



**YOUR RELIABLE PARTNER**

# 领先的甾体激素原料生产商

A leading manufacturer of steroid hormone APIs and intermediates

**浙江仙居君业药业有限公司**

Zhejiang Xianju Junye Pharmaceutical Co., Ltd.



## 发展历程 Our History



1998

浙江仙居君业药业成立

Zhejiang Xianju Junye Pharma established

2006

米非司酮获准中国GMP「2019证书更新」

Mifepristone CFDA GMP approved 「renewed in 2019」

2011

成立江西君业生物制药有限公司

Jiangxi Junye Bio-pharmaceutical Co.,Ltd.

炔诺酮获得CEP证书

Norethisterone CEP approved

2015

醋酸普拉雄酮通过美国FDA审计

Prasterone acetate US-FDA approved

获得墨西哥GMP

Cofepris GMP approved

2019

零缺陷通过美国FDA现场审计

Re-inspected and approved by US-FDA with Zero 483

2021

智能工厂建成

Smart Factory established

2024

2024年 获得“单项制造冠军”称号

Awarded the Single Champion in Manufacturing by the Ministry of Industry and Information Technology (MIIT)

2002

国内率先研发成功替勃龙工艺

Tibolone API first introduced in China by Junye Pharma

2009

ISO14000&OHSAS18001 认证通过「2018证书更新」

ISO14000&OHSAS18001 approved 「renewed in 2018」

2013

君业研究院获国家重点研究院称号

「National Top Research Institute」 title won by Junye Pharma Research Institute

2017

炔诺酮与炔雌醇通过日本官方审计

Norethisterone and Ethinylestradiol PMDA approved

2020

烯丙孕素获得GMP证书

Altrenogest GMP approved

2022

浙江省科学技术进步一等奖

Won the First Prize of Zhejiang Provincial Science and Technology Progress Award



## 关于我们 About Us



君业药业成立于1998年，是一家专业从事甾体激素原料药与中间体的研发、生产及销售的企业，我们秉承「共创、共赢、共享」的企业精神，致力于为广大客户提供稳定优质的甾体产品以及甾体与非甾体的定制服务。

Established in 1998, Junye Pharma is a high-tech enterprise concentrated on developing, manufacturing and marketing of hormone APIs & intermediates. Our expertise lies in building close relationship with our customers and providing them with stable, quality steroid products as well as CMO, CDMO service for steroid and non-steroid compounds.

## 占地面积 Area Coverage

### 浙江厂区

Zhejiang manufacturing site

**165,000m<sup>2</sup>**

### 江西工厂

Jiangxi manufacturing site

**350,000m<sup>2</sup>**

### 内蒙古工厂

Inner Mongolia manufacturing site

**133,000m<sup>2</sup>**

### 研发中心

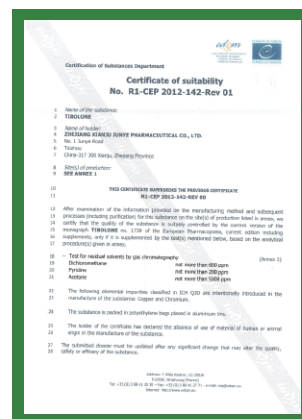
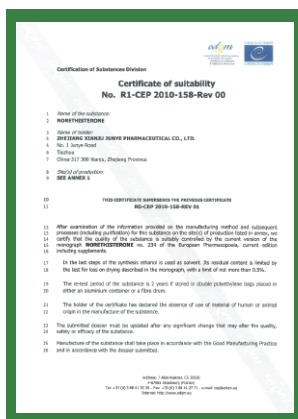
R&D center

