

LIFE SCIENCES

LIFE INSPIRED, QUALITY DRIVEN

NITROSAMINE TESTING SOLUTIONS



The presence of the nitrosamine, N-nitrosodimethylamine (NDMA), in certain sartan API's has resulted in several regulatory warnings and recall of contaminated products. Concerns over the presence of this class of genotoxins has now widened to include other medicines such as the well-known diabetes drug, Metformin. The US Food & Drug Administration (USFDA) and European Medicines Agency (EMA) have responded by publishing documents for the pharmaceutical industry that address requirements and limits related to nitrosamine contaminants. Pharmaceutical Manufacturers are now taking a pro active approach to risk assessment and mitigation of genotoxic contaminants within global pharmaceutical supply chains. Central to these activities is a coordinated analytical capability to identify and quantify contaminants across global geographies and regulatory zones.

SGS

WHY USE SGS

SGS Life Sciences has considerable expertise in the method development of nitrosamine determination in pharmaceutical products. SGS has established a specific method for NDMA which can be applied to various different matrices. Alternatively, a platform method, based on trace-level detection by LC-MSMS, is also available and provides rapid and simultaneous determination of up to ten different, targeted nitrosamines. Although with more limited application, the SGS network is also able to support specialist methodologies such as GC-MSMS. Our experience in optimizing extraction

procedures allows application of these methods to drug products, API's, and raw materials.

By establishing these nitrosamine methods within centers of expertise across a global laboratory network, SGS can provide an unrivaled service offering that incorporates a harmonized methodological approach together with flexible management of capacity and capability requirements.

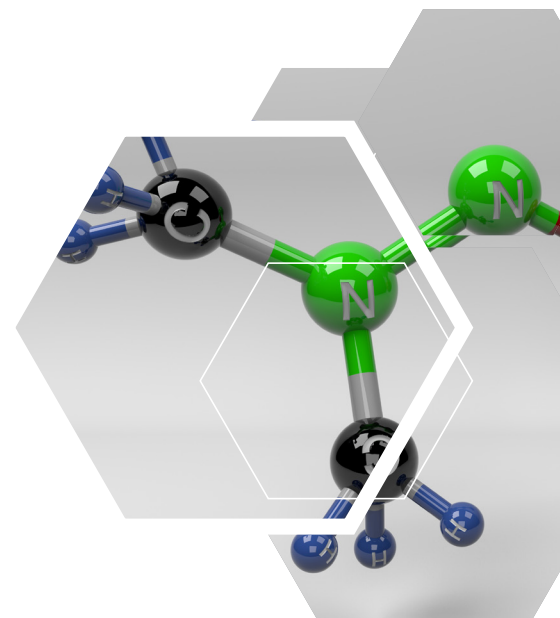
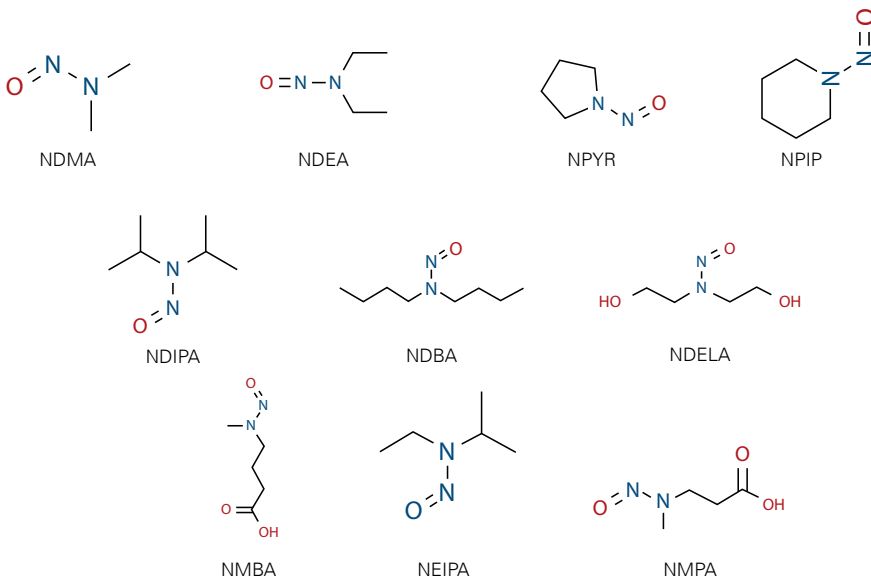
SGS offers a variety of partnership models and can collaborate in such testing programs using fee-for-service to outsourced staffing models all exploiting resources of the SGS network.

ABOUT SGS

SGS is the world's leading inspection, verification, testing and certification company. We are recognized as the global benchmark for quality and integrity. With more than 94,000 employees, we operate a network of more than 2,600 offices and laboratories around the world.

Our conveniently located network of laboratories and clinical trial facilities offer an array of integrated services and expertise, providing you with the knowledge, flexibility and ability to scale.

- Wide-range of laboratories and clinical research sites and qualified partners.
- Size and diverse testing capabilities matching biologics and small molecules needs
- International network across America, Europe and Asia-Pacific



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WHEN YOU NEED TO BE SURE

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