

Company Introduction

Yuhan Chemical is a major subsidiary of Yuhan Corporation, exporting APIs, Intermediates, RSMs to leading global pharmaceutical companies. Our excellent cGMP quality system enables us to manufacture high quality products which comply with GMP standards of regulatory agencies, such as U.S. FDA, European EDQM, Japanese PMDA, and Australian TGA.

◎ Contributing to the improvement of human health through the production of superior drug substances

Built on the founding philosophy formulated by Dr. Ilhan New, which was to provide his fellow Koreans with the best medications and treatments available, we strive to continue his legacy by improving the health and well-being of people, contributing to the country's economy and promoting social welfare.

◎ Corporate Social Responsibility

Following the founder's belief that "a company's profits should be returned to the society", we contribute to the promotion of social welfare by returning the profits to the society in order to fulfill our corporate social responsibility.

◎ Pursuing customer value first and foremost

Based on integrity and trust, our top priority is to pursue customer satisfaction by creating customer value and the protection of intellectual property.

◎ Management of Environment, Health, and Safety (EHS)

We pursue safety and environment health management with the goal of creating a healthy society and a clean environment through the respect for human beings and eco-friendly management.

Contract Development and Manufacturing Organization



cGMP Manufacturing Facility

Yuhan Chemical's cGMP-compliant production facilities consist of HVACs, PW systems, IPC, and Warehouses for each production building in compliance with cGMP.

Furthermore, our production facilities have an independent production bay and an HVAC system with a One-Way Path Air Flow that does not recirculate, preventing from potential cross contamination.

Since our foundation in 1980, Yuhan Chemical has been building the CDMO business for global pharmaceutical companies as our core competency. We have pilot facilities suitable for research that is in the early stages of development, including initial candidates for new drugs and clinical research.



Your Trusted Partner in Quality, Technology & Safety.

We go Above and Beyond!



Production Facility



Ansan Plant

With continuous investment in our synthetic facilities at the Ansan plant, we poses the best API pharmaceutical production capacity in South Korea

- Total Land Area: 31,598 m²
 - 45, Jiwon-ro, Danwon-gu, Ansan-si, Gyeonggi-do, Republic of Korea
 - Production Capacity : 501,700L
 - Reactor Volume : 1,500~12,000L
 - Pilot Production (300~1,500L)
 - Containment System (OEL Category 3A)
 - Hydrogen reactor 3,000L
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Hwaseong Plant

Our second plant, built to expand our CDMO business, is equipped with the latest facilities, including a pilot facility.

- Total Land Area: 36,564 m²
 - 162, Cheongwonsandan 8-gil, Mado-myeon, Hwaseong-si, Gyeonggi-do, Republic of Korea
 - Production Capacity : 233,350L
 - Reactor Volume : 2,000~12,000L
 - Pilot Production (100~300L)
 - Containment System (OEL Category 3A)
 - Hydrogen reactor 6,000L, 150L (Pilot)
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Ansan Plant view



Hwaseong Plant view

Business Introduction

Contract Development and Manufacturing Organization (CDMO)

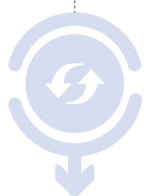
Yuhan Chemical is based on the best production system and quality control system in the world.

CDMO Service for Drug Substance



	Early Stage	Late Stage	Commercial
Process Development	<ul style="list-style-type: none"> · Synthetic Route Scouting · Process Research · Broad range of Scale-Up · Polymorphism Study · Non-GMP Supply 	<ul style="list-style-type: none"> · Process Optimization · Crystallization Process Optimization · Safety & Hazard Assessment · Process Simulation · Control Strategy (PAR Study, DoE Study) 	<ul style="list-style-type: none"> · Technical Transfer · Process Validation
Analytical Development	<ul style="list-style-type: none"> · Analytical Method Development · Impurity Identification 	<ul style="list-style-type: none"> · Characterization of Reference Standards · Trace Analysis (Genotoxic Impurities & Elemental Impurities) · Forced Degradation Studies · Method Validation/Transfer · CMC Documentation 	<ul style="list-style-type: none"> · Analytical Support
Manufacturing	<ul style="list-style-type: none"> · Containment System (Category 3A) · Non-GMP Kilo Lab (60~150L) · cGMP Pilot (100L~) · Strong R&D Support for Tech Transfer 	<ul style="list-style-type: none"> · cGMP Manufacturing (Typical Batch Size: 10kg~) 	<ul style="list-style-type: none"> · cGMP Manufacturing · Continuous Improvement for Cost Reduction

