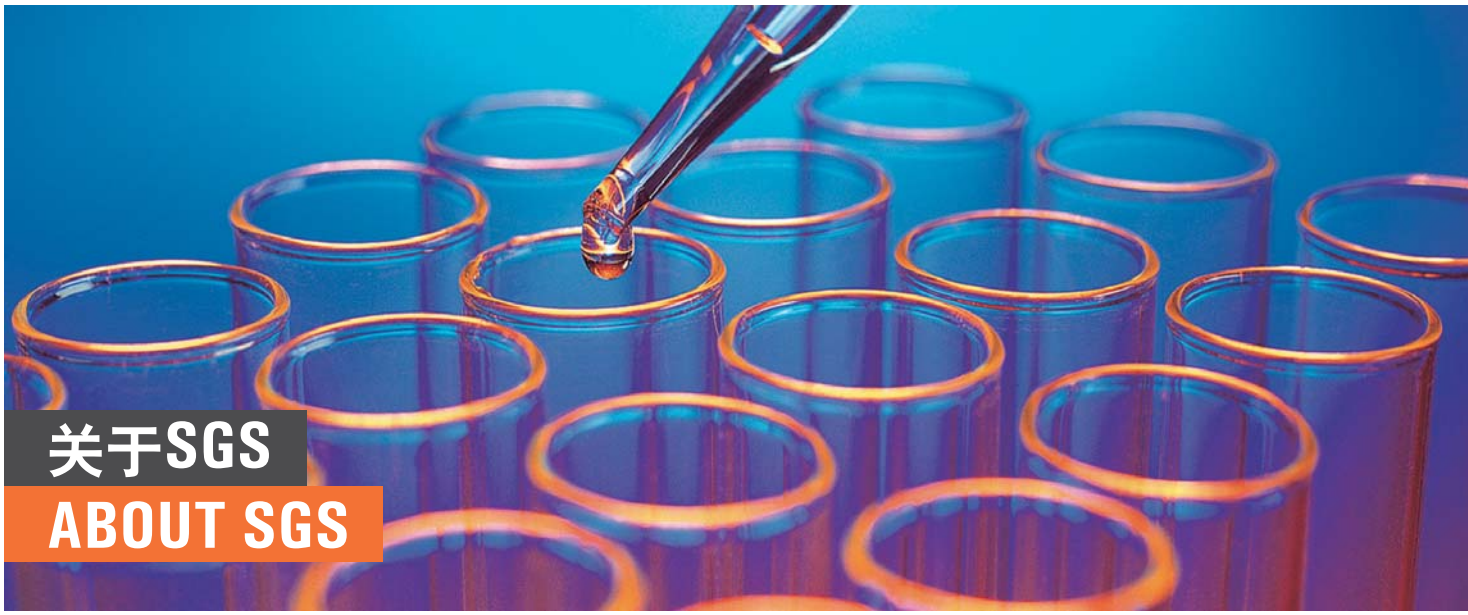
生命科学服务 — 药品及包装材料检测服务

LIFE SCIENCE SERVICES
TESTING SERVICE FOR DRUG AND PACKAGING

ANALYTICAL & TESTING NETWORK
WORKING FOR YOU

SGS

When you need to be sure



关于SGS
ABOUT SGS

SGS是国际公认的测试、检验和认证机构，是公认的品质与诚信的全球基准。SGS集团在世界各地共有99,600多名员工，分布在2,600多个分支机构和实验室，构成了全球性的服务网络。

SGS is the world's leading inspection, verification, testing and certification company. Recognized as the global benchmark for quality and integrity, with more than 99,600 employees and operates a network of over 2,600 offices and laboratories around the world.

通标标准技术服务有限公司是SGS集团和隶属于原国家质量技术监督局的中国标准技术开发公司共同建成于1991年的合资公司，在中国设立了90个分支机构和200多间实验室，拥有16,000多名训练有素的专业人员。

SGS-CSTC Standards Technical Services Co., Ltd. was founded in 1991 as a joint venture between SGS Group and China Standard Technology Development Corp., under the State Administration of Quality Technical Supervision. SGS-CSTC boasts over 200 laboratories and 90 branches with over 16,000 professionals.

SGS生命科学实验室的运作依循cGMP、ISO 17025或者ISO 9001质量体系，并通过美国食品药品监督管理局(US FDA)及当地管理机构的现场核查。SGS生命科学部为制药及医疗器械相关行业提供专业、独立的测试研究服务，为我们的客户、员工、股东和世界各地的患者创造价值、以确保药品/医疗器械品质安全。

SGS's life sciences laboratories operate according to the highest quality standards (cGMP, ISO 17025 or ISO 9001) and passed audits from US FDA and local regulatory authorities. The life sciences mission at SGS is to safeguard the quality of medicines/medical devices by providing professional and independent services in clinical research, biologics characterization, analytical development, and quality control testing of pharmaceuticals, biopharmaceutical and medical devices creating value for our clients, employees, shareholders and patients worldwide.

