Improve drug safety through low-migration labeling

To reduce materials cost, improve efficiency and increase convenience for end users, more pharmaceutical companies are swapping glass containers and bottles for plastic product packaging. Plastic containers offer a number of advantages; however, regulatory groups have raised concerns because of their higher potential for migration — the occurrence of packaging materials leaching through the plastic and contaminating the medicine within. Accordingly, there is a real opportunity for the market to address migration concerns originating from inks, adhesives, coatings and even the plastic itself.

Changes in migration testing

Beginning in the early 1990s and 2000s, pharmaceutical manufacturers started utilizing HDPE, LDPE and other plastics in primary drug packaging. Eyedrop and eardrop manufacturers were particularly attracted to the “squeezable” qualities of thinner plastic containers. Plastic containers were also less breakable, less expensive and more efficient to produce than glass.

Over the years, however, cases emerged in which packaging components were migrating into a medicine, or extractables from the packaging were interacting with the medicine. In Europe, regulatory groups realized that increased risk of chemical contamination from plastic container usage required a fresh look at existing migration and extraction studies.

In the past, migration testing was only performed on containers, closures and other packaging components. Labels were never included in that testing because they were considered a secondary part of packaging that had no direct contact with the medicine. Using more advanced, sophisticated instruments and improved testing processes, EU regulators began to perform new migration and extraction tests on product samples to better identify leachable and extractable components.

What they found was troubling. Not only did the research show that certain label components were migrating through plastic packaging, but the components leached into both liquid and pill-form medicines. In addition, the contaminated medicine was often dangerous for patients treated with it.

The need for low migration

Improvements in migration testing and research were critical to increasing awareness about label migration in plastic packaging. They were also the driver in the European Union's 2005 guidelines around plastic packaging materials, which explained the importance of extraction and migration testing for plastic packaging components and, for the first time, included labels in the testing process. The U.S. FDA also developed guidelines for pharmaceutical manufacturers, in 1999 releasing Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics." This guide specifies that "packaging components should be constructed of materials that will not leach harmful or undesirable amounts of substances to which a patient will be exposed when being treated with a drug product."

The chief way that regulatory agencies in the U.S. and Europe are encouraging pharmaceutical companies to address migration issues is by requiring that they use low-migration label materials. The term low migration is used because some amount of migration will always occur in plastic packaging. However, if the migration or interaction happens within the accepted window determined by regulatory authorities, the packaging components are deemed safe for use.

There are two certifications that pharmaceutical companies can obtain to certify low-migration label materials. Both certifications can be secured through the independent, globally accepted testing agency, ISEGA. One certifies the materials under EU guidelines and the second certifies them for the U.S., ensuring they meet regulations such as 21 CFR 175.105, which governs adhesive use in pharmaceutical and food packaging. Typically, ISEGA certification can take up to two years to complete before the label is cleared for companies to use in production, making it a long and costly process for businesses that want to get their products to market quickly and efficiently. At the same time, this certification is necessary for pharmaceutical companies if they want to sell products with plastic containers to the European or the U.S. markets.

It is the ideal time for pharmaceutical companies to adopt low-migration label materials.

Low-migration adhesives, inks and varnishes

Some label developers have used the challenges around low-migration regulation as an opportunity to better serve pharmaceutical companies. Their solution? To develop low-migration products that can be readily available for the pharmaceutical market.

Label stock chiefly consists of a combination of a face stock, adhesive and label liner. But it is the label adhesive that has the most contact with the pharmaceutical packaging and that contains numerous elements with the potential to leach out and cause contamination.

Seeing this, certain label manufacturers now offer low-migration adhesives that are pretested to meet regulatory requirements in the North American and European markets. Many are also encouraging companies to work with converters to choose inks and varnishes that have a low-migration certification.

As the use of plastic increases and migration testing methods improve, it is the ideal time for pharmaceutical companies to adopt low-migration label materials. By choosing pretested, low-migration adhesives in combination with low-migration base materials, inks and varnishes for plastic containers, pharmaceutical companies can minimize the time and money they spend on migration certification, and in some cases can bypass it altogether. Other benefits include faster product approval and time to market, and the peace of mind of knowing that their medicinal products are safe for patients. >

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