**3,000m<sup>2</sup>**



## 黄体酮中国GMP

## 米非司酮中国GMP



## Drospirenone CEP

## Norethisterone CEP

## Tibolone CEP



产品清单·原料药&中间体  
Product List • APIs & Intermediates

孕激素 Progestogens

| CAS No.     | 中文品名Chinese Name             | 英文品名English Name                                               | 法规状态 Regulatory Status                                 |
|-------------|------------------------------|----------------------------------------------------------------|--------------------------------------------------------|
| 67392-87-4  | 屈螺酮                          | Drospirenone                                                   | 地方GMP/DMF/Local GMP/DMF                                |
| 82543-15-5  | Q4/D7                        | D7/Q4                                                          | 技术包/TDP                                                |
| 82543-16-6  | Q5/D8                        | D8/Q5                                                          | DMF                                                    |
| 84371-65-3  | 米非司酮                         | Mifepristone                                                   | China-GMP/EU-DMF                                       |
| 84371-64-2  | 十一位                          | 3-Ethylene dioxy-17-oxo-13β-methyl estra-5(10)9(11)-diene      | 技术包/TDP                                                |
| 5571-36-8   | 3-缩酮                         | Ethylene deltenone                                             | 技术包/TDP                                                |
| 65928-58-7  | 地诺孕素                         | Dienogest                                                      | 研发/R&D                                                 |
| 3962-66-1   | 碱脱                           | 19-Nor-5(10)-androstene-3,17-dione                             | 技术包/TDP                                                |
| 5173-46-6   | 4,9物/雌甾                      | Estra-4,9-diene-3,17-dione                                     | 技术包/TDP                                                |
| 68-22-4     | 炔诺酮                          | Norethisterone                                                 | CEP/DMF                                                |
| 51-98-9     | 醋酸炔诺酮                        | Norethisterone acetate                                         | 地方GMP/DMF/Local GMP/DMF                                |
| 3836-23-5   | 庚酸炔诺酮                        | Norethisterone enanthate                                       | Cofepris/DMF                                           |
| 734-32-7    | 酸脱                           | 19-Nor-4-androstene-3,17-dione                                 | 技术包/TDP                                                |
| 57-83-0     | 黄体酮*                         | Progesterone*                                                  | DMF/GMP                                                |
| 68-96-2     | 17α-羟基黄体酮                    | 17α-Hydroxyprogesterone                                        | 技术包/TDP                                                |
| 302-23-8    | 17α-羟基黄体酮醋酸酯/单酯              | 17α-Hydroxyprogesterone Acetate                                | 技术包/TDP                                                |
| 31981-44-9  | 格氏孕酮醋酸酯                      | Gestonorone acetate/ 17α-hydroxy-19-norprogesterone-17-acetate | 技术包/TDP                                                |
| 5630-53-5   | 替勃龙                          | Tibolone                                                       | CEP                                                    |
| 88247-84-1  | 替醚化物                         | 7α-Methyl-3,3-dimethoxy-5(10)-estrene-17-one                   | DMF                                                    |
| 54024-22-5  | 去氧孕烯                         | Desogestrel                                                    | 研发/R&D                                                 |
| 54048-10-1  | 依托孕烯                         | Etonogestrel                                                   | 研发/R&D                                                 |
| 797-63-7    | 左炔诺孕酮                        | Levonorgestrel                                                 | 技术包/TDP                                                |
| 54024-21-4  | 乙基酮 / 去氧孕烯N-1                | 11-methylene-18-methyl-Estra-4-ene-17-one                      | 研发/R&D                                                 |
| 100071-90-7 | 三酮                           | 8-Methyl-estra-4en-3,11,17-Trione                              | 技术包/TDP                                                |
| 2322-77-2   | 沃氏物                          | Methoxydienone                                                 | 技术包/TDP                                                |
| 53067-82-6  | 11α羟基左旋乙基甾烯双酮                | 11α-hydroxy-18-methyl-Estra-4-en-3,17-dione                    | 技术包/TDP                                                |
| 68917-50-0  | 锂氨物                          | 18-methyl-3-methoxy-2,5(10)- estradiene-17-ol                  | 技术包/TDP                                                |
| 6615-00-5   | 11羟酸脱                        | 11α-Hydroxy-estr-4-ene-3,17-dione                              | 研发/R&D                                                 |
| 81968-78-7  | 3-羟基-5,7-孕甾二烯-20-酮           | 3-hydroxy-5,7-pregnadien-20-one                                | 技术包/TDP                                                |
| 19592-55-3  | 3,20-二（乙烯二氧基）孕甾-5,7-二烯 / 丙酰奋 | 3,20-Bis(ethylenedioxy)pregna-5,7- diene / Proketal            | 技术包/TDP                                                |
| 427-51-0    | 醋酸环丙孕酮                       | Cyproterone acetate                                            | 研发/R&D                                                 |
| 2701-50-0   | 醋酸环丙孕酮酰化物                    | 17-Hydroxy-1a,2a-methylenepregna- 4,6-diene-3,20-dione acetate | 技术包/TDP                                                |
| 850-52-2    | 烯丙孕素*                        | Altrenogest*                                                   | 中国兽药GMP/Veterinary China-GMP<br>DMF编制阶段/DMF Undergoing |
| 10109-66-7  | 烯丙孕素N-2                      | Altrenogest N-2                                                | 技术包/TDP                                                |

