

# YOOYOUNG PHARMACEUTICAL

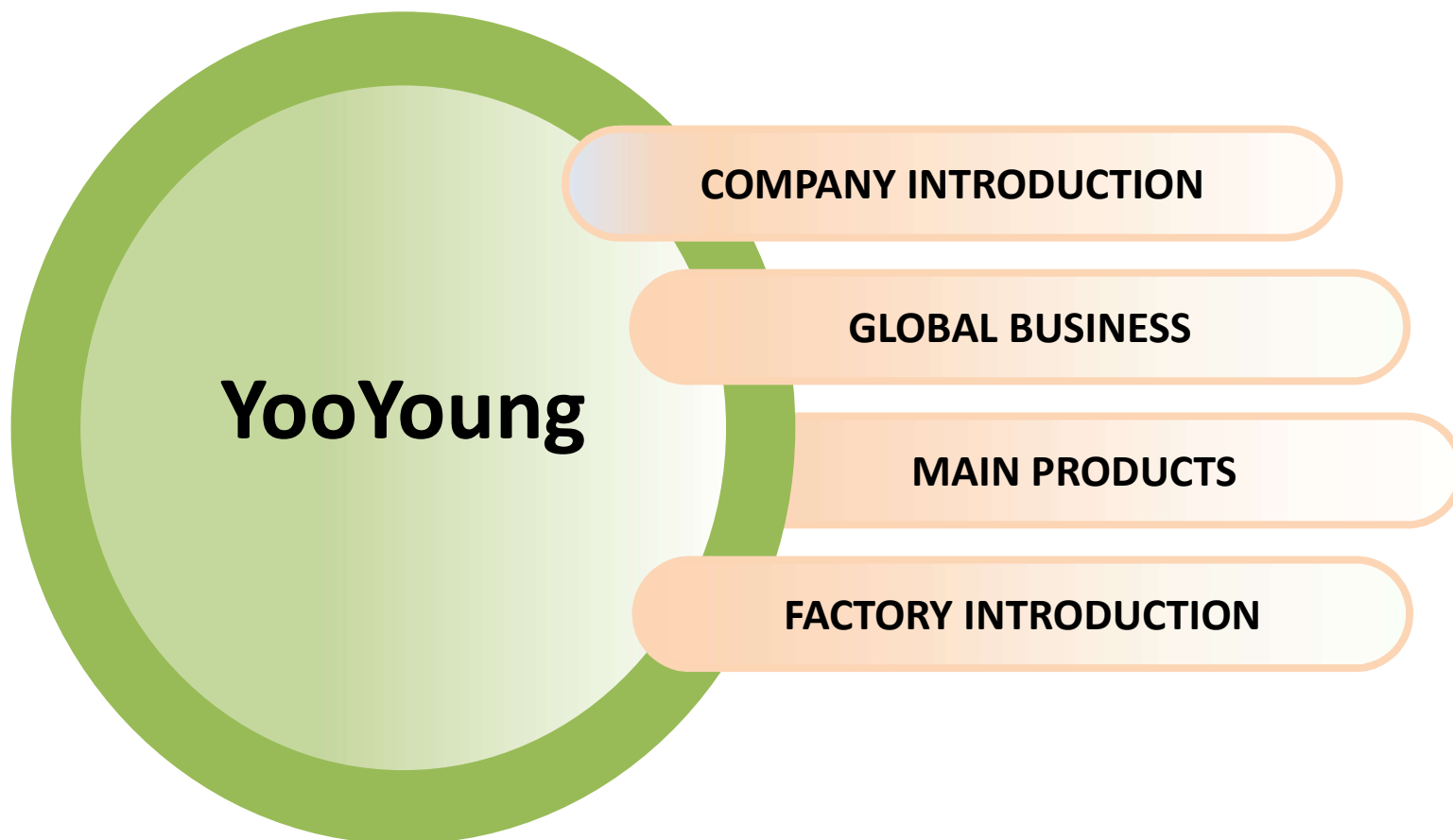
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*“COMPANY PROFILE 2024”*