遍布全球的分析实验室网络
GLOBAL NETWORK OF CONTRACT ANALYTICAL LABS

SGS生命科学致力于为生物/制药和医疗器械行业提供检验和实验室服务，服务网络遍及欧洲，美洲和亚洲12个国家，共有30个GMP/GLP合规实验室，3,000多名员工。

With more than 3,000 employees, a state-of-the-art clinical pharmacology unit and the global network of GMP/GLP-compliance laboratories, SGS serves the pharmaceutical, biotechnology and medical device industries across Europe, the Americas and Asia with 30 labs located in 12 countries.

AMERICAS

CANADA
- Toronto (Markham, ON)
- Toronto (Mississauga, ON)

USA
- Chicago (Lincolnshire, IL)
- New Jersey (Fairfield, NJ)
- Philadelphia (West Chester, PA)
- Boston (Hudson, NH)

EUROPE

BELGIUM
- ● Brussels (Wavre, Zellik)

FRANCE
- Paris (Villeneuve-la-Garenne)
- ● Poitiers

GERMANY
- Aachen
- Berlin
- Berlin
- Frankfurt (Taunusstein)
- Munich
- Wiesbaden

AUSTRIA
- Wörgl

IRELAND
- Cork (Ringaskiddy)

SWITZERLAND
- Geneva (Plan-les-Ouates)
- ● Basel (Birsfelden)

UNITED KINGDOM
- ○ Chester (Deeside)
- Glasgow

CZECH REPUBLIC
- Prague

ASIA

CHINA
- Shanghai (Xuhui)
- ● Shanghai (Pudong)

INDIA
- Navi-Mumbai

- QC / R&D
- ● Bioanalysis
- ○ Formulation & CDMO
- Medical / Clinical

中国
- 上海徐汇
  - 成立于2006年
  - 7000m²实验室
  - 300⁺本地员工
  - cGMP，ISO 17025
  - FDA现场核查
- 上海浦东
  - 成立于2022年
  - 2000m²实验室
  - GLP, ISO 17025

CHINA
- SHANGHAI Yishan Rd
  - Since 2006
  - 7000m²
  - Over 300 employees
  - cGMP，ISO 17025
  - FDA inspected
- SHANGHAI Pudong
  - Since 2022
  - 2000m²
  - GLP, ISO 17025

基于cGMP/GLP的质量管理体系
QUALITY MANAGEMENT SYSTEM BASED ON cGMP/GLP

SGS符合国际监管机构的准入要求

质量管理系统包含6个方面：
- 总部质量手册
- 总部政策
- 总部标准操作程序
- 本地质量手册
- 本地标准操作程序
- 本地质量文件

遵照GxP法规和本地其他的体系认证：
- ISO 17025
- ISO 9001
- WHO (资格预审方案)

SGS与国际监管机构合作：
- US FDA
- EMA/MHRA
- Health Canada

COUNTRY	LABORATORIES	QUALITY MANAGEMENT SYSTEM	ISO STANDARD	US-FDA REGISTERED	US-FDA INSPECTED
CANADA	Toronto (Markham)	GMP	–	•	•
CANADA	Tronto (Mississauga)	GMP	9001/13485	•	•
USA	Chicago (Lincolnshire)	GMP/GLP	9001	•	•
USA	New Jersey (Fairfield)	GMP	9001	•	•
USA	Philadelphia (West Chester)	GMP	–	•	•
BELGIUM	Brussels (Wavre)	GMP/GLP/GCP	17025	•	•
BELGIUM	Brussels (Zellik)	GMP	–	–	–
FRANCE	Paris (Villeneuve La Garenne)	GMP	–	•	•
FRANCE	Poitiers	GLP/GCP	–	•	•
GERMANY	Berlin	GMP	–	•	•
GERMANY	Frankfurt (Taunusstein)	GMP	17025	•	•
GERMANY	Wiesbaden	R&D	–	–	–
SWITZERLAND	Geneva	GMP/GLP/GCP	–	•	•
UK	Glasgow	GMP/GLP	–	•	•
CHINA	Shanghai	GMP/GLP	17025	•	•
CHINA	Qingdao	–	17025	–	–

分析方法开发&质量控制测试
ANALYTICAL DEVELOPMENT & QUALITY CONTROL TESTING

SGS已为制药行业提供数十年高质量的分析测试服务。我们提供广泛的质量控制检测服务，以支持药物的研究，注册与生产。SGS提供定制化的解决方案，以满足客户的特殊需求。

SGS has been offering high quality analytical testing services to the pharmaceutical industry for decades. We perform a wide range of quality control testing services to support drug research, registration and production. Biopharmaceutical companies use many of the same services, SGS delivers customized solutions to accommodate your unique needs. We perform a variety of tests that are client-specific, particularly in the area of analytical chemistry.

