

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.



STRIVE TO BE A GLOBAL FULLY INTEGRATED HEALTHCARE SOLUTION PROVIDER



PART 1

HUMANWELL HEALTHCARE GROUP

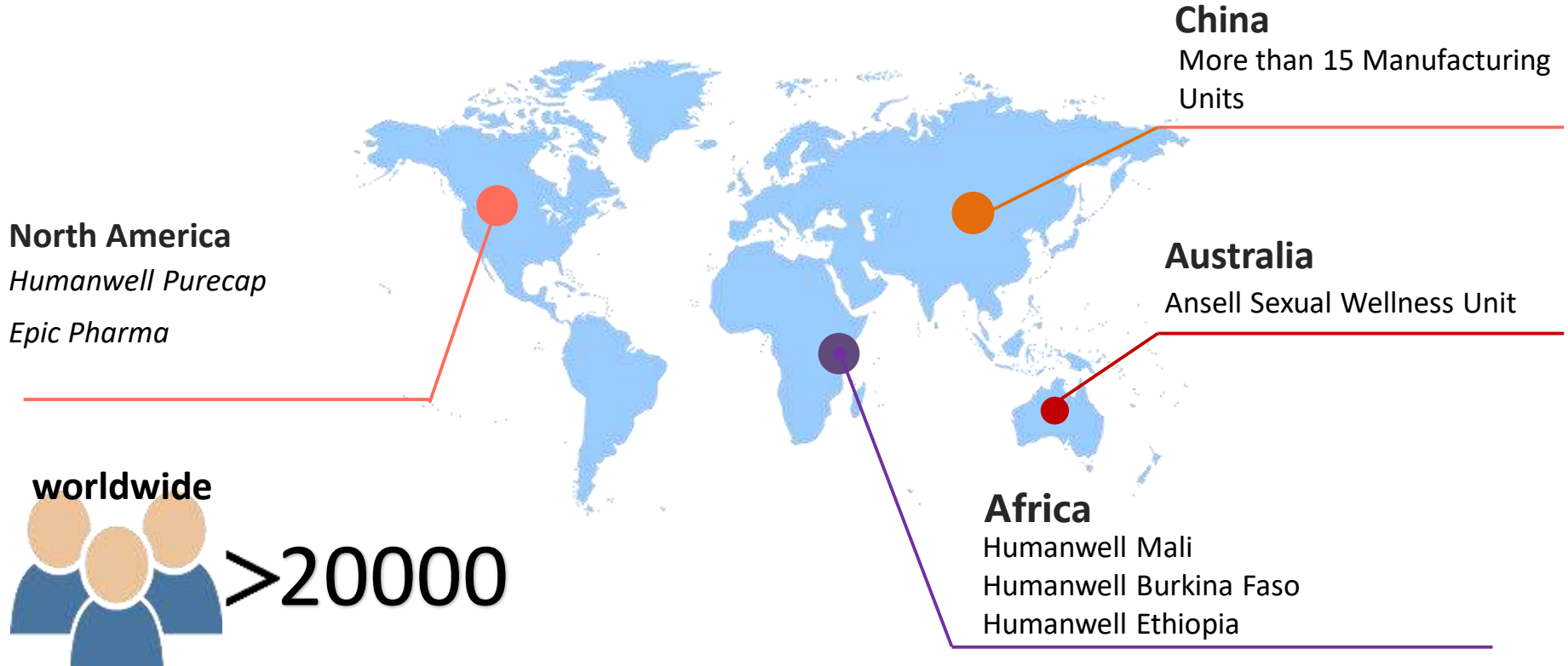
- ❖ Company Profile
- ❖ Core Business
- ❖ Global Presence

