

**Bioequivalence Pilot Study of Two Multivitamin Formulations in Healthy Adults**

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**Objectives:** Bioequivalence of vitamins (vit) E, B12 and folate in a single oral dose multivitamin (MVI) gummies vs. tablets

**Methods:** This crossover clinical trial involved healthy adults randomized to either gummy or tablet MVI containing vitE, B12 and folate as a single dose in Phase 1 with serial blood samples obtained to measure vitE, B12 and folate at baseline 0, 0.5-, 1-, 2-, 4-, 6-, 8-, 9-, 10-, 24-, and 48-hrs followed by a 2-wk washout period. In Phase 2, participants then crossed over to receive MVI in the form not previously given, with blood sampling at same timepoints. Time course of absorption of gummy vs. tablet form was compared: Cmax and Area Under the Curve (AUC) calculated for each subject for vitamins at specific time intervals based on known  $t_{1/2}$ . Data analyzed using SAS 9.4 (Cary, NC).

**Results:** Six healthy subjects completed the study. For vitE, there were no differences in AUC geometric mean ratios (GMR), log AUC

GMR, or Cmax compared as GMR, log GMR or for Tmax GMR for gummy vs. tablet. For vitB12, no statistical differences on any of metrics with Cmax and Tmax GMR similar between gummy vs. tablet. For folate, there were significant differences in time course of absorption: folate absorption peaked earlier in gummy group (Tmax 1.59 hrs) vs. tablet group (Tmax 4.08 hrs), shifting mean values in the gummy group to earlier timepoints, with higher mean values at mid timepoints in tablet group. Shorter Tmax in gummy group suggested a difference in bioavailability in that preparation when compared to tablet. For folate, geometric and log AUC GMR, incremental AUC ratios, and Cmax measures showed no statistically significant differences in the gummy vs. tablet groups.

**Conclusions:** Overall, under the conditions of this pilot study, both gummy and tablet showed similar absorption of vitamins E and B12. The time course of absorption of folate differed significantly between gummy vs. tablet formulation, with more rapid absorption with the gummy form. Cmax for gummy vs. tablet were similar for the 3 vitamins. A definitive study is planned with a larger sample size powered to verify these preliminary results.

**Funding Sources:** Church & Dwight Co., Inc.