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SAMYANG BIOPHARMACEUTICALS CORPORATION

PHARMACEUTICALS

SYB-OV-CTG-201901V0



INGREDIENTS THAT ADD VALUE TO LIFE

Samyang helps you design a life worth smiling about

"Adding quality to your life"- this is what we are called to do in a way as natural as breathing.

Over the last 100 years, Samyang has been working to make our life more abundant and convenient to improve the standard of living.

Guided by both traditional values and the growth mindset,

Samyang is now preparing for another great 100 years.

Samyang aims to grow into a global company by strengthening the core business that involves several interrelated sectors spanning chemicals, food, biopharmaceuticals and packaging, and advancement of its business structure. Dedicated to creating a more abundant and convenient lifestyle, Samyang is looking forward to the next 100 years of even greater achievements.

SAMYANG GROUP



YEAR OF ESTABLISHMENT
1924



REVENUE
USD 3.8 billion (By 2018 Standard)



NUMBER OF EMPLOYEES
Approximately 3,000



BUSINESS
Chemicals, Food, Biopharmaceuticals, Packaging



2020 VISION
Globalization, Specialty, New Business

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Samyang at a glance

Samyang is dedicated to creating a healthy and abundant future for all humanity

Since its founding in 1924 by Kim Yeon-su, also known under the pseudonym Sudang, Samyang Group has entered into the markets of sugar manufacturing, integrated synthetic fiber and flour milling based on upright, trustworthy management and greatly contributed to both increasing the country's living standards through the provision of essentials and the development of the national economy. Upon entering the 21st century, Samyang Group defined its vision of becoming a company creating an abundant and convenient living, empowered by its core businesses of chemicals, food, biopharmaceuticals and packaging. Having utilized its competitive edge, especially in these sectors, it has dedicated itself to the pursuit of change and innovation in order to become an R&D-based global company offering specialized products and services while exploring new business growth engines. In November 2011, Samyang Group was launched as a holding company to set apart the manufacturing and investment businesses to essentially promote corporate governance transparency and increase its brand name value. Samyang Holdings Corporation has various subsidiaries that operate main businesses, including Samyang Corporation, Samyang Biopharmaceuticals Corporation and Samyang Packaging Corporation. Through this structure, it practices expedient decision-making and responsibility in management tailored to the traits of each business sector.

samyang

1931, Renamed 'Samyang Corporation'
Founded 'Samsu Company'
1924

1955
Entered into Food business
 Completion of Ulsan sugar Refining Plant

Completion of Jeonju polyester plant
Entered into Chemical business
1969

1979
Entered into Packaging business
 First production of PET bottle in Korea

Completion of Daedeok Pharmaceutical plant
Entered into Pharmaceutical business
1996

2011
Shifted to holding company
 Established Samyang Holdings, Samyang Corporation, Samyang Biopharmaceuticals Corporation



BIOPHARMACEUTICALS

Samyang Biopharmaceuticals Corporation
 Pharmaceuticals / Medical Devices / Biologics
 Samyang Biopharm USA Inc.
 Medichem Co., Ltd.

FOOD

Samyang Corporation
 Food ingredients (Sugar, starch, starch sugar, flour milling, ready-made mix, oils/fats), food service distribution, hangover relief product, home-made
Samyang Qinhuangdao Food Co., Ltd.
 Starch sugar
Samyang F&B
 Salad & grill restaurant / Salad & brunch cafe

PACKAGING

Samyang Packaging Corporation
 PET Bottles
 PET Preform
 Aseptic Filling System

CHEMICALS

Samyang Corporation
 Engineering plastics / IT & electronic materials / Ion-exchange resin / White biotechnology
Samnam Petrochemical Co., Ltd.
 TPA (Terephthalic Acid)
Samyang Kasei Co., Ltd.
 Polycarbonates
Samyang Innochem Corporation
 BPA (Bisphenol A)
Samyang Fine Technology
 UPS(Uniform Particle Sized) Ion-exchange resin
Samyang Engineering Plastics (Shanghai)
 Engineering plastics
Samyang Engineering Plastics (Hungary) Co., Ltd.
 Engineering plastics
Samyang EP Vietnam
CREA CHEM
 LFT (Long Fiber Reinforced Thermoplastic)
KCI
 Polymers / Surfactants / Rheology modifier

