Tablet Delivery & Stearic Acid

There is quite a bit of controversy in the natural healthcare community concerning the biological availability of nutrients in different delivery forms. 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.

Depending upon the composition and application, Metagenics markets products in a variety of delivery forms—powdered beverage mixes, bars, time-release or quick-release tablets, softgels, and hard-gel capsules. We use minimal excipients, binders and diluents in our products, and where we do they are derived from natural sources.

Some companies that utilize capsules as the delivery form have chosen to promote their products by disseminating misleading information about the inadequacy of tablets as delivery forms. Their contention is that while capsules dissolve in the upper intestine to allow full availability of their contents, tablets undergo a slower breakdown and reduced bioavailability due to use of excipients.

At Metagenics we take pride in producing the highest quality formulations possible. We pay meticulous attention to all details, including bioavailability. It would make no sense for us to purchase high quality and expensive raw materials and then put them into an ineffectual delivery system. Moreover, tablets render many ingredients more stable and provide a delivery form that delivers more active ingredients per dose than a comparable number of capsules.

Use of Excipients

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. Metagenics uses several excipients in its 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.

Some companies that market formulas in capsules state that their formulas contain only the active ingredients with no added ingredients such as excipients. Although some simple formulas may not require the use of excipients, most formulations require some added ingredients to aid in manufacture. This is true for both tablets and capsules. For example, 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 filler when the volume of active ingredients is small, such as seen with vitamin B₁₂ and folic acid preparations or materials to protect fat-soluble ingredients from oxidation.

Facts about Stearic Acid

Lubricants are added in the formulation of many capsules or tablets to help the raw ingredients flow freely through the equipment in which they are made. Metagenics utilizes stearic acid or its salt, magnesium stearate, as a natural lubricant. It is of vegetable origin, of the highest purity grade, and does not turn rancid. Because it has a lubricant function within the product, it is used in small amounts—typically comprising 2% of a tablet’s weight. Stearic acid is a GRAS (generally recognized as safe) ingredient that has been utilized for many years.

Some manufacturers of nutritional supplements have produced marketing materials claiming that tablets made with stearic acid as an excipient are “bad for you.” They claim that stearic acid is “indigestible” and will “prevent you from absorbing the active nutrients” in a tablet. They also state that “nutrients are only partially absorbed or not at all” because “every nutrient particle becomes coated with a layer of these lubricants.” In short, the claim is that the use of stearic acid as an excipient results in “reduced dissolution and inhibited absorption.” The truth is that there is no scientific basis for these claims. In fact, published scientific research indicates quite the opposite.

What Exactly is Stearic Acid?

Stearic acid is a natural fatty acid found in many foods of both vegetable and animal origin, such as fish, dairy products, meat and processed grain products (Table 1). Although stearic acid is a saturated fatty acid, it is unique in that it does not raise plasma cholesterol, even when consumed in high amounts.\(^1,2\)

<table>
<thead>
<tr>
<th>Food</th>
<th>Stearic Acid Content</th>
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</thead>
<tbody>
<tr>
<td>Fish oil, cod liver (1 oz.)</td>
<td>784 mg</td>
</tr>
<tr>
<td>Fish oil, salmon (1 oz.)</td>
<td>1,176 mg</td>
</tr>
<tr>
<td>Olive oil (1 oz.)</td>
<td>700 mg</td>
</tr>
<tr>
<td>Sesame oil (1 oz.)</td>
<td>1,344 mg</td>
</tr>
<tr>
<td>Soybean lecithin (1 oz.)</td>
<td>812 mg</td>
</tr>
<tr>
<td>Soybean oil (1 oz.)</td>
<td>1,064 mg</td>
</tr>
<tr>
<td>Sunflower oil, linoleic (1 oz.)</td>
<td>1,260 mg</td>
</tr>
<tr>
<td>½ chicken breast (w/out skin)</td>
<td>100 mg</td>
</tr>
<tr>
<td>Cheddar cheese (1 oz.)</td>
<td>1,120 mg</td>
</tr>
<tr>
<td>Butter (1 pat)</td>
<td>500 mg</td>
</tr>
<tr>
<td>Semi-sweet chocolate (1.45 oz.)</td>
<td>4,800 mg</td>
</tr>
</tbody>
</table>

