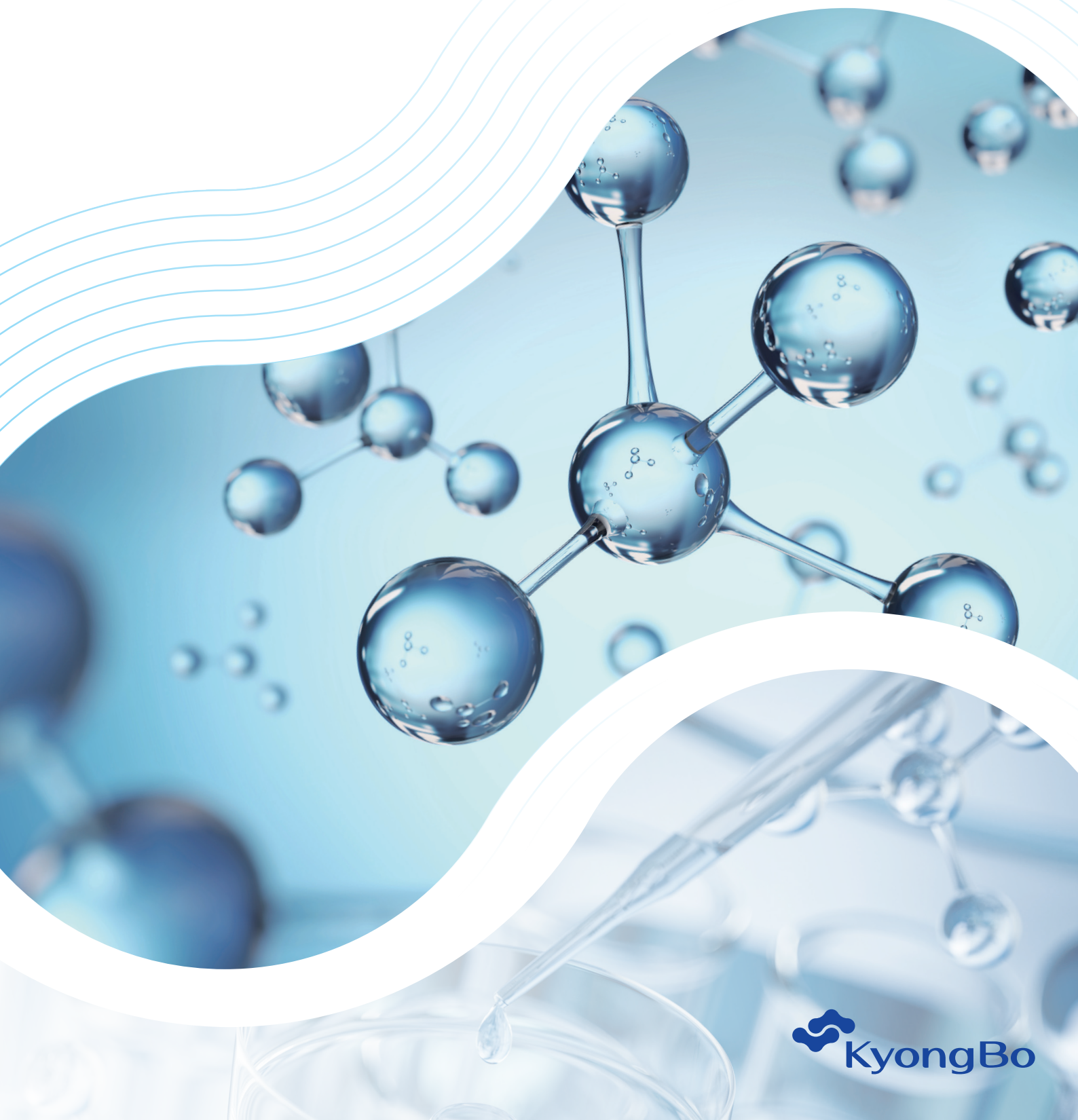


Reliable CDMO Partner Total Services for Peptide Synthesis



Peptide synthesis

- Milligram to gram on lab scale
- Kilogram-scale under GMP conditions

Process Development & Optimization

- Feasibility Test (Synthetic Method Development)
- General Randomized Design of Experiment
- Optimal Design of Experiment, Safety & Environment controls

Test Method Development under cGMP and ICH

- Raw Materials, Intermediates & Drug Substance Test Method Development
- Qualified HPLC, GC and General Test Methods
- Test Method Development based on Design of Experiment
- Validation based on cGMP
- CMC documentation and registrations

Technical Transfer Process for Safety and Control Quality with PAT Tools

- Process Development for Safety with RC1, Process Qualification based on cGMP

Lab, Pilot (<50L) and Full-scale (1,000~2,000L) Manufacturing

- Pilot Scale and Reproducibility
- Low-Temperature Reaction
- High-Pressure & Hydrogenation Reaction

High Potency (Cytotoxic APIs, SafeBridge OEL 4 Categorization)

* OEL : 0.19 ng/m³ for 8 hrs with Naproxen sodium



YOUTUBE CHANNEL

CDMO Facilities

Non-GMP Zone

R&D Center

- 4 Easy Max Reactor System 50 mL ~ 400 mL
- Crystal 16 Solubility-Crystallization system
- 3 Glass Reactors 30 L ~ 100 L
- 2 Freeze Dryers -86°C/3 L
- 1 Freeze Dryers -50°C/10 L
- 3 Prep-HPLC DAC system : ID=5 cm ~ 15 cm
- LC-MS/MS Agilent 1290(2D) & 6545XT
- Hydrogenation reaction system 10L
- TCU (Temperature Control Unit)
- UF/NF-Lab Filtration System
- 1 Nutsche Filter 30 L
- Tray Vacuum Dryer

