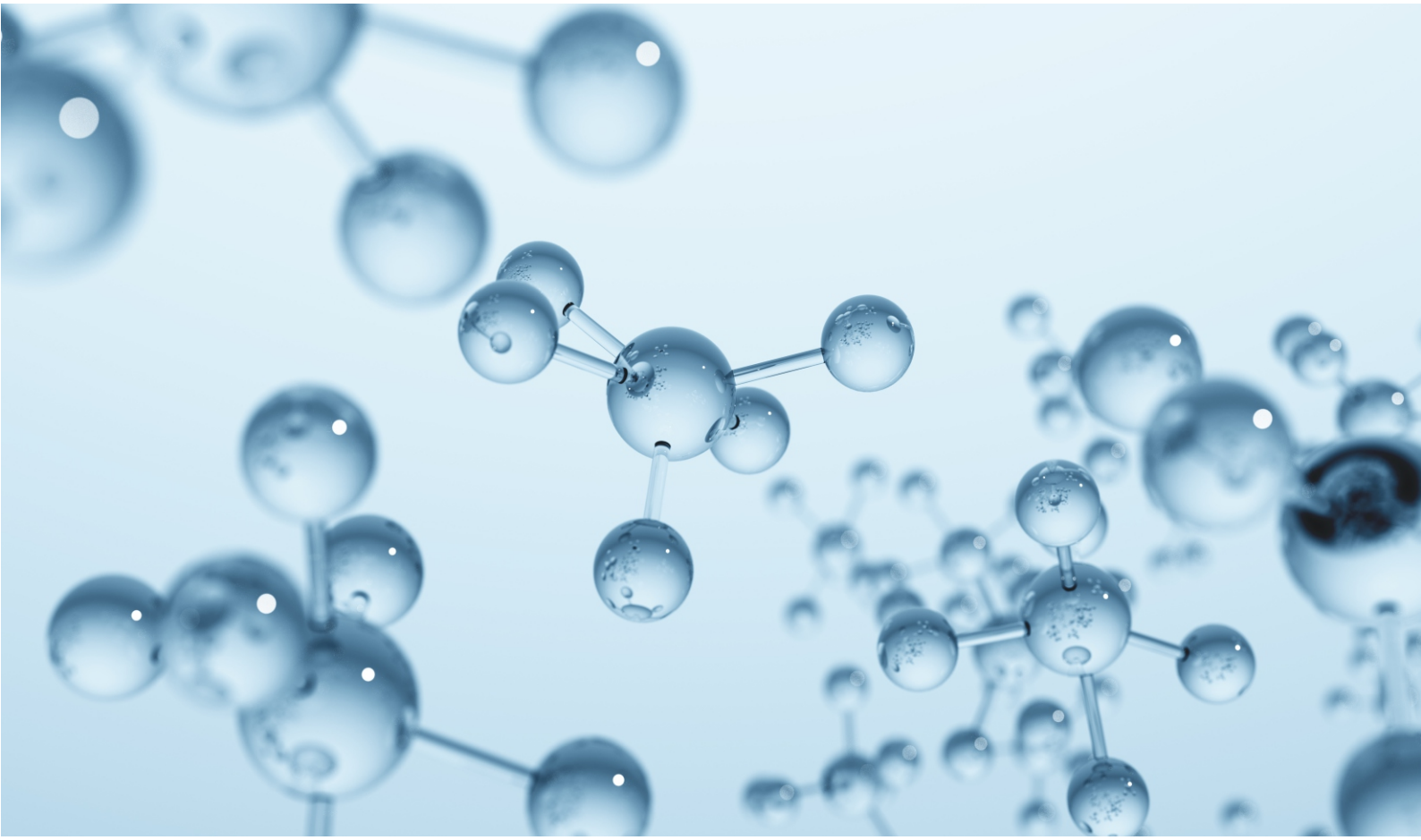
ASSURE PHARMA

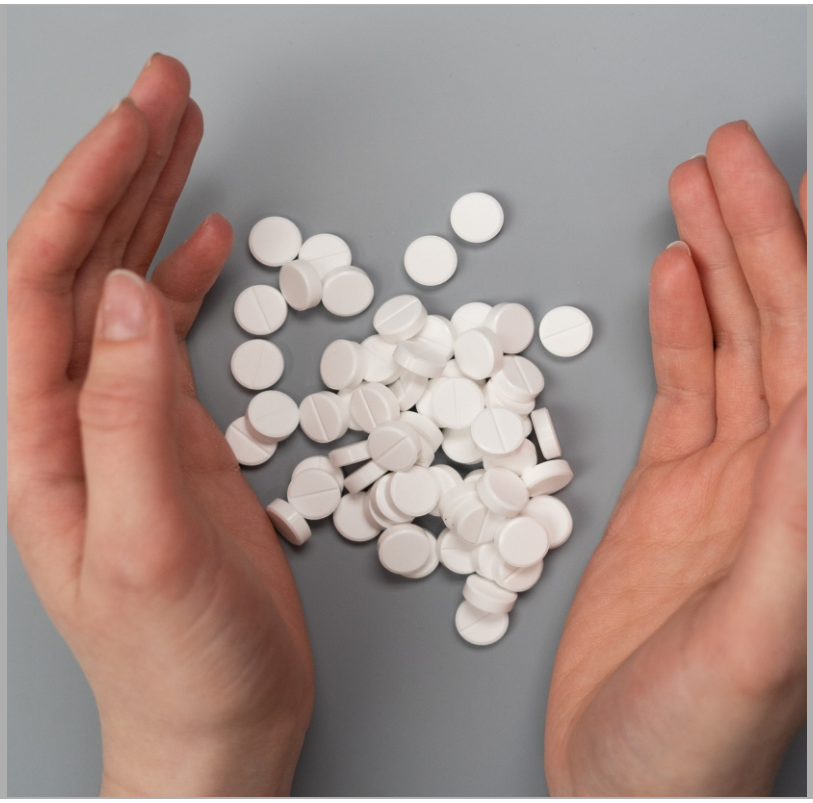


艾苏莱生物科技

Assure Pharma

江苏艾苏莱生物科技有限公司

Jiangsu Assure Pharma Biotechnology Co., Ltd.



