Certificate of Analysis
检验报告单

检验报告编号: CP210204

Product 品名	Heparin Sodium 肝素钠		Batch No. 批号	YN010112107004
Quantity 批量	27.500Kg /5500mega		Specification 规格	EP10.0
MFG. Date 生产日期	Year Month Day 2021 年 07 月 09 日		Retest Date 复验期	Year Month Day 2024 年 07 月 08 日
Test Date 检测日期	Year Month Day 2021 年 07 月 26 日		Report Date 报告日期	Year Month Day 2021 年 08 月 04 日
MFG Line 生产车间	Line P1 P1 车间		Storage condition 储存条件	Storage in airtight container below25℃ 置于密闭容器中，在 25℃以下保存

Items 项目	Specifications 检验标准		Results 检验结果
Origin 来源	The intestinal mucosa of healthy pigs suitable for human consumption. 适用于人类的健康猪肠粘膜		Complies 符合规定
Characters 性状	Appearance 外观	White or almost white powder, hygroscopic powder. 白色或类白色，吸湿性粉末	Complies 符合规定
	Solubility 溶解性	Freely soluble in water 易溶于水	Complies 符合规定
Identification 鉴别	A. It complies with the requirements described under assay. 符合"含量"分析项目下的要求		Complies 符合规定
	The ratio of anti-factor Xa activity to anti-factor Ⅱa activity determined as described under Assay, ranges between 0.9-1.1 B. 抗 Xa 与抗Ⅱa 的比值在 0.9-1.1 之间		1.0
	C. NMR	The large heparin sodium must be present: 2.04ppm,3.27ppm(doublet),4.34ppm,5.22ppm and 5.42ppm,all within ± 0.03 ppm; The 1H-NMR spectrum obtained with the test sample and that obtained with heparin sodium for NMR identification CRS are compared qualitatively after the 2 spectra have been normalised so as to have a similar intensity; dermatan sulfate with a methyl signal at 2.08 ± 0.02 ppm may be observed; no unidentified signals larger than 4 per cent compared to the height of the heparin signal at 5.42ppm are present in the ranges 0.10-2.00ppm,2.10-3.10ppm and 5.70-8.00ppm;signals form the solvent or process-related substances may be present and have to be identified to be accepted; variations in the intensity of some signal regions of the spectrum of heparin may occur: the intensity-variable regions are between 3.35ppm and 4.55ppm,where the signal pattern is approximately kept but intensity varies. 肝素钠主要峰信号应为 2.04、3.27(d)、4.34、5.22 和 5.42，均可在其值的 ± 0.03 ppm 范围内；调整测试样品和肝素钠 NMR 鉴别化学参考标准品的 H-NMR 图谱强度一致后，对 2 者进行定性比较；硫酸皮肤素的甲基信号应在 2.08 ± 0.02 ppm；在 0.10~2.00, 2.10~3.10, 5.70~8.00 ppm 范围内不允许有峰高大于 5.42 ppm 处峰高值的 4%的未识别峰出现；允许溶剂及相关添加物的峰出现，但这些峰必须鉴别且可接受；肝素图谱的某些峰值区域可能会出现不同的强度值，在 3.35~4.55ppm 不同强度区域的信号化学位移一致但强度可能有差异。	Complies 符合规定 Contract analysis (委托检验)
	D:HPLC	The principal peak in the chromatogram obtained with test solution is similar in retention time and shape to the principal peak in the chromatogram obtained with reference solution 样品溶液和标准溶液所获得图谱中主要峰的保留时间和峰形均相似	Complies 符合规定
	E. Sodium E. 钠	It complies with the test for sodium 应符合"检查"项目中钠的检查实验	Complies 符合规定
Tests 检测	Appearance of solution 溶液外观	Clarity: The solution is clear 澄清度：澄清	Complies 符合规定
		Color: not more intensely colored than intensity 5 of the range of reference solutions of the most appropriate colour (2.2.2, Method II) 颜色：不深于 BY5	Complies 符合规定

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Items 项目	Specifications 检验标准		Results 检验结果
	pH	5.5 ~ 8.0	6.6
	Nucleic Impurities 核酸杂质	≤ 0.15(260nm)	0.070
	Protein 蛋白	≤0.5%(Based on dried substance) ≤0.5%（干物质）	0.04%
	Related Substances 相关物质	Not more than the area of the peak due to dermatan sulfate and chondrotin sulfate in the chromatogram obtained with reference solution (e)(2.0 per cent) No peak with an area greater than 0.01 times the area of the peak due to dermatan sulfate and chondroitin sulfate in the chanromatogram obtained with reference solution (e) is detected(corresponding to a disregard limit of 0.02 per cent) 待测溶液（b）中硫酸皮肤素和硫酸软骨素的峰面积不大于参考溶液（e）中硫酸皮肤素和硫酸软骨素的峰面积（2.0%）；其他单个杂质峰面积不得大于对照溶液（e）中的硫酸皮肤素和硫酸软骨素的峰面积之和的 0.01 倍（0.02%）。	Complies 符合规定
	Nitrogen 氮	1.5%~2.5%(Based on dried substance) 1.5%~2.5%(干物质)	2.1%
	Sodium 钠	10.5%~13.5%(Based on dried substance) 10.5%~13.5%(干物质)	12.6%
	Loss on drying 干燥失重	≤8.0%	1.6%
	Residual Solvent 残留溶剂	≤0.5% (ethanol) ≤0.5% (乙醇)	0.1%
	Bacterial endotoxins 细菌内毒素	≤0.01EU/IU	Complies 符合规定
Microbial Limits 微生物检查	Total Plate Count: ≤ 100 CFU/g	菌落总数: ≤ 100 CFU/g	<10 CFU/g
	Mould and Yeast: ≤ 10 CFU/g	霉菌和酵母菌菌落: ≤ 10 CFU/g	<10 CFU/g
	Bile-tolerant: absent /g	耐胆汁的革兰阴性菌: 不得检出/g	未检出 Absent
	Escherichia coli: absent /g	大肠埃希菌: 不得检出/g	未检出 Absent
	Staphylococcus aureus: absent/g	金黄色葡萄球菌: 不得检出/g	未检出 Absent
	Salmonella : absent/10g	沙门菌: 不得检出/10g	未检出 Absent
Assay/Potency 含量/效价	Anti-factor Ⅱa activity based on "dried substance": NLT 180iu/mg 以干品计算，每 1mg 的抗Ⅱa 因子含量不得少于 180IU		204 IU/mg
	Anti-factor Ⅱa Based on "As Is" 湿品计，每1mg的抗Ⅱa因子含量报告数据		200 IU/mg

Conclusion: comply (comply/fail) **with the specifications of EP10.0.**
结论：本品按照 EP10.0 检测，结果 符合 （符合/不符合）规定

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