OTHERS

Samyang Corporation
 Cosmetics
 Samyang Data Systems Inc.
 IT Service



Samyang Biopharmaceuticals Corporation

Samyang Biopharmaceuticals Corporation is a subsidiary specializing in biopharmaceutical business of Samyang Group, and is constantly tapping into the global market with a great emphasis on research and development (R&D) activities, focusing on drug delivery system (DDS) technology as well as biodegradable medical devices.

- Samyang Biopharmaceuticals Corporation
- Samyang Biopharm USA Inc.
- Medichem Co., Ltd.



Business Area



Major Locations



Samyang Discovery Center (Headquarter & R&D Center)

Completion	2016
Related Department	Marketing & Sales / Clinical & Regulatory Affairs / Planning / R&D Center
Location	Seongnam-si, Gyeonggi-do, Korea

Pharmaceuticals Plant

COMPLETION
1997

PRODUCT
Injections, API

LOCATION
Daejeon, Korea

CERTIFICATIONS
EU GMP, JGMP (Japan), KGMP (Korea), PIC/s

Medical Devices Plant

COMPLETION
1996

PRODUCT
Sutures, Hemostats, Patches

LOCATION
Daejeon, Korea

CERTIFICATIONS
KGMP, CE Mark, ISO13485 (Medical Devices), KGMP, PIC/s (Pharmaceuticals)

Samyang Biopharm USA Inc.

