



YZ

# WELCOME





# Introduction

## 公司简介





# ABOUT US

## Development Course 发展历程

2015

Diosmin GMP and Written Confirmation

获得地奥司明GMP证书和WC

2014

Drug Rregistration Certificate of Diosmin

地奥司明获药品注册批件

2005

GMP of Natural Herbal Extracts (16-Dehydropregnenolone acetate)

植物提取药16-醋酸双烯醇酮获得GMP证书

2002

The company was changed to "Chengdu Yazhong Bio-pharmaceutical Co., Ltd." in cooperation of "the 5719th Factory of the Chinese People's Liberation Army"

与5719厂合作成立亚中生物制药

1992

Chengdu Yazhong Pharma was founded.

亚中制药成立





# 机构与人员

## Organization & Personnel

公司人数约105人, 中高级技术职称及大学本科以上技术人员30多人, 约占全体员工比重为30%。

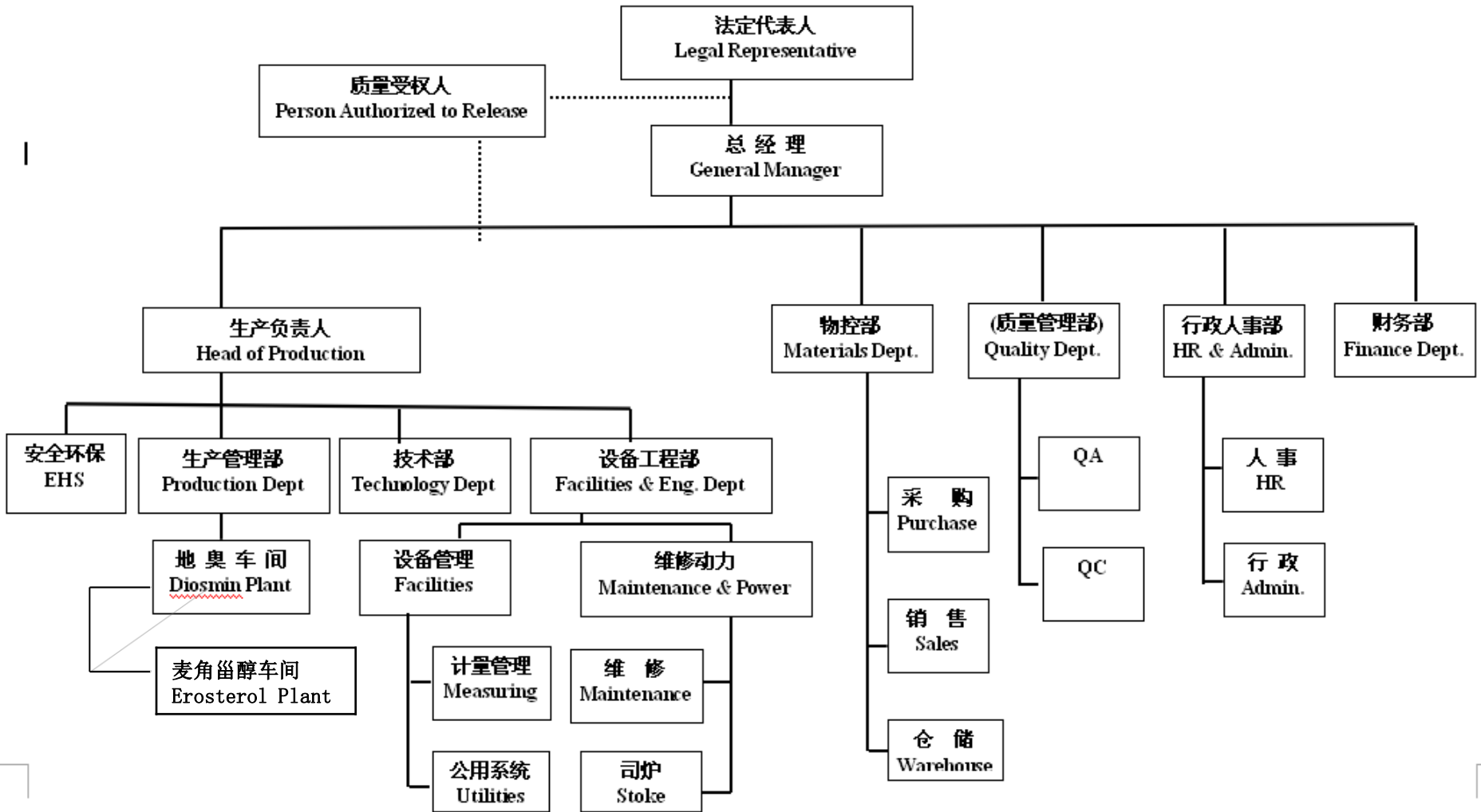
There are about 105 staff involved in Diosmin, and the number of personnel who have junior and senior technical titles is over 30, about 30% of total staff.

