



Nitrosamine Testing Solutions

Health Inspired, Quality Driven.

SGS

Identification & quantification

The nitrosamine challenge

Our network of laboratories develop analytical solutions to identify and quantify all nitrosamine contaminants, including the challenging nitrosamine drug substance related impurities (NDSRIs). This class of contaminants, specific to each drug substance, demands dedicated expertise, to fully characterize contaminants with a view to developing an analytical solution to monitor them.

Our solutions

OPTIMIZING EXTRACTION PROCEDURES

Our experience enables us to reach the relevant limit of quantitation in drug products, drug substances and raw materials (based on the acceptable daily intakes defined by the USFDA and EMA). As a result, a method for any relevant nitrosamine (from generic small nitrosamines such as NDMA, NDEA, etc. to NDSRI's) can be developed specifically for a product. In addition, to help assess materials or the formation of

nitrosamines we have methods for nitrite determination in API/excipients and drug products with LOQ 10-50ppb.

COLLABORATE IN TESTING PROGRAMS

We offer a variety of partnership models and collaborate in testing programs using fee-for-service to outsource staffing models.

SAMPLE LOGISTICS

Using our preferred audited partners, we provide sample shipment management from clients' manufacturing sites to SGS laboratories all over the world.

Why use SGS?

SGS has developed a network of center of excellence laboratories across all regions to better serve our clients. Our experts specialise in method development using mass spectrometry equipment, for complete accuracy and reliability.

A global network

	EMEA			NAM			SEAP	NEA
	Geneva	Aachen	Ireland	Mississauga	West Chester	Markham	Mumbai	Shanghai
Equipment	LC-MS/MS (triple quadrupole and high-resolution mass spectrometer)	LC-MS/MS (triple quadrupole and high-resolution mass spectrometer) GC-MS	GC-MS/MS (triple quadrupole)	LC-MS/MS (triple quadrupole and high-resolution mass spectrometer)	LC-MS/MS (triple quadrupole and high-resolution mass spectrometer)	LC-MS/MS (triple quadrupole and high-resolution mass spectrometer) GC-MS/MS (triple quadrupole)	LC-MS/MS (triple quadrupole and high-resolution mass spectrometer)	LC-MS/MS (triple quadrupole and high-resolution mass spectrometer) GC-MS
Type of nitrosamines	Nitrosamines & NDSRI							
Types of method	Targeted and screening	Targeted	Targeted	Targeted and screening	Targeted and screening	Targeted	Targeted and screening	Targeted
Additional services	Method Development, Transfer, Validation & Batch Release Sample logistics support from clients' site to our labs							
Accreditation	GMP and FDA Registered							

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Contact us

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WHEN YOU NEED TO BE SURE

SGS