微谱
WEIPU

生物制品研发及实验室服务

BIOPHARMACEUTICAL R & D AND LABORATORY SERVICES

值得信赖的医药研发伙伴

TRUSTWORTHY PHARMACEUTICAL R & D PARTNER

CATALOG

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01.

关于我们
ABOUT US

微谱，大型研究型检测机构
WEIPU, A LARGE RESEARCH-ORIENTED TESTING COMPANY

始于2008年，总部上海，30+分子公司，10万平方米以上实验室及办公场地。具备国家市场监督管理局授权的CMA资质和中国合格评定认可委员会认可的CNAS资质，具备CATL资质，具备中华人民共和国海关总署认定的进出口商品检验鉴定机构资格证书，被认定为国家中小企业公共服务示范平台、国家服务型制造示范平台、高新技术企业、院士专家工作站等。
基于十多年的专业技术积累和遍布全国的服务网络，微谱每年出具近二十七万份技术报告，累计服务客户二十五万+家，高端技术水准和高质量技术服务深获客户好评。

Established in 2008 with its headquarters in Shanghai, the group has over 30 subsidiaries and more than 100,000 square meters of laboratory and office space. It possesses CMA qualification authorized by the State Administration for Market Regulation and CNAS accreditation recognized by the China National Accreditation Service for Conformity Assessment. It also has CATL qualification and is identified by the General Administration of Customs of the People's Republic of China as an import and export commodity inspection and identification institution. The group has been recognized as a National SME Public Service Demonstration Platform, National Service-type Manufacturing Demonstration Platform, High-tech Enterprise, and Academician Expert Workstation, among others.
With over a decade of professional technical experience and a nationwide service network, Weipu issues nearly 270,000 technical reports annually and has served more than 250,000 clients, earning high praise for its advanced technical level and high-quality technical services.

生物医药领域 >> Biomedical areas

微谱致力于成为您值得信赖的医药研发伙伴。我们密切关注全球生物医药行业发展趋势，立足药物及医疗器械实验室服务全产业价值链，以完备的质量体系、高速的交付周期、丰富的项目经验及不断创新和持续扩充的能力布局，为行业提供契合全生命周期的化学药、生物制品、医疗器械的研发及相关实验室服务，法规咨询与合规验证，药学CMC，临床医学研究等。我们的服务得到了中国、欧盟、美国、WHO等国际主要市场监管机构的认可，成功助力超过3000余家医药、医疗器械企业加速产品上市进程！

Weipu is committed to becoming your trusted pharmaceutical R & D partner. With close attention to the development trend of the global biopharmaceutical industry, based on the whole industrial value chain of pharmaceutical and medical device laboratory services, and relying on a complete quality system, high-speed delivery cycle, rich project experience and continuous innovation and continuous expansion, we provide the industry with R & D and related laboratory services of chemical drugs, biological products and medical devices that fit the whole life cycle, regulatory consultation and compliance verification, pharmaceutical CMC, clinical medical research, etc. Our services have been recognized by major international market regulators such as China, the European Union, the United States and WHO. We have successfully assisted more than 3，000 pharmaceutical and medical device enterprises to accelerate the process of product commercialization!

实验室及仪器配置

LABORATORY AND INSTRUMENT CONFIGURATION

微谱生物医药研发及实验室服务参照GMP和ISO/IEC17025质量体系要求,建设了23000+m^2的独立生物医药实验室。除上海总部外，针对不同服务管线设置了专门的生物医药宝山研究中心、杂质研究中心、医疗器械研究中心、生物分析研究中心、生物安全研究中心、临床研究中心、药学CMC研究中心等。

当前，微谱生物医药实验室有近800人组成的国际化专业团队，配合400多台的大型精密仪器，更包括2个BSL-2级高规格实验室,持续为客户提供智慧、精准、敏捷的专业服务。

Weipu has set up an independent biomedical laboratory covering an area of more than 23,000 square meters according to the GMP and ISO/IEC17025 quality system.In addition to Shanghai headquarters, Weipu also set up Baoshan Biomedical Research Center, Impurity Research Center, Medical Device Research Center, Biological Analysis Research Center, Biosafety Research Center, Clinical Research Center, Pharmaceutical CMC Research Center for different service pipelines.

At present, the Weipu Biomedical Laboratory has an international professional team composed of more than 800 people, more than 400 large-scale precision instruments, and 2 BSL-2 high-specification laboratories to continuously provide customers with intelligent, accurate and agile professional services.

分类 CLASSIFICATION	仪器 METHOD	型号 MODEL	离子源 ION SOURCE	参考依据 REFERENCE
电感耦合等离子体类 Inductively coupled plasma class (ICP)	直读光谱仪（ICP-OES） Optical emission spectrometer	PE：AVIO 200	N/A	0411电感耦合等离子体原子发射光谱法 0411 Inductively coupled plasma atomic emission spectrometry
	质谱（ICP-MS） Mass spectrometry	PE:NexION350X PE:NexION1000 PE:NexION1000G Agilent:7900 Agilent:7800	N/A	0412电感耦合等离子体质谱法 0412 Inductively coupled plasma mass spectrometry
气相类 Gas chromatography (GC)	顶空气相色谱-串联质谱联用(HS-GC-MSMS)离子阱分析器 Headspace gas chromatography-tandem mass spectrometry (HS-GC-MSMS) ion trap analyzer	7697A-7890B-G7000D	电子轰击离子化（EI）（高灵敏和普通） electron impact ionization (EI) (High and normal sensitivities)	0431质谱法 0431 Mass spectrometry
	顶空气相色谱-质谱联用(HS-GC-MS)四极杆分析 Headspace gas chromatography - mass spectroscopy (HS-GC-MS) quadrupole analyzer	7697A-7890B-5977B		
	气相色谱-质谱联用(GC-MS)四极分析器 Gas chromatography - mass spectroscopy (GC-MS) quadrupole analyzer	7890B-5977B 8890-5977B GCMS-QP2020NX		
	顶空气相色谱-质谱联用(HS-GC-MS)四极杆分析器 Headspace gas chromatography - mass spectroscopy (HS-GC-MS) quadrupole analyzer	7697A-7890B-5977B HS-GCMS-QP2020NX		
	气相色谱法 Gas chromatography 火焰离子化检测器（FID） Flame ionization detector 电子捕获检测器（ECD） Electron capture detector 氮磷检测器（NPD） Nitrogen phosphorus detector	7890B 8890	N/A	521气相色谱法 521 Gas chromatography
高分辨质谱类 High resolution mass spectrometry class	飞行时间分析器（TOF） Time of flight analyzer	Agilent 1290 infinity II &G6545B	N/A	0431质谱法 0431 Mass spectrometry
	液相色谱四极杆飞行时间质谱联用仪 Ultra-performance liquid chromatography quadrupole time-of-flight mass spectrometry	ACQuity H-CLASS Plus Xevo G2-XS QTOF		
	Thermo高分辨质谱 Thermo High Resolution Mass Spectrometer	Q Exactive Plus Orbitrap		
毛细管电泳类 Capillary electrophoresis class	毛细管电泳仪 Capillary electrophoresis instrument	Beckman PA800 Plus	PDA/UV/LIF检测器 PDA/UV/LIF detector	0542毛细管电泳法 0542 Capillary electrophoresis
酶标仪类 Microplate reader class	酶标仪 Microplate reader	Biotck H1@Synergy LX	紫外/荧光 UV/Fluorescence	
液相类 Liquid Chromatogram class (LC)	LC-MS		电喷雾离子化（ESI> 大气压化学离子化（APCI）大气压光离子化（APPI） Electrospray ionization (ESI) Atmospheric pressure chemical ionization (APCI) Atmospheric pressure photoionization (APPI)	0431质谱法 0431 Mass spectrometry
	串联质谱（MS~MS）离子阱分析器 Tandem mass spectrometry (MS-MS) Ion trap analyzer	ACQuity I CLASS&QTRAP 6500 ACQuity I CLASS&TRIPLE QUAD5500+ ExionLC&TRIPLE QUAD 4500		
		ACQuity I CLASS& XEVO TQ-S micro 1290 infinity II &G6470A		
	飞行时间分析器（TOF） Time of flight analyzer	1290 infinity II &G6545B		
	液相色谱四极杆飞行时间质谱联用仪 Ultra-performance liquid chromatography quadrupole time-of-flight mass spectrometry	ACQuity I CLASS Plus Xevo G2-XS QTOF		
	高效液相色谱法 High performance liquid chromatography 紫外可-见分光（含二极管阵列）检测器 UV/VIS spectrophotometer (including diode array) 蒸发光散射检测器 Evaporative light-scattering detector 示差折光检测器 Differential refraction detector 荧光检测器 Fluorescence detector 离子色谱 Ion chromatography 电雾式检测器 Charged aerosol detector	ACQuity I CLASS	N/A	0512液相色谱法 0512 Liquid chromatography
粒度分布类 Particle size distribution(PSD)	位置探测器（PSD） Location detector	Mastersizer 3000	/	0982粒度和粒度分布测定法 0982 Particle size and particle size distribution determination
核磁共振类 Nuclear magnetic resonance class (NMR)	核磁共振波谱分析仪（NMR） Nuclear Magnetic Resonance spectroscopy analyzer	Bruker AVANCE II 400 MHz	/	/
XRD	多晶X射线衍射仪 X-ray polycrystalline diffractometer	Bruker D8 Advance	/	/

