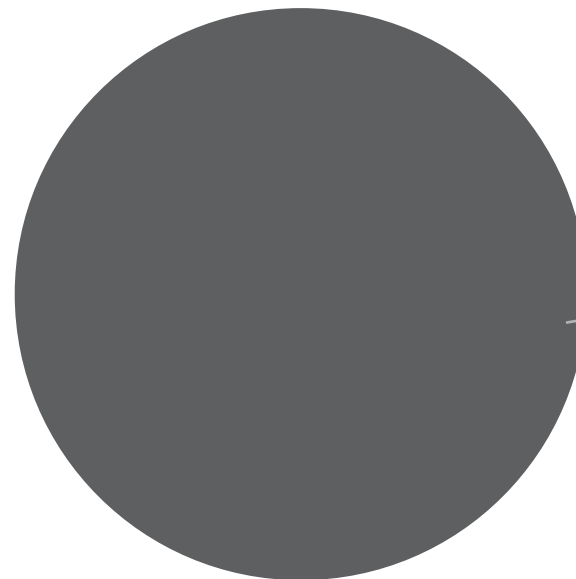




云南汉德生物技术有限公司  
中国·云南省昆明市安宁太平新城创智2.5产业园

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Yunnan Hande Bio-Tech Co.,Ltd



YUNNAN.  
。HANDE



全球鲜有的紫杉醇原料药生产商

A rare manufacturer of paclitaxel API in the whole world

SMART  
PHYTOEXTRACTION  
SINCE

1993

有“质”慧的植提家  
始于1993



—  
产品质量问题退货率：0%

Product quality problem return rate: 0%.

—  
USP紫杉醇标准品和其他紫杉烷类标准品提供者

USP reference standards supplier of Paclitaxel and other taxanes.

—  
法规认证：美国FDA、欧洲CEP、中国GMP；印度、澳洲、日本等市场注册报备

Regulation and certification: in U.S. FDA, CEP, Chinese GMP;

Drug Registration: in India, Australia, Japan etc.



YUNNAN  
HANDE



COMPANY PROFILE 公司简介



我们，是全球鲜有的紫杉醇原料药生产商

We, a rare manufacturer of paclitaxel API in the whole world.

我们，从1993和时间携手步程20余年

We, from 1993 to now, a company with more than twenty-year experiences still full of vigor.

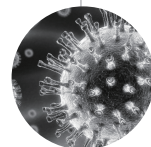


我们，荣获美国FDA、欧洲CEP、CGMP认证

We, Passed U.S. FDA, CEP, and Chinese GMP.

我们，孕养高才能的团队，以智慧和经验的结晶浇注坚固的质量体系

We, a talented team, enhance our quality system with the combination of wisdom and experience.



我们，以至高品质为铭；为锻造精良工艺而生

We, born to make perfect, work to achieve high quality.

我们的优势

OUR STRENGTHS



## OUR STRENGTHS

### 1. 齐全的主流法规认证

Comprehensive Regulation Certification

美国FDA、欧洲CEP、中国GMP；印度、澳洲、日本市场注册报备  
Certified by U.S. FDA, CEP, Chinese GMP; Registration in India, Australia and Japan.

### 2. 可靠的质量

Reliable Quality

20多年来，汉德生产的450多批产品均无任何质量问题，纯化工艺独特，杂质及纯度控制同时符合  
USP\EP\CP标准

Over 20 years, more than 450 batches of products produced by Hande have no any quality problems, unique  
purification process, impurity and purity control meet spec of USP, EP and CP.



