

“You simply can’t lie to an allergy patient.” *Al Czap, 1984*

Quality Control

Thorne Research was established in 1984 in response to an important need in preventive medicine. Prior to the introduction of the Thorne line of products, there were no truly hypoallergenic products available in the marketplace. While there were some very good companies offering technically advanced formulas, their products were still produced as excipient-containing tablets or capsules containing potentially allergenic flowing agents and diluents.

Thorne’s first products were simple: pure, undiluted ascorbic acid capsules made without any flowing agents (such as magnesium stearate, the most commonly-used excipient in the industry), and pure pancreatin, the first available in North America without being standardized by the U.S.P. method, which dictates the use of lactose or other sugars.

Physicians found something remarkable in the Thorne supplements they prescribed. Since they did not contain unnecessary diluents, sensitive patients no longer suffered bloating, nausea, and diarrhea from supplements that contained hidden lactose. Traditionally, standardized enzyme products were diluted with lactose, although this fact never seemed to be disclosed on the label. With Thorne products, however, a physician’s patients could take bromelain, pancreatin, pepsin, and other products without fear of reaction.

The response came in other areas also. Health-care practitioners quickly discovered when a supplement is immediately bioavailable, patient outcomes are greatly improved. The offering of a complete product line of Thorne

supplements made without magnesium stearate, palmitic acid, or stearic acid as flowing agents revolutionized the way a supplement’s performance was perceived. Why? By not coating each nutrient particle with a complete layer of saturated fat, nutrients are available to be immediately absorbed by patients who need the nutrients most – the digestive and immune compromised patient. Physicians now realize not only are Thorne Research products best for their “worst case” patients, but they work better for all patients.

In a classic study published in *Pharmaceutical Technology*, the results of mixing a nutrient with magnesium stearate were demonstrated. After just ten minutes mixing time with magnesium stearate, the percent dissolution of the nutrient (after 20 minutes in solution) decreased from 80-90% dissolution without magnesium stearate, to 25% with magnesium stearate. When mixing time of the nutrient with the stearate was extended to 28 minutes, less than 20% dissolution was obtained, even after 35 minutes in solution.

It is crucial that customers realize whenever they see *magnesium stearate* or *stearic acid* on a label that the supplement contains a mixture of saturated fats used as flowing agents. Stearic acid melts at about 156OF, palmitic acid melts at about 146 OF — so imagine your nutrients trapped in a sphere of waxy substances similar to candle wax. The National Formulary monograph for stearic acid requires it be composed of at least 40% palmitic acid. Ascorbyl palmitate, a compound of ascorbic acid and palmitic acid, is a waxy,

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soapy, slippery substance utilized by some companies as a flowing agent, but labeled as a vitamin C source. Interestingly, a manufacturer using ascorbyl palmitate can claim ascorbyl palmitate is included as a therapeutic vitamin C source, or that its antioxidant activity protects the integrity of the other ingredients in the capsule. The physician's question to such a statement should be, "Why isn't the ascorbyl palmitate added to that company's bulk powder product with the same ingredient?"

At Thorne, our manufacturing process is considerably more difficult, since no product-compromising flowing agents are utilized. To produce the same number of bottles as a competitor who utilizes magnesium stearate or stearate/palmitate acid, Thorne literally needs to have more than twice the number of comparable encapsulating machines, since most products will only run at a greatly reduced speed without flowing agents. More manufacturing rooms are necessary, more employees, and more support equipment, such as compressors and air removal systems. Manufacturing Thorne products to our rigid standards requires much more effort than any other method. It is Thorne's commitment to our customers.

The addition of any stearic/palmitic acid during the manufacturing process of any dietary supplement product can have an adverse impact on both solubility and bioavailability of the nutrients in the supplement being manufactured. The result? In patients with compromised digestion or absorption, the presence of stearic/palmitic acid in their dietary supplement can possibly

jeopardize utilization by the patient of the intended nutrients. On the other hand, supplements manufactured without these lubricants or additives demonstrate rapid dissolution in the stomach and unimpeded absorption in the intestinal tract, resulting in the most efficient nutrient delivery possible.

Why is stearic/palmitic acid added?

Most supplement products are manufactured by "jobbers" who have large production facilities that churn out a multitude of formulas for various companies. Look on the label of any dietary supplement. Federal law requires the label to state who manufactured the product. If the label doesn't say "Manufactured By" – but instead says "Manufactured For" – then the dietary supplement was not made in a facility owned and controlled by the company who markets it. Jobbers work on a given profit margin and if a product does not run on specific machinery at optimum speed, then various lubricants, such as stearic/palmitic acid are added to ensure tablet or capsule production meets schedule.

