

# PHARMACEUTICAL & MEDICAL Packaging NEWS

## New IVD Applications Demand Smart Sorbents

*Novel diagnostic chemistries require optimized packaging protection.*

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**D**ropping a sorbent into in vitro diagnostic (IVD) product packaging is a proven method for preventing product damage from moisture and maintaining shelf life and IVD product accuracy. New IVD devices and packaging configurations, coupled with the ever-present pressures to speed new IVD products to market, often require that sorbents become intelligent. Rather than simply serving as a moisture absorber, sorbents must fit the role of environmental managers, providing a specific range or steady-state level of protection to IVD product packaging that is increasingly taking different and more innovative shapes.

An intelligent sorbent is designed to provide a specific management outcome, which could be controlling the level of moisture, oxygen, or hydrocarbons in a product's packaging system.

**Multisorb desiccants are customized to accompany pregnancy test packs.**

In some cases a sorbent must carry out multiple protective functions. A sorbent might maintain a specific humidity range to maintain an IVD product's stability, or reduce or eliminate volatilized hydrocarbons.

As the IVD landscape has changed rapidly, packaging solutions need to become more innovative. In turn, IVD devices in development today are changing the format of the sorbent itself, sometimes requiring customization and incorporation into a packaging design much earlier in the process. Manufacturers need to be aware of intelligent sorbent solutions as they struggle to meet packaging protection needs of novel IVD technologies in a very competitive marketplace.

Sorbents can be customized to perform the role of specialty oxygen absorbers for IVD products subjected to oxidative and moisture-mediated degradation. They can be developed to eliminate oxygen from the packaged environment while managing free

moisture and maintaining a specific ERH in the package. This is critical to ensuring the integrity of IVD product compositions requiring both oxygen and moisture management.

Another important function of the modern-day sorbent involves hydrocarbon management. Residual solvents from reagents, substrate, and packaging materials can form volatilized hydrocarbons that end up in the headspace of an IVD product's package. In addition to potentially destabilizing the IVD product, this can produce a noxious odor that must be removed through the use of activated carbon. In these instances an intelligent sorbent can be tailored to perform the dual function of removing odors while maintaining moisture control.

Determine the type of hydrocarbon management needed for a particular product, as this will determine an intelligent sorbent's configuration. For example, a sorbent made from a specific type of molecular sieve could be configured to function as a hydrocar-



bon scrubber, which removes volatilized hydrocarbons. The functionality of the sorbent depends upon the specific need. In some cases, it may be necessary to remove hydrocarbons but to retain water molecules, in which case a sorbent must be constructed so that it does not overdesiccate a product.

Intelligent sorbent requirements also may include the management of moisture, oxygen, and hydrocarbons in one solution. In such cases, a specific sorbent formulation for moisture regulation is designed to manage to a customized, steady-state equilibrium relative humidity condition. Simultaneously, oxygen is removed from the hermetically sealed IVD product package and volatilized hydrocarbons are adsorbed.

#### **FASTER REACTION TIMES & CHEMICAL INSTABILITY**

New IVD platforms that are coming to the market are often based on fast acting chemistries, each with unique chemical stability challenges. These challenges mean traditional desiccant products no longer satisfy the package protection needs. Thanks to new intelligent sorbent technologies, however, some of these

inherently unstable IVD platforms are being successfully stabilized.

The result is increased pressure on analytical chemists and packaging engineers charged with keeping IVD products stable. These engineers increasingly need to work with analytical chemists to understand the specifics of the reagents or biologically active materials that are the basis of their IVD platform.

In most cases, the goal of a sorbent is to prevent degradation of chemical reagents or biologically active proteins within the IVD product's packaging. An aggressive and active sorbent that dries an environment works well for some IVD chemistries because it reduces the molecular mobility and inhibits the chemical reactions that can lead to product degradation. Conversely, overdrying can degrade an IVD product because biologically active proteins can denature if overdesiccated. For example, overdesiccation of certain blood-glucose OTC test strip platforms can cause physical and aesthetic damage to the substrate resulting in slower blood sample wicking and related reaction times. In these cases, aggressive moisture management can cause serious problems skewing the result of a blood glucose test.

More companies than ever face numerous IVD platforms with different stability challenges that require intelligent sorbents, so a one-size-fits-all approach to packaging protection is not a viable strategy. This also holds true for new IVD platforms and related instrumentation technologies coming onto the market. A significant number of resources go into packaging, and without careful planning and consideration of all the factors required for protecting an IVD product, the result may be a product with compromised stability.

A sorbent packaging strategy must be intelligent, and it must be optimized based on the specific application. It must consider the product, its chemistries, instrumentation, and required shelf-life—essentially the entire life cycle of a product from manufacturing to end-use. It's a common mistake to assume a sorbent's function is simply to absorb or adsorb excess moisture, or that the answer to an unstable chemical compound is simply to insert additional sorbents into a package. Though most often sorbents are inserted into packaging at or near the end of the packaging line, the choice of sorbent strategy cannot be an afterthought. ■

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