资质荣誉

QUALIFICATION HONOR

体系规范 荣誉载身 多元合作

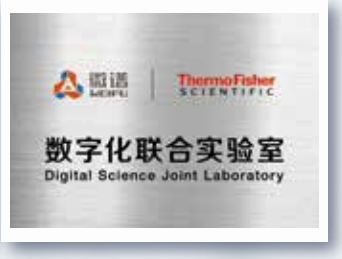
规范的质量体系与资质备案，持续的行业信赖与认可，时刻接受官方监管，扎实保障服务品质。开发多元化联合实验室创新模式，加速研发制造一体化迭代创新，更好地服务药物及医疗器械客户，助力产品化进程。

Weipu has been filed with standardized quality system and qualifications, continuously trusted and recognized by the industry, always under the official supervision and provide firm guarantee for service quality. Weipu has developed a diversified joint laboratory innovation mode to accelerate the iterative innovation of R&D and manufacturing integration, better serve the customers of drugs and medical devices and facilitate the process of industrialization.









行业认可

INDUSTRY RECOGNITION

十年的研究积累加良好的审评沟通渠道，为客户产品研发与申报成功提供不间断保驾护航。截止2022年10月，微谱已经完成了千余个品种的药品注册申报项目，并助力客户近400余款产品顺利通过一致性评价，包括诸多首家过评或热门产品。多款品种顺利完成CDE审批并通过研制现场核查，更有多项成果获得FDA突破性认定、临床试验默示许可、中选国家集采目录、器审中心评审、CE认证等。同时，在创新药制剂开发领域也有诸多成功案例。尤其在中外双报项目中，我们已协助客户将超百种项目进行全球市场产品的开发及商业推出。

With ten years of research accumulation and good review communication channels, Weipu can provide customers with continuous protection for successful product development and application.As of October 2022, Weipu has completed more than 1000 drug registration and application projects, and helped customers successfully pass the consistency evaluation of Nearly 400 products, including many first evaluated or popular products. Many varieties have successfully completed the CDE approval and passed the on-site verification. Many more achievements have obtained the breakthrough recognition of FDA, the implied permission of clinical trials, the selected national centralized procurement catalogue, the review of the equipment review center, and the CE certification. At the same time, there are many successful cases in the field of innovative drug preparation development. In particular, we have assisted customers in the development and commercial launch of more than 100 projects in the global market.

CDE

众多品种顺利完成CDE审批并通过研制现场核查

Many varieties have successfully completed CDE approval and passed the on-site verification of development

多项成果获得FDA突破性认定

A number of achievements have been recognized by FDA

FDA

CE

临床试验默示许可、中选国家集采目录
器审中心评审、CE认证等

Implied permission of clinical trials, selected national centralized procurement catalogue, review of the equipment review center, and CE certification

已协助客户将超百种项目进行
全球市场产品的开发及商业推出

We have assisted our customers in the development and commercial launch of more than 100 projects in the global market

100

阿达木单抗丨利妥昔单抗丨PD-1丨维迪西妥单抗丨重组人源化康CTLA-4单抗丨CD3/CD19双特异性抗体丨重组人干扰素丨重组人CD22单抗重组新型冠状病毒疫苗丨重组人源化抗PD-1单克隆抗体丨鼻喷流感病毒载体新冠肺炎疫苗丨重组细胞因子基因衍生蛋白注射液丨冻干人用狂犬病疫苗丨重组新型冠状病毒蛋白疫苗

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Adalimumab丨rituximab丨PD-1丨vidicizumab丨recombinant humanized Kang CTLA-4 monoclonal antibody丨CD3 / CD19 bispecific antibody丨recombinant human interferon丨recombinant human CD22 monoclonal antibody丨recombinant novel coronavirus vaccine丨recombinant humanized anti-PD-1 monoclonal antibody丨nasal influenza virus vector COVID-19 vaccine丨recombinant cytokine gene derived protein injection丨lyophilized human rabies vaccine丨and recombinant novel coronavirus protein vaccine

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*以上提及的资质、荣誉等相关数据来源：微谱科技集团旗下分子公司及其关联公司；
*以上提及的各项业务，由拥有相应业务资质的微谱科技集团旗下分子公司及其关联公司承接；其中专利代理业务由上海微略知识产权代理有限公司全权受理。
The qualifications, honors, and other related data mentioned above are sourced from subsidiary companies and associated companies of WeipTech Group.
The business operations mentioned above are undertaken by subsidiary companies and associated companies of WeipTech Group that possess the relevant business qualifications; among them, the patent agency services are exclusively handled by Shanghai Weilve Intellectual Property Agency Co., Ltd.

02.

服务优势

SERVICE ADVANTAGE

系统布局 精益赋能

System layout lean empowerment

高品质研发服务与系统化管理思维结合
加速产品上市进程

Combination of high-quality R & D service and systematic management thinking
Accelerate the process of product launch

我们为制药企业、研究机构及科研工作者提供符合全球药政法规的化学药、生物制品、医疗器械的研发及相关实验室服务，法规咨询与合规验证，药学CMC，临床医学研究服务等。依托系统化的核心优势，微谱可以为广大药械伙伴降低研发风险，缩短研发周期，控制研发成本，保证项目质量，最终加速产品市场化进程。

We provide pharmaceutical enterprises, research institutions and scientific research workers with research and development of chemical drugs, biological products, medical devices and related laboratory services, regulatory consultation and compliance verification, pharmaceutical CMC, clinical medical research services, etc. that comply with global pharmaceutical regulations. Relying on the core advantages of systematization, Weipu can reduce the R & D risk, shorten the R & D cycle, control the R & D cost, ensure the project quality, and finally accelerate the process of product marketization for the majority of pharmaceutical partners.

