

Dissolvable Oral Delivery Technology: No Water or Chewing Necessary

From films to tablets, fast-dissolve pharmaceutical products are gaining in popularity. Delivering a drug by oral disintegration can be a very attractive factor for patients, especially for pediatrics and geriatrics who have trouble swallowing pills or do not have access to water at the time they need to take their medication. With the patient convenience and compliance that fast dissolve drugs offer, efficacy is increased.

Eurand's (Milan, Italy) "AdvaTab" tablets dissolve in the mouth within 15–30 seconds without the need for chewing or water. According to John Fraher, president of Eurand North America, AdvaTab tablets are based on a proprietary tablet composition that was designed and patented by Kyowa Hakko Kogyo Co., Ltd. (Tokyo, Japan) in which the lubrication is dispensed onto each tablet by using a spray during the production process. The external lubrication system won't reduce the binding action of drug particles and therefore helps keep the tablet hard and durable. Upon contact with saliva, the tablets disintegrate because there are no water-insensitive cohesive bonds between the particles. Because the lubrication is only on the surface of the tablet, the drug content can be increased, which allows for a higher drug load. AdvaTab uses 10–30 times less hydrophobic lubricant

in production than conventional tablet production, which can make the tablet stronger than conventional tablets. Currently, the tablets are being produced at a rate of 60,000 tablets per hour, according to Fraher.

"One of the advantages that we have over our competitors is that AdvaTab tablets can be tableted and packaged on standard packaging equipment," says Fraher. The tablets can be packaged in both standard bottles and push-through blisters.

Currently, AdvaTab tablets are used in several products that are on the market in Japan, including triazolam (Flosign Tab 0.25 milligrams) marketed by Moham, a medication that is used for the short-term treatment of insomnia. Eurand plans to eventually launch the technology worldwide. "We're predicting a range of volumes," said Fraher, "We're targeting a lot of attractive products and are expecting about 100 million tablets by next year." According to a report entitled, "Orally Disintegrating Dosage Forms," by Karsten Cremer, PhD (Pharma Concepts GmbH & Co. KG, 2001), the market value of drugs that incorporate a fast-dissolve technology is approaching \$1 billion and has an annual growth rate of more than 40%.

Eurand plans to combine AdvaTab with its other oral drug delivery platforms to develop more-advanced

medications and to address the specific needs of each compound. The company promises that the combination can accelerate onset of action, lower dosage levels, decrease side effects, and enhance product performance.

According to Fraher, fast-dissolve technology can be marketable particularly to the cough and cold medicines arena because of the large amount of active ingredients in those drugs. One of the advantages that Eurand claims to have in its products is the company's Microcaps—a taste-masking technology that can be incorporated into other technologies such as AdvaTab. "Our taste-masking technology is currently being used by a number of companies for both suspension products and fast-dissolve products," said Fraher. "The ability to combine our fast dissolve technology with our taste-masking technology is a significant advantage for us in this market as it enables us to develop convenient, fast-dissolve products with a taste that patients will appreciate."

Other targets for AdvaTab include a range of pain medications, anti-emetic, anti-histamine, and anti-migraine medications. AdvaTab is expected to be used in both over-the-counter and prescription drugs.

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