UPDATE TO ANVISA NITROSAMINE REGULATORY EXPECTATIONS

Aptar CSP Technologies

ANVISA (Brazil's Health Regulatory Agency) has significantly stepped up regulatory expectations around nitrosamine control in pharmaceutical products. Companies operating in or exporting to Brazil need to determine a pathway for compliance with these new regulations, and N-Sorb technology can be a powerful method to proactively comply with ANVISA's standards.

Key Updates from ANVISA

New Guidance Issued: ANVISA released an updated Guide on the Control of Nitrosamines (Guide No. 50/2021, Version 3) that includes expanded limits for 28 specific nitrosamines and nitrosamine drug substance related impurities (NDSRIs). Companies must evaluate risk, conduct testing, and submit mitigation plans using ANVISA's Solicita system.

Active Monitoring Program: ANVISA initiated a Medicines Nitrosamine Monitoring Program focused on surveillance and deeper control of APIs and drug products, especially high-risk classes like sartans.

New Degradation Study Requirements (RDC 964/2025): Updated standards now require forced degradation studies aligned with ICH guidelines, reinforcing the need to identify and manage nitrosamine risks.

Inclusion in Herbal Medicines: ANVISA has also moved to limit nitrosamine levels in herbal medicines, signaling broader application of impurity control across pharma and nutraceutical categories.

Three-Phase Risk Management Approach: Companies are expected to perform:

1. Risk assessments
2. Confirmatory testing
3. Implementation of mitigation and manufacturing changes if needed

How Can CSP Help?

Companies must now demonstrate proactive nitrosamine control to regulators and customers. Aptar CSP's N-Sorb technology is a proprietary material designed to passively scavenge nitrosamines and nitrites from the packaging environment offering a fast, low-risk compliance path for products **without CMC or formulation delays.** N-Sorb enables easy integration into existing packaging configurations, provides validated scavenging of nitrosamines, and helps meet ANVISA and global compliance needs. This solution is especially relevant for oral solid dose products, sartan analogs, APIs, and herbal medicines.

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