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(71) Applicant(s):

CISEN PHARMACEUTICAL CO., LTD. [CN/CN]; Tongji Science and Technology Industrial Zone, Jining High-Tech Zone Jining, Shandong 272073 (CN) *(for all designated states)*

SHANDONG CHENZHONG BIOPHARMACEUTICAL CO., LTD. [CN/CN]; Zhanghuang Industrial Zone, Yutai County Jining, Shandong 272350 (CN) *(for all designated states)*

(72) Inventor(s):

ZHOU, Xia; Zhanghuang Industrial Zone, Yutai County Jining, Shandong 272350 (CN)

LEI, Xiaogang; Zhanghuang Industrial Zone, Yutai County Jining, Shandong 272350 (CN)

GUO, Wei; Zhanghuang Industrial Zone, Yutai County Jining, Shandong 272350 (CN)

(74) Agent(s):

CHOFN INTELLECTUAL PROPERTY; Room 1215-1218, Floor 12 Left Bank Community No.68 Beisihuanxilu, Haidian District Beijing 100080 (CN)

(54) Title (EN): STANDARD LIBRARY OF LOW-MOLECULAR-WEIGHT HEPARIN, DALTEPARIN SODIUM, AND PREPARATION METHOD THEREOF

(54) Title (FR): BIBLIOTHÈQUE STANDARD D'HÉPARINE DE FAIBLE MASSE MOLÉCULAIRE, LA DALTÉPARINE SODIQUE, ET SON PROCÉDÉ DE PRÉPARATION

(54) Title (ZH): 一种低分子肝素达肝素钠标准品库及其制备方法

(57) Abstract:

(EN): The present invention provides a method for preparing a standard library of a low-molecular-weight heparin, dalteparin sodium, and a product thereof. The method uses crude heparin sodium as a raw material and is based on compound enzymatic hydrolysis and a modified nitrite degradation method. After the steps of enzymatic hydrolysis, oxidation, purification by ultrafiltration, purification by ethanol precipitation, degradation, reduction, alkaline oxidation and purification, refining by ultrafiltration, freeze drying, etc., a standard library of a low-molecular-weight heparin, dalteparin sodium, with a particular average molecular weight can be prepared.

(FR): La présente invention concerne un procédé de préparation d'une bibliothèque standard d'une héparine de faible masse moléculaire, la daltéparine sodique, et un produit associé. Le procédé utilise de l'héparine sodique brute comme matière première et est basé sur une hydrolyse enzymatique du composé et un procédé de dégradation de nitrite modifié. Après les étapes d'hydrolyse enzymatique, d'oxydation, de purification par ultrafiltration, de purification par précipitation à l'éthanol, de dégradation, de réduction, d'oxydation alcaline et de purification, de raffinage par ultrafiltration, de lyophilisation, etc, une bibliothèque standard d'une héparine de faible masse moléculaire, la daltéparine sodique, ayant une masse moléculaire moyenne particulière peut être préparée.

(ZH): 本发明公开了一种低分子肝素达肝素钠标准品库的制备方法及其产品,该方法以粗品肝素钠为原料,以符合酶解和改良的亚硝酸盐降解法为基础,经酶解、氧化、超滤除杂、醇沉除杂、降解、还原、碱氧纯化、超滤精制、冻干等步骤制得具有特定平均分子量的低分子肝素达肝素钠标准品库。

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