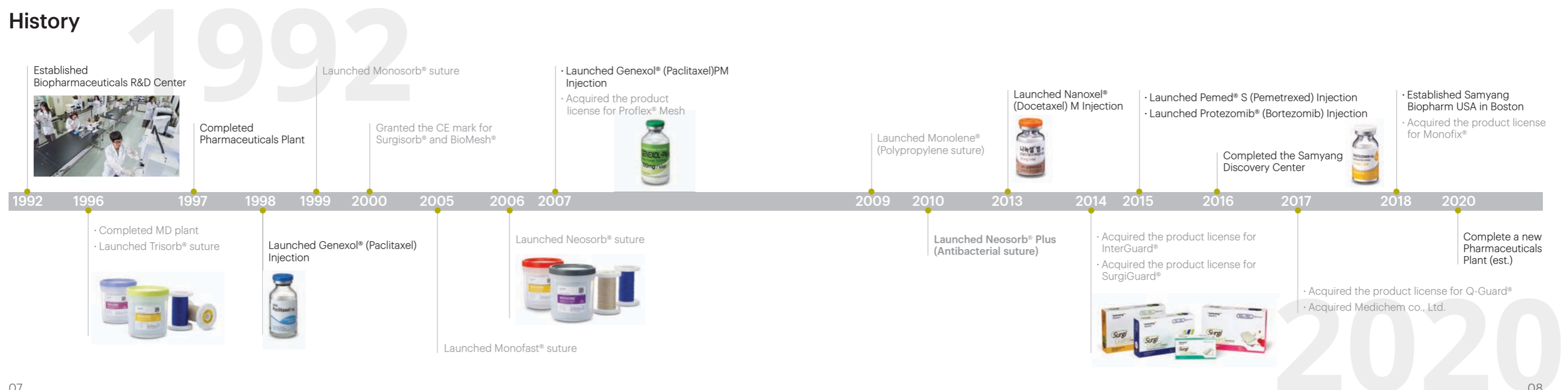
ESTABLISHMENT
2018

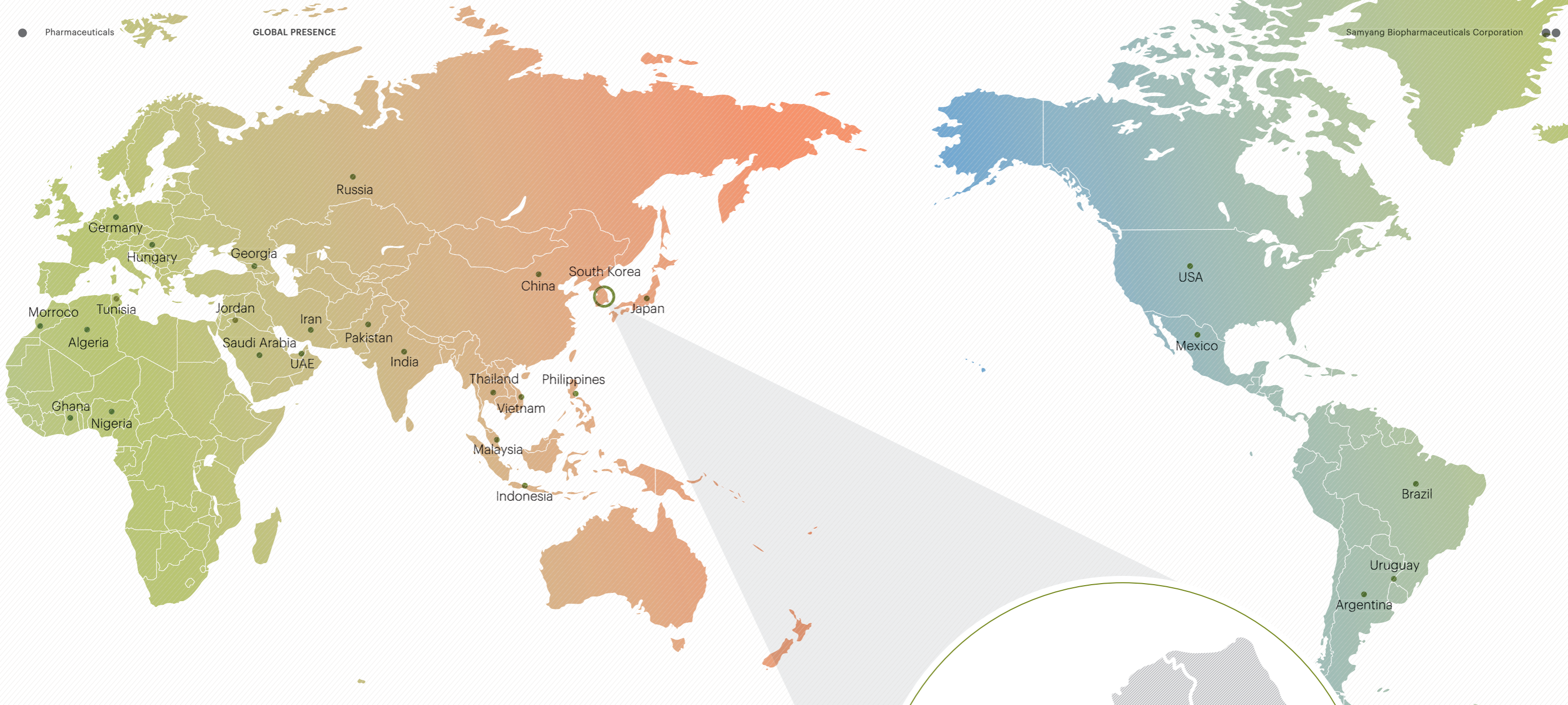
BUSINESS MODEL

- NRDO (No Research Development Only)
- Therapeutics for Oncology and Rare Diseases
- License-in/out

LOCATION
Cambridge, MA, USA

History





ONCOLOGY SPECIALIST

Samyang pharmaceuticals have been present in over 25 countries around the world. With more than 20 years of experience, Samyang provides a wide range of portfolio in oncology, cytotoxic APIs, and patches along with Drug Delivery System (DDS) technology. To achieve future vision: 'Value Generating Pharma Company', it has been focusing all its R&D and innovative capabilities on the field of oncology that is a core area of the 21st century.

