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ESTECHPHARMA Co., Ltd.

Company

Estechpharma reached a considerable amount of sales in a short period due to the constant challenge and rapid decision making. We were able to lead API business successfully in Japan, China, Europe, United States and rest of the world. Estechpharma is aiming for developing new active pharmaceutical ingredients, biopharmaceuticals and finished drug products, and pursues the global partnership with partners.

cGMP Factory's Facilities

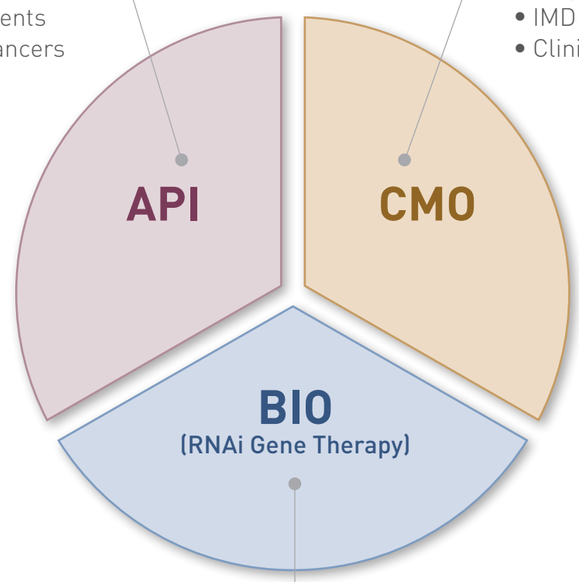
Major Production Facilities		Pilot Production Facilities	
Reactor(STS)	18 sets	Reactor(STS), 630L	2 sets
Reactor(G/L)	18 sets	Reactor(G/L), 500L	1 set
Dryer	12 sets	Reactor(G/L), 250L	1 set
PW System(Purified water)	1 Lot	Filter Dryer,	2 set
C/F(Centrifuge)	2 Sets	Dryer(Hot Blast)	1 set
Process Vacuum Pump	6 Sets	Vacuum Dryer	2 set
Scrubber (Air Pollution Prevention Facility)	1 Lot	C/F(Centrifuge)	1 set
		Vacuum Pump	2 sets
Out Door Storage Tank	8 sets	TCU & Sub TCU – 40~200°C	4 sets

Brief History

2012. 05.17	Received the "Silver Medal in Korean Industry"
03.30	Received the "Trader of the Month in Korea Award" in the 47th Korea International Trade Association
2011. 12.15	Received "Thirty Million Dollar's Export Award"
06.29	Received the "Best Marketing Award" in the 5th Korea KOSDAQ Award from KOSDAQ Association
2010. 07.30	Registered the Pranlukast(Anti-asthmatic) patent in Japan
2009. 12.22	Received "CEO of the Year Award" from Korea Productivity Center
06.16	Received agreement of cooperate research development with CTIbio Co., Ltd. for the non-narcotic analgesic
2008. 09.22	Inspection certificate from EDQM for Aceclofenac(Anti-inflammatory)
05.27	Inspection certificate from EDQM for Acamprosate Calcium(Anti-alcoholism)
2007. 10.16	Completed cGMP plant in Baran
06	Contracted MRI contrast agent supply worth 3.6 billion won
2006. 06.25	Received an Award from Korea Ministry of Environment
2004. 02.06	Registered in KOSDAQ Market
2001. 10.30	Approved BGMP from KFDA
1996. 06.01	Foundation of Estechpharma

Business Divisions

Successful Pharma Solutions



Successful Pharma Solutions

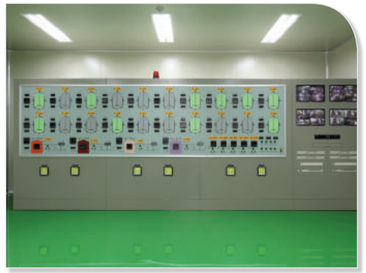
Core Technologies

Chiral Technology	Developed the synthesis and separation technology of chiral compound using enzymes
Chemical Synthesis	Manufacturing technology of Anti-inflammatory drug, Anti-alcoholism drug, Anti-depression drug, Anti-ulcerant drug, muscle relaxant drug and etc.
Metal Complex	Accumulated technology of organometals like MRI contrast agent, Anti-anemia drug and etc.
Micronization Technology	Increase the bioavailability using the particle size control technology
Formulation Research	Various formulation research such as tablet, capsule, injection and etc. Bioavailability improvement and stability test
High Pressure/ Temperature Reaction	Efficient production for Alibendol and Triflusal
Environment-friendly Technology	Process development technology to prevent the generation of hazardous substances

Major Production Facilities

▶ Reactor

▶ Storage Tank

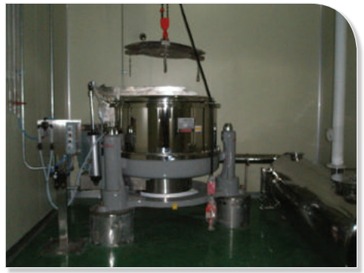


▶ Control Box

▶ Purified Water System

▶ Filter & Dryer

▶ Convection Dryer



▶ Centrifuge

▶ Temperature Control Units

▶ Air Handling Unit

cGMP Factory's Facilities

As an integral part of Quality system, documents for regulatory filing are compiled to support the registration and marketing of customer's products.
Authorities and official bodies audits regularly to verify and certify quality, technical instrumentation, methods and procedures.

- Regulatory submissions, such as CEP, DMF and Technical package
- Regulatory relations
- Pharmacopoeia relations

Quality Control

- Every step of the production is monitored by qualified Quality Control lab.
- Analytical validation
- Conduct stability studies
- Covered all Standardized test and methods
- Specialized technical instruments experience such as NMR, MS, HPLC, GC, IR, AAS.

Quality Assurance

- External audits of suppliers
- Internal audits : Batch record review and trend analysis
- Deviation, out of specification date, rejections: investigation and corrective action
- Analytical validation
- Documentation management
- Audits by customers
- Process validation
- GMP training

Health, Safety and Environment

Estechpharma Co., Ltd. takes safety of all employees and environment protection as its managements policy with first priority, and those who work in the company are continuously trying to do their best to accomplish a healthy and clean working place.

As a credible API(Active Pharmaceutical Ingredients) supplier, Estechpharma implements the most stringent of quality management, environment practices, healthy & safety and manufacturing excellence throughout all facilities.