

Welcome to FSP

EDQM,USFDA and CFDA GMP approved manufacturer.

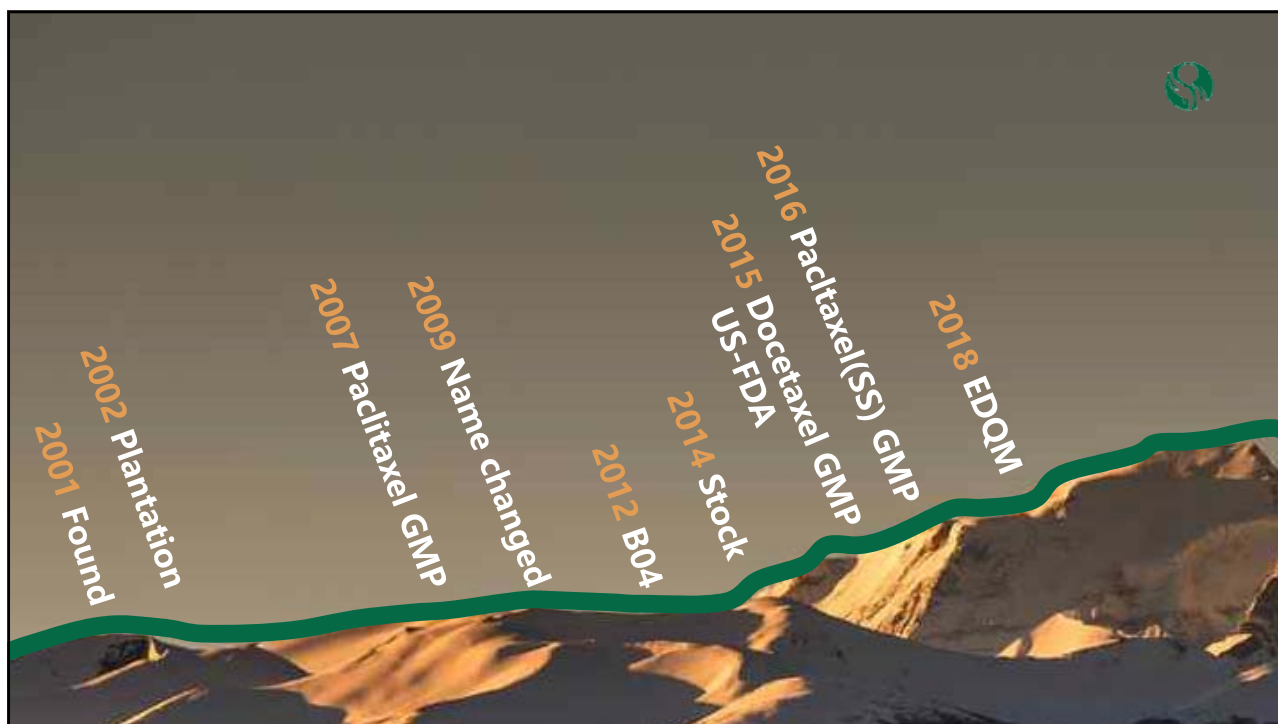


Dedicated to Taxane Oncology Products

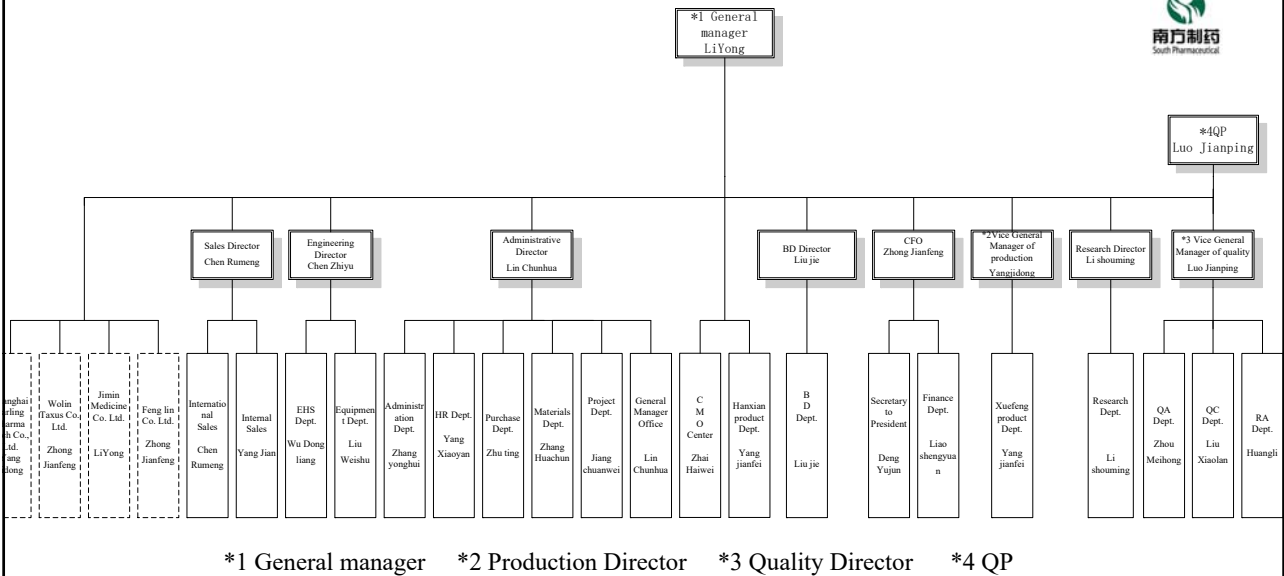


General Information

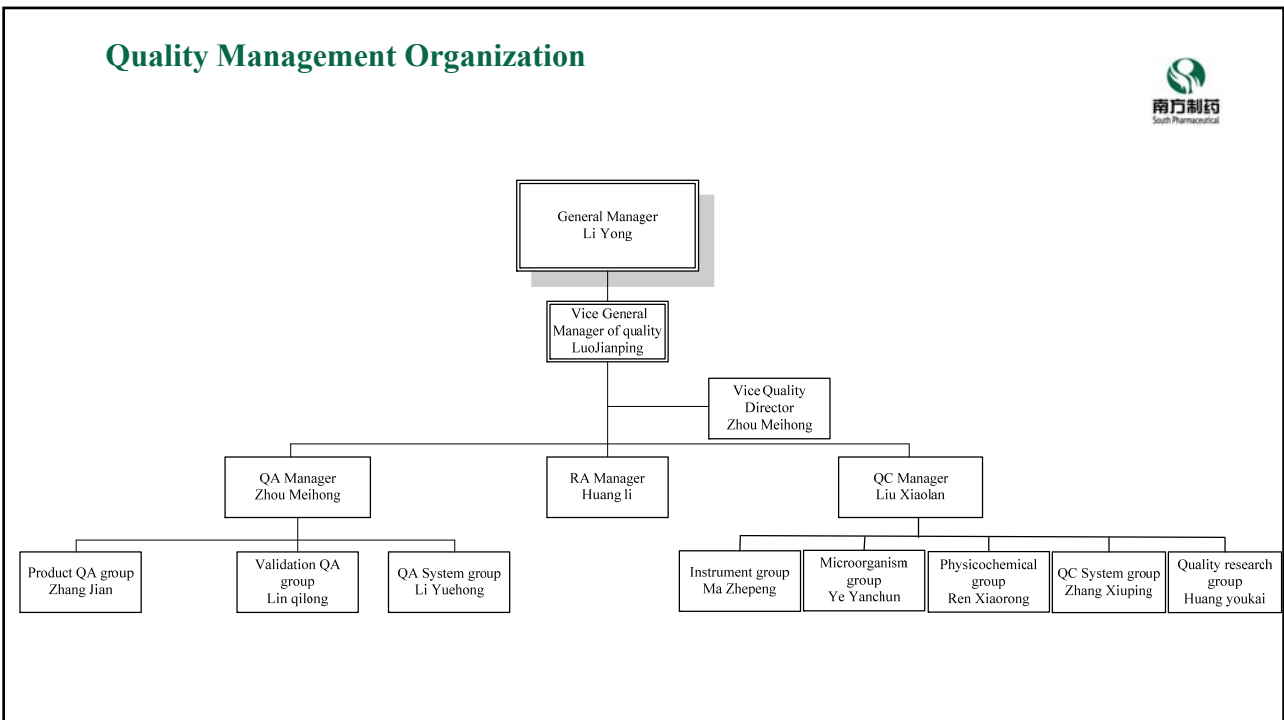
Name and official address of the manufacturer (headquarter)	Fujian South Pharmaceutical Co., Ltd. (abbreviated as FSP) No.98 Dongxin Road, Xuefeng Town, Mingxi County, Fujian Province 365200, China	
Names and street addresses of the manufacturing site	Fujian South Pharmaceutical Co., Ltd. No.98 Dongxin Road, Xuefeng Town, Mingxi County, Fujian Province 365200, China	
Contact information of the manufacturer	Tel:	+86-598-2860412
	Fax:	+86-598-2860416
Contact personnel	Mr. Rumeng Chen	
	24 hrs telephone number:	+86-13365918102
	E-mail:	sales@southpharma.com
Identification number of the site	D-U-N-S Number:	52-792-9643
	GPS details:	Latitude (N 26°21' 18.57") Longitude (E 117°12' 25.98")



