

SAMYANG BIOPHARMACEUTICALS CORPORATION

ONCOLOGY CONTRACT DEVELOPMENT & MANUFACTURING



ONCOLOGY CONTRACT DEVELOPMENT & MANUFACTURING



Introduction of Pharmaceuticals Business

• Overview

Samyang Group started pharmaceuticals business in 1996 with the establishment of biopharmaceuticals R&D center. Following business separation of Samyang Group, Samyang Biopharm was founded as a pharmaceuticals company in 2011.

Samyang Group's expertise in polymer chemistry and biopolymer dedicated to Samyang Biopharm's novel drug delivery systems (DDS). The development of DDS resulted in technology platforms that can be applied to cancer treatment, pain management, smoking cessation, and other therapeutic areas.

Genexol® PM and Nanoxel® M injections are Samyang's differentiated anti-cancer drugs developed by polymeric micelle (PM) technology for drug delivery.

Also, Samyang is the first company that developed plant-cell culture technology. Applying this unique fermentation method, it succeeded the mass production of Paclitaxel API with extremely high purity.

Based on R&D and production capability, Samyang Biopharm commercialized a series of drugs for cancer treatment.

In domestic market, Samyang has rapidly expanded its market share with its own sales network across the country. Especially, Genexol® M and Pemed® S ranked first-in anti-cancer drug sales in each market. Samyang's drugs have been exporting to more than 25 countries and were recognized by overseas companies.

Now, it desires to expand its business area to Contract Development & Manufacturing. Samyang's pharmaceutical plant is GMP-compliance certified by regulatory authorities in Europe and Japan. Also, a new pharmaceuticals plant, which will be completed in 2020, is expected to achieve full cGMP operation. Samyang continues to develop advanced drugs that will lead the future pharmaceutical trends while enhancing its product portfolio based on its R&D.

• Business Area

Service	Product		
Contract Development & Manufacturing	Oncology	Cytotoxic APIs	Patches
Cytotoxic Injectables Capsules and Tablets Cytotoxic APIs	Polymeric Micelle (PM) Technology- based Product Generics for Solid Tumors Generics for Blood Cancers	Fermented Semi-synthetic	Transdermal Drug Delivery System Technology-based Product

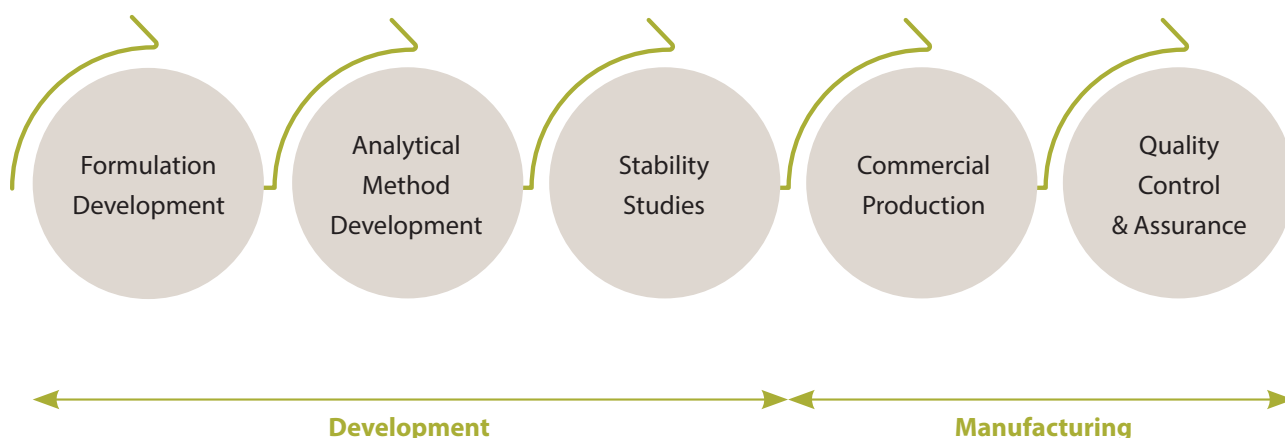
Oncology Contract Development & Manufacturing For Cytotoxic Injectables

• Product

- Lyophilized Vials
- Liquid Vials



• Process



• Feature

• Development Service

Oncology Specialist

Samyang offers a wide range of in-house developed products for cancer treatment.

