



Activ-Film™ materials

Adhesive-Free Head-space Management for Transdermal Drug Delivery Systems

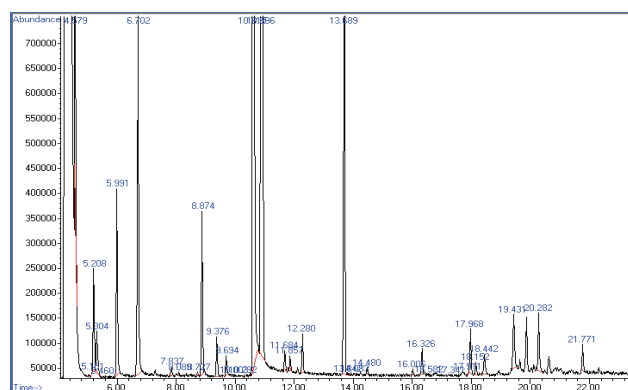
The challenge

The Transdermal Drug Delivery Systems (TDDS) market faces unique challenges when incorporating desiccant and scavenger materials into packaging. As a result, TDDS applications are best served by thin, flexible materials such as films. Most often, it is necessary to attach these desiccant and scavenger films to the pouch's interior surface. For this process, adhesives are commonly used.

The challenge? These adhesives typically retain small amounts of residual solvents, and these solvents have the potential to migrate into the package headspace and the product itself. These solvents can show up in analytic tests as impurities and can also adversely react with components in the drug product, causing adverse effects on the physicochemical properties, that could lead to changes in dissolution properties. Excess solvent retention can also create an odor in the package and color changes in finished products, leading to customer complaints.

There are also regulatory ramifications. The International Conference on Harmonisation (ICH) provides limits for residual solvents in pharmaceutical products. Manufacturers must measure and report the levels of residual solvents using quantitative techniques like gas chromatography (GC) (graph 1) and methods described in the various pharmacopeia. Since many TDDS products also depend on an adhesive for drug delivery to the patient, manufacturers will already be burdened by the residual solvents present in their product. Adding another source of residual solvents from the desiccant and/or scavenger film adhesive will require additional testing, and potentially reduce the quantities of residual solvents that the final package can tolerate from the product itself. This can quickly become an expensive design and quality challenge.

Graph 1: Solvent outgassing from a medical grade adhesive



Major solvent peaks: Ethyl alcohol (class 3), Isopropyl alcohol (class 3), Benzene (class 1) and Toulene (class 2)

Chart above shows a typical GC chromatogram of solvent outgassing from a medical grade adhesive.

A solvent-free alternative: Activ-Film™ materials

To address this problem, CSP Technologies, Inc. developed Activ-Film™ materials, that not only provide effective desiccant and scavenger performance but also can utilize heat-staking, rather than adhesives. The aptly-named innovation represents a breakthrough in active pharmaceutical packaging.

Activ-Film™ materials can be tailored for moisture adsorption and to seek out polar and/or non-polar compounds by incorporating a wide range of chemistries. For example, Activ-Film™ materials can effectively remove oxygen, carbon dioxide and formaldehyde. Additionally, it can be formulated to desiccate in combination with scavenging.

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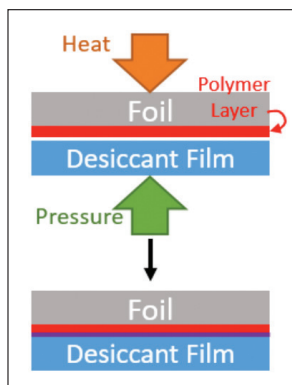


About CSP Technologies, Inc.

CSP Technologies, Inc. is a leader in delivering innovative, high-quality product and packaging solutions that give customers a competitive edge and consumers a better product experience.

Activ-Film™ materials

Scavenging Volatile Chemicals from Transdermal Drug Delivery Systems



Heat staking

Activ-Film™ materials employ a method known as heat staking, an adhesive-free option to adhere desiccant and scavenger film to packaging materials in which heat and pressure are used to securely bind the film to the polymer layer of a foil pouch. Heat staking does not introduce residual solvents, so there is no need to monitor an additional source of solvents or to manage unexpected interactions with the product.

The method is simple to incorporate into automated lines and equipment is readily available. In addition, the elimination of adhesives and the backing material they require leads to reduced production costs.

Activ-Film™ materials exemplify the type of custom polymeric and packaging solutions that CSP Technologies, Inc. regularly develops for its customers. The materials science company offers a growing line of active polymer chemistry solutions, and is the global leader for, among other solutions, Activ-Vial™ products for pharmaceuticals and diagnostics applications.