

# Re-imagining Oral Solid Dose Drug Delivery

Extend shelf life and enhance stability







## Material Science Solutions for Oral Solid Dose Protection

# Premier protection to extend shelf life and enhance stability of sensitive oral solid dose drugs

Oral solid doses are often the most convenient, safest, and least expensive way to administer medication, and therefore, also the most often used drug delivery method. However, in their development, there can be stability issues associated with moisture, oxygen and reactive impurities resulting in the loss of potency or degradant growth. Aptar CSP Technologies' proprietary 3-Phase Activ-Polymer™ platform technology can be deployed in multiple formats to protect these sensitive API's and assure patients receive accurate dosage. Our technology enables the creation of a specific, optimized microclimate for oral solid dose drugs in order to meet stability requirements. Our range of solutions include:

#### **Activ-Blister™ Solutions**

This innovative technology integrates Activ-Film™ material into each individual blister cavity. Having multiple formulations, outfitted blisters can adsorb tailored amounts of water vapor, scavenge oxygen, or a combination of the two, and can be produced in shapes and sizes to accommodate any tablet and capsule size. The film is securely bound to the lid stock via our proprietary heat staking process without using adhesives.

#### Benefits of Activ-Blister™ Solutions

#### Extend shelf life:

Advanced product protection for controlling humidity, oxygen and reactive impurities that can reduce shelf life or cause the API to degrade

#### Reduce package complexity:

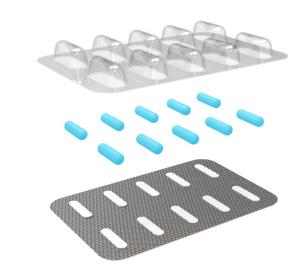
Actively control internal headspace without nitrogen flush/purging, secondary packaging, or refrigeration

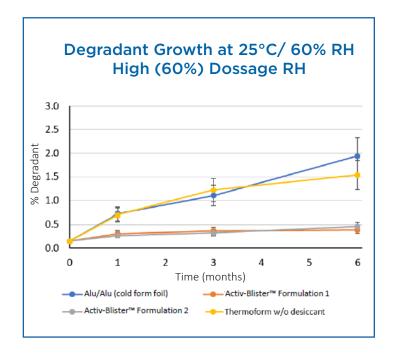
#### Move from cold-form to thermoform blisters:

Visible oral solid dose with a 40-60% smaller blister footprint

#### Provide an alternative to bottles:

Allows products traditionally packaged in bottles, with canisters or sachets, to use thermoformed blister cards without sacrificing headspace protection

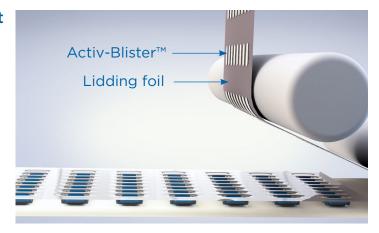




#### Turnkey Activ-Blister™ Manufacturing Support

Through our partnership with PCI Pharma Services, we simplified the process of bringing sensitive oral solid dose drugs to market.

Together with PCI, we invested in the design and implementation of the world's first Activ-Blister™ Film Application Machine (FAM) on commonly used clinical and commercial blister packaging equipment. Following FDA approval of drug products using Activ-Blister™ solutions, the proven manufacturing process ensures speed to market.



Patented Activ-Blister™ implementation process

#### Activ-Vial™ Portfolio

Our active bottles and vials feature an engineered, integrated 3-Phase Activ-Polymer™ liner that completely surrounds the product. This unique solution reduces initial water activity levels and provides a mechanism for actively controlling moisture, ensuring greater product stability and extending shelf life of moisture-sensitive oral solid doses over traditional bottles using a desiccant canister or sachet.

#### Benefits of Activ-Vial™ Portfolio

#### Extend shelf life:

Advanced product protection for controlling humidity, oxygen and reactive impurities that can reduce shelf life or cause the API to degrade

#### Seamless integration:

Consistent packaging format relative to current traditional bottles and easily integrated into existing packaging lines without significant reconfiguration costs

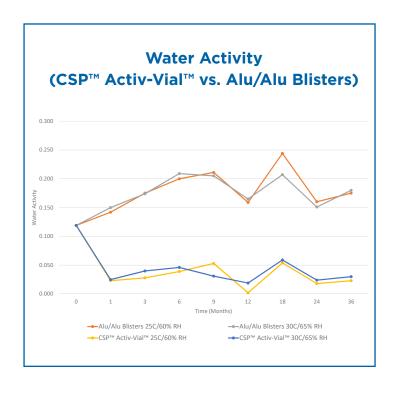
#### Assured consumer safety:

No risk of accidentally ingesting dessicant canisters or sachets that are included in traditional bottle packaging

#### • Enhanced moisture protection:

Oral solid dose drugs see virtually no moisture because it is trapped before entering headspace







### Partnering with Aptar CSP Technologies

- Expedite speed to market:
   Full suite of co-development services to quickly meet stability requirements and shorten development time
- Enhance user experience and patient compliance:

Elegant solutions that deliver API protection to enhance stability and assure patients receive accurate dosage Broaden market access:
 Provide optimal microclimate protection to

enable distribution to markets in ICH Stability

Zones 3 and 4

Expand formulation development opportunities:

Enable development of unstable APIs that are not feasible in solutions that provide less moisture protection

