ST PHARM : DONG-A SOCIO GROUP

World Leader in Pharmaceutical Manufacturing Services

I New Drug and Generic I Nucleoside and Oligonucleotides I New Drug Development I

DONG-A SOCIO GROUP | ST PHARM

WHO we are

World Leader in Pharmaceutical Manufacturing Services

ST Pharm provides reliable and on-time services under cGMP condition

Established in 1983, ST Pharm (formerly known as Samchully Pharma) has manufactured active pharmaceutical ingredients (APIs) and provided customized service from lab to commercial scale. In 2010, ST Pharm became a member of Dong-A Socio Group that has been the leading healthcare company in Korea since 1967. In 2016, ST Pharm was listed as a public company under KOSDAQ and keeps growing to be a top-tier CDMO.

Our Mission

Continuous challenge to pursue health and happiness for humanity

We will help more people enjoy a healthier and happier life, and prosper alongside them by focusing our R&D on better products and services, while fulfilling our social responsibilities.

Our Vision

To be a global healthcare player by establishing distinctive competencies in each business area

We will become a global healthcare group by developing the core competitiveness of each business area through the integration of business portfolio.

Member of Dong-A Socio Group

DONG-A SOCIO GROUP

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Pharmaceuticals

- **Dong-A ST** — Prescription drug, Medical equipment
- **Dong-A Pharmaceutical** — OTC
- **ST Pharm** — API
- **DM Bio** — Biosimilar

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Non-Pharmaceuticals

- **Dong-A Otsuka DONGCHEONSU** — Food & Beverage
- **Soo Seok** — Bottle Glass
- **Yongma Logis** — Logistics
- **DA Information** — IT

Key Figures

20 times

From 2011, we've been inspected over 20 times by US FDA, MFDS, EDQM, WHO, ANVISA, HPRA and TGA

2.1 mol scale

Due to the expansion of Oligonucleotide plant, our capability increased up to 2.1mol scale

90%

More than 90% of our R&D researchers have M.S. or Ph.D. degree in the field of analysis, synthetic and process chemistry

Core Values

- Pursue Innovation
- Trust Each other
- Lead Change
- Grow Mutually
- Green Management

WHY ST PHARM

World Leader in Pharmaceutical Manufacturing Services

Compliance

- Following the ICH Guidelines, ST Pharm puts every effort to achieve world-class quality system
- ST Pharm operates both “CDS (Chromatographic Data System)” and “SDMS (Scientific Data Management System)” in order to improve the reliability of the data management from analysis (21 CFR Part 11, Annex 11 “Networked/Lab Computerized System for Data Integrity)

* CDS for LC/GCs: “EMPOWER 3” Network System
* SDMS : “NUGENESIS 8” model

Quality Control

ST Pharm stringently controls the quality of all manufacturing processes from raw materials to final product, API. This is supported and implemented by our CMC team that has experienced analytical expertise and system including analysis of impurity profiles.

Physical Tests

- Chromatography : HPLC (UV, RI), UPLC, GC, Ion chromatography
- Mass spectrometry : LC-MS, LC-MS/MS (Q-Tof), LC-MS/MS
- Nuclear magnetic resonance (NMR) : 400 MHz
- Particle size analyzer : Wet/dry type PSD
- Water determination : Karl-Fischer (Coulometric/Volumetric)
- Optical rotation : Polarimeter
- Solid state properties : XRD, DSC
- Others : Densitometer, Melting point meter, Conductivity, pH meter, TOC etc.