SGS生命科学为药品全生命周期提供专业服务
PROVIDE PROFESSIONAL SERVICES FOR DRUG LIFE CYCLE

SERVICES		Preclinical	Exploratory Development	Confirmatory Development	Post-Approval	Routine Production	Trade Distribution
实验室服务 LABORATORY SERVICES	质量控制 稳定性研究及分析方法开发 Quality Control, Stability Studies & Analytical Development	方法研发、优化及验证 Method Development, Optimization & Validation					
		GMP化学分析 – 质量放行 GMP Analytical Chemistry – QC Release					
		微生物检测 Microbiological Testing					
		可提取物与浸出物 – 包装测试 Extractables & Leachables – Container Testing					
		稳定性研究(ICH)及放置 Stability Studies (ICH) & Storage					
		环境监控（气体、大气、水及物体表面） Environmental Monitoring (Gas, Air, Water & Surface)					
		设施/设备性能确认及校准服务 Facilities Qualification & Calibration					
	大分子结构表征 生物安全性 Biologics Characterization Biosafety	生物安全性测试 – 细菌内毒素、病毒、支原体 Biosafety – Bacterial Endotoxin, Virus, Mycoplasma					
		病毒学 – 细胞、病毒建库及表征 Virology – Cell Bank and Virus Seeds Characterization					
		电镜技术 Electron Microscopy Studies					
		细胞及分子生物 – qPCR分析 Cell & Molecular Biology – qPCR Assays					
		蛋白质及多肽分析与定量 Protein, Peptide Analysis & Quantification					
		产品表征 Product Characterization					
		宿主细胞杂质检测与鉴别 Host Cell Impurity Testing & Identification					
		细胞水平分析和毒性测试(ATCC & CDC) Cell-Based Assays, Cytotoxicity (ATCC & CDC)					
	生物分析 Bioanalysis	生物标记 – 免疫原性及抗体中和测试 Biomarkers – Immunogenicity and Neutralizing Antibody Testing					
		生物分析 – PK/PD分析 – 大小分子 – ADME – ^{14}C示踪 Bioanalysis – PK/PD Mass Spectrometry – Large & Small Molecules – ADME – ^{14}C Trials					
临床研究 CLINICAL RESEARCH	临床试验 Clinical Services	试验监测与管理 — 生物统计 Trial Monitoring & Management - Biometrics					
		药物安全及警戒 — 法规咨询 Drug Safety & Pharmacovigilance - Regulatory Consulting					
		药效、药代动力学建模及模拟 PK/PD Modeling & Simulations					

分析服务
ANALYTICAL SERVICES

理化测试

- 含量及纯度(色谱法，光谱法，滴定法等)
- 鉴别(色谱法，光谱法，常规理化方法等)
- 制剂相关(溶出度、装量、重量差异、可见异物等)
- 制药用水
- 物理化学性质(密度，粒度，粒径分布，pH，黏度，摩尔渗透压等)
- 阴离子、阳离子
- 无机杂质(元素杂质、炽灼残渣等)
- 水分(干燥失重，卡尔费休法等)
- 有机杂质(环氧乙烷、二氧六环、乙二醇、二甘醇等)
- 性状(外观，颜色，澄清度，熔点等)
- 蛋白质结构表征(一级结构、高级结构、修饰分析)
- 不溶性微粒

微生物测试

- 生物负载&微生物限度
- 无菌
- 细菌内毒素
- 抑菌效力测试
- 培养基质控试验
  (培养基pH值，适用性检查，灵敏度检查)
- 环境监控
- 微生物检定
  (微生物形态，生化和DNA特征序列鉴定)
- 生物指示剂芽孢计数
- 消毒剂验证
- 包装密封性研究(微生物挑战法)
- 支原体测试
- 细菌回复突变
- 透气包装材料微生物屏障
- 过滤器除菌验证

生物测试

- 细胞毒性测试
- 人血白蛋白测试
- 白介素测试
- 血红蛋白测试
- 细胞培养基生长测试
- 重组胰蛋白酶活性(效价)
- 过氧化值检测
- DNase和RNase测试