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# COMPANY INTRODUCTION



## COMPANY OVERVIEW



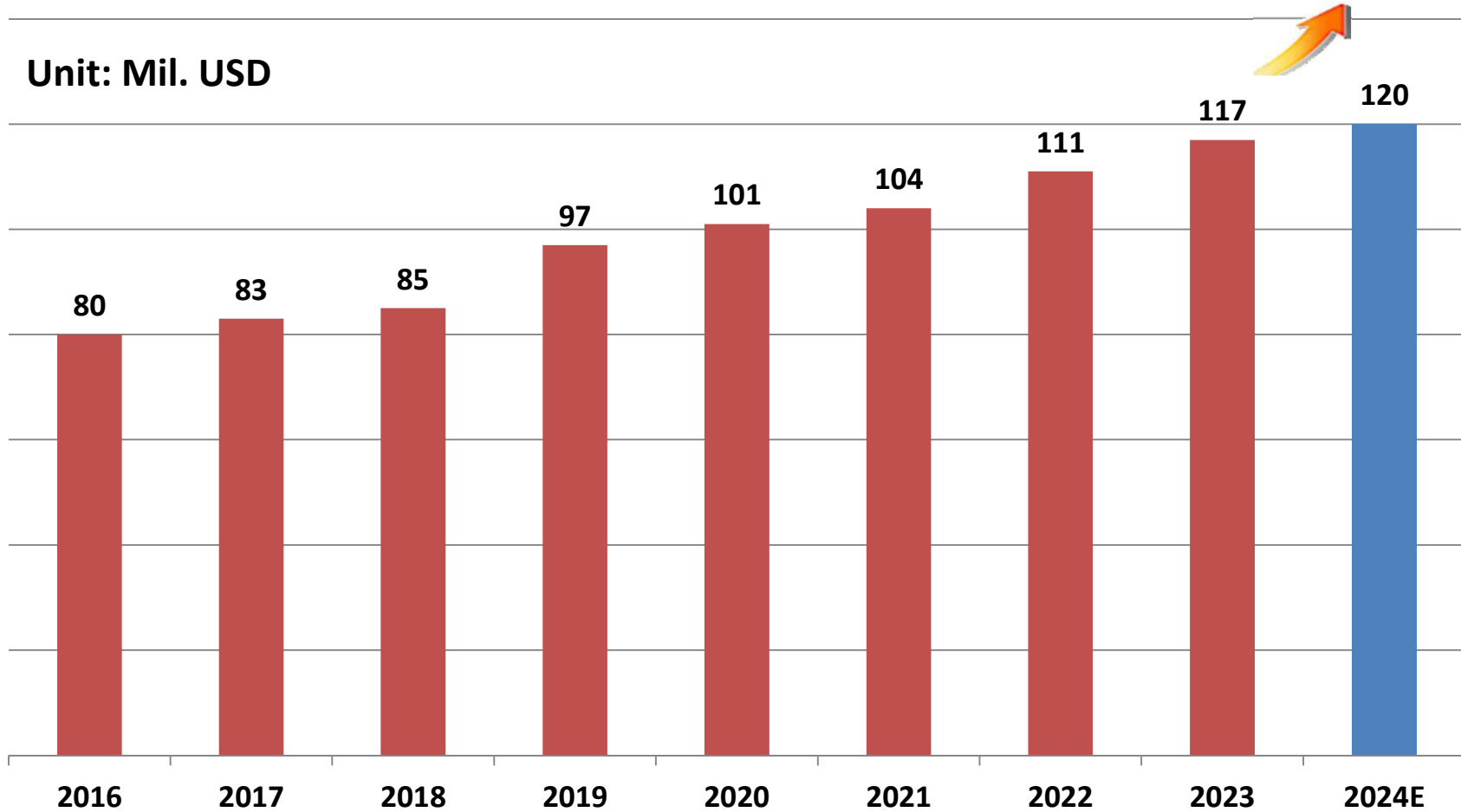
Sales revenue	Mil. USD 111 (Y 2022) Mil. USD 13 (Y 2022) * Export
Business Field	Pharmaceuticals & Medical Devices
Business Scope	Fully integrated pharmaceutical company ↳ In-house R&D ↳ Manufacturing ↳ Sales & marketing ↳ Overseas Sales

