



Yung Zip Chemical Company Profiles



Outline

Our Group

*Company
Introduction*

*Products &
Services*

*Strength &
Accreditation*



Our Group



Yung Shin Group

Introduction

- Founded in 1952 by Dr. Lee
- Numerous FDA approved products
- Obtained various certified patents both domestic and international.
- Human drugs, veterinary drugs, cosmeceutical products, Health supplements, Raw Pharmaceutical materials, Specialized chemicals, diagnostic agents, in-house health care products.



Yung Shin Group

Yung Shin Social Welfare Foundation



- National volley ball tournaments



- Built Yung Shin Recreational Park



- Tian-de Lee Bio-medical Award



- YSP Song-bo-yuan Nursing Home



Yung Shin Group- Taiwan



Pharmaceutical Manufacture

1965 YUNG SHIN PHARM. IND. CO., LTD.



API Manufacture

1978 YUNG ZIP CHEMICAL IND. CO., LTD.

TAIWAN



Yung Shin Group- Global



1990

1994

1990

2013

CARLSBAD TECHNOLOGY, INC. YUNG SHIN PHARM. IND. (KS) CO., LTD.

Y.S.P. INDUSTRIES (M) SDN. BHD.

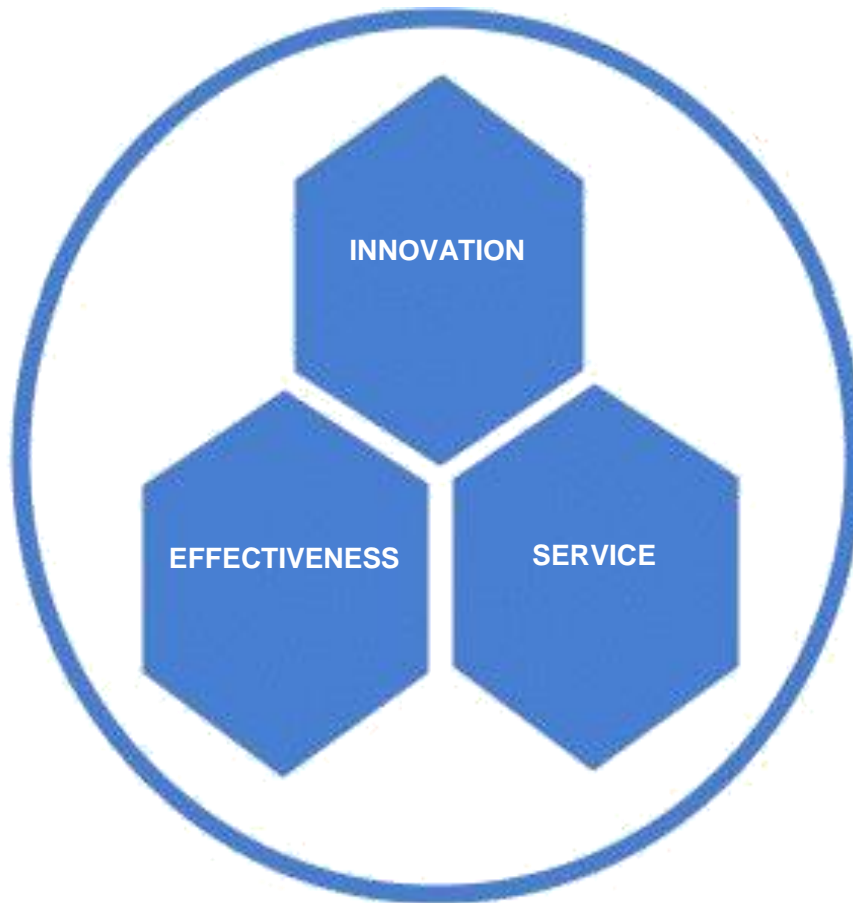
YUNGSHIN CHEMIX INC.