覆盖药械研究全产业链

Covering the whole industrial chain of Pharmaceutical Machinery Research

高速的交付效率

High speed delivery efficiency

稳定且专业的管理团队
持续且分级的培训体系

Stable and professional management team
Continuous and graded training system

丰富的项目研发经验

Rich project R & D experience

广泛且深厚的客户基础

Broad and deep customer base

持续扩张的产业生态布局

Sustainable expansion of industrial ecological layout

完善的管理体系

PERFECT MANAGEMENT SYSTEM

控 制 CONTROL

人 LABOR

- 关键岗位授权
  Key position authorization
- 持证上岗
  Work with certificate
- 监督计划
  Supervision plan
- 培训计划
  Training plan
- 质控计划
  Quality control plan

料 MATERIAL

- 物料分类管理，使用前QA放行
  Material classification management, QA release before use
- 菌毒种、样品专人双人双锁管理
  Bacteria and virus species and samples managed by special personnel (double person and double lock)
- 标准物质专人管理
  Reference materials managed by specially assigned personnel

法 STATUTE

- 方法验证/确认
  Method validation / validation
- 方法转移
  Method transfer
- 能力验证、测量审核
  Capability verification and measurement review

机 EQUIPMENT

- 独立设备档案+计量+验证
  Independent equipment archives + measurement + verification
- 期间核查
  Intermediate checks
- 设备使用授权
  Equipment use authorization
- 电子数据定期备份
  Regular backup of electronic data

环 SECURITY

- 门禁管控、生物安全培训考核合格方可进入
  Access control and accessible only when passing the biosafety training appraisal
- 环境监测计划
  Environmental monitoring plan
- EMS监控
  EMS monitoring
- 废气经高效排出
  Exhaust gas discharged efficiently
- 废液交资质单位统一处理
  Waste liquid submitted to the qualified unit for unified treatment
- 固废经高厌菌后交资质单位
  Solid wastes submitted to the qualified unit after being highly resistant to bacteria

微谱生物技术产品服务地图

WEIPU BIOTECHNOLOGY PRODUCT SERVICE MAP

药物发现
DRUG DISCOVERY

- 分析测试
  Analysis test
- 病毒包装
  Virus packaging
- 载体筛选
  Vector screening

R&D

- 分析测试
  Analysis test
- 细胞建库/病毒建库/菌种建库
  Cell library building / virus library building / strain library building
- 产品活性测试
  Product activity test
- 工艺开发与验证
  Process development and verification
- 工艺相关杂质研究
  Study on process related impurities
- 病毒载体表征
  Characterization of viral vectors
- 蛋白多肽类药物结构表征
  Structural characterization of protein peptide drugs
- mRNA药物结构及关键质量属性
  MRNA drug structure and key quality attributes
- 样品稳定性研究
  (影响因素实验/长期/加速)
  Study on sample stability
  (influencing factor experiment / long term / acceleration)
- 分析方法验证及样品放行
  Analysis method validation and sample release

临床前
PRECLINICAL

- 分析测试
  Analysis test
- 细胞建库/病毒建库/菌种建库
  Cell library building / virus library building / strain library building
- 产品活性测试
  Product activity test
- 工艺开发与验证
  Process development and verification
- 病毒清除验证
  Virus clearance verification
- 工艺相关杂质研究
  Study on process related impurities
- 细胞库/菌种库/病毒库检定
  Cell bank / strain bank / virus bank verification
- 微生物检测解决方案
  (无菌快检、支原体快检等)
  Microbial detection solutions
  (rapid sterility test, rapid Mycoplasma test, etc.)
- 病毒载体表征
  Characterization of viral vectors
- 蛋白多肽类药物结构表征
  Structural characterization of protein peptide drugs
- mRNA药物结构及关键质量属性
  MRNA drug structure and key quality attributes
- 相容性研究
  Compatibility study
- 包材密封性研究
  Study on sealing property of packaging materials
- 药用原辅料检测(含微生物)
  Detection of pharmaceutical raw and auxiliary materials (including microorganisms)
- 样品稳定性研究
  (影响因素实验/长期/加速)
  Study on sample stability
  (influencing factor experiment / long term / acceleration)
- 分析方法验证及样品放行
  Analysis method validation and sample release
- 生物样本分析
  Biological sample analysis
- 药品及医疗器械注册
  Registration of drugs and medical devices
- GMP合规咨询
  GMP compliance consulting
- 合规验证解决方案
  Compliance verification solution

临床 I -III
CLINICAL I-III

- 病毒清除验证
  Virus clearance verification
- 工艺相关杂质研究
  Study on process related impurities
- 细胞库/菌种库/病毒库检定
  Cell bank / strain bank / virus bank verification
- 微生物检测解决方案
  (无菌快检、支原体快检等)
  Microbial detection solutions
  (rapid sterility test, rapid Mycoplasma test, etc.)
- 蛋白多肽类药物结构表征
  Structural characterization of protein peptide drugs
- mRNA药物结构及关键质量属性
  MRNA drug structure and key quality attributes
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  Compatibility study
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  Detection of pharmaceutical raw and auxiliary materials (including microorganisms)
- 样品稳定性研究
  (影响因素实验/长期/加速)
  Study on sample stability
  (influencing factor experiment / long term / acceleration)
- 分析方法验证及样品放行
  Analysis method validation and sample release
- 生物样本分析
  Biological sample analysis
- 药品及医疗器械注册
  Registration of drugs and medical devices
- GMP合规咨询
  GMP compliance consulting
- 合规验证解决方案
  Compliance verification solution

商业化
COMMERCIALIZATION

- UPB等商业化批次放行检测
  Commercial batch release test such as UPB
- 蛋白多肽类药物结构表征
  Structural characterization of protein peptide drugs
- mRNA药物结构及关键质量属性
  MRNA drug structure and key quality attributes
- 药用原辅料检测(含微生物)
  Detection of pharmaceutical raw and auxiliary materials (including microorganisms)
- 分析方法验证及样品放行
  Analysis method validation and sample release
- GMP合规咨询
  GMP compliance consulting
- 合规验证解决方案
  Compliance verification solution

03.

服务内容

SERVICE CONTENT

我们凭借符合国际质量标准的生物制品研发及实验室服务，以积极的探索精神与贴心的服务理念，为客户提供专业的蛋白质结构表征研究。2021年，微谱生物安全研究BSL-2实验室落地苏州，服务版图扩展到生物安全研究领域。综合微谱生物医药平台内强大的相容性研究、包装材料密封性研究、药用原辅料全检、微生物检测、验证咨询(GMP)等服务，为生物制品研发提供专业的一体化综合解决方案。

We can provide professional protein structure characterization with active exploration spirit and caring service concept by virtue of our biologics R&D and laboratory services that meet international quality standards. In 2021, our BSL-2 Biosafety Laboratory has been set up in Suzhou with its services extended to the biosafety field. This laboratory can provide professional integrated solutions for biologics R&D relying on the powerful compatibility study, package integrity study, full Inspection of pharmaceutical raw materials and excipients, microbiological testing, verification consultation (GMP) and other services on our biomedical platform.

