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Profile Mineralization Inhibition Testing for Tartar Control Dentifrice

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The diversity of commercial formulations including tartar control demands the development and application of technical profile standards to ensure clinical efficacy of market variations. Here we describe the standardized application of combined *in vitro* and *in vivo* profile studies for the confirmation of PP_i dentifrice tartar control efficacy. Clinical proven control dentifrices including formulations with both soluble (dose = 1.3, 3.3, 5%) and dispersed (3.3% - baking soda base) pyrophosphate (PP_i) were compared with placebo for: I) soluble PP_i in 25% w/w *aq.* dilutions [ion exchange chromatography]; II) crystal growth inhibition (CGI) (pH potentiostat calcium hydroxyapatite - White *et al*. in *Recent Advances in the Study of Dental Calculus*, 1989); III) mPGM plaque calcification (White *et al*., *J Dent Res*, 1992); IV) rat calculus (Briner and Francis, *Calc Tiss Res*, 1973). Tests were then applied to Crest® MultiCare™ dentifrice (3.3% PP_i) - in advance of clinical evaluation. Controls produced: 80-100% of soluble PP_i predicted, CGI in excess of 50% (vs. placebo) and significant inhibition ($p<0.05$ ANOVA) of both mPGM microbial plaque biofilm calcification (27-39%) and rat calculus formation (28-33%). Crest® MultiCare™ produced similar efficacy results in profile evaluations in advance of clinical testing: > 7500 ppm soluble PP_i; 55% CGI; 52.4% (s) mPGM inhibition; 33% (s) rat calculus inhibition. These results predicted clinical tartar control activity for this modified pyrophosphate dentifrice which was recently confirmed (> 30% red. in supragingival calculus - *J Clin Dent* in press). **These results support the use of the proposed profile testing system to establish tartar control efficacy for generic pyrophosphate dentifrices.**

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Tartar Control Efficacy of Chinese Herbal/Triclosan/Pyrophosphate 'Multicare' Dentifrice

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The efficacy of modified tartar control formulations can be assessed in the mPGM plaque biofilm calcification model (J Dent Res 71: 173 (#543-544) 1992). The purpose of this experiment was to test activity of a 3.3% pyrophosphate (PP_i) dentifrice containing triclosan/Chinese-herbal combinations in comparison to clinically validated control formulations. Plaque biofilms were prepared and mineralized by alternate immersion of glass rods in pooled human saliva and artificial mineralization solution supersaturated with respect to HAP, OCP, and DCPD (White *et al., J. Dent. Res.* 70; 276 (#84) 1991). Topical applications of 25% w/w dentifrice water slurries were carried out for 30 seconds daily for 8 treatment days, between saliva and mineralization solution immersions. Plaque calcium levels were determined post treatment by digestion and AA. Test dentifrices included: A) Crest® Regular (control); B) Original Crest® Tartar Control (3.3 % PP_i), C) combined herbal/triclosan/PPi dentifrice (3.3 %PP_i + 0.28 % triclosan - also formulated with 0.31 % NaF) - laboratory formulation, D) combined herbal/triclosan/PP_i dentifrice (3.3 % PP_i + 0.28 % triclosan - also formulated with 0.31 % NaF) - China "All-In-One" dentifrice, and E) Positive control dentifrice (1.1 % AHP diphosphonate). Results of the study (expressed as % reduction in mineralization vs. control - a¹b ANOVA Duncan's comparison) were: A) 0.0, a; B) 25.8, b; C) 27.6, b; D) 36.3, bc; E) 49.4, c. **Herbal / triclosan / pyrophosphate dentifrices exhibited comparable / directionally improved tartar control efficacy to clinically validated control formulations comprised of 3.3 % pyrophosphate. These results support clinical results on this formulation.**