

- 公司成立于上个世纪八十年代
- 通过了CFDA、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
- Successful inspections by CFDA, MHRA, EDQM, FDA, PMDA and COFEPRIS, over 50 audits each year
- Professional manufacturer on oncology & animal/botanical derivative APIs and CMO services
- 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 submission 500+ times.
- Sustainable development with EHS management

- 专门的项目管理支持
- 为客户提供从临床前期到商业化生产的定制服务
- 丰富的国际注册经验
- 企业自有检测服务
- 国际专利战略和解决方案支持
- Dedicated project management
- Customized support from pre-clinical to commercial production
- Rich experience in international regulatory affairs
- In-house analytics
- Global IP strategy & solution



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

抗肿瘤原料药 Oncology APIs



Site 1 工厂
API, Formulation
原料药, 制剂
• cGMP
• EU GMP
• Japan GMP
• EHS

Site 2 工厂
API
原料药
• cGMP
• EU GMP
• FDA
• EHS

Site 3 海外工厂
Overseas Factory
Intermediate 中间体
• Vietnam Factory
• EHS



四川协力制药股份有限公司
SICHUAN XIELI PHARMACEUTICAL CO., LTD.



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工厂地址：四川省彭州市天彭镇牡丹大道中段588号，邮编611930

· 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	CFDA/MHRA
曲克芦丁	★ Troxerutin	DMF/CEP (R0-CEP 2016-279-Rev 01)	CFDA/MHRA
槲皮素	Quercetin		
水溶性芦丁	Rutin Water Soluble		

枳实系列 Citrus Aurantium L. Series			
橙皮甙	★ Hesperidin	DMF	CFDA
地奥司明	★ Diosmin	DMF/CEP (R0-CEP 2013-229-Rev 03)	CFDA/EDQM

胆酸系列 Cholic Acid Series			
熊去氧胆酸	★ Ursodeoxycholic Acid	DMF	CFDA
牛磺熊去氧胆酸	Tauroursodeoxycholic Acid		
奥贝胆酸	Obeticholic Acid		

其他提取物 Other Extracts			
金雀花碱	★ Cytisine	DMF	
青黛	★ Natural Indigo		CFDA
青蒿素	Artemisinin		CFDA
盐酸小檗碱	Berberine HCl		CFDA
罗通定	Rotundine		CFDA
酸枣仁提取物	Zizyphus Spinosa Extract		
肾上腺皮质激素	ACTH		

· 合同制造加工 ·

CMO 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
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★ 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/GDUFA/CEP (R0-CEP 2017-096-Rev 01)	CFDA/PMDA
羟喜树碱	10-Hydroxy-CPT		CFDA
拓普替康	Topotecan HCl		

替尼类 -nibs			
厄洛替尼	★ Erlotinib	DMF/GDUFA	COFEPRIS/FDA
尼洛替尼	★ Nilotinib	DMF	
吉非替尼	★ Gefitinib	DMF/GDUFA	FDA
达沙替尼	★ Dasatinib		
索拉非尼	Sorafenib		
舒尼替尼	Sunitinib		
托法替尼	Tofacitinib		
瑞格非尼	Regorafenib		
卡博替尼	Cabozantinib		

其他-Others			
巨大戟醇甲基丁烯酸酯	★ Ingenol Mebutate	DMF/GDUFA	FDA
卡巴他赛	★ Cabazitaxel	DMF	
阿那曲唑	★ Anastrozole	DMF/CEP (R0-CEP 2017-114-Rev 00)	
来曲唑	Letrozole		

· 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		

· 中国注册及进口服务 ·

China Registration & Import Services

中国注册: 原料药及制剂 卡培他滨 盐酸莫西沙星	China registration: API & FDF Capecitabine Moxifloxacin HCl
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