Yuhan Chemical's Business Managerial Strengths



Cross-Functional
Project Management



Strong R&D Support
and Involvement



Nimble and Flexible
with Scheduling



Strong Management
Support and Investment



Yuhan Chemical CDMO Partners

Contract Analytical Testing Service

Analytical Capabilities

- cGMP Compliant Quality Control Testing
- Stability Testing in Compliance with ICH Guidelines
- Establishment of the Specifications & Test Methods for Raw Materials, Intermediates & APIs
- Analytical Method Development & Validation
- Reference Standard Characterization
- Elemental Analysis & Trace Metals Testing
- Contract Analytical Services

Computerized Data Integrity System

- NuGenesis LMS

Yuhan Chemical has established a Comprehensive Computerized Data Integrity System compliant to the guidelines of FDA, EMA and PIC/S on data integrity, and provides a variety of analytical testing services to suit regulatory standards and customer requirements using state of the-art analytical equipment. We also provide a range of pharmacopeia compendial testing services as per USP/EP/BP/JP/KP.

- Empower CDS

- LabX Network System

All analytical instruments at Yuhan Chemical, from Simple Instruments to the Chromatography System, operate on a network basis.

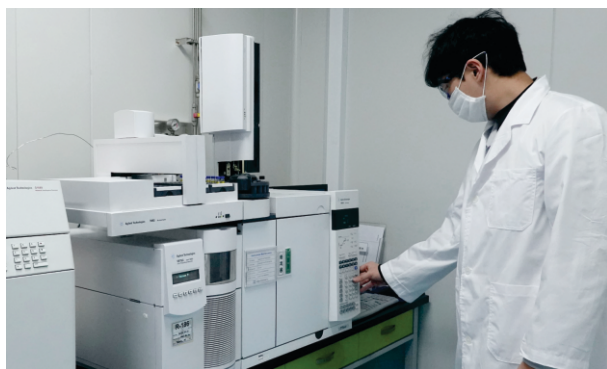
- tiamo Network System

- ECM Network System

Yuhan Chemical integrates and manages all analytical data, including certificate of analysis, through a laboratory information management system consisting of Electronic Lab Notebook and Scientific Data Management System.



Laboratory View



GC/MS



ICP/MS



LC/MS



NMR Spectrometer



X-Ray Diffractometer

Laboratory Instrumentation

- HPLC
- LC/MS & GC/MS
- GC
- UPLC
- ICP/OES & IPC/MS
- Ion Chromatograph
- NMR Spectrometer
- X-Ray Diffractometer
- UV-Vis Spectrophotometer

- FT/IR Spectrophotometer
- Differential Scanning Calorimeter
- Karl Fischer Titrator
- Polarimeter
- Total Organic Carbon Analyzer
- Potentiometric Titrator
- Refractometer
- Conductivity Meter
- Particle Size Analyzer

Quality System

Yuhan Chemical is a CDMO supplying APIs, Intermediates and RSMs with strict cGMP quality system and best production equipment. Furthermore, Yuhan Chemical is in compliance with regulatory authority standards (MFDS, USFDA, PMDA, EDQM, TGA, etc.).



Features of Yuhan Chemical's GMP Quality Assurance System



Supply of highest quality APIs, Intermediates and RSMs

Yuhan Chemical has grown into a global CDMO measured by our competitiveness in both quality and price. We supply the highest quality of products to multinational pharmaceutical companies.

cGMP Compliance

In order to supply the best quality products, we have established systematic and specialized training system, the latest production and test equipment, and a Data Integrity System. To this end, we introduced TrackWise, Empower CDS, NuGenesis, LabX, tiamo, ComplianceWire and VeevaVault.

Global GMP System

Yuhan Chemical operates an international standard quality system based on the Six System. We strive to continuously improve the GMP system through inspections and audits from regulatory agencies and global pharmaceutical companies.

Strict Compliance

Manufacturing and quality control at Yuhan Chemical strictly complies with customer requirements and regulations of regulatory bodies.

Systematic quality assurance

With integrity and professionalism, we strictly comply with standard operation procedures to ensure the highest quality in all manufacturing processes.



Process Development

Yuhan Chemical has outstanding capabilities in Process Development that are based on the accumulated industry experiences.

