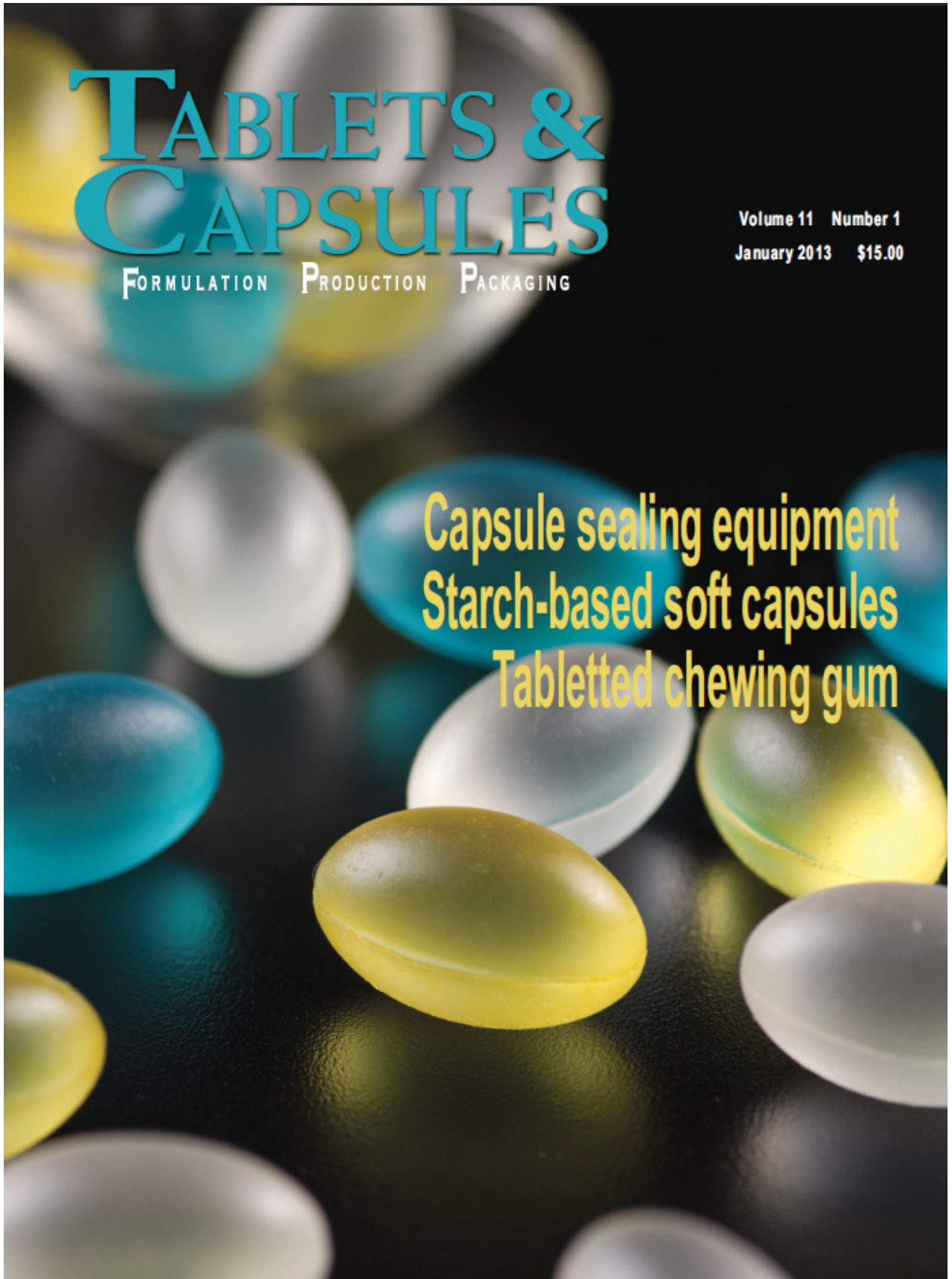


TABLETS & CAPSULES

FORMULATION PRODUCTION PACKAGING

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Capsule sealing equipment
Starch-based soft capsules
Tabletted chewing gum



Swiss firm develops starch-based soft capsules

Several companies offer vegetable-based soft capsules, but few pharmaceutical manufacturers favor them over gelatin because of their drawbacks. Yet starch-based Sana Caps are different, said Adrian Krahn, chief executive officer of Acsana, Cham, Switzerland. Its capsules use a simpler process, cost less, and have properties that are at least as good as gelatin and other substitutes.

"Mixing our starch and plasticizers is much easier than the gelatin process, because there's no heating or soaking," Krahn said. The material is also less expensive. "Compared to gelatin, it is normally up to 60 percent cheaper, and it can be even higher depending on where you buy it, what your sources are. It's quite dramatic." In addition, the process simplicity, use of standard equipment, and easier cleaning reduce production costs by about 25 percent compared to gelatin soft capsules, he said.