Organization Chart



Quality Management Organization



FSP-Regulatory Inspections (in passed 5 years)

Agency		Inspection dates	Inspected substance(s)	Inspection outcome
Int'l	EDQM	2014/09/04-2014/09/06	Docetaxel	Withdraw CEP
	USFDA	2015/09/21-2015/09/25	60%~70% Paclitaxel (Natural) Crude	pass
	EDQM	2018/06/27-2018/06/29	Docetaxel	Pass
CFDA	Local CFDA	2016/01/09~2016/01/11	Paclitaxel (Semi-Synthetic)	pass
	Local CFDA	2017/08/08~2017/08/09	Paclitaxel (Semi-Synthetic)	pass
	Local CFDA	2017/08/08~2017/08/09	Multiple products	pass
	Local CFDA	2017/09/28~2017/08/29	Paclitaxel (natural)	pass
	Local CFDA	2017.12.14	Docetaxel	pass
	Local CFDA	2018/07/24~2018/07/28	Paclitaxel (natural)	pass
	Local CFDA	2018/09/25~2018/09/28	Docetaxel	pass
	Local CFDA	2018/09/25~2018/09/28	Docetaxel	pass

GMP Certificates



Manufacturing License



FDA EIR



Japanese Site Registration Certificate



Swiss GMP for Docetaxel Certificate



CGMP for Paclitaxel Natural



CGMP for Docetaxel



GGMP for Paclitaxel Semi-synthetic



CEP for Docetaxel

Building List (1/2)

No	Building description	No	Building description
B-01	501 section (Solid dosage form) and Warehouse (4)	B-05	Warehouse (1)
B-02	101 section (Extraction from plant sources) 201 section (Crude isolation)	B-06	Warehouse (2)
B-03	202 section (Crude isolation)	B-07	Warehouse (3)
	401 section (Purification, drying, and packaging)	B-08	QC Lab
	301 section (Synthesis for pilot production) 203 section (Isolation for pilot production)		
B-04	1st floor: 305 section (Synthesis)	B-09	Power Distribution room
	302 section (Synthesis)+ 402 section (Physical processing, and packaging)	B-10	R&D and Calibration Station
	601 section (Utilities)	B-11	Technology / Calibration Station / Machine maintenance group
	2nd floor: 303 section (Synthesis) +403 section (Physical processing, and packaging)		B-12
	304 section (Synthesis) +404 section (Purification, drying, and packaging)	B-13	Toilet
	3rd floor: 307 section (Isolation and purification)	B-14	Fire pool
	4th floor: 308 section (Synthesis)	B-15	Water pump house

Building List (2/2)

No	Building description	No	Building description
B-16	Duty room at backdoor	B-27	Hardware warehouse
B-17	Boiler Room	B-28	Office building
B-18	Boiler	B-29	Warehouse for wastes
B-19	Sewage station	B-30	Warehouse (5)
B-20	Cooling tower	B-31	Warehouse for retired equipment
B-21	Guard room at the production area	B-32	Canteen
B-22	Company entrance	B-33	Warehouse (6)
B-23	Staff dormitory (1)	B-34	UASB pool
B-24	Staff dormitory (2)		
B-25	Staff dormitory (3)		
B-26	Staff dormitory (4)		

Facility



Waste water treatment



Purified water



HVAC



Seperation



Column



Extraction

Planting of *Taxus Wallichiana*(1/3)

With Taxus Wallichiana germchit breeding tech.