Customized Solution

Samyang's experienced team provides tailored development services to meet strict and various requirements from each client and each health authorities.

• Manufacturing Service

Dedicated Facility to "Cytotoxic" Materials

Samyang's pharmaceuticals' plant handles cytotoxic materials only to prevent the risk of contamination. The plant is designed to manufacture cytotoxic API and cytotoxic injectables.

"EU GMP" and "JGMP" Certified Pharmaceuticals Plant

Samyang's pharmaceuticals plant is certified by EU GMP, JGMP, KGMP, and PIC/s.

The new plant, which will be completed in 2020, will introduce cGMP-level equipment with state-of-the-art isolator system.

Current Pharmaceuticals Plant

• Profile



• Construction Year

- 1996 (API), 2007 (FDF), 2010 (API, Chemical Synthesis)

• Certification

- EU GMP, JGMP, KGMP, PIC/s

• Production

- Product : Cytotoxic APIs, Cytotoxic Injectables
(Liquid, Lyophilized vials)

- Capacity : 10~200L as bulk solution

- Range of vials : 0.5~50mL

• Area (Storage & Production)

- 7,216m²

• Major Equipment

- Autoclave, WFI & Clean Steam Generator, Vial Washing Machine, Tunnel Sterilizer, Filling Line, Capping Machine, Freeze Dryer

• Equipment

Equipment	Manufacturer	Remarks
RABS	Korean	Negative Pressure Room
		Cooling Condition
Weighing System	Korean	Local Protection
Formulation System	Korean	Semi-automatic
		10 ~200 L
		Vacuum Mixer
		Teflon Coated Tank
		Cooling under -5°C
Filling System	Korean	Fully Automatic : Vial Washer ~ Capping Machine
		Filling speed : 60 Vial/min
		Range of vial : 1 ~ 50mL
Freeze Dryer	Korean	Shelf Area : 4m ² , Ice Capacity : 50kg
	Zirbus	Shelf Area : 4m ² , Ice Capacity : 100kg
Exterior Washer	Korean	100 Vial/min
Visual Inspection	-	Manual
Packaging	Korean	Semi-automatic
Part Washer	-	Manual

• GMP Certifications / Inspection

• GMP Certifications

Initial Year	Content	Authority
2011	BGMP (Chemical synthesis)	MFDS
2010	JGMP (API FDF, Last recertification 2015)	PMDA
2010	EU GMP (FDF, Last recertification 2019)	BGV
2009	Iranian GMP (API and FDF)	MHME
2008	EU GMP (API, Last recertification 2014)	BGV
2007	KGMP (FDF, Last recertification 2015)	MFDS
2005	EU GMP (API, Last recertification 2014)	BGV
2005	Hungarian GMP (API)	OGYÉI
2005	BGMP (Fermentation)	MFDS

• Recent Inspection History

Date	Country	Authority	Scope
2019.05	Japan	PMDA	Drug Product
2019.04	Germany	BGV	Drug Product
2018.03	Korea	MFDS	Drug Substance, Drug Product
2017.07	Germany	BGV	Drug Product
2015.11	Japan	PMDA	Drug Substance, Drug Product
2015.09	Germany	BGV	Drug Product
2015.03	Korea	MFDS	Drug Substance, Drug Product
2014.06	Germany	BGV	Drug Substance
2013.06	Korea	MFDS	Drug Product
2013.05	Japan	PMDA	Drug Substance

- BGV : Behörde für Gesundheit und Verbraucherschutz (Agency for Health and Consumer Protection, Hamburg)
- PMDA : Pharmaceuticals and Medical Devices Agency (Japan)
- MFDS : Korean Ministry of Food and Drug Safety (Former name = KFDA, Korea)
- MHME : Ministry of Health and Medical Education
- OGYÉI : National Institute of Pharmacy and Nutrition