Chemical Tests

- Spectrophorometric identification : UV/Vis, FT-IR
- Elemental composition and impurities : ICP-OES, ICP-MS
- Residual solvents : GC (Headspace)

Microbiological Tests

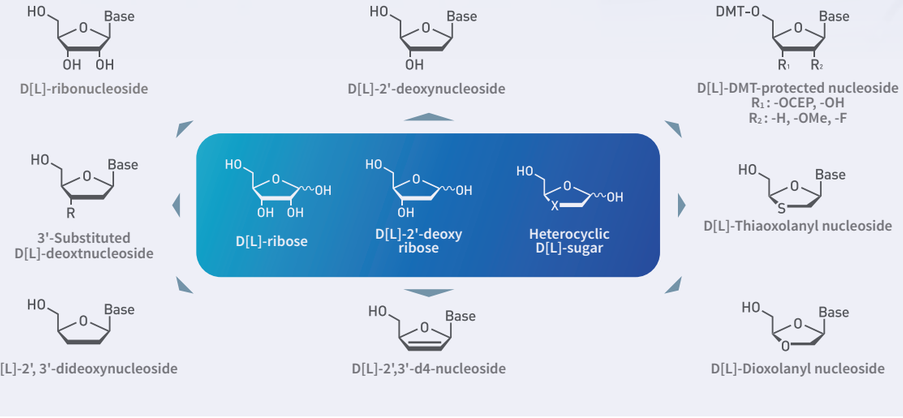
- Endotoxins : LAL (Kinetic tubidometric), Gel-clot
- Bioburden test

Successfully inspected by

Ministry of Food and Drug Safety · edqm European Directorate for the Quality of Medicines & HealthCare · ANVISA · TGA Health Safety Regulation · HPRA · FDA · Pmda

Innovative Technology : Nucleoside & Carbohydrate Chemistry

Various Nucleosides from Sugars

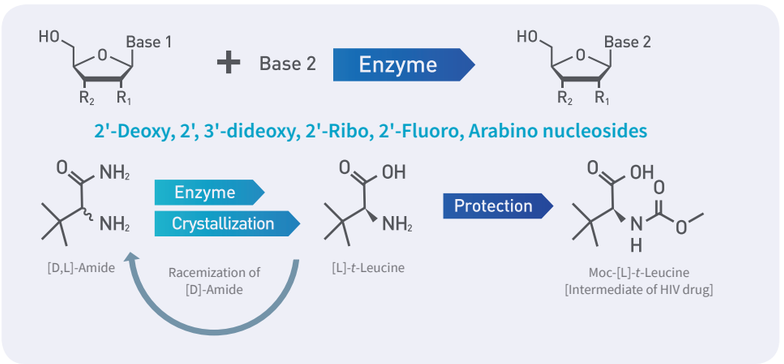


Innovative Technology : Biotransformation Technology

Proprietary Gene Expression System

- Effective enzyme screening and optimization system
- Recombinant E. coli expression system applicable to variety of enzymes
- Suitable for hyper-production of various enzymes

