



## 河北常山生化药业股份有限公司

Hebei Changshan Biochemical Pharmaceutical Co.,Ltd

肝素系列原料药国际知名供应商

Internationally known company manufacturing heparin and related products

# COMPANY PROFILE

## 公司简介

Hebei Changshan Biochemical Pharmaceutical Co.,Ltd, abbreviated as "CSBIO", was established in 2000, which is one of the few specialized manufacturing enterprises with complete industrial chain in domestic heparin industry. Our new plant covers an area of 145,000 square meters, with 12,686 square meters for API workshop, 16,380 square meters for FDF workshop, and 9,186 square meters for warehouse.

河北常山生化药业股份有限公司，简称“常山药业”，股票代码：300255，创建于2000年，目前是国内肝素行业中少数具有完整产业链的专业化生产企业之一。新厂区占地面积145000m<sup>2</sup>，其中原料车间12686m<sup>2</sup>，制剂车间16380m<sup>2</sup>，综合仓库9186m<sup>2</sup>。



- 
- 2021** ● Set up ChangShan Europe S.R.L.  
成立常山欧洲有限公司
  - 2018** ● Set up Hebei Changshan Hep Crude Biotechnology Co., Ltd  
成立河北常山凯库得生物技术有限公司
  - 2017** ● Set up Hebei Changshan Hyaluronic Biotech Co.,Ltd  
成立河北常山凯络尼特生物技术有限公司
  - 2016** ● Set up Sino-Germany JV company - CS D.MED GmbH  
成立中德合资公司-常山德迈生物有限公司
  - Set up Changshan Hemodialysis center  
成立石家庄新华常山药业血液透析中心
  - Set up Hebei Changshan Jiukang Biotechnology Co., Ltd  
成立河北常山久康生物科技有限公司
  - 2015** ● Set up Shijiazhuang Changshan Pharmacy  
成立石家庄常山大药房
  - Set up Hebei Meishan Polysaccharide & Polypeptide Technology Co., Ltd  
成立河北梅山多糖多肽科技有限公司
  - 2014** ● Set up Changshan Pharma (Hongkong)  
成立常山药业（香港）有限公司
  - Set up Jiukang Medical Investment Management (Hebei) Co., Ltd  
成立久康医疗投资管理河北有限公司
  - 2013** ● New plant establishment and operation  
新厂区建立运营
  - Set up Sino-America JV company -Changshan Conjuchem  
Biopharmaceutical R&D (Hebei) Co.,Ltd.  
成立中美合资公司-常山凯捷健生物药物研发（河北）有限公司
  - 2012** ● Acquisition subsidiary company-Changshan Biochemical Pharmaceutical (Jiangsu)  
Co., Ltd.  
收购分公司-常山生化药业（江苏）有限公司
  - 2011** ● Shenzhen Stock Exchange IPO  
深交所创业板上市
  - 2000** ● Company establishment  
公司建立

# API PRODUCTS

## 原料产品

### Heparin Sodium

#### 肝素钠

Grade: Injectable / Topical / Crude  
级别：注射级/外用级/粗品  
Capacity: 5 million mega / year  
产能：5万亿单位/年  
Specification: EP / USP / BP / CP / IP  
规格：EP/USP/BP/CP/IP  
Packaging: 5kgs/tin  
包装：5公斤/铝箔袋

### Heparin Calcium

#### 肝素钙

Grade: Injectable  
级别：注射级  
Capacity: Customized  
产能：订单式生产  
Specification: EP / USP / BP / CP  
规格：EP/USP/BP/CP  
Packaging: 5kgs/tin  
包装：5公斤/铝箔袋

### Heparin Lithium

#### 肝素锂

Grade: Injectable  
级别：注射级  
Capacity: Customized  
产能：订单式生产  
Specification: In-house specification  
规格：企业标准  
Packaging: 1kg/tin  
包装：1公斤/铝箔袋

### Enoxaparin Sodium

#### 依诺肝素钠

Grade: Injectable  
级别：注射级  
Capacity: 5,000 kgs / year  
产能：5000公斤/年  
Specification: EP / USP / BP / IP  
规格：EP/USP/BP/IP  
Packaging: 5kgs/tin  
包装：5公斤/铝箔袋

