



SAMYANG HOLDINGS CORPORATION

PHARMACEUTICALS

• VIEW PDF •



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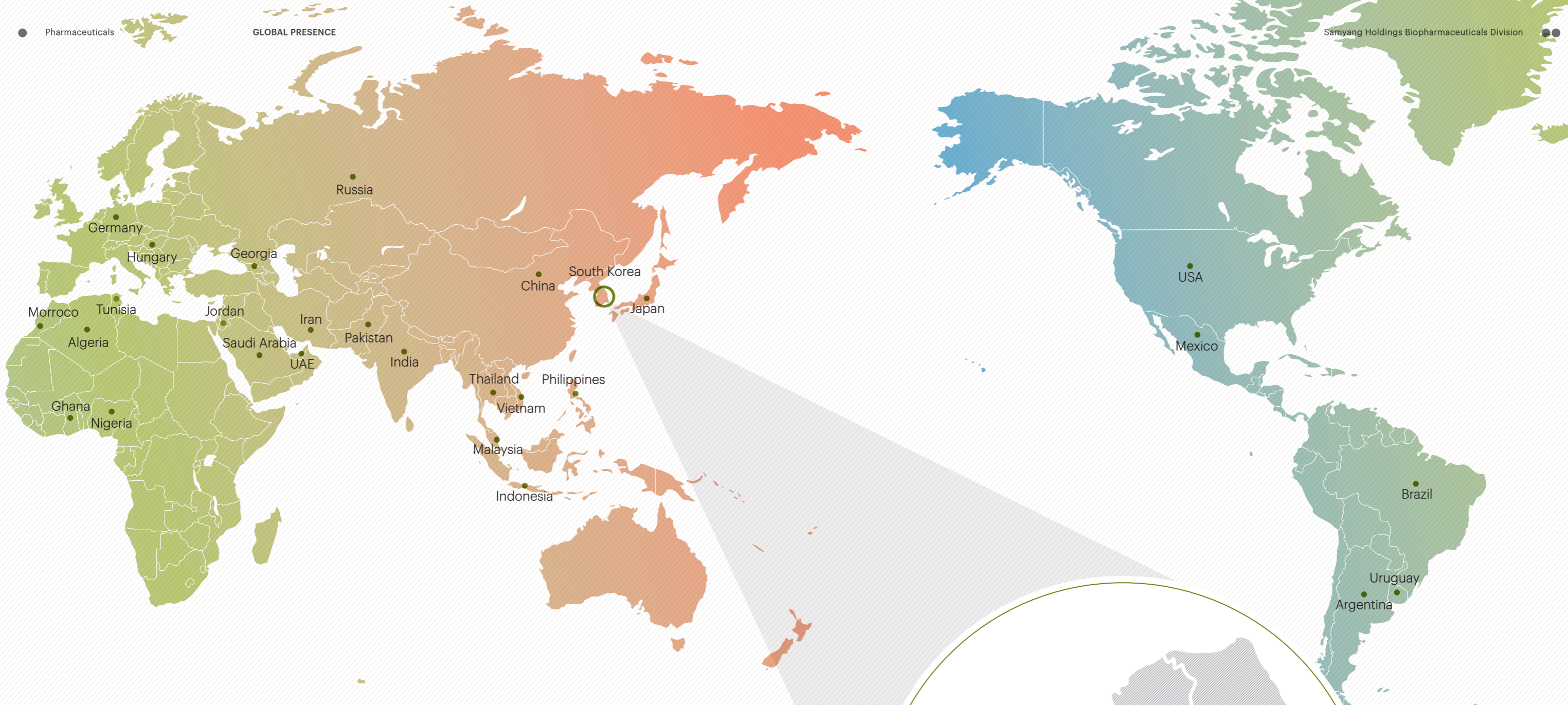
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SYB-OV-CTG-20210V0





ONCOLOGY SPECIALIST

Samyang has been present in over 25 countries around the world. With more than 30 years of experience, Samyang provides a wide range of portfolios in oncology and cytotoxic APIs, along with Drug Delivery System (DDS) technology. To achieve the future vision: "Value Generating Pharma Company", the company has been focusing on its R&D and innovative capabilities in the field of oncology, which is one of the key areas of interest in the 21st century.

No.1
 “Market Leader in Paclitaxel Injection”

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

Services

CONTRACT DEVELOPMENT & MANUFACTURING

Products

- ONCOLOGY
- CYTOTOXIC API

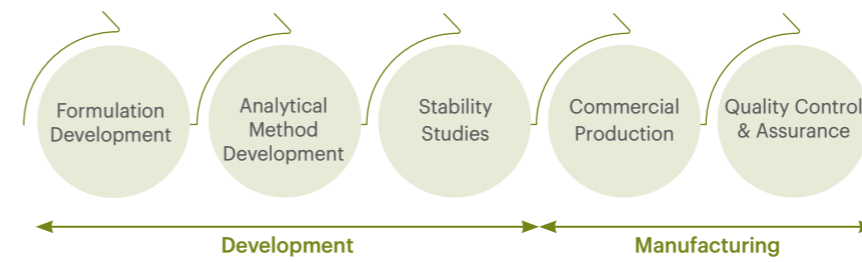


Contract Development & Manufacturing



Products

- Cytotoxic Injections (Lyophilized and Liquid)

Process



Production

Pharmaceuticals Plant	
Current	New (Expansion)
	 (Expansion from the current plant)

Certification

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

Product

Cytotoxic Injections (Liquid, Lyophilized)