C-Hetero Bond Formation	<ul style="list-style-type: none"> • Amide coupling with various activating agents • Glycosylation with pyrimidine and purine derivatives • Sulfide formation with thiols 	Reduction & Oxidation	<ul style="list-style-type: none"> • Catalytic hydrogenation (max 10 bar) • Various metal hydride reductions - NaBH₄, LAH, LTTBA, Red-Al, etc. • Ozonolysis • Various oxidation reactions with TEMPO, DDQ, mCPBA and H₂O₂
Chiral Technology	<ul style="list-style-type: none"> • Enzymatic resolution • Diastereomeric crystallization • Synthesis using chiral auxiliaries • Asymmetric reduction (CBS reduction) 	Hazardous Chemicals Handled at Plant Scale	<ul style="list-style-type: none"> • Grignard reagent : CH₃MgCl, iPrMgCl • Organolithium bases - BuLi, n-HexLi, and LiHMDS • In situ generation of borane (BH₃) • Nucleophilic fluorination with HF-pyridine
C-C Bond Formation	<ul style="list-style-type: none"> • Suzuki coupling • Sonogashira coupling • Wittig reaction • Julia-Kocienski Olefination 	Aromatic Ring Substitution	<ul style="list-style-type: none"> • Friedel-Craft Acylation • Sugasawa reaction
		Heterocyclic Compounds	<ul style="list-style-type: none"> • Aziridine, pyrrolidine, imidazole, pyrimidine, quinoline & purines



Communication and collaboration

CDMO business capability through communication and collaboration with the world's leading pharmaceutical companies.

Process safety

Secure process safety based on EH&S and RC1 data.

Synthetic technology know-how

Process Development Know How through various and specialized synthesis techniques.

Process Management Support

Process management support from process research to stable commercial production.

Process optimization

Optimization technology of scale-up production process conducted by professional research staff.

Problem Solving Capabilities

Scientific root cause investigation and problem solving capabilities in case problems occur.

Cost Reduction and Increased productivity

Ability to improve processes to reduce manufacturing costs and improve productivity.

Pilot plant

Pilot plant and Kilo-Lab with the containment system to conduct process optimization studies and accommodate small-scale needs for customers.

SH&E Management

Pursuing corporate safety and health and environment-oriented values are our top priorities. To this end, Yuhan Chemical has set four SH&E management principles: building an advanced SH&E system, building a 4 ZERO workplace, building a people-oriented work system, and complying with sustainable environmental policies. We seek to secure business contingency plans by improving the quality of our safety, health and environmental systems and by maintaining emergency response partnerships with local communities.

Advanced SH&E System

- Introduction and application of the highest level of SH&E standards reflecting domestic and foreign laws. (NFPA, OSHA, etc.)
- Establishment of a contingency plan and the collaborative emergency response system with nearby business sites.
- Rapid incident response procedure through integrated notification system.

4 ZERO Safety Plant

- ZERO injuries → Near Miss → Establishment and activation of an incident investigation reporting system.
- ZERO process incidents → Process risk assessment for HAZOP, LOPA, CA, etc.
- ZERO environmental incidents → Systematic safety management of environmental facilities, such as air & water.
- ZERO penalty → Daily monitoring and risk assessment of SH&E related laws.

Establishment of a people-oriented work system

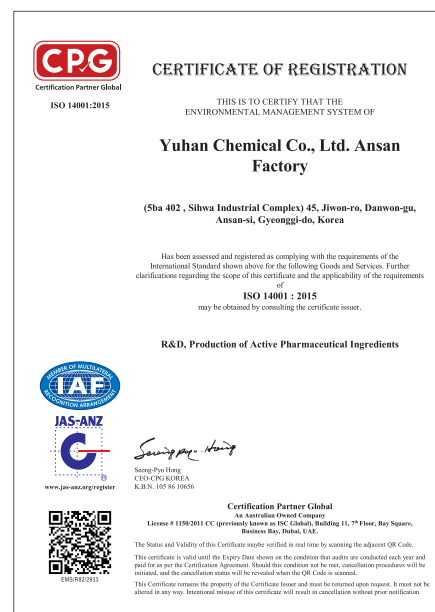
- Establishment of the containment system with the Occupational Exposure Band to prevent chemical exposure.
- Securing Hazard and Risk information through K-REACH response of new and existing chemicals.
- Follow-up management through work environment measurement and medical examination.

