

Study examines folic acid absorption rates from softgel capsule and standard tablet

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Folic acid, an essential vitamin formulated to be part of a multivitamin + DHA liquid softgel capsule, is absorbed and available within the body in amounts similar to folic acid formulated for solid tablets, according to a study presented in a late breaking session at the Experimental Biology (EB) 2011 annual meeting. Different formulations, fillers and coatings of vitamin products may affect the degree or rate at which the product dissolves and releases its contents, which can alter the vitamin's absorption into the body and its bioavailability, a calculation of how much of a given dose of a compound reaches the blood stream to circulate within the body and have a potential effect.

Typically, folic acid supplements are available in tablet form, but many consumers find softgel capsules easier to swallow than tablets. All women of childbearing age — especially those planning a pregnancy — are recommended by the U.S. Centers for Disease Control and Prevention to consume about 400 micrograms (µg) of folic acid daily to reduce the risk for neural tube defects during fetal development.

"With the increasing science on folic acid and the rise in popularity of softgel capsules, we felt it was important to examine the differences in vitamin formulations, specifically prenatal <u>multivitamin</u> with folic acid + DHA softgels versus tablets, and how that might affect their <u>bioavailability</u>. We found that softgels are just as effective as the tablets in delivering folic acid," said study coauthor James Brooks, Ph.D., vice president of Science and Technology at Pharmavite, LLC, which conducted the study with investigators from Biofortis-Provident Clinical



Research in Glen Ellyn, IL.

The United States Pharmacopeia (USP) has disintegration and dissolution standards for dietary supplements. Current USP guidance exempts formulations for softgels, gelatin-based shells containing a liquid, from the dissolution standard, but Pharmavite, as a leading manufacturer of dietary <u>supplements</u>, seeks to have its products meet or exceed USP standards for quality, purity and composition through rigorous testing and inspections, explained Brooks.

Bioavailability of Folic Acid Similar between Softgel Capsules and Tablets

The folic acid in a multivitamin + DHA softgel was absorbed in the <u>blood stream</u> and provided systemic bioavailability at amounts similar to that from tablets. The rate of <u>absorption</u> from the softgels was slower than the tablet. Also, investigators documented that iron was absorbed from the softgel capsule, a secondary endpoint of the study.

In this crossover study, investigators randomly assigned 16 women, ages 18 to 45, to receive a single dose of either 800 µg folic acid in two tablets (Nature Made® Folic Acid 400 mcg) or 800 µg folic acid in a multivitamin + DHA softgel capsule (Nature Made® Prenatal Multi + DHA). Researchers then drew patients' blood samples prior to dosing and then at one, two, three, four, six and eight hours after dosing. About one week later, the women were tested with the alternate product. The women consumed low-folate meals during the testing period. Investigators did not know which product patients received during each phase until the study ended.

The average levels of total folate in the blood, a calculation called area under the curve (AUC), did not significantly differ between softgel



capsules and tablets, 122.0 versus 112.2 hour x nanograms per milliliter respectively (P = 0.562). Also, the average peak plasma concentration of folate, a calculation called Cmax, did not significantly differ, 49.0 vs. 43.1 nanomoles per liter for the softgels and <u>tablets</u> respectively, (P = 0.259).

More information: Experimental Biology Presentation:

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Provided by Porter Novelli

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