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QUESTIONS TO ASK YOUR LABORATORY PARTNER

NDSRI TESTING

Following FDA's September 2024 revised guidance, which clearly differentiates nitrosamine drug substance-related impurities from small molecule nitrosamines like NDMA or NDEA, manufacturers face distinct analytical challenges requiring product-specific method development rather than standardized testing approaches. Because NDSRIs share structural similarity with the API itself, detecting them at parts-per-billion levels within complex matrices demands specialized instrumentation and proven experience managing the matrix effects that arise from high API and excipient concentrations.

Selecting the right laboratory partner becomes critical when building an effective NDSRI testing program. The questions below provide a framework for evaluating analytical laboratories' technical capabilities, regulatory compliance, and operational readiness to support your NDSRI control strategy. This helps you distinguish between providers with general analytical capabilities and those equipped to handle the unique complexities these impurities present.

Use this checklist during your laboratory evaluation process to ensure you're partnering with a provider whose expertise matches the technical and regulatory demands your program requires.

Evaluation Questions

Experience and Expertise

☐ Do you have experience developing NDSRI methods for APIs in our drug class?

☐ How many NDSRI method development projects have you completed?

☐ Can you provide examples of similar products you've tested?

Technical Capabilities

☐ What instrumentation do you use for NDSRI testing?

☐ How do you handle matrix effects from high API concentrations?

Methods may include matrix-matched calibration, standard addition techniques, or specialized sample preparation protocols

☐ What's your approach to forced degradation studies under nitrosating conditions?

☐ What are your typical detection limits for NDSRI testing?

Process and Timeline

☐ What's your typical timeline for product-specific NDSRI method development and validation?

Method development requires optimization of extraction, chromatography, and mass spectrometry parameters

☐ How do you approach method validation for product-specific NDSRIs?

☐ Do you have capacity to meet our project timeline?

Regulatory and Quality

☐ Are you FDA-registered and inspected?

☐ Can you provide documentation suitable for regulatory submissions?

☐ What quality control measures do you implement for NDSRI testing?

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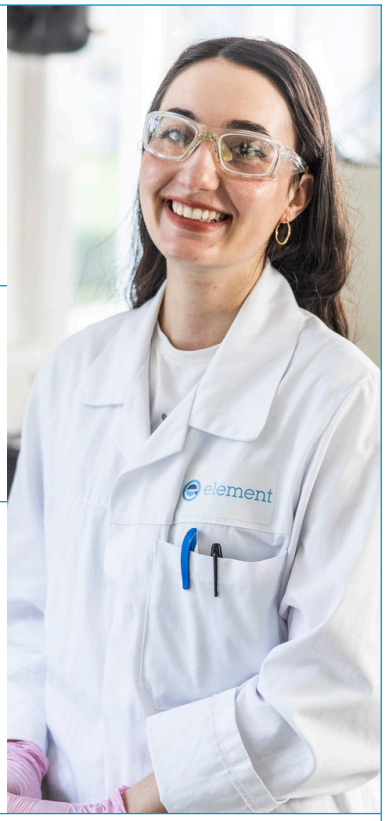

Risk Assessment Support

☐ Can you support NDSRI risk assessment, or only testing?

Risk assessment requires understanding of structural evaluation and NDSRI formation pathways

☐ Do you have experience with risk assessments for our type of product?

Communication and Partnership

☐ Who will be our primary technical contact?

Direct access to experienced scientists facilitates problem-solving

☐ How do you handle unexpected results or method challenges?

Product-specific method development often requires troubleshooting and optimization

☐ Can you provide interim updates during method development?

Choosing the Right Testing Partner

The complexity of NDSRI testing, from product-specific method development through parts-per-billion detection in matrices dominated by high API concentrations, requires laboratory partners with specialized analytical capabilities and relevant experience navigating these technical challenges. Look for laboratories that can articulate their specific approach to matrix effect management and forced degradation study design, since their responses to these questions reveal not just technical specifications but the depth of hands-on experience that distinguishes capable NDSRI testing providers from those offering general analytical services.

Your choice of laboratory partner directly impacts your program timeline, data quality, and ability to meet the regulatory expectations FDA established in its September 2024 revised guidance, making the evaluation process a critical component of your overall NDSRI control strategy.

Element's NDSRI Testing Services

Element provides comprehensive NDSRI testing through our FDA-registered analytical chemistry laboratories, supporting pharmaceutical manufacturers from risk assessment through confirmatory testing and ongoing monitoring programs.

Our capabilities include product-specific method development with advanced LC-MS/MS and LC-HRMS instrumentation, experience across diverse API classes and complex matrices, forced degradation study design and execution, method validation for regulatory submissions, and scientific consultation on risk assessment approaches. We combine the specialized analytical expertise these impurities demand with the regulatory compliance infrastructure your submissions require.

Our scientific team brings extensive experience with nitrosamine impurity programs, understanding both the analytical complexity of parts-per-billion detection in challenging matrices and the regulatory strategy considerations manufacturers face when building sustainable NDSRI control programs.

Questions About Your Specific NDSRI Testing Requirements?

Connect with our pharmaceutical testing experts to discuss your program needs and timeline.

Click or scan the QR code to start the conversation.

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