

*YOUR HEALTH, OUR PRIORITY*

# **SAMJIN**

## **PHARMACEUTICAL CO.,LTD**

**SAMJIN**

# SAMJIN PHARM

is a Korean pharmaceutical company that manufactures finished formulations and active pharmaceutical ingredients and develops finished formulations as generics and new drugs.



Headquarters  
(Seoul)

Established in  
**1968**

About  
**800** Employees

### Business Area

- API
- Finished Formulation
- Consumer Health
- Medical Device
- CMO

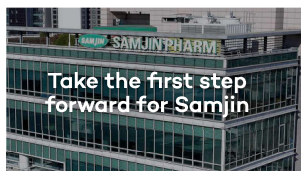
Headquartered in  
**Seoul, Korea**

### Organization

**Fully Integrated  
Pharmaceutical Company**

- In-house R&D
- In-license development  
& distribution
- Manufacturing
- Sales & marketing

## SAMJIN's History



**1968. 04**  
Foundation  
of SAMJIN Pharm. Co.,Ltd.



**1985. 06**  
Established R&D Center to  
Develop new drugs.

**1987. 03**  
WHO-GMP Approval for  
Finished Product Plant



**2013. 09**  
WHO-GMP Approval for  
API Plant.

**2015. 06**  
Technology Transfer for  
Platless Tablet  
(Clopidogrel Bisulfate) to  
Indonesia.



**2021. 11**  
Built up New R&D Center  
to innovate new bio-  
technology.

**2024. 06**  
New Factory approved  
according to PIC/S WHO-  
GMP for Injectable products.





# Osong Plant

PIC/S WHO GMP

API

Injection



## API Major Facilities

### Building A

- Reactor(STS) : 20 Sets
- Reactor(G/L) : 2 Sets
- Dryer : 7 Sets
- Mill : 4 Sets
- Nutsche Filter : 6 Sets

### Building B

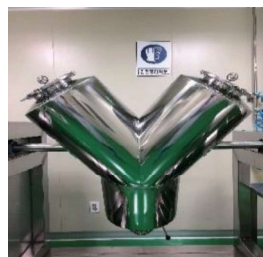
- Reactor(G/L) : 1 Sets
- Reactor(STS) : 5 Sets
- Dryer : 3 Sets
- Mixer : 1 Sets
- Nutsche Filter : 3 Sets

## Injectable Capacity (per year)

- 7.4 million solution for injection (vial)
- 4 million powder for injection (vial)
- 23 million solution for injection (ampoule)



Jet Mill



V-mixer



Reactor



Purified water system

# Hyangnam Plant

PIC/S WHO GMP

Tablet

Capsule



## Factory Automatic Systems

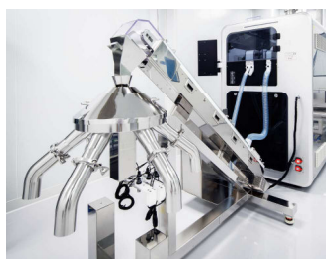
- BMS (Building Management System)
- WMS (Warehouse Management System)
- LIMS/RWS (Laboratory Information Management System/Raw material Weighing System)

## Manufacturing Capacity (per year)

- Tablet (12 billion tablets)
- Capsule (3 billion capsules)



Dry Granulator



Screening Machine



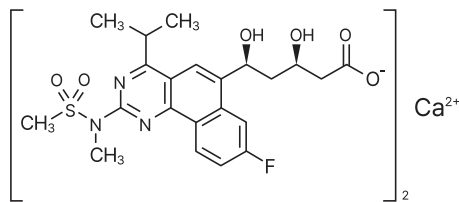
Film Coating Machine



Tableting Machine

# Active Pharmaceutical Ingredient

## Rosuvastatin Ca.



**CAS No :** 147098-20-2  
**Specification :** EP, JP  
**Formulation Method :** DC  
**DMF :** Available

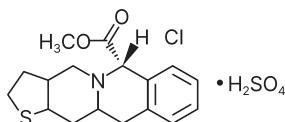
### \* High purity and excellent stability

Samjin Rosuvastatin Calcium, significantly lower than the EP related substances standard and manufactured homogeneously.