Company Profile: Humanwell Healthcare Group

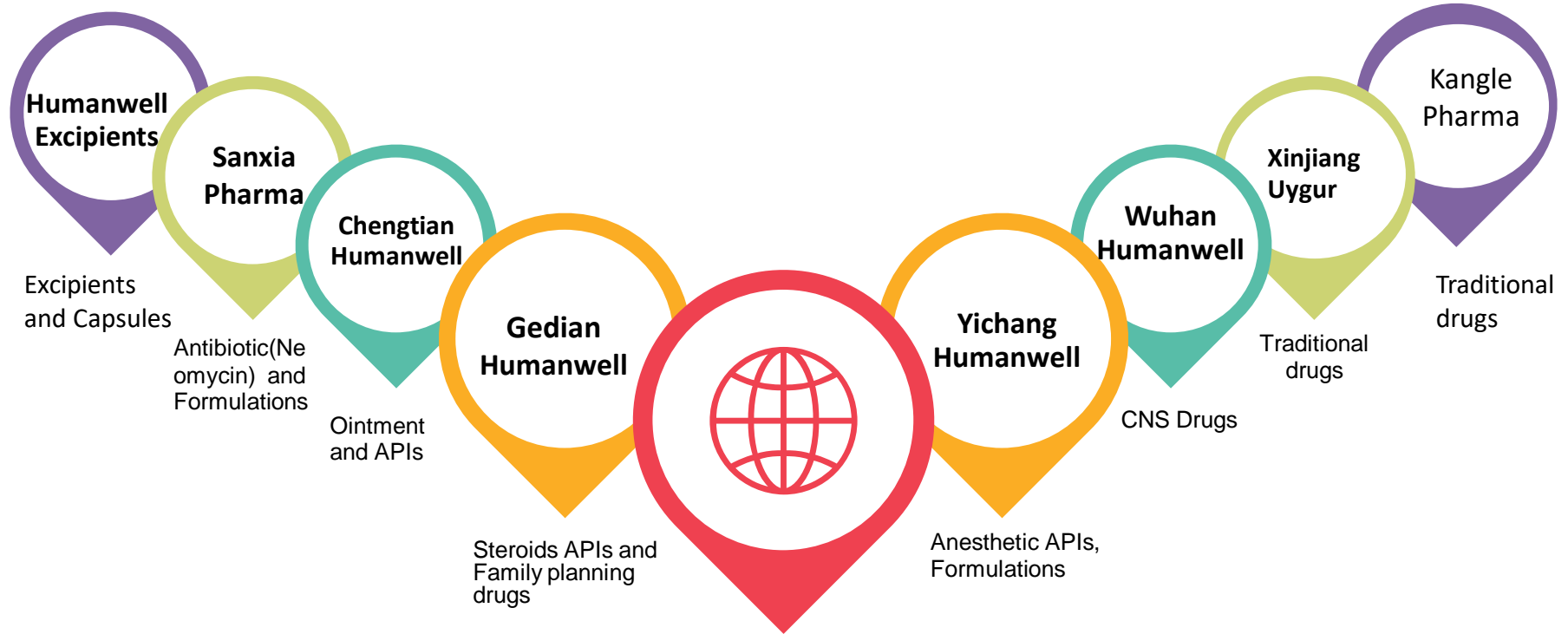


- ❖ Founded in 1993 in Wuhan, China
- ❖ Listed in Shanghai Stock Exchange since 1997
- ❖ Top 13 Pharmaceutical Enterprise in China.

Global Presence



Core Manufacturers in China



PART 2

HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO., LTD

- ❖ Company Profile
- ❖ Facility Introduction
- ❖ Quality Introduction
- ❖ Products and Marketing

Company Profile



2000

Gedian was founded

1993

Group was founded

Hubei Gedian Humanwell is a fruitful pharmaceutical company engaged in R&D, manufacturing and marketing of steroidal APIs and intermediates, and reproductive health medicines.



> 800(R&D 100)

\$²⁰²²

=

\$150 Million

Manufacturing sites



Gedian Site, E-Zhou
API site

Accreditation: CFDA, USFDA,
EDQM, TGA, PMDA



Zhuxi Site, Shiyang
Intermediate and API site

Accreditation: CFDA

2000

2013

2014

2015



Jiulong Site, Wuhan,
FDF site

Accreditation: CFDA, WHO (in
progress)



Gedian Excipient, E-Zhou
Excipient site

Accreditation: CFDA, Excipact™
(in progress)

API Manufacturing Facilities & Equipment



❖ Gedian site:

- 6 segregated steroid API production lines and 2 nonsteroidal API production lines
- Dedicated production lines
- 108 reactors and 124000L reactor capacity.
- The biggest production base of progesterone and Finasteride in China.