\* Reference: Internal Data 2022  
\* Exchange rate: 1 USD= 1,100 KRW

# COMPANY INTRODUCTION



## ■ Sales Performance (Total)



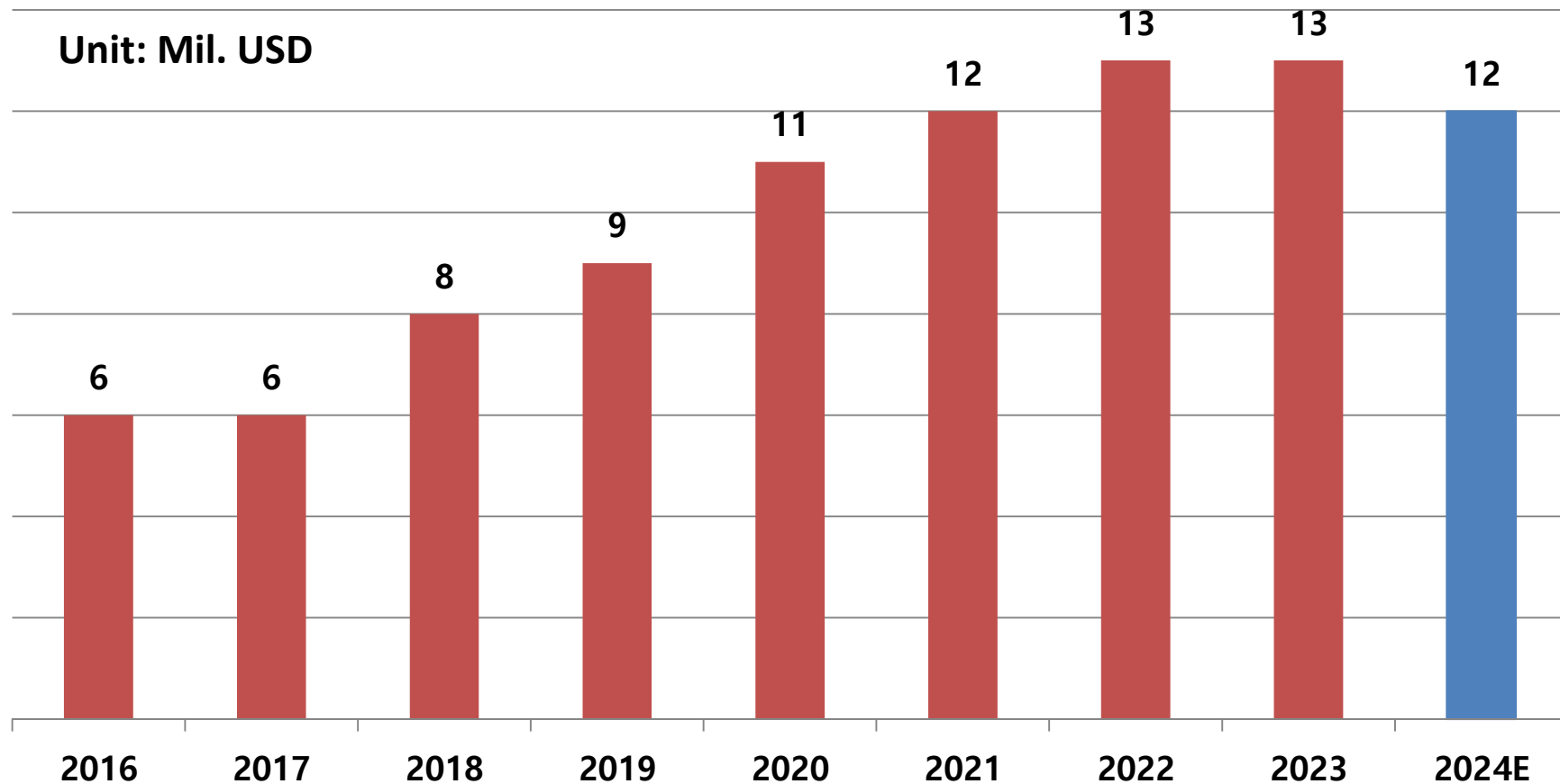
\* Reference: Internal Data 2024

\* Exchange rate: 1 USD= 1,100 KRW

# COMPANY INTRODUCTION



## ■ Sales Performance (Export only)

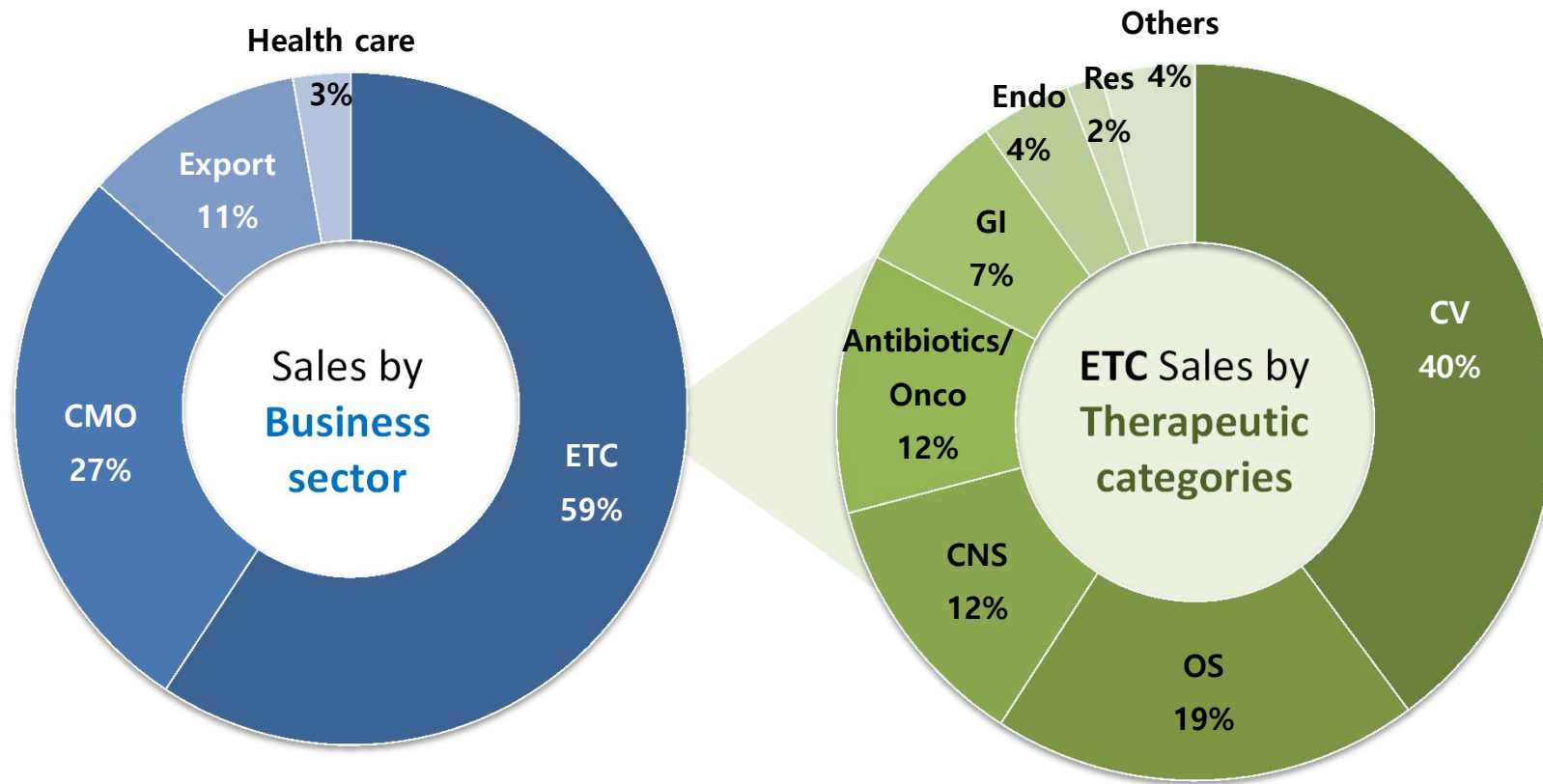


\* Reference: Internal Data 2024

\* Exchange rate: 1 USD= 1,100 KRW

# COMPANY INTRODUCTION

## ■ Sales By Category



- Current emerge in IM especially CV, Endo with Pravafenix.
