

## Harnessing desiccant tech for inhalation therapies

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Exubera—the first inhaled form of insulin for treatment of diabetes—made headlines when it received FDA approval earlier this year because it promises to free diabetics from the discomfort and intrusiveness of mealtime injections. This new drug joins a growing suite of pharmaceuticals that are being packaged in fine powder form for use in inhalation devices. For clinicians and patients, respiratory drug delivery offers several advantages over conventional delivery methods, including precise dosing, speed of action, and convenience. To succeed in the emerging market for inhalation therapies, pharmaceutical manufacturers need to understand the design and production challenges unique to this form of drug delivery.

Active packaging components are a critical consideration for creating a successful dry powder inhaler (DPI) system, especially the role of sorbents for regulating moisture levels inside a DPI. Sorbents facilitate the smooth flow of drug particles and ensure that the device works, accurately, throughout its life cycle. The choice of sorbents, however, and their incorporation into a package or delivery device requires careful consideration to ensure effectiveness.

### Understanding the market

The demand for inhalation therapies is fuelled by several factors, including new clinical applications and the growth of chronic

conditions. Delivering drugs through the lungs is faster than oral delivery and can offer more controlled dosing, thus avoiding or minimizing most systemic side effects. Inhalation therapies are commonly used for treatment of asthma or chronic obstructive pulmonary disease-the world's fourth-greatest cause of death. However, inhalation therapies have begun to be used with biologics, which have typically been administered intravenously or through injection. Inhalation therapies are also being deployed for pain management, in which speed and ease of delivery are paramount.

Because inhalation therapies offer a relatively painless, convenient mode of drug delivery, industry experts note that they could increase patient compliance with recommended treatment-a particularly important consideration for management of chronic conditions. By improving compliance and providing more accurate dosing, DPIs have the potential to increase the efficacy and cost-effectiveness of drug treatments

### **Going with the flow**

New inhalation therapies are made possible through the creation of novel delivery systems. There are a variety of DPI models, which manufacturers often customize to meet the needs of a particular product or patient population. Some DPIs include pre-measured doses of medicine in blisters, capsules, or other cavities that are inserted into the device before use. Once a patient uses all the doses, they discard the device. By contrast, "reservoir" devices offer continued use from a drug reservoir until the reservoir is depleted. They include an internal supply of a drug, which is measured and dispensed in the device itself.

Sorbent technologies are an important component of any DPI system. Not only do sorbents preserve the potency and stability of drug formulations, but they also maintain air flow dispersion, ensuring accurate dosing. Like other pharmaceuticals, powdered drugs are subject to physical and chemical degradation. If moisture builds up inside a device, drug particles tend to agglomerate-making them too large to be inhaled or leaving some amount stuck to the device walls. Drug particle agglomeration can reduce the ability of the dry powder to flow through the system and affect the accuracy of dosage. In addition, excess moisture can cause changes in the potency or stability of powdered drugs by increasing their molecular mobility and fostering chemical degradation.

### **Advantage of new desiccant technology**

Because proper desiccation is an integral part of DPI device functioning, the choice of sorbent is crucial. Today's sorbents are often described as "active packaging components" because they respond to changes in the headspace of packaging relative to outside conditions. In this way, they regulate humidity levels within a DPI device without making contact with the dry powder and optimize conditions for drug delivery.

A new generation of desiccants-coated solid format (CSF) sorbents-is particularly well suited for DPI applications because they significantly increase the level of functional desiccation per unit volume. Through condensed density technology, CSF sorbents are able to deliver twice the moisture protection in the same dimensional space as a typical loose-fill desiccant. CSF sorbents can be made from silica gel, activated carbon, or a combination of both.

To facilitate ease of use, manufacturers are designing inhaler devices in discreet forms, along the lines of lipstick cases or eyeglass holders. CSF sorbents can easily integrate into DPI designs because they can be manufactured into a variety of shapes and sizes. If there is an available cavity inside a particular DPI device, a CSF sorbent can be customized to fit inside of it, creating an "onboard" solution for pharmaceutical preservation. If there is no available space within the inhalation device itself, CSF sorbents can be produced in strip format and packaged alongside a DPI.

### **Fine-tuning the desiccation process**

Finding the right level of desiccation for powdered drugs, however, can be tricky. While excess moisture can degrade drugs, over-desiccating can change electrical charges, generating static electricity that interferes with the dispersion of drug particles or denaturing biologically active molecules. Determining the correct desiccation formula should be part of an overall DPI design, in which, user-control, air-flow, static-electricity, and moisture play interdependent roles.

When evaluating the desiccation requirements for inhalation devices, pharmaceutical manufacturers should consider the interactions between drug formulation, de vice, and packaging. They must also consider all of the sources of moisture, including the plastic from which a device is manufactured and any inserts or other components of the package. Sorbent producers should be able to provide expert advice to manufacturers during the design, production, and approval processes.

### **Finding the right solution**

Respiratory drug delivery is a significant new trend, offering clinical benefits, dosage control, and patient convenience.

Integrating sorbent technologies into dry powder inhalation devices will preserve the quality and safety of pharmaceutical formulations and ensure that the device functions accurately and effectively each time it is used.

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