❖ Zhuxi Site:

- 60 reactors and 140000L reactor capacity.
- The biggest manufacturing base of 16-DPA and DHEA in China.

API Manufacturing Facilities & equipment



- ❖ Newly manufacturing facilities can accommodate almost all types of reactions.
- ❖ Advanced QC laboratory can meet the requirements of the analysis of all kinds of products.
- ❖ Capability of sewage treatment : 800 MT/day.

Main product portfolio

Product/ Specification	Indication	DMF filing	Certificate	Production capacity	Note
Progesterone (CP, IP, USP, EP, BP, JP)	Natural progestin	US EU JP Brazil India	EU-GMP CEP	200 T	Flagship product Top 1 API exportation (90%)
Finasteride (CP, IP, USP, EP, BP, JP)	Anti-BPH	US EU JP Brazil India	CEP	10 T	Flagship product Occupy 98% domestic market share
Dutasteride (USP ,EP)	Anti-BPH	CP US EU	CEP	1T	
Abiraterone Acetate (USP)	Anti-Prostate cancer	CP US EU	DMF	50T	
Cyproterone acetate (USP, EP, BP)	Contraception	CP EU Brazil Canada	CEP TGA	6 T	
Drospirenone (CP,USP,EP)	Contraception	CP US EU (in process)	CEP in process	10T	
Budesonide (CP, IP, USP, EP)	Anti-inflammatory	CP US EU India Canada	CEP	6 T	
Testosterone (USP, EP)	Anti-age	CP US EU	CEP	20T	



Main product portfolio

Product/ Specification	Indication	DMF filing	Certificate	Production capacity	Note
Levonorgestrel (CP, IP, USP, EP)	Contraception	CP US EU	CEP	6 T	
Medroxyprogesterone acetate (CP,USP,EP,IP)	Progestin	CP , US EU(in process)		20T	
Methylprednisolone /Hemisuccinate (CP, US, EU)	Anti- inflammatory	CP , US EU(in process)	CEP in process	20T	
Fluticasone Propionate (USP,EP)	Anti- inflammatory	CP , US EU(in process)		3T	
Eplerenone (USP, EP)	Cardiovascular	US EU	CEP in process	8 T	
Oxcarbazepine (CP, IP, USP, EP)	Anti-epileptic	CP US EU Brazil India	CEP	300 T	
Eslicarbazepine acetate (In-house)	Anti-epileptic	In process		50T	
Valganciclovir (CP,EP,USP)	Antiviral	CP US EU		10T	
Nintedanib esilate (USP)	IPF	CP US EU		8T	

Historical Regulatory Inspection

No.	Official authorities	Specifying substances	Reference	Inspection time
1	USFDA	Finasteride Progesterone	GMP compliance	10/2013
2	USFDA	Progesterone Finasteride	GMP compliance	05/2016
3	EDQM	Progesterone	GMP compliance	05/2016
4	USFDA	Progesterone Finasteride Budesonide	GMP compliance	06/2019
5	PMDA	Finasteride	GMP compliance	10/2019
6	TGA	Cyproterone acetate	GMP compliance	12/2020
7	NMPA	Progesterone, Finasteride Methylprednisolone sodium succinate Desonide	GMP compliance	02/2023
8	MFDS	Oxcarbazepine Dutasteride	GMP compliance	03/2023

Certificates



人福医药
HUMANWELL HEALTHCARE

**中华人民共和国
药品GMP证书**

CERTIFICATE OF GOOD MANUFACTURING PRACTICES FOR PHARMACEUTICAL PRODUCTS
PEOPLE'S REPUBLIC OF CHINA

证书编号: HB20170306
Certificate No.