With Taxus Wallichiana fast growing and high yield tech.

- Currently, FSP planted 200hectares *Taxus Wallichiana*(high yield since 2010s), harvest 300tons/year leaves(dried) .
- FSP, one of players, has own *Taxus* cultivation and commercial utilizing to make sure sustainable and safety of *Taxus* supply in 10-DAB III extraction and *Taxanes* GMP production.
- CITES certificate for *Taxus* harvest and import & export.



Planting of *Taxus Wallichiana*(2/3)



1. In different area in the county, spread over 4 towns(20 villages)
2. Most of the lands are farmland with a small portion on hill/mountain sides eliminating worry of losing fields because of mud/debris slides.
3. Good drainage system to avoid flooding of fields
4. Good shade protection from strong direct light
5. Established irrigation systems to avoid drought, most of the plantation location is nearby to source of water, eg river/canal
6. Regular tracing, testing and recording of 10-DAB III concentration and other taxane compounds in different location, different temperature, needles in different ages.
7. Train people on how to plant, how to handle daily management of plantations.

Planting of *Taxus Wallichiana*(3/3)



Product List-APIs

Product Name	Code	Facility and Section	Registration Number
Paclitaxel(Natural)	901	B-02、B-03; 101、202、401 section	CDE code: Y20170002034 USDMF#23558, NMPA GMP
Paclitaxel (Semi-Synthetic)	902	B-04; 303、403 section	CEP R0-CEP 2019-110-Rev.00 USDMF#25822 , NMPA GMP
Docetaxel Anhydrous	903	B-04; 308、404 section	CEP R0-CEP 2016-204-Rev00 CDE code: 20170001931 USDMF#25295, NMPA GMP
Docetaxel·Trihydrate	904	B-04; 308、404 section	CDE code: 20180001153
Bendamustine Hydrochloride	893	B-04; 302、402 section	MHRA: File passed, no site Audit CDE code: 20180001674
Imatinib Mesylate (α form)	809	B-04; 302、402 section	—
Imatinib Mesylate (β form)	809	B-04; 302、402 section	Clinical Trial Authorization : 2015L05493
Erlotinib Hydrochloride	829	B-04; 302、402 section	Clinical Trial Authorization : 2016L05421
Letrozole	801	B-03、B-04; 302、402 section	Y20170000758
Temozolomide	808	B-04; 302、402 section	—
Gemcitabine Hydrochloride	849	B-04; 302、305、402 section	—
Tenfovir disproxil semi fumarate	528	B-04; 305、405 section	—

Product List- Intermediates (1/2)

Product Name	Code	API	CAS No.	Facility and section
60%~70% Paclitaxel (natural) Crude	901-I3	Paclitaxel	33069-62-4	B03 ; 202 section
7-Troc-Paclitaxel	902-I4	Paclitaxel	114915-17-2	B04 ; 303 section
Baccatin III	902-I1	Paclitaxel	27548-93-2	B04 ; 303 section
7,10-Ditroc-10-DABIII	903-I1	Docetaxel	183133-94-0	B04 ; 308 section
7,10-DiTroc-Docetaxel	903-I4	Docetaxel	114915-14-9	B04 ; 308 section
Cephalomannine	906	Paclitaxel	71610-00-9	B03 ; 202 section
10-Deacetyl Baccatin III	905	Various	32981-86-5	B04 ; 307 section
10-Deacetyl Paclitaxel	908	Paclitaxel	78432-77-6	B03 ; 301 section
(4S,5R)-3-Benzoyl-2-(4-methoxyphenyl)-4-phenyl-5-oxazolidinecarboxylic acid	912	Paclitaxel	949023-16-9	B04 ; 305 section
(4S,5R)-3-tert-Butoxycarbonyl-2-(4-anisyl)-4-phenyl-5-oxazolidinecarboxylic acid	913	Docetaxel	196404-55-4	B04 ; 305 section

