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Nitrosamine Risk Assessment

Discovery of the N-Nitrosodimethylamine impurities in marketed pharmaceutical product put the spotlight on the potential risk associated with nitrosamine impurities in pharmaceuticals. The regulatory agencies have issued the guideline on the risk assessment and tighten the grip on Nitrosamine limit, it is essential to proactively assess the product to comply with industry standard and ensure consumer safety.

Risk assessment is the process of identifying and evaluating the potential presence and possibility of formation of nitrosamine impurities. Risk assessment involves evaluation of finish product, drug substance, manufacturing process, the raw material and degradation pathway. Report of risk assessment is mandatory for regulatory agencies, if risk of nitrosamine is identified in drug product, then confirmatory testing should be conducted.

Our Solution

Risk Evaluation - We assess your manufacturing process, raw material, synthesis route, and product formulation to identify the potential Nitrosamine formation pathway and associated risk. Our team conducts thorough analysis to identify critical area and develop effective risk management strategies.

Confirmatory testing - Analytical method development & validation to quantify N-nitrosamines in drug substances and drug products with high precision, allowing to make informed decision.

Mitigation & Remediation strategy - Our team can offer mitigation strategy if nitrosamine is detected. We closely work with you to support in implementing necessary process changes or alter formulation to minimize or eliminate risk.

Testing & analysis - We can provide periodic assessment to monitor effectiveness of mitigation strategy, stability storage & analysis and commercial batch testing, ensuring your product meet safety standards.

Key Benefits with Aragen

Knowledge & Experience - In-house expert team of analytical scientist, chemist, toxicologist, and formulation scientist to provide comprehensive solution of nitrosamine, team has over 5 years' experience exclusively on NSA in testing.

Regulatory Compliance - US-FDA audited, GMP facility for the analytical, stability and commercial batch release. OECD-GLP facility to support nitrosamine assessment as per the ICH M7 (R1).

State of the Art Facility - Aragen has six world-class facilities compliant with global requirements and equipped with advanced instrumentation. 10,000 Square feet analytical lab with 60,000 L stability storage.

Confidentiality & trust - We prioritize the confidentiality and security of data and follow the strict protocols.

About Aragen

Aragen, a Contract Research & Development Organization that services the global pharmaceutical industry is headquartered in Hyderabad, India and has six sites across the globe. Established in 2001, Aragen serves pharmaceutical industry across the value chain with a focus on speed and quality, ensuring safety and compliance. Aragen's team of over 4500+ scientists, are supported by a no-conflict business model, modern facilities, strong customer-centric culture, and focus on bringing their customers' products to market rapidly and cost effectively.

Let's begin the conversation

E: bd@aragen.com
W: aragen.com
in /company/aragen-life-sciences
f /AragenLifeSciences

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