

# Position Paper

## The Reality of Tablet Delivery Forms & Stearic Acid

Some nutritional supplement manufacturers would like you to believe that tablets and the excipients used to make them are a bad thing. Often they focus on one small ingredient-stearic acid (or its salt, magnesium stearate)-and create widespread misconceptions about its use and its effects on patient health. It's time to clear up these misconceptions.

**Misconception:** Capsules are better than tablets.

**Reality:** There is no one delivery system that is best for all applications. The skilled formulator employs the specific delivery system that best provides stability, bioavailability, convenience, tolerance, and efficacy for each product-whether it be a powdered beverage mix, bar, time-release or quick-release tablet, softgel, or hard-gel capsule.

**Misconception:** Capsules don't require excipients.

**Reality:** Excipients are ingredients added to a formula to aid in the manufacture of tablets and capsules that are of uniform size, weight, texture, and shape. Nutri and Metagenics use several excipients in tablet formulations, choosing hypoallergenic ingredients and including them in the lowest amounts that are compatible with tablet integrity. For example, cellulose-a non-reactive plant fiber-is used to hold the tablet together and to regulate the rate at which the tablet disintegrates in the stomach.

Although some simple formulas may not require excipients, most formulations require some added ingredients to aid in manufacture. This is true for both tablets and capsules. Some formulas may require the addition of excipients to aid powder flow during encapsulation, to ensure even dispersal of the raw materials, and to protect ingredients during storage. Capsules may also contain excipients when the volume of active ingredients is very small, such as seen with vitamin B12 and folic acid preparations, or contain materials to protect fat-soluble ingredients from oxidation.

**Misconception:** Stearic acid is an unnecessary excipient used in low-grade tablet manufacturing.

**Reality:** A manufacturer of high quality nutritional supplements will ensure that excipients, binders, or diluents are derived from natural sources. Stearic acid, for example, may be of a vegetable origin. Stearic acid enables providers to manufacture tablets of uniform size, weight, texture, and shape that help to ensure a pure, safe, and effective product. Both the FDA and the United States Pharmacopeia (USP) recommend the use of stearic acid and magnesium stearate in the production of high quality nutritional and pharmaceutical products.

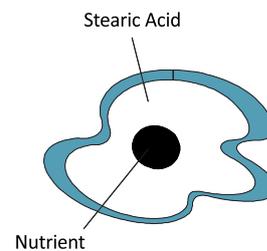
**Misconception:** Stearic acid adds unhealthy fat.

**Reality:** To help put it into proper perspective, a high quality tablet may contain only 20 mg of stearic acid, which means that a daily recommendation of six (6) tablets would contain approximately 120 mg of stearic acid (less than ¼ of 1% of a person's daily fat intake based on a 2,000-calorie diet). In comparison, a small pat of butter contains 500 mg of stearic acid-over four times that amount! You'll get far more stearic acid in your normal diet than any ordinary regimen of tablets could ever deliver. While it is a saturated fatty acid, stearic acid does not raise plasma cholesterol, even if consumed in large amounts.<sup>1,2</sup> In fact, naturally derived stearic acid has been shown to be associated with lowered risk of cardiovascular disease.<sup>3</sup>

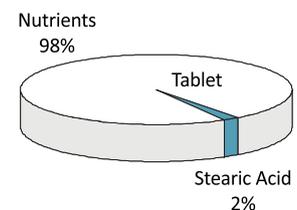
**Misconception:** Stearic acid forms a coating that inhibits digestion.

**Reality:** Remember that 20 mg in a tablet is still a very small amount, which could only be used in the blending of our ingredients-not as a coating. Stearic acid may represent only 2% of a typical tablet's composition, which would not be enough to create a layer or coating-and certainly not enough to encapsulate the active ingredients that outweigh stearic acid by 50 times. Actually, stearic acid helps control tablet density and compression to enable quick and easy disintegration in the stomach. Human studies report that stearic acid itself has excellent intestinal absorption rates.<sup>4-6</sup>

### Fiction



### Fact



Ongoing research by the scientific community continues to report findings that support the decision to use stearic acid to help ensure the active ingredients live up to their maximum potential. We caution you to question the validity and accuracy of any future claims made by those who may proliferate unscientific statements and misconceptions without the benefit of proper research.

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2. Bonanome A, Grundy SM. Effect of dietary stearic acid on plasma cholesterol and lipoprotein levels. *N Engl J Med.* 1988;318:1244-1248.
3. Yli-Jama P, Meyer HE, Ringstad J, et al. Serum free fatty acid pattern and risk of myocardial infarction: a case-control study. *J Intern Med.* 2002;25:19-25.
4. Bonanome A, Grundy SM. Intestinal absorption of stearic acid after consumption of high fat in meals in humans. *J Nutr.* 1989;119(11):1556-1560.
5. Denke MA, Grundy SM. Effects of fats high in stearic acid on lipid and lipoprotein concentrations in men. *Am J Clin Nutr.* 1991;54(6):1036-1040.
6. Emken EA. Metabolism of dietary stearic acid relative to other fatty acids in human subjects. *Am J Clin Nutr.* 1994;60(Suppl):1023S-1028S.