

Encapsulation Focus

Weighing the Choices in Encapsulation

by Heather Granato

Nutraceutical ingredients can be delivered in myriad forms. There are powders, liquids, tablets, capsules, bars, beverages and much more. The functional food category holds the promise of opening up nutrient enhancement to a wider array of consumers. However, there are certain limitations to every delivery system, as well as special benefits a manufacturer gains from each process.

Hard-shell capsules are a popular delivery system for many botanicals, while softgels have an increasing market in the area of oily products such as vitamin E and essential fatty acids (EFAs). Capsules are not limited to only a gelatin exterior, as innovations in production are yielding vegetarian alternatives to the primarily bovine encapsulation source.

Currently, many more manufacturers offer hard-shell encapsulation, and a majority of capsule products are delivered in this more traditional form. "The market for nutritional products in hard-shell capsules is obviously much larger than that of soft-shell capsules, both domestically and overseas, as there are more manufacturers in the hard-shell business," said Rezaur R. Yousuf, director of business operations for Kabco Inc., Amityville, N.Y. "Of course, many soft shell encapsulators are doing OTC [over the counter] products, which is perhaps more profitable than most nutritional products."

Soft gel encapsulation produces a smooth—often clear—exterior engulfing the ingredients within. "Soft capsules are generally considered to be a premium dosage form," said Robin Koon, vice president of sales/marketing for Best Formulations, City of Industry, Calif. "They are easier to swallow and offer a point of differentiation. They also don't have the taste issues that can occur with hard capsules."

Softgels are generally best for oil-based or liquid products, as mentioned previously. In particular, because of total encapsulation, softgels offer more protection to oxygen-susceptible ingredients. Oxidized ingredients, as well as some more pungent natural compounds, carry strong scents that gelatin coating can also quash. For example, fish oil encapsulated in gelatin tends to have less of an odor than a dried fish oil powder in a hard capsule.

Another benefit to softgels is enhanced bioavailability of some products, according to Nehru Gaddipati, Ph.D., president of Somerset, NJ.-based Strides Inc. "A classic example is the solubilized formulation of coenzyme Q10 (CoQ10), which has been shown to have better bioavailability than the hard-shell capsules," he said.

However, softgel encapsulation is not without its difficulties. Koon said some of the difficulties include developing innovative products, maintaining high quality standards and providing competitive pricing. Other industry members add because softgel encapsulation is a semi-automatic process that requires oversight, it often means running a multi-shift operation with the added costs that entails. "Soft-shell encapsulation is, perhaps, more sophisticated than hard-shell encapsulation, with very little room for error," Yousuf said.

Hard-shell encapsulation, on the other hand, has been in use longer, and can be run automatically and at greater rates of speed. Most contract manufacturers offer hard-shell encapsulation services, though some are more concentrated than others in that area. NHK

laboratories, for example, specializes in filling two-piece hard-shell capsules. "We recently added a new high-speed Bosch encapsulation line to better accommodate large runs," said M. Amirul Karim, president of the Santa Fe Springs, Calif.-base company. It has also developed technology to enteric coat two-piece capsules for a time-release effect.

Generally, hard-shell encapsulation permits a wider range of ingredients to be used. Most botanicals, vitamins and minerals can be used in the process. "If we can ensure stability of a formula in a two-piece capsule, and we deem it feasible to manufacture using dry powders, we advise our clients that the two-piece capsule is an appropriate dosage form, Karim said. "It boils down to the stability and feasibility of the product."

Hard-shell encapsulation does pose its own set of challenges. Because of the set capsule size, adding too much or too little of an ingredient or formula is a challenge to be addressed at the beginning of a process. "If we have to encapsulate a multi-ingredient product that contains some hygroscopic material, it can become a nightmare," Yousuf said. "Or a customer will want a single ingredient in a capsule that does not have the required density to meet the fill weight."

The density issue is particularly difficult with botanicals. "Herbal extracts have lower densities than other ingredients, such as coral minerals or MSM," Karim said. "Due to the lower density, it becomes difficult to fill several hundred milligrams of any given herbal extract into a two-piece capsule. Along with density is the flowability factor. Herbal extracts by nature are 'sticky' and do not have good flow characteristics. This makes producing the product very time consuming and difficult."

In fact, many herbs have long been available as herbal tinctures. Extraction in water or alcohol, depending on the botanical, maximizes delivery of active components. However, the taste aspect has kept many consumers away from liquid extracts, driving demand for encapsulated products.

Some manufacturers are finding ways to merge consumers' desire for a liquid product with the manufacturing capabilities of hard-shell capsules. Capsugel and LiquidCeuticals both offer HPMC two-piece hardshell capsules that are band-sealed. "Band sealing of capsules minimizes leakage issues and increases the tamper resistance of all two-piece capsules," said Fred Miller, marketing director for LiquidCeuticals in Clearwater, Fla.

"Natural vitamin E or any natural oil combination in an HPMC capsule can be all-natural because the delivery form does not require any binders, fillers, excipients or plasticizers that are common with many soft gel delivery forms. Liquid filled capsules are a very visually appealing product because consumers can easily see the material they are ingesting."

Before it launched its Licaps® product in 2001, Greenwood, S.C.-based Capsugel conducted a nationwide product concept test to quantitatively measure consumer interest in a two-piece liquid-filled capsule. Their findings confirmed that consumers connected their perceived benefits of liquids with the Licaps supplements. Of those

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surveyed, 74 percent of participants who chose Licaps said they would purchase their supplements in that dosage form, if it was available.

In addition, HPMC capsules used in these systems are vegetarian, meeting a rising consumer trend. Many contract manufacturers report increased interest in vegetarian formulas and delivery systems. "We have noticed a tremendous growth in vegetarian capsules," confirmed Jay Kaufman, president of Torrance, Calif.-based Paragon Laboratories. "More customers are requesting capsules from a vegetable source."

Whether vegetarian or gelatin, marketers are turning to experts in the field when deciding what system to use for encapsulation. "Certain molecules are more appropriate for hard versus soft encapsulation due to several factors related to the internal formulation's reaction to the shell," said Robert Whitelaw, director of sales/marketing for Capsugel. "There is a difference in the oxygen permeability of hard gelatin capsules as compared to soft gelatin capsules. Some formulations are more odorous or have a strong taste. Those formulations, when compatible for use with hard gelatin capsules, are usually best encapsulated in hard gelatin capsules because the smaller matrix of the HGC shell provides greater masking of odor and taste. Other factors, including the ratio of water and/or alcohol, also affect the decision. These factors are precisely why it is important to partner with a

capsule supplier who can provide formulation information and support as part of the partnership."

After considering the issues, many marketers are choosing to outsource capsule production. "It comes down to cost, volume and knowledge," Koon said. "The cost of installing and running a softgel facility is high. Since these machines run much slower than tablets or two-piece hard-shell capsules, attention must be made toward efficiencies."

Even marketers who have the capability for producing hard-shell capsules may look for an expert in the soft gel field, Gaddipati said. "Manufacturing of softgels is still considered an art because the product quality is dependent on a skilled operator that can understand the viscoelastic properties and sealing characteristics of gelatin," he added. "Contract manufacturing facilities usually have the knowledge and understand the intricacies of formulation to troubleshoot any manufacturing issues in a timely manner."

The efficiencies come down to savings of dollars, which can then be put toward marketing instead of product development. "A customer who is success fully marketing a product, be it hard-shell or soft-shell capsules, need not go into the manufacturing process," Yousuf said. "It is not only too expensive but may also be a difficult proposition to manage, especially when his products are already being marketed well." □