主要部门 Department	质量管理部 QA	质量管理部 QC	物控部 Materials	生产管理部 Production	设备工程部 Facilities	技术部 Tech.
Number	5人	8人	5人	50人	17人	2人





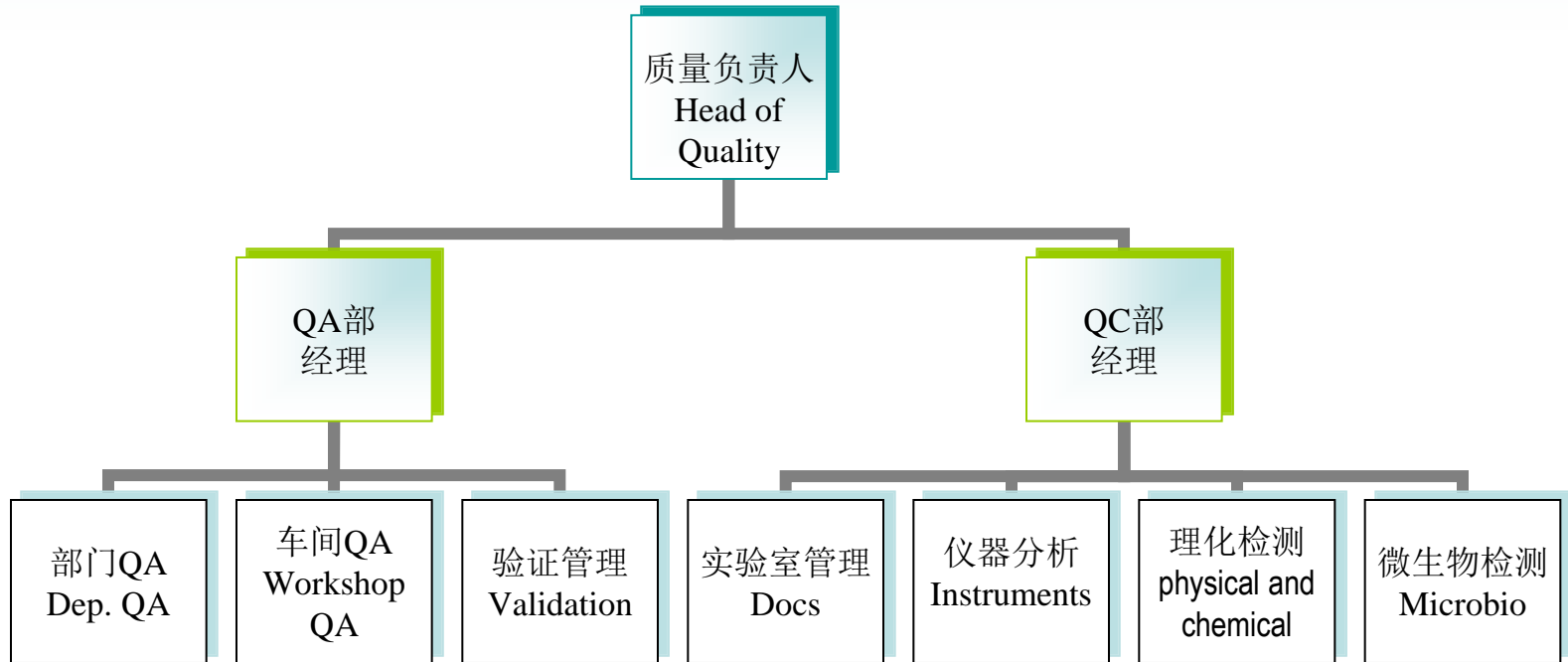
# Organization Chart 组织机构





# 机构与人员 Organization & Personnel

---质量管理部门组织机构图  
---Organization Chart of Quality Department





# Buildings and Facilities

## 厂房与设施





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# Buildings 厂房







# HVAC SYSTEM 净化空调系统





# Purified Water System

## 纯化水系统





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# Clean Area 洁净区

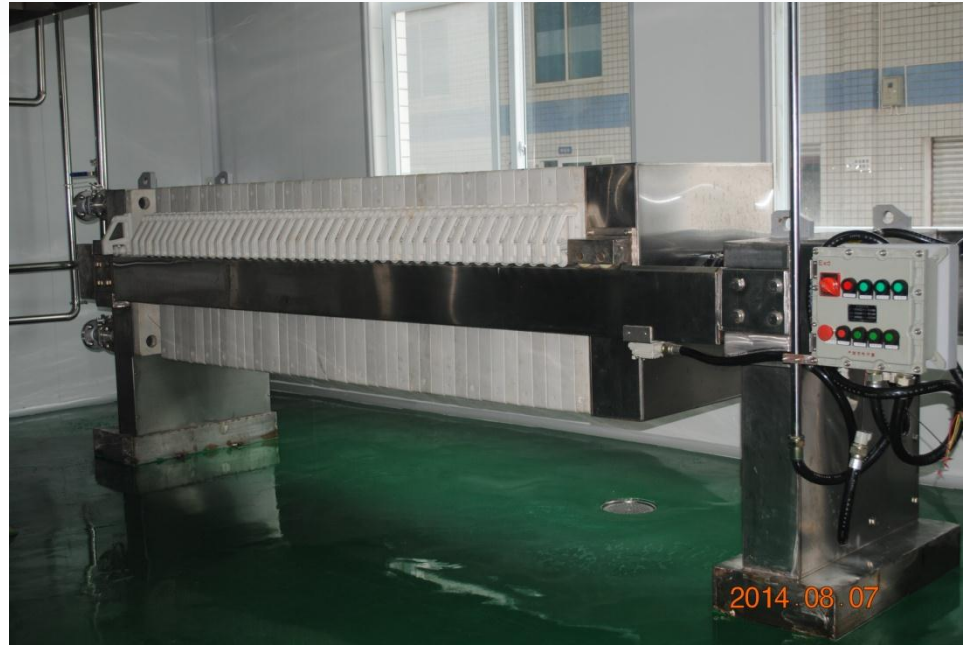


2014.08.07