OUR STRENGTHS

### 3. 健全的质量体系

Comprehensive Quality System

质量保证体系 Quality Assurance System

文件控制 Document control

验证系统 Validation system

培训系统 Training system

内审计划 Internal audit protocol

供应商审计系统 Supplier audit system

设施、设备系统 Equipment & Facilities System

物料控制体系 Material Control System

生产控制系统 Production Control System

包装与标签系统 Packaging & Labeling System

实验室控制系统 Laboratory Control System

验证和确认系统 Verification & Validation System

药政法务系统 Regulatory Affairs System

## OUR STRENGTHS



### 4. 严格管控源头及过程

Control Whole Sources and Processes

严格控制所有原料、辅料、包材，优先选择具有美国DMF文号的原辅料、包材供应商

Strictly controlled all raw materials, accessories and packaging materials. Preferred raw materials and accessories and packaging materials supplier with U.S. DMF number.

依托浙江和云南上万亩高含量云南红豆杉种源，紫杉醇平均含量达万分之三，10-DAB含量达千分之

四，含量均超传统云南红豆杉

Expected Paclitaxel assay is 300ppm with local Yew resources in Zhejiang and Yunnan Provinces, assay of 10-DAB is 4000ppm in plants, far beyond these content in traditionally cultivated Yunnan Yew.

具有多个原料供应商作供应保障

Several raw material suppliers as supply assurance.

## 5. 质量控制标准

Quality Control Specification

USP紫杉醇标准品和其他紫杉烷类标准品提供者

USP reference standards supplier of Paclitaxel and other taxanes.

紫杉醇放行标准以CP/EP/USP标准控制，杂质检测方法涵盖USP/EP/CP的所有

杂质，且杂质含量质量标准严于上述法规标准

The release spec of Paclitaxel controlled by spec of CP/EP/USP. The impurity analytical method covers all impurities in USP/EP/CP, and the impurity contents spec are way beyond that in regulatory standards.

紫杉醇残留溶剂标准低于法规标准

Spec of Residual solvents in Paclitaxel are below spec of regulatory standards.



## 6. 强大的合作机构作支撑

Strong Cooperative Institutions to support

中国科学院 Chinese Academy of Sciences

昆明植物研究所 Kunming Institute of Botany

云南大学 Yunnan University

云南微生物研究所 Yunnan Institution Of Microbiology

清华大学 Tsinghua University



## GMP发展历程

GMP HISTORY



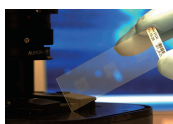
◆ 建立了质量体系，并按照GMP要求进行管理；  
Established quality system and performed as per GMP;  
◆ 向美国FDA递交天然紫杉醇的DMF文件，获得DMF文号11909。  
Filed first DMF to U.S.FDA for natural Paclitaxel (#11909).

1996



◆ 第一次接受国内GMP认证现场检查，并顺利通过获得GMP证书；  
Passed CFDA's GMP inspection and obtained GMP Certificate;  
◆ 接受并通过美国FDA现场符合度检查。  
Passed U.S.FDA's cGMP inspection.

2004



◆ 获得10-DAT半合成紫杉醇的CEP证书；  
Obtained CEP for 10-DAT semi-synthetic Paclitaxel;  
◆ 通过美国FDA的检查。  
Passed U.S.FDA's inspection.

2011



◆ 接受国内2010版GMP认证现场检查并获得GMP证书。  
Passed CFDA's GMP inspection and obtained GMP Certificate.

2013



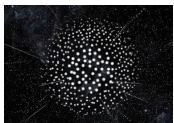
◆ 接受美国FDA检查；  
Accepted U.S.FDA's inspection;  
◆ 完成天然紫杉醇和10-DAT半合成紫杉醇在台湾地区TDMF注册报备；  
TDMFs of natural and 10-DAT semi-synthetic paclitaxel approved by TFDA,12;  
◆ 同年8月拿到日本药品注册证书，9月拿到印度药品注册证书。  
At the same year, PMDA certificate was approved in Aug. Drug registration certificate in India was approved in Sept.

2015



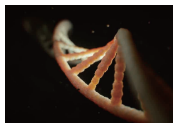
◆ 第一次通过美国FDA现场符合度检查。  
Passed U.S.FDA's inspection for the first time.