助力安全药品诞生

Assist Innovation of Safe Medicine

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关于艾苏莱
About Assure Pharma

大健康领域的最后一道防线是药品，如何提供有效安全的药品是科学家和企业家核心的出发点。所有参与者都应该以尊重生命的态度，维护这份崇高的事业。艾苏莱的投资者和全体工作人员为此而聚在一起，也正基于此，我们努力工作，为安全药品的诞生和生产提供专业的相关安全性质量研究包括但不限于原辅包相容性研究、稳定性研究、基因毒性杂质研究等服务。

艾苏莱是由多位药物分析专家共同组建而成的优秀团队，致力于打造药物质量安全研究领域世界一流的CRO实验室。实验室投资4300万元人民币，面积3900平方米。实验室通过CMA/CNAS(ISO/IEC17025)认证认可，参照cGMP规范运行，已获得苏州药品协会颁发的GMP符合证明。我们提供的研究测试服务严格按照客户要求，参照现行版 ICH/FDA, ChP/USP/EP/JP/ISO/GB 等标准方法进行研究和测试，数据和报告可用于中国和全球新药申报。我们不断加强团队技术能力和质量体系建设，为客户提高研发效率、降低项目成本和规范整体流程。我们希望通过共同努力，成为客户信赖的药物质量安全研究首选CRO实验室，为人类的健康贡献我们的力量。

The last defense in the field of health is medicine. How to provide effective and safe medicine has always been the core concern of scientists and entrepreneurs. All participants should maintain this noble cause with a respect for life. Thus, the investors and the staff of Assure Pharma get together, thereupon, we work hard to provide professional services for the R&D and manufacture of safe drugs.The services we provide include but are not litimited to pharmaceutical stability study , compalibility study on container closure system, genotoxic impurity research and other services.

Assure Pharma is an excellent team formed by many analysis experts and is committed to building a world-class CRO laboratory in the field of pharmaceutical quality and safety research. The investment was 6 million dollars covering an area of 3,900 square meters. The laboratory has passed the CMA / CNAS (ISO/IEC17025) accreditation, operates in accordance with the cGMP rules, and has obtained the GMP compliance certificate issued by Suzhou Pharmaceutical Association. We provide research and testing services in strict accordance with customer requirements, with reference to the current version of ICH / FDA, ChP / USP / EP / JP / ISO / GB and other standard methods. Data and reports can be used for new drug applications in China and worldwide.We continuously strengthen the technical capabilities and quality system construction to improve R & D efficiency, reduce project costs and standardize the overall process for our customers. We hope that through joint efforts, we will become the first choice of CRO laboratory that our customers trust in pharmaceutical quality and safety research, and contribute our efforts to human health.

我们的实验室
Our Laboratory

艾苏莱公司的建筑面积4300平方米，其中实验室面积3900平方米，设有样品接收室、综合理化实验区、分析检测实验区、药品杂质制备纯化室、实验数据处理中心、微生物实验室（BSL 2）、样品暂存区、长期稳定性样品存储区、加速稳定性样品存储区、受控数据管理室、药品暗室、档案室等功能区。

艾苏莱实验室仪器设备等硬件投资3100万，覆盖药品质量研究及日常质控需求，我们在包材相容性研究、注射液质量控制、降解杂质研究、基因毒性杂质研究、药物杂质制备纯化等方面拥有世界一流的分析仪器设备。

Assure Pharma's laboratory is 3,900 square meters. It has many areas, such as sample receiving room, General physical and chemical experimental area, analysis and determination area, drug impurity preparation and purification room, experimental data processing center, microbiology laboratory (BSL 2), temporary sample storage area, long-term stability sample storage chamber, accelerated stability sample storage chamber, controlled data management room, dark room, archive room and other functional areas.

The investment in fixed asset of Assure Pharma Labs instruments and equipment is 6 million dollars, covering drug quality research and routine quality monitoring. We have world-class analytical instruments and equipment in the research of packaging material compatibility, injection quality control, degradation impurities study, genotoxic impurities, pharmaceutical impurity preparation and purification.

Mass Spectrometers 9 sets

- Thermo Orbitrap QE Focus
- SHIMADZU LC-MS/MS-8060×2
  LC-MS/MS-8045
- AB SCIEX 4000×2
- SHIMADZU GC-MS/MS-8040
- Agilent GC-MS/MS-7000
- Agilent ICP-MS 7800

LC/GC Spectrometers 23 sets

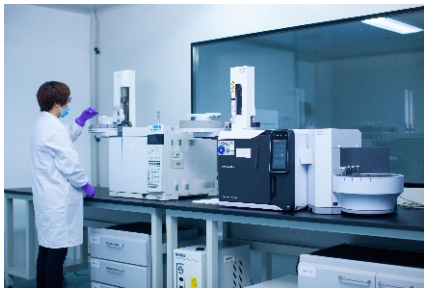
- Waters ACQUITY UPLC、Alliance 2695
- Agilent-1200 series、HS-GC 7890
- SHIMADZU LC-20 series、HS-GC2030

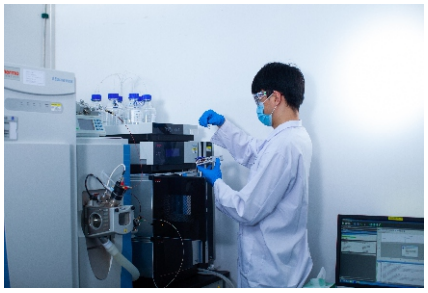
Spectral Instruments 6 sets

- Perkin Elmer 900T
- Agilent Cary 610 /Infrared Microscope System
- SHIMADZU UV-2600

General Instruments 61 set

- TOC (GE SIEVERS-M9)
- TA (Mettler TGA/DSC 3+)...





