

Lonza Capsugel Launches Integrated Offering Supporting Drug Product Nitrosamine Risk Management

New service combines sensitive nitrite testing, capsule and formulation expertise, and regulatory support to help manufacturers navigate increasingly complex nitrosamine assessments.

BASEL, Switzerland, September 24, 2026 – Lonza Capsugel, a global leader in oral dosage solutions, today announced a new integrated service offering designed to help pharmaceutical manufacturers assess and understand nitrite levels in empty capsules through nitrite testing supported by a validated analytical method, scientific interpretation and regulatory support from a single trusted partner.

As nitrites in empty capsules may contribute to nitrosamine formation in the drug product, scientific expertise and reliable nitrite testing data are required to perform a product-specific evaluation and support informed risk management decisions. Lonza Capsugel's integrated service enables customers to generate reliable evidence and define an appropriate nitrite risk-management approach aligned with their product needs. Services include nitrite testing, data interpretation, documentation to support regulatory submissions, scientific consultation, risk investigations, collaborative studies that facilitate engaging with regulators, all through a single point of contact for testing and technical support.

At the core of the offering is Lonza Capsugel's fit-for-purpose nitrite quantification method specifically developed for the gelatin capsule matrix. The method combines ion chromatography with Griess derivatization, has been extensively validated in accordance with ICH Q2(R2) principles and can quantify nitrite levels as low as 100 ppb. By addressing matrix-specific extraction, selectivity and potential interferences, the method delivers sensitive and reliable nitrite quantification. The analytical capability supports capsule and comparative nitrite testing and customer-specific investigations.

"As the industry's understanding of nitrosamine risk continues to evolve, manufacturers are moving beyond broad risk assessments toward more product-specific decision-making," said Bart Pelgrims, Vice President, R&D, Lonza Capsugel. "That shift requires not only reliable analytical data,

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but also the ability to interpret that data in the context of drug formulation, manufacturing processes and regulatory requirements. By bringing these capabilities together, we help customers develop risk management strategies that are both scientifically robust and practical to implement at scale."

Regulatory authorities worldwide require marketing authorization holders to assess and mitigate potential nitrosamine risks. Acceptable daily intake limits for individual nitrosamine impurities are translated into product-specific concentration limits for patient safety. These measures may include nitrite concentration limits on excipients depending on the product composition.

The new offering expands Lonza Capsugel's portfolio of scientific and technical services, providing manufacturers with a comprehensive approach to nitrite evaluation and support for product-specific nitrosamine assessments.

For more information, visit www.capsugel.com.

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