GMP Zone

Plant-1

- 6 Glass Lined (G/L) Reactors 100 L ~ 8,000 L
- 10 Stainless (STS) Reactors 1,500 L ~ 6,000 L
- Pilot room
 - 1 Glass Lined (G/L) Reactors 300 L
 - 2 Stainless (STS) Reactors 100 L ~ 500 L
 - 2 Glass Reactors 30 L ~ 100 L

Plant-4 (Cytotoxic API)

- 2 Glass Reactors 60 L ~ 100 L
- 4 Glass Lined Reactors 1,000 L ~ 2,000 L
- 1 Stainless Reactor 2,000 L
- 2 Prep-HPLC DAC system : ID=10 cm ~ 60 cm
- 1 Freeze Dryers -86°C/50 L
- 3 Drum Containment System (DCS) 25 kg
- 3 Powder Transfer System (PTS) 2000 L/h

Plant-3

- 8 Glass Lined (G/L) Reactors 2,000 L ~ 10,000 L
- 5 Stainless (STS) Reactors 2,000 L ~ 8,000 L
- 1 Prep-HPLC DAC system : ID=60 cm
- 1 Freeze Dryers -50°C/500 L
- PV Pilot
 - 5 Glass Lined (G/L) Reactors 1,000 L ~ 5,000 L
 - 2 Stainless (STS) Reactors 2,000 L
 - 2 Filter Dryer System 400 L ~ 3,000 L

Plant-5 (HPAPI)

- 3 Glass reactors 10 L ~ 100 L
- 1 Freeze Dryers -86°C/30 L
- 6 Isolators
- Jet Mill & Isolator 50 g/h ~ 500 g/h
- Tray Vacuum Dryer 40 L
- Batch size is not more than 1 kg

Extensive Experience in Peptide Synthesis

Peptide Synthesis CDMO Projects	Peptide Drug Development	Advanced Peptide Synthesis Platforms
• 2022 : Peptide New Drug Development Over 100 novel peptides synthesized for drug discovery (MFDS Phase 1) • 2023 : Peptide Drug Conjugate (PDC) API Production 300g-scale peptide API produced for clinical PDC project (Clinical Phase 1) • 2024 : HBV Entry Inhibitor Peptide Production 5g-scale cyclic peptide (21mer) manufactured for HBV entry inhibitor	• Tech Transfer and clinical supply management • Impurity profiling, purification, and method validation (DS)	• Specialized in convergent and cyclic peptide synthesis • Two innovative process patents preparation (proprietary and scalable synthetic technologies)
	Convergent Synthesis 	Cyclic peptide Synthesis

Total Services for Peptide Synthesis

Kyongbo Pharmaceutical provides comprehensive services for peptide synthesis to help clients' discovery from early development through pre-clinical and clinical manufacturing. We offer integrated services including GMP manufacturing, documentation, process development, and analytical method development. As a trusted CDMO partner, we provide integrated CDMO services for peptide solutions to meet the needs of clients.

Process Development & Optimization	Analytical Development & Validation	GMP Manufacturing & Documentation
• Feasibility study • Process optimization • Scale up production • Non-GMP production • Preliminary quality assessment	• Analytical method development • Method Validation • Impurity profiling • Reference standard qualification • Preliminary stability test	• GMP batch manufacturing • In-Process and final product quality control • Batch release testing and COA issuance • Full-time stability testing for IND filing • CTD Documentation

Peptide Synthesis Services	PDC Development Services
• Custom, Generic, Cosmetic peptides • New peptide drugs • Milligram to gram on lab scale • Optimization & Validation	• Peptide, Payload, and Linker Synthesis • PDC conjugation & Purification • PDC Analysis & Characterization

Equipment and Instruments

Synthesis	Purification	Freeze drying	Analysis
• Peptide Synthesizer • Jacketed Glass Vessels	• Preparative LC - 10cm • Preparative LC - 15cm	• Pilot-Freeze Dryer • Freeze Dryer	• HPLC • LC-MSMS • GC



Reliable CDMO Partner Total Services for Peptide Synthesis

Since its establishment in 1987, Kyongbo Pharmaceutical has grown into one of Korea's leading API pharmaceutical companies, supplying raw materials to more than 30 countries at home and abroad.

We strive to advance the standards of pharmaceutical manufacturing and quality control and have successfully achieved a track record in various regulatory agencies around the world, including the FDA, EDQM, PMDA, NMPA, and MFDS.

Kyongbo Pharmaceutical has been investing in facilities and research and development for decades. It has also been collaborating with domestic and foreign pharmaceutical companies.

We have expanded our business into the field of Peptide Synthesis, providing CDMO services. We are focusing on the development of Peptide CDMO services through pre-clinical and clinical manufacturing to satisfy the needs of our clients and help them achieve rapid market entry.

Contact

Headquarter

174 Sirok-Ro, Asan-Si, Chungcheongnam-Do, 31510, Republic of Korea

T. 82-41-420-0433

H. www.kbpharma.co.kr/en/home

E. aryang@kbpharma.co.kr

Seoul Office

4F, Chongkun-Dang Bldg. 8, Chungjeong-Ro, Seodaemun-Gu, Seoul, 03742, Korea