质量管理体系
Quality Management System

体系建设： CMA/CNAS(ISO/IEC17025) 认证认可实验室
cGMP 合规服务实验室
独立的QA体制

仪器设备： IQ/OQ/PQ 验证合格的专业仪器设备
年度例行验证、期间检查、计量校准
分级授权管理

数据管理： 符合 FDA 21 CFR Part 11 要求
网络版和数据库版工作站、审计追踪、数据异地备份
数据保密性管理

人员培训： 专业技能培训
合规培训
保密培训

分析方法： 参照 ICH/FDA/ChP/USP/EP/JP/ISO/GB 等标准方法
数据、报告可用于中国和全球新药申报

System: CMA / CNAS (ISO / IEC17025) Accreditation
cGMP Compliance Laboratory
QA System Independent

Equipment: IQ / OQ / PQ Qualification
Annual Qualification, Intermediate Check, Calibration
Access Management

Data : Meets FDA 21 CFR Part 11 Requirements
Network and Database Workstations, Audit Trails, Data
Remote Backup
Data Confidentiality Management

Personnel Training:
Professional Skills Training
Compliance Training
Confidentiality Training

Analysis Method:
Refer to ICH / FDA / ChP / USP / EP / JP / ISO / GB and
Other Standard Methods
Data and reports can be used for new drug applications
in China and globally market

我们的团队
Our Team

艾苏莱团队由资深科学家领衔，科研团队的核心成员均曾任职于全球著名的医药企业，在各自领域有十年以上的研究经验。我们在稳定性研究、杂质谱研究、包材相容性研究、降解杂质、基因毒性杂质和杂质制备纯化等方面具有很强的研发能力和丰富的仪器使用经验。

我们的质量和体系专家熟悉药物注册流程与要求。遵守 CMA/CNAS (ISO/IEC17025) 认证认可，建立符合实验室研究测试流程的实验和数据报告程序。我们的团队富有社会责任感和职业素养，为药物研发和药品生产的客户提供专业的安全评价测试和质量研究服务。

The Assure Pharma's team is led by senior scientists. The core members of the scientific research team have all worked in world-renowned pharmaceutical companies and have more than ten years of research experience in their fields. We have strong research and development capabilities and instrument use experience in stability research, impurity spectrum research, packaging material compatibility research, degradation of impurities , GTI genotoxic impurities and impurity preparation and purification.

Our quality system experts are familiar with the drug registration process and requirements. Comply with CMA / CNAS (ISO/IEC17025) accreditation, establish experimental and data reporting procedures that conform to laboratory research and testing procedures. Our team is full of social responsibility and professionalism, and provides professional safety evaluation testing and quality research services for customers in drug development and drug production.

药物稳定性研究
Pharmaceutical Stability Study

稳定性研究的目的是考察原料药或药物制剂在温度、湿度、光线的影响下随时间变化的规律，为药品的生产、包装、贮存、运输条件提供科学依据，同时通过试验建立药品的有效期。

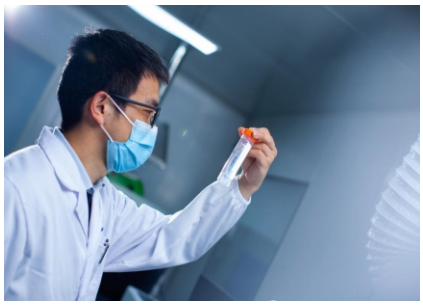
稳定性研究是药品质量控制研究的主要内容之一，与药品质量研究和质量标准的建立紧密相关。其具有阶段性特点,贯穿原料药、制剂产品及中间产物的药品研究与开发的全过程，一般始于药品的临床前研究，在药品临床研究期间和上市后还应继续进行持续稳定性考察。

The purpose of the stability study is to investigate the regularity of the API or pharmaceutical preparations under the influence of temperature, humidity, and light, to provide a scientific basis for the production, packaging, storage, and transportation conditions of the drug, and to establish the validity period of the drug through experiments.

Stability study is one of the main contents of pharmaceutical quality control research, and is closely related to drug quality research and the establishment of quality standards. It has a phased characteristic, which runs through the entire process of drug research and development of API, preparations and intermediate products. It generally starts from the preclinical research of drugs. On-going stability study should be continued during the clinical study of the drug and post-marketing.

稳定性研究的现行法规与指南
Current Regulations and Guidelines for Stability Study

- 中国药典（现行版）， ChP（2020）
- ICH， Q1A-Q1F Stability，2003.
- FDA， Drug Stability Guidelines，2008.
- EMA，EU Guidelines for GMP for Medicinal Products for Human and Veterinary Use，2015.
- WHO，Stability testing of active pharmaceutical ingredients and finished pharmaceutical products，2016.