Company Introduction



Operation principles



**“ Providing the best pharmaceutical products,
Improving health of human beings. ”**

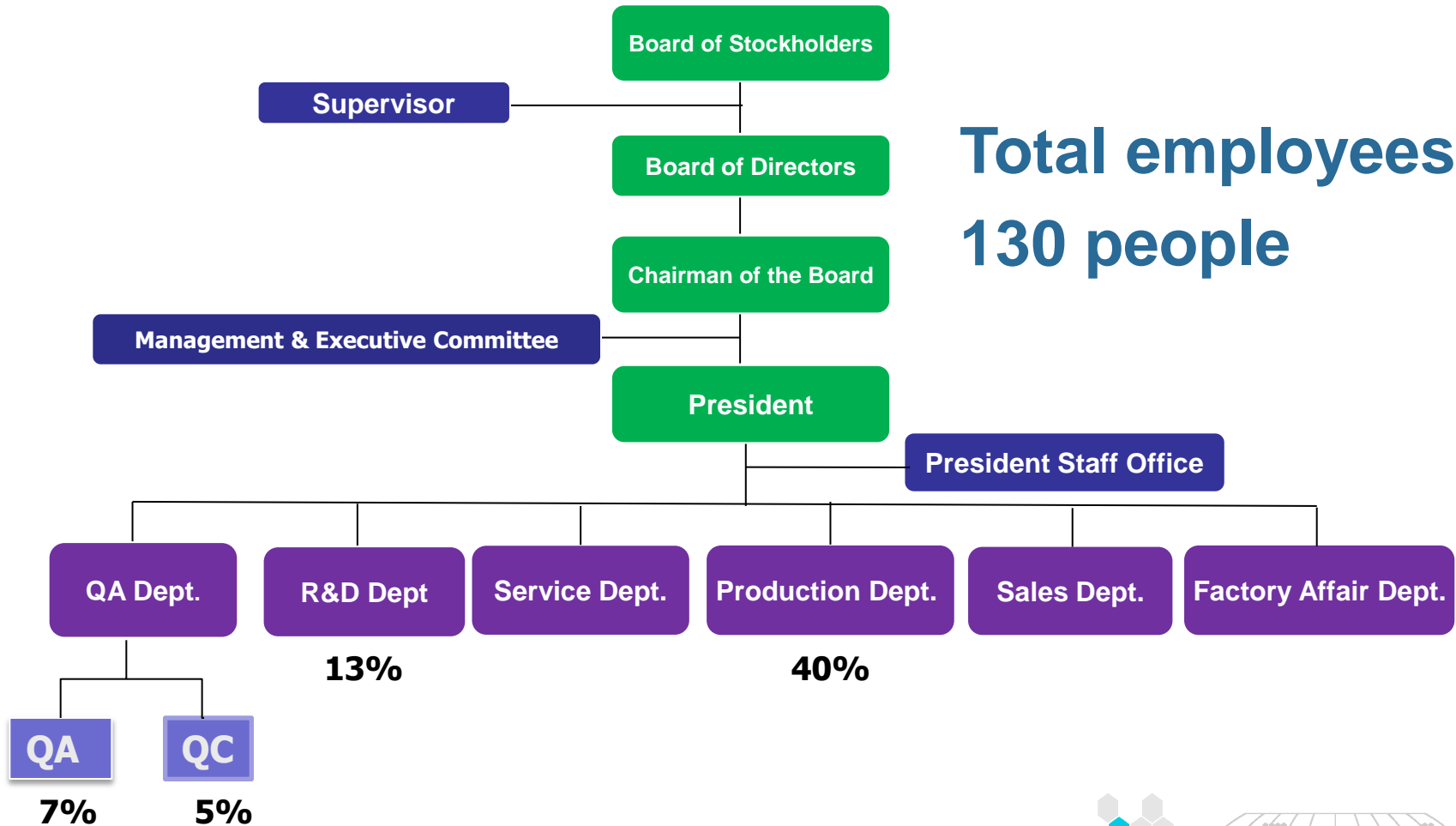


Background

- Established in June of 1978 (experience over 35 years) for manufacturing and supplying the active pharmaceutical ingredients (APIs) to Yung Shin Pharma.
- In 2001 listed in the OTC market and approved by US FDA.
- Capital USD\$14,000,000
- Supported over 6% annual sales on R&D
- SAP system in 2010



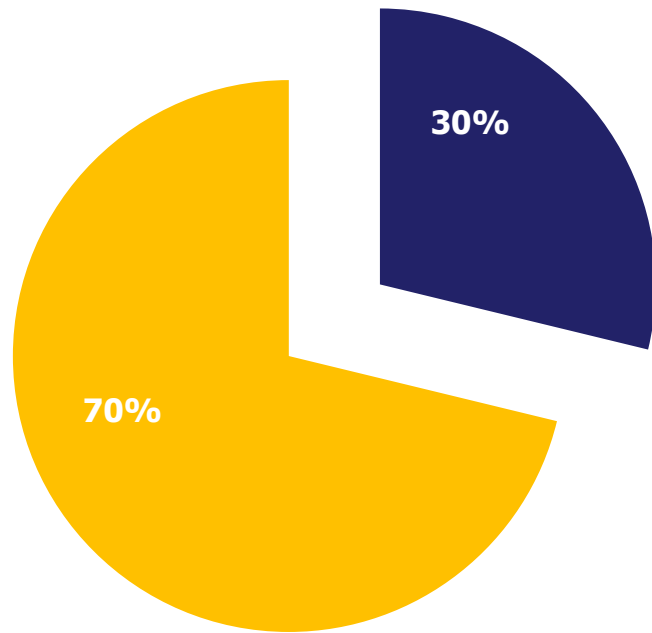
Organization



Business Concept

- Sales volume distributed by Domestic market and Export market.