Impurity	Impurity C (NMT 0.8%)		Total impurities (NMT 1.2%)	
	Initial	Final	Initial	Final
Forced degradation study	0.002%	0.17%	0.05%	0.6%
Accelerated stability study	0.003%	0.08%	0.08%	0.18%
Long-term stability study	0.003%	0.07%	0.08%	0.12%

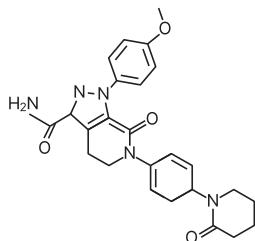
\* Forced degradation study (40°C, 75%RH): 200 days / Accelerated stability study (25°C) : 6 months / Long-term stability study (2-8°C): 24 months

## Clopidogel Bisulfate



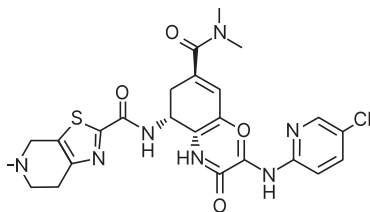
**CAS No. :** 120202-66-6  
**Specification :** USP, JP  
**Formulation :** DC  
**Type :** Form I  
**DMF :** Available

## Apixaban



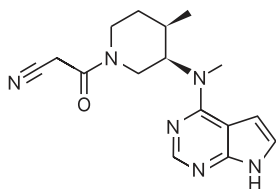
**CAS No. :** 503612-47-3  
**Specification :** In-house  
**DMF :** Available

## Edoxaban Tosylate Monohydrate



**CAS No. :** 480449-70-5  
**Specification :** In-house  
**DMF :** Available

## Tofacitinib Citrate



**CAS No. :** 540737-29-9  
**Specification :** In-house  
**DMF :** Available



# Finished Formulation



- **Active Ingredient & Strength** : Clopidogrel 75mg, 300mg
- **Indication** : Antiplatelet agent
- **BE data** : Available
- **CTD** : Available



- **Active Ingredient & Strength** :  
Apixaban 2.5mg, 5mg
- **Indication** : Non-vitamin K antagonist oral anticoagulant (NOAC)
- **BE date** : Available
- **CTD** : Available (including Elemental Impurities data)



- **Active Ingredient & Strength** :  
Micronized Macitentan 10mg
- **Indication** : Pulmonary arterial hypertension (PAH)
- **BE date** : Available
- **CTD** : Available



# Finished Formulation

## Neustatin™ R Tab.

- **Active Ingredient & Strength** : Rosuvastatin 5mg, 10mg, 20mg
- **Indication** : Anti-hyperlipidemia agent
- **BE data** : Available
- **CTD** : Available



## Fetra™ Tab.

- **Active Ingredient & Strength** : Letrozole 2.5mg
- **Indication** :  
Postmenopausal hormone receptor-positive breast cancer
- **BE data** : Available
- **CTD** : Available



## TOFANUS Tab.

[API : Tofacitinib Citrate 5mg, 10mg]

- **BE data** : Available
- **CTD** : Available
- **Efficacy**
  - ★ **Rapid and Consistent Response.** It provides a rapid onset of action, with improvements in joint pain, swelling, and physical function observed within the first few weeks of treatment.

Under Development

- ★ **Sustained Clinical Benefits.** It demonstrates sustained reduction in disease activity and improved quality of life for patients with inadequate response to conventional DMARDs.