稳定性研究的流程
Stability Study Process

稳定性试验方案 Stability Study Protocol → 样品准备 Sample Preparation → 取样计划 Sampling Schedule → 质量标准 Quality Specification → 稳定性报告 Stability Study Report

稳定性试验条件
Stability Study Conditions

21 ℃ / 45% RH (温带)	30 ℃ / 35% RH (干热带)
25 ℃ / 40% RH	30 ℃ / 65% RH (湿热带)
25 ℃ / 60% RH (亚热带)	30 ℃ / 75% RH (非常湿热带)
30 ℃ / 25% RH	40 ℃ / 75% RH

高温条件
Cabinets 50 ℃, 57 ℃, 60 ℃
低温条件
Storage at 2-8℃, -20℃, -40℃, -80℃
光照条件
Photostability Condition
特殊条件
Special Condition (ICH Q1B Options 1 & 2)
冻融循环条件
Freeze/Thaw Cycle Condition

半渗透性包装的存储条件示例
Storage Solutions of Semi-permeable Containers

长期条件	Long-term conditions	25 ℃ / 40% RH
中间条件	Intermediate conditions	30 ℃ / 35% RH
加速条件	Acceleration conditions	40 ℃ / NMT25% RH

我们的优势
Our Advantages

- 专业的科学家领衔的团队和符合各国注册要求的数据报告
  A team led by professional scientists and data reports that meet the registration requirements of various countries
- 德国 Weiss 步入式稳定性箱和 Binder/MMM 恒温恒湿设备
  Germany Weiss walk-in stability box and Binder / MMM constant temperature and humidity equipment
- 符合各气候类型的存储条件，总空间达2700立方米
  Storage conditions of various climate zone type, with a total space of 2700 cubic meter
- 双电源系统、每个条件双重备份方案、灾难恢复系统
  Dual power supply system, dual backup scheme for each condition, disaster recovery system
- 电子化样品管理系统、温湿度在线管理和实时监控报警系统
  E-management system, temperature and humidity online management and real-time monitoring and alarm system
- 符合 GMP 规范和 FDA 21CFR Part 11数据完整性要求
  Complies with GMP regulations and FDA 21CFR Part 11 data integrity requirements
- CMA/CNAS (ISO/IEC17025) 认证认可，参照 cGMP 合规实验室
  CMA / CNAS (ISO/IEC17025) Accreditation, refer to cGMP compliance laboratory
- 稳定性研究基于cGMP/ ChP/ FDA / ICH/ WHO 等指导原则
  Stability studies are based on cGMP / ChP / FDA / ICH / WHO guidelines
- 总体上可降低客户50%以上的药物稳定性研究成本
  It can reduce the cost of pharmaceutical stability research for customers by more than 50% on the whole.



稳定性研究服务内容
Stability Study Services

原料药 / API

影响因素试验 / Stress Testing
- 高温试验 / High Temp. Testing
- 高湿试验 / High Humidity Testing
- 低温试验 / Low Temp. Testing
- 冻融试验 / Freeze/Thaw Testing
- 光照试验 / Photostability

加速试验 / Accelerated Stability Testing
长期试验 / Long-term Stability Testing

药物制剂 / Pharmaceutical Preparation

加速试验 / Accelerated Stability Testing
长期试验 / Long-term Stability Testing
模拟使用试验 / In-use Stability
持续稳定性考察（上市后）
On-going Stability Study (post-marketing)
承诺稳定性试验（上市后）
Stability Commitment (post-marketing)

特殊食品类 / Special Food

特殊医学用途食品稳定性研究
Stability Study of Food for Special Medical Purpose
功能性食品稳定性研究
Stability Study of Functional Food

医疗器械稳定性研究
Medical Device Stability Study
化妆品稳定性研究
Cosmetic Stability Study

为您定制个性化的稳定性研究方案和符合法规的测试服务
Customized Stability Research Solutions and Compliant Testing Services

原辅包相容性研究
Compatibility Study on Container Closure System

相容性研究是考察包装材料与药品之间没有发生严重的相互作用，并导致药品有效性和稳定性发生改变，或者产生安全性风险的过程；研究内容应包括包装材料对药品的影响和药品对包装材料的影响。

对于药品来说，包装应适用于其预期的临床用途，并应具备如下特性：保护作用、相容性、安全性和功能性。包装系统一方面为药品提供保护，以满足其预期的安全有效性用途；另一方面还应与药品具有良好的相容性，即不能引入可引发安全性风险的浸出物，或引入浸出物的水平符合安全性要求。

Compatibility study is a process that evaluates the fact that there is no serious interaction between packaging systems and drugs, which leads to changes in the effectiveness and stability of drugs, or a safety risk; the study should include the effects of packaging materials on drugs and the impact of drugs on packaging materials.

For drugs, the packaging system should be suitable for its intended clinical purpose with the following characteristics: protection, compatibility, safety and functionality. The packaging system provides protection to meet the intended purpose on safety and effectiveness; Meanwhile, it should have good compatibility with the drugs, that means it cannot introduce extractable s that can cause safety risk s or the level can meet safety requirements.

原辅包研究的现行法规与指南
Current Regulations and Guidelines for Compatibility Study

- ChP, 四部9621，药包材通用要求指导原则
- ChP, 四部9622，药用玻璃材料和容器指导原则
- 化学药品与弹性体密封件相容性研究技术指导原则（试行），2018
- ICH M7, Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk
- ICH Q3D, Guideline for Elemental Impurities
- EMEA, Guideline on Plastic Immediate Packaging Materials（2005）
- EP, Chapter 3, Materials and Containers
- USP <661> <1660> <1661> <1663>

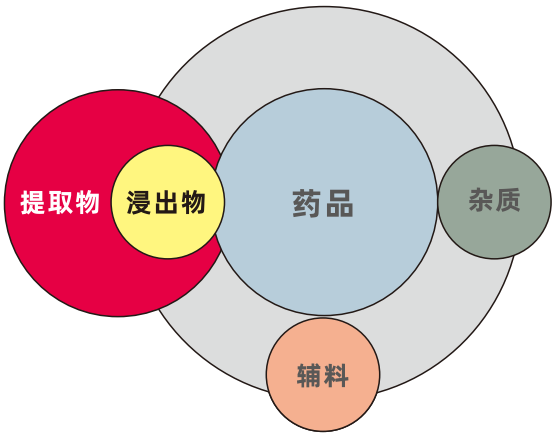


原辅包相容性研究的流程
Compatibility Study Process

信息收集、风险评估 → 模拟、提取实验 → 方法学验证 → 迁移、吸附实验 → 安全性评估 → 相容性报告

Information Collection, Risk Assessment → Simulation, Extraction Test → Method Validation → Migration, Adsorption Test → Safety Assessment → Compatibility Report