- Long & strong history in OS sector with injection products.

# COMPANY INTRODUCTION



## ■ YOOYOUNG HISTORY

**2021. 12.** Awarded “USD 10million Export Trophy” at the Trade day.

**2021. 01.** Renewal of ISO 13485.

**2020. 02.** Renewal of CE Mark for HA Inj. for Knee Arthritis.

**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.

**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].

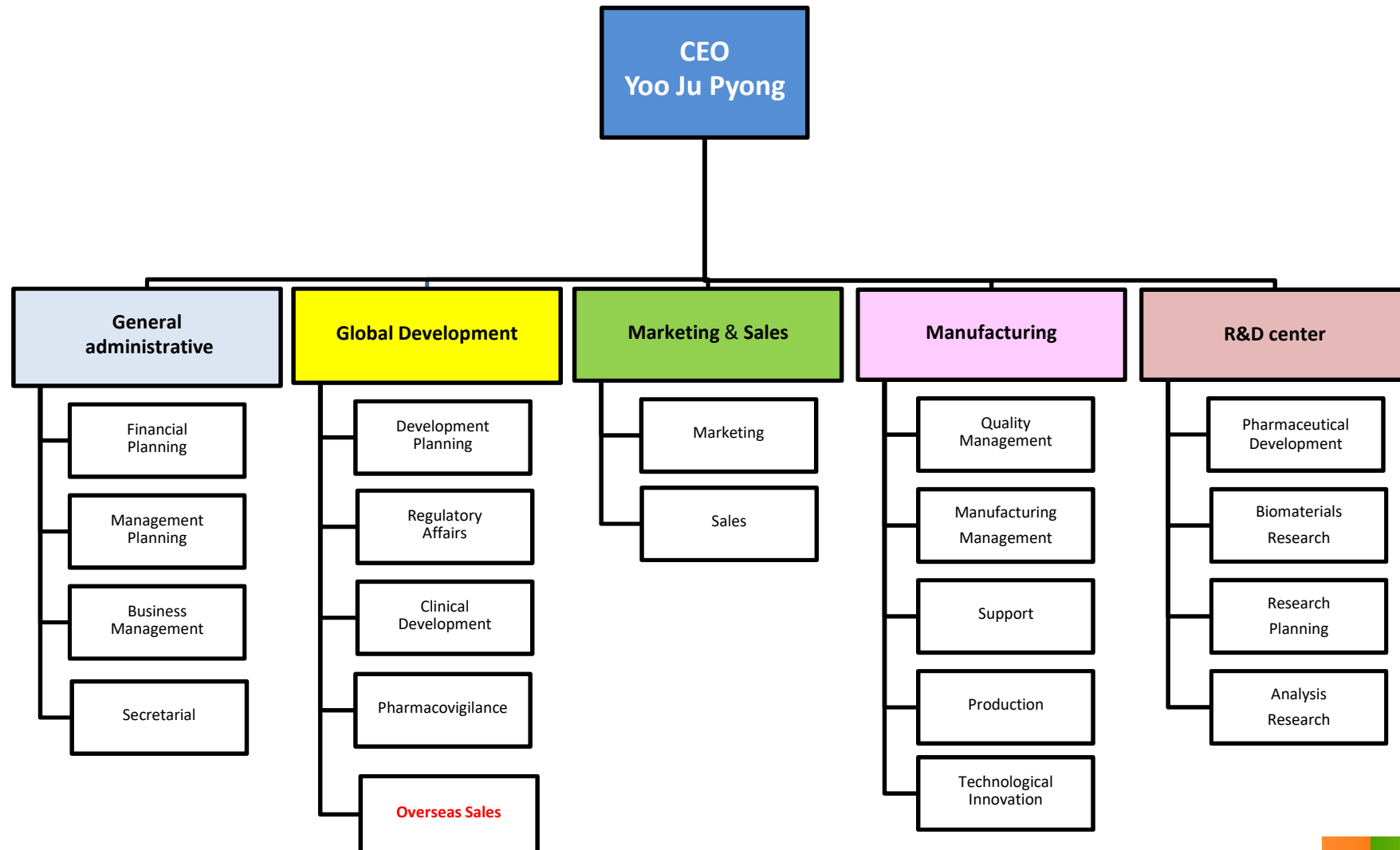
**1981. 12.** Established.



