



China Heparin Industry Report, 2010-2011

Sep. 2011

This report

- ◆ **Analyzes the status quo of China heparin industry and operating environment**
- ◆ **Focuses on the heparin API and heparin preparation industry development.**
- ◆ **Highlights the operation of major heparin manufacturers in China.**

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Abstract

With richness in heparin materials and the quality of heparin API getting accredited by the international community, China has become one of the largest heparin API producers and exporters in the world. In 2010, there were 24 heparin API manufacturers with the heparin sodium API production license granted by SFDA in China, with the export volume of heparin API reaching 15.9 trillion units, a 52.1% market share globally.

Export Volume and Proportion in the World of Heparin API in China, 2007-2010 (trillion units)



Source: ResearchInChina

Europe and America are the major export destinations of heparin API made in China. From January to July of 2011, heparin and heparinate made in China were exported to 44 countries. In terms of export volume, the top 5 export destinations were France, Germany, America, Austria and Italy, with the combined export volume standing at 83.7%.

It is required to obtain CEP certification of EU or FDA authentication of the US for companies to access into the European and American markets. Due to the stringent authentication criterion, many unqualified enterprises are forced to withdraw from the market. As of August, 2011, China had 6 CEP certified heparin API producers and 2 FDA certified ones. In particular, both Shenzhen Hepalink Pharmaceutical and Changzhou Qianhong Bio-Pharma obtained the two certifications, an edge over the oppositions.

Although it is a large producer of heparin API, the production of downstream unfractionated heparin (UFH) sodium preparations and low-molecular-weight (LMW) heparin preparations in China is still in its infancy.

In the UFH preparation market, 26 Chinese companies have obtained the heparin sodium injection drug production licenses granted by SFDA. Due to the mounting pressure arising from the soaring price of heparin API, there are less than 10 companies that seem competitive in Chinese market, such as Tianjin Biochemical Pharmaceutical, Wanbang Biopharmaceuticals and Shanghai No.1 Chemical & Pharmaceutical, but all of them need to procure upstream raw material for production.

Restricted by the technology, the LMW heparin preparation market of China is dominated by foreign brands. In 2009, Chinese markets of LMW heparin sodium and LMW heparin calcium were dominated by France-based Sanofi's Clexane and GSK's Fraxiparine, topping the market with the respective share of 54.5% and 59.0%. However, the LMW heparin preparation products made by domestic companies become increasingly competitive with the enhanced strength in R&D and technology. For instance, the sales of Hebei Changshan Biochemical Pharmaceutical, a company producing LMW heparin calcium injection, rose 72.6% YoY to RMB51.612 million in 2010.

1. Profile of Heparin Industry

- 1.1 Definition & Classification
- 1.2 Industry Chain

2. International Operating Environment of Heparin Industry

- 2.1 Demand of Heparin Medicine
- 2.2 Distribution of Heparin Medicine Demand
- 2.3 Heparin API Demand
- 2.4 Overseas Competitors
- 2.5 Related Policies
- 2.6 Market Forecast

3. Current Development of China Heparin API Industry

- 3.1 Market Overview
- 3.2 Demand & Supply
- 3.3 Competition
- 3.4 Dynamics
- 3.5 Related Policies
- 3.6 Market Forecast

4. Current Development of China Heparin Preparation Industry

- 4.1 Overview of Antithrombotic Drugs
- 4.2 Market Overview
- 4.3 UFH Preparations