生物制品质量研究服务
QUALITY RESEARCH SERVICE OF BIOLOGICAL PRODUCTS

生物安全研究服务
BIOSAFETY RESEARCH SERVICES

相容性研究服务
COMPATIBILITY STUDY

包装材料密封性研究服务
PACKAGE INTEGRITY STUDY

药用原辅料全检
FULL INSPECTION OF EXCIPIENTS

微生物检测
MICROBIOLOGICAL TESTING

法规咨询
REGULATORY CONSULTATION

合规验证解决方案
REGULATORY CONSULTATION AND COMPLIANCE VERIFICATION SERVICES

生物制品质量研究服务

QUALITY RESEARCH SERVICE OF BIOLOGICAL PRODUCTS

蛋白多肽类药物结构表征(Structural characterization of protein peptide drugs)

特性检定 >> Characterization

■ 蛋白一级质谱结构表征 (Spectrometrical characterization of first-order protein structures)

分子量:完整蛋白分子量丨脱糖完整蛋白分子量丨还原蛋白分子量丨脱糖还原蛋白分子量
Molecular weight: whole protein molecular weight丨deglycated whole protein molecular weight丨reductive protein molecular weight丨deglycated reductive protein molecular weight

还原肽图:序列覆盖率丨N/C端氨基酸序列确认丨翻译后修饰鉴定丨质量肽图丨N糖位点确认
Reducing peptide mapping: sequence coverage丨N/C terminal amino acid sequence confirmation丨post-translation modification identification丨mass peptide mapping

非还原肽图:二硫键配对分析
Non-reducing peptide mapping: paired analysis of disulfide bonds

质谱法游离糖谱鉴定:N-糖谱分析
Identification of free sugar profile by mass spectrometry: N-sugar profiling

■ 蛋白高级结构表征 (Spectrometrical characterization of advanced protein structures)

CD、DSC、FLR、FTIR、DLS

■ 其他理化性质 (Other physical and chemical properties)

氨基酸组成、消光系数、游离巯基、Edman N端测序
Amino acid composition, extinction coefficient, free sulfhydryl group, Edman N-terminal sequencing

mRNA药物结构及关键质量属性(mRNA drug structure and key quality attributes)

- >> 加帽率 / >> Capping rate
- >> Poly A 长度 / >> Poly a length
- >> 金属残留 / >> Metal residue
- >> 溶剂残留 / >> Solvent residue
- >> 蛋白酶残留 / >> Protease residue
- >> mRNA(鉴别/含量/纯度/杂质) / >> MRNA (identification / content / purity / impurity)
- >> 脂质(鉴别/含量/纯度/杂质) / >> Lipids (identification / content / purity / impurities)

工艺相关杂质 >> Process-related impurities

二甲基硅油丨泊洛沙姆丨吐温丨MSX
Simethicone丨poloxamer丨Tween丨MSX

抗生素等小分子残留
Antibiotics and other micromolecule residues

HCP丨HCD

产品相关杂质 >> Product-related impurities

酸丨碱性峰质谱鉴定
Identification of acid and alkali peaks by mass spectrometry

鉴别 >> Identification

分子量(SDS-PAGE电泳法)
Molecular weight (SDS-PAGE electrophoresis)

肽图分析
Peptide mapping

等电点
Isoelectric point

理化分析 >> Physical and chemical analysis

氨基酸组成及消光系数分析
Amino Acid Composition and Extinction Coefficient Analysis

游离巯基
Free sulfhydryl group

Edman N端测序
Edman N-terminal sequencing

SEC-MALS聚合物分析
SEC-MALS Polymer analysis

SEC/RP/CE-SDS纯度分析
SEC/RP/CE-SDS Purity analysis

生物学活性检测 >> Biological activity test

ADCC效应丨CDC效应丨酶标仪丨C1q丨FcRn丨FcγRIa丨FcγRIIb/c丨FcγRIIb ... ...
ADCC effect丨CDC effect丨microplate reader丨C1q丨FcRn丨FcγRIa丨FcγRIIb/c丨FcγRIIb ... ...

生物安全研究服务
BIOSAFETY RESEARCH SERVICES

细胞/病毒/菌种建库(Cell/virus/strain banking)

细胞建库 >> Cell banking

我们提供充分表征、详细记录、同质的主细胞库(MCB)和工作细胞库(WCB)。对关键属性的严格质控，大大降低了生物产品的质量安全风险。提供细胞建库、检定、存储的一整套解决方案，可满足疫苗、抗体、细胞及基因治疗产品的生产。主要包括原始细胞库（PCB）、主细胞库（MCB）、工作细胞库（WCB），具备多种检测方法能力，可为生物技术制品的生产提供明确检定、质量一致且能持续稳定传代的细胞。

We provide fully characterized, well documented, homogeneous master cell bank (MCB) and working cell bank (WCB). Strict quality control of key attributes greatly reduces the quality and safety risks of biological products. We provide a complete set of solutions for cell library building, verification and storage, which can meet the production of vaccines, antibodies, cells and gene therapy products. It mainly includes original cell bank (PCB), main cell bank (MCB) and working cell bank (WCB). It has the ability of multiple detection methods and can provide cells with clear verification, consistent quality and continuous and stable passage for the production of biotechnology products.

细胞建库优势：经验证的环境和设备、符合国际监管标准细胞库测试、复苏后具有>80%活力、建库总结报告、根据客户需求量交付指定细胞活性和数量的细胞库、批次放行具备CoA报告。

Advantages of cell bank building: verified environment and equipment, cell bank testing in line with international regulatory standards, viability > 80% after resuscitation, bank building summary report, delivery of cell bank with specified cell activity and quantity according to customer demand, and COA report for batch release;

病毒建库 >> Virus banking

基于丰富的项目经验，我们为国内外客户提供病毒建库服务，并对相应病毒的生产计划进行测试，以确保为客户提供从临床前到临床试验的优质产品与服务，为客户降低前期研发投入，大大缩短研发周期，赋能生物技术产品快速创新。

Based on our rich project experience, we provide virus library building services for domestic and foreign customers, and test the production plans of corresponding viruses to ensure that we provide customers with high-quality products and services from preclinical to clinical trials, reduce early R & D investment for customers, greatly shorten the R & D cycle, and enable rapid innovation of biotechnology products.

病毒建库：原始毒株库（PVB）、主病毒库（MVB）、工作病毒库（WVB）。
Virus library: original virus library (PVB), main virus library (MVB), working virus library (WVB);

病毒分析表征：病毒滴度测试、病毒纯度测试、病毒稳定性测试。
Virus analysis and characterization: virus titer test, virus purity test, virus stability test;

病毒存储及附加服务：从临床前到临床试验的供应存储、提供病毒生产的总结报告、实时监控温度控制的超低温存储系统，满足长期保存及安全性存取需求。
Virus storage and additional services: supply and storage from preclinical to clinical trials, provide summary reports of virus production, and real-time monitoring and temperature control ultra-low temperature storage system to meet long-term storage and security access requirements;

菌种建库 >> Strain banking

菌种建库优势

- 经验证的洁净区环境（C+A）及设备
- 成熟的建库方案和建库总结
- 超过20余种菌种的建库经验(CMCC&ATCC)
- 定制化的菌种鉴定项目，提供COA
- 多元化的存储条件：液氮、-80°C；

Advantages of strain library building

- Verified clean area environment (c + a) and equipment
- Mature database building scheme and database building summary
- More than 20 kinds of bacteria library building experience (CMCC & ATCC)
- Customized strain identification project, providing COA
- Diversified storage conditions: liquid nitrogen, - 80 °C;

细胞库/病毒库/菌种检定 (Cell /virus/strain bank verification)

细胞库检定 >> Cell Bank Verification

检测项目 (Test item)		PCB	MCB	WCB	EOPC	UPB
细胞鉴别 (Cell identification)		(+)	+	+	(+)	-
细菌、真菌检查 (Bacteria and fungus inspection)		(+)	+	+	+	-
分枝杆菌检查 (Mycobacterium test)		-	(+)	(+)	(+)	-
支原体检查 (Mycoplasma test)		(+)	+	+	+	+
内、外源性病毒因子检查 Internal and external source virus contamination inspection	细胞形态观察及血吸附试验 Cell morphology observation and blood adsorption test	(+)	+	+	+	-
	体外不同细胞接种培养法 In vitro inoculation culture of different indicator cells	-	+	+	+	+
	动物和鸡胚体内接种法 In vivo inoculation of animal and chicken embryos	-	+	-	+	+
	逆转录病毒检查 Retrovirus check	-	+	-	+	+
	种属特异性病毒检查 Specific virus check	-	(+)	-	-	-
	牛源性病毒检查 Bovine virus check	-	(+)	(+)	(+)	-
	猪源性病毒检查 Porcine-derived virus check	-	(+)	(+)	(+)	-
	其他特定病毒检查 Other specific virus check	-	(+)	(+)	(+)	-
染色体检查 (Chromosome check)		-	(+)	(+)	(+)	-
成瘤性检查 (Tumorigenicity test)		-	(+)	(+)	-	-
致瘤性检查 (Oncogenicity test)		-	(+)	(+)	-	-