PHYSICO-CHEMICAL TESTING

- Assay and Purity (Chromatography, Spectroscopy, Titration, etc.)
- Identification (Chromatography, Spectroscopy, Routine physiochemistry method, etc.)
- Foreign related (Dissolution, Filling, Weight Variation, Visible Foreign Matter, etc.)
- Water for Pharmaceutical
- Physiochemical Properties (Density, Particle Size, Particle Size Distribution, pH, Viscosity, Molar osmolality, etc.)
- Detection of Anion and Cation
- Inorganic Impurities (Elemental Impurities, Ignition Residues, etc.)
- Moisture (Loss on Drying, Karl Fischer Method, etc.)
- Organic Impurities (Ethylene Oxide, Dioxan, Glycol, Diglycol, etc.)
- Characters (Appearance, Colour, Clarity, Melting Point, etc.)
- Protein Structure Characterization (Primary Structure, Higher Order Structure, Modification Analysis)
- Particulate Matter

MICROBIOLOGY TESTING

- Bioburden & Microbial Limit
- Sterility
- Bacterial Endotoxin
- Antimicrobial Effectiveness
- Quality Control of Culture Media
  (pH, Suitability Tests, Sensitivity Test)
- Environment Monitoring
- Microbial Identification
  (Morphological, Biochemical, Gene Sequences)
- Biological Indicators Spore count
- Disinfectant Validation
- Package Integrity Evaluation (Microbial Ingress Challenge)
- Mycoplasma
- Ames/Bacterial Reverse Mutation
- Microbial Barrier for Porous Packaging Materials
- Validation of Sterilization Filter

BIOANALYSIS TESTING

- Cytotoxicity
- Human Albumin
- Interleukin
- Hemoglobin
- Cell Culture Media Growth Promotion
- Recombinant Trypsin Activity (Assay)
- DNase and RNase

项目研究
PROJECT STUDY

方法开发与验证
- 杂质(有关物质、基因毒杂质、元素杂质、溶剂残留、生物工艺残留等)
- 依照ICH指南或客户需求进行方法验证
- 药典方法的方法确认
- 稳定性测试方法的开发和验证
- 方法转移
- 方法再验证

药物接触系统相容性研究
- 容器/内容物相互作用
  - 可提取物
  - 浸出物/迁移物研究
- 包装材料测试(塑料、胶塞等)
  - 鉴别
  - 限度测试
  - 细胞毒测试
  - 重金属
  - 性能测试
  - 水蒸气透过率
  - 密封性测试
  - 微生物屏障

稳定性研究
- 长期稳定性研究
- 影响因素试验
- 加速稳定性研究
- ICH放置条件或其他指定要求
  - 24小时在线电子记录仪和报警系统
  - 经过验证的监控系统符合21 CFR part 11要求
  - 随时可用的稳定性备用箱
  - 全面的文件和记录

药物警戒服务
- 药物警戒体系构建、维护和培训
- 上市后安全性信息来源监测
- 个例报告管理
- 产品上市后安全性相关计划和报告的撰写/审核
- 药品安全性信号检测
- 药物警戒翻译服务
- 临床试验期间药物警戒

现场服务
- 设备验证
- 水系统验证
- 压缩气体验证
- 洁净室验证
- 空调系统验证
- 计算机化验证

METHOD DEVELOPMENT & VALIDATION
- Impurities (Related Substance, Genotoxic Substance, Elements, Residual Solvents, Bioprocess Residue etc.)
- Method Validation According To ICH Guidelines and/or Customer Requirements
- Verification of Pharmacopeia Method
- Method Development and Validation of Stability Test
- Method Transfer
- Method Re-Validation

STUDY ON COMPATIBILITY OF DRUG CONTACT SYSTEM
- Container/Content Interaction
  - Extractables and Leachables
  - Migration Studies
- Container Testing (Glass, Plastics, Rubber Closure,Etc.)
  - Identification
  - Limit Tests
  - Cytotoxicity Test
  - Heavy Metals
  - Performance Tests
  - Water Vapor Permeation
  - Leak Testing
  - Microbial Barrier

STABILITY STUDY
- Long-Term Testing
- Affecting Factor Testing
- Accelerated 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

PHARMACOVIGILANCE SERVICES
- Set up and maintenance of MAH pharmacovigilance systemis), and related training
- Surveillance of post-marketing safety information sources
- Processing and management of individual case safety reports (ICSPs)
- Writing/reviewing of various kinds of safety-related post-marketing plans and summary reports
- Safety signal detection of drugs
- Translation for pharmacovigilance
- Pharmacovigilance in clinical projects