# Clean Area 洁净区





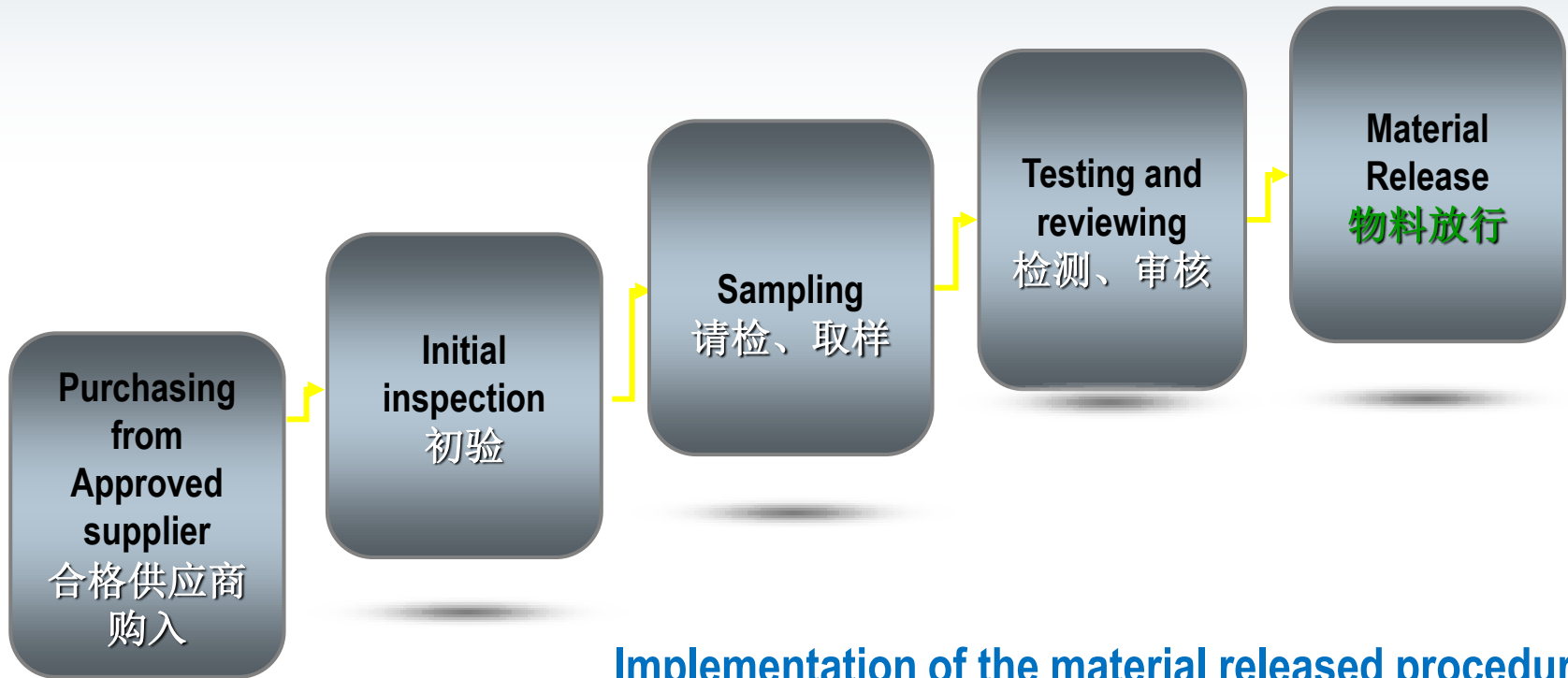
# Clean Area 洁净区





# Materials and Products

## 物料和产品



Implementation of the material released procedure

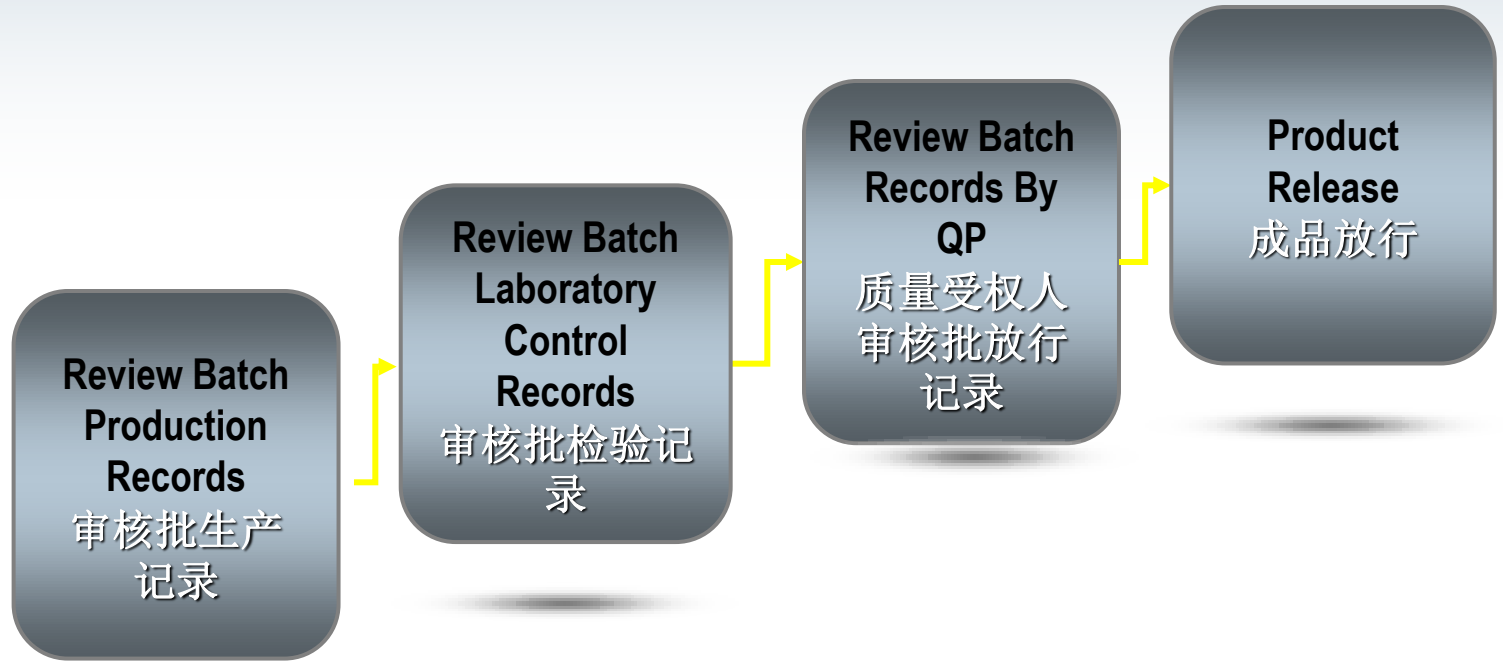
执行物料放行制度





# Materials and Products

## 物料和产品



**Product Release System**  
产品放行制度





# Production Control

## 生产管理

**Avoid contamination, mix up, and human mistake**  
避免污染、混淆和人为差错

Product and batch product documents; complete quality assurance system

建立完善质量保证体系

**Traceability of materials and product.**  
有据可查

Materials management system, IPC quality control, QA site inspection.

记录完备，标识清晰

**Operation by SOPs**  
依法办事

All operation according to the SOPs

按照规程进行生产

**Conform to GMP**  
有法可依

Manage all production activity by SMPs and SOPs.

制定详细的管理规程及操作规程







# Laboratory Controls

## 实验室控制

- ◆ QC — Responsible for sampling, test, OOS investigation, environmental monitoring and purified water monitoring
- ◆ QC —负责取样、检验、OOS调查、环境监测和纯化水监测
- ◆ QC — Making sure the test method is confirmed and validated
- ◆ QC —确保分析方法经过验证
- ◆ QC — Reference standard management
- ◆ QC —标准品管理
- ◆ QC — Record and document management system and data integrity.
- ◆ QC —文件记录管理及数据完整性
- ◆ QC —stability study
- ◆ QC —稳定性考察