浸出物/提取物与药品的关系
The Relationship Between E/L & Drug



我们的优势
Our Advantages

- 专业的科学家领衔的团队，在玻璃、金属、塑料、橡胶、硅胶等材料的相容性研究方面，拥有丰富的经验
  The team led by professional scientists has extensive experience in the compatibility study on container closure system, such as glass, metal, plastic, rubber, silicone, etc.
- 在半渗透性包材研究领域，开发了全面的成熟方案，可为客户项目申报提高效率和成功率
  In the field of semi-permeable packaging materials research, we have developed a comprehensive and mature solution, which can improve the efficiency and success rate of customer project application
- 建立了强大的图谱检索库，可与客户共享数据并不断更新
  Established a powerful and continuously updated spectrum library that can share data with our customers
- 可同时提供稳定性存储和稳定性测试研究服务，相容性研究与稳定性研究相结合，可大幅降低项目研发成本
  Provide stability sample storage and stability test services simultaneously. The combination of compatibility research and stability study can greatly reduce the cost.

原辅包相容性研究服务内容
Compatibility Study Services

包材组件 / Packaging Components

安瓿瓶 / Ampoule
西林瓶 / Penicillin Bottle
弹性体 / Elastomer
输液袋 / Infusion Bags
预灌封注射器 / Pre-filled Syringe

生产系统组件 / Production System Components

浓配罐/稀配罐/缓冲罐
Concentrated Tank / Thin tank / Buffer Tank
滤芯/阀门/隔膜阀垫片
Filter element / valve / diaphragm valve gasket
管道/硅胶管 / Pipe / Silicone Tube
垫圈（密封圈/O型圈）/ Gasket (seal ring / O-ring)
陶瓷泵 / Ceramic Pump

输液系统组件 / Infusion System Components

输液管路 / Infusion Pipe
一次性输液器 / Disposable Infusion Set

原料药及辅料质量控制
Quality Control of APIs and Excipients

为您定制个性化的相容性研究方案和符合法规的测试服务
Customized Compatibility Research Solutions and Compliant Testing Services

药物杂质研究
Impurity Study on Drug Substances

ICH 指南将原料药相关杂质分为三个大类：有机杂质（包括遗传毒性杂质）、无机杂质和溶剂残留。杂质的研究是药品研发的一项重要内容。它包括选择合适的分析方法，准确地分辨与测定杂质的含量并综合药学、毒理及临床研究的结果确定杂质的合理限度。这一研究贯穿于药品研发的整个过程。

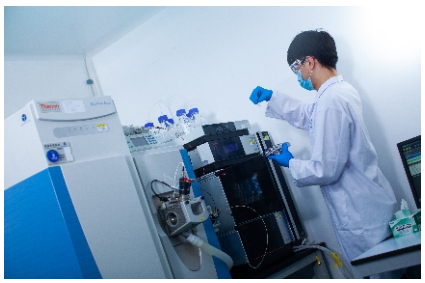
质量源于设计（QbD），药品从研发开始就要考虑最终产品的质量。在配方设计、工艺路线确定、工艺参数选择、物料控制等各个方面都要进行深入研究，积累详实的数据，并依此确定最佳的产品配方和生产工艺。我们和药物研发科学家们共同面对药物研发，为科学家们提供杂质分离、纯化、鉴定和安全性评价服务。为客户提供科学的、高效的药物质量安全研究CRO服务。

The ICH guidelines classify API-related impurities into three categories: organic impurities (including genotoxic impurities), inorganic impurities, and solvent residues. The study of impurities is an important part of drug research and development. It includes selecting appropriate analysis methods, accurately distinguishing and determining the content of impurities, and integrating the results of pharmaceutical, toxicological and clinical studies to determine the reasonable limits of impurities. This research runs through the entire process of drug development.

Quality by design (QbD), the quality of the product must be considered from the beginning of drug development. In-depth research should be conducted in various aspects such as formula design, process route determination, process parameter selection, material control, etc. to accumulate detailed data, and then determine the best product formula and production process accordingly. We and scientists work together on R&D research to provide scientists with separation, purification, identification and safety evaluation services. To provide customers with scientific and efficient drug quality and safety research CRO services.

药物杂质研究的现行法规与指南
Current Regulations and Guidelines for Impurity Study

- Q3A(R2): Impurities in New Drug Substances, 新原料药中的杂质
- Q3B(R2): Impurities in New Drug Products (Revised Guideline), 新制剂中的杂质
- Q3C(R3): Impurities: Guideline for Residual Solvents, 残留溶剂指南
- Q3D: Impurities: Guideline for Elemental Impurities, 元素杂质指导原则
- ICH M7: Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk Reference:
- 国家药典委员会：《遗传毒性杂质控制指导原则》（征求意见稿），2019
- EMA：《基因毒性杂质限度指南》，2006


