



Nitrosamine testing solutions

Health Inspired,
Quality Driven.

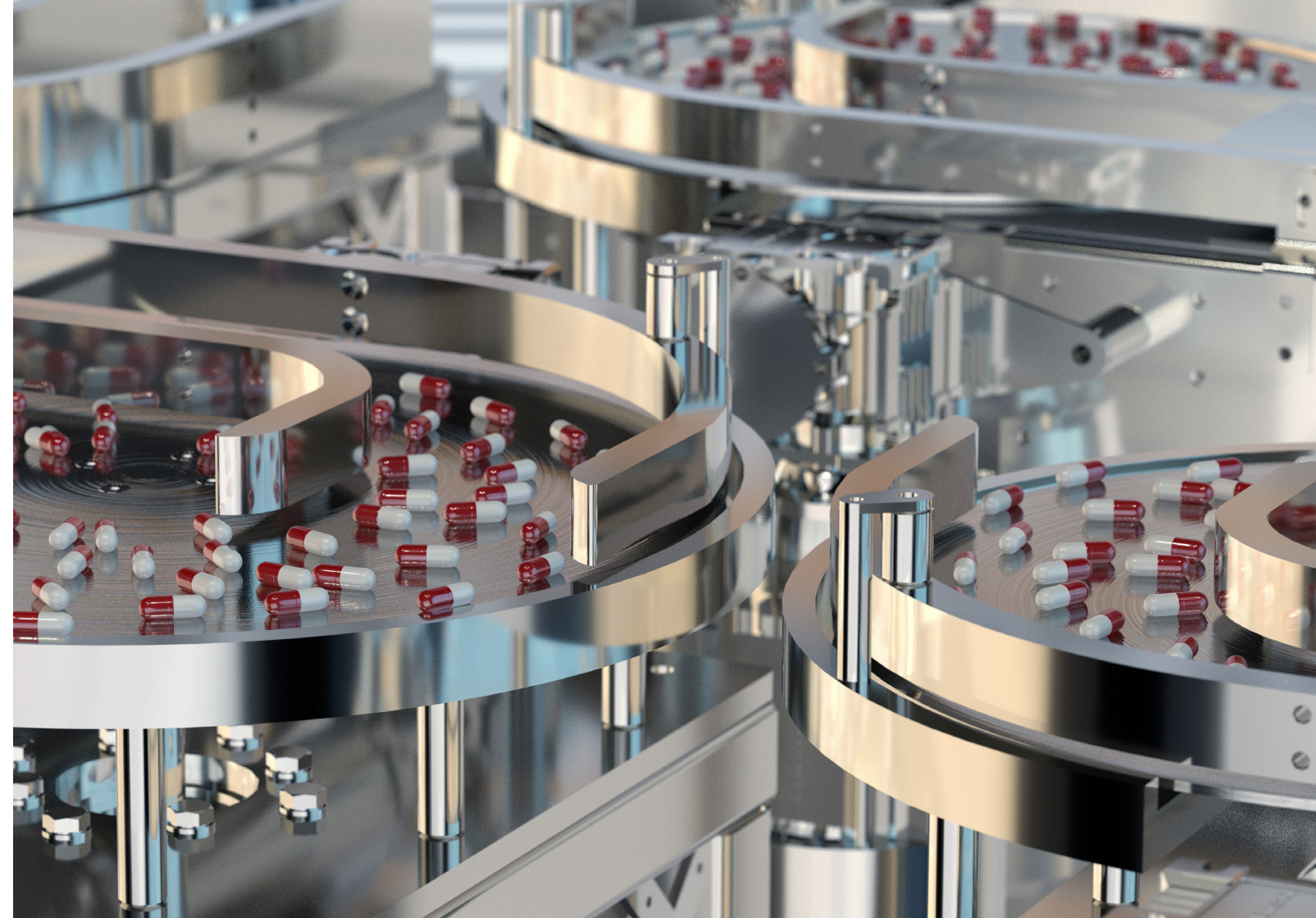
SGS

The nitrosamine challenge

We have developed advanced analytical solutions to identify and quantify all nitrosamine contaminants, including challenging Nitrosamine Drug Substance-Related Impurities (NDSRIs). This class of contaminants – unique to each drug substance – requires specialized expertise to develop tailored analytical methods for effective monitoring.

The U.S. Food and Drug Administration emphasizes the importance of control strategies to prevent or limit nitrosamine impurities in pharmaceutical products, including – risk assessment, testing, control measures, and where necessary, process improvement.

U.S. Food and Drug Administration, 2023



Our tailored solutions

- **Flexible testing models**

We offer a variety of partnership and service models to match every testing program specificity – from classical fee-for-service, to scientific staffing models and end-to-end program management

- **Extraction procedure optimization**

We can develop tailored methods for detecting any relevant nitrosamines – from simple compounds such as NDMA and NDEA, to structurally complex NDSRIs – across a wide variety of drug products, drug substances and raw materials. Each method is optimized to achieve a limit of quantitation that aligns with the most recent acceptable daily intake levels set by regulatory agencies, including the US Food and Drug Administration (US FDA), Health Canada and the European Medicines Agency (EMA)

- **Sample logistics**

We manage the seamless shipment of samples from your manufacturing site to one of our global laboratories through a trusted, audited partner. Simply send your samples and await your nitrosamine results

- **Scalable testing**

Whatever your testing needs – whether it is a few lots per year or hundreds per month – our solutions are tailored to your production scale

- **Fast turnaround times**

From sample collection to results, we can deliver within two weeks

WHY USE SGS?

We have developed a network of center of excellence laboratories across all regions to better serve our clients. Our experts specialize in method development using mass spectrometry equipment to ensure complete accuracy and reliability



A global network

SITE LOCATION	EUROPE			NORTH AMERICA				ASIA PACIFIC	
	Geneva, CH	Aachen, DE	Cork, IE	Mississauga, CA	Markham, CA	Fairfield, US	Lincolnshire, US	Mumbai, IN	Shanghai, CN
EQUIPMENT	LC-MS/MS and GC-MS/MS (triple quadrupole and high-resolution mass spectrometer)								
TYPE OF NITROSAMINES	Nitrosamine & Nitrosamine Drug Substance-Related Impurities (NDSRIs)								
ANALYTICAL SERVICE SOLUTIONS	Method development, transfer, validation & batch release								
SUPPLY CHAIN SOLUTIONS	Sample logistics support from client production sites to SGS laboratories								
ACCREDITATION	GMP and US FDA registered								



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Contact us

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When you need to be sure