# Agilent-6850 GC 气相色谱仪





# LC-2010AHT HPLC 高效液相色谱仪





# Agilent HPLC 高效液相色谱仪





# Laboratory Testing Equipments

## 质量检测设施



**Laser Particle Analyzer**  
激光粒子分析仪



**WHG-30A IR 红外分光光度计**



**Metrohm 870 KF Titrino**  
卡尔费休氏水分测定仪





# Laboratory Testing Equipments

## 质量检测设施



1900PC UV 紫外分光光度计



Microbiological Testing 微生物检测





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# Quality Assurance 质量保证

- ◆ Established quality policy and quality objectives, and quality management system; Clear responsibilities of personnel and department at all levels.
- ◆ 建立质量方针和质量目标，质量管理体系，明确各级人员职责。
- ◆ Quality risk management : For Quality defects and complaints, trend analysis, Major Deviation , OOS, and exceptions in validation, need to initiate risk management.
- ◆ 制定质量风险管理程序，对质量缺陷、投诉、趋势分析、主要偏差、调查和OOS结果以及验证过程中的异常情况，启动风险管理；
- ◆ Change Control : Established formal change control system, reviewed and approved by the quality unit. All Changing records should be archived in QA department. Major changes will be informed to customers and regulatory agency.
- ◆ 变更控制：对变更进行分类，所有变更均经质量保证部审核、批准后实施，变更均进行记录，涉及变更的记录由QA部归档保存。重大变更将会通知到客户以及注册部门。





# Quality Assurance 质量保证

- ◆ Handling of Deviation: Deviation report, record, investigating, handing, records kept in the QA.
- ◆ 偏差处理：偏差报告、记录、调查、处理及记录
- ◆ Supplier management : selection, evaluation, audit and approval and continue to improve.
- ◆ 供应商管理：供应商选择、评估和审核
- ◆ Complaints and recall : record, response briefly first, investigation, risk evaluation, root reason analysis, CAPA, or recall product as required, report to management or regulatory agency timely.
- ◆ 用户投诉和产品召回：记录、反馈、调查、风险评估、根本原因分析、CAPA、产品召回、报告







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# Documentation 文件管理



文件 (sort)

文件类别 (file)

标准管理规程  
(standard management procedures)

质量保证管理 (QA)

质量控制管理 (QC)

行政人事管理 (Admin & HR)

生产管理 (Production)

物控管理 (PMC)

设备管理 (Facility)

验证管理 (VM)

操作管理规程  
(standard operating procedures)

行政人事操作 (Admin & HR)

质量操作 (QC)

生产操作 (production)

设备操作 (Facility)

技术性文件  
(technical documentation)

产品工艺规程 (Manufacturing Process)

质量标准 (Specifications) /  
检验操作规程 (SOP-QC)

验证/确认 (VM)

记录 (Records)

