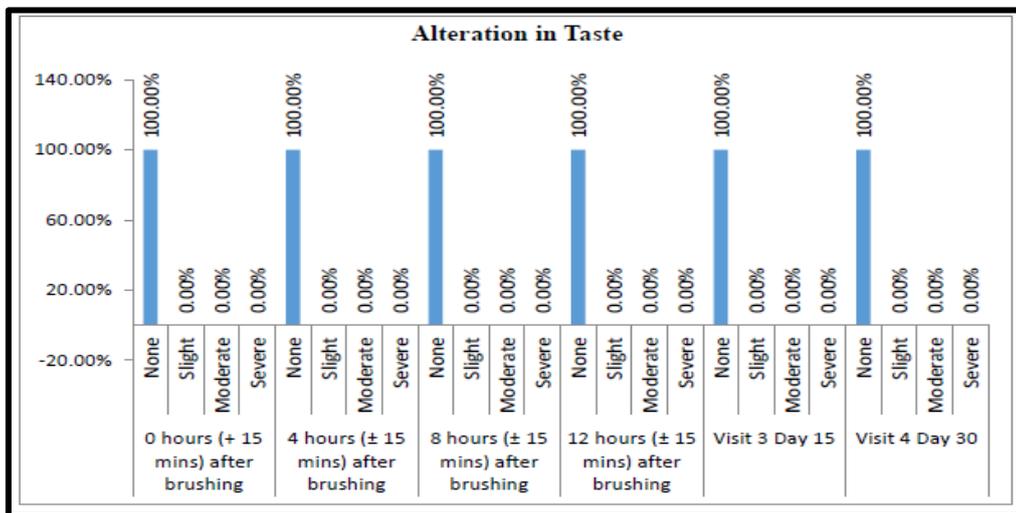


Figure No. 8: Graphical Representation for Alteration in Taste

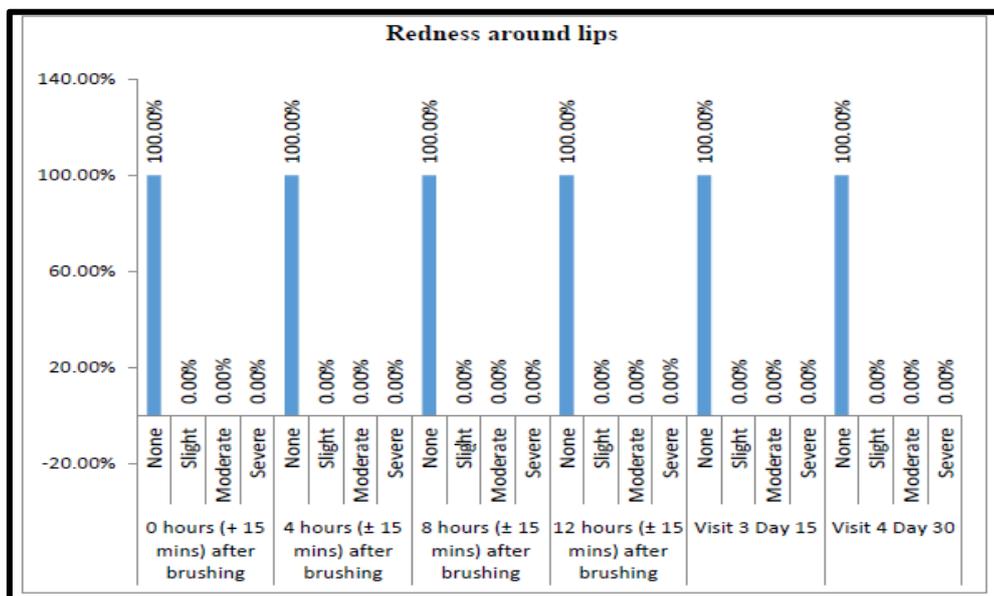


Figure No.9: Graphical Representation for Redness around lips

### CONCLUSION

Test product was found to be effective in subjects. There were no adverse events (AEs) reported during the conduct of the study. On the basis of subject perception, test product was appealing in taste, giving long lasting effect of freshness and cooling sensation till 60 mins post brushing. 100 % subjects agreed on test product reducing the bad breath after usage of 30 days. 90% subjects agreed on the test product providing better mouth feel from their current toothpaste. 96.67 % subjects agreed that this test product is better than their current toothpaste. Thus, the test product was found to be efficacious and well tolerance for dental care.

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