The amount of stearic acid in a tablet is truly insignificant in the context of a normal diet, which might contain 20 mg of stearic acid. If a person consumed a 2000-calorie diet with 500 (25%) of those kcal from butter, the amount of stearic acid consumed would be well within the normal range. Therefore, claims that stearic acid is “indigestible” are both unfounded and wrong.
calories from fats, they would be consuming 56 grams of fat daily. In this example, the stearic acid from 6 tablets would equal less than ¼ of 1% of daily fat intake—a truly insignificant level.

Is Stearic Acid Indigestible?
One hypothesis to explain how stearic acid consumption does not raise cholesterol was that it is poorly absorbed by the body, and thus is excreted. However, several human studies have disproved this theory. Another study demonstrated that the intestinal absorption of stearic acid is similar to that of palmitic acid, which is well absorbed. Another study showed that stearic acid absorption in humans was quite high (90% to 94% absorption). (Naturally derived stearic acid has also been shown to be associated with lowered risk of heart disease.)

Does Stearic Acid Coat Nutrients?
A diagram such as Figure 1 below has been used to claim that stearic acid creates an indigestible layer around nutrients that inhibits or prevents their absorption. We’ve already shown that this concept is not accurate because stearic acid is quite easily digested. But it is also misleading because it suggests that there is more stearic acid than active ingredient.

Figure 1. Misconception of Stearic Acid Coating

This is highly misleading because a typical tablet is comprised of approximately 2% stearic acid (Figure 2). This means that the tablet contains 50 times more active ingredients. So not only is stearic acid easily digested by humans, but there is not enough in a typical tablet to encapsulate or create a “layer” around the active ingredients.

Figure 2. Typical Tablet Composition

Does Stearic Acid Reduce Absorption?
Metagenics has supported research regarding absorption of some of our products. One example is a folate tablet was studied by a large medical group for absorption and effectiveness as compared to injectable B12. Although the folate tablet is made with stearic acid as an excipient, the study demonstrated excellent absorption of the active ingredients. The positive results of this study led the medical group to recommend the folate tablet over the current standard injectable product.

How Does Metagenics Assure Timely Bioavailability of Active Nutrients?
Metagenics manufactures products in facilities that are certified for Good Manufacturing Practices (GMP) as the ultimate assurance of quality. Besides using the highest quality raw materials and state-of-the-art equipment, the manufacturing process includes regular assays to ensure the quality of the finished products. Among these are assays for disintegration and dissolution. These assays are the industry standards for demonstrating the bioavailability of active ingredients.

Disintegration refers to the actual physical breakdown of the dosage form. Disintegration time (DT) is the time that it takes for the tablet or capsule to lose its physical integrity and collapse into a heap of powder after being placed in a solution. Timely disintegration of the tablet or capsule during travel through the gastrointestinal tract is important for release of the active ingredients it contains. Metagenics tablets are carefully manufactured to achieve a DT of 30 minutes or less.

Dissolution refers to the ability of active ingredients to diffuse into solution in the short time that it takes for them to pass through the proximal half of the small intestine, which is where 90% of the absorption by the gut mucosa takes place. The dissolution assay measures the amount of certain ingredients (selected vitamins and minerals) present in solution after the sample has been subject to specific conditions for a specified period of time, as outlined in United States Pharmacopeia guidelines.

Get the Facts
Remember, there is no single delivery system that is best for all applications. Furthermore, ongoing research by the scientific community continues to report findings that support the decision to use stearic acid to help ensure 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.