# COMPANY INTRODUCTION



## ■ ORGANIZATION



# COMPANY INTRODUCTION

## ■ BUSINESS INFORMATION

- The lead of Pre-filled syringe product
- Long & strong history and specializing in OS sector



- Export to over 20 countries (EU, Japan, etc.)
- Japanese Market: 75%
- Top 4 in Contract Manufacturing Business in Korea

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



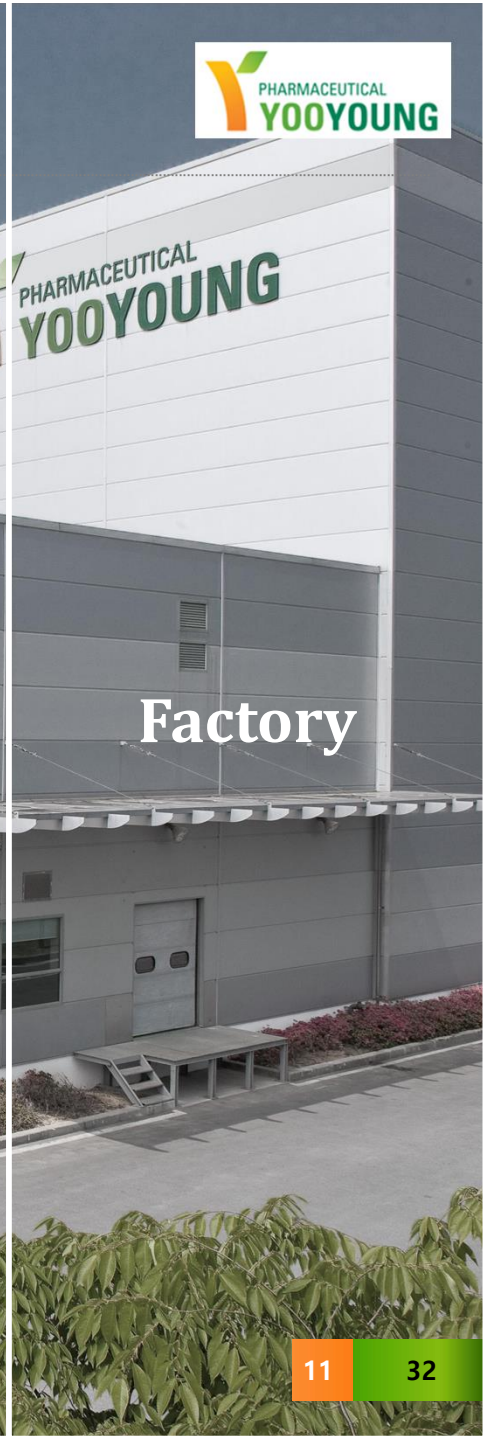
## Company Introduction



## Global Business



## Main Products



## Factory



## EXPORTING COUNTRIES

“We are exporting high-quality pharmaceutical products to over 20 countries!!”



### EU

- FRANCE • AUSTRIA • POLAND

### MENA

- KUWAIT • SYRIA • NIGERIA

### CIS

- MONGOLIA • GEORGIA

### SEA

- SINGAPORE • TAIWAN
- INDONESIA • MALAYSIA
- THAILAND • VIETNAM
- PHILIPPINES • HONGKONG
- MYANMAR • CAMBODIA

### LATIN AMERICA

- MEXICO • COLOMBIA
- CHILE • PERU
- ECUADOR • COSTA RICA
- PANAMA • PARAGUAY
- BOLIVIA • EL SALVADOR
- DOMINICA

# GLOBAL BUSINESS

## ■ Major exporting countries

- Japan: Sulfasalazine Tablet 250/500mg [CMO business]
- EU(France, Poland and Turkey), CIS: HA Inj.
- MENA: Enoxaparin sodium Inj., HA Inj.
- SEA: HA Inj., Rabeprazole Tab., Alendronate Tab.
- LaTam: HA Inj., Enoxaparin sodium Inj , Baclofen Tab.,  
Ibandronic Acid Inj., Pregabalin 75/150mg . Etc.