菌种库检定 >> Cell Bank Verification

表型检定 (Phenotyping)	
类别 (Category)	特征 (Features)
培养物 Culture	菌落形态、菌落颜色、形状和大小等 Colony morphology, colony color, shape and size, etc
形态学 Morphology	细胞形态、大小、形态、鞭毛类型、革兰氏染色 Cell shape, size, morphology, type of flagellum, Gram stain
生理生化 Physiology and Biochemistry	氧气耐受性、碳水化合物的氧化或发酵、酶的模式 Oxygen tolerance, oxidation or fermentation of carbohydrates, pattern of enzymes
抑制性 Inhibitive	胆盐耐受性、抗生素敏感性 Bile salt tolerance, antibiotic susceptibility
血清学 Serology	凝集反应、荧光抗体 Agglutination reaction, fluorescent antibodies
化学分类 Chemical classification	脂肪酸构成、微生物毒素、全细胞组分 Fatty acid composition, microbial toxins, whole cell components
生态学 Ecology	微生物来源 Microbial sources

基因型/系统发育检定 (Genotype / phylogenetic test)	
类别 (Category)	特征 (Features)
基因型 Genotype	DNA-DNA杂交、G+C、核酸序列、酶切图谱 DNA-DNA hybridization, G + C, nucleic acid sequences, and digestion maps
系统 System	16S rDNA、18S rDNA 、ITS、全基因组序列 16S rDNA, 18S rDNA, its, whole genome sequence

病毒库检定 >> Virus bank verification

微谱生物医药病毒库检定方面经验丰富，可以提供符合中国药典、ICH等法规要求的病毒库检定。针对客户不同类型病毒样本，提供科学合理的检测方案，并且在送样前为客户提供合理的样本送样计划，指导客户合理送样。

We have abundant experience in virus bank verification, and can provide virus bank verification services according to Chinese Pharmacopoeia, ICH regulations and other laws and regulations. We can provide scientific and reasonable test protocols for different types of virus samples from customers, and make reasonable sample delivery plans for customers before

以重组工程毒种MVB检测项目为例

Examples include the test items of recombinant engineering virus MVB

重组工程毒种MVB检测项目 (Test items of recombinant engineering virus MVB)	
全基因序列测定 (Whole gene sequence determination)	
目的基因序列测定 (Determination of target gene sequence)	
病毒滴度检查 (Virus titer test)	
目的蛋白表达量 (Target protein expression)	
细菌、真菌检查 (Bacteria and fungus inspection)	
分枝杆菌检查 (Mycobacterium test)	
支原体检查 (Mycoplasma test)	
内、外源性病毒因子检查 Internal and external source virus contamination inspection	细胞形态观察及血吸附试验 Cell morphology observation and blood adsorption test
	体外不同细胞接种培养法 In vitro inoculation culture of different indicator cells
	动物和鸡胚体内接种法 In vivo inoculation of animal and chicken embryos
	逆转录病毒检查 Retrovirus check
	种属特异性病毒检查 Specific virus check
	牛源性病毒检查 Bovine virus check
	猪源性病毒检查 Porcine-derived virus check
	其他特定病毒检查 Other specific virus check

病毒载体分析 >> Viral vector analysis

病毒鉴别 Virus identification	DNA测序 | 基因组酶切图谱 | 外壳蛋白 | 其他特殊方法 DNA sequencing | genome macrorestriction map | coat protein | Other special methods
纯度检查 Purity check	空壳率测试 | 病毒蛋白含量测试 | 病毒颗粒纯度 Empty virus test|virus protein content test|virus particle purity
效力检查 Potency test	病毒基因组拷贝数测定 | 病毒颗粒数 | 感染滴度 | 比活度 Viral genome copy number test | virus particle number | infection titer | specific activityv
安全性检查 Safety test	宿主DNA残留 | 宿主蛋白残留 | BSA残留 | 前体蛋白 | 无菌检查 | 支原体检查 | 内毒素检查 | 外源因子检查 Host DNA residue test | host protein residue test | BSA residue test | precursor protein test | sterility test | mycoplasma test | endotoxin test | exogenous factor test
稳定性研究 Stability study	稳定性留样 | 病毒效力考察 | 基因组的稳定性考察 Stability sample retention | virus potency study | genome stability study

病毒清除验证(Virus Clearance Verification)

>>抗体类	>>Antibodies
>>重组蛋白	>>Recombinant proteins
>>基因治疗载体	>>Gene therapy vectors
>>疫苗	>>Vaccine
>>细胞治疗产品	>>Cell-based gene therapy products
>>血液制品	>>Blood products
>>其他动物体液/组织来源制品	>>Other animal fluids/tissues derived products

微生物检测解决方案(Microbiological Detection Solution)

支原体检查 >> Mycoplasma test

做为最小的微生物，支原体对培养细胞的污染发生率高。这种污染非常隐秘不容易被发现并且在实验室内会潜在的扩散。支原体污染使得用被污染的细胞样本做的实验完全失去意义和价值。因此对支原体建立可靠的方法进行检测至关重要。微谱可以支持中国药典、美国药典、欧洲药典、日本药典方法的支原体检测。

Mycoplasma, the smallest microorganism, has a high possibility of contamination to cultured cells. This contamination is not easy to detect and will potentially spread in the laboratory. Mycoplasma contamination makes the experiment conducted with contaminated cell samples completely meaningless and valueless. Therefore, it is crucial to establish a reliable method for the detection of mycoplasma. We support the detection of mycoplasmas according to Chinese Pharmacopoeia, United States Pharmacopeia, European Pharmacopoeia and Japanese Pharmacopoeia.

无菌检查 >> Mycoplasma test

无菌检查法系用于检查药典要求无菌的药品、医疗器具、原料、辅料、及其他品种是否无菌的一种方法。若供试品符合无菌检查法的规定，仅表明了供试品在该检验条件下未发现微生物污染。对于无菌检查，微谱可以根据不同客户需求，不同样品种类，提供多元的定制化无菌检查方案。

Sterility test is a method used to check the presence of bacteria in medicines, medical instruments, raw materials, excipients, and other varieties that should be sterile according to relevant pharmacopoeia. If the test article meets the requirements of sterility test, it only indicates that no microbial contamination is detected in the test article under this test condition. For sterility test, we can provide multiple customized sterility test options according to the different customer needs and different sample types.

一对一定制化服务： 针对供试品数量有限的细胞库和病毒库，及不易溶解或质地粘稠的原辅料，我们可以制定与产品一对一的直接接种法方法适用性试验及无菌检查法。

One-to-one customized service: For the cell bank and virus bank with limited test articles, and insoluble or viscous raw materials and excipients, we can formulate one-to-one direct inoculation method, method suitability test and sterility test for products.

能力覆盖多元方法： 根据客户需求想扩大单次检验量，提高检出率的供试品，我们可以提供薄膜过滤法方法适用性试验及无菌检查法。

Availability of multiple methods: According to customer needs, we can provide membrane filtration method, method suitability test and sterility test for samples to expand single inspection quantity and improve detection rate.

