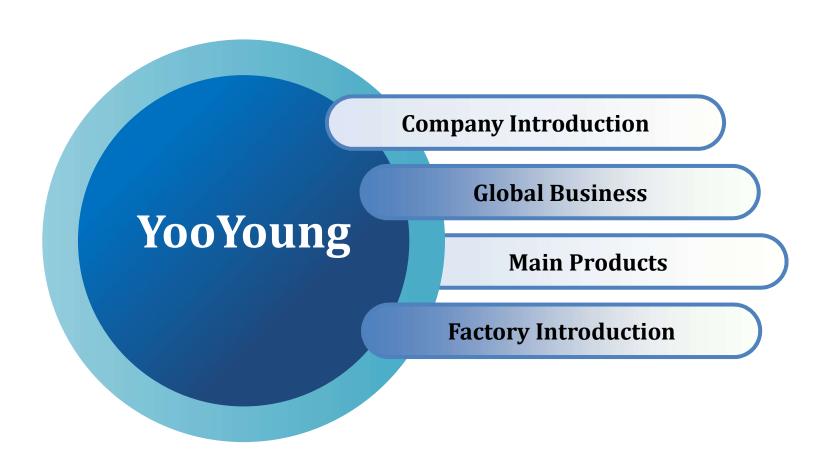
# YOOYOUNG PHARMACEUTICAL



English Ver. (Sep 2020)

## **CONTENTS**









#### COMPANY OVERVIEW

## **YOOYOUNG**

Pharmaceutical Co., Ltd.

Established Year: 1981

No. of Employees: 390

Capital: USD 3 M

Sales: Total 19': USD 100 M

"Export 19": USD 9.6 M"

Location: Head Office - Seoul

**Manufacturing site - Jincheon** 



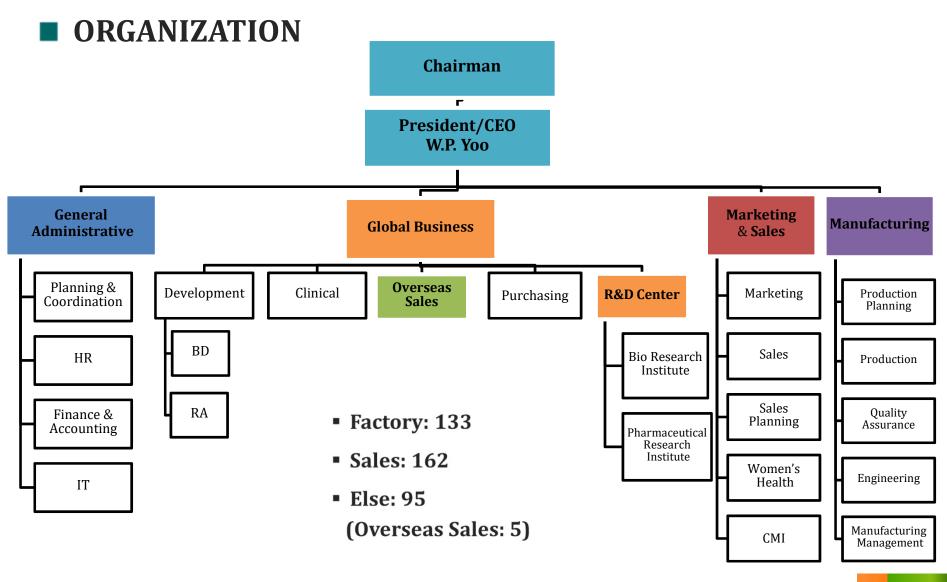


#### YOOYOUNG HISTORY

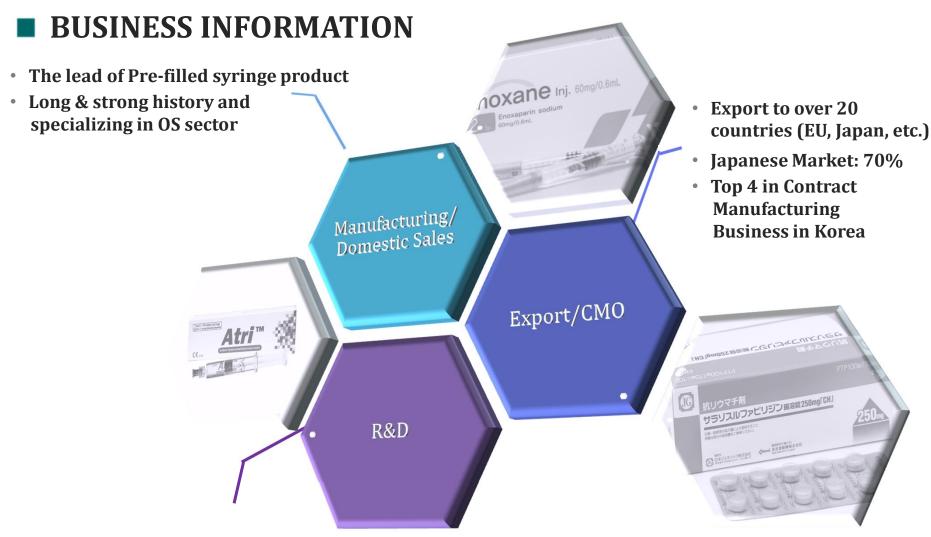
- 2019. 02. Approved GMP [PPB, Kenya].
- 2018. 05. Re-accredited as foreign drug manufacturer by JAPAN MHLW.