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# Main Products



## ■ PRODUCTS LIST

PRODUCT NAME	COMPOSITION	INDICATION
Atri Injection [CE]	Sodium Hyaluronate 25mg/2.5mL	Arthritis, Scapular periarthritits
Atri Plus Injection [CE]	Sodium Hyaluronate 20mg/2.0mL	Arthritis, Scapular periarthritits
Resyno one Injection	Cross-linked Sodium Hyaluronate Hydrogel	Osteoarthritis(OA) of the knee
Yooridion Injection	Sugammadex Sodium 108.8mg/ml	Reversal of neuromuscular blockade
Cnoxane Injection	Enoxaparin Sodium 20/30/40/60/80mg	LMWH : Anti-Coagulants
Yoosetron Injection	Palonosetron HCl 0.056mg/mL (1.5, 5ml)	Chemotherapy Induced Nausea and Vomitting
Ibandronate Injection	Sodium Ibandronate 3.375mg/3mL	Osteoporosis in postmenopausal women
Ramoset Injection	Ramosetron HCl 0.3mg/2mL	Anti-emetic agents
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
Lalaca Capsule	Pregabalin 75mg/150mg	Epilepsy, Neuropathic pain, Fibromyalgia syndrome

## MAIN PRODUCTS

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

#### 5 cycle Inj.

CE



#### ATRI Inj.

As a major component of normal joint synovial fluid, it has the effect of improving joint function

- ✓ Sodium Hyaluronate 25mg/2.5ml
- ✓ Arthritis, Scapular periarthritis
- ✓ CE approved

#### Single Inj.

CE on-going



#### Resyno One Inj.

New drug in Korea!  
One dose lasts for 6 months

- ✓ Cross-linked sodium hyaluronate hydrogel (as HA 40mg/2.0ml)
- ✓ Knee arthritis
- ✓ CE on-going

#### 3 cycle Inj.

CE



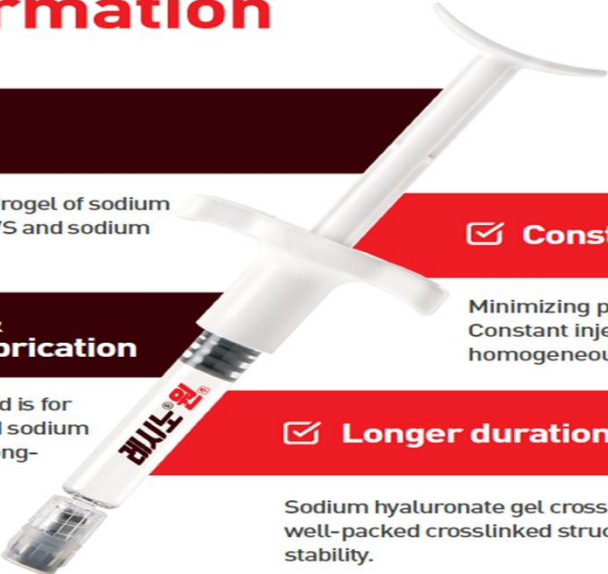
#### ATRI Plus Inj.

It has an excellent therapeutic effect on osteoarthritis, and is excellent for inhibiting and protecting cartilage decomposition

- ✓ Sodium Hyaluronate 20mg/2.0ml
- ✓ Arthritis, Scapular periarthritis
- ✓ CE approved

## 1-2. Resyno-one inj (Cross-linked HA inj. ): Monotherapy

### Product Information



**Resyno<sup>®</sup> ONE<sub>inj</sub>**

Resyno ONE is 4:1 w/w mixed hydrogel of sodium hyaluronate gel crosslinked by DVS and sodium hyaluronate fluid in one syringe.

- Immediate & sustained lubrication**  
 Sodium hyaluronate fluid is for Early onset, Crosslinked sodium hyaluronate gel is for Long-lasting efficacy.
- Constant & soft injection**  
 Minimizing particle size to 300 μm, Constant injection force with homogeneous particle size.
- Longer duration**  
 Sodium hyaluronate gel crosslinked by DVS with well-packed crosslinked structure enhances stability.

<b>Composition</b>	4:1 w/w mixed hydrogel of sodium hyaluronate gel crosslinked by DVS and sodium hyaluronate fluid in one syringe
<b>Dosage form</b>	Pre-filled syringe injection (including 23G needle)
<b>Indication</b>	Osteoarthritis of the knee
<b>Posology</b>	Monotherapy. The recommended treatment regimen is one 2mL injection in the knee. Injection interval (more than 6 months after the last injection) should be carefully considered according to the patient's symptoms.

