

PEN TSAO GROUP





PEN TSAO GROUP



Mission Statement

- We are a renowned manufacturer of Active Pharmaceutical Ingredients, Advanced Intermediates and High-End Fine Chemicals and provide a broad range of products, services and technologies to our customers.
- As a reliable partner with high quality awareness, state-of-the-art technology and highly skilled personnel, Pen Tsao Group delivers added value products and services.

Strategic Focus

- Innovative Pharmaceutical Industry (Custom Manufacturing)
- Generic Pharmaceutical Industry (FDF, API and Custom Manufacturing)
- High End Fine Chemicals Industry (High-End Intermediates, Custom Manufacturing)



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Key performance indicators

- Top product quality from back-integrated manufacturing site in China
- Highest quality and safety standards
- Independent private owned company
- Continuous investment of profits in expansion and maintenance
- Full Service provider (seamless upscaling from laboratory to production to formulation)





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- Established in 1985 in Hong Kong as private owned company
- Operations moved to Shanghai in 1995
- New site Rodallis in Pinghu founded in 2019. Will be operational in late 2023.



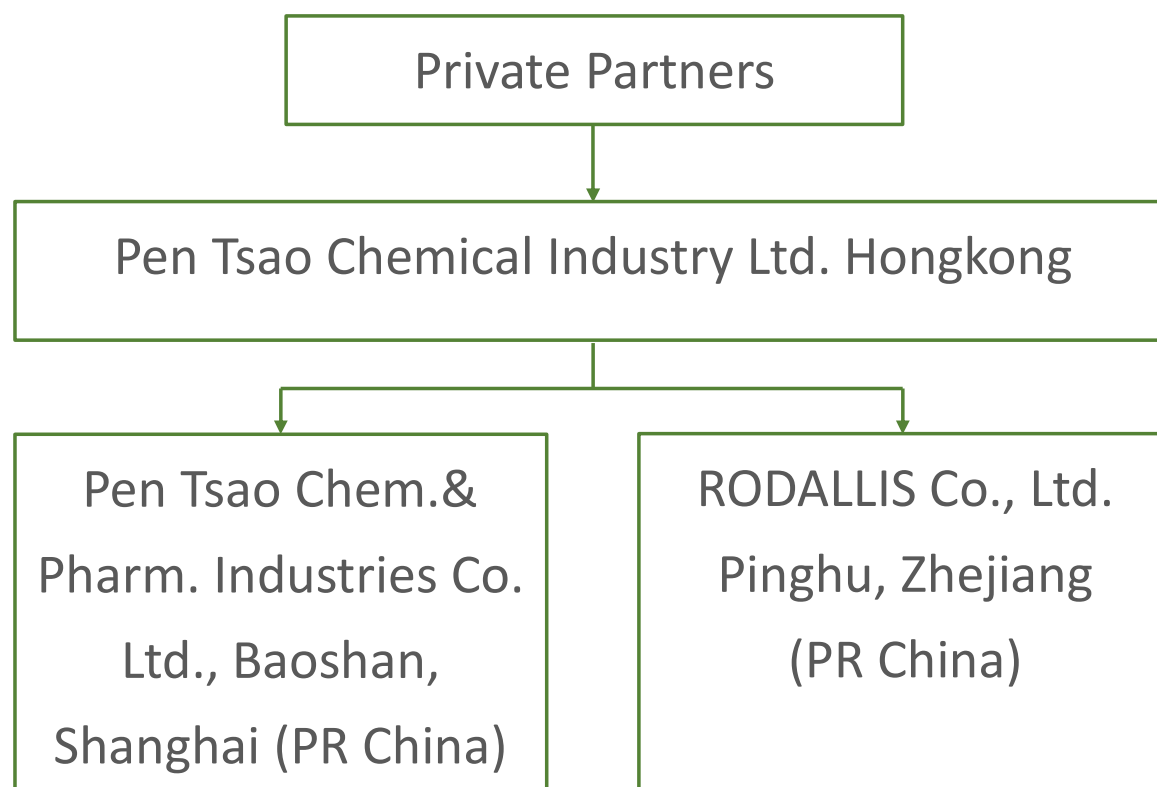
- Full cGMP operation (WHO qualified supplier, PMDA approved, EU GMP)



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- The Pen Tsao Group is managed by private partners from Hong Kong, Switzerland and Germany





OUR LOCATIONS



Baoshan site (Shanghai): Area of 11.000 m², 50 m³ of reactor volume, over 400 different structures manufactured more than 150 of them commercialized. 35 km from Hongqiao Intl. Airport, 45 km from Pudong Intl. Airport, direct connection to subway line 3.

