

**China Heparin Industry Report, 2010-2011** 

Sep. 2011





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### 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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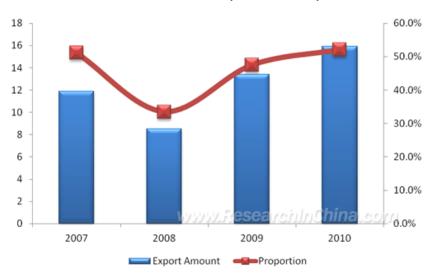
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### **Abstract**

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.

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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.

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