人福医药
HUMANWELL HEALTHCARE

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

STRIVE TO BE A GLOBAL FULLY INTEGRATED HEALTHCARE SOLUTION PROVIDER

人福医药
HUMANWELL HEALTHCARE

PART 1

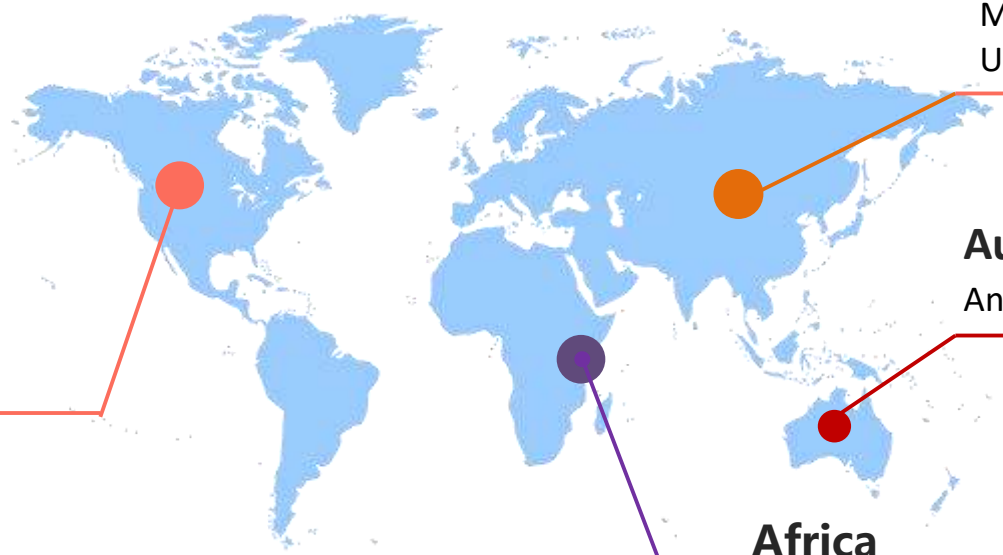
HUMANWELL HEALTHCARE GROUP

- 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



China

More than 15 Manufacturing Units

North America

Humanwell Purecap

Epic Pharma

Australia

Ansell Sexual Wellness Unit

Africa

Humanwell Mali

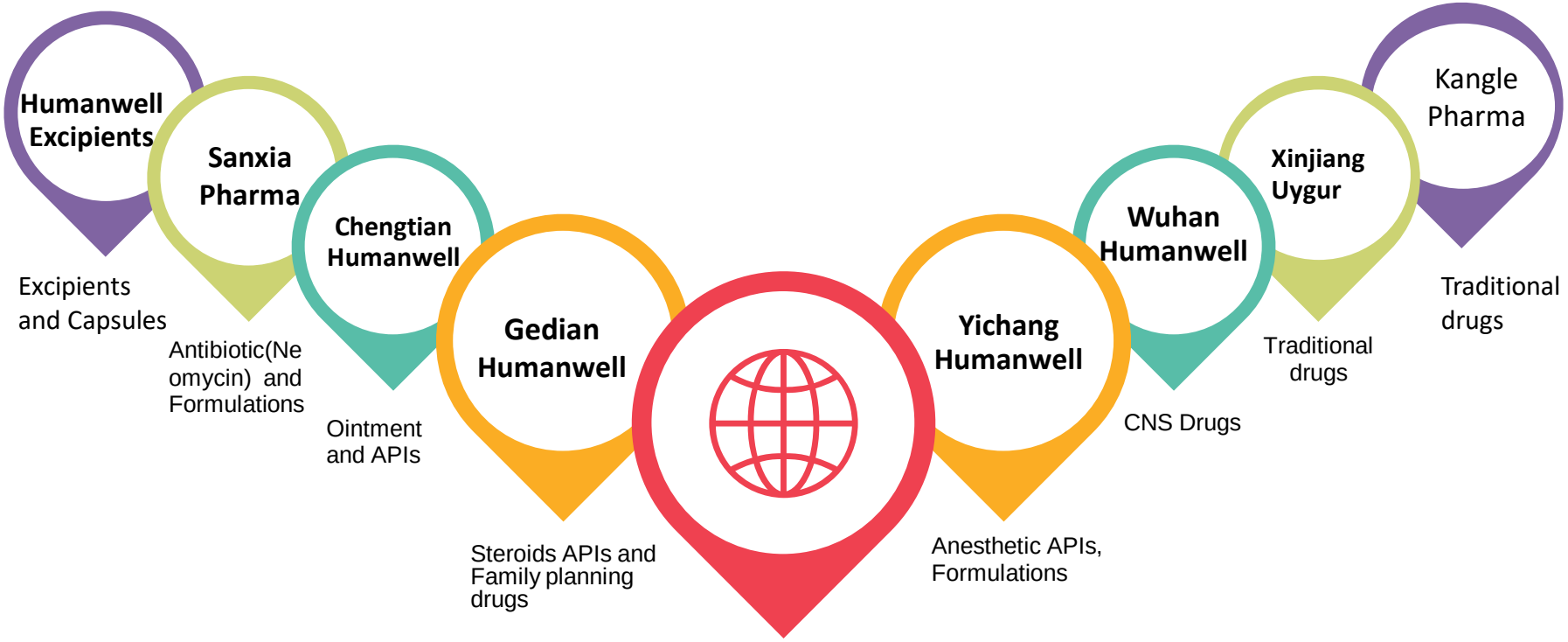
Humanwell Burkina Faso

Humanwell Ethiopia

worldwide

>20000

Core Manufacturers in China



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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, Shiyan
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

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 Certificate No HB20170036

企业名称 Manufacturer：湖北省恩施人福药业有限责任公司

Hubei Enshi Humanwell Pharmaceutical Co.,Ltd.

地 址 Address：湖北省恩施州市恩施经济技术开发区

Enshi Economic Development District, Enshi City, Hubei Province

认证范围 Scope of Inspection：

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：

Issued By

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

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): HB20000028

证明文件编号：HB20000028

1.Name and address of site (including building number, where applicable):

Hubei Gedian Humanwell Pharmaceutical Co., Ltd.

湖北葛店人福药业有限责任公司