  Renewal of GMP Inspection by JAPAN PMDA for OSD.
  - **04.** Renewal of ISO 13485.
- 2017. 04. Renewal of CE Mark for HA Inj. for Knee Arthritis.
- 2016. 12. Awarded "\$5 Million Export Trophy" at the Trade day.
- 2015. 08. Accredited by PIC/s GMP Inspection.
- 2014. 07. First export to Europe [HA Inj. for Knee Arthritis]
  - 01. Consolidated and Extended of research laboratory [Pharmaceutical + Bio]
- **2012. 04. GMP Inspection by JAPAN PMDA for the Injections Obtained CE Mark for HA Inj. for Knee Arthritis.**
- 2009. 09. GMP Inspection by JAPAN PMDA for OSD.
- 2008. 05. Accredited as foreign drug manufacturer by JAPAN MHLW.
- 2007. 06. Extended Jincheon Factory on the level of EU-GMP.
- 1991. 04. Approved KGMP by Korea MOH [Ministry of Health].
- 1981, 12, Established.









- Bio, Pharmaceutical Research Laboratory Center
- Focusing on development of Incrementally modified drug and Biologics



#### **GLOBAL BUSINESS**



#### **■ EXPORTING COUNTRIES**



#### **GLOBAL BUSINESS**



#### Major exporting countries

- Japan: Sulfasalazine Tablet 250/500mg [CMO business]
- EU: Atri & Atri Plus Inj. [CE]
- CIS: Atri & Atri Plus Inj.
- MENA: Cnoxane Inj., Atri & Atri Plus Inj.
- SEA: Atri & Atri Plus Inj., Rabeprazole Tab., Alendronate Tab.
- LaTam: Atri & Atri Plus Inj., Baclofen Tab., Ibandronic Acid Inj., Lalaca Cap 75/150mg. Etc.





























## **■ PRODUCTS LIST**

PRODUCT NAME	COMPOSITION	INDICATION
Atri Injection [CE]	Sodium Hyaluronate 25mg/2.5mL	Arthritis, Scapular periarthritis
Atri Plus Injection [CE]	Sodium Hyaluronate 20mg/2.0mL	Arthritis, Scapular periarthritis
Cnoxane Injection	Enoxaparin Sodium 20/30/40/60/80mg	LMWH : Anti-Coagulants
Yoosetron Injection	Palonosetron HCl 0.056mg/mL (1.5, 5ml)	Chemotheraphy Induced Nausea and Vomitting
Ibandronate Injection	Sodium Ibandronate 3.375mg/3mL	Osteoporosis in postmenopausal women
Asasurfan Tablet	Sulfasalazine 500mg/250mg	Ulcerative colitis
Yooritek Tablet	Riluzole 50mg	Amyotrophic Lateral Sclerosis(ALS)
Rabetra Tablet	Rabeprazole Sodium 10/20mg	PPI
Baclan Tablet	Baclofen 10mg	Muscle relaxants
Altoriton Plus Tablet	Risedronate 35mg + Vitamin D	Osteoporosis in postmenopausal women
Arenmax Tablet	Alendronate 70mg	Osteoporosis, Bone-resorption inhibitor
Lalaca Capsule	Pregabalin 75mg/150mg	Epilepsy, Neuropathic pain, Fibromyalgia syndrome



#### **■ MAIN PRODUCTS**

#### 1-1.Sodium Hyaluronate Inj. (Pre-filled): Intra-Articular





PRODUCT NAME	COMPOSITION	REMARK
Atri Inj.	Sodium Hyaluronate 25mg/2.5ml [M.W: 1,000,000 ~ 1,500,000 Da]	5 cycle Inj.
Atri Plus Inj.	Sodium Hyaluronate 20mg/2.0ml [M.W: 2,500,000 ~ 3,000,000 Da]	3 cycle Inj.