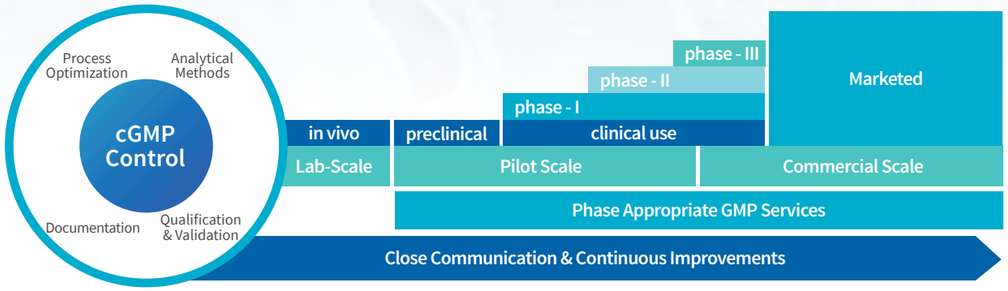
Enzyme Applications



NEW DRUG CDMO

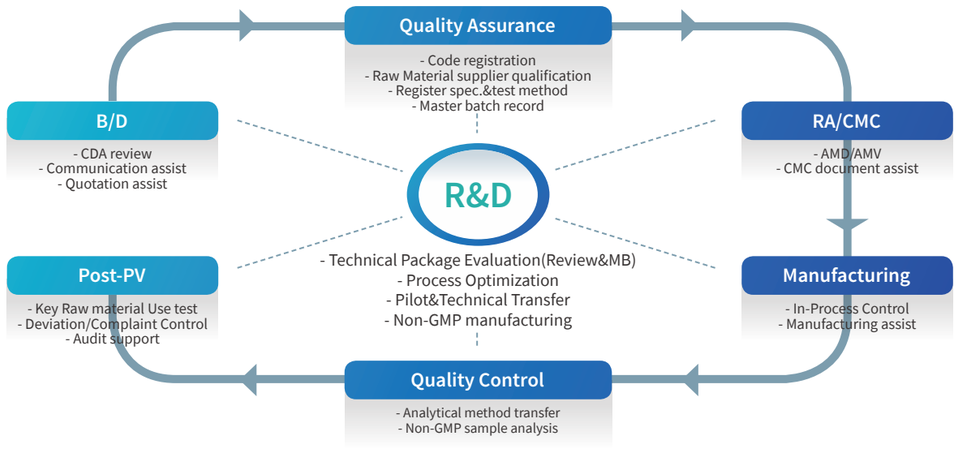
World Leader in Pharmaceutical Manufacturing Services

Work Scope



- From lab to commercial scale, ST Pharm provides customized service under cGMP condition
- ST Pharm has established a strong partnership with global clients by creating customer-oriented network
- ST Pharm carries out a study of process development/optimization and provides CMC service

Work Flow



ST Pharm is committed to provide total services to clients
for successful drug development and commercialization

Capacity

General Capacity

	Sihwa Site	Banwol Site	TOTAL
Area	16,400m^2	28,220m^2	44,620m^2
Reactors	67	58	125
Capacity	286,100 L	139,000 L	425,100 L

Commercial Scale Plants

	Sihwa Site	Banwol Site
Commercial Scale Plants	Five Plants (Plant 1, 2, 3, 5 and 6)	Four Plants (Plant A sector 1-2/B/C)
Reactor Size	3,000 to 7,000 L	100 to 7,000 L

Pilot Scale Plants

	Sihwa Site		Banwol Site	
Pilot Scale	Kilo-lab	Pilot Plant	Sector 4	Sector 3
Reactor Size	50 - 100 L	200 - 500 L	500 - 1,000 L	1,000 - 2,000 L

Oligo Plants

line	Sihwa Site	Banwol Site
Small Scale	(nmol - µmol scale) : MM-192, MM-12	
Mid Scale	(mmol scale) : 3x OP100	
Large Scale	(300 mmol scale) : 2 x AKB	(1.5 mol scale) : 1 x GE

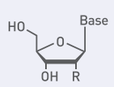
OLIGONUCLEOTIDES

World Leader in Pharmaceutical Manufacturing Services

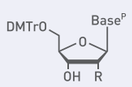
Fully Integrated In-house Production Capability

Nucleosides to oligonucleotides under one roof

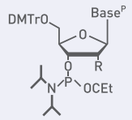
Nucleosides



Protected Nucleosides



Phosphoramidites



Oligonucleotides

- siRNA/ microRNA
- Aptamers
- Antisense
- Decoys
- Other novel oligos

Base : A, G, C, T[U] R : DNA[deoxy], RNA[O-TBDMSi, O-Methyl, Fluoro] and others

Phosphoramidites and Monomers

ST Pharm also offers various phosphoramidites, key starting materials to be utilized in oligonucleotide synthesis, from sugars and/or nucleosides with field-credited excellent quality and cost

- The world's largest supplier of Thymidine [dT] in the late 1990s
- DMT-protected nucleosides [PNS] in the early 2000s
- Over 100 different monomers including over 50 different types of amidites
- Supported by ST Pharm's scale-up and biotransformation technology

