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PFAS-free coatings for MDI canisters: What to look for

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Scrutiny of per- and polyfluoroalkyl substances (PFAS) is increasing globally. PFAS exhibit excellent non-stick properties and chemical resistance; however, they are persistent in the environment and are often referred to as “forever chemicals”.

Within metered-dose inhalers (MDIs), PFAS are used in key components, including canisters, valves,1 and propellants. With forthcoming REACH decisions on PFAS, the challenge is how to preserve MDI performance using PFAS-free alternatives while maintaining safety, product performance, and regulatory compliance.

BACKGROUND

Accurate and precise dose delivery has been the hallmark of MDIs for the last 70 years. In addition to a stable formulation, the contribution of the container closure system, including the canister and valve, has been critical to achieving consistent performance. At present, canisters with FEP or PTFE fluoropolymer coatings are used to mitigate challenges related to drug adhesion and degradation. Patient safety and regulatory compliance are non-negotiable, and innovation in PFAS-free coatings must continue to meet these standards.

REGULATORY CONTEXT

The proposed universal PFAS restriction under REACH (ECHA’s five-country proposal) would restrict the manufacture and use of PFAS above very low thresholds, with time-limited derogations for “essential uses”. Regulatory and public pressure are increasing due to concerns surrounding persistence, bioaccumulation, and emerging toxicity data.

Many PFAS-free internal lacquer systems, including non-fluorinated epoxy-phenolic, polyester, and BPA-NI epoxy coatings, have been evaluated previously with limited success and have not demonstrated equivalent performance to PTFE, FEP, or PFA fluoropolymer coatings.

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WHAT DEVELOPMENT TEAMS SHOULD EVALUATE NOW

Developing PFAS-free alternatives requires careful consideration of several key technical factors:

- Drug compatibility and chemical resistance must be ensured.
- Extractables and leachables (E&L) profiles must meet ICH/USP requirements and be appropriately qualified to ensure patient safety.
- Dose consistency must be achieved by minimising drug deposition within the canister and valve, reducing shot-to-shot variability and tail-off.
- Manufacturability, coating adhesion, and durability under propellant exposure and crimping stresses must demonstrate long-term coating integrity.
- Adsorption and leaching must be minimised to reduce metal-ion catalysis and prevent active pharmaceutical ingredients or excipients (e.g. formoterol and beclomethasone) from adsorbing to bare aluminium.
- Propellant compatibility is particularly important with current HFA propellants and emerging low-GWP propellants, including HFO-1234ze(E) and HFA-152a. Coating performance must be demonstrated with these propellants, ethanol/water co-solvents, and the intended APIs.
- Moisture and chemical barrier properties are essential to improve the stability of moisture-sensitive APIs.

THE PATHWAY TO PFAS-FREE SOLUTIONS FOR MDI

Material scouting (including advanced silicones, parylenes, hybrid ceramics, and engineered polymers), together with rigorous extractables and leachables (E&L) testing, formulation stability studies, and phased validation with pharmaceutical partners, represents the long-term pathway towards achieving regulatory compliance and performance parity without PFAS.

Overall, replacing fluoropolymer coatings remains a significant technical challenge. These coatings have long been established as the preferred solution for demanding MDI formulations because of their proven performance. Consequently, extended transition periods or exemptions continue to be proposed for critical MDI products that support patient health.

H&T PRESSPART IS PROGRESSING A PORTFOLIO OF PFAS-FREE SURFACE TECHNOLOGIES

H&T Presspart's fluorocarbon polymerisation (FCP) plasma treatment is compliant with current PFAS-free regulatory requirements, offering enhanced drug stability and reducing potential degradation pathways.

In addition, H&T Presspart is advancing multiple PFAS-free spray coating candidates from laboratory development through to validated production-scale processes on our purpose-built coating lines.

To discuss validation status, application suitability, or how these technologies could support your development programme, please get in touch. We'd be delighted to discuss your requirements.

H&T Presspart Low GWP Propellant Metered-Dose Inhaler Sample Filling Equipment

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