4.3.1 International Environment

4.3.2 Market Size

4.3.3 Competition

4.4 LMW Heparin Preparations

4.4.1 International Environment

4.4.2 Market Size

4.5 Demand & Supply

4.6 Competition

4.7 Dynamics & Patents

4.8 Market Forecast

5. Import & Export

5.1 Export

5.1.1 Export Volume

5.1.2 Export Destinations

5.2 Import

5.2.1 Import Destinations

5.2.2 Import Origins

6. Heparin Manufacturers in China

6.1 Shenzhen Hepalink Pharmaceutical

6.1.1 Profile

6.1.2 Operation

6.1.3 Dynamics

6.2 Changzhou Qianhong Bio-Pharma Co., Ltd

6.1.1 Profile

6.1.2 Operation

6.1.3 Dynamics

6.2 Changzhou Qianhong Bio-Pharma Co., Ltd

6.2.1 Profile

6.2.2 Operation

6.2.3 Dynamics

6.3 Tianjin Chase Sun Pharmaceutical

6.3.1 Profile

6.3.2 Operation

6.3.3 Dynamics

6.4 Hebei Changshan Biochemical Pharmaceutical

6.4.1 Profile

6.4.2 Operation

6.4.3 Dynamics

6.5 Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd

6.5.1 Profile

6.5.2 Operation

6.6 Yantai Dongcheng Biochemicals Co., Ltd

6.6.1 Profile

6.6.2 Operation

6.7 Wanbang Biopharmaceuticals

6.7.1 Profile

6.7.2 Operation

6.7.3 Dynamics

- 
- Application of Heparin Preparations
 - Heparin Industry Chain
 - Sales of Heparin Drugs Worldwide, 2003-2012E
 - Distribution of Heparin Drug Consumption Worldwide, 2010
 - Market Size and Growth Rate of Heparin API Worldwide, 2007-2013
 - Forecast of Global Heparin Drug Market Development
 - Export Volume and The Global Proportion of Heparin API in China, 2007-2010
 - Number of Slaughtered Fattened Hogs (Head) and Year-end Number of Hogs (Head) of China, 2003-2010 Price Trend of Crude Sodium Heparin API in China, 2008-2010
 - Top ten Pharmaceutical Companies by Export Value of Heparin in China, Jan.-Sep.2010
 - Gross Margin of Major Heparin API Manufacturers in China, 2008-2010
 - Heparin Sodium API Supply in China and the World and China's Share, 2011-2013
 - China Antithrombotic Drug Market Size, 2003-2012
 - Market Share of China's Major Varieties of Anti-thrombosis Drug in Hospital, 2005-2009
 - Market Size of Heparin Drug in China,2007-2013
 - Chinese Market Share of Heparin Preparation Products, 2009
 - Market Size of Global UFH Preparations,2006-2012
 - Sales of UFH Preparations in China,2006-2012
 - Market Demand for Heparin Sodium Injection Solution in China, 2007-2012
 - Manufacturers of Heparin Sodium Injection Solution and Heparin Calcium Injection Solution in China
 - Operation of Major UFH Preparations Manufacturers in China,2008-2009
 - Performance Comparison between Low Molecular Weight Heparin Preparations and UFH Preparations
 - Market Size of Global Low Molecular Weight Heparin Preparations,2006-2012
 - Market Size of Low Molecular Weight Heparin Preparations in China,2006-2010
 - Proportion of Low-molecular Heparin Calcium and Low-molecular Heparin Sodium in Anticoagulant Medicines of China, 2005-2011