ON-SITE SERVICE
- Equipment Validation
- Water System Validation
- Compressed Gas
- Cleanroom Validation
- Heating Ventilation and Air Conditioning
- Computerized System Validation

我们的承诺
OUR GUIDING PRINCIPLES

在SGS，我们以信任、质量、专业、可靠和诚信的价值观为指导。同时相信，当SGS从事生命科学事业时，我们的承诺等同于拯救生命。这意味着我们要对自己的行动与实践负责，以确保药品的安全及患者的健康。

At SGS, we are guided in all that we do by the values of trust, quality, expertise, reliability and integrity. We also believe that while we are in the business of life sciences, our commitment lies equally in life-saving. This mean taking responsibility for our own operations and practices to ensure we are protecting and preserving all life.

快速、安全、高效地准入市场
GET TO MARKET QUICKLY, SAFELY & EFFICIENTLY

我们的仪器设备
OUR EQUIPMENT AND TECHNIQUES

• 液相-串联质谱连用仪/飞行时间质谱仪	• LC-MS-MS/LC-MS/UPLC-Q-TOF-MS
• 高效液相色谱仪(紫外检测器、二极管阵列检测器、示差折光检测器、荧光检测器和电喷雾)	• HPLC (UV/DAD/RI/Florescence/CAD)
• 气相质谱联用仪	• GC-MS/GC-FID-MS
• 气相色谱仪(顶空进样器，火焰离子化、电子捕获、氮磷)	• GC (Headspace, FID, ECD, NPD)
• 稳定性试验箱	• Stability chambers
• 紫外-可见分光光度计/傅里叶红外分光光度计/荧光分光光度计	• UV-Vis/FT IR/Fluorescence
• 多功能滴定仪	• Titration & KF
• 粘度计	• Viscometer
• 离子色谱仪	• IC
• 溶出度测定仪	• Dissolution
• 原子吸收分光光度计	• AAS
• 电感耦合等离子体质谱仪/电感耦合等离子体发射光谱仪	• ICP-MS/ICP-OES
• API菌种鉴定系统	• API strain identification system
• 水活度仪	• Water activity
• 酶标仪	• Microplate Reader
• 激光散射粒度分布仪	• Laser Diffraction Particle Size Analyzer
• 不溶性微粒计数仪	• Liquid Particle Counter
• 聚合酶链式反应仪	• PCR
• 凯氏定氮仪	• Kjedahl Apparatus
• 圆二色光谱仪	• Circular Dichroic Spectrometer
• 毛细管电泳仪	• Capillary Electrophoresis Instrument
• 气相–飞行时间质谱仪	• GC-QTOF
• 氨基酸分析仪	• Amino-Acid Analyzer

以上仅为宣传列表，欲问询更多服务，敬请垂询
For your information only, please enquire for the services.

为什么选择SGS生命科学?
WHY TEST WITH SGS LIFE SCIENCES?

可靠&准确的结果

SGS为您提供专业的定制化解决方案。作为专业的第三方服务机构，我们为您提供可靠且准确的结果报告。

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. As a fully accredited, professionally recognized organization, you can rely on us to act as a neutral third party CRO and deliver unbiased results.

质量&合规性

SGS拥有40多年的经验，是一个值得信赖的公司，在满足法规要求和将项目推向市场方面具有极其丰富的经验。我们以卓越的质量和完善的流程而著称。

QUALITY & COMPLIANCE

Pushing the boundaries of innovation can be challenging. Identifying, analyzing and mitigating compliance risks are essential in developing an effective compliance program. With more than 40 years of experience, SGS is a trusted name with a history of excellence in meeting regulatory compliance and bringing projects to market. We have a reputation for clinical & laboratory quality & operational excellence (Harmonized QMS and Validation & Transfer methods, LIMS, Lean).

专业建议

SGS帮助您快速、安全地将产品推向市场，降低成本并提高利润；同时减少因错误导致产品延迟上市所产生的额外成本。

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 stakeholder engagement activities while reducing errors and potentially costly mistakes that can delay bringing your product to market.

合作与成长

以诚信著称的SGS是全球众多药物开发和生产企业的合作伙伴；我们便利的实验室网络提供一系列综合及专业服务。

PARTNERSHIP & GROWTH

With a long standing reputation for our integrity, many companies trust SGS as their global drug development partner; our conveniently located network of labs offer an array of integrated services and expertise, providing you with the knowledge, flexibility and ability to scale.

联系我们
CONTACT US

400-885-5558

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www.sgsonline.com.cn/industry/lifescience

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When you need to be sure