2016 Sales volume



■ Domestic
■ Export

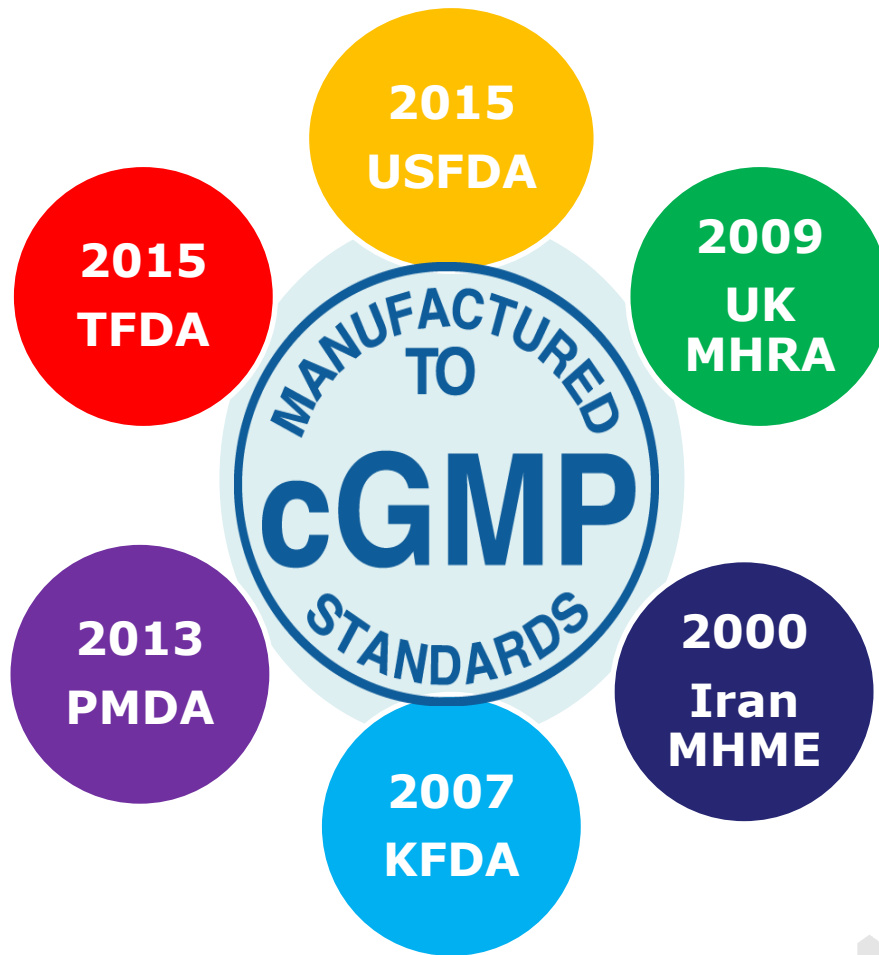
**Exported to
32 countries**



Location



Inspection by International Authorities



Manufacturing plant (7,730 m²)



Warehouse (2,110 m²)



Capabilities



Reactor :

20L ~ 12,000L

Temperature :

-60°C ~ 160°C



Products & Services



- **APIs**
- **Excipients**
- **Contract manufacturing**
- **New development**



APIs

**Indication: Osteoarthritis, Dysmenorrhea ,
mild to moderate pain**

Product	DMF	Pharmacopoeia
Diclofenac Epolamine	USDMF	In-house
Diclofenac Potassium	TDMF/USDMF/	USP/EP/BP
Diclofenac Sodium	TDMF/USDMF/JPD MF	USP/EP/BP/JP
Mefenamic Acid	TDMF/USDMF/CEP	USP/EP/BP/JP



APIs

Indication: Herpes

Product	DMF	Pharmacopoeia
Acyclovir	TDMF/USDMF/JP DMF	USP/EP/BP/JP
Famciclovir	Under Process	USP
Valacyclovir Hydrochloride	JPDMF	USP/EP/BP



APIs

Indication: Tinea, Vaginal yeast, candidiasis

Product	DMF	Pharmacopoeia
Econazole Nitrate	TDMF/USDMF	USP/EP/BP
Miconazole Base	USDMF	USP/EP/BP
Miconazole Nitrate	TDMF/USDMF/JP DMF	USP/EP/BP/JP



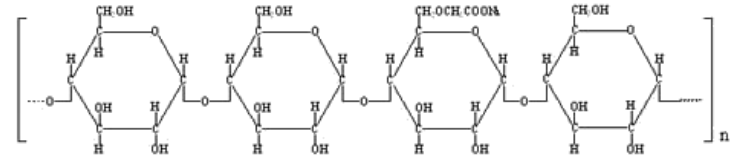
APIs

Indication: Hypertension

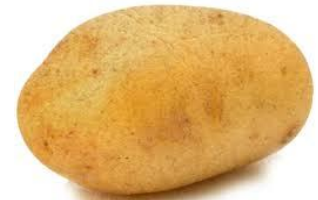
Product	DMF	Pharmacopoeia
Clonidine Hydrochloride	TDMF/USDMF	USP/EP/BP/JP
Metoprolol Succinate	USDMF	USP/EP/BP