Gedian Economic Development District, E-Zhou City, Hubei Province, 436070

湖北省鄂州市葛店经济开发区，邮编：436070

Manufacturer's licence 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 SUBSTANCE(S) EXPORTED TO THE EU FOR MEDICINAL PRODUCTS FOR HUMAN USE

Active substance(s)	Activity(ies)	Chinese drug approval number
Budesonide	Chemical Synthesis	H20183795
Finasteride	Chemical Synthesis	H20041188
Levonorgestrel	Chemical Synthesis	H20107226
Progesterone	Chemical Synthesis	H20066109
Oxcarbazepine	Chemical Synthesis	H20040191

WC

Certificates


Certification of Substances Division

Certificate of suitability

No. R0-CEP 2013-328-Rev 00

PROGESTERONE

HUBEI GEDIAN HUMANWELL PHARMACEUTICAL CO., LTD.

SEE ANNEX 1

CEP


Certification of Substances Division

ATTESTATION OF INSPECTION

Inspected site	Hubei Gedian Humanwell Pharmaceutical Co., Ltd Gedian Economic Development District China-436 070 E-Zhou, Hubei Province
Holder of the Certificate of Suitability	Hubei Gedian Humanwell Pharmaceutical Co., Ltd Gedian Economic Development District China-436 070 E-Zhou, Hubei Province
Reference of CEP dossier	CEP 2013-328 / Progesterone
Inspection dates	[illegible]
Inspector / Name of organisation	MAIN PHARMACEUTICAL INSPECTORATE, Poland EDQM, Council of Europe
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 AP-CSP (07) 1. This attestation is valid only in conjunction with a valid version of a CEP for the dossier mentioned above.