New Pharmaceuticals Plant

• Profile



• Construction Year

- 2020 (a rear extension to the current building)

• Certification

- Expected to achieve cGMP certification

• Production

- Product : Cytotoxic Injectables
(Liquid, Lyophilized vials)
- Capacity : 30~300L as bulk solution
- Range of vials : 0.5~50mL

• Area (Storage & Production)

- 11,821m²

• Major Equipment

- Isolator, Freeze Dryer (+ALUS), Automatic Inspection Machine, Auto Packaging Machine, Automatic Filling Line and Exterior Washer, PW & WFI Generator

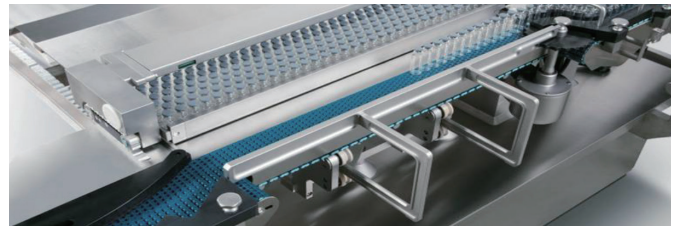
• Equipment

Equipment	Manufacturer	Remarks
Isolator	Telstar	Aseptic and Containment Isolator
		Cooling Condition
Weighing System	Mettler	Isolator
Formulation System	Tofflon	Automatic
		30 ~300 L
		Vacuum Mixer
		Teflon Coated Tank
		Cooling under -5°C
Filling System	Bausch	Fully Automatic : Vial Washer ~ Exterior Washer
		Filling speed : 200 Vial/min
		Range of vial : 0.5 ~ 50mL
Freeze Dryer & ALUS	GEA	Shelf Area : 10m ² x 2, Ice Capacity : 200kg x 2
Visual Inspection	Seidenader	Automatic
Packaging	Korean	Automatic
Part Washer	Korean	Automatic

- Isolator



- Freeze Dryer & ALUS



- Automatic Inspection Machine



- Auto Packaging Machine

Box wrapper (Primary)



Box wrapper (Secondary)



Cytotoxic Injectables

Manufactured in Pharmaceuticals Plant

Product		Form	Strength	Specifications
Genexol® PM (Paclitaxel)		Lyophilized Vial	30mg, 100mg/vial	in-house
Nanoxel® PM (Docetaxel)		Lyophilized Vial	20mg, 80mg/vial	in-house
Paclitaxel		Liquid Vial	30mg, 100mg, 150mg, 300mg/vial	USP, EP
Docetaxel		Liquid Vial	20mg, 80mg, 140mg, 160mg/vial	EP
Oxaliplatin		Liquid Vial	50mg, 100mg, 200mg/vial	EP, JP
Gemcitabine		Liquid Vial (Cold Storage)	200g, 1g/vial	USP
Pemetrexed		Liquid Vial (Cold Storage)	1g/Vial	in-house
		Liquid Vial* (Room Temperature)	100mg, 500mg/vial	in-house
		Lyophilized Vial	100mg, 500 mg/vial	in-house
Azacitidine		Lyophilized Vial	100mg, 150mg/vial	in-house
Decitabine		Lyophilized Vial	40mg, 50mg/vial	in-house
Bortezomib		Lyophilized Vial	2.5mg, 3.5mg/vial	in-house
Bendamustine*		Lyophilized Vial	25mg, 100mg/vial	USP

* Under Development

Samyang Biopharmaceuticals Corp. Headquarter & R&D Center

6F, 295, Pangyo-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, Korea Tel. 82-2-2157-9862 Fax. 82-2-2157-9062

Samyang Biopharmaceuticals Corp. Pharmaceuticals Plant

79, Sinildong-ro, Daedeok-gu, Daejeon, Korea Tel. 82-42-930-9303 Fax. 82-42-934-1403



samyang
Biopharm