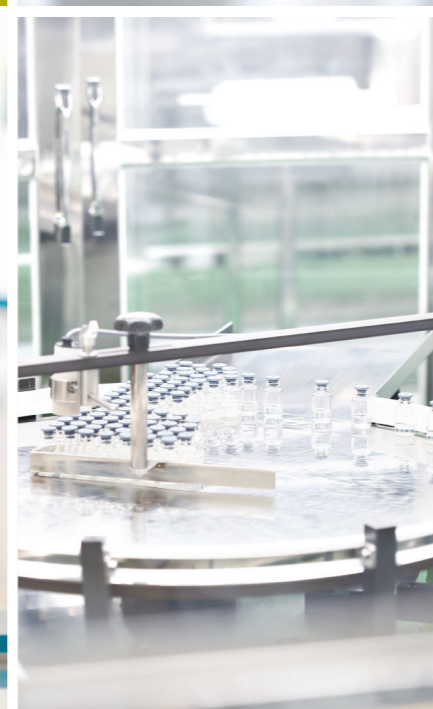
Characteristic

- Dedicated Facility for cytotoxic APIs and cytotoxic injections
- Customized batch size
- Capacity: 10 ~ 200L as bulk solution
- Range of vials: 1 ~ 50mL

- Dedicated Facility for cytotoxic injections
- Customized batch size
- Capacity: 30 ~ 300L as bulk solution
- Range of vials: 1 ~ 50mL



- ### ONCOLOGY
- Genexol® PM Inj.
 - Nanoxel® M Inj.
 - Genexol® Inj
 - Docetaxel Inj.
 - Nexatin® Inj.
 - Everose® Tab.
 - Pemed® S Inj.
 - Azalid® Inj.
 - Decilid® Inj.
 - Lenalid® Tab.
 - Protezomib® Inj.
 - Bendalid® Inj.
 - Zolenic® Inj.



Polymeric Micelle (PM) Technology

Genexol® PM Inj.	Nanoxel® M Inj.
	
API	
Paclitaxel	Docetaxel
Formulation	
Lyophilized Injection	Lyophilized Injection(Cold Storage)
Strength	
30mg, 100mg/vial	20mg, 80mg/vial
Indication	
Breast cancer, NSCLC ¹⁾ , Ovarian cancer	Breast cancer, NSCLC ¹⁾ , Esophageal cancer, H&N cancer ²⁾ , 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 for 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 the 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
 2) H&N Cancer: Head and Neck Cancer

Generics For Solid Tumors



Genexol® Inj.	Docetaxel Inj.	Nexatin® Inj.	Everose® Tab	Pemed® S Inj.
Paclitaxel	Docetaxel	Oxaliplatin	Everolimus	Pemetrexed

Formulation				
Liquid Injection	Liquid Injection	Liquid Injection	Oral Tablet	Liquid & Lyophilized Injection

Strength				
30mg, 100mg, 300mg/vial	20mg, 80mg, 140mg, 160mg/vial	50mg, 100mg, 200mg/vial	2.5mg, 5mg, 10mg /tab(30tabs/package)	Liquid (Cold Storage): 1g/vial Lyophilized and Liquid(Room Temperature): 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	Breast Cancer, pNET, TSC, RCC, GI/Lung NET	NSCLC, 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)

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 Breast Cancer	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	Protezomib® Inj.	Bendalid® Inj.	Zolenic® Inj.
Azacitidine	Decitabine	Lenalidomide	Bortezomib	Bendamustine	Zoledronic Acid

Formulation					
Lyophilized Injection	Lyophilized Injection	Oral Tablet	Lyophilized Injection	Lyophilized Injection	Liquid Injection

Strength					
100mg, 150mg/vial	40mg, 50mg/vial	2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg, 25mg/tab (7tabs/package)	2.5mg, 3.5mg/vial	25mg, 100mg/vial	4mg/vial

Indication					
MDS ¹⁾ , AML ²⁾ , CMML ³⁾	MDS, AML	MM ⁴⁾ , MDS, MCL ⁵⁾ , FL ⁶⁾	MCL, MM	NHL ⁷⁾ , CLL	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
 6) FL: Follicular Lymphoma
 7) NHL: Non-Hodgkin Lymphoma

Lenalid® Tab.

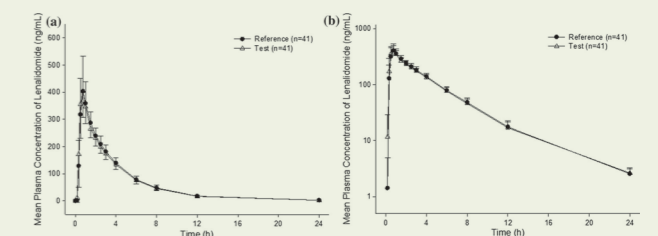
Characteristics

- 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 API

- Paclitaxel
- Pemetrexed
- Bortezomib



Cytotoxic APIs

Paclitaxel	Pemetrexed	Bortezomib
Indication		
Ovarian cancer, Breast cancer, NSCLC, Gastric cancer	NSCLC, Mesothelioma	MCL, MM
Package		
Up to 500g Per Request	Up to 1kg Per Request	Up to 40g Per Request
Feature		
<ul style="list-style-type: none"> · Plant Cell Culture · US DMF# 014388 · CEP: R1-CEP 2009-255-Rev 02 · KDMF · J-MF : 221MF10165 	<ul style="list-style-type: none"> · KDMF · J-MF : 302MF10105 	<ul style="list-style-type: none"> · KDMF

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
- Large batch size