Film coatings for dietary supplements

Unlike the prescription and over-the-counter drug products that patients take to relieve pain or treat an illness, taking dietary supplements (DS) reflects consumers’ quest for enhanced nutrition, health, or lifestyle. In fact, consumers drive the DS market, and manufacturers often turn to film coatings to differentiate their products and increase their appeal. Film coatings mask odors and improve tablet swallowability, just as they do when used with pharmaceuticals.

Yet formulating film coatings for today’s DS tablets can pose greater challenges than formulating for pharmaceuticals. That’s because many DS tablets, particularly herbas, are soft and friable, so the coating must add strength to help them withstand packaging, shipping, and consumer handling. Plus, consumers (and thus DS manufacturers) increasingly prefer coatings derived from “natural” ingredients. It’s part of the “clean label” trend. However, no US or European statute yet defines the term “natural,” so manufacturers and marketers decide for themselves when and how to use the term.

Most film coating suppliers avoid the “natural” claim, preferring instead to categorize a coating’s components based on origin, be it mineral, animal, vegetable, or microbiological in nature. Suppliers can also formulate using minimally processed ingredients whose chemical nature remains intact and that contain no synthetic additives.

Some consumers and DS manufacturers are also seeking to avoid allergens, such as wheat, eggs, soy, yeast, gluten, dairy, and nuts, as well as genetically modified organisms (GMOs). Many are increasingly interested in ingredients derived from sustainable and/or renewable sources, and more products are being developed to meet the USDA’s organic standards. Essentially, consumers want the same attributes in supplements that they want in their food.

Meeting those demands is challenging because most pharmaceutical film coatings use synthetic polymers, plasticizers, pigments, and additives. Even so, Colorcon has already introduced DS-specific coating products, and those product lines will continue to evolve in functionality and appearance.

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Consider color, for example. It’s not easy to replace traditional synthetic pigments, such as aluminum lakes and iron oxides, with alternative (non-synthetic) pigments because most have less color stability. Thus incorporating these more “natural” pigments requires extensive formulation and stability programs to obtain the best quality profiles, including acceptable shelf-life of the formulations and the finished film-coated tablets.

So far, we’ve developed an extensive palette of colors based on more than a dozen non-synthetic pigments, and more are under qualification. Ideally, each new colorant will have broad, even global, regulatory acceptance; we have even filed regulatory petitions for approval of non-synthetic colorants that are not currently approved for use in DS film coatings.

We’re also working to eliminate potential allergens and GMO ingredients, which requires finding new sources of materials that have similar functionality, as well as making changes to the formulation technology. In fact, it’s possible to develop new formulation platforms based on these replacement materials. One example is Opadry NutraPure, a clear coating that contains no synthetics and meets the USDA’s guidelines for organic certification. All its ingredients—including the film-forming polymers—are derived from non-GMO plants that undergo minimal processing. This product has also been verified through the Non-GMO Project. Other products include Opadry NS, an aesthetic coating, and Nutrateric, a functional enteric coating for tablets and capsules.

While certified-organic supplements are a small part of the DS market today, we see a bright future for coatings that make tablets easy to swallow, add gloss, and satisfy the demand for an “all-natural,” consumer-friendly label.

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