雌激素 Estrogens

| CAS No.    | 中文品名Chinese Name | 英文品名English Name                    | 法规状态 Regulatory Status |
|------------|------------------|-------------------------------------|------------------------|
| 57-63-6    | 炔雌醇              | Ethinylestradiol                    | DMF/Japan-GMP          |
| 50-28-2    | 雌二醇              | Estradiol                           | DMF                    |
| 35380-71-3 | 半水雌二醇            | Estradiol hemihydrate               | DMF                    |
| 4956-37-0  | 庚酸雌二醇            | Estradiol enanthate                 | Cofepris/DMF           |
| 979-32-8   | 戊酸雌二醇            | Estradiol valerate                  | Cofepris/DMF           |
| 50-27-1    | 雌三醇              | Estriol                             | 按需准备/Upon request      |
| 53-16-7    | 雌酚酮              | Estrone                             | DMF                    |
| 510-64-5   | 开环物              | 19-Hydroxy androst-4-ene-3,17-dione | DMF                    |

皮质激素 Cortisones

| CAS No.     | 中文品名Chinese Name       | 英文品名English Name                   | 法规状态 Regulatory Status       |
|-------------|------------------------|------------------------------------|------------------------------|
| 50-02-2     | 地塞米松                   | Dexamethasone                      | 技术包/TDP                      |
| 2392-39-4   | 地塞米松磷酸钠*               | Dexamethasone sodium phosphate*    | 中国兽药GMP/Veterinary China-GMP |
| 24916-90-3  | 地塞米松环氧水解物              | 8DM / 16α-methyl epoxide           | 技术包/TDP                      |
| 50-23-7     | 氢化可的松                  | Hydrocortisone                     | 技术包/TDP                      |
| 50-03-3     | 醋酸氧化可的松                | Hydrocortisone acetate             | 技术包/TDP                      |
| 83-43-2     | 甲基泼尼松龙                 | Methylprednisolone                 | 按需准备/Upon request            |
| 1035-69-4   | 雄甾-4,9(11)-二烯-3,17-二酮  | 9-Dehydroandrostenedione           | 技术包/TDP                      |
| 7753-60-8   | 氢化可的松中间体酯化物;<br>醋酸阿奈可他 | Anecortave acetate / H6            | 技术包/TDP                      |
| 14484-47-0  | 地夫可特                   | Deflazacort                        | 墨西哥 GMP/DMF/Cofepris/DMF     |
| 2135-17-3   | 氟米松                    | Flumethasone                       | 技术包/TDP                      |
| 28416-82-2  | 氟米松酸                   | Flumethasone acid                  | 技术包/TDP                      |
| 107724-20-9 | 依普利酮                   | Eplerenone                         | 研发/R&D                       |
| 192569-17-8 | 11α-羟基坎列酮              | 11α-Hydroxy canrenon               | 技术包/TDP                      |
| 192704-56-6 | 11α-羟基坎列酮丙烯酸甲酯         | 11α-Hydroxy canrenone methyl ester | 技术包/TDP                      |
| 37413-91-5  | 3TR ; 醋酸四烯物            | 3TR                                | 技术包/TDP                      |
| 13647-35-3  | 曲洛斯坦*                  | Trilostane*                        | DMF                          |