满足中美欧药典需求： 我们提供的服务符合《中国药典》、《欧洲药典》、《美国药典》等国内外法规要求。

Sastifaction with Chinese, American and European Pharmacopoeia: Our services meet the requirements of Chinese Pharmacopoeia, European Pharmacopoeia, United States Pharmacopoeia and other laws and regulations at home and abroad.

精准 有效 快速 合规： 依据客户样品类型，提供更加精准、有效、快速、合规的无菌检查方法适用性试验方案和技术服务。

Accurate, effective, rapid and compliant: According to the sample types of customers, we can provide more accurate, effective, rapid and compliant protocol and technical services for sterility test and method suitability test.

支原体快检 >> Rapid mycoplasma test

支原体的传统药典检测方法业内认可度高，但是检测周期均较长，这样传统的方法对于样本时效性较短的药品（如Car-T、干细胞样本）来说，这个检测周期无疑还是不能满足实际需要的，因此快检方法被越来越多的关注到，这类方法的合规应用也迫在眉睫。

使用者需筛选、确认或验证支原体NAT法的商品化试剂盒，如自行建立方法，需进行充分的方法学验证。供多元的定制化无菌检查方案。

The traditional pharmacopeial test method of mycoplasma is highly recognized in the industry. However, with long detection cycle, traditional method cannot meet the actual demands for drugs with short sample timeliness (e.g. Car-T and stem cell samples). Therefore, the demand for a quick detection method is increasingly focused, and the compliant application of such a method is extremely urgent.

Users shall screen, confirm or verify the commercial kits of mycoplasma NAT assay and perform sufficient methodological verification for self-developed methods.

A：应用商业化试剂盒，该试剂盒按照EP/JP要求执行了充分的方法学验证，客户拿到了该试剂盒的方法验证报告。
Commercial kits will be used after the methodology is thoroughly verified according to EP/JP requirements and the methodology verification report is sent to the customer.

解决方案： 使用前进行方法的适用性验证，开展药典方法的平行检测研究。
Solution： Method suitability test is verified before use while the testing study of pharmacopeial methods is conducted to provide data support.

B：应用未验证过的商业化试剂盒。
Unverified commercial kits are used.

解决方案： 按照国外的法规要求（EP或JP要求）进行充分方法学验证，使用前进行方法的适用性验证，开展药典方法的平行检测研究。
Solution： The methodology is thoroughly verified and method suitability test is verified before use while the testing study of pharmacopeial methods is conducted to provide data support according to foreign and domestic regulatory requirements (EP or JP).

C：使用了获得监管方认可的支原体参比物质，自行开发方法。
Mycoplasma reference substances approved by regulatory authorities and self-developed methods will be used.

解决方案： 进行充分方法学验证，使用前进行方法的适用性验证，开展药典方法的平行检测研究。
Solution： The methodology is thoroughly verified and method suitability test is verified before use while the testing study of pharmacopeial methods is conducted to provide

无菌快检 >> Quick sterility test

针对供试品的效期短、价格昂贵、数量有限、不易溶解、粘稠或者想要提高检出率的需求，我们可以根据不同产品提供无菌快速检验方法，包括无菌检查替代验证方案、替代方法验证、方法适用性试验及检测服务。

Considering the short validity period, high price, limited quantity, insolubility, viscosity or the demand for improving detection rate of test articles, we can provide quick sterility test for different products, including sterility test alternative verification, alternative method verification, method suitability test and testing services.

相容性研究

COMPATIBILITY STUDY

包装材料(Packaging materials)：原辅料和终产品储存容器 Storage containers for final products and intermediates

玻璃 (Glass)	硼硅玻璃安瓿瓶(无色或棕色)、硼硅玻璃西林瓶、钠钙玻璃注射剂瓶、笔式注射器(卡式瓶)、预灌封注射器。 Borosilicate glass ampoules (colorless or brown), borosilicate glass penicillin bottles, soda-lime glass bottles for injection, pen injector (cartridges), pre-filled syringes.
弹性体 (Elastomer)	注射用冷冻干燥用溴化(氯化)丁基橡胶塞、预灌封注射器用活塞、注射液用溴化(氯化)丁基橡胶塞、注射液用局部覆膜溴化(氯化)丁基橡胶塞、注射用冷冻干燥用局部覆膜溴化(氯化)丁基橡胶塞、口服液体用聚乙烯聚酯铝聚乙烯密封垫片。 Brominated (chlorinated) butyl rubber stopper for freezing, drying and injection, piston for prefilled syringes, brominated (chlorinated) butyl rubber stopper for injection, locally coated brominated (chlorinated) butyl rubber stopper for freezing, drying and injection, polyethylene polyester-aluminum polyethylene sealing gasket for oral solution.
聚合物 (Polymer)	环烯烃类共聚物(COC)瓶、三层共挤输液袋、直立式聚丙烯输液袋、细胞冻存管、细胞冻存袋、多层共挤输液袋、聚丙烯输液袋、铝塑复合膜袋、药用低密度聚乙烯塑料袋、低密度聚乙烯药用滴眼剂。 Cyclic olefin copolymer (COC) bottle, three-layer co-extrusion infusion bag, vertical polypropylene infusion bag, cell cryopreservation tube, cell cryopreser vation bag,Multi layer co extrusion infusion bags, polypropylene infusion bags, aluminum-plastic composite film bags, medical low-density polyethylene plastic bags, low-density polyethylene medical eye drops.

工艺组件(Process components)：生产过程中接触的材料 Materials exposed in the production process

非聚合物 (Non-polymer)	316L不锈钢管道、316L不锈钢罐体、316L不锈钢过滤器壳、316L不锈钢灌装针头。 316L stainless steel pipe, 316L stainless steel tank, 316L stainless steel filter shell, 316L stainless steel filling needle.
聚合物 (Polymer)	铂金硫化硅胶管、灌装用硅胶软管、硅胶垫片、聚四氟乙烯密封垫片、硅橡胶密封垫片、O型硅胶垫圈、聚醚砜滤芯、PES/PP微孔折叠滤芯、除菌过滤滤芯。 Platinum vulcanized silicone tube, silicone hose for filling, silicone gasket, polytetrafluoroethylene sealing gasket, silicone rubber sealing gasket, silicone O-ring, polyethersulfone filter element, PES/PP microporous folded filter element, sterilization filter element.
一次性使用系统 (Disposable system)	一次性使用多层共挤袋、一次性储液袋、一次性使用塑料血袋、AT无菌冻存瓶、一次性搅拌袋、一次性生物反应袋、一次性无菌取样袋。 Disposable multilayer co-extrusion bag, disposable liquid storage bag, disposable plastic blood bag, AT sterile cryopreservation bottle, disposable stirring bag, disposable biological reaction bag and disposable sterile sampling bag.

给药器具(Dosing apparatus)：实际使用过程中接触的材料 Materials contacted during actual use

注射 (Injection)	一次性使用精密过滤输液器带针、一次性使用便携式输注泵、一次性使用静脉留置针、回缩自毁式一次性使用无菌注射器、一次性使用植入式给药装置专用针。 Disposable precision filter infusion set with needle, disposable portable infusion pump, disposable venous indwelling needle, retraction self destruction disposable sterile syringe, disposable implantable drug delivery device special needle.
输注 (Infusion)	一次性使用精密过滤输液器(带针)(PVC、TPU、TPE等材质)、电子输注泵、一次性使用输注导管包、一次性使用带输液贴式输液器、一次性使用压力输液器。 Disposable precision filter infusion set (with needle) (PVC, TPU, TPE and other materials), electronic infusion pump, disposable infusion catheter bag, disposable patch infusion set with infusion, and disposable pressure infusion set.
其他 (Other)	经外周插管的中心静脉导管、一次性使用补液管路、一次性使用配药器(带针)、一次性使用血液采集器(转移袋)、一次性使用内窥镜给药管。 Central venous catheter intubated through the periphery, disposable fluid replenishment pipeline, disposable dispenser (with needle), disposable blood collector (transfer bag), and disposable endoscopic drug delivery tube.