No.1
 “Market Leader in Paclitaxel Injection and Nicotine Patch,”

A circular callout with a green border contains the text 'No.1' in large green font, followed by a quote in smaller green font: 'Market Leader in Paclitaxel Injection and Nicotine Patch,'. Below the text is a grey silhouette map of South Korea.

Services

CONTRACT DEVELOPMENT & MANUFACTURING

Products

- ONCOLOGY
- CYTOTOXIC APIS
- PATCHES

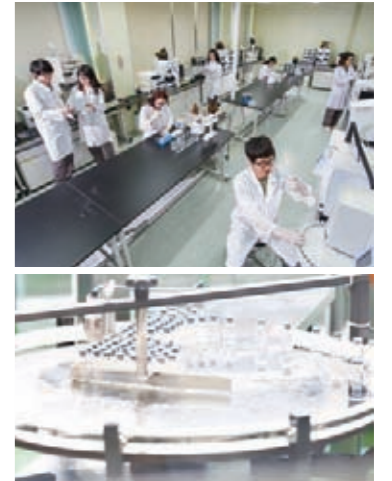
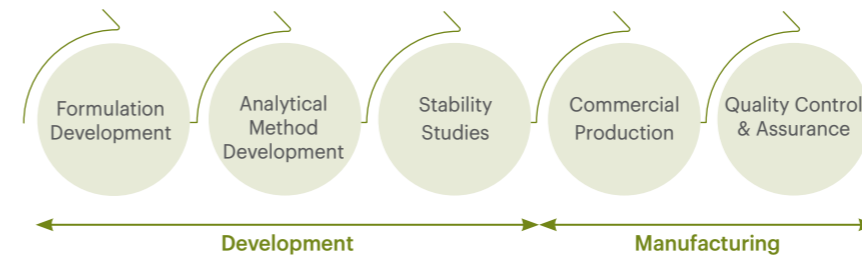


Contract Development & Manufacturing


Products

- Cytotoxic Injections (Lyophilized and Liquid)
- Capsules and Tablets
- Cytotoxic APIs
- Patches and Plasters

Process



Production

Pharmaceuticals Plant		Medical Devices Plant
Current	New (From 2020)	
	 (Extension to the current plant)	

Certification

EU GMP, JGMP (Japan), KGMP (Korea), PIC/s	KGMP, PIC/s
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Product

Cytotoxic APIs, Cytotoxic Injections (Liquid, Lyophilized)	Cytotoxic Injections (Liquid, Lyophilized)	Patches, Plasters
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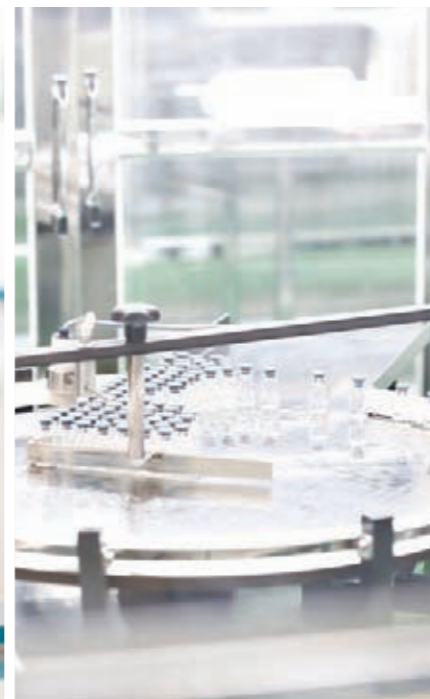
Characteristic

<ul style="list-style-type: none"> · Dedicated Facility for cytotoxic APIs and cytotoxic injections · Customized batch size · Capacity: 10 ~ 200L as bulk solution · Range of vials: 1 ~ 50mL 	<ul style="list-style-type: none"> · Dedicated Facility for cytotoxic injections · Customized batch size · Capacity: 30 ~ 300L as bulk solution · Range of vials: 1 ~ 50mL 	<ul style="list-style-type: none"> · A wide range of size - Patch: 2.5-30cm² - Plaster: 49cm² · Accurate slot-die coating method · Various cutting design
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ONCOLOGY

