



An Open Label, Single Arm, Clinical Study to Evaluate Efficacy and Safety of Herbs & More Herbal Dental Paste in Dental Care of Healthy Adults.







Clinical Study Standards:

The study was conducted as per ICMR Ethical Guidelines, ICH-GCP, Schedule Y and Declaration of Helsinki.

Study Objectives:

The study was conducted to assess efficacy of the Herbal Dental Paste using parameters for :

- 1. Reduction in Gingivitis (inflammation of gums)
- 2. Gum tightening
- 3. Malodour control
- 4. Reduction of Dental plaque
- 5. Reduction in gum bleeding
- 6. Reduction in dental caries
- 7. Subjective tolerance and acceptance of product.

The study also evaluated safety of the product using

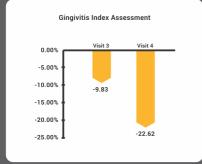
- 1. Appearance of adverse events as evaluated by subjects & dentists
- 2. Non compliance
- 3. Any other safety issues

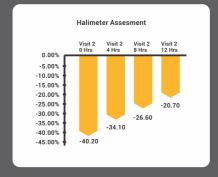


Observations

The study shows statistically significant decrease observed in Gingivitis Index from baseline to visit 3 (P-value = 0.0000) and visit 4 (P-value = 0.0000), which indicates test product significantly reduces the Gingivitis compared from baseline to visits 3 and visit 4.

The study shows statistically significant decrease observed in Halimeter Assessment from baseline to 0 hour (P-value = 0.0000), 4 hour (P-value = 0.0000), a hour (P-value = 0.0000) and 12 hour (P-value = 0.0000), which indicates a significant reduction in halitosis (oral malodor) from baseline to at all-time points.



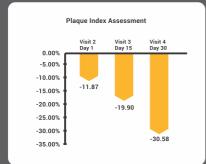


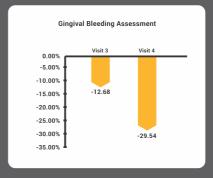


Observations

The study shows statistically significant decrease observed in Plaque Index Assessment from baseline to visit 2 (P-value = 0.0000), visit 3 (P-value = 0.0000) and visit 4 (P-value = 0.0000), which indicates significant reduction in plaque formation up to Visit 4 (Day 30).

The study shows statistically significant decrease observed in Gingival Bleeding Assessment from baseline to visit 3 (P-value = 0.0000) and 4 (P-value = 0.0000), which indicates significant reduction in gingival bleeding up to Visit 4 (Day 30).









Clinical Efficacy:

- 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.
- There were no adverse events (AEs) reported during the conduct of the study.
- 100% subjects agreed on 'NO' redness around the lips, 'NO' alteration in taste and
- 'NO' burning sensation from baseline on day 30.