Customized Service Scope

Discovery

Small Scale

High-throughput service
nmol-µmol

For reserch use in
RNAi / Aptamer / Antisense

Asian leader in siRNA

Various modifications available

Development

Mid scale

0.2~5mmol-scale

For Preclinical use or process optimization for large scale

GMP / non-GMP available

Clinical

Mid to large scale

10~300mmol scale
50g~50kg

For clinical / Commercial use

GMP / non-GMP available

Commercial

Large scale

Expansion to 1,500mol-scale line in preparation
250 ~ 500kg

Expansion of Oligonucleotide Capability

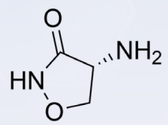
Line	Sihwa Site	Banwol Site
Small Scale	(nmol - µmol scale) : MM-192, MM-12	
Mid Scale	(mmol scale) : 3x OP100	
Large Scale	(300 mmol scale) : 2 x AKB	(1.5 mol scale) : 1 x GE

ST Pharm is constructing a new facility at its Banwol Site, Korea. The expansion is expected to be completed by June 2018. Once the new facility starts to operate in October 2018, ST Pharm's oligonucleotide manufacturing capacity will increase to 2.1mol scale. The new facility has the capability to expand to 3.0mol scale in the near future.

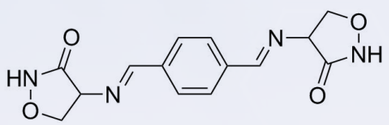
GENERIC APIs "Targeting Niche Market"

Anti-Tuberculosis

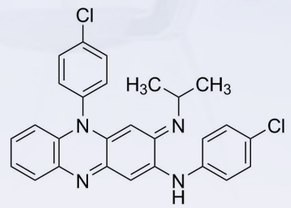
- The world's key supplier of API Cycloserine / Terizidone with our affiliate Dong-A ST
- Targetted in Europe, CIS, Russia, China and WHO
- In preparation of API Clofazimine



Cycloserine



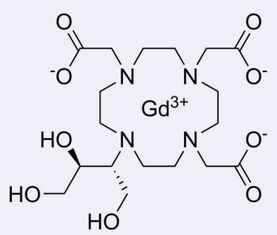
Terizidone



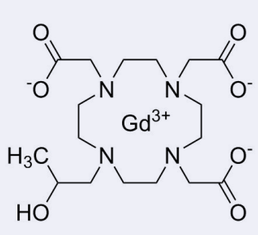
Clofazimine

MRI Contrast Agents

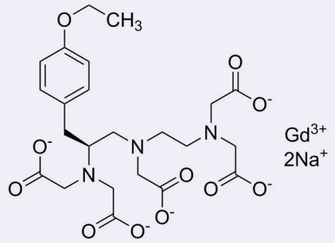
- API Gadobutrol
  - Technology & know-how through continuous process improvement from 2011
  - Targetted in Europe, USA, Turkey, Russia, CIS and Asia
- In preparation of API Gadoteridol & Gadoxetate



Gadobutrol



Gadoteridol



Gadoxetate

NEW DRUG DEVELOPMENT

Virtual R&D Strategy

ST Pharm focuses on new drug discovery using a strategy of innovative virtual R&D. Virtual R&D employs limited internal core resources to organize and monitor the drug development process work flow, thereby, increasing the efficiency of the R&D investment and still enabling the management of the entire drug discovery platform. Another important strategic pillar is partnership with global big pharmaceutical companies. ST Pharm can expedite the drug development process and facilitate the creative research by collaborating on projects with overseas partners.

New Drug Development Pipeline

New Drug Development by Innovative Virtual R&D Strategy

	Lead	Preclinical	Clinical Trial Phase I	Phase II
*Tankyrase Inhibition [Colorectal cancer]		STP06-1002	Clinical Trial in 2018	
*Oral Heparin [DVT, CAT]		STP02-3725	Clinical Trial in 2019	
HIV Integrase Inhibition [AIDS]		STP03-0404	Clinical Trial in 2019	
Influenza Virus [Flu]		Lead Optimization		
Enteroviruses [Polio, HFMD]		Lead Optimization		
SMAD4 miRNA [Sarcopenia]		Hit Identification		

* Korean Drug Development Fund selected projects

DONG-A SOCIO GROUP

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