## IRONJECT Inj.

[API : FERRIC CARBOXYMALTOSE]

- **Efficacy**
  - ★ Patients with iron deficiency for whom **oral iron preparations** are ineffective or cannot be administered
  - ★ Patients with iron deficiency who require **rapid clinical iron supplementation**

It can be rapidly administered at a high dose of up to **1000 mg within 15 minutes** at a neutral pH, reducing the administration time and frequency. Compared to existing treatments, it has **fewer side effects** and **vascular pain**, thereby **improving patient compliance.**

# Product List

## Finished Formulation

Category	Product Name	API	Indication	BE data	Export
Cardiovascular system	ARB XG (Tablet)	Amlodipine + Valsartan 5/80mg, 5/160mg, 10/160mg	Antihypertensives (CCB + ARB Combination)	o	Vietnam
	Elxaban (Tablet)	Apixaban 2.5mg, 5mg	NOAC (Direct Xa Inhibitor)	o	Azerbaijan
	Aspirin (Tablet)	Aspirin 100mg	Antiplatelet agent		Hong Kong
	Neustatin-A (Tablet)	Atorvastatin 10mg, 20mg, 40mg	Anti-hyperlipidemia agent	o	
	Intrack (Tablet)	Carvedilol 6.25mg, 12.5mg, 25mg	Antihypertensives	o	
	Platless (Tablet)	Clopidogrel (as bisulfate) 75mg	Antiplatelet agent	o	Singapore, Philippines
	ARB (Tablet)	Losartan potassium 50mg	Antihypertensives	o	Malaysia
	ARB S (Tablet)	Olmesartan 10mg, 20mg	Antihypertensives	o	
	ARB-SD (Tablet)	Olmesartan + Hydrochlorothiazide 20mg/ 12.5mg	Antihypertensives	o	
	Neustatin-R (tablet)	Rosuvastatin 5mg, 10mg, 20mg	Anti-hyperlipidemia agent	o	Hong Kong, Vietnam
	Exvan (Tablet)	Valsartan 80mg, 160mg (Tablet)	Antihypertensives	o	
	Exvan Plus (Tablet)	Valsartan+Hydrochlorothiazide 80mg/12.5mg, 160mg/12.5mg	Antihypertensives		Hong Kong, Cambodia
	Rivoxaban (Tablet)	Rivaroxaban 2.5mg, 10mg, 15mg, 20mg,	NOAC	o	Vietnam
	Maciten (Tablet)	Macitentan 10mg	Treatment of pulmonary arterial hypertension	o	Hong Kong, Moldova, Australia
	Samjin Dron(Tablet)	Dronedarone HCL 400mg	Paroxysmal or persistent atrial fibrillation	o	Hong Kong
	Pamus(Tablet)	Ginkgo Biloba Leaf Dried Extract 240mg	Cognitive impairment, dizziness		
Diabetes	Gladin M (Tablet)	Glimepiride + Metformin 2/500mg	Antidiabetics	o	Cambodia
	Dafozin (Tablet)	Dapagliflozin 5mg, 10mg	Treatment of type 2 diabetes	o	Hong Kong
	Fovigl (Tablet)	Dapagliflozin propandiol + Sitagliptin 100/10mg	Simplication of co-administration for SGLT2 + DPP-4	o	
Neurological	Serocover (Tablet)	Escitalopram 5mg, 10mg, 20mg	Antidepressant (SSRI)	o	
	Neurocover (Capsule)	Gabapentin 100mg, 300mg	Anticonvulsant, treatment of neuropathic pain	o	Hong Kong
	Epilatam (Tablet)	Levetiracetam 250mg, 500mg, 1000mg	Treatment for Epilepsy	o	
	Epilatam (Solution for Injection)	Levetiracetam 500mg/5mL	Treatment for Epilepsy		
	Samjin Naloxone Hydrochloride (Solution for Injection)	Naloxone hydrochloride 0.4mg/1mL, 2mg/2mL, 5mg/5mL	To counter decreased breathing in opioid overdose		
	Nimodipine 10mg (Solution for Injection)	Nimodipine 10mg	Prevention of cerebral vasospasm		Mongolia
	Neurocover-PG (Capsule)	Pregabalin 25mg, 50mg, 75mg, 150mg, 300mg	Anticonvulsant, Treatment of neuropathic pain	o	Philippines