其他类甾体结构化合物 Other steroid compounds

|             | 中文品名Chinese Name     | 英文品名English Name                                                                        | 法规状态 Regulatory Status    |
|-------------|----------------------|-----------------------------------------------------------------------------------------|---------------------------|
| 98319-26-7  | 非那雄胺                 | Finasteride                                                                             | 技术包/TDP                   |
| 302-97-6    | 3-氧代-雄甾-4-烯-17β-羧酸   | F5; AD Acid                                                                             | 技术包/TDP                   |
| 2681-55-2   | 3-氧代-雄甾-4-烯-17β-羧酸甲酯 | F4                                                                                      | 技术包/TDP                   |
| 131267-80-6 | F6                   | N-tert-butyl-3-oxo-4-Androsten-17β- carboxamide                                         | 技术包/TDP                   |
| 166896-74-8 | F8                   | 17β-(t-Butylcarbamoyl)-4-aza-5α-androsten-3-one                                         | 技术包/TDP                   |
| 98319-24-5  | F9; 二氢波斯卡            | F9; dihydroproscar                                                                      | 技术包/TDP                   |
| 103335-55-3 | F9酸                  | F9 acid;M3 acid;3-oxo-4-aza-5-α-androstane-17-β-carboxylic acid                         | 技术包/TDP                   |
| 104239-97-6 | F10酸                 | F10 acid; M4 acid;4-Aza-5α-androstan-1-ene-3-one-17β-carboxylic acid                    | 技术包/TDP                   |
| 129453-61-8 | 氟维司群                 | Fulvestrant                                                                             | 研发/R&D                    |
| 2590-41-2   | 6-去氢诺龙醋酸酯            | 6-Dehydronandrolone acetate                                                             | 技术包/TDP                   |
| 571-92-6    | 6-酮基雌二醇              | 6-keto estradiol                                                                        | 技术包/TDP                   |
| 875573-66-3 | 氟维斯群中间体N-3           | Fulvestrant intermediate N-3                                                            | 技术包/TDP                   |
| 875573-67-4 | 氟维斯群中间体N-3水解物        | Fulvestrant intermediate N-3 hydrolysate                                                | 技术包/TDP                   |
| 875573-69-6 | 氟维斯群中间体N-2           | Fulvestrant intermediate N-2                                                            | 技术包/TDP                   |
| 153004-31-0 | 氟维斯群N-1              | Fulvestrant intermediate N-1                                                            | 研发/R&D                    |
| 261506-24-5 | 氟维斯群N-1              | Fulvestrant intermediate N-1                                                            | 研发/R&D                    |
| 154229-18-2 | 醋酸阿比特龙               | Abiraterone acetate                                                                     | DMF                       |
| 154229-19-3 | 阿比特龙                 | Abiraterone / (3β)-17-(Pyridin-3-yl)- androsta-5,16-dien-3-ol                           | 技术包/TDP                   |
| 32138-69-5  | 碘化物                  | Iodo DHEA/ 17-Iodoandrosta - 5.16- dien-3β-oL                                           | 技术包/TDP                   |
| 853-23-6    | 醋酸去氢表雄酮              | Prasterone Acetate                                                                      | 美国FDA审计通过/US-FDA approved |
| 119302-20-4 | 罗库溴铵中间体1             | Roc-diol / (2b,3a,5a,16b,17b)-2-(4-Morpholinyl)-16-(1-pyrrolidinyl)androstane-3,17-diol | 技术包/TDP                   |
| 50588-42-6  | 罗库溴铵烯酯物              | 17-Acetoxy-5a-androsta-2,16-diene                                                       | 技术包/TDP                   |
| 50588-22-2  | 罗库溴铵环氧化物             | 2α,3α,16α,17α-Diepoxy-17β-acetoxy-5α-androstane                                         | 技术包/TDP                   |

说明 Note

\* 可做兽药。\* can be used as veterinary drug.

