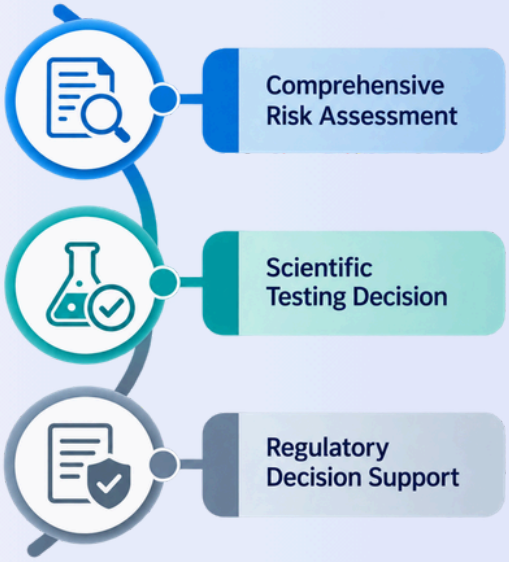
Nitrosamines – Testing Decision & Risk Evaluation

Confirmatory analytical testing should be performed based on scientific evidence rather than routine testing alone. Zamann provides a structured risk evaluation framework that consolidates product, material and process knowledge to determine whether confirmatory testing is required. Developed in accordance with ICH M7, EMA, and FDA guidance, the framework supports consistent, scientifically justified and inspection-ready testing decisions.

Comprehensive Risk Assessment

The framework systematically evaluates all relevant sources that may contribute to nitrosamine or NDSRI formation. This includes Drug Substance information, formulation design, excipients, manufacturing processes, primary packaging, storage conditions, API supplier information and available scientific evidence. By bringing these data together, a complete product-specific risk profile is established before any testing decision is made.



Scientific Testing Decision

Rather than applying a one-size-fits-all approach, the collected evidence is evaluated using a structured decision logic to determine whether the potential presence of nitrosamines is unlikely, cannot be excluded, or likely. This enables a scientifically justified decision on whether confirmatory analytical testing is required, whether additional information should be collected, or whether the documented assessment sufficiently demonstrates that testing is not necessary. .

Regulatory Decision Support

Each conclusion is supported by a documented scientific rationale, providing transparency, consistency and traceability throughout the decision-making process. The framework supports inspection readiness and provides a robust basis for confirmatory testing strategies, regulatory submissions and future lifecycle activities where required.