Many companies talk about purity and superior raw materials, but they have not managed to solve the problem of flowing agents. Companies have tried to duplicate the Thorne Research manufacturing process, but none have been successful.

When Thorne Research fills additional space in a capsule, only those hypoallergenic ingredients we have utilized for the past 18 years are added: magnesium citrate, aspartic acid, leucine, or silicon dioxide.

There are four basic requirements for manufacturing a truly hypoallergenic product:

1. Actually being a manufacturer

Thorne Research is a manufacturer, not just a sales or distribution company. The most important words to look for on any dietary supplement product label are “Manufactured By.” Thorne Research products are manufactured to exact specifications by our production staff, in our own state-of-the-art facility in Dover, Idaho. Mixing and encapsulating are done in separate, sealed, individually-ventilated rooms with filtered air, to ensure there is no cross-contamination of materials. From the mixing of raw materials to packaging and labeling, numerous quality control checks are made before the finished product is released for sale.

2. Raw material choice

To produce our truly hypoallergenic encapsulated supplements, we use only the purest raw materials available. Every manufacturer has two basic choices available for raw materials: purchase either truly pure raw materials, or purchase raw materials to which substances have been added to facilitate manufacturing. Typical choices every manufacturer must make are: purchase pure vitamin C or purchase vitamin C with additives; purchase pure B vitamins or purchase coated B vitamins for taste masking, purchase pure enzymes such as pancreatin, pepsin and bromelain, or purchase enzymes diluted with lactose.

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The choices made by your supplement manufacturer makes the difference between an excellent, effective, well-tolerated product and an inferior, poorly-absorbed product which may potentially cause allergenic problems for your patient.

3. Avoiding Unnecessary Ingredients

Tablets must contain flowing agents, lubricants, binders, fillers, and disintegrants in order to be made into tablets. Many times, tablets also include allergenic coloring agents. Pharmaceutical glaze, confectioners glaze, or natural glaze may be the name of the ingredient you see on the label, but these are just euphemisms for the real name of the ingredient – SHELLAC – that’s right, the same substance used to varnish furniture. Shellac is used because it makes a tablet “shiny” and easier to swallow. Labels will also list natural vegetable coating, natural protein coating, vegetable coating, or maize protein — all euphemistic names for Zein, which is CORN PROTEIN. Many people are allergic or sensitive to corn protein, and would readily recognize its presence in a supplement if it were correctly identified. It very rarely, if ever, is.

Encapsulated products are not free from these kinds of ingredients either. Lubricants such as stearic/palmitic acid, labeled also as magnesium stearate or calcium stearate, or sometimes ascorbyl palmitate are employed by almost all manufacturers, as are diluents such as lactose, dextrose, sucrose, and corn starch.

Since 1984 Thorne has been the
“Original Specialists in Pure
Encapsulations.”™

The entire Thorne Research line of over 280 products was designed to meet the needs of physicians treating the worst allergy patients in the world. These doctors realize the effects of even minute amounts of allergens and chemical additives, and immediately see the positive results obtained by using our “as pure as humanly possible” products.

4. Quality Control

Since 1984, Thorne Research has been dedicated to providing the practitioner with the best nutritional supplements in the world. As an adjunct to this mission, we utilize an in-house quality control laboratory, as well as outside, independent laboratories. Near-infrared spectrophotometry (NIRS), atomic absorption spectrophotometry, inductively coupled plasma technology, or high performance liquid chromatography (HPLC) are used to check every raw material purchased, every mineral we manufacture, and every finished product before it is released for sale. These items are assayed for purity, quality, heavy metals, and potency. Those materials that do not meet our rigid specifications are rejected. In addition, products are sent to an independent lab for microbial analysis, and fatty acids (including fish oils) are sent out for pesticide analysis. There is simply no way that a manufacturer of dietary supplements, who purchases already-manufactured supplements from a jobber, can have the quality control Thorne Research does.

When the Dietary Supplement Health and Education Act (DSHEA) was passed in 1994, a mandate was created for the FDA to develop Good Manufacturing Practices, or GMPs, for the nutritional supplement industry. Of course, the wheels move slowly in Washington, DC, and we do not yet have government guidelines regarding manufacturing. However, we have always manufactured to GMP standards that exceed those currently proposed by the industry. These internal GMPs include written, stringent, standard operating procedures for every step of the manufacturing process, including (but not limited to) receiving raw materials, cleaning the manufacturing facility, material storage, product encapsulation, shipping, and quality control procedures. And since January 2000 our GMPs have been approved by the Australian Therapeutic Goods Association, the most stringent governmental health organization in the world.

“Hypoallergenic” — Definition: non-allergy producing. A term applied to a preparation in which every possible care has been taken in formulation and manufacture to ensure minimum instance of allergenic reactions. (Blakiston’s Medical Dictionary)