### Nadroparin Calcium

#### 那屈肝素钙

Grade: Injectable  
级别：注射级  
Capacity: 3,000 kgs / year  
产能：3000公斤/年  
Specification: EP / BP  
规格：EP/BP  
Packaging: 3kgs/tin  
包装：3公斤/铝箔袋

### Dalteparin Sodium

#### 达肝素钠

Grade: Injectable  
级别：注射级  
Capacity: 3,000 kgs / year  
产能：3000公斤/年  
Specification: EP / USP / BP  
规格：EP/USP/BP  
Packaging: 3kgs/tin  
包装：3公斤/铝箔袋

## Heparinoid

类肝素

Capacity: 3,000 kgs / year

产能：3000公斤/年

Specification: In-house specification

规格：企业标准

Packaging: 15kgs/ drum

包装：15公斤/纸板桶

## Sildenafil Citrate

枸橼酸西地那非

Grade: Pharmaceutical Grade

级别：药用级

Specification : Inhouse

规格：内控

## Sodium Hyaluronate

透明质酸钠

Grade: Cosmetic/ Food/ Eye Drop/  
Injectable Grade

级别：化妆品级/食品级/滴眼液级/注射级

Capacity: 21MT/year

产能：21吨/年

## Ectoin

依克多因

Grade: Cosmetic

级别：化妆品级

Capacity: 21MT/year

产能：21吨/年



# INJECTION PRODUCT

## 注射液产品

### 肝素钠注射液 Heparin Sodium Injection

规格/ Strength:  
5ml:25000IU 5ml:5000IU

包装/ Package:  
5西林瓶/盒  
5Vials/Box



#### 适应症/ Indications:

防治血栓形成或栓塞性疾病（如心肌梗死、血栓性静脉炎、肺栓塞等）

预防各种原因引起的弥漫性血管内凝血(DIC)

用于血液透析、体外循环、导管术、微血管手术等操作中及某些血液标本或器械的抗凝处理

1. Prophylaxis of deep vein thrombosis and pulmonary embolism.
2. Treatment of deep vein thrombosis and pulmonary embolism, unstable angina pectoris and acute peripheral arterial occlusion.
3. Prophylaxis of mural thrombosis following myocardial infarction.
4. In extracorporeal circulation and haemodialysis.

### 依诺肝素钠注射液 Enoxaparin Sodium Injection

规格/ Strength:  
0.2ml:2000IU 0.4ml:4000IU 0.6ml:6000IU 0.8ml:8000IU

包装/ Package:  
2支预灌针注射器/盒  
2 Prefilled Syringes / Box



#### 适应症/ Indications:

预防和治疗静脉血栓栓塞性疾病

治疗不稳定性心绞痛及非Q波心肌梗死

治疗急性ST段抬高型心肌梗死

1. Prophylaxis of Deep Vein Thrombosis
2. Treatment of Acute Deep Vein Thrombosis
3. Prophylaxis of Ischemic Complications of Unstable Angina and Non-Q-Wave Myocardial Infarction
4. Treatment of Acute ST-Segment Elevation Myocardial Infarction

## 那屈肝素钙注射液 Nadroparin Calcium Injection

### 规格/ Strength:

0.4ml:4100IU 0.6ml:6150IU

### 包装/ Package:

2支预灌针注射器/盒

2 Prefilled Syringes / Box

### 适应症/ Indications:

在外科手术中，用于静脉血栓形成中度或高度危险的情况，预防静脉血栓栓塞性疾病

治疗已形成的深静脉血栓

联合阿司匹林用于不稳定性心绞痛和非Q波性心肌梗死急性期的治疗

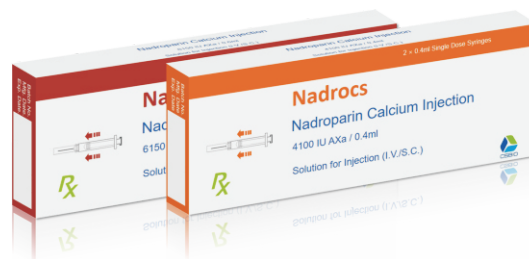
在血液透析中预防体外循环中的血凝块形成

1. During surgery, it is used in cases of moderate or high risk of venous thrombosis to prevent venous thromboembolic disease.