- Genexol[®] PM Inj.
- Nanoxel[®] M Inj.
- Genexol[®] Inj.
- Docetaxel Inj.
- Nexatin[®] Inj.
- Crabcitabine[®] Inj.
- Pemed[®] S Inj.
- Azalid[®] Inj.
- Decilid[®] Inj.
- Lenalid[®] Tab.
- Protezomib[®] Inj.
- Palonosetron Inj.
- Zolenic[®] Inj.



Polymeric Micelle (PM) Technology

Genexol [®] PM Inj.	Nanoxel [®] M Inj.
	
API	
Paclitaxel	Docetaxel
Formulation	
Lyophilized Injection	Lyophilized Injection
Strength	
30mg, 100mg/vial	20mg, 80mg/vial
Indication	
Breast cancer, NSCLC ¹⁾ , Ovarian cancer	Breast cancer, NSCLC ¹⁾ , Esophageal cancer, H&N cancer, Ovarian cancer, Gastric cancer, Prostate cancer
Dosage	
260mg/m ²	75mg/m ²
Solubilizer	
mPEG-PDLLA	mPEG-PDLLA
Characteristic	
<ul style="list-style-type: none"> · Cremophor EL free <ul style="list-style-type: none"> - Reduce toxicity and hypersensitivity derived from Cremophor EL · High Maximum Tolerated Dose (MTD) <ul style="list-style-type: none"> - High dose chemotherapy is available Breast cancer - Ovarian cancer: 260mg/m² - NSCLC: 230mg/m² · High Objective Response Rate (ORR) <ul style="list-style-type: none"> - High paclitaxel concentration at tumor site increases the tumor's response rate - Breast cancer : 39% (phase III) - NSCLC : 38% (phase II) · Convenient Usage <ul style="list-style-type: none"> - No special infusion set or filter is necessary when administering drugs 	<ul style="list-style-type: none"> · Polysorbate 80 Free <ul style="list-style-type: none"> - Avoid serious disruption within immune system - Increase level of oxidation of G-CSF - Reduce liver toxicity · Alcohol Free <ul style="list-style-type: none"> - Alcohol content may affect central nervous system. - Patients are allowed to drive or use machines immediately after infusion · Bioequivalent <ul style="list-style-type: none"> - Comparative human PK study proves Nanoxel[®] M is bioequivalent to conventional Docetaxel in terms of AUC and Cmax with less adverse reactions

1) NSCLC: Non-Small Cell Lung Cancer

Generics For Solid Tumors

Genexol [®] Inj.	Docetaxel Inj.	Nexatin [®] Inj.	Crabcitabine [®] Inj.	Pemed [®] S Inj.
API				
Paclitaxel	Docetaxel	Oxaliplatin	Gemcitabine	Pemetrexed
Formulation				
Liquid Injection	Liquid Injection	Liquid Injection	Liquid Injection (Cold Storage)	Liquid (Cold Storage)& Lyophilized Injection
Strength				
30mg, 100mg, 300mg/vial	20mg, 80mg, 140mg, 160mg/vial	50mg, 100mg, 200mg/vial	200mg, 1,000mg/vial	Liquid: 1,000mg/vial Lyophilized: 100mg, 500mg/vial
Indication				
Ovarian cancer, Breast cancer, NSCLC, Gastric cancer	Breast cancer, NSCLC, Esophageal cancer, Ovarian cancer, H&N cancer, Gastric cancer, Prostate cancer	Colorectal cancer, Gastric cancer	Pancreas cancer, NSCLC, Ovarian cancer, Breast cancer, Bladder cancer, Biliary tract cancer	NSCLS, Mesothelioma