Pinghu site (Dushan Port, Zhejiang): Area of 33.300 m², (+ 16.600 m² for extension), 65 km from Hongqiao Airport, 3 km south of Jinshan Chemical Park, 20 km east of Pinghu City
API Part: 150 m³ reactor volume, Multi-Purpose
OSD Part: 70 tons Formulations





HIGH QUALITY CHEMISTRY



- We are a leading Specialty API Manufacturer under German management, selling our products worldwide as well in China Pharma market.
- Our Multi Purpose Technology platform, in full compliance with international cGMP, gives us the flexibility to produce a broad product portfolio and meet client's specific needs for new developments and projects.
- Leveraging our strength in Specialty API's we are in transformation to an integrated OSD* Pharma with our own API base.

* Oral Solid Dosage Forms



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Recent Inspections

- CFDA: July 2019; Flying inspections quarterly by local FDA
- WHO Prequalification: February 2021
- EU Written Confirmation: March 2021, July 2022
- Client On-Site Audits: 2 in 2020; 3 in 2021, 3 in 2022 (Online)



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Development Services

- Process evaluation and development with goal to minimize costs and development time
- Patent evaluation and route scouting
- Upscaling, technical transfer and validation of production processes
- Appropriate application of GMP and regulatory requirements to ensure highest quality standards
- Product registration, BSE/TSE certification, other HSE services



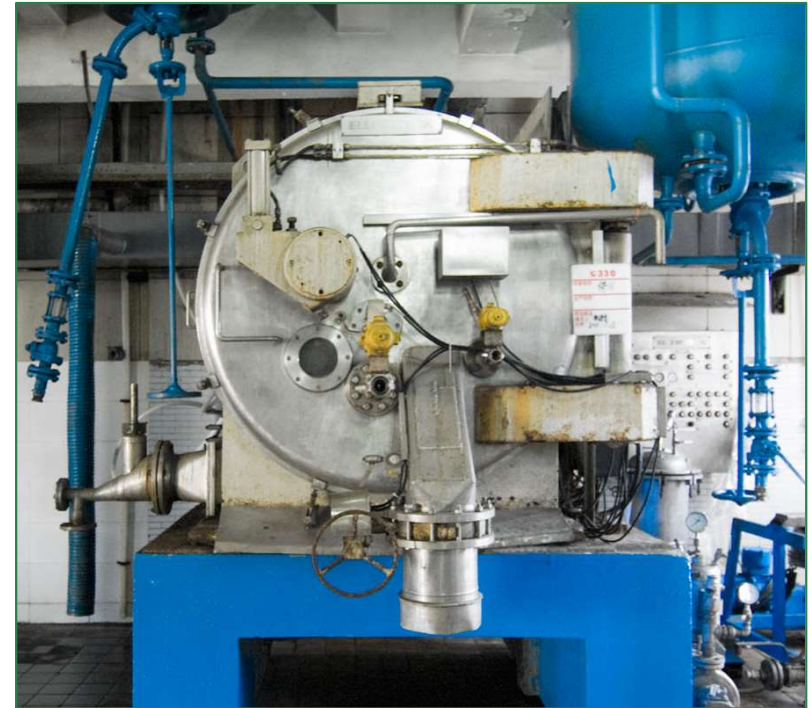


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Multipurpose Plant Baoshan (Current Production Facility)

- 21 Glass Lined Multi-Purpose Reactor Units
(Size ranging 200 l - 5,000 l; Total volume 56 m³)
- Temperature: -20°C to 280°C
- Pressure: 1mbar – 100 bar
- Fractionated Vacuum Distillation
- 7 Vertical & Horizontal Peeler Centrifuges
- Vacuum Filters and 1 Pressure Filters, various type vacuum dryers, multi layer filters
- Milling, Grinding and Homogenization Equipment





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Clean Room Workshops - Class D

- 3 Glass Lined Multi Purpose Reactors (3000l each)
- 3 Vertical Centrifuges, 3 Vacuum Tumble Dryers
20 mbar vacuum and max 120°C
- Granulation and Homogenization Equipment,
Final Primary and Secondary Packaging
- 2 Milling Machines (auto feed and discharge)
- Purified Water System with Filtration, Softening, RO, Mixed Bed and Microfiltration
serving the Clean Room workshops.





