



# Activ-Blister™ solutions

## Scavenging Volatile Chemicals from OSDs

### The challenge

The Oral Solid Dose (OSD) drug delivery market continues to experience tremendous growth. The expansion is predicated, in part, by expanding OSD technologies that enable more challenging APIs and delivery needs. Along with traditional capsule and tablet technologies, these new technologies can result in products that face significant stability challenges, especially from moisture, oxygen or a combination of both. An additional and even more challenging stability risk factor: reactive impurities such as formaldehyde and formic acid.

Unfortunately, these impurities, or hydrocarbons, often can be found in the excipients used for these dosage forms, and can off-gas during the product shelf life. Formaldehyde found in excipients has been implicated in the degradation of several drug products, in which it has formed adducts with primary and/or secondary amine groups.

These reactive impurities have also been shown to cause cross-linking in gelatin capsules, impacting dissolution performance. Main contributory factors to this cross-linking are storage stress (high temperatures, high humidity, and excessive light exposure) and the presence of aldehydes, of which formaldehyde is among the most formidable. These impurities also can create odors noticeable to customers.

### Blister packaging solutions

Housing OSD products in blister packaging is growing in popularity in the United States, driven partly by customer preference and regulatory requirements. Though it offers patient safety and compliance benefits as well as individual dosage protection, blister packaging faces its own unique head-space management challenges from moisture, air, and hydrocarbons – issues that occur both during packaging and over time by ingress and off-gassing from the capsule/tablet.

Traditional options for headspace management cannot address scavenging of these impurities. Purging will only remove oxygen and moisture from the headspace at the time of packaging. Secondary packaging with sachets can only reduce ingress into blister cavities – and at the expense of adding size and complexity. Neither of these technologies/options address off-gassing over time from the capsule/tablet.

### Aptar CSP Technologies' formaldehyde absorbing Activ-Blister™ solutions

To address these stability challenges, Aptar CSP Technologies developed Activ-Blister™ solutions which utilize Activ-Polymer™ technology to facilitate discrete head-space management. Activ-Film™ materials control the internal atmosphere of each blister cavity, allowing for improved product performance and shelf-life. Utilizing its patented technology, Aptar CSP Technologies offers a variety of film formulations to absorb gasses such as moisture, oxygen and volatile organic compounds like formaldehyde. The Activ-Film™ material (typically 0.3mm to 0.6mm thick) is die-cut to match the size of the capsule footprint and is heat staked – free of adhesives – to the foil lidding, just prior to sealing the blister pack.

Utilizing Activ-Blister™ solutions allows pharma manufacturers to achieve headspace management comparable or superior to existing bottle options. It extends the shelf life of alu/alu and thermoform blisters by reducing moisture and gasses in existing headspace at the time of production and, afterwards, from ingress and off-gassing from the capsule or tablet.

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# About Aptar CSP Technologies

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

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Use of this groundbreaking technology can reduce packaging complexity and costs by eliminating the need for purging and secondary or fishbone packaging. Further, actively desiccating and/or scavenging from within the blister can enable a switch from coldform to thermoform, which can reduce material costs and results in a smaller footprint (40-60% size reduction). Activ-Blister™ solutions also are adhesive-free through the use of heat staking; eliminating adhesive off-gassing and expense.

Activ-Blister™ solutions are highly flexible and can be produced in virtually any shape. It is compatible with foil lid stock used for cold formed and thermoformed blisters.

Activ-Blister™ solutions exemplify the type of custom polymeric and packaging solutions that Aptar CSP Technologies regularly develops for its customers. Aptar CSP Technologies is a material science company that offers a growing portfolio of active polymer solutions.

