

LIFE SCIENCES

ANALYTICAL CHEMISTRY SERVICES

LIFE INSPIRED, QUALITY DRIVEN



SGS

YOUR GLOBAL LABORATORY NETWORK FOR ANALYTICAL CHEMISTRY

Delivering a product from discovery to the market is a long and often difficult process filled with a great number of scientific, safety and regulatory challenges. From early discovery to final product release, SGS offers a broad portfolio of high quality, analytical chemistry services using advanced methods and instrumentation.

SGS leverages its conveniently located network of laboratories present in North America, Europe and Asia-Pacific, to deliver harmonized solutions to local markets as well as international pharmaceutical and biotechnology firms.

Our recognized experts assist in providing effective and efficient solutions for R&D, analytical development, and quality control testing, helping to expedite the molecule to market.

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 89,000 employees, we operate a network of more than 2,600 offices and laboratories around the world.

WHY WORK WITH SGS LIFE SCIENCES?

RAPID, RELIABLE & ACCURATE RESULTS

When it comes to the pursuit of developing life-changing solutions, there's no such thing as one size fits all; our studies are engineered to your unique needs whether they be routine, compendium testing or complex, multifaceted projects. We guarantee reliable and accurate testing using state-of-the-art facilities, equipment and techniques and offer integrated advanced drug development solutions.

EXPERT GUIDANCE

Reduce costs and improve profits by bringing your products to market quickly and safely; let our experienced consulting and project management teams develop a market access strategy with specific tools and tactics to plan, implement, and monitor your activities while reducing errors and potentially costly mistakes that can delay bringing your product to market.

PARTNERSHIP & GROWTH

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

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

ANALYTICAL CHEMISTRY CAPABILITIES

METHOD DEVELOPMENT & VALIDATION

- Method development for identity, assay and purity of drug products, APIs and degradation products
- Phase appropriate method validation according to ICH guidelines and/or customer requirements
- Verification of accuracy and suitability of the developed method
- Development and validation of stability indicating methods
- Analytical method transfer
- Re-development and re-validation
- Cleaning validation studies
- Method development for identity, assay and purity of drug products, APIs, degradation products and leachables

DISCOVERY

- Identification of unknowns
- Extractable investigations
- Structural characterization
- In-vitro metabolomics
- Bio-marker screening / identification

ROUTINE CHEMISTRY

- Assay and purity (e.g. chromatography, titration, limit tests)
- Identity (e.g. spectroscopy, chromatography, spectrometry)
- Dissolution test (on line / off line)
- Pharmaceutical water analysis (e.g. TOC)
- Water content (loss on drying, KF titration)
- Disintegration
- Appearance (e.g. clarity, opalescence)
- pH and conductivity
- Pharmacopeia testing
- Osmolality, osmolarity
- Melting point, boiling point etc.
- Viscosity, rheology
- Uniformity of mass
- Leachable analysis

COMPARABILITY

- Biopolymer sequencing
- Primary to tertiary structure characterization
- Post-translational modifications
- Bio equivalence
- Impurity profiling

STABILITY TESTING

- Long term stability studies
- Short term, accelerated studies
- Follow-up stabilities
- Photostability testing
- All ICH conditions + specific conditions
- Fully controlled and monitored
- All systems with 24 H / 7D - monitoring and alert system
- Validated monitoring system, 21 CFR part 11 compliant
- Back-up chambers available
- Comprehensive documentation



APPLICATIONS

The network of experts at SGS have a broad range of experience in the analysis of a wide range of API's, excipients, ancillary products, extractables, and many other chemical-types used in the development of bio/pharmaceutical therapeutics.

- Antibiotics
- Steroids
- Alkaloids
- Nitrosamines
- Heavy metals
- Antihistamines
- Amino acids
- Nucleic acids
- Anions
- Vitamins
- Lipids
- Glycosides
- Peptides
- Oligonucleotides
- Oligosaccharides
- Sugars
- Proteins
- Synthetic polymers
- Amphetamines
- Vaccines
- Analgesics
- Chelating agents
- Diuretics
- Enzyme inhibitors
- Glucocorticoids
- Enzyme inhibitors
- Glucocorticoids
- Insecticides
- Surfactants
- Anti-foam agents
- Minerals
- Neurotoxins
- Opioids
- Gasses
- Anesthetics
- Emulsifiers
- Cytostatic products
- Cytotoxic products

HARMONIZED QUALITY MANAGEMENT SYSTEMS

SGS complies with the requirements of all global regulatory authorities necessary for approval, and operates from GMP / GLP / GCP facilities.

OUR 6 LAYER SYSTEM:

- Global quality manual
- Global policies
- Global SOPs
- Local quality manual
- Local SOPs
- Site quality documents

BASED ON GXP PRINCIPLES:

- Incorporates additional certifications on local levels
- ISO 17025
 - ISO 9001
 - WHO (prequalification scheme)

GLOBAL REGULATORY AUTHORITIES WE WORK WITH INCLUDE:

- FDA (US, China, India)
- EMA / MHRA / FAMHP
- Health Canada
- Swiss Medic
- ANSM
- WHO

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WHEN YOU NEED TO BE SURE