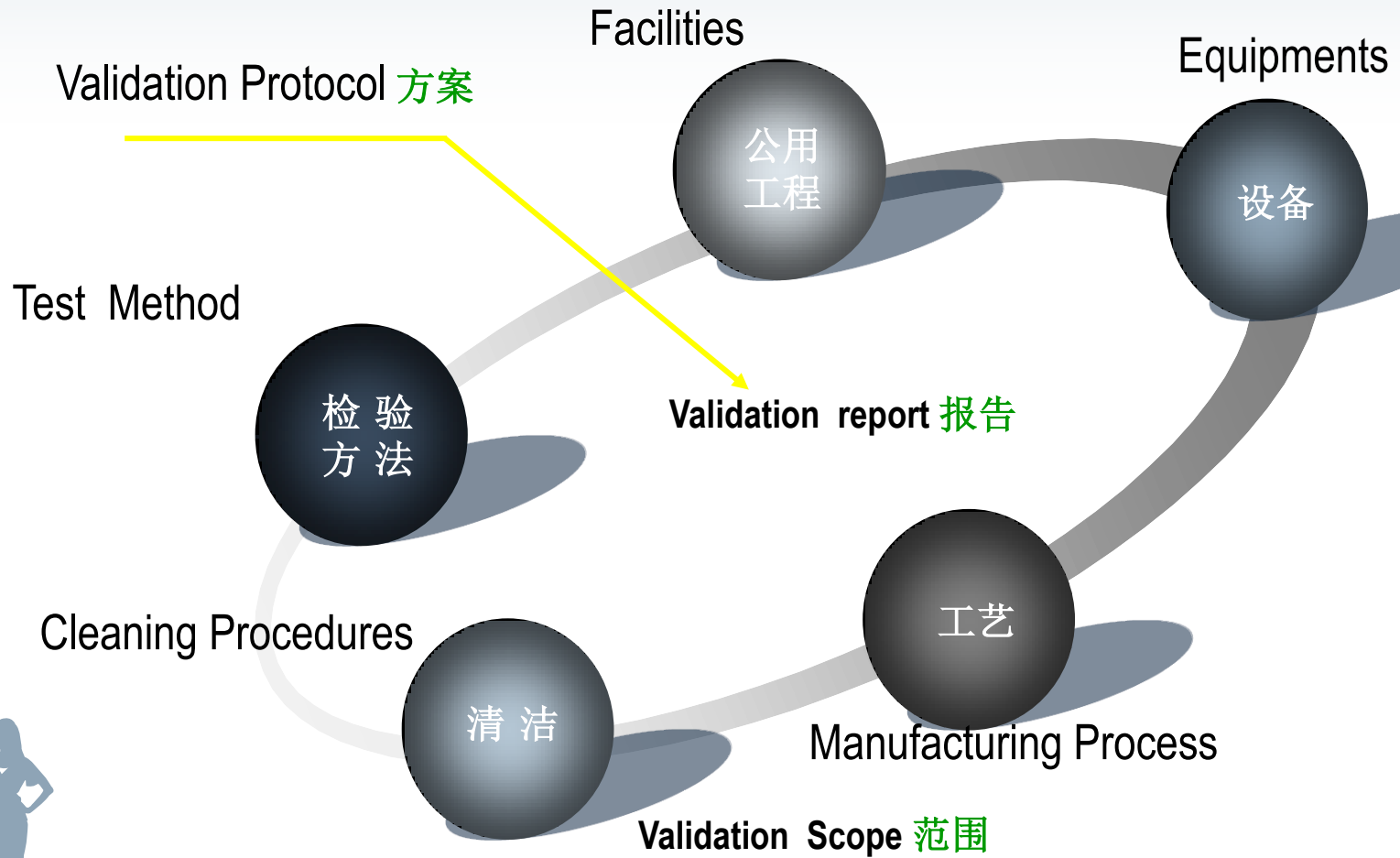




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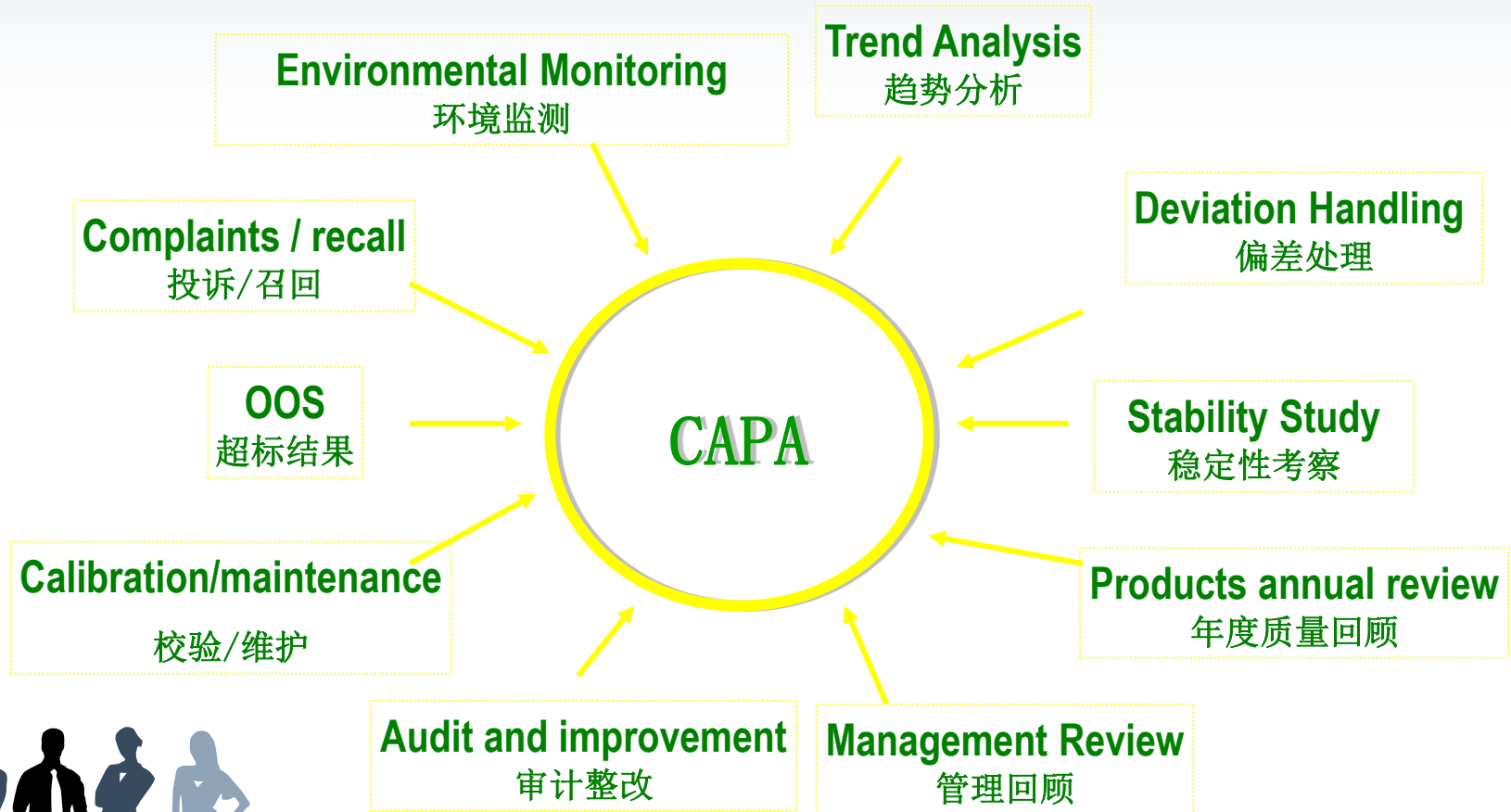
# Validation 验证