1999



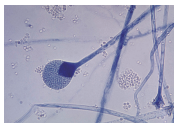
◆ 接受国内GMP换证现场检查并通过获得GMP证书；  
Passed GMP Inspection performed by CFDA;  
◆ 向美国FDA递交10-DAT半合成紫杉醇的DMF文件，获得DMF文号22839；  
Filed DMF to U.S.FDA for 10-DAT semi-synthetic Paclitaxel (#22839);  
◆ 获得天然紫杉醇产品的CEP证书。  
Obtained CEP for natural Paclitaxel.

2009



◆ 接受澳大利亚TGA的现场检查并获得GMP证书；  
GMP Certificate issued by TGA;  
◆ 接受美国FDA检查并顺利通过。  
Passed U.S.FDA's inspection.

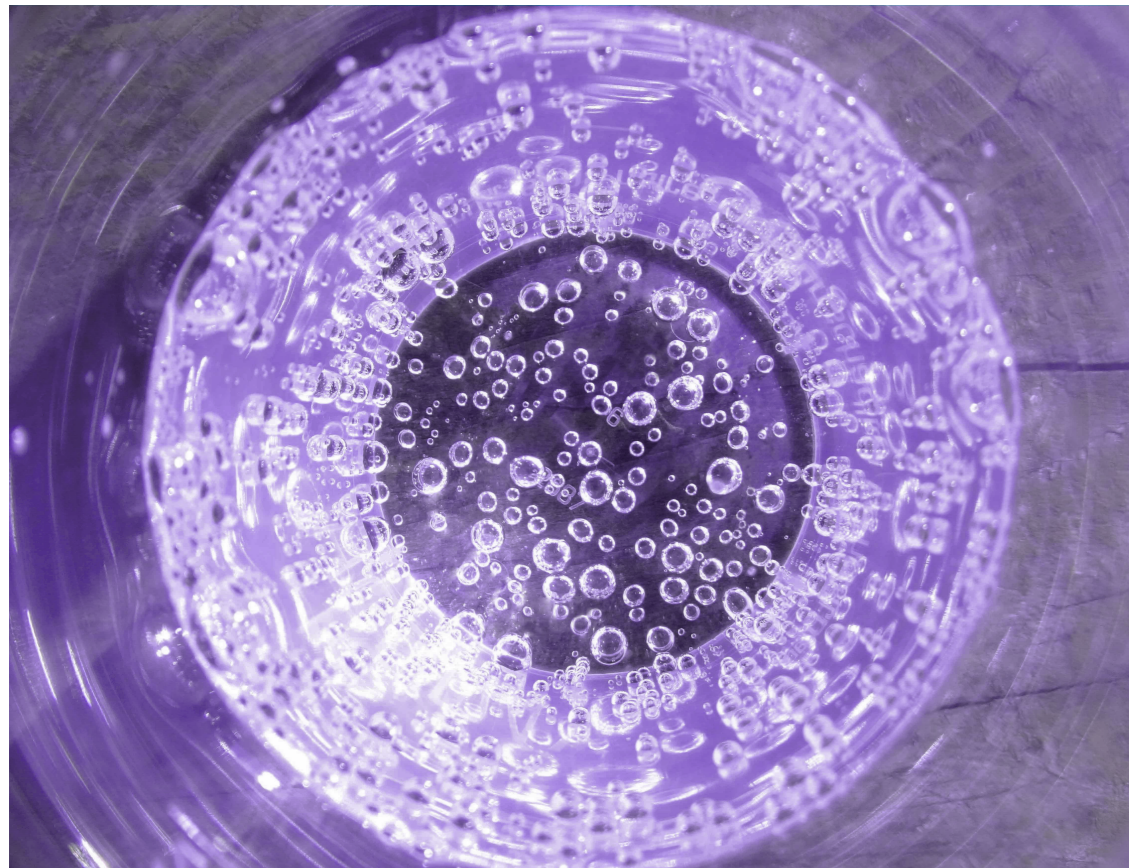
2012



◆ 接受美国FDA检查；  
Accepted U.S.FDA's inspection;  
◆ 完成天然紫杉醇和10-DAT半合成紫杉醇在台湾地区TDMF注册报备。  
TDMFs of natural and 10-DAT semi-synthetic paclitaxel approved by TFDA.

