

Pharmaceutical manufacturers are increasingly facing compliance challenges in worldwide markets from complexities of regulatory business requirements. Here, non-compliance has a profound effect on cost, brand reputation, and, ultimately, the lives of their customers or patients.

Safe. Compliant. Efficient

SGS assists the global health science industry by providing industry leading solutions in testing and expertise within regulated environments. This allows pharmaceutical companies to deliver products and formulations that are high-quality, safe and compliant while keeping pace for a fast go-to-market.

Extractables & Leachables

Drug manufacturers are required to demonstrate that no toxic or harmful substances migrate from packaging materials into a drug during its expected product shelf life. Similarly, in single-use systems (SUS) and other consumables used in pharmaceutical production, there is significant interest in the investigation of potential leachables that end up in the finished drug product.

Our E&L services

- Analytical Chemistry
- Consultancy E&L Strategies
- Qualification Services
- Extractables & Leachables (Container, Medical Device, SUS)
- · Leachables Screening
- Method Development & Validation
- Stability Studies

Nitrosamine Testing Services

For consumer safety, regulators recommend that drug manufacturers and providers should test their products and ensure that effective measures are taken to prevent impurities like nitrosamines from being present in these. We assure the safety of your drug products, raw materials and active pharmaceutical ingredients (APIs) with accurate tests to detect the presence of nitrosamines.

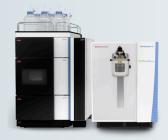
Volatile and Semi-Volatile Organic Compound (VOC & SVOC)

Elemental Impurities





Non-Volatile Organic Compound (NVOC)



THERMO ORBITRAP EXPLORIS 120 (LCMS)



AGILENT ICP MS 7800

Non-Volatile Organic Compound (NVOC)



THERMO TSQ QUANTIS TRIPLE QUAD LCMS/MS

Our cGMP compliant laboratories use technologies that detect ultra trace levels of leachables.

Using LC-MS/MS GC-MS/MS and LC-HRMS capabilities, we can detect the presence of nitrosamine traces at recommended LOD/LOQ levels and specifications.

Advanced Analytics

Health Inspired, Quality Driven.

Contact us





in sgs.com/healthcommunity