Genexol[®] Inj. The first-in Paclitaxel Injection in Korea Approved in 1998 by MFDS*
 * MFDS: Ministry of Food and Drug Safety (Korean Health of Ministry)

Clinically-Proven Safety and efficacy

Type	Code of clinical trials	Study period	Cancer	No. of patients
SIT	Korea GXL-BC	'99.8 - '00.8	Breast cancer	45
	Korea GXL-LC	'01.1 - '01.12	Non-small cell lung cancer	27
	Korea GXL-GC	'02.12 - '03.9	Gastric cancer	33
PMS	Korea PMS-BC	'01.3 - '02.7	Breast cancer	107
	Korea PMS-LC	'02.6 - '03.7	Non-small cell lung cancer	124
	Korea PMS-GC	'04.2 - '06.2	Gastric cancer	273
IIT	Korea GNX-0702	'07.5 - '16.12	Metastatic or recurrent BC	231
	Korea GNX-0703	'08.11 - '10.12	Advanced Gastric cancer	12
	Korea GNX-0704	'08.9 - '14.5	Advanced of recurrent esophageal squamous cell carcinoma	45
	Korea GNX-0901	'08.11 - '10.12	HER-2 negative stage II / III Breast cancer	15
	Korea SNUBH-GO-039	'14.10 - '15.10	Ovarian cancer	12
	Korea EG PG	'14.10 - '18.9	Breast cancer	118
	Korea GNX-PO1	'10.11 - '18.10	Breast cancer	1,323
	Singapore	'03.9 - '04.12	Nasopharyngeal cancer	28
	Indonesia	'05.1 - '05.12	Non-small cell lung cancer	28
	Egypt	'05.5 - '06.1	Non-small cell lung cancer	16

Generics For Blood Cancers & Supportive Care

Azalid [®] Inj.	Decilid [®] Inj.	Lenalid [®] Tab	Protezoimib [®] Inj.	Palonosetron Inj.	Zolenic [®] Inj.
API					
Azacitidine	Decitabine	Lenalidomide	Bortezomib	Palonosetron	Zoledronic Acid
Formulation					
Lyophilized Injection	Lyophilized Injection	Oral Tablet	Lyophilized Injection	Liquid Injection	Liquid Injection
Strength					
100mg, 150mg/vial	40mg, 50mg/vial	2.5mg, 5.0mg, 7.5mg, 10mg, 15mg, 20mg, 25mg/pc (21 pcs/package)	2.5mg, 3.5mg/vial	0.075mg 0.25mg, 0.4mg/vial	4mg/vial
Indication					
MDS ¹⁾ , AML ²⁾ , CMML ³⁾	MDS, AML	MM ⁴⁾	MCL ⁵⁾ , MM	Anti-emetics	Hypercalcemia of malignancy Bone metastasis

1) MDS: Myelodysplastic Syndrome
 2) AML: Acute Myeloid Leukemia
 3) CMML: Chronic Myelomonocytic Leukemia
 4) MM: Multiple Myeloma
 5) MCL: Mantle Cell Lymphoma

Lenalid[®] Tab.

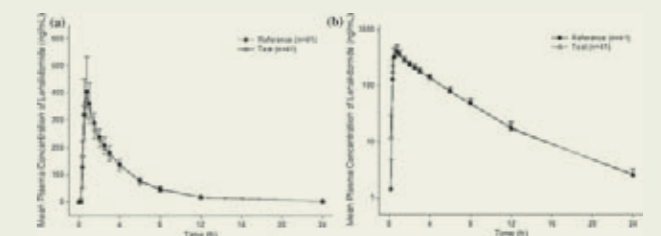
Characteristics

- Easy to swallow
Compact-sized tablets are easy to swallow for elderly patients
- Safe to handle
Double-layered polymer coating prevents exposure of API
- Easy to administer
7 strengths are available; 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg, 25mg
- Bioequivalent
Pharmacokinetic and tolerability profiles prove that Lenalid[®] is comparable to conventional lenalidomide

Bioequivalence Study

Single-Dose Comparative Pharmacokinetics of Two Formulations of Lenalidomide 25mg in Healthy Subjects: A Randomized Crossover Study

Adv Ther. 2018 Feb;35(2):210-217.