- Manufacturers of Low-molecular Heparin Sodium Preparations and Low-molecular Heparin Calcium Preparations
- Competition Pattern of China Low-Molecular-Weight Heparin Sodium Market, 2009
- YoY Growth Rate for Sales of Main Competitive Enterprises of Low-molecular Weight Heparin Sodium in China, 2009
- Competition Pattern of China Low-Molecular-Weight Heparin Calcium Market, 2009
- YoY Growth Rate for Sales of Main Competitive Enterprises of Low-molecular Weight Heparin Calcium in China, 2009
- Main Patents for LMW Heparin
- China LMW Heparin Drug Market Size, 2010-2014
- Export of Key Western Medicines of China, Jan.-Jul. 2011
- Export Value and Its Growth Rate of Heparin and Its Salts in China, 2008-2011
- China's Export Volume and Price Trend of Heparin Products, 2008-2011
- Overseas Market Distribution of Heparin Products in China, Jan.-Jul. 2011
- Main Chinese Exporting Enterprises of Heparin API and Their Percentages by Export Value, Jan.-Sep., 2009 and Jan.-Sep., 2010
- Import Volume and Unit Price Trend of Heparin Products in China, 2008-Jan-Jul. 2011
- Destinations of China's Heparin Product Imports, 2008- Jan-Jul. 2011
- Import Origins of China Heparin Products, 2008- Jan-Jul. 2011
- Heparin Sodium API Operating Revenue and YOY of Shenzhen Hepalink Pharmaceutical Co., Ltd., 2007- H1 2011
- Heparin Sodium API Revenue of Shenzhen Hepalink Pharmaceutical Co., Ltd by Product Grade, 2007- H1 2011
- Gross Margin of Heparin API (by Product) of Shenzhen Hepalink Pharmaceutical Co., Ltd., H1 2007-2011
- Operating Revenue of Shenzhen Hepalink Pharmaceutical Co., Ltd. by Region, 2007- H1 2011
- Total Profit and YPY of Shenzhen Hepalink Pharmaceutical Co., Ltd., 2007- H1 2011
- Operating Revenue and Net Income of Changzhou Qianhong Bio-Pharma Co., Ltd., 2007- H1 2011
- Operating Revenue (by Product) of Changzhou Qianhong Bio-Pharma Co., Ltd., 2008- H1 2011
- Gross Margin (by Product) of Changzhou Qianhong Bio-Pharma Co., Ltd., 2009- H1 2011
- Operating Revenue of Changzhou Qianhong Bio-Pharma Co., Ltd. by Region, 2007- H1 2011
- Top Five Clients of Heparin Sodium API of Changzhou Qianhong Bio-Pharma Co., Ltd, 2009-2010

- R&D Input and Its Ratio to Operating Revenue of Changzhou Qianhong Bio-Pharma Co., Ltd, 2008-2010
- Operating Revenue and Net Income of Tianjin Chase Sun Pharmaceutical Co., Ltd., 2007- H1 2011
- Operating Revenue (by Product) of Tianjin Chase Sun Pharmaceutical Co., Ltd, 2009 - H1 2011
- Gross Margin (by Product) of Tianjin Chase Sun Pharmaceutical Co., Ltd, 2008- H1 2011
- Heparin Calcium Operating Revenue and YoY Growth of Tianjin Chase Sun Pharmaceutical Co., Ltd, 2007- H1 2011
- Operating Revenue of Tianjin Chase Sun Pharmaceutical Co., Ltd. by Region, 2008-2011H1
- Competition and Distribution of Major Businesses of Tianjin Chase Sun Pharmaceutical Co., Ltd.
- Operating Revenue and Net Income of Hebei Changshan Biochemical Pharmaceutical Co., Ltd, 2008-2010
- Operating Revenue (by Product) of Hebei Changshan Biochemical Pharmaceutical Co.,Ltd., 2008-2010
- Gross Margin (by Product) of Hebei Changshan Biochemical Pharmaceutical Co.,Ltd., 2008-2010
- Operating Revenue of Hebei Changshan Biochemical Pharmaceutical Co., Ltd. by Region, 2008-2010
- Sales of Top Five Customers of Hebei Changshan Biochemical Pharmaceutical Co., Ltd. and Their Proportion to total Operating Revenue,2008-2010
- R&D Input and Its Ratio to Operating Revenue of Hebei Changshan Biochemical Pharmaceutical Co.,Ltd.,2008-2010
- Projects under R&D and Expected Target of Changshan Biochemical Pharmaceutical Co., Ltd.
- Raising Project of Changshan Biochemical Pharmaceutical Co.,Ltd.
- Heparin API Export of Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd., 2009-2010 (Jan.-Sep.)
- Operation of Nanjing King-Friend Biochemical Pharmaceutical Co., Ltd, 2008-2009
- Operation of Yantai Dongcheng Biochemicals Co., Ltd, 2008-2009
- Heparin API Export of Yantai Dongcheng Biochemicals Co., Ltd, 2009-2010 (Jan.-Sep.)
- Operation of Wanbang Biopharmaceuticals, 2008-2009

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