企业名称: 湖北葛兰人福药业有限责任公司
Manufacturer: Hubei Godan Humanwell Pharmaceutical Co., Ltd.

地址: 湖北省鄂州市葛州经济技术开发区
Address: Godan Economic Development District, Ezhou City, Hubei Province

认证范围: 原料药(布洛芬、非布佐芬、塞来昔布、吡罗昔康、吡罗昔康、吡罗昔康、吡罗昔康) ***
Scope of Inspection: Bulk Drug (Ibuprofen, Fexofenadine, Celecoxib, Piroxicam, Piroxicam, Piroxicam, Piroxicam) ***

经审查, 符合中华人民共和国《药品生产质量管理规范》要求。
特发此证。
This is to certify that the above-mentioned manufacturer complies with the requirements of Chinese Good Manufacturing Practices for Pharmaceutical Products.

有效期至: 2022 年 07 月 23 日
This certificate remains valid until 23 / 07 / 2022

发证机关: 湖北省药品监督管理局
Issued By: HUBEI PROVINCE FOOD AND DRUG ADMINISTRATION

Date for issuing: 24 / 07 / 2017 2017 年 07 月 24 日

国家食品药品监督管理总局制
CHINA FOOD AND DRUG ADMINISTRATION

GMP

湖北省食品药品监督管理局
药品再注册批件

受理编号: 201706001
受理日期: 20170606 批件号: 201706001

药品名称	药品通用名: 布洛芬 汉语拼音: 布洛芬片剂, Piroxicam 汉语拼音: Piroxicam		
剂型	原料药		
规格	—	药品分类	化学药品
生产批准文号	国药准字 H20100113	药品注册日期	2010 年 7 月
药品生产企业	名称: 湖北葛兰人福药业有限责任公司 生产地址: 湖北省鄂州市葛州经济技术开发区		
申报日期	受理日期: 本品符合《药品注册管理办法》的有关规定, 依法予以受理。		
药品说明书	说明书编号: 201706001	药品说明书生效日期	2017-12-29
备注			
申请	湖北葛兰人福药业有限责任公司		
受理	湖北省食品药品监督管理局		
药品	鄂州市葛州经济技术开发区		
备注			

Registration license

中华人民共和国
湖北省药品监督管理局
出口欧盟原料药证明文件

PEOPLE'S REPUBLIC OF CHINA
HUBEI MEDICAL PRODUCTS ADMINISTRATION
Written confirmation for active substances exported to EU

Confirmation no. (given by the issuing regulatory authority): HB2016002
证书文件编号: HB2016002

1. Name and address of site (including building number, where applicable):
工厂名称与地址(包括楼号如适用)
Hubei Godan Humanwell Pharmaceutical Co., Ltd.
湖北葛兰人福药业有限责任公司
Godan Economic Development District, Ezhou City, Hubei Province, 436070
湖北省鄂州市葛州经济技术开发区, 鄂州, 436070
Manufacturer's license number(s): 鄂 20160196
(药品生产许可证) 编号: 鄂 20160196

REGARDING THE MANUFACTURING PLANT UNDER (1) OF THE FOLLOWING ACTIVE SUBSTANCES EXPORTED TO THE EU FOR MEDICINAL PRODUCTS FOR HUMAN USE
下列 1) 所列生产企业生产的下列用于出口欧盟的人用原料药

Active substance(s) 原料药名称(国际通用名)	Activity(ies) 加工方法	Chinese drug approval number 中国药品批准文号
布洛芬 Ibuprofen	化学合成 Chemical Synthesis	国药准字 H20101795
非布佐芬 Fexofenadine	化学合成 Chemical Synthesis	国药准字 H20041188
左旋布洛芬 Levoibuprofen	化学合成 Chemical Synthesis	国药准字 H20101226
黄体酮 Progesterone	化学合成 Chemical Synthesis	国药准字 H20096109
奥沙唑嗪 Oxcarbazepine	化学合成 Chemical Synthesis	国药准字 H20048191

注: 出口欧盟原料药应标注“天”。
Note: "Good" in case where there is for export only active substances.

