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# Nutritional Outlook

THE MANUFACTURER'S RESOURCE FOR DIETARY SUPPLEMENTS & HEALTHY FOODS AND BEVERAGES

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CARDIOVASCULAR HEALTH • DIABETES • 10TH ANNIVERSARY ISSUE

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## MANUFACTURING TECHNOLOGY

# Formulation Problem Solving with Aqueous Shellac

**A specially designed resin avoids esterification and cross-linking.**

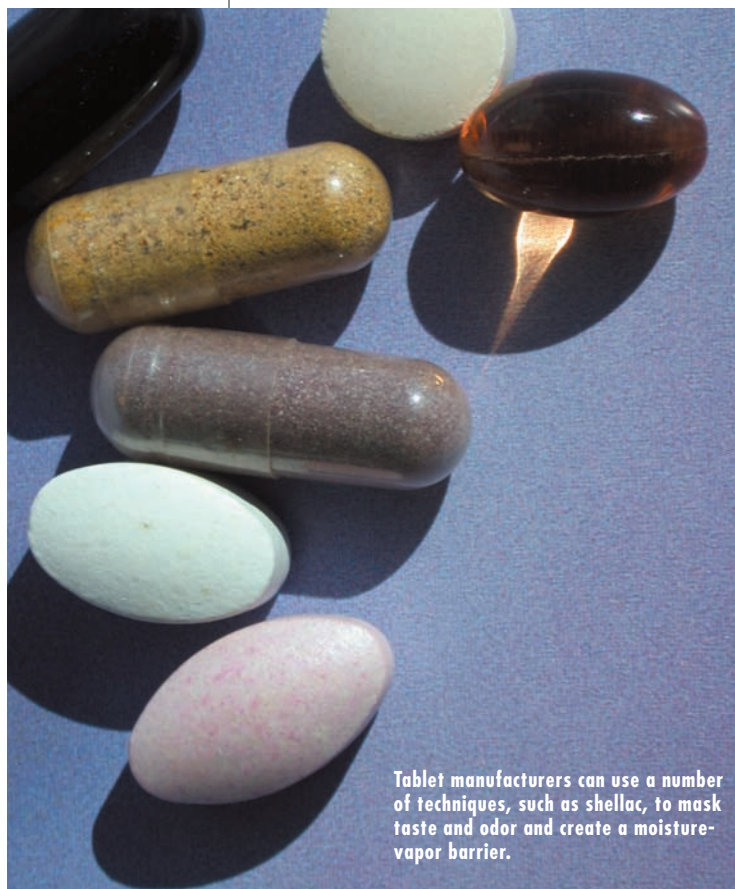
**F**or many formulations, the presenting issue is the need for taste- and odor-masking, or a moisture-vapor barrier. Traditional taste-masking and moisture barrier have been accomplished using sugarcoating, and, more recently, with enteric polymers, ethyl cellulose, and polyvinyl alcohol. While these techniques may be used successfully, they are not without complicating issues of their own, including length of processing time, use of organic solvents in processing, cost of raw materials, and concern over using materials not considered to be natural.

There is, however, an alternative that is traditional and natural in origin, and improved in effectiveness with modern scientific advancement. Aqueous shellac, available as Marcoat 125, is a natural polyester resin that provides excellent taste- and odor-masking properties, as well as a strong moisture-vapor barrier.

Shellac is a polymer with a long history of use in pharmaceutical-coating applications, most commonly known as pharmaceutical glaze. Pharmaceutical glaze, made from bleached shellac dissolved in alcohol, historically has been used as the seal coat for sugarcoating applications and also has been used for enteric applications. While well-known as an excellent moisture-vapor barrier, pharmaceutical glaze has a serious issue of its own, a changing release profile over time.

The use of alcohol as a solvent and sodium hypochloride in the bleaching process contribute to the further esterification and cross-linking of the shellac polymer. Esterification is caused by alcohol, which reduces the free carboxyl groups, and thus the polymer's aqueous solubility. Cross-linking is caused by the bleaching process, which

**BY STEPHEN P. LEVINE, CHARLES A. SIGNORINO,  
PETER FREED, DANA MOSESON, AND RYAN  
MULCRONE**



Tablet manufacturers can use a number of techniques, such as shellac, to mask taste and odor and create a moisture-vapor barrier.

## MANUFACTURING TECHNOLOGY

### Excipient Sales to Rise to Nearly \$3 Billion by 2011

Demand for excipients is growing at a 4.5% annual rate and could reach \$2.9 billion by 2011, according to *Excipients*, a new study by The Freedonia Group Inc. (Cleveland).

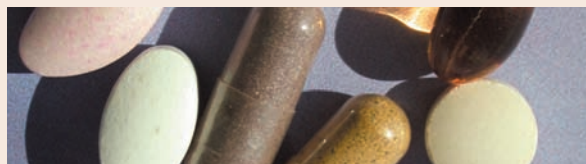
Although minerals should achieve the fastest growth among excipients through 2011, specialty and multifunctional polymers that improve safety and bioavailability should benefit from higher demand. In addition, starch-based excipients that provide economic and quality advantages should also extend their market opportunities. According to the report, lactose, sorbitol, and mannitol should perform well.