密封性研究
SEALING STUDY

确定性方法(Deterministic method)

真空衰减法 >> Vacuum attenuation method

非破坏性定量测量方法，用于检测刚性或柔性包装中的泄漏。在适当设计的测试参数和产品属性允许下，可用于包装顶空气体区域或产品填充水平以下的泄漏检测。

A non-destructive quantitative measurement method for detecting leakage in rigid or flexible packaging. It can be used for leakage detection in the gas area of the packaging head space or below the filling level of the product under the permission of properly designed test parameters and product properties.

压力衰减法 >> Pressure attenuation method

用于检测刚性或柔性包装中泄漏的定量测量方法，用于测试

A quantitative measurement method for detecting leakage in rigid or flexible packaging, used for integrity detection of the gas headspace area of the test sample.

高压放电法 >> High pressure discharge method

检测通过药品和包装的电流来判断泄漏。具有灵敏度高、稳定性好、无损检测等优势，适用于玻璃安瓿、塑料安瓿、输液软袋等产品的商业化在线检测。

Detect the current through the medicine and package to judge the leakage. It has the advantages of high sensitivity, good stability and non-destructive testing. It is suitable for commercial online testing of glass ampoules, plastic ampoules, infusion soft bags and other products.

概率性方法(Probabilistic method)

微生物侵入法 >> Microbial invasion method

浸没式微生物挑战法是一种破坏性的定性测量方法，可用于判断刚性或柔性包装中的泄漏。

The submerged microbial challenge method is a destructive qualitative measurement method that can be used to determine leakage in rigid or flexible packaging.

气泡法 >> Bubble method

液下气泡检漏测试是一种破坏性的定性测量方法，用于检测和定位含有顶空气体的刚性或柔性包材。

Underwater bubble leak detection test is a destructive qualitative measurement method used to detect and locate rigid or flexible packaging materials containing headspace gas.

液体迁移（色水法）>> Liquid migration (aqueous colour method)

微谱主要研究的液体浸没测试方法是将待测样品浸没在真空腔体里的示踪元素溶液配方中，主要种类有：色油法和色水法。

The liquid test method mainly investigated by Weipu is to submerge the sample to be tested in a tracer element solution formulation in a vacuum chamber, "which is mainly divided into" the oil-color method and the water-color method.

现场指导/验证服务 (Site directed / validated services)

>> 包装材料密封性研究，与其他研究领域的不同之处在于，最终的落脚点是在工厂生产线。

Packaging material sealing studies, differing from other research areas in that the final foot drop point is at the plant line.

自2020年下半年CDE对于方法学验证灵敏度的要求提高后，我们基于对大量发补案例的统计研究发现，大多数发补原因集中在生产线上缺少密封性在线设备的方法学验证，现场验证已经成为生产线上不可或缺的一环。至今我们已经成功完成了多个在线设备的方法学验证项目，包装类型涵盖安瓿瓶、输液袋、BFS等，协助客户依从法规开展商业化检漏与现场验证，为客户产品顺利转化保驾护航。

Since the CDE requirement for sensitivity in method validation increased in the second half of 2020, we found based on a statistical study of a large number of refill cases that most of the reasons for the refill focused on the lack of methodological validation of sealing online equipment on the manufacturing line, and on-site validation has become an integral loop on the manufacturing line. To date we have successfully completed several methodological validation projects of online devices with package types covering ampoules, infusion bags, BFS, etc., to assist customers in compliance with regulations to conduct commercial retinoscopy versus field validation for the smooth transformation of customer products to escort.

01 **方案制定** Program development
>
02 **整装出行** Whole mount travel
>
03 **现场预实验** On site pre experiments
>
04 **数据校准** Data calibration
>
05 **周期保障** Cycle assurance

药用原辅料全检

MEDICINAL RAW AND AUXILIARY MATERIALS

微谱药用辅料全检研究团队，拥有出色的一站式辅料全套指标检测服务，能力范围可覆盖中国药典、美国药典、欧洲药典、日本药局方等，助力制药企业产品合规并加速产品商业化进程。

Our full inspection study team of pharmaceutical excipients can provide excellent one-stop inspections for pharmaceutical excipients with a complete set of indicators, with its inspection range covering Chinese Pharmacopoeia, United States Pharmacopoeia, European Pharmacopoeia, Japanese Pharmacopoeia, etc., facilitating the compliance of pharmaceutical companies with drug regulations and accelerating the commercialization of drug products.

服务产品 (Service products)

酸碱及无机盐类： 常规辅料如稀盐酸、硫酸；氢氧化钠、碳酸氢钠、氯化钠、碳酸钙等；
Acids, bases and inorganic salts: conventional excipients such as diluted hydrochloric acid and sulfuric acid; sodium hydroxide, sodium bicarbonate; sodium chloride, calcium carbonate, etc.

纯化水及注射用水： 水系统验证、全检；
Purified water and water for injection: water system verification and full inspection.

大分子类： 如聚山梨酯系列、纤维素等；
Macromolecules: such as polysorbates, cellulose, etc.

小分子类： 如乙酸乙酯、乙醇、二甲基亚砜等辅料及化学原料药等；
Micromolecules: such as ethyl acetate, ethanol, dimethyl sulfoxide and other excipients and chemical drug substance, etc.

其他： 如甲氧基、乙氧基与羟丙氧基的测定等；
Others: such as methoxy, ethoxy and hydroxypropoxy, etc.

物理常数类： 熔点，凝点，旋光，折光，pH值，黏度，电导率，TOC等
Physical constants: melting point, condensation point, optical rotation, refraction, pH value, viscosity, conductivity, TOC, etc.

特性检测类： 颜色，澄清度，结晶，粒度，比表面积，密度等
Characterization: color, clarity, crystallization, particle size, specific surface area, density, etc.

限量检查类： 氯化物，硫酸盐，铁盐，铵盐，重金属，砷盐，干燥失重，炽灼残渣，水分等
Limit inspection: chloride, sulfate, iron salt, ammonium salt, heavy metals, arsenic salt, weight loss on drying, residues on ignition, moisture, etc.

质谱类： 分子量，基因毒杂质等
Mass spectrometry: molecular weight, genotoxic impurities, etc.

光谱类： 红外，紫外，荧光，原子吸收，核磁共振等
Spectrum:infrared, ultraviolet, fluorescence, atomic absorption, nuclear magnetic resonance, etc.

色谱类： 含量（含滴定），有关物质，溶剂残留，鉴别等
Chromatography: content (including titration), related substances, solvent residues, identity, etc.

微生物检测

MICROBIOGICAL DETECTION

微谱生物医药经过在药械研究领域的深耕厚植，已经搭建出经验丰富、专业强大的微生物检测研究团队，配备相关大型精密仪器设备和超1000㎡微生物实验室，以科学、合规、精准、智慧的专业服务，满足不同客户的项目需求，为药品研发申报提供整体解决方案和策略，为产品顺利上线提供有力保障。2021年12月，微谱微生物实验室顺利获得“上海市病原微生物实验室备案凭证”，实验室等级BSL-2，证书编号：宝字第0220210017号。

We have built a talent team with abundant experiences and expertise in microbiological testing. We have owned relevant large-scale precision instruments and equipment and microbiology laboratories covering over 1,000 ㎡ We are striving to satisfying the project needs of different customers with scientific, compliant, accurate and intelligent professional services and providing overall solutions and strategies for drug R&D and declaration, so as to ensure the smooth launch of products. The business scope includes preparations and their raw materials and excipients, packaging materials and intermediates. On December 30, 2021, our microbiology laboratory successfully obtained the Registration Certificate of Shanghai Pathogenic Microbiology Laboratory, with laboratory grade BSL-2 and certificate number: BZ No. 0220210017.