Product List- Intermediates (2/2)

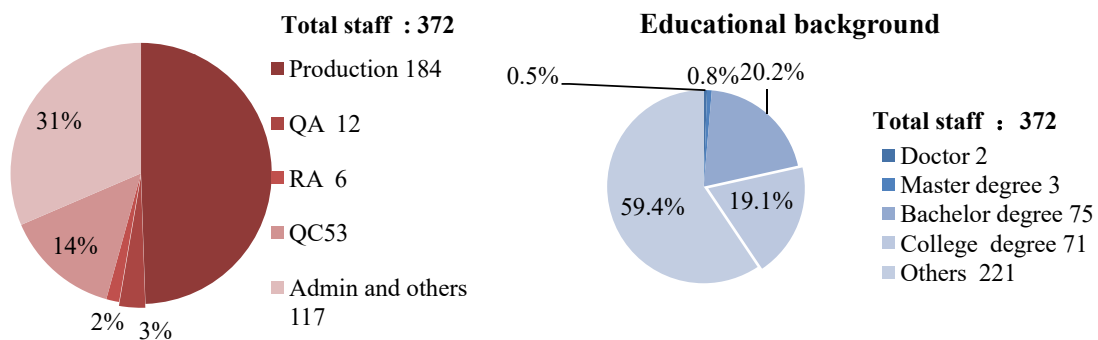
Product Name	Code	API	CAS No.	Facility and section
(3R,4S)-1-Benzoyl-3-(1-ethoxyethoxy)-4-phenyl-2-azetidinone	918	Paclitaxel	201856-53-3	B03 ; 301 section
(3R,4S)-3-hydroxy-4-phenyl-2-azetidinone	918-13	Paclitaxel	132127-34-5	B04 ; 302 section
(4S,5R)-3-(tert-Butoxycarbonyl)-2,2-dimethyl-4-phenyloxazolidine-5-carboxylic acid	910-D	Docetaxel	143527-70-2	B03 ; 301 section
Methyl(2R,3S)-3-(tert-butoxycarbonylamino)-2-hydroxy-3-phenylpropionate	914	Side chain	124605-42-1	B04 ; 305 section
4-bromobenzonitrile	501	Pemetrexed	623-00-7	B04 ; 305 section
(3R,4S)-tert-Butyl 2-oxo-4-phenyl-3-(triethylsilyloxy)azetidine-1-carboxylate	917-D	Docetaxel	149198-47-0	B04 ; 305 section
Methyl 2-oxindole-6-carboxylate	133	Nintedanib	14192-26-8	B03 ; 301 section
5-Fluoro-2-Oxindole	816-15	Sunitinib	56341-41-4	B04 ; 305 section
N-(2-(Diethylamino)ethyl)-5-formyl-2,4-dimethyl-1H-pyrrole-3-carboxamide	817	Sunitinib	356068-86-5	B02; 309 section
3-(dimethylamino)-1-(3-pyridinyl)-2-propen-1-one	813-11	Nilotinib	55314-16-4	B03 ; 301 section
3-[(Aminoiminomethyl)amino]-4-methylbenzoic acid methyl ester nitrate	813-12	Nilotinib	1025716-99-7	B03 ; 301 section

Product List--FDf

Product Name	Strengths	Registration Number
Imatinib Mesylate Tablets	0.1g	Clinical Trial Authorization : 2015L06285
Erlotinib Hydrochloride Tablets	100mg	Clinical Trial Authorization : 2016L05422
	150mg	Clinical Trial Authorization : 2016L05423
Letrozole Tablets	2.5mg	Clinical Trial Authorization : 2016L08919
Temozolomide Capsules	20mg	——
	100mg	——



Human Resources



Quality Policy

- ✓ Contribute to human health 致力于人类健康
- ✓ Strive to improve medicine quality 用心提升产品质量
- ✓ Enhance quality concept 贯彻质量生产意识

Quality Main Goals

- ✓ Guarantee the compliance, legality of production and business management;
- ✓ Maintain the safety and effectiveness of our products;
- ✓ Ensure effective implementation of our quality management system;
- ✓ Constantly enhance our quality management sense and data integrity awareness;
- ✓ Satisfy customers' needs.

FSP, improving faster!