2014





PRODUCT

PRODUCT

## 产品PRODUCT

### ▼ 原料药 APIs

- GMP** 天然紫杉醇 Natural Paclitaxel

**C<sub>47</sub>H<sub>51</sub>NO<sub>14</sub>**

**CAS# 33069-62-4**

**% 含量 Contents: ≥99.0% ~ 101.0%**

---

- Q** 10-DAB半合成紫杉醇  
10-DAB Semi-synthetic Paclitaxel

**C<sub>47</sub>H<sub>51</sub>NO<sub>14</sub>**

**CAS# 33069-62-4**

**% 含量 Contents: ≥99.0% ~ 101.0%**

---

- Q** 卡巴他赛 Cabazitaxel

**C<sub>45</sub>H<sub>57</sub>NO<sub>14</sub>**

**CAS# 183133-96-2**

**% 含量 Contents: ≥98%**

### ▼ 中间体 Intermediates

- ISO** 10-脱乙酰基巴卡亭III  
10-Deacetylbaaccatin III

**C<sub>29</sub>H<sub>36</sub>O<sub>10</sub>**

**CAS# 92999-93-4**

**% 含量 Contents: ≥98%**

---

- ISO** 13-乙酰基-9-羟基巴卡亭III  
13-Acetyl-9-dihydrobaaccatin III

**C<sub>33</sub>H<sub>42</sub>O<sub>12</sub>**

**CAS# 142203-65-4**

**% 含量 Contents: ≥98%**

---

- ISO** 7-O-(三乙基甲硅烷)紫杉醇  
7-O-(Triethylsilyl) paclitaxel

**C<sub>53</sub>H<sub>65</sub>NO<sub>14</sub>Si**

**CAS# 148930-55-6**

**% 含量 Contents: ≥98%**

- ISO** 紫杉醇EP杂质C  
Paclitaxel EP Impurity C

**C<sub>46</sub>H<sub>57</sub>NO<sub>14</sub>**

**CAS# 153415-45-3**

**% 含量 Contents: ≥98%**

---

- ISO** 10-去乙酰紫杉醇  
10-Docacetyl Paclitaxel

**C<sub>45</sub>H<sub>49</sub>NO<sub>13</sub>**

**CAS# 78432-77-6**

**% 含量 Contents: ≥98%**

---

- ISO** 7-表-10-去乙酰紫杉醇  
7-Epi-10-Deacetyl-Taxol

**C<sub>45</sub>H<sub>49</sub>NO<sub>13</sub>**

**CAS# 111149-94-1**

**% 含量 Contents: ≥98%**

- ISO** 巴卡亭III Baccatine III

**C<sub>31</sub>H<sub>38</sub>O<sub>11</sub>**

**CAS# 27548-93-2**

**% 含量 Contents: ≥98%**

---

- GMP** 三尖杉宁碱 Cephalomannine

**C<sub>45</sub>H<sub>53</sub>NO<sub>14</sub>**

**CAS# 71610-00-9**

**% 含量 Contents: ≥95%**

- ISO** 中间体 Condensates

**C<sub>35</sub>H<sub>38</sub>Cl<sub>6</sub>O<sub>14</sub>**

**CAS# 95603-44-4**

**C<sub>57</sub>H<sub>65</sub>Cl<sub>6</sub>NO<sub>17</sub>Si**

**C<sub>49</sub>H<sub>55</sub>Cl<sub>6</sub>NO<sub>18</sub>**

**C<sub>55</sub>H<sub>69</sub>Cl<sub>6</sub>NO<sub>18</sub>Si**

**C<sub>57</sub>H<sub>61</sub>Cl<sub>6</sub>NO<sub>19</sub>**

**CAS# 859498-31-0**

**C<sub>55</sub>H<sub>57</sub>NO<sub>15</sub>**

**CAS# 222726-76-3**

**C<sub>51</sub>H<sub>59</sub>NO<sub>15</sub>**

**% 含量 Contents: ≥98%**

- GMP** 7-(2,2,2-三氯乙氧基羰基)紫杉醇  