Fillers and diluents will "remain the leading application served by excipients," according to the study.

### Excipient Demand (in \$ Millions)

| Excipient          | 2001 | 2006 | 2011 |
|--------------------|------|------|------|
| Gelatin            | 367  | 450  | 547  |
| Cellulose          | 309  | 407  | 515  |
| Synthetic Polymers | 214  | 279  | 350  |
| Minerals           | 150  | 197  | 252  |
| Other              | 760  | 957  | 1196 |

Source: The Freedonia Group Inc.



has a side effect of converting jalaric acid to shellolic acid, which is more reactive and available to engage in cross-linking. The effects of these undesired modifications are to slow the release profile over time, and as a result shellac has received a negative reputation in the film-coating industries.

Marcoat 125 is shellac designed for film coating that overcomes these traditional issues. Because Marcoat 125 is aqueous based and manufactured with an aqueous process, the esterification caused by the alcohol base of the pharmaceutical glaze is avoided. And because Marcoat 125 is made from decolorized shellac (as opposed to

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bleached shellac), the unwanted cross-linking is avoided. Emerson Resources has conducted a series of experiments that on the one hand demonstrate Marcoat 125 to be effective

**While well-known as an excellent moisture-vapor barrier, pharmaceutical glaze has a serious issue of its own, a changing release profile over time.**

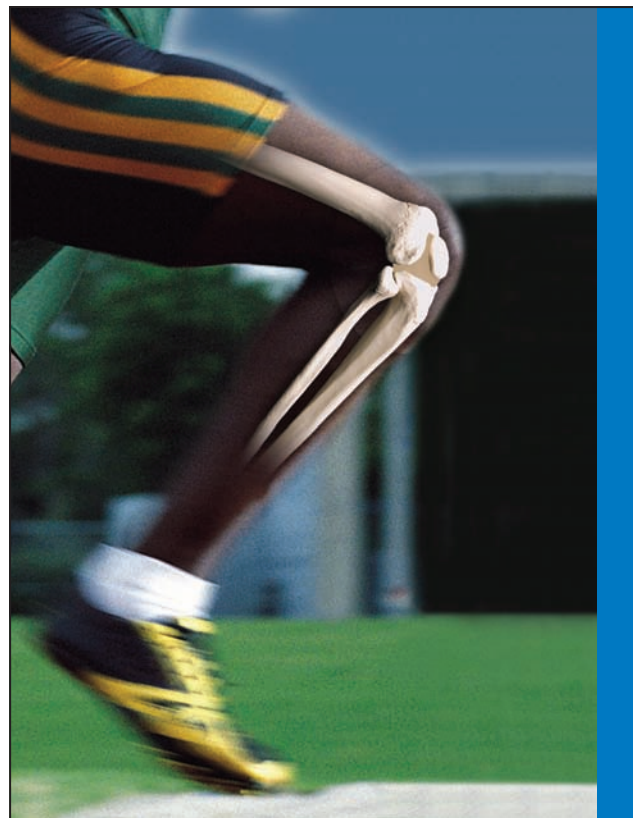
tive at taste masking and as a moisture-vapor barrier, and on the other hand show the stability of the polymer's release profile.

In one study designed to show moisture uptake within a tablet, tablets with various coatings were placed in accelerated stability at 40°C and 75% relative humidity for 168 hours. Tablets coated with hydroxyl propyl methylcellulose (HPMC) yielded a 1.69% weight gain (due to moisture uptake). Tablets coated with methacrylic acid copolymer gave a moisture uptake of 1.20%. Tablets coated with Marcoat 125 gave the lowest moisture uptake of 0.91%.

Another study was designed to show the effectiveness of aqueous shellac as a taste-masking agent. In this study, active tablets coated with various levels of shellac, including no shellac, were given to a panel of taste testers.

The study conclusively demonstrated that the higher the level of shellac in the film, the better the taste-masking results. A third study was designed to show the real-time stability of Marcoat 125 as a seal coat. Tablets were coated using HPMC only and a ratio of 2.5 parts HPMC solids to 1 part Marcoat 125 solids and placed in real-time ambient stability for three years. Initial disintegration time for HPMC only was three minutes, and also three minutes at three years' ambient stability. Initial disintegration time for HPMC with Marcoat 125 was five minutes and four minutes at three years' ambient stability. ♦

*Stephen P. Levine is group leader at Emerson Resources Inc. (Norristown, PA). For more information about Emerson Resources, visit [www.emersonresources.com](http://www.emersonresources.com) or call 610/279-7450. For more information on aqueous shellac and/or Marcoat, visit [www.marcoat.com](http://www.marcoat.com).*



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