微生物限度 >> Microbial limit detection

- 指产品上存活的微生物总数
  Refers to the total number of microorganisms living on the product
- 包括需氧菌总数、霉菌酵母菌总数、控制菌
  Including the total number of aerobic bacteria, the total number of molds and yeasts, and the control bacteria; Protease residue

细菌内毒素 >> Bacterial endotoxin

- 可引起恒温动物体温异常升高的物质，属于热原的一种
  A substance that can cause an abnormal rise in the body temperature of a constant temperature animal, belonging to a pyrogen
- 革兰氏阴性菌死亡自溶时，才表现其毒性
  The toxicity of Gram-negative bacteria was only shown when they died and autolysed

无菌 >> Sterility

- 判断产品是否无菌，定性
  Judge whether the product is sterile and qualitative
- 若样品符合无菌检查法的规定，表明该样品在该检验条件下未发生微生物污染
  If the sample complies with the provisions of sterility test method, it indicates that the sample has not been contaminated by microorganisms under the test conditions

抑菌效力 >> Bacteriostatic potency

- 药物本身不具有充分的抗菌效力
  The drug itself does not have sufficient antibacterial efficacy
- 添加适当的抑菌剂后，确定其是否能有效防止药物里的微生物污染和繁殖
  After adding appropriate bacteriostatic agent, determine whether it can effectively prevent microbial contamination and propagation in the drug

法规咨询

REGULATORY CONSULTATION

微谱法规咨询服务专注于为药品提供注册咨询、GMP合规咨询等专业咨询服务，凭借丰富的项目经验，精准把握产品各阶段要点，熟稔监管部门的审评流程和决策机制，充分理解监管部门的具体要求，助力客户加速市场化进程。

The Weipu's regulation consulting service focuses on providing professional consulting services such as registration consulting and GMP compliance consulting for drugs. With rich project experience, Weipu accurately grasps the key points of each stage of the product, is familiar with the review process and decision-making mechanism of the regulatory authorities, fully understands the specific requirements of the regulatory authorities, and helps customers accelerate the marketization process.

国内注册 >> Domestic registration

- 创新药临床试验申请
  Application for clinical trial of innovative drugs
- 创新药上市许可申请及上市后维护
  Application for marketing license of innovative drugs and post marketing maintenance
- 仿制药上市许可申请及上市后维护
  Application for marketing license of generic drugs and post marketing maintenance
- 原料药登记
  API registration
- 药用辅料和药包材登记
  Registration of pharmaceutical excipients and drug packaging materials

国际注册 >> International registration

- 制剂欧洲注册
  European registration of drug products
- 欧盟CEP/COS申请
  EU CEP / COS application
- 欧盟ASMF/EDMF文件制作
  EU ASMF / edmf document preparation
- 美国IND申请
  US IND application
- 美国NDA申请
  US NDA application
- 美国ADNA申请
  American ADNA application
- 美国DMF文件制作
  US DMF document production
- FDA工厂注册、自认证与NDC申请
  FDA factory registration, self certification and NDC application

中国GMP >> China GMP

- 中国新版GMP认证
  New GMP certification in China
- GMP第三方审计
  GMP third party audit
- GMP远程审计支持
  GMP remote audit support
- 研发试验质量管理体系法规符合
  Regulatory conformity with R&D test quality management

国际GMP >> International GMP

- 欧盟GMP咨询
  EU GMP consultation
- 美国FDA认证咨询
  FDA certification consultation
- WHO认证咨询
  WHO certification consultation

合规验证解决方案

COMPLIANCE VERIFICATION SOLUTION

凭借丰富的GMP实验室服务经验，专业出色的技术团队，以及严格校准和验证的仪器配备。结合中国NMPA、美国FDA和欧盟EMA等认证要求，为广大医药企业提供高品质、高性价比的验证咨询服务。

With rich GMP laboratory service experience, professional and excellent technical team, and strict calibration and verification of instruments. In combination with the certification requirements of China nmpa, US FDA and EU EMA, we provide high-quality and cost-effective verification consulting services for pharmaceutical enterprises.

文件编制 >>
Document preparation

URS, VMP/VP, RA, SOP等

设备设施确认 >>
Equipment and facilities confirmation

洁净区，温控类设备等

Clean area, temperature control equipment, etc

计算机系统验证 >>
Computer system verification

气相和液相等团硬件验证

Hardware verification of gas phase and liquid phase clusters

运输验证 >>
Transport verification

确认最佳包装工艺作业方法

Confirm the best packaging process and operation method

咨询类 >>
Consulting

差距化分析，体系建立等

Gap analysis and system establishment

服务流程

SERVICE PROCESS

01
了解客户需求，
填写客户需求表
Understand customer demand and fill in customer demand form

02
编制
文件/方案
Prepare documents / plans

03
审核和批准
文件/方案（客户）
Review and approve documents / plans (customer)

04
根据方案
现场执行
Implement on site according to the scheme

05
执行完成
出具报告
Complete implementation and issue reports

06
审核和批准
报告（客户）
Review and approve reports (by customers)

04. 未来展望
OUR FUTURE

当前，科技创新与产业升级浪潮迭起，医药行业已经步入黄金发展期。
未来，我们将继续怀揣赤诚之心，与广大医药创新力量携手，共同拥抱国内外市场的深刻变化，迎接崭新药物研发模式的到来，并为构建良好的产业生态圈持续奉献自身力量。

At present, the tide of scientific and technological innovation and industrial upgrading is rising one after another, and the pharmaceutical industry has entered the golden development period.

In the future, we will continue to embrace the profound changes in the domestic and foreign markets, welcome the arrival of new drug R & D models, and continue to contribute our own strength to the construction of a good industrial ecosystem with a sincere heart and hand in hand with the vast number of pharmaceutical innovation forces.

愿景
为人类的生命
健康保驾护航
Protect human life and health

使命
值得信赖的
医药研发伙伴
Trustworthy pharmaceutical R & D partner

理念
全力以赴
不负所托
Go all out and live up to your expectations

微谱生物医药实验室服务布局
SERVICE LAYOUT OF WEIPU BIOMEDICAL LABORATORY

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Baoshan Biomedical Research Center: 1-3 / F, building 3, No. 69 Yuanfeng Road, Baoshan District, Shanghai

医疗器械研究中心：上海市宝山高新技术产业园区园丰路69号3号楼2层
Medical Device Research Center: 2nd floor, building 3, No. 69, Yuanfeng Road, Baoshan District, Shanghai

杂质研究中心：上海市杨浦区国伟路135号11号楼4-5层
Impurity Research Center: floor 4-5, building 11, No. 135, Guowei Road, Yangpu District, Shanghai

生物安全研究中心：苏州工业园区东长路88号B3栋2层
Biosafety Research Center: 2nd floor, building B3, No. 88 Dongchang Road, Suzhou Industrial Park

临床研究中心：苏州工业园区新平街388号腾飞创新园B座1110室【微研众方】
Clinical Research Center: room 1110, Tower B, Tengfei Innovation Park, No. 388 Xinping street, Suzhou Industrial Park

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微谱生物医药研发及实验室服务

Weipu Biomedical R & D andLaboratory Services

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Shanghai Guangzhou Shenzhen Suzhou Nanjing Hangzhou Ningbo Beijing Tianjin Qingdao Jinan Zibo Shijiazhuang Chengdu Chongqing

Hefei Bozhou Wuhan Xi'an Taiyuan Zhengzhou Changsha Jiangxi Fujian Guiyang Taicang Changshu Huhehaote Yinchuan

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