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Efficacy of ClōSYS Flavored and Unflavored Oral Rinse in Human Subjects in Controlling Oral Malodor

Statistical Analysis Plan

Intraclass correlation coefficients (ICCs) were used to measure organoleptic rater agreement.

Organoleptic data were of the ordinal type. Distributions were checked for skewness and kurtosis for any extreme values.

Therefore, data were analyzed by non-parametric tests. The Mann-Whitney U tested for differences between the two independent mouthwash groups at each data-collection visit and of the final overall organoleptic score between groups.

Specifically, the Mann-Whitney test determined if there were statistically significant differences between mouthwashes at baseline and at each of the eight assessments. Friedman's non-parametric repeated measures analysis of variance was applied to the raw organoleptic scores over the assessment periods and to change scores within and between phases and groups.

Finally, the change scores in the Phase I – before crossover and washout period – were also analyzed by Friedman's test across the three states of change that occurred in each of Phases I and II.