Excipients

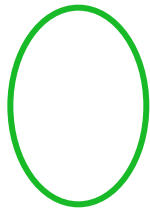


- **Sodium Starch Glycolate (DST[®])**
- Using potato starch as starting material (from Europe)
- It is used as tablet and capsule disintegrant.
- Faster disintegrants
- Non-GMO
- Appearance: White powder, very few black spots
- Good Fluidity
- Strongly swelling superdisintegrants and Efficient
- Registration: US DMF No. 7247
- Specification: USP/EP/BP/JP/CP



Sodium Starch Glycolate DST®

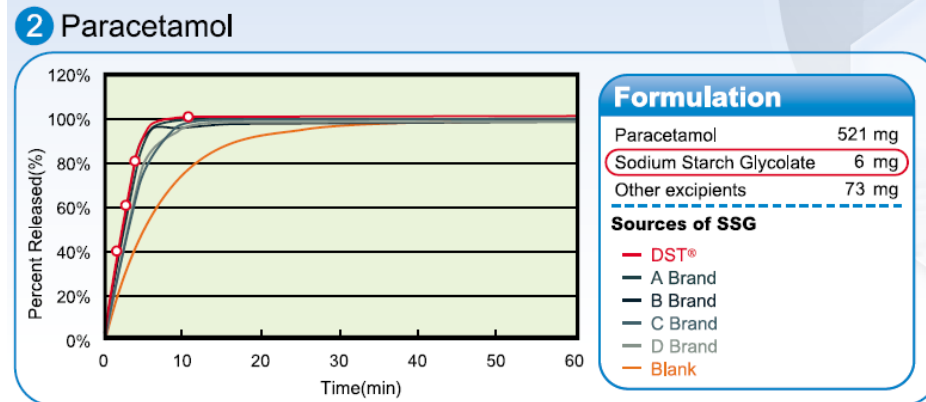
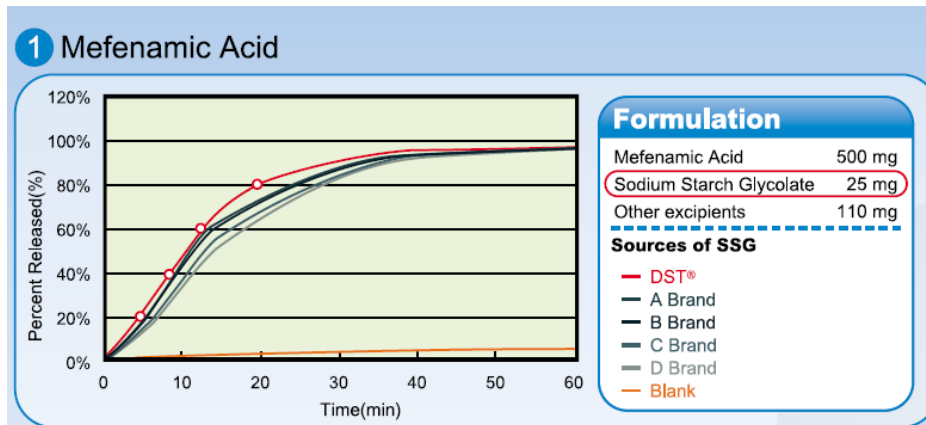
*Effect of Different Sources of Starch on Disintegration



Sodium Starch Glycolate DST®

Comparison of Dissolution Profile

- *Enhancing dissolution rate by adding DST®
- *Disintegration ability of DST® is better than other brands.



Sodium Starch Glycolate DST®

The European Pharmacopoeia and USP/NF differentiate of Types A and B as following.

Type	A	B
Applications	Conventional disintegrant for solid oral dosage forms.	Designed to resist acidic pH and maintain stability in strongly acidic drug formulations.
pH	Between 5.5 to 7.5	Between 3.0 to 5.0
Assay	2.8%~4.2% of sodium	2.0%~3.4% of sodium



Contract Manufacturing

✱ API

✱ Natural extraction

Production Environment	Equipment	Capability
General production area	Reactor: 17 PCS Capacity: 2,000L-12,000L Material: SUS 316 ; Glasslined	Right for alkaline and acid reaction
Environmental control area	Centrifuge (48"): 3 PCS Dryer: 5 PCS Drying capacity: 200L-4,000L Material: SUS 316 ; SUS 304	Well-controlled Pressure Stabilized Temperature