 原料药 API     中间体 Intermediate

声明Disclaimer

以上所列产品，不在受专利保护的市场进行商业销售。任何涉及专利的责任由买方承担。  
We will not manufacture products listed above for commercial purpose in any countries where related patents are still valid. Buyers are responsible for any patent infringement.



## 客户定制服务 CMO&CDMO SERVICE



君业向客户提供医药原料药，中间体，化学品等的定制服务。  
We provide customers with CMO and CDMO service for pharmaceutical APIs, intermediates and chemicals.

### 生产 Manufacturing Assets

#### 生产场地 Manufacturing sites

3个生产场地，有不同规模的车间及实验室，可满足从克级到吨位级等不同规模的生产，同时多个生产场地可保证供应的安全性及稳定性。

3 manufacturing sites with workshops and labs of different scales, meeting manufacturing from grams to tons. Multiple sites can guarantee the supply security and stability.

#### 认证 Certificates

场地通过ISO-9001,14001及OHSAS18001认证，其中，浙江仙居生产场地通过美国FDA审计。  
ISO-9001,14001 and OHSAS18001 approved sites, one of which has been approved by US-FDA (Xianju, Zhejiang).

#### 支持体系 Supporting System

完善的GMP管理体系和强大的注册团队支持。  
Well-established GMP management system and strong registration team support.

### 研发R&D

#### 3个研发中心 3 Locations

浙江仙居君业研究院(总部)、上海研发中心、天津联合实验室(生物实验室)。  
Zhejiang Xianju Junye Research Institute (headquarter), Shanghai R&D Center, Tianjin joint R&D Center(Bio-tech).

#### 研发团队 R&D Teams

化学合成组9组，生物化学组3组，包括9名博士，21名硕士，42名学士。占公司总人数15%。  
9 teams on Chemistry and 3 teams on Biochemistry, with 9 PhDs, 21 Masters and 42 Bachelors, accounting for 15% of the total employees.

#### 生产规模 Manufacturing scale

从克级到公斤级。  
from grams to kilos.

### 环境·健康·安全EHS

#### 三废处理 Waste Treatment

完善的三废处理体系，各项排放均达国家要求。  
complete waste treatment system, meeting the national requirement.

#### 工业卫生 Industrial Hygiene

参考多种专业标准，并选择最严格数据评价IH风险。基于WRS分析结果，设置配置矩阵，相应配备各种防护设施。  
different professional standards are referred to and the strictest data is selected for the IH risk assessment. WRS is applied for the risk analysis, different types of PPE are used based on the analysis result.

#### 工艺安全管理 Process Safety Management

参考OSHA 29 CFR 1910.119 PSM、杜邦PSM和AQ/T3034-2010化工企业工艺安全管理实施导则，建立了工艺安全管理体系，并使用HAZOP、WHATIFs LOPA等工具进行风险分析。  
Refer to OSHA 29 CFR 1910.119 PSM, DuPont PSM and AQ/T3034-2010 chemical industry process safety management implementation guidelines as guidance and apply HAZOP, WHATIF and LOPA as risk analysis tools.

WORKING TOGETHER

GROWING TOGETHER

SHARING TOGETHER

共 创

/

共 赢

/

共 享

## 联系方式 Contact

### 国内销售 Domestic Sales

中国 China

+86-576-87821302

+86-576-87821310

### 国际销售 International Sales

欧美 Europe & America

+86-576-87710577

南亚及新兴市场 South Asia & Emerging Market

+86-576-87821311

邮箱 E-mail: [junye@junyepharm.com](mailto:junye@junyepharm.com)

网页 Website: [www.junyepharm.com](http://www.junyepharm.com)

地址: 浙江省台州市仙居县现代工业园区灵秀路1号

Address: No.1 Lingxiu Road, Modern Industrial Centralization Zone, Xianju, Taizhou, Zhejiang, China