1. Treatment of deep vein thrombosis

2. Combined with aspirin for the acute phase of unstable angina and non-Q-wave myocardial infarction.

3. Prevent the formation of blood clots during cardiopulmonary bypass during hemodialysis.



## 达肝素钠注射液 Dalteparin Sodium Injection

### 规格/ Strength:

0.2ml:5000IU, 0.3ml:7500IU

### 包装/ Package:

2支预灌针注射器/盒

2 Prefilled Syringes / Box

### 产品说明/ Indications:

治疗血栓(静脉血栓栓塞)和防止复发

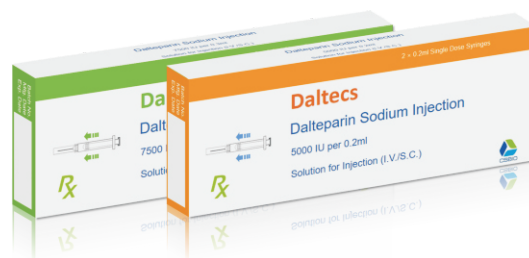
治疗不稳定性冠状动脉疾病

血液透析时防止体外循环系统中凝血

1. Treat blood clots (venous thromboembolism) and to prevent their recurrence

2. Treat unstable coronary artery disease.

3. Prevention of clotting in extracorporeal circuits in hemodialysis



# NEW PRODUCT

## 新产品

Name

Strength

**Albenatide Injection**  
**艾本那肽注射液**

0.2ml : 2mg

Albenatide injection is a GLP-1 long-acting diabetes drug, which is injected once a week. It was developed by CSBIO since 2000. Complete clinical trial has been completed in 2023, and achieved the expected clinical results.

艾本那肽注射液是由常山药业在2000年开始研发的一款长效GLP-1类糖尿病药物，2023年完成III期临床，达到预期临床效果。

**适应症/ Indications:**

This product is suitable for the treatment of patients with type 2 diabetes.

本产品适用于2型糖尿病患者的治疗。

**剂型/ Dosage form:**

Injection

注射液

**给药途径及方法/ Route and method of administration:**

Subcutaneous injection, once a week.