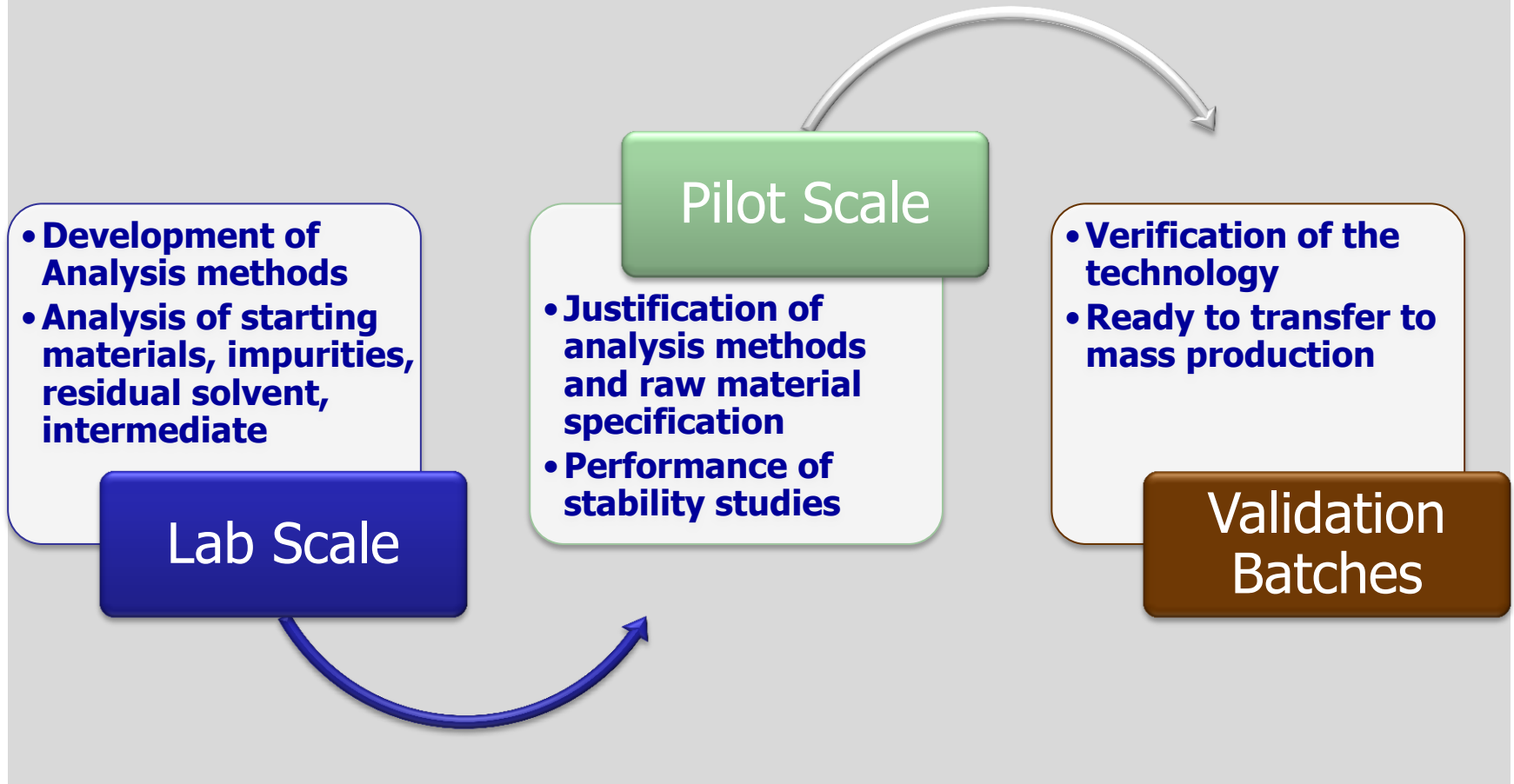
Hydrogenation

Drying Equipment



New Development

The pathway to new APIs



New Development

Validation

Product	Indication	Batch size	Patent
Deferasirox	Chronic iron overload	18kg	2019 (US) 2020 (TW) 2021 (JP)
Olanzapine	Chronic iron Thalassenia	10kg	Expired

Updated: June 16th, 2017



New Development

Lab Scale

Product	Indication	Patent
Mirabegron	Beta3-adrenoceptor	2023.11
Dabigatran	Antithrombotic Agents	2025.09
Glimperide	Diabetes	
Thiamine Disulfide	VIT-B1	
Zopidem Tartrate	Insomnia	