# Main Products



## 1-2. Resyno-one inj (Cross-linked HA inj. ): Monotherapy

\* Comparison with competitors

<b>3-w injection</b>	Atri Plus Inj	Supartz	Synvisc	Orthovisc	Hyalgan	Artz(5wks)	Hyruan plus
<b>Monotherapy</b>	<b>Resyno-one</b>	<b>Durolane</b>	<b>Synvisc-One</b>	<b>Monovisc</b>	<b>Hyal-One</b>	<b>Gel-One</b>	<b>Synovian</b>
<b>Volume</b>	2mL	3mL	6mL	4mL	4mL	3mL	3mL
<b>Injection site</b>	Knee	Knee	Knee	Knee	Knee	Knee	Knee
<b>FDA approval</b>	-	O	O	-	-	O	-
<b>Launched</b>	-	US/EU	US/EU	EU	Italy	US	Korea
<b>Manufacturer</b>	YooYoung	Q-Med	Genzyme	Anika	Fidia	Seikagaku	LG Chem
<b>Source</b>	Streptococcus strain	Streptococcus strain	Chicken comb	Streptococcus strain	Streptococcus strain	Streptococcus Strain	Streptococcus strain
<b>HA content</b>	40mg	60mg	48mg	Unknown	Unknown	30mg	60mg
<b>Needle Gauge</b>	23G	18~22G	18~20G			18~20G	21G

- Resyno-one is Low Volume & Longer duration of HA compared to other competitors.

# Main Products

## 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

# Main Products

## 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	- Reumathritis, Ulcerative Colitis - Exporting to Japan (CMO)



# Main Products

## 6. Yooridion Inj. : (Pre-filled): Reversal of neuromuscular blockade



PRODUCT NAME	COMPOSITION	REMARK
Yooridion Inj.	Sugammadex Sodium 108.8mg/ml (2ml, 5ml- Prefilled syringe)	- CTD Dossier Available - Reversal of neuromuscular blockade

## 7. Yooritek Tab. : Amyotrophic Lateral Sclerosis(ALS)



PRODUCT NAME	COMPOSITION	REMARK
Yooritek Tab.	Riluzole 50mg	- Amyotrophic Lateral Sclerosis(ALS) - The only generic in Korea

# Main Products

## 8. Ramoset Inj. (Pre-filled): Anti-emetic agents



PRODUCT NAME	COMPOSITION	REMARK
Ramoset Inj.	Ramosetron HCl 0.3mg/2mL	- Anti-emetic agents - Transformed product from Ampoule to PFS

## 9. Yoosmezole DR Cap. :GERD



PRODUCT NAME	COMPOSITION	REMARK
Yoosmezole DR Cap.	Esomeprazole 20/40mg	- GERD - IMD - Launched in Aug 2021

# Main Products

## 10. Yoodapaduo XR Tab. 10/500mg, 10/1000mg : Diabetes



PRODUCT NAME	COMPOSITION	REMARK
Yoodapaduo XR Tab.	Dapagliflozin 10mg + Metformin 1000mg  Dapagliflozin 10mg + Metformin 500mg	- Type 2 Diabetes

## 11. Yoodapa Tab. 10mg : Diabetes



PRODUCT NAME	COMPOSITION	REMARK
Yoodapa Tab.	Dapagliflozin 10mg	- Type 2 Diabetes

# Main Products \_ Product Pipeline



Classification	Active Ingredient	Indication	Stage of Development
FDC	Tramadol+Celecoxib	Osteoarthritis	Phase 3
	Atrovastatin+Fenofibrate	Hyperlipidemia	
Generic	Vonoprazan	GERD(P-CAP)	Under Development
	Edoxaban	NOACs	