药物杂质研究的流程
Impurity Study Process

沟通客户需求 Communicate with Customer

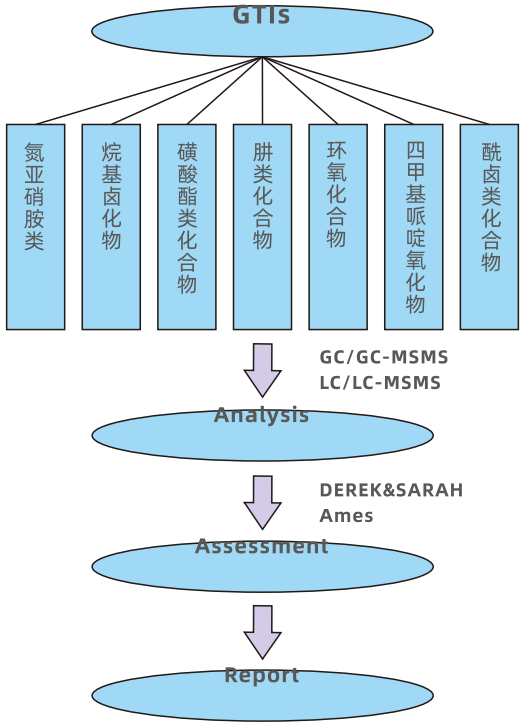
杂质来源分析 Analysis of Impurity Source

杂质限度标准 Standard of Impurity Limit

分析方法开发与检测 Development Analytical Methods and Testing

出具报告 Issue Report

基因毒性杂质研究
Genotoxic Impurities Research



我们的优势
Our Advantages

- 艾苏莱实验室目前拥有高端液相色谱质谱联用仪6套、气相色谱质谱联用仪2套、电感耦合等离子光谱质谱联用仪1套。其中Thermo Orbitrap QE 主要用于NDMA、NDEA、NDIPA等氮亚硝胺类项目的检测。
  Our Lab currently has 6 sets of LC-MSMS, 2 sets of GC-MSMS, and 1 set of ICP-MS. And Thermo Orbitrap QE is mainly used for the detection of nitrosamines such as NDMA, NDEA, and NDIPA.
- 建立了强大的图谱检索库，可与客户共享数据并不断更新
  Established a powerful spectrum library that can share data with customers and continuously update
- 符合 GMP 规范和 FDA 21CFR Part 11数据完整性要求
  Complies with GMP regulations and FDA 21CFR Part 11 data requirements
- CMA/CNAS（ISO/IEC17025）认证认可，参照 cGMP 合规实验室
  CMA / CNAS（ISO/IEC17025）accreditation, cGMP compliance laboratory

药物杂质研究服务内容
Impurity Study Services

有机杂质 / Organic Impurities

杂质谱研究 / Impurity Spectrum Research
工艺杂质分析 / Process Impurity Analysis
降解杂质分析 / Degradation Impurities Analysis
杂质制备服务 / Impurity Preparation Service
杂质鉴定服务 / Impurity Identification Service
杂质假阳性高分辨质谱确证
Confirmation of False-positive Impurity by High-Resolution MS
原料药与制剂的分析方法开发
Development of Analytical Methods for APIs and Preparations

无机杂质 / Inorganic Impurities

1 类： 镉 Cd/ 汞 Hg（无机）
铅 Pb/ 砷 As（无机）
2A类： 钴 Co/ 矾 V/ 镍 Ni
2B类： 铊 Tl/ 金 Au/ 钯 Pd/ 铱 Ir
锇 Os/ 铑 Rh/ 钌 Ru/ 硒 Se
银 Ag/ 铂 Pt
3 类： 锂 Li/ 锑 Sb/ 钡 Ba/ 钼 Mo
铜 Cu/ 锡 Sn/ 铬 Cr

溶剂残留 / Solvent Residue

第一类溶剂（应避免使用）：苯、四氯化碳、1,2-二氯乙烷、1,2-二氯乙烷、1,1-二氯乙烯、1,1-二氯乙烯
第二类溶剂（应该限制使用）：甲醇、乙腈、N,N-二甲氧基甲酰胺、1,4-二氧六环、乙二醇等
第三类溶剂（GMP质量要求限制使用）：乙醇、乙酸、乙醚、异丙醇、乙酸乙酯等

为您定制个性化的药物杂质研究方案和符合法规的测试服务
Customized Impurity Study and Compliant Testing Services

GMP 公用系统验证
Validation of GMP Utility System

GMP (Good Manufacture Practice) 公用系统包括给排水、工艺用水、电力、自动化、空气净化、压缩空气、蒸汽、冷冻水、真空和惰性气体等系统。上述系统在生产中起着十分重要的作用，或为生产创造舒适并符合洁净要求的环境，或为各生产操作工序提供必要的热（冷）量，制动支持，或直接产生物料供给进入生产环节。GMP 是一套行之有效的先进的科学管理制度，特别对消灭药品生产过程中的污染、混淆和差错的隐患，保证产品质量起到重要的作用。

GMP (Good Manufacture Practice) utility systems include water supply and drainage system, process water, electricity, automation, air purification, compressed air, steam, chilled water, vacuum and inert gas systems. These systems play a very important role in production, or create a comfortable and clean environment for production, or provide the necessary heat (cold) for each production operation process, brake support, or directly generate material supply into production. GMP is a set of effective advanced scientific management system, especially plays an important role in eliminating the pollution, confusion and errors in the production process of drugs, and ensuring product quality.

GMP 公用系统验证的现行法规与指南
Current Regulations and Guidelines for Validation of GMP Utility System

- 《药品生产质量管理规范（2010年修订）》
- AEME, BPE-2009, Bioprocesing Equipment
- ASME, B31.3-2006 Process Piping
- ASTM, A380-99(2005), 不锈钢零件、设备和系统的清洗、除垢和钝化
- ASTM, A967-01, 不锈钢零件的化学钝化处理
- ISO 8573-1 ~9, Compressed air 压缩空气
- ISO 14644-1~9， Cleanrooms and associated controlled enviroments
- GB50073-2013；GB 50591-2010；GB/T 16292-2010；GB/T 16293-2010；GB/T 16294-2010...