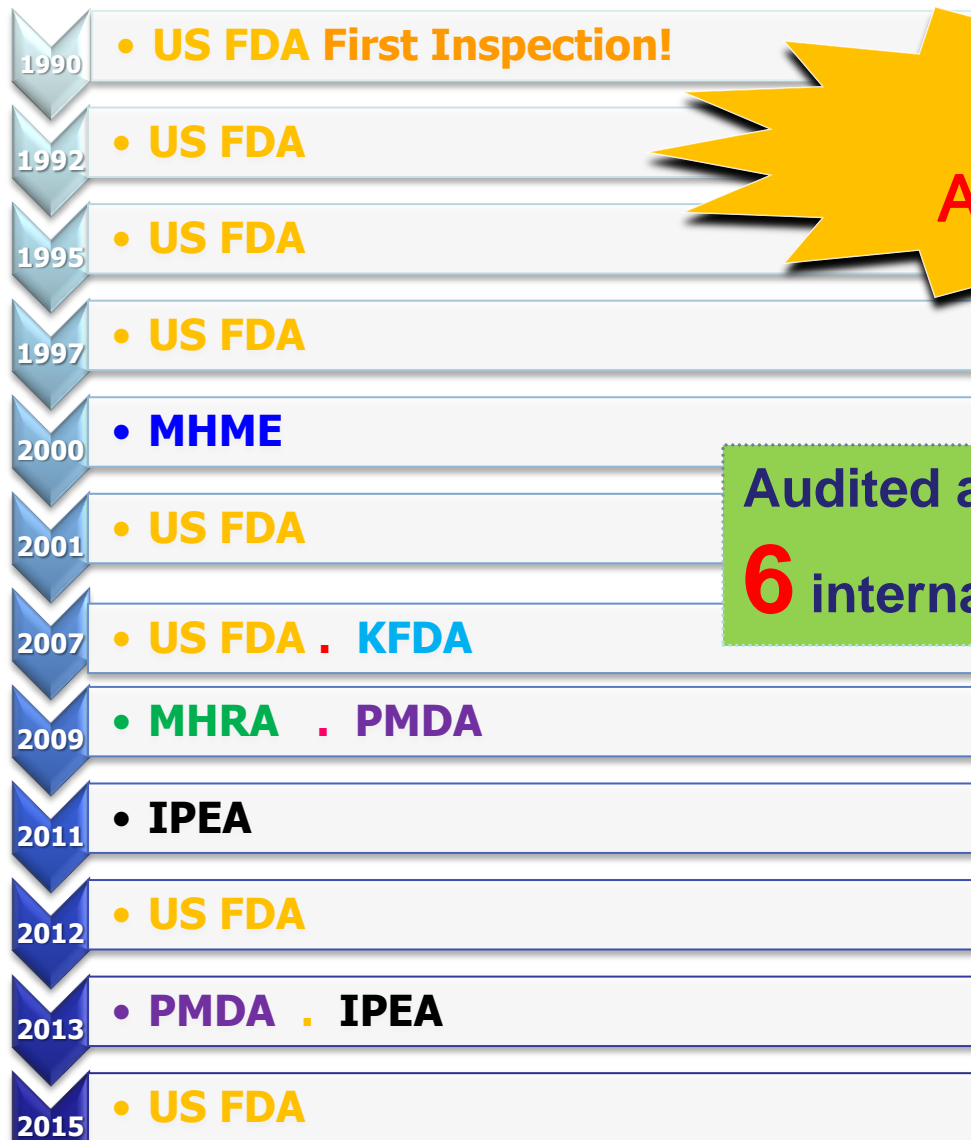
Updated: June 16th, 2017



Strength & Accreditation



History of audits

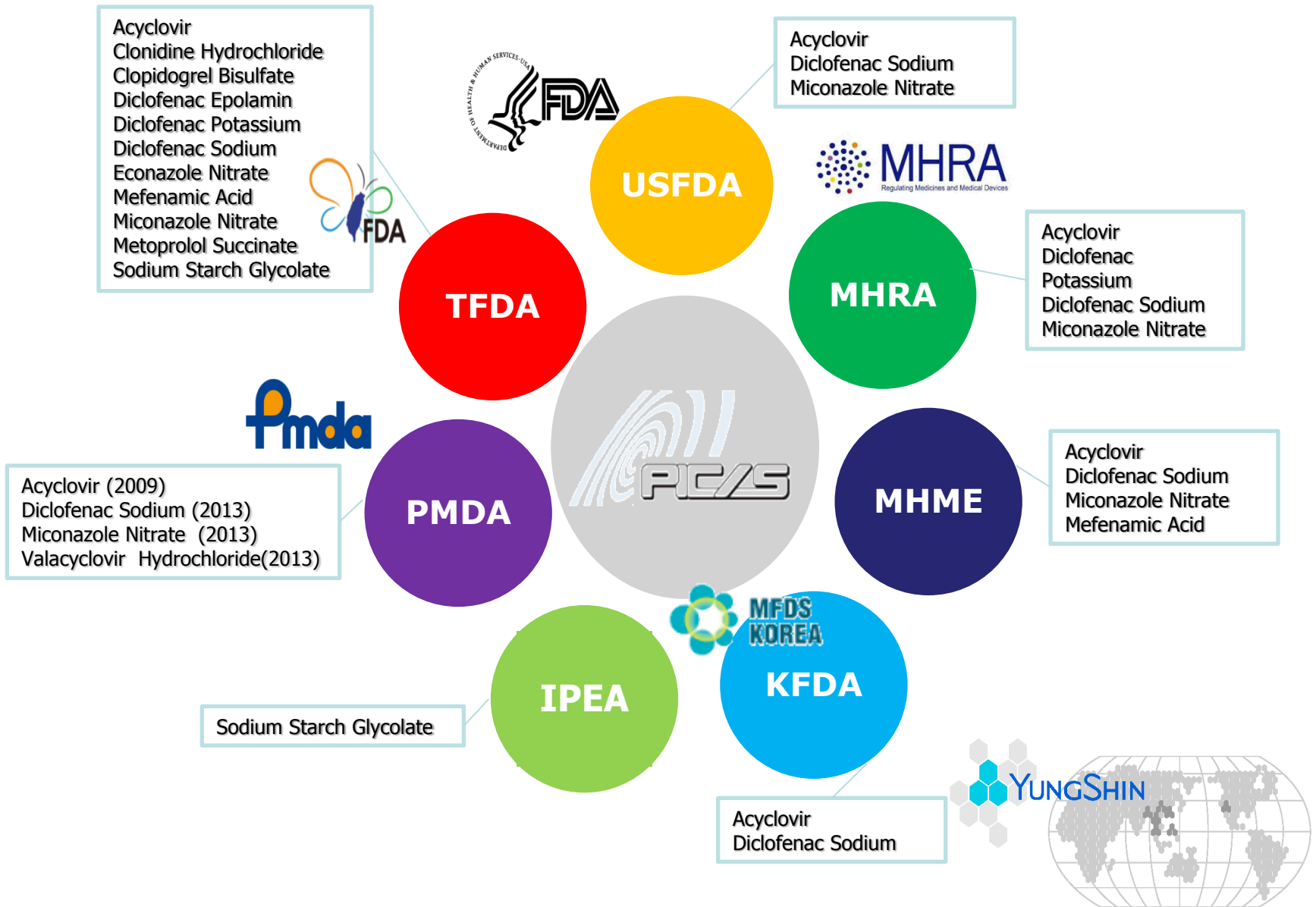


**ALL
ACCEPTABLE**

Audited and Approved by
6 international authorities!



Approved APIs



DMF availability

Have registered 12 APIs DMF in 20 countries

America

Canada
United States

Asia

Japan
Singapore
South Korea
Taiwan

Oceania

Australia
New Zealand

Europe

Belgium
France
Greece
Iceland
Ireland
Italy
Netherlands
Norway
Spain
Switzerland
The Republic of Cyprus
United Kingdom



Certificates

IPEA

KOSHER

HALAL

**International
Pharmaceutical
Excipients Auditing, Inc.**



FINAL AUDIT REPORT ON THE MANUFACTURE OF:

Sodium Starch Glycolate
Yung Zip Chemical Industrial Co Ltd
Taichung, Taiwan
Nov. 20, 2011



101 W. 34th Street, N.Y. 10018
(646) 582-4444
Fax: (646) 255-0796
Rabbi Yossi Lipshitz
President
Rabbi Moshe Sosen
Administrative Headquarter
Barry R. Eisk
Chairman

November 23, 2014

LETTER OF CERTIFICATION

YUNG ZIP CHEMICAL INDUSTRIAL CO., LTD.
TAIWAN

THIS IS TO CERTIFY THAT
SODIUM STARCH GLYCOLATE (DST®)

produced by
YUNG ZIP CHEMICAL INDUSTRIAL CO. LTD., TAIWAN
Taichung City, Taiwan

is inspected and approved by **NATIONAL KASHRUTH**
and is accordingly endorsed **KOSHER / PAREVE**.

This endorsement is valid through **JANUARY 15, 2018**,
and is subject to renewal at that time.

Sincerely yours,
NATIONAL KASHRUTH

Rabbi Yossi Lipshitz
President

BY: Mr.



MHRA

USFDA

TFDA

PMDA

MHRA

Safeguarding public health
Certificate No UK AP1 11283 Imp GMP 12352020-002

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

PART 1

Issued following an inspection in accordance with Art. 11(2) of Directive 2003/93/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer **YUNG ZIP CHEMICAL IND. COMPANY LIMITED**
88 YU SHIH ROAD,
YOUTH INDUSTRIAL DISTRICT
TAICHUNG
TAIWAN

Has been inspected in accordance with Art. 11(3) of Directive 2003/93/EC (concerning the following national legislation: Regulation (EC) of the European Parliament and of the Council concerning the Mutual Recognition of Medicines for Human Use (Manufacturing, Wholesale Distribution and Medication Amendments) (Regulations (EC) 2003/70 and Section 152) of the Medicines Act 1968 as amended).

Is an active substance manufacturer that has been inspected in accordance with Art. 11(3) of Directive 2003/93/EC (concerning the following national legislation: The Medicines for Human Use (Manufacturing, Wholesale Distribution and Medication Amendments) Regulations 2005 (SI 2005/285)).

From the knowledge gained during inspection of this manufacturer, the label of which was considered on 2003/93/EC, it is concluded that it complies with the principle of GMP for active substances.

The certificate reflects the state of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status of more than three years have elapsed since the date of last inspection, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.

