

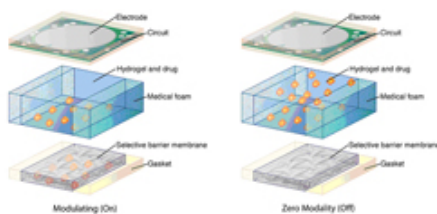
Adhesive Ushers Intelligent, Transdermal Drug Delivery

Shirley Monte

The Challenge: An adhesive that would adhere to the body for three to seven days was needed for a transdermal drug delivery patch.

The Solution: Design engineers from the device maker worked with an adhesive supplier to find a cosmetically elegant, hypoallergenic solution that also met the timeline requirement.

Shirley Monte is a business development manager for FLEXcon's Performance Products Business Team. She can be reached at 508-826-4646 or smonte@flexcon.com [1].



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When Providence, RI-based startup Isis Biopolymer Inc. set out to develop its IsisIQ transdermal drug delivery platform, it faced the same challenges as all other transdermal drug delivery companies. One of those challenges—a moving target of sorts for all transdermal drug delivery systems—is the skin itself, says Shawna Gvazdauskas, chief commercial officer for Isis.

"We were looking for the best adhesives and films, because we required [a] combination that was going to be hypoallergenic, cosmetically elegant and adhere to the body for three to seven days. We were seeking materials that are water-resistant to withstand normal daily activities such as showers and perspiration, as well as the torque and abrasion of body movement," she explains.

Design engineers from Isis, Gvazdauskas says, turned to FLEXcon Co. Inc., a manufacturer of pressure-sensitive films and adhesives, for help in choosing the right product combination to not only ensure application success, but also meet time-to-market demands.

"We worked with their design engineers to make sure they had the right adhesive, taking into consideration everything from torque to perspiration, even body hair," says Mark Mudgett, the FLEXcon Sales Representative for Isis.

Manufacture of the first commercially available IsisIQ patches began in December 2009, says Gvazdauskas.



Isis Biopolymer's intelligent, selective barrier membrane allows compounds to be transported or completely blocked from transport through the skin. Their unique single-electrode design eliminates skin irritation, which is common with other transdermal delivery devices. In addition to proprietary technology, IsisIQ uses state-of-the-art Blue Tooth LE, microprocessors, thin film batteries and adhesives. As a result, Isis Biopolymer has developed an innovative and intelligent solution for transdermal drug delivery as well as biosensing, says Emma A. Durand, founder, CEO, and chief technology officer for Isis.

"Breakthroughs in pliable polyester substrate and hydrogels support lower cost development and manufacturing, as well as a more diverse range of delivery of drugs than is currently available. IsisIQ can deliver up to three drugs in one small patch," she explains.

While its appearance is similar to the passive nicotine-replacement patch, the ultra thin band aid-like IsisIQ is an active transdermal drug delivery device. The passive nicotine patch, while effective, combines the active pharmaceutical ingredient with the medical-grade adhesive. IsisIQ, however, employs iontophoresis, which involves the application of a small, yet constant electrical-charge that transports an active pharmaceutical ingredient directly into the skin. Transdermal administration of drugs has assumed an important place in drug therapy, with many of the shortcomings of previous generations of products now being addressed by more portable, user friendly applications.

FLEXcon's Shirley Monte and Brian Bressette, a technical service representative who also worked directly with Isis officials, say IsisIQ uses dermaFLEX P.E.F. 32 White H-566. This FLEXcon product combination not only embodies the IsisIQ, it also holds the delivery device in place on the body, allowing Isis Biopolymer's proprietary technology to make direct contact with skin for iontophoretic, transdermal drug delivery.

IsisIQ uses FLEXmount H-566, a hypoallergenic acrylic adhesive designed for skin that meets United States Pharmacopeial Class 6 requirements for medical grade materials. It also uses FLEXcon's dermaFLEX white, polyethylene foam coated with the H-566 adhesive and backed with a semi-bleached Kraft release liner. An additional FLEXcon adhesive, FLEXmount V-66, is used to encapsulate the Isis

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Biopolymer's proprietary iontophoretic and biosensing technology. V-66 is a general purpose, permanent acrylic adhesive with good tack and adhesion to a variety of surfaces. In particular, it exhibits excellent adhesion to cross-linked polyethylene gasketing foam.

Combinations of these FLEXcon products are provided to Isis in the 18-inches-by-24-inches sheet format required by Isis manufacturing process. "Our ability to customize product rolls helps streamline their production process," says Bressette.



Transdermal drug delivery is a desirable alternative, especially when considering treatments that are taken orally or injected. Needles are invasive and painful; taking tablets, pills, and orally delivered treatments can be easily forgotten. Even the faithfully compliant grow tired of swallowing pills, especially those who take multiple medications.

Transdermal delivery minimizes unpleasant side effects too, because a drug bypasses the gastrointestinal tract and first pass metabolism by the liver. Further, steady or modulated delivery and absorption of a drug over many hours or even days is usually preferable to the blood level peaks and troughs typically produced by oral dosage forms.

Transdermal delivery is a great alternative for providing contraceptives and treating high blood pressure, cancer, mental health disorders, and nicotine addiction. Moreover, the chemical structure of the drugs to treat these conditions, including clonidine, estradiol, fentanyl, and nicotine, represent potent, low molecular weight molecules that are highly active and function well in a transdermal delivery platform.

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For example, the challenge of inadvertent drug delivery caused by changes in body temperature or moisture is now addressed by selective barrier membranes; applying principles of facilitated diffusion. Incorporating such functionality into the microprocessor-controlled patch ensures that compounds are transported or blocked from transport, thereby ensuring controllable, predictable, and accurate dosing.

By preventing inadvertent delivery of current classes of transdermally delivered drugs, Isis has paved the way for improved dosing compliance of new and existing drugs for transdermal delivery. Newer, active transdermal drug delivery approaches are on the near-term horizon, promising much more patient- and physician-friendly, as well as more reliable and effective methods of drug administration. The Isis Biopolymer team has combined its experience in advanced polymer development, medical devices, and system design to develop the innovative and intelligent IsisIQ patch.

Online

For additional information on the technologies and products discussed in this article, see *MDT* online at www.mdtmag.com [3] and the following websites:

- www.flexcon.com [4]
- www.isisbiopolymer.com [5]

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