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Class D Solid Dosage Formulation Pilot Unit

- Material storage and Dispensing area
- SS-Blender with up to 200 l batch size
- Fluid Bed Dryer with Micro pelleting unit
- Fully automated German Tablet Press
(Capacity up to 300,000 Tabl./h)
- Tablet Coating System





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Regulatory Affairs Services

- Development and validation of analytical methods - including inprocess controls
- Stability and impurity profiling
- Synthesis and characterization of impurities
- Elaboration and submission of Drug Master Files or other regulatory documents (we are approved by CFDA, PMDA, KFDA, DCGI India, Russia and various European Authorities)
- Supplier qualification and auditing (materials and services)





NEW API's (DEVELOPMENT)



Current developments of new API's will strengthen our market position for Specialty API's international and in the Chinese market and will part of our growth strategy for both API's and Formulations:

<u>Product Name</u>	<u>CAS-No</u>	<u>Quality</u>
Cycloserine (MDR-Anti-Tuberculosis)	68-41-7	PHINT/USP/JP
Raloxifen HCl (Anti-Osteoporotic)	8449-90-1	USP
Lacidipine (Anti-Hypertension)	103890-78-4	USP/EP
Quetiapine (Anti-Psychotic)	111974-69-7	USP/EP
Dimeflin HCL (Respiratory Stimulant)	2740-04-7	CP
Terizidone (MDR & XDR Anti-Tuberculosis)	25683-71-0	PHINT*
Methimazole (Antithyroid)	60-56-0	USP
Terazosin (Benign prostatic hyperplasia)	63590-64-7	USP



CURRENT API's (1)



<u>Product Name</u>	<u>CAS-No</u>	<u>Quality</u>
• Bucillamine (Anti-Rheumatic)	65002-17-7	JP *
• Carbinoxamine Maleate (Anti-Histamine)	3505-38-2	JP*
• Clofazimine (MDR & XDR Anti-Tuberculosis)	2030-63-9	EP*
• Clonixin Lysinate (Anti-Inflammatory)	55837-30-4, 17737-65-4	KP/AP*
• Cloperastine Hydrochloride (Anti-Tussive)	14984-68-0	JP/EP*
• Cloperastine Fendizoate (Anti-Tussive)	85187-37-7	Inhouse Standard
• Ethionamide (MDR Anti-Tuberculosis)	536-33-4	EP/USP/IP*
• Lonazolac Calcium (Anti-Rheumatic)	75821-71-5	Inhouse Standard



CURRENT API's (2)



<u>Product Name</u>	<u>CAS-No</u>	<u>Quality</u>
• Loxoprofen Sodium (Anti-Inflammatory)	80382-23-6	JP/CP/KP*
• Mequitazine (Anticholinergic)	29216-28-2	JP
• Morniflumate (nonsteroidal anti-inflammatory)	65847-85-0	KP
• Prothionamide (MDR & XDR Anti-Tuberculosis)	14222-60-7	BPD/IP/JP/CP
• Sulfinpyrazone (uricosuric)	57-96-5	USP/EP*
• Sulfisoxole Sodium (sulfonamide antibacterial drug)	79921-43-0	Inhouse Standard
• Talniflumate (MDR Anti-Tuberculosis)	66898-62-6	KP/AP*
• Tamoxifen Citrate (Anti-Rheumatic)	54965-24-1	EP/USP*
• Tauro-Ursodeoxycholic Acid (TUDCA) (treatment of gallstones and liver cirrhosis)	14605-22-2	EP*



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RODALLIS BIOPHARMA Co., LTD.

The Rodallis site has an area of 50 Mu (ca. 3,3 Ha) with an option of further 25 Mu (ca. 1,67 Ha) extension.

Location

Dushan Port Economic Development Zone, Pinghu, Jiaxing County, Zhejiang

Reach

110 km south of Pen Tsao, Shanghai, 65 km south of Hongqiao Airport & Hub,

3 km south of Jinshan Chemical Park

20 km east of Pinghu City



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Rodallis BioPharma - OSD Formulation

- Clofazimine; 50 & 100 mg film coated tablet
Anti-leprosy drug; off label MDR-TB drug (WHO), launch in China and WHO tender
- Bucillamine; 100 mg film coated tablet
Anti-rheumatic drug (Originator Santen Japan) NDA launch in China & Japan Generic
- TUDCA; 250 mg film coated tablet
Treatment of Cholestatic Liver disease, Gallstone, NDA launch in China
Investigative drug for ALS (European Phase 3 study), Alzheimer, Parkinson's, Huntington diseases.
- Ethionamide; 250 mg film coated tablet
MDR-TB drug, generic launch in several East-European countries with high % of multidrug resistant TB.
- Terizidone; 250 mg film coated tablet
MDR-TB drug, NDA launch in China and generic launch in several East-European countries (WHO)
- Loxoprofen Sodium; 60 mg film coated tablet
Anti-inflammatory drug for pain treatment, generic launch in China



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3D model view
Rodallis Biopharma



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3D Model
Formulation Bldg.



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View from East Side



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API Production Bldg.



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Laboratory Building
Dangerous Goods
Warehouse & API Bldg.



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The vertical integrated Pharma Group
serving China and the World