WC

Certificates



Certification of Substances Division

Certificate of suitability
No. R0-CEP 2013-328-Rev 00

1 Name of the substance:
2 **PROGESTERONE**

3 Name of trade:
4 **HUBEI HUMANWELL PHARMACEUTICAL CO., LTD.**

5 Gaoxin Economic Development District
6 China-CEP OTC 2-Sub, Hubei Province

7 City of production:
8 **SEE ANNEX I**

9 Also indication of the registration (approval) of the manufacturing method and subsequent
10 provisions (including perfection) for the substance on the date of production (date) in annex, we
11 certify that the quality of the substance is suitably controlled by the current version of the
12 monograph **PROGESTERONE** in all of the European Pharmacopoeia, current edition (including
13 supplements, only if it is supplemented by the (s)(x) monographs followed, based on the statistical
14 provisions, given in annex.

15 - Test for residual solvents by gas chromatography (Annex 2)
16 Ethanol: not more than 2000 ppm
17 Methanol: not more than 2000 ppm

18 The substance is packed in a double subpackage bag placed in a few doses.

19 The labels of the certificate are enclosed the absence of use of material of human or animal
20 origin in the manufacture of the substance.

21 The submitted dossier must be updated after any significant change that may affect the quality,
22 safety or efficacy of the substance.

23 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice
24 and in accordance with the dossier submitted.

25 Parties to comply with these provisions will render this certificate void.

Address: 1-666 Easton St. Bldg.
1-1400 Easton Street
Tel: (+86) 136-4-11-11-1111 (11) 11-1111-1111 (11) 11-1111-1111
Email: info@humanwell.com

CEP

Certification of Substances Division

ATTESTATION OF INSPECTION

Inspected site:	Hubei Hubei Humanwell Pharmaceutical Co., Ltd. No. 25 Jiaxin Road Gaoxin Economic Development District China-CEP OTC 2-Sub, Hubei Province
Holder of the Certificate of Suitability:	Hubei Hubei Humanwell Pharmaceutical Co., Ltd. No. 25 Jiaxin Road Gaoxin Economic Development District China-CEP OTC 2-Sub, Hubei Province
Reference of CEP dossier:	CEP 2013-328 / Progesteron
Inspection date:	14/07/2016 to 16/07/2016
Inspector / Name of organization:	Dr. MICHAEL SCHMIDT and Mr. MARGARET CESTERAK, HBM PHARMACEUTICAL INSPECTORATE, PERWIS, A-1284 LITOMERICE, CZECH REPUBLIC, GERMANY
Scope of the inspection:	The inspection focused on the compliance with the information provided in the above-mentioned application for a certificate of suitability, as well as the implementation of a suitable Quality Management System based on the Good Manufacturing Practice as laid down in the EU Rules governing Medicinal Products in the European Union, Volume 4.
Conclusion:	The company operates in accordance with the application submitted and the requirements of the Resolution 40-CEP (07) L. This attestation is valid only in conjunction with a valid version of a CEP for the dossier mentioned above.

GDQ Inspection Reference number: 060-2016-011-001

Strasbourg, 17 October 2016

On behalf of the Director of GDQ

Address: 7-11th Floor, US Bldg.
1-1400 Easton Street
Tel: (+86) 136-4-11-11-1111 (11) 11-1111-1111 (11) 11-1111-1111
Email: info@humanwell.com

EU-GMP

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH

Office of Manufacturing and Production
Division of International Drug Quality
Regulatory Compliance Branch
1401 Rockledge Drive, Room 2204
Silver Spring, MD 20910
TELEPHONE: (301) 796-8340
FAX: (301) 796-8340

April 3, 2016

Mr. Zhang, Managing General Manager
Hubei Hubei Humanwell Pharmaceutical Co., Ltd.
Gaoxin Economic Development District
Yichang, Hubei 444017
China

Reference: 07D-2016-17448

Dear Mr. Zhang:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your active pharmaceutical manufacturing facility in Yichang, China by Inspectors from L. Malabarba during the period of October 14 and 17, 2015.