# Product List

## Finished Formulation

Category	Product Name	API	Indication	BE data	Export
Antibiotics	Fullgram (Capsule)	Clindamycin hydrochloride 150mg	Lincosamide Antibiotics		
	Fullgram (Solution for Injection)	Clindamycin phosphate 300mg/2mL, 600mg/4mL	Lincosamide Antibiotics		Philippines, Vietnam
	Nesomicin (Solution for Injection)	Netilmicin sulfate 100mg, 150mg	Antibiotics (Aminoglycosides)		
	Samjin Tobramycin (Solution for Injection)	Tobramycin 80mg	Antibiotics (Aminoglycosides)		Vietnam
	Hanomycin (Powder for Injection)	Vancomycin hydrochloride 250mg, 500mg, 1g	Antibiotics (Tricyclicglycopeptides)		Vietnam, Mongolia
Anti-Inflammatory	Synerjet (Tablet)	Acetaminophen(Paracetamol) +Tramadol hydrochloride 162.5/18.75mg 325/37.5mg	Analgesics (Moderate to severe pain)	o	Hong Kong
	Klicox (Capsule)	Celecoxib 100mg, 200mg, 400mg	Analgesics and antiinflammatory agent (COX-2 inhibitor)	o	Vietnam, Myanmar
	Kinpoin (Solution for Injection)	Diclofenac sodium 75mg/2mL, 75mg/3mL	NSAIDs		Philippines
	Kerasin (Solution for Injection)	Ketorolac tromethamine 30mg/mL	NSAIDs		
Rheumatismus	Fexorin (Tablet)	Febuxostat 40mg, 80mg	Treatment of chronic gout and hyperuricemia	o	
Anesthetic	Samjin Lidocaine (Solution for Injection)	Lidocaine HCl 25mg/5mL	Local anesthetic drug		
Gastro-intestinal	Nemeol (Tablet)	Esomeprazole Ma. Trihydrate 20mg, 40mg	Proton pump inhibitor (PPI)	o	Hong Kong
	Cospan (Solution for Injection)	Butylscopolamine bromide 20mg/1mL	Antispasmodics		Singapore
	With-A (Tablet)	Lafutidine 10 mg	Anti-peptic ulcer	o	
	Isomeric (Tablet)	Levosulpiride 25mg	GIT Regulator	o	Cambodia
	Rapiz (Capsule)	Nifuroxazide 200mg	Antidiarrheals		Hongkong, Armenia
	Bamedin (Tablet)	Rebamipide 100mg	Treatment of gastroduodenal ulcers and gastritis	o	Cambodia, Guatemala
Antiviral	Afoliva (Tablet)	Adefovir dipivoxil 10mg	Antivirus agent (Hepatitis B virus)	o	Cambodia
	Tenolid F (Tablet)	Tenofovir disoproxil fumarate 300mg	Antiviral agent for hepatitis B and HIV	o	Hong Kong
	Taflead (Tablet)	Tenofovir alafenamide hemimalate	Treatment of chronic hepatitis B virus (HBV)	o	Hong Kong
Liver Disease	Peaceliva (Tablet)	Biphenyl dimethyl dicarboxylate 25mg	Hepatic Protector	o	Ecuador
Anticancer	Ferbon Vial (Solution for Injection)	Folate 10mg/mL (as Folate Ca. 10.8mg)	Detoxifying agent for antineoplastic treatment		Georgia
	Fetra (Tablet)	Letrozole 2.5mg	Postmenopausal hormone receptor-positive breast cancer	o	
Urinary system	Happigra (Tablet)	Sildenafil 50, 100mg	Antierectile dysfunction	o	Hong Kong
	Happilong (Tablet)	Tadalafil 5mg, 10mg, 20mg	Antierectile dysfunction	o	Hong Kong, Mongolia



**Contact to.**

Samjin Pharmaceutical Co., Ltd.  
121 Wausan-ro, Mapo-gu, Seoul, 04054  
Republic of Korea

TEL : +82 2 3140 0728

FAX : +82 2 392 5315

Email : [skkang@samjinpharm.co.kr](mailto:skkang@samjinpharm.co.kr)

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