Furthermore, the starch-based material—like other gelatin substitutes—meets a demand for products that comply with today's lifestyle and religious preferences. "Customers are more and more aware and critical of any problems or scandals with meat and meat waste," Krahn said. "Fewer people are willing to compromise on that, and the number of vegetarians is rising. Additionally, with Sana Caps, you have one capsule shell formulation for the whole world, because it complies with kosher, halal, and other requirements." Another benefit: Gelatin soft capsules typically start melting at 40°C, whereas Sana Caps withstand a much higher temperature, eliminating the need for special protective packaging.

Nor do Sana Caps become brittle or entail complicated processing steps, such as pressurized spreaders or a cooling system. In addition, the material includes no problematic ingredients, as other gelatin substitutes may, Krahn said, citing a WHO report that deemed carrageenan a potential carcinogen. He said every ingredient in Sana Caps capsules has pharmaceutical approval.

Seeing is believing

Acsana is a subsidiary of NovoGel Holding, an R&D firm spun off from ETH Zurich, a science and technology institute. It has no plans to launch products. "Our core competence is R&D, so we are not commercializing products for the market," Krahn said. Instead, Acsana is seeking to sell the company and its soft capsule technol-

With a higher melting temperature than gelatin, the starch-based dosage forms require no special packaging.

ogy. "To build it up from scratch, yes, I would like to do that," said Krahn, who has managed production operations. "But that would take too much time for us to do, especially for pharmaceutical products. Another owner would be able to realize the full value of the technology much faster."

Yet the sale has proved elusive because of other's earlier failures. "So



The starch-based material in Sana Caps soft capsules costs as much as 60 percent less than gelatin and exhibits properties that are at least as good.

many companies have tried with starch-based capsules, and they've never succeeded in the last 20 or 30 years," Krahn said. "So companies are really concerned that it does not work. We hear, 'Yeah, yeah, yeah. Another someone trying to do something that doesn't work.'" To counter that notion, Acsana hired experts, established a complete soft capsule manufacturing line, and began inviting people to see the production facility. "That has really made a difference. People who came and looked at the production site were astonished." To those who can't visit, Krahn offers to share a video of the production facility.

Any buyer must plan to manufacture a product or products with wide appeal. "We envision a buyer with global presence. We do not want the niche of a niche. We want it to really make sense, to have a bigger market," Krahn said. "Not only fish oil, but more like a medicine for hypertension, for example, that needs to be in modern pharmaceuticals."



Acsana's sister company, InNutriGel, manufactures center-filled jelly gums, a promising delivery platform for pediatric drug products.

The prospective buyer must also agree to follow through with the purchase once Acsana's filled capsules meet agreed-upon benchmarks and production assessment. "Tell us what kind of filling you want, and we'll encapsulate it and give you an amount of capsules that you can test," Krahn said. "When we actually reach the goal of the benchmark, then you have to buy the technology. We would like to do that with only one potential buyer in order to safeguard our know-how and to save the know-how for the potential buyer."

While Krahn, a veteran of Roche, expressed confidence in the technology and its commercial promise, he recognizes the risk-averse climate of today's pharmaceutical industry. "Big corporations are really reluctant to get new technology on board," he said, contrasting today's reality with what prevailed in the 1990s, when just a patent and a business plan—with no production facility—would have fetched millions. "The reason for that is bureaucracy. It has increased tremendously, especially from the FDA. If you have a product in a hard capsule and you know that it is 100 times better in a soft capsule, [large companies] won't exchange it for the existing product because then you have to do all the clinical testing to get the FDA approval. In terms of safety for people, that's good. But on the other hand, it really hinders getting new innovation to those patients."

Center-filled jelly gums

Another delivery platform—center-filled jelly gums—also shows promise. Developed by a sister company, the starch-based jelly gums, resemble fruit-flavored gelatin confec-

tions. "We can take the material and fill it with nutraceuticals or even drugs," Krahn said, including heat-sensitive APIs because the material isn't heated when prepared or molded.

"You chew on it and the filling comes out, and you have a reaction that's quite interesting," Krahn said. The jelly gums, like the soft capsules, only become sticky at around 70°C, eliminating the need for special packaging. The platform is also well suited for pediatric use. "We've already got

doctors and pharmacists asking us, 'Can you put in some drugs for kids?'" Krahn said. "We also found out that about 40 percent of all people who have to take drugs have problems swallowing them, even soft capsules, hard capsules, or tablets. This would be a perfect alternative dosage form for them." T&C

Acsana, Cham, Switzerland.
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