7-(2,2,2-Trichloroethyloxycarbonyl)taxol

**C<sub>50</sub>H<sub>52</sub>Cl<sub>3</sub>NO<sub>16</sub>**

**CAS# 114915-17-2**

**% 含量 Contents: ≥98%**

---

- ISO** 7,10-二甲氧基-10-DAB III  
10-Dimethoxy-10-DAB III

**C<sub>31</sub>H<sub>40</sub>O<sub>10</sub>**

**CAS# 183133-94-0**

**% 含量 Contents: ≥98%**

---

- ISO** 2'乙酰基紫杉醇  
2-decetyl-paclitaxel

**C<sub>49</sub>H<sub>53</sub>NO<sub>15</sub>**

**CAS# 92950-40-8**

**% 含量 Contents: ≥98%**

## 产品PRODUCT

### ▼ 植提 Phytoextraction

ISO 蜕皮激素 Hydroxyecdysone

C27H44O7

CAS# 5289-74-7

% 含量 Contents: 85-99%

ISO 人参皂苷Rb1 Ginsenoside Rb1

C54H92O23

CAS# 41753-43-9

% 含量 Contents: 10-98%

ISO 人参皂甙Rh2 Ginsenoside Rh2

C36H62O8

CAS# 78214-33-2

% 含量 Contents: 10-98%

ISO 人参皂苷Rg3 Ginsenoside Rg3

C42H72O13

CAS# 14197-60-5

% 含量 Contents: 10-98%

ISO 红杉醇 Sequoyitol

C7H14O6

CAS# 523-92-2

% 含量 Contents: 10-98%

### ▼ 在研产品 Product Under Research

ISO 石杉碱甲 Huperzine A

C15H18N2O

CAS# 102518-79-6

% 含量 Contents: N.A

GMP 高三尖杉酯碱 Homoharringtonine

C29H39NO9

CAS# 26833-87-4

% 含量 Contents: N.A

其他植物提取物

Other Phytpextraction

### ▼ 标准品 Standards

GMP 天然紫杉醇 Taxol A

C47H51NO14

CAS# 33069-62-4

% 含量 Contents: ≥99%

ISO 10-脱乙酰基巴卡亭III  
10-Deacetylbaaccatin III

C29H36O10

CAS# 92999-93-4

% 含量 Contents: ≥95%

ISO 13-乙酰基-9-羟基巴卡丁III  
13-Acetyl-9-dihydrobaaccatin III

C33H42O12

CAS# 142203-65-4

% 含量 Contents: ≥99%

ISO 7-(2,2,2-三氯乙基氧基羰基)紫杉醇  
7-(2,2,2-Trichloroethyloxycarbonyl)taxol

C50H52Cl3NO16

CAS# 114915-17-2

% 含量 Contents: ≥99%

GMP 三尖杉宁碱 Cephalomannine

C45H53NO14

CAS# 71610-00-9

% 含量 Contents: ≥95%

ISO 10-去乙酰-7差向紫杉醇  
10-Deacetyl-7-epi-paclitaxel

C45H49NO13

CAS# 78432-77-6

% 含量 Contents: ≥99%

ISO 2'乙酰基紫杉醇  
2-decetyl-paclitaxel

C49H53NO15

CAS# 92950-40-8

% 含量 Contents: ≥99%

ISO 巴卡亭III Baccatine III

C31H38O11

CAS# 27548-93-2

% 含量 Contents: ≥95%

### ▼ 服务 Other Service

植提定制服务

Phytoextraction

Customized Service

H·D