VMP 验证总计划





# CAPA





## Diosmin (地奥司明)

Other Name (别名) : Diosmina, Diosmine

CAS No. (化学文摘号) : 520-27-4

Molecular Formula (分子式) :  $C_{28}H_{32}O_{15}$

Specification (规格): Diosmin EP Non-Micronized

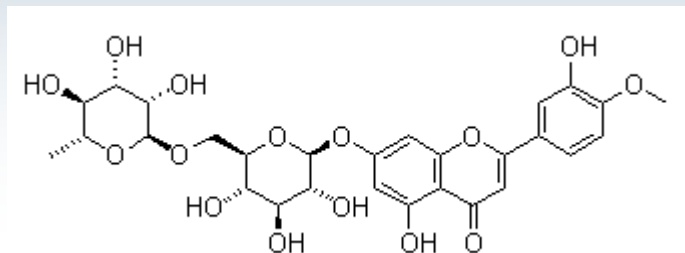
Diosmin EP Micronized

Diosmin/Hesperidin (90/10)

Diosmin/Hesperidin (90/10)

Indication: Help maintain a healthy venous system and cure acute hemorrhoid.

适应症: 治疗静脉曲张; 治疗急性痔疮发作有关的各种症状





## Diosmin (地奥司明)

Documents Available:

Certificate of GMP

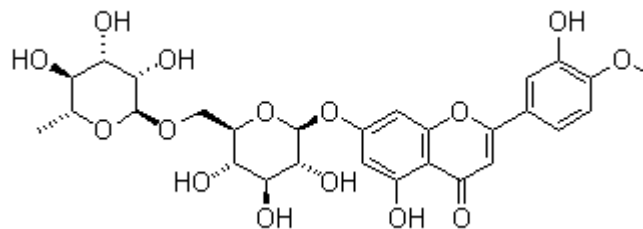
WC for Active Substance Exported to EU

SMF

DMF in CTD format

TSE / BSE certificate

MSDS





## **ERGOSTEROL 麦角甾醇**

### **【Character 性状】**

White Crystalline powder

本品为白色片状或针状晶体，无臭，无味

### **【Item 项目】**

**Melting Point 熔点：** 157~164°C

**Specific Point 比旋度：**  $\geq -120^\circ$

**Purity 纯度：**  $\geq 97.0\%$





# Certificates 证书

**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： SC20140104  
Certificate No. : SC20140104

企业名称： 成都亚中生物制药有限责任公司  
*Manufacturer :* Cheng Du YaZhong Bio-Pharmaceutical Co.,Ltd.

地 址： 四川省彭州市丽春镇（生产车间：地奥司明生产车间）  
*Address :* Lichun Town Pengzhou City, Sichuan Province (Workshop: Diosmin Workshop)

认证范围： 原料药（地奥司明）  
*Scope of Inspection :* Bulk Drug (Diosmin)

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 2020年 02月 27日  
*This certificate remains valid until 27/02/2020*

发证机关：  
*Issued By*

*Date for Issuing* 28/02/2015 2015年 02月 28日

**国家食品药品监督管理局制**  
PRINTED BY STATE FOOD AND DRUG ADMINISTRATION





# Certificates 证书

**中华人民共和国**  
**四川省食品药品监督管理局**  
**出口欧盟原料药证明文件**  
**PEOPLE'S REPUBLIC OF CHINA**  
**SICHUAN FOOD AND DRUG ADMINISTRATION**  
**Written confirmation for active substances exported to EU**

Confirmation no. (given by the issuing regulatory authority):  
 证明文件编号: SC150001

1. Name and address of site (including building number, where applicable):  
 Cheng Du YaZhong Bio-Pharmaceutical Co., Ltd.  
 Lichuan Town Pengzhou City, Sichuan Province (Workshop: Diosmin Workshop)  
 工厂名称与地址(包括建筑物门牌号): 成都亚中生物制药有限公司, 四川省彭州市丽春镇
2. Manufacturer's licence number(s):  
 《药品生产许可证》编号: 川 20100321

REGARDING THE MANUFACTURING PLANT UNDER (1) OF THE FOLLOWING ACTIVE SUBSTANCE(S) EXPORTED TO THE EU FOR MEDICINAL PRODUCTS FOR HUMAN USE

