

四川灵生益制药有限公司

Sichuan Elixir Pharmaceutical Co., Ltd.

- 公司成立于2021年
 - 专注于化学原料药及医药中间体的研发、生产和销售，提供小分子化合物的CMO/CDMO业务
 - 专注于高活性细胞毒原料药领域，聚焦ADC药物毒素（Payload）和连接子（Linker）的研发和生产以及新盐新晶型研发平台，与改良型新药客户以及仿制药首仿客户进行深度合作
 - 全球化注册平台和专业团队，配有国际接轨的cGMP生产质量体系
 - 原料药的CMO/CDMO业务，配合客户进行中美欧三报及全球化注册
 - 制剂板块，保证公司重要战略：原料药+制剂的双规发展
- Company founded in 2021
- Professional manufacturer on R&D, production and sales of APIs and intermediates, providing CMO/CDMO service of small molecule compounds
- Specializing in high-potency and cytotoxic APIs, focusing on R&D and production of ADC Payload and Linker as well as R&D platform for new salt and new crystal, cooperating deeply with customers in 505(b)(2) and first generics
- Global registration platform and professional team, equipped with international standards of cGMP production quality system
- CMO/CDMO service of API, cooperating with customers to apply global registration and register in China, US and EU simultaneously
- For FDF, the company's important strategy: dual development of API and FDF

四川协力制药股份有限公司

Sichuan Xieli Pharmaceutical Co., Ltd.

- 公司成立于上个世纪八十年代
 - 通过了NMPA、MHRA、EDQM、FDA、PMDA、COFEPRIS官方认证，工厂平均每年接受50多次审计
 - 专注于抗肿瘤原料药及动植物源性原料药及其衍生物生产，定制服务及国内外联合申报
 - 独立的研发中心，中试平台，配有克到吨级生产能力，以及制粒和微粉生产
 - 专业的注册团队，全球超过100个国家登记注册经验，DMF涵盖17个品类，递交次数累计超过500+
 - EHS管理体系
- Company founded in the 1980s
- Sichuan Xieli Pharmaceutical Co., Ltd.
- Successful inspections by NMPA, MHRA, EDQM, FDA, PMDA and COFEPRIS, over 50 audits each year
- Professional manufacturer on oncology & animal/botanical derivative APIs, providing CDMO services and global registration
- Independent R&D center, pilot-scale workshop from gram to metric ton's scale production, multiple particle size capabilities from micronization to granules
- RA team with rich experience for global registration, DMF including 17 products registered in 100+ countries and submitted 500+ times
- Sustainable development with EHS management

销售总部 Sales Headquarters

成都市高新区交子大道300号环汇商业广场M3座2018-2019室
Room 2018-2019, Building M3, ICP, No.300, Jiaozhi Avenue, Gaoxin District, Chengdu City.

工厂地址 Factory Address

四川省彭州市天彭镇牡丹大道中段588号，邮编611930
Factory address: No. 588, Middle Section of Mudan Avenue, Tianpeng Town, Pengzhou City, Sichuan Province

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Site 1 眉山工厂

API, Formulation
原料药, 制剂

- cGMP
- EU GMP
- Japan GMP
- China GMP

Site 2 彭州工厂

API 原料药

- NMPA
- FDA
- PMDA
- EDQM
- COFEPRIS
- PSCI (EHS)

Site 3 海外工厂

Overseas Factory
Intermediate 中间体

- Vietnam Factory
- EHS

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Sichuan Elixir Pharmaceutical Co., Ltd.

四川奥吉瑞药业有限公司

Sichuan Regen Pharmaceutical Co., Ltd.

四川协力制药股份有限公司

Sichuan Xieli Pharmaceutical Co., Ltd.

动植物源性原料药

Botanical/Animal Derivative APIs

抗肿瘤原料药

Oncology APIs



动植物源性原料药 Botanical/Animal Derivative APIs

芦丁及其衍生物 Rutin & its derivatives		DMF	GMP
芦丁	★ Rutin	DMF	NMPA/ MHRA
曲克芦丁	★ Troxerutin	DMF/ CEP	NMPA/ MHRA
槲皮素	Quercetin		
水溶性芦丁	Rutin Water Soluble		

枳实系列 Citrus Aurantium L. Series		DMF	NMPA
橙皮甙	★ Hesperidin	DMF	NMPA
地奥司明	★ Diosmin	DMF/ CEP	NMPA/ EDQM

胆酸系列 Cholic Acid Series		DMF	NMPA
熊去氧胆酸	★ Ursodeoxycholic Acid	DMF	NMPA
奥贝胆酸	Obeticholic Acid		

其他提取物 Other Extracts		DMF	EDQM
金雀花碱	★ Cytisine	DMF	EDQM
青黛	★ Natural Indigo		NMPA
青蒿素	Artemisinin		NMPA
盐酸小檗碱	Berberine HCl		NMPA
罗通定	Rotundine		NMPA
肾上腺皮质激素	ACTH		
鱼精蛋白	Protamine Sulfate		

合同制造加工 CDMO Service

FDA: 现场审计0缺陷
 产能: 100克~500kg/月
 EHS: PSCI审计通过
 法规: 配合客户ANDA, NDA申请

FDA: On-site inspection with "0" observation
 Capacity: 100g~500kg/m
 EHS: PSCI audited
 Regulatory: ANDA, NDA application with customers

★ 拳头产品/Hit products
 Products with patent protection can't be used for commercial purpose.

抗肿瘤原料药 Oncology APIs

喜树碱系列 Camptothecin Series		DMF	GMP
盐酸伊立替康	★ Irinotecan HCl	DMF/ CEP /GDUFA	NMPA/ PMDA
7-乙基-10-羟基喜树碱	SN-38		NMPA
依喜替康	Exatecan		
羟喜树碱	10-Hydroxy-CPT		

替尼类 -nibs		DMF/GDUFA	COFEPRIS/FDA
厄洛替尼	★ Erlotinib	DMF/GDUFA	COFEPRIS/FDA
尼洛替尼	★ Nilotinib	DMF	
吉非替尼	★ Gefitinib	DMF/ CEP /GDUFA	FDA
达沙替尼	★ Dasatinib	DMF/GDUFA	
卡博替尼	Cabozantinib		

其他-Others		DMF/GDUFA	FDA
巨大戟醇甲基丁烯酸酯	★ Ingenol Mebutate	DMF/GDUFA	FDA
卡巴他赛	★ Cabazitaxel	DMF/GDUFA	FDA
阿那曲唑	★ Anastrozole	DMF/ CEP	
来曲唑	Letrozole		
甲氨蝶呤	Methotrexate		

高级中间体 Advanced Intermediates

7-乙基-10-羟基喜树碱	★ SN-38
巨大戟醇	Ingenol
间氨基苯乙炔盐酸盐	3-aminophenylacetylene HCl