Strasbourg, 17 October 2016

On behalf of the Director of EDQM

EU-GMP


DEPARTMENT OF HEALTH & HUMAN SERVICES

FDA

Company Profile : API Marketing Partners

人福医药
HUMANWELL HEALTHCARE

MERCK

SANOFI

BAYER

Johnson & Johnson

BESINS HEALTHCARE
Innovating for Well-being

Mylan®

CHEMO

SUN PHARMACEUTICAL INDUSTRIES LTD.

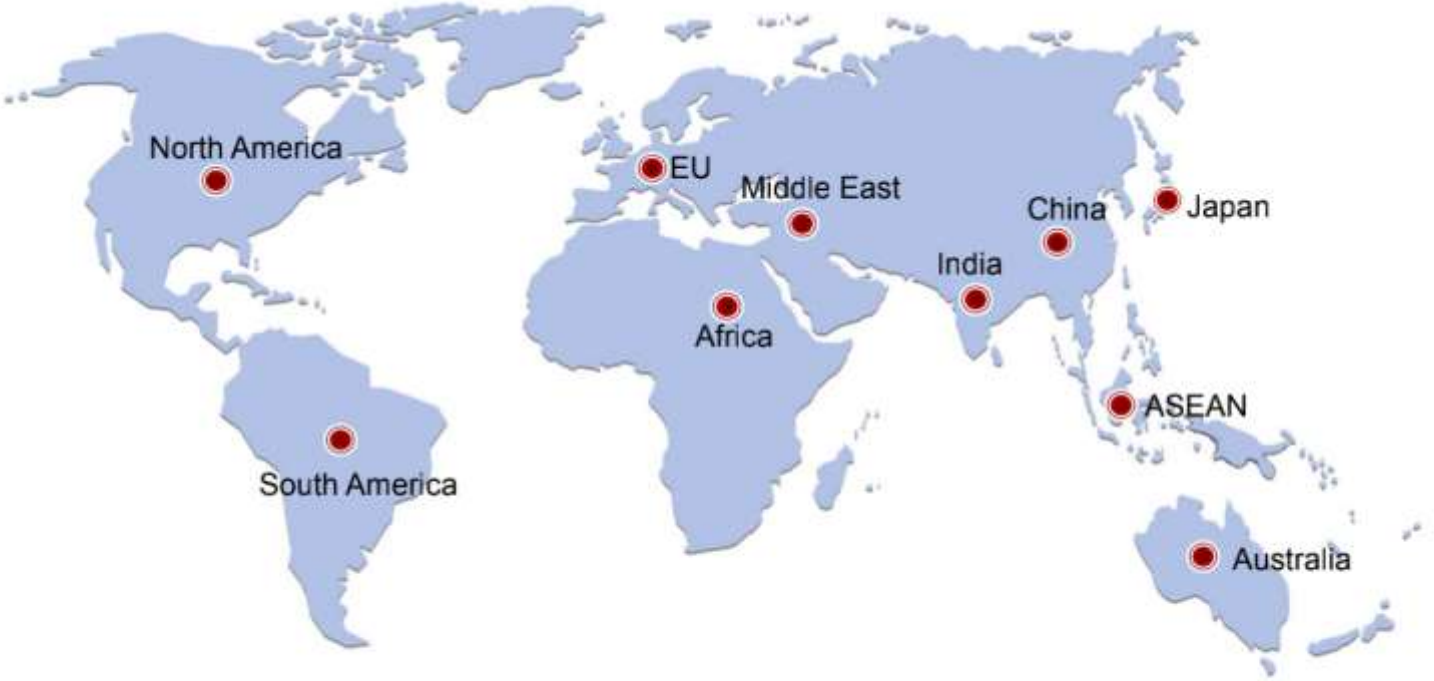
Boehringer Ingelheim

douglas

なによりも患者さんのために
沢井製薬

Cipla

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

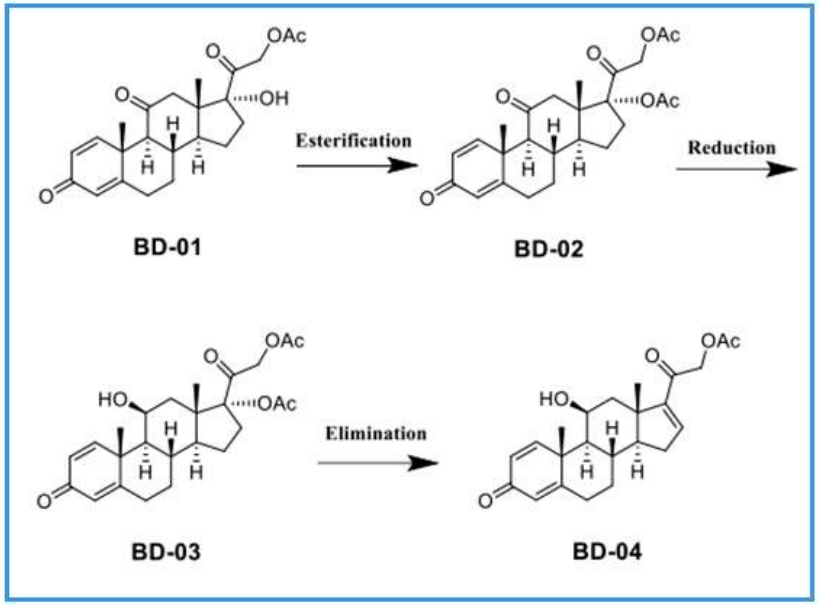
- Abiraterone acetate is the flagship GMP product of Humanwell.
- The API complies with the latest specifications like USP and the customers' specification.
- US-DMF No. is 37965 ,EDMF and Written confirmation are available.
