

生物化学工程与技术

## 促肝细胞生长素冻干粉针剂的性状与结构

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**摘要** 借助X-衍射分析和显微成像研究促肝细胞生长素原药、辅料及冻干粉针剂的结构, 结合对冻干制剂的含水量以及水溶解时限的测定, 确定注射用促肝细胞生长素的合理冻干时间。结果表明, 促肝细胞生长素原药和右旋糖酐溶液的冻干品为无定形结构, 右旋糖酐不影响甘露醇的结晶, 促肝细胞生长素多肽链干扰了甘露醇的结晶并使其晶型发生改变。当冷冻干燥时间低于30 h时, 产品的组成是不均一的。因此, 冻干粉针剂的结晶相由其中甘露醇的结晶构成, 甘露醇的晶粒构成了粉针剂的骨架支撑材料, 无定形的右旋糖酐是促肝细胞生长素的保护剂和分散剂, 而形成性状良好的促肝细胞生长素冻干粉针剂所需冻干时间为36小时。

**关键词** [促肝细胞生长素](#) [冻干粉针剂](#) [性状](#) [结构](#)

分类号

## Characteristics and configuration of hepatocyte growth promoting factor freeze-dried powder injection

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### Abstract

The characteristics and configuration of hepatocyte growth promoting factor freeze-dried powder injection were studied with optical micrography and X-ray diffraction analysis, and the suitable freeze drying time of hepatocyte growth promoting factor for injection was determined by the freeze drying test. The results indicated that the bulk drug and dextran had amorphous configurations and mannitol was crystalline and the freeze dried powder included tiny mannitol crystals dispersed in the powder uniformly. The crystal form of mannitol in the freeze dried powder injection changed and the grains became tinier. When the time for freeze drying was less than 30 h, the powder configuration was not homogeneous. The amorphous dextran was used as the protective agent and disperser for hepatocyte growth promoting factor, the grains of mannitol constituted the framework of freeze dried powder injection. It was necessary to take 36 h to produce a good form of hepatocyte growth promoting factor freeze dried powder injection.

### Key words

[hepatocyte growth-promoting factors](#) [freeze-dried powder injection](#) [characteristics](#) [configuration](#)

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