Based on the results discussed during the inspection, we are classifying your facility as acceptable. This status is not limited to an acceptance or certification of the facility. A serious quality responsibility is always maintained at all times with current good manufacturing practice (CGMP).

Please be advised that all manufacturers must register annually as required by 21 CFR 312.67. Information on how to register is available on <http://www.fda.gov/oc/registration>, Listing 603.

Additionally, we require a copy of the establishment inspection report (EIR), including the EIR as you is part of FDA's file in order to make its regulatory process and with your firm to appear in the regulatory industry. It is being provided to you for the above purposes only and may reflect some information available to the Agency in accordance with the Freedom of Information Act and 21 CFR 312.67. Copies provided to other registrants may have additional redactions of trade secret and confidential commercial information.

If you have any questions regarding this letter, you may contact us at the above address or number.

Sincerely,
Francis W. Williams
Compliance Officer
Division of International Drug Quality

Enclosure: 008
Reference:

FDA

Company Profile : API Marketing Partners



Johnson + Johnson



なによりも患者さんのために
沢井製薬



Global Marketing



Progesterone Project---Introduction

- ❖ The API product complies with the latest specifications like EP/USP/JP, and product quality conforms to all specifications of formulation including Softgel, Vaginal Gel, Vaginal tablet/capsule, Injection ,Pessary.
- ❖ US-DMF (16-DPA Route: No. 27668, BA Route: NO.033003), Thrice FDA on-site inspections and EIR letter are available. DMFs have been triggered by our customer's ANDA.
- ❖ CEP(16-DPA Route: 2013-238, BA Route: 2018-166),EU-GMP on-site inspection Jointly by EDQM and Polish FDA.
- ❖ Current total capability is 200MT/year, with Sufficient internal source of upstream raw material. With leading technology, we are the first one to start BA process manufacturing and registration which is approved by the authority, and we can offer the most competitive price.
- ❖ As flagship product of Gedian Humanwell, progesterone API has been already marketed to different areas including Europe, North America, and South America, Middle East , India and China, our API is highly appreciated by our global customers including originator.

Finasteride Project---Introduction

- ❖ Finasteride is the flagship GMP product of Humanwell, well distributed all over the world.
- ❖ Our facility has passed FDA on-site inspection thrice, EIR letter is available.
- ❖ PDMA approval of Finasteride in May,2019.
- ❖ US-DMF No. is 25056,CEP and Written confirmation are available.
- ❖ The Total capability is 10MT/year.
- ❖ Sufficient upstream raw material supply internally,price is competitive.

Abiraterone Acetate Project---Introduction

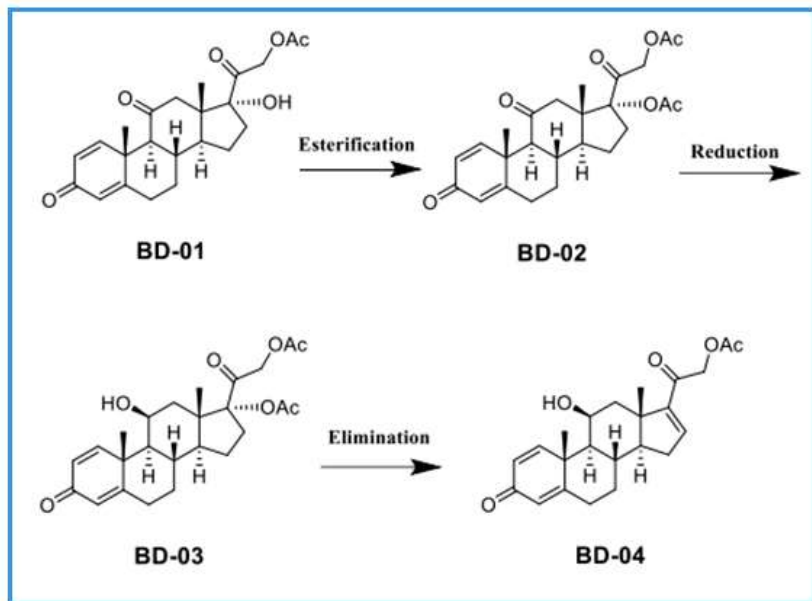
- ❖ Abiraterone acetate is the flagship GMP product of Humanwell.
- ❖ The API complies with the latest specifications like USP and the customers' specification.
- ❖ US-DMF No. is 37965 ,EDMF and Written confirmation are available.
- ❖ Batch size: 100-200kg, total capability is 20MT/year.
- ❖ Upstream raw material integrated, API price is competitive.