- Batch size: 100-200kg, total capability is 20MT/year.
- Upstream raw material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

Budesonide Project---Introduction

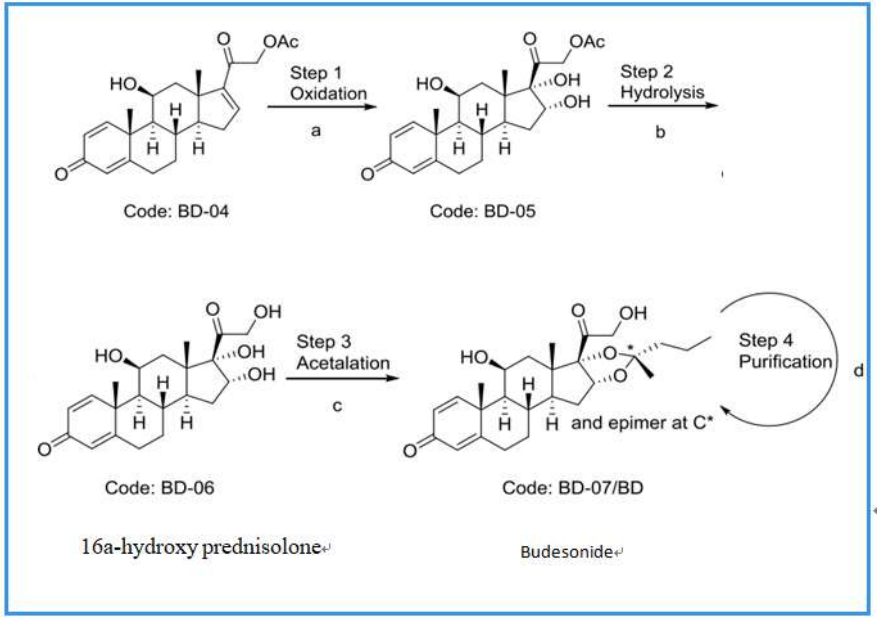
- The quality of our Budesonide complies with EP/USP/CP and meets the particle size requirements of different dosage forms including suspension inhalation, aerosol, nasal spray, dry powder, oral, etc.
- The Chinese DMF(Y20190009886) of our Budesonide API status is A, US-DMF No. is 34268, and CEP is available.
- 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.

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The End

Thanks for your attention!

Looking forward to cooperating with you!