Sustainable Environmental Policy Compliance

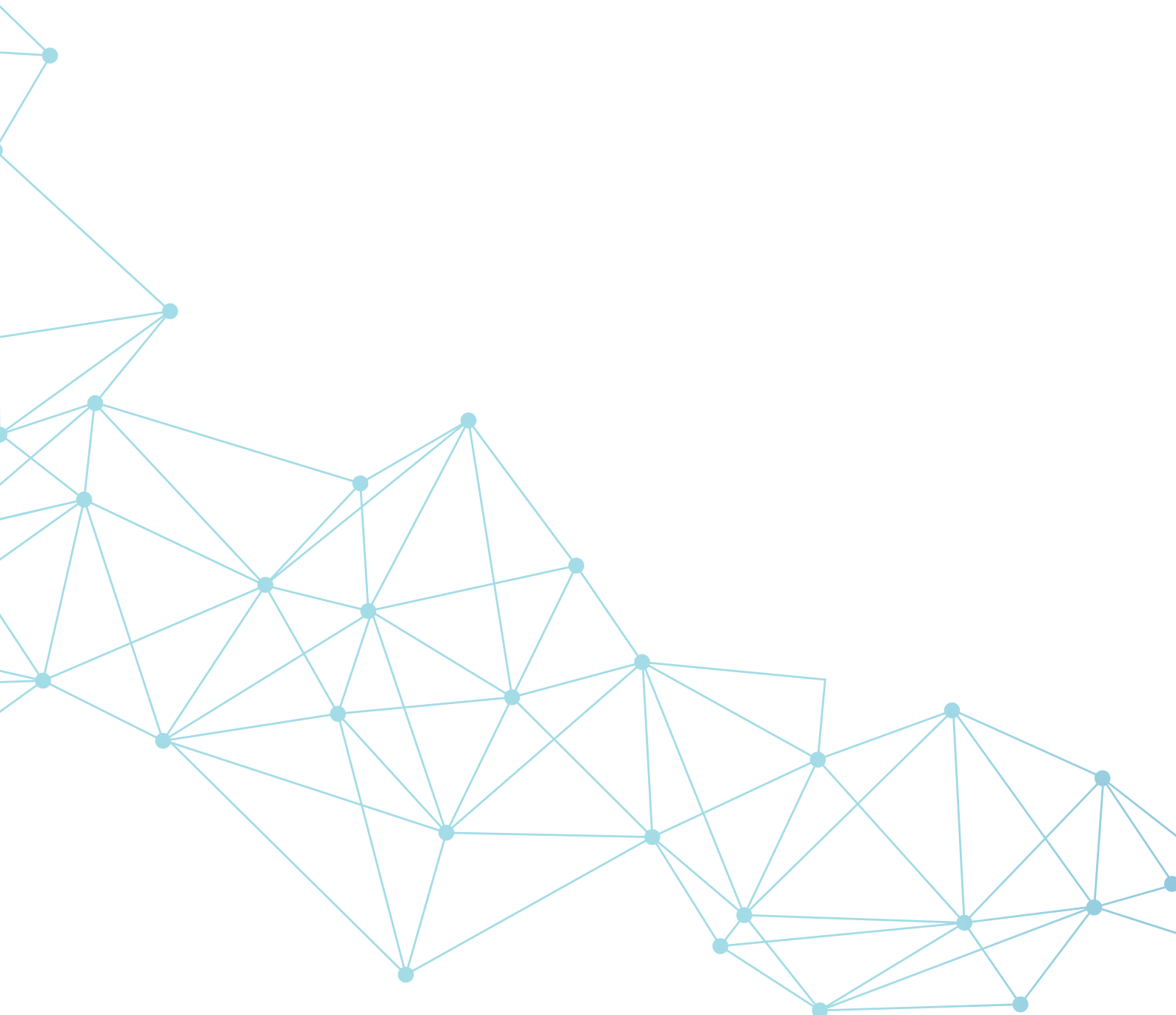
- Establishment of the continuous environmental impact assessment system by complying with the ISO 14001 environmental management system.
- Implementation of Greenhouse Gas Target Management System (Tier 1, 2) under the Low Carbon Green Growth Framework Act.
- Participation of in organizations such as Chemical Safety Council.



Automatic fire extinguishing system



ISO 14001 Certificate



Ansan Plant

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Hwaseong Plant

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