皮下注射，每周一次。





# DIVERSIFIED INDUSTRIAL STRUCTURE

## 多元化产业结构



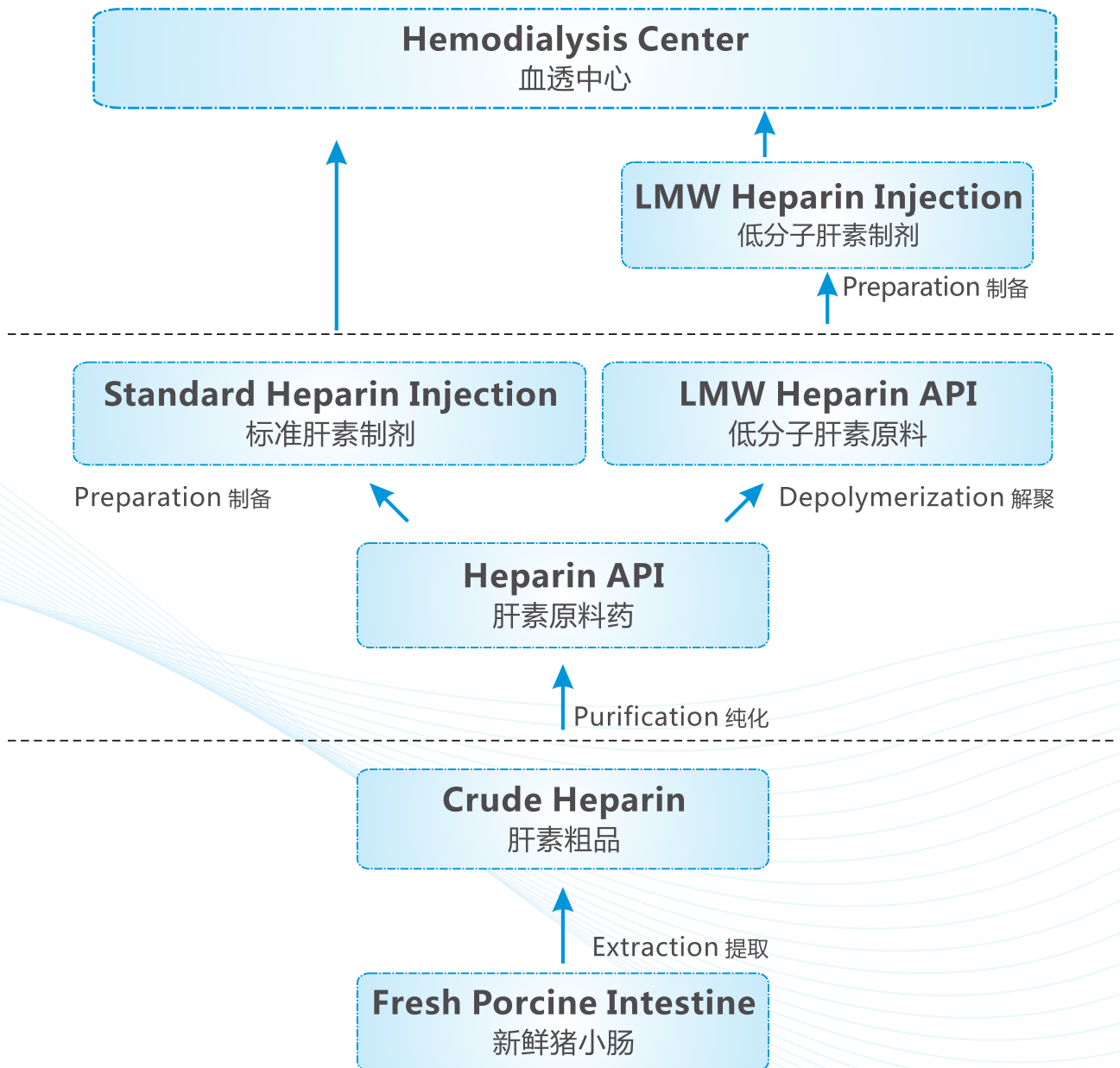
### INDUSTRY INTRODUCTION 旗下产业介绍

For many years, CSBIO has focused on the research and development and registration of heparin series products and hyaluronic acid series products at home and abroad, and will gradually increase its research and development efforts in the fields of diabetes drug albenatide and Antineoplastic drug c-met. We will build a strategic layout with the heparin series as the core and the development of multi-disciplinary innovative drugs.

常山药业多年来专注于肝素系列产品、透明质酸系列产品在国内外的研发与注册，而今后将逐步加大对糖尿病药艾本那肽、抗肿瘤药c-met 等领域的研发力度，打造以肝素系列产品为核心，以多领域创新药为发展的战略布局。

# COMPLETE HEPARIN PRODUCTION CHAIN

## 完整产业链





Based on the integrated management experiences and technical advantages, CSBIO has built its crude heparin base, which helps to guarantee the product quality and stability.  
常山药业依据自身丰富的管理经验和技術优势，建立自己的粗品肝素基地，从而保证产品的质量和稳定性。



The first dialysis center is located in the center of Shijiazhuang City. Bed: 80  
第一家透析中心位于石家庄市中心。总床位80张。

Cooperating with D.Med company and introducing the European dialysis technology and conception into China.  
与德国D.Med公司合作，把欧洲先进的透析技术及理念引入中国。



# QUALITY MANAGEMENT

## 质量管理

CSBIO's quality management system is in full compliance with ICH Q7 and other applicable industry guidelines.

We guarantee that every step of our manufacturing process is controlled and recorded, and our raw material is fully traceable.

CSBIO's quality dynamic management system insures all heparin products meet the most current CP, EP and USP quality standard.

