



Final Report: RDA Test on Powdered Abrasives
Study Number RDA 19-82

Study Number

Dental Product Testing Study Number 19-82

Study Sponsor

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Purpose

The purpose of this study was to determine the relative abrasion level of powdered abrasives to dentin.

Procedure

The procedure used was the ISO / ADA recommended procedure for determination of dentifrice abrasivity as detailed in ISO 11609 and ANSI/ADA Standard No. 130. The dentin specimens (8) were placed in a neutron flux under the controlled conditions outlined by the ISO / ADA. The specimens were then mounted in methyl methacrylate so they would fit in a V-8 cross-brushing machine. The specimens were brushed for a 1500-stroke precondition run using a slurry consisting of 10g ISO / ADA reference material in 50 ml of a 0.5% CMC glycerin solution. The brushes used were those specified by the ISO / ADA and the brush tension was set to 150g.

Following the precondition run, the test was performed using 150g and 1500 strokes in a sandwich design in which each test material slurry (10g/50ml 0.5% CMC/glycerin solution for powdered abrasives) was flanked by the reference material slurries (10g / 50 ml 0.5% CMC/glycerin) as outlined below.



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Run	Treatment
1	ADA Reference Material
2	Teeth Whitening Coconut Activated Carbon Powder
3	ADA Reference Material

One (1.0) ml samples were taken, weighed (0.01g) and added to 4.5 ml of scintillation cocktail. The samples were mixed well and immediately put on the scintillation counter for radiation detection. Following counting, the net CPM values were divided by the weight of the sample to calculate a net CPM/gram of slurry. The net CPM/g of the pre and post ADA reference material for each test slurry were then calculated and averaged to use in the calculation of RDA (relative dentin abrasion) for the test material. The ISO / ADA material was assigned a value of 100 and its ratio to the test material was calculated. As of 8-16-99, a new lot of the ADA reference material has been used. This material is 3.6% less abrasive than old batches, thus requiring the addition of 3.6% to the reference material CPM. This allows the direct comparison of this data to previous data.

GLP Compliance

This study was run in compliance with the FDA GLP as closely as possible. This study may be monitored by an internal (TTI) audit. Any deviations or amendments were discussed with and recorded and reported to the sponsor and outlined in the final report. There were no deviations from protocol reported for this study.

Records Maintained

DPT will be responsible for the storage, expiration, and destruction of all specimens, raw data and the final report unless requested differently by the sponsor. Products will be held for three-months following report and then destroyed. Data will be held for at least five years.

Results

The results are detailed in the attached table and summarized in Table I below. All raw data (individual specimen RDA values) was reported. In addition, the Mean (N=8), S.D. and SEM for each group were calculated. Statistical analyses were not performed due to this being a single test product assessment.



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Conclusions

Test abrasive Teeth Whitening Coconut Activated Carbon Powder exhibited a Mean (N=8) \pm SEM relative dentin abrasion (RDA) value of 84.67 ± 2.20 . The RDA value exhibited in this *in vitro* assessment was within the acceptable limits for dentifrice dentin abrasivity as defined in ISO and ANSI/ADA standards.

Heath C. McClure
Director
Dental Product Testing Division
21-Mar-2019

This study has been conducted and reviewed according to the FDA Monograph on Anticaries Drug Products for Over the Counter Human Use and the FDA Good Laboratory Practices to the best of our knowledge.

21-Mar-2019

Heath C. McClure
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Therametric Technologies, Inc.

Date



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Table I:

Summary of Relative Dentin Abrasion (RDA) Data of Powdered Abrasives

Test Abrasive	RDA Value
Teeth Whitening Coconut Activated Carbon Powder	84.67 ± 2.20 *

* Mean ± SEM (N = 8)

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21-Mar-2019