Budesonide Project---Introduction

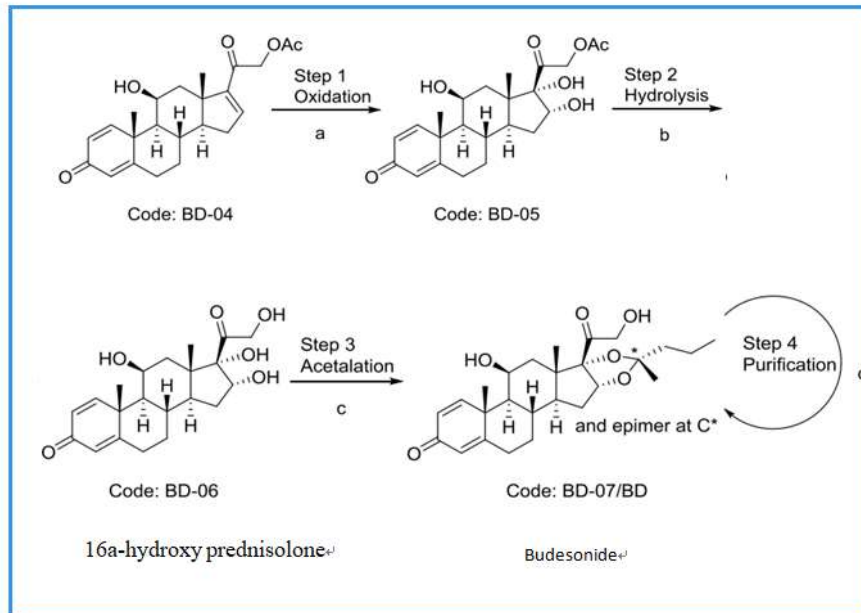
- ❖ The quality of our Budesonide complies with EP/USP/CP and meets the particle size requirements of different dosage forms including suspension inhalation, aerosol, nasal spray, dry powder, oral, etc.
- ❖ The Chinese DMF(Y20190009886) of our Budesonide API status is A, US-DMF No. is 34268, and CEP is available.
- ❖ Thrice FDA on-site inspections and EIR letter are available,EU-GMP on-site inspection Jointly by EDQM and Polish FDA.
- ❖ Production capacity is 6MT/year and Gedian Humanwell has the capacity for customized production.
- ❖ Sufficient internal source of upstream raw material, our Budesonide's raw materials are self-produced, which can effectively ensure the safety of the supply chain.
- ❖ High quality budesonide API has been already marketed to different areas including China, Europe, North America, South America, and Middle East. Our API is highly appreciated by our global customers.

Budesonide ROS

ROS of Starting material



ROS of API



Oxcarbazepine project: Introduction

- ❖ The API product complies to almost all the compendia specifications like EP, USP, CP, IP.
- ❖ Modern facility with cGMP standard guarantees the high quality of Oxcar API.
- ❖ Dedicated production line and clean rooms for Oxcar to avoid the risk of cross-contamination.
- ❖ Production capacity 300MT/year, and Batch size : About 500KG-1T/Batch.
- ❖ Sufficient internal source of upstream raw material.
- ❖ The Chinese DMF(Y20190009885) of our Oxcarbazepine API status is A, US-DMF No. is 32999, and CEP is available.
- ❖ High quality Oxcarbazepine API has been already marketed to different areas including China, Europe, North America, South America, and Middle East. Our API is highly appreciated by our global customers.

The End

Thanks for your attention!

Looking forward to cooperating with you!

