

Mitigating N-Nitrosamine Risks with Novel Active Material Science Innovations

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Abstract

Recent landmark discoveries of mutagenic N-nitrosamine impurities in pharmaceuticals have led to significant regulatory responses, including drug recalls and new regulatory guidances. New strict, extremely low limits for N-nitrosamine impurities in pharmaceutical products were instituted by many Health Authorities. With all the scrutiny from regulatory bodies about the N-nitrosamine risk and the multiple factors that can trigger N-nitrosamine formation, pharmaceutical developers must assess this risk in their current drug products as well as in new APIs in development. They need to find solutions to protect against the potential for a drug recall and the associated direct and indirect costs (i.e., lost sales, litigation costs, fines, impact to brand reputation, etc.).

Active packaging can serve as a primary solution or as an additional measure of protection to compliment other strategies used to prevent N-nitrosamine formation. Aptar CSP Technologies' R&D strategies combines the advantages of interdisciplinary research, where materials and organic chemistry (synthesis, shaping and characterization of the obtained materials), thermodynamic/dynamic (adsorption, kinetics, etc.), and computational chemistry synergistically work together to focus on the most promising adsorbents (nanoporous materials) or organic scavengers for the challenging targeted mitigation of N-nitrosamines (see one proposed solution to mitigate N-nitrosamines present in gas phase inside the packaging below). These nanoporous materials and/or organic scavengers can be engineered and deployed as bespoke versions of Aptar CSP's Activ-Blister™ Solutions, which integrates a piece of flexible active film into traditional blister packaging designs.

THE PROBLEM
Recent discoveries of mutagenic N-Nitrosamine impurities in pharmaceuticals have led to drug recalls and new regulatory guidance to address this risk and protect patients from these carcinogens.

THE CHALLENGE
Pharmaceutical companies need to address the source of N-Nitrosamine development and implement changes to their formulation, manufacturing processes or packaging materials.

THE SOLUTION
Active material science innovations enable active packaging based solutions that mitigate N-Nitrosamine formation and/or adsorb these molecules post-formation with minimal impact to current processes.

[Click here to download the full technical white paper.](#)