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# FACTORY INTRODUCTION





# FACTORY INTRODUCTION

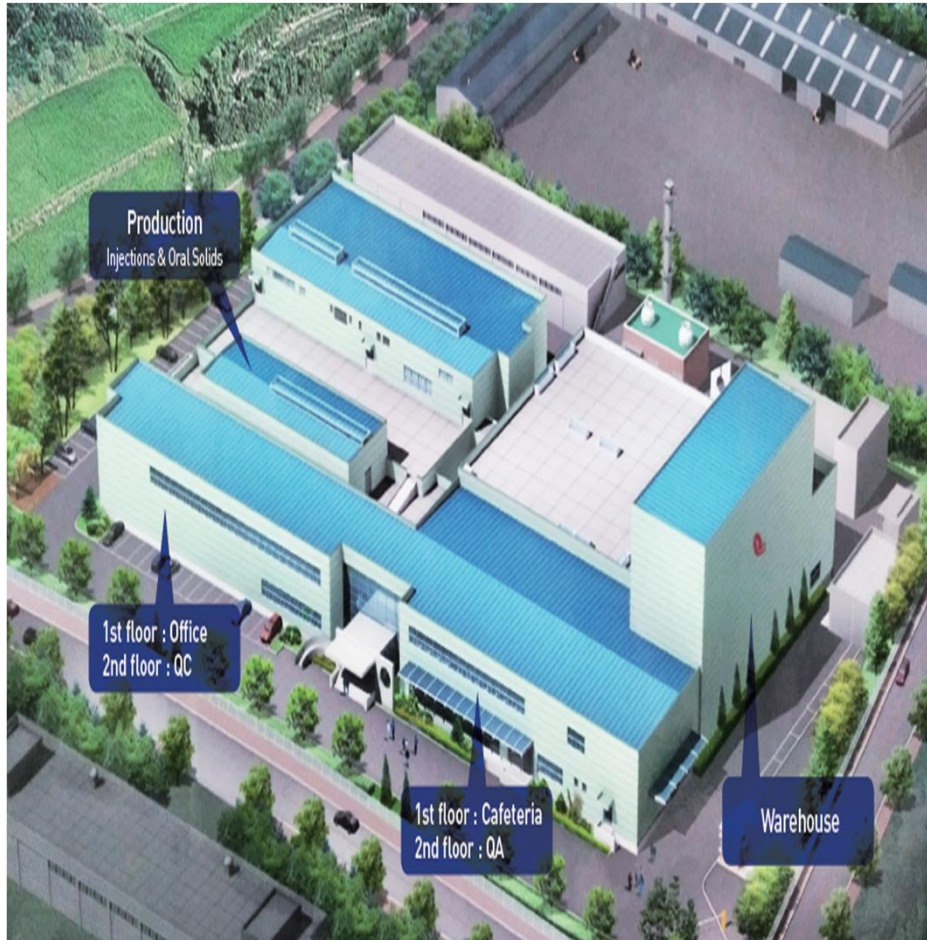
## ■ SITE DESIGN

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



# FACTORY INTRODUCTION

## MANUFACTURING CAPACITY



Classification	Dosage	Capacity (1 Year)
Oral Solid Dosage	Tablet	350,000,000 Tab.
	Capsule	65,000,000 Cap.
Injection	Pre-filled Syringe	15,000,000 PFS.

# FACTORY INTRODUCTION



## OVERSEAS INSPECTION HISTORY

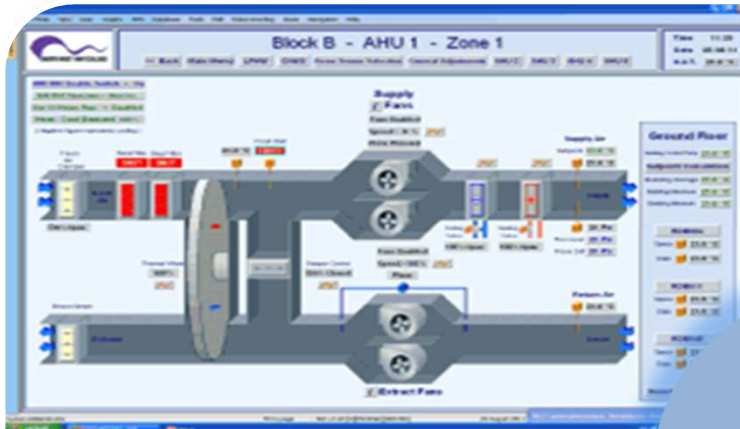
- 2008.05 Accredited as Foreign Drug Manufacturer by Japan
- 2009.09 Japan PMDA Approval of Oral Solid Dosage
- 2012.01 Approved EU CE Certificate
- 2012.04 Japan PMDA Approval of Pre-filled Syringe
- 2015.08 Approved PIC/s GMP [MFDS, Korea]
- 2016.03 Inspection by Japanese Company “Choseido & Nichi-iko”
- 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]
- 2020.02 Re-approved ISO 13485
- 2021.01 Re-approved EU CE Certificate





# FACTORY INTRODUCTION

## ■ FEATURE OF PRODUCTION FACILITIES



**Building Management System (BMS)**

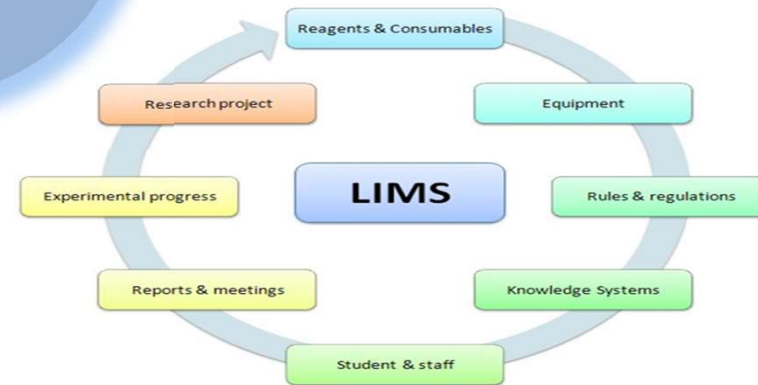


**Warehouse Management System (WMS)**

**Global Standard Plant**



**Inj./OSD Manufacturing Execution System (MES)**



**Laboratory Information Management System (LIMS)**

# FACTORY INTRODUCTION

## ■ MANUFACTURING FACILITY



Pre-filled Syringe Line



Tableting Line



Film Coating System



Automatic Ampoule filling Line



Automatic Packaging Line



Automatic warehouse

**Be With YooYoung!**