2014

Medicines and Healthcare products Regulatory Agency
Medicine Division, Victoria Street, London EC1A 3FB
T: 020 7276 6000 F: 020 7276 6001 www.mhra.gov.uk

An official agency of the United Kingdom

DEPARTMENT OF HEALTH & HUMAN SERVICES

Center for Drug Evaluation and Research
Center for Food Safety and Inspection Administration

Division of Quality Assurance Administration
1401 Rockville Pike
Rockville, MD 20852
Telephone: 301-795-9000
www.fda.gov

March 23, 2011

Ms. Jen-Yen Hsiao
President
Yung Zip Chemical Industrial Company, Ltd.
88 Yu Shih Road
Youth Industrial District
Taichung, Taiwan, 40701

Reference: PFI 30032818
Reference Inspection Date: 10 January 12, 16, 2011
Establishment Location: Taichung, Taiwan

Dear Ms. Hsiao:

We are receiving a copy of the Establishment Inspection Report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced dates and dates. When the Agency concludes that an inspection is "satisfactory" under 21 CFR 312.63(a)(2)(1), it will release a copy of the EIR to the inspecting establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

This Agency routinely makes available regulatory process and activities, except information that is confidential. Regarding the EIR, it is in part of the public effort. The copy being provided to you, comprises the material in public of the report, if any, which information made to the Agency in accordance with the Freedom of Information Act (FOIA), 5 U.S.C. 552, CFR Part 201. This, however, does not preclude you from requesting additional information under FOIA.

If there is any question about the referenced information, feel free to contact one of the above address or contact:

Secretary

Medicine Administration
National Association of Drug

Enclosure: 2/2

衛生福利部
MINISTRY OF HEALTH WELFARE

CERTIFICATE OF GOOD MANUFACTURING PRACTICE

Issue Date: April 8, 2014

Issued following an inspection in accordance with Article 17 of the Pharmaceutical Affairs Law and under the supervision of the Republic of China (Taiwan).

The competent authority of the Republic of China confirms the following:

The manufacturer **Yung Zip Chemical Ind. Co., Ltd.**
The address: 88, Yu Shih Road, Youth Industrial District, Taichung, Taiwan 40701, R.O.C.
Manufacture's license number: 42812017

Is the manufacturer of medicine products that has been inspected with the following Active Pharmaceutical Ingredients: **Amoxicillin, Cloxacillin, HCL, Diclofenac, Erythromycin, Diltiazem, Propafenone, Dabigatran, Sildenafil, Economic Nicotine, Imipenem, Acid, Aspirin, Saccharin, Hydrochloric Acid, Sodium Starch Glycolate.**

From the knowledge gained during inspection performed on November 16/20, 2011, it is concluded that the manufacturer complies with the Pharmaceutical Inspection Convention/Cooperation Scheme Guide on Good Manufacturing Practice for medicine products (PIC/S/GMP/PART I)-GMP at WHO/ICH Q7C1.

This certificate is valid until September 23, 2018.
This certificate may be renewed at a given or extended.

Signed by:

Chiang Yu-Mei
TSMC/ITC
Director-General
Food and Drug Administration
Medicine Administration

Inspector by Inspection Report:
Keen Sheng Chung, etc.
Ministry of Health and Welfare
Republic of China (Taiwan)

2014

衛生福利部
MINISTRY OF HEALTH WELFARE

報告年月日: 平成25年6月7日

GMP 調査結果報告書

(8) 医薬品製造業種別適合性検査承認 認

調査実施日付: 品質管理課 調査部門長 野村 貴典
調査実施者: 品質管理課 (調剤1) 野村 貴典

1. 参照番号: 17769, 18075

2. 一般的事項

(1) 検査実施日
平成25年 6月24日 9:00~17:00
平成25年 6月25日 9:00~17:00
平成25年 6月26日 9:00~17:00
平成25年 6月27日 9:00~17:00
平成25年 6月28日 9:00~17:00

(2) 調査対象製造業種別適合性検査 (GMP/ICH-Q7C1, 確認)

Yung Zip Chemical Ind. Co., Ltd.
88, You Shih Road, Youth Industrial District, Taichung, Taiwan 40701, R.O.C.

(4) 調査対象製造業種別適合性検査
Yung Zip Chemical Ind. Co., Ltd.
88, You Shih Road, Youth Industrial District, Taichung, Taiwan 40701, R.O.C.

(5) 調査対象製造業種別適合性検査
Yung Zip Chemical Ind. Co., Ltd.
88, You Shih Road, Youth Industrial District, Taichung, Taiwan 40701, R.O.C.

(6) 調査対象製造業種別適合性検査報告書【調剤】の発行、発行日及び年月日
発行日付: 平成25年 6月 7日
認定番号: AD1060040 認定年月日: 平成25年2月 18日

(7) 調査対象製造業種別適合性検査 (調剤) 適合性検査 (GMP/ICH-Q7C1)
製剤製造業種別適合性検査 (調剤) 適合性検査 (GMP/ICH-Q7C1) 調査、GMP/ICH-Q7C1、調剤、製剤工工程、輸入、品質検査、品質管理、品質保証、品質管理

3/14



YOU CAN TRUST FOREVER

Thank You for Your Attention!