项目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 (药品通用名)	Activity(ies) 加工方法	Chinese drug approval number 中国药品批准文号
地奥司明 Diosmin	化学合成 Chemical synthesis	国药准字 H20143088

THE ISSUING REGULATORY AUTHORITY HEREBY CONFIRMS THAT:  
 兹证明:

This manufacturing plant complies with the requirements of the Chinese Good Manufacturing Practice (= GMP of EU, WHO/ICH Q7);  
 该企业所实施的 GMP 符合中国药监 GMP 要求, 等同于欧盟、世界卫生组织以及 ICH Q7 药品 GMP 要求;

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure the protection of public health, which is at least equivalent to that in the EU; and

该生产工厂接受定期、严格和透明的监管以及有预兆的药品 GMP 监督检查, 包括反复的飞行检查, 确保保护公众健康, 其水平与欧盟相当; 并且

该出口口的原料药在此栏填写“无”。  
 Record "none" in case where there is for export-only active substance.



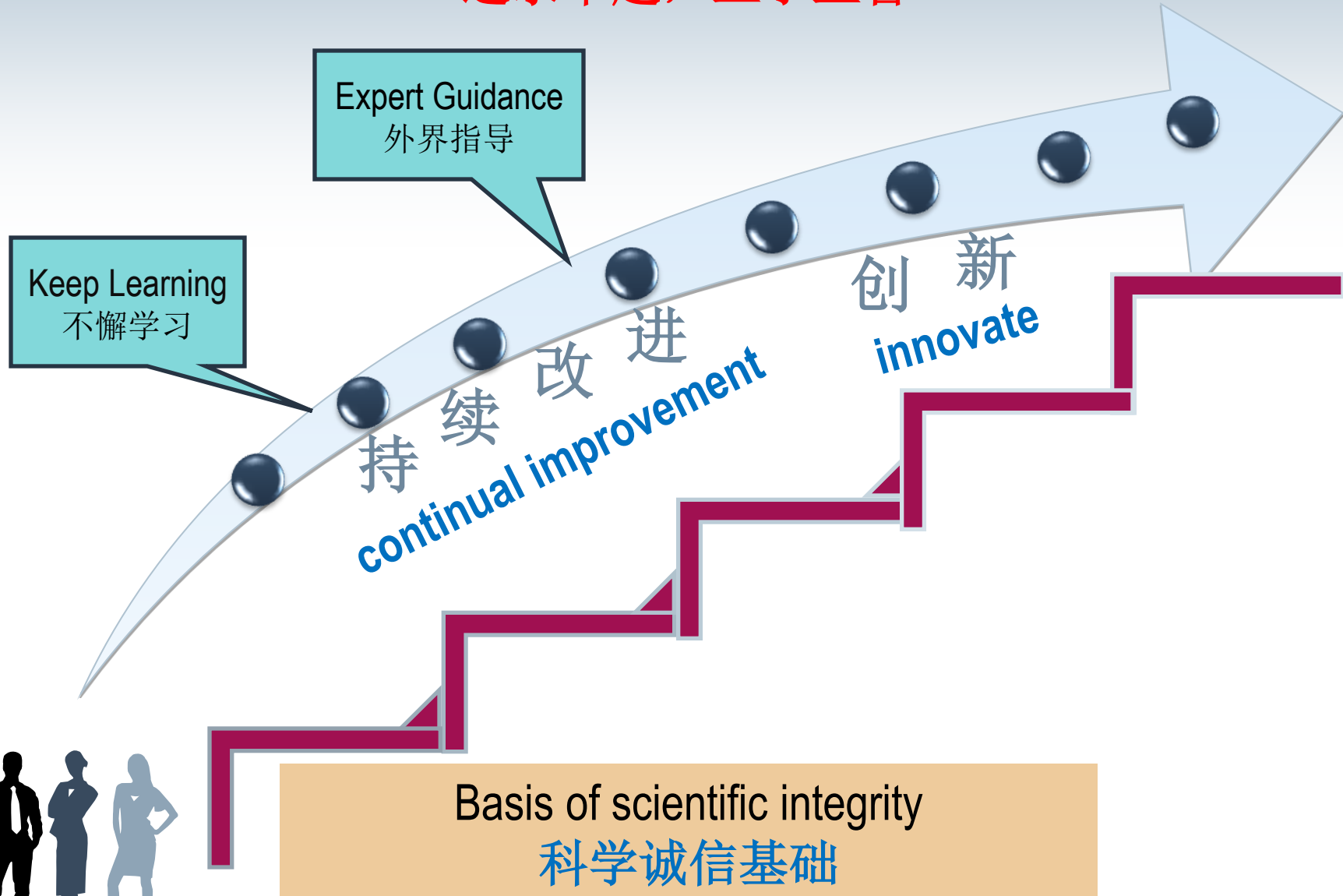




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# Pursue Excellence , Strive for Perfection

## 追求卓越，止于至善





**THANK YOU**