GMP 公用系统验证的流程
Validation Process of GMP Utility System

沟通客户需求	合同评审	项目报价	测试方案	现场采样	检测报告
Communicate with Customer	Contract Review	Project Offer	Test Program	On-site Sampling	Testing Report

全球洁净环境检测项目对比
Comparison of Global Clean-Room Testing Projects

序号	洁净环境检测标准	区域	温湿度	压差	悬浮粒子	换气次数	照度	浮游菌	沉降菌	风速	气流流形	风量	高效过滤器完整性	自净时间	表面菌
1	局令第13号	中国	√	√	√	√	√	√	√	√	-	-	-	-	-
2	YBB00412004 2015	中国	√	√	√	√	√	√	√	√	√	-	-	-	-
3	GB/T16292-2010	中国	-	-	√	-	-	-	-	-	-	-	-	-	-
4	GB/T16293-2010	中国	-	-	-	-	-	√	-	-	-	-	-	-	-
5	GB/T16294-2010	中国	-	-	-	-	-	-	√	-	-	-	-	-	-
6	GB 50591-2010	中国	√	√	√	√	√	√	√	√	√	√	√	√	-
7	GMP2010	中国	√	√	√	√	√	√	√	√	√	√	√	√	√
8	GB/T36066-2018	中国	-	-	-	-	-	-	-	-	-	-	-	-	-
9	欧盟GMP	欧盟	√	√	√	√	√	√	√	√	√	√	√	√	√
10	美国GMP	美国	√	√	√	√	-	√	√	√	√	√	√	-	√
11	澳大利亚GMP	澳大利亚	√	√	√	√	√	√	√	√	√	√	√	√	√
12	PIC/S PE009-14 2018	PIC/S	√	√	√	√	√	√	√	√	√	√	√	√	√
13	日本GMP	日本	√	√	√	√	-	√	√	√	√	√	√	-	√
14	ISO14644-1/2:2015	ISO	-	-	√	-	-	-	-	-	-	-	-	-	-
15	ISO 14644-3 - 2005	ISO	√	√	√	√	-	-	-	√	√	√	√	-	-
16	ISO 14698-1:2003E	ISO	-	-	-	-	-	√	√	-	-	-	-	-	√

我们的优势
Our Advantages

- 团队核心成员拥有二十余年行业经验，精通国内和国际的洁净环境适用标准
  Our core members have more than 20 years of work experience, proficient in domestic and international clean environment applicable standards
- 公司拥有生物二级安全实验室（BSL-2），实验室人员和病原体处理人员都是经过特定培训和高级培训的科学家
  Laboratory personnel and pathogen handling personnel are scientists with specific training and advanced training
- 实验室配备超净工作台、生物安全柜、微生物检测仪、尘埃粒子计数器、浮游菌采样仪、压缩空气采样系统等GMP公用系统验证设备
  Equipped with GMP public system verification instruments such as ultra-clean workbench, biological safety cabinet, microbial detector, dust particle counter, plankton sampler, compressed air sampling system, etc.



GMP 公用系统验证服务内容
Validation Services of GMP Utility System

洁净环境测试 / Clean-Room Test
高效检漏 / Efficient Leak Detection
静压差（压力）/ Static Pressure Difference
换气次数(风量）/ Ventilation Frequency
自净时间 / Self-purification Time
温湿度 / Temperature and Humidity
照度 / Illuminance
噪声 / Noise
悬浮粒子 / Airborne Particles
浮游菌 / Airborne Microbe
沉降菌 / Settling Microbe
表面菌 / Surface Microbe

水质检测 / Water Quality Testing
氨 / Ammonia
pH值 / pH Value
硝酸盐 / Nitrate
亚硝酸盐 / Nitrite
电导率 / Conductivity
易氧化物 / Readily Oxidizable Substances
不挥发物 / Non-Volatile Matter
重金属 / Heavy Metals
微生物限度 / Microbial Limit
TOC / Total Organic Carbon
细菌内毒素（凝胶法）/ Bacterial Endotoxin

压缩空气/氮气 / Compressed Air / Nitrogen
水分/露点 / Moisture / Dew point
油份 / Oil Content
粒子 / Particles
微生物 / Microorganism
微生物限度 / Microbial Limit
需氧菌总数 / Total Aerobic Bacteria
霉菌、酵母菌总数 / Total Mold and Yeast
控制菌 / Control Bacteria
细菌内毒素（凝胶法）/ Bacterial Endotoxin
微生物鉴定 / Identification of Microbial
GMP系统调试/诊断/运行/维护（HVAC）

为您定制个性化的GMP公用系统验证方案和符合法规的测试服务
Customized Solutions of Validation Service and Compliant Testing Services

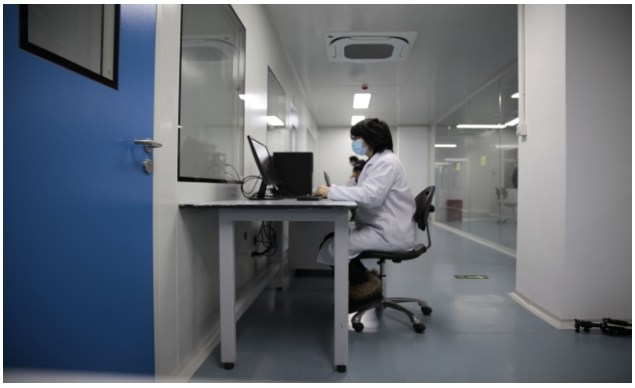
微生物检测与鉴定
Microbial Detection and Identification

微生物检查法包括：无菌检查法、非无菌产品微生物限度检查、细菌内毒素检查法等。此外，对产品进行检测时应进行方法适用性试验，以确认所采用的方法适合于该产品。

微生物检测与鉴定可确定药品是否被污染、控制药品质量，保证用药的有效性和安全性。因此，微生物检测与鉴定的结果是衡量药品生产全过程卫生水平的重要依据之一。

Biological inspection methods include: sterility test, microbial limit test of non sterile products, bacterial endotoxins test, etc. In addition, the method suitability test should be conducted when testing the product to confirm that the method used is suitable for the product.