Mean plasma concentration-time curves for lenalidomide (a linear scale, b log scale) after a single oral dose of the test and reference formulation of 25 mg lenalidomide. Error bars represent standard deviations



CYTOTOXIC APIS

- Paclitaxel
- Docetaxel
- Pemetrexed
- Bortezomib
- Cabazitaxel



Cytotoxic APIs

Paclitaxel	Docetaxel	Pemetrexed	Bortezomib	Cabazitaxel
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Indication

Ovarian cancer, Breast cancer, NSCLC, Gastric cancer	Breast cancer, NSCLC, Esophageal cancer, Ovarian cancer, H&N cancer, Gastric cancer, Prostate cancer	NSCLC, Mesothelioma	MCL, MM	Prostate cancer
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Package

Up to 500g Per Request	Up to 500g Per Request	Up to 500g Per Request	Up to 500g Per Request	Up to 500g Per Request
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Feature

Plant Cell Culture · US DMF# 014388 · CEP: R1-CEP 2009-255-Rev 00 · KDMF Semi-synthesis · US DMF# 27560 · CEP: RO-CEP 2014-061-Rev 00	Anhydrous · US DMF# 25678 · CEP: RO-CEP 2013-185-Rev 01 Trihydrate · US DMF# 25672 · CEP: RO-CEP 2012-240-Rev 01	KDMF	KDMF	Under Development
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Paclitaxel

Samyang's Strength

- First company that developed plant-cell culture technology
- 20 years of experience in manufacturing Paclitaxel API

EU GMP & JGMP-certified Production

- Supply Paclitaxel API for European and Japanese customers
- Comply with US/EU/JP GMP guidelines (ICH Q7A)
- Receive regular inspections from European and Japanese authorities
- Own manufacturing facility dedicated to cytotoxic APIs and injections

Feature

- High Purity (> 99.5% by HPLC)
- Large Production capacity (+120kg)
- Large batch size (5 - 10 kg)



PATCHES

- Nicostop[®] Patch
- Fentanderm[®] Patch
- Demencure[®] Patch
- Rheumatop[®] Plaster
- Tulobuterol Patch
- Angiderm[®] Patch



Transdermal Drug Delivery System (TDDS)

Nicostop [®] Patch & Gum		Fentaderm [®] Patch	Demencure [®] Patch	Rheumastop [®] Plaster	Tulobuterol Patch	Angiderm [®] Patch
API						
Nicotine		Fentanyl	Rivastigmine	Diclofenac Sodium / Diclofenac Diethylammonium	Tulobuterol	Nitroglycerin
Formulation						
Patch	Gum	Patch	Patch	Plaster	Patch	Patch
Strength						
14mg 28mg 42mg	2mg	12 μ g, 25 μ g, 50 μ g, 100 μ g/h	6mg(4.6mg/24hr), 12mg(9.5mg/24hr)	120mg	0.5mg, 1mg, 2mg	22.4mg(0.2mg/hr)
Package						
16pcs/ carton	16pcs, 32pcs/ carton	10pcs/carton	30pcs/carton	10pcs/pouch	30pcs/carton	30pcs/carton
Indication						
Smoking cessation		Chronic pain	Dementia	Rheumatoid arthritis	Bronchial asthma	Angina
Feature						
No. 1 Brand in Korea		· Bioequivalent with less API · Reduced patch size	· Bioequivalent with less API · Reduced skin irritation	· Initial cool feeling · Potent and long-lasting therapeutic efficacy · Flexible and elastic	· Good controlled drug permeation · Excellent wearing property	· Useful for preventing early morning heart attacks
Excel- lent wearing	Good- chewing ability					

Memo

● samyang ●
Biopharm

● samyang ●
Biopharm

SAMYANG WILL ENSURE THE
WELL-BEING OF ALL HUMANITY