常山药业的质量管理体系完全符合ICH Q7和其他适用的行业准则。

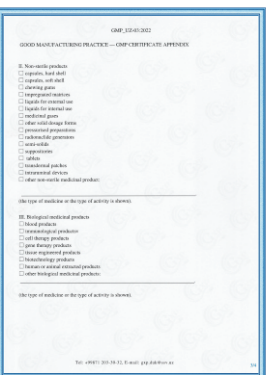
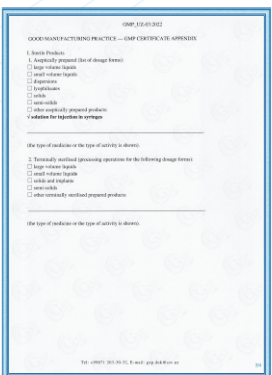
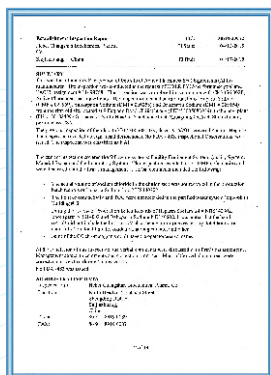
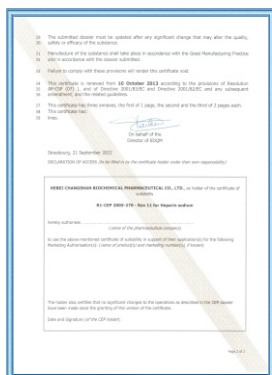
我们保证我们制造过程的每一步都受控制并记录，而且我们的原材料是完全可追溯的。

常山药业的质量动态管理系统可确保所有的肝素产品符合最新的CP，EP和USP质量标准。



# GMP CERTIFICATION LIST AND RELATED CERTIFICATES FOR THE PAST FIVE YEARS

## 近五年GMP认证清单及相关证书



# CHANGSHAN R&D INSTITUTE

## 药物研究院

Changshan R&D Institute, consisting of Polysaccharide Research Lab, Analytical Lab, Pharmaceutical Formulation Lab, Generic Drug Research Lab, Polypeptide Synthesis Lab, Polypeptide Bioactivity Analytical Lab, Molecular Biology Lab, Cell Lab, and Large molecular Bioanalytical Lab, etc., has developed a variety of advanced technology and Market-oriented products, with innovative drug, heparin and generic drugs as the key products, relying on talents and technical advantages.

常山药物研究院，设有多糖研究实验室、分析实验室、制剂实验室、仿制药研究实验室、多肽合成实验室、多肽生物活性分析实验室、分子生物学实验室、细胞实验室和大分子生物分析实验室等，以创新药、肝素类产品和仿制药为核心，依托人才和技术优势，开发出多种先进技术和市场急需产品。



## SALES MARKET

### 销售网络



Heparin sodium and Low molecular weight heparins API/FDF of CSBIO have been exporting to more than forty countries all over the world.

常山药业的肝素钠和低分子肝素原料药及制剂已经远销全球四十多个国家。

企业宗旨：一切为了人类健康事业  
*The enterprise tenet... All for human healthcare*



## 河北常山生化药业股份有限公司

Hebei Changshan Biochemical Pharmaceutical Co.,Ltd

Add: No.71, Menglong Street, South District of Zhengding High-tech Industrial Development Zone, Zhengding Area of China (Hebei) Pilot Free Trade Zone.

地址：中国(河北)自由贸易试验区正定片区正定县高新技术产业开发区南区梦龙街71号

### API sales department

Tel: 86-311-89190165

E-mail: info@hbcsbio.com

### API domestic sales department

Tel: 86-311-89190161

E-mail: info@hbcsbio.com

### FDf export department

Tel: 86-311-89199752

E-mail: FDF@hbcsbio.com

### Import trade department

Tel: 86-311-89190279

E-mail: yajie.zhang@hbcsbio.com

### Administration

Tel: 86-311-89190198

E-mail: csad@hbcsbio.com

### 原料药销售出口部

电话：0311-89190165

邮箱：info@hbcsbio.com

### 原料药销售内贸部

电话：0311-89190161

邮箱：info@hbcsbio.com

### 制剂出口部

电话：0311-89199752

邮箱：FDF@hbcsbio.com

### 进口贸易部

电话：0311-89190279

邮箱：yajie.zhang@hbcsbio.com

### 行政部

电话：0311-89190198

邮箱：csad@hbcsbio.com