Microbiological testing and identification can determine whether the drug is contaminated, control the quality of the drug, and en-sure the effectiveness and safety of the drug. Therefore, the results of microbial testing and identification is one of the important basis for measuring the hygienic level of the whole process of drug production.



微生物检测与鉴定的现行法规和指南
Current Regulations and Guidelines for Microbial Detection and Identification

- 中国药典（现行版），ChP（2020）
- 《伯杰氏系统细菌学手册》，Bergey's Manual of Systematic Bacteriology

我们的优势
Our Advantages

- 生物安全实验室（BSL2级），满足GMP和中国药典要求
  Microbiological clean laboratory that meets the requirements of GMP and Chinese Pharmacopoeia
  配制室 / Preparation Room
  灭菌室 / Sterilization Room
  镜检室 / Microscope Room
  菌种室 / Strains Room
  培养室 / Incubation Room
  阳性室 / Positive Room
- 双电源系统、每个条件双重备份方案、灾难恢复系统
  Dual power supply system, dual backup scheme for each condition, disaster recovery system
- CMA/CNAS (ISO/IEC17025) 认证认可，参照 cGMP 合规实验室
  CMA / CNAS (ISO/IEC17025) Accreditation, refer to cGMP compliance laboratory

微生物鉴定与检测服务内容
Microbial Detection and Identification Service

微生物鉴别
Identification of Microorganisms

菌落总数
Total Colonies

霉菌及酵母菌
Molds and Yeasts

大肠菌群
Coliforms

铜绿假单胞菌
Pseudomonas Aeruginosa

沙门氏菌
Salmonella

金黄色葡萄球菌
Staphylococcus Aureus

白色念球菌
Candida Albicans

微生物检测
Microbial Testing

微生物限度检测
Microbial Limit Testing

无菌试验
Sterility Testing

抑菌效果试验
Bacteriostatic Effect Testing

细菌内毒素
Bacterial Endotoxin

支原体检测
Mycoplasma Detection

微生物表型鉴定
Identification of Microbial Phenotypes

大肠菌群
Coliform Bacteria

铜绿假单胞菌
Pseudomonas Aeruginosa

沙门氏菌
Salmonella

金黄色葡萄球菌
Staphylococcus Aureus

白色念球菌
Candida Albicans

中药材及饮片检测
Analysis of Traditional Chinese Medicine

中药材作为天然植物药的代表，在中国具有悠久的历史。中药饮片为中药材根据需要，经过炮制处理而形成供配方使用的中药，可直接用于中医临床的中药。国家对中药产业的高度重视，消费者对天然药物的青睐，国际市场出口的大幅度增加，都使得中药材及饮片的质量安全问题显得愈发的重要。

中药材及饮片检测主要是对中药材中有效成分的检测及对中药材自身制作过程中的水分残留、农药残留、重金属残留等方面开展的相关检测服务。

As a representative of natural botanical medicine, Chinese medicinal materials have a long history in China. Chinese herbal medicine decoctions are Chinese herbal medicines that are processed according to need to form traditional Chinese medicines for use in formulas, which can be directly used in traditional Chinese medicine. The great importance that the country attaches to the Chinese medicine industry, consumers' preference for natural medicines, and the significant increase in exports in the international market have made the quality and safety of Chinese herbal medicines and slices increasingly important.

The detection of Chinese medicinal materials and slices is mainly related to the detection of active ingredients in Chinese medicinal materials and the relevant testing services carried out in the residual moisture, pesticide residues and heavy metal residues in the production process of Chinese medicinal materials themselves.

中药材及饮片检测的现行法规和指南
Current Regulations and Guidelines for Analysis of Traditional Chinese Medicine

▶ 中国药典（现行版），ChP（2020）

中药材及饮片检测服务内容
Analysis of Traditional Chinese Medicine Service

有效成分检测：
Active Ingredient Detection:
植物有效成分
Plant Active Ingredients
动物药有效成分
Active Ingredient of Animal Medicine

常规理化测试
Routine Physical and Chemical Testing

真菌毒素检测
Mycotoxins Detection

矿物质及重金属：
Minerals and Heavy Metals:
人体必需矿物质
Human Essential Mineral
有害重金属分析
Analysis of Harmful Heavy Metals

微生物检测
Microbial Detection

兽药残留检测
Veterinary Drug Residues Detection

农药残留检测：
Pesticide Residues Detection:
有机氯农药残留
Organochlorine Pesticide Residues
有机磷农药残留
Organophosphorus Pesticide Residues
拟除虫菊酯类农药残留
Pyrethroid Pesticide Residues

MAH委托第三方审计服务
MAH Third Party Audit Service

药品上市许可持有人（MAH）制度是国际较为通行的药品上市、审批制度，是一项与世界接轨的制度。

MAH制度的核心是将药品上市许可与药品生产许可分离，允许药品生产企业、研发机构或科研人员成为独立的药品上市许可持有人(药品上市许可证明文件的持有者)，有权自行或委托其他药品生产企业生产药品，并对生产、销售的药品质量承担主要法律责任。

The drug marketing authorization holder (MAH) system is an internationally popular drug marketing and approval system. It is a system that is in line with the world.

The core of the MAH system is to separate the drug marketing license from the drug manufacturing license, allowing drug manufacturers, R & D institutions or scientific researchers to become independent drug marketing license holders (holders of drug marketing license certificates), and have the right to Entrust other pharmaceutical manufacturers to produce drugs, and bear the main legal responsibility for the quality of the drugs produced and sold.

MAH委托第三方审计服务法规与指南
Current Regulations and Guidelines for MAH Third Party Audit Service

- 中国药典（现行版），ChP（2020）
- 《药品管理法》，Drug Administration Law
- 《药品注册管理办法》，Administrative Measures for Drug Registration

珍视生命

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