#### 2. Enoxaparin Sodium Inj. (Pre-filled): Anti-Coagulant



PRODUCT NAME	COMPOSITION	REMARK
Cnoxane Inj.	Enoxaparin Sodium 20/30/40/60/80mg	- CTD Dossier Available - First and only generic in Korea

#### 3. Palonosetron HCl Inj. (Pre-filled): Anti-emetic Agent



PRODUCT NAME	COMPOSITION	REMARK
Yoosetron Inj.	Palonosetron HCl 0.056mg/ml (1.5ml, 5ml)	- Pre-filled Syringe - Avoid Patent Infringement



#### 4. Sodium Ibandronate Inj. (Pre-filled): Osteoporosis



PRODUCT NAME	COMPOSITION	REMARK
Yoodron Inj	Sodium Ibandronate Monohydrate 3.375mg/3ml (3mg as Ibandronic Acid)	- Osteoporosis in postmenopausal women

#### 5. Sulfasalazine Enteric Coated Tab.: Gastro-Intestinal



PRODUCT NAME	COMPOSITION	REMARK
Asasurfan Tab.	Sulfasalazine 500/250mg	- Reumarthritis, Ulcerative Colitis - Exporting to Japan (CMO)









#### ■ SITE DESIGN

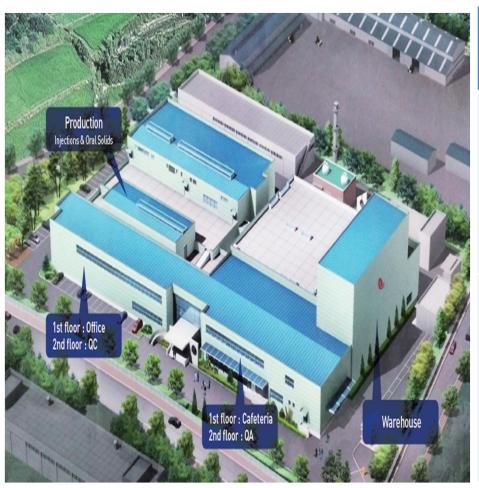
Size	23,000m <sup>2</sup> (Land) 15,000m <sup>2</sup> (Building)
Extension date	June 2007
Dosage form	<ul><li>Oral Solid : Tablet, Capsule</li><li>Injection : Pre-filled syringe,</li><li>Ampoule</li></ul>
Inspected by	<ul><li>- Korean MFDS (PIC/s)</li><li>- Japanese PMDA</li><li>- CE Authority</li></ul>







#### ■ MANUFACTURING CAPACITY



Classification	Dosage	Capacity (1 Year)
Oral Solid	Tablet	350,000,000 Tab.
Dosage	Capsule	65,000,000 Cap.
Injection	Pre-filled Syringe	3,000,000 PFS.
	Ampoule	16,000,000 Amp.



#### OVERSEAS INSPECTION HISTORY

- 2008.05 Accredited as Foreign Drug Manufacturer by Japan
- 2009.09 Japan PMDA Approval of Oral Solid Dosage
- 2012.01 Approved EU CE Certificate
- 2012.04 Japan PMDA Approval of Pre-filled Syringe
- 2015.08 Approved PIC/s GMP [MFDS, Korea]
- 2016.03 Inspection by Japanese Company "Choseido & Nichi-iko"
- 2017.04 Re-approved EU CE Certificate
- 2018.04 Re-approved ISO 13485
- 2018.05 Re-accredited as Foreign Drug Manufacturer by Japan Japan PMDA Re-approval of Oral Solid Dosage
- 2019.02 Approved GMP [PPB, Kenya]









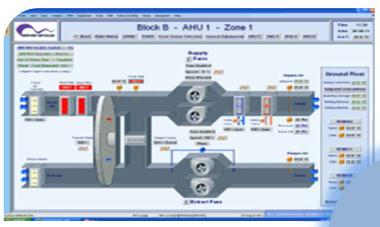


#### **■ FEATURE OF PRODUCTION FACILITIES**

**Global** 

**Standard** 

**Plant** 



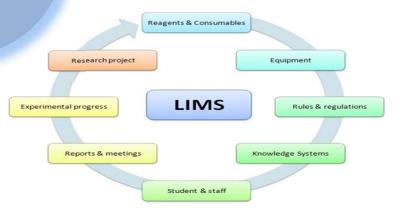
Building Management System (BMS)



Inj./OSD Manufacturing Execution System (MES)



Warehouse Management System (WMS)



Laboratory Information Management System (LIMS)



#### ■ MANUFACTURING FACILITY



**Pre-filled Syringe Line** 



**Tableting Line** 



**Film Coating System** 



**Automatic Ampoule filling Line** 



**Automatic Packaging Line** 



**Automatic warehouse** 



## **Be With YooYoung!**