Certificate of Analysis
肝素钠检验报告单

检验报告编号 Report No.：CP190132

Product 品名	Heparin Sodium 肝素钠	Batch No. 批号	YN010111902004
Quantity 批量	104.706kg	Specification 规格	USP42
MFG. Date 生产日期	Year Month Day 2019 年 02 月 26 日	Retest Date 复验期	Year Month Day 2021 年 02 月 25 日
Test Date 检测日期	Year Month Day 2019 年 04 月 04 日	Report Date 报告日期	Year Month Day 2019 年 07 月 26 日
MFG Line 生产车间	Line P1 P1 车间	Storage condition 储存条件	Storage in airtight container below 25℃ 置于密闭容器中，在 25℃以下保存

Items 项目	Specification 检验标准		Result 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
Identification 鉴别	A. The ppm values for H1 of GlcNAc/GlcNS, 6S (signal 1), H1 of IdoA2S (signal 2), the H2 of GlcNS (signal 3), and the methyl of GlcNAc (signal 4) of heparin are present at 5.42, 5.21, 3.28 (doublet centered at 3.28 ppm), and 2.05 ppm, re- spectively. The .chemical shiftssof these signals do not differ by more than ±0.03 ppm. Measure the signal heights above the baseline of signal 1 and signal 2, and calculate the mean of these signal heights Other signals of variable heights and ppm values, at- hepatributable to heparin and HOD, may be seen between signal 2 and 4.55 ppm. Residual solvent signals may be observed in the 0.10–3.75 range. No unidentified signals greater than 4% of the mean of signal height of 1 and 2 are present in the following ranges: 0.10–2.00, 2.10–3.20 and 5.70–8.00 ppm. No signals greater than 200% signal height of the mean of the signal height of 1 and 2 are present in the 3.75–4.55 ppm for porcine heparin A .^{1}H NMR 光谱：肝素钠样品中GlcNAc/GlcNS,6S的H-1（信号1），IdoA2S的H-1(信号2)，GlcNS的H-2(信号3)和GlcNAc的-CH3(信号4)的化学位移分别为5.42 ppm，5.21 ppm，3.28 ppm(d)，2.05 ppm，所有信号化学位移值变化在±0.03 ppm范围内；可能在2~4.55 ppm范围内出现其他肝素钠和HOD的化学位移信号；可能在0.1~3.75 ppm范围内出现残留溶剂信号；在0.10-2.00 ppm，2.10- 3.20 ppm，5.70-8.00 ppm的范围内均不得检测到信号强度大于信号1和信号2平均高度的4%的未知峰；在3.75 ppm与4.55 ppm之间，不得检测到信号强度大于信号1和信号2的平均高度的200%的信号峰		Complies 符合规定 Contract analysis (委托检验)
	B. Chromatographic: The retention time of the major peak from the Sample solution corresponds to that of the Standard solution B. 液相色谱：样品溶液中主峰的保留时间应与标准溶液中主峰的保留时间一致		Complies 符合规定
	C. The ratio of anti-factor Xa activity to anti-factor Ⅱa activity determined as described under Assay, ranges between 0.9-1.1 C. 抗Xa效价与抗Ⅱa效价的比值：0.9~1.1		1.0
	D. Molecular weight determinations D.分子量检测	M_{24000}：≤20%	10%
		M_w：15000~19000	16000
		$M_{8000-16000}/M_{16000-24000}$：≥1.0	1.6
	E. A solution of heparin sodium imparts an intense yellow color to a nonluminous flame E. 符合钠火焰鉴别反应的要求		Complies 符合规定
Assay 含量	The potency of Heparin Sodium, calculated on the dried basis, is NLT 180 USP Heparin Units in each mg 抗Ⅱa效价≥180 USP-u/mg（干物质）		207 USP-u/mg
	Anti-factor Ⅱa activity "As is" 湿品计，每 1mg 的抗Ⅱa因子含量报告数据		203 USP-u/mg
Test 检查	Nitrogen : 1.3%~2.5%(on the dried basis,) 氮含量：1.3%~2.5%(干物质)		2.2%
	Residual on ignition: 28.0%~41.0% 炽灼残渣：28.0%~41.0%		39%

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重庆伊诺生化制品有限公司

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	Heavy mental: ≤30ppm 重金属：≤30ppm		Complies 符合规定
	Limit of galactosamine in total hexosamine: ≤1% 总氨基己糖中氨基半乳糖的限度：≤1%		未检出 Absent
	Nucleic Impurities: ≤0.1% (w/w) 核酸杂质：≤0.1% (w/w)		未检出 Absent
	OSCS	Proceed as directed in *Identification* test *A*. No features associated with oversulfated chondroitin sulfateare found between 2.12 and 3.00 ppm 鉴别 A 中，在 2.12ppm~3.00ppm 范围内，无 OSCS 相关的信号出现	Complies 符合规定
	OSCS	Proceed as directed in Identification test B. No peaks corresponding to oversulfated chondroitin sulfateshould be detected eluting after the heparin peak 在鉴别 B 中，肝素峰之后无 OSCS 峰出现	Complies 符合规定
	Protein impurities : ≤0.1% (w/w) 蛋白杂质：≤0.1% (w/w)		0.07%
	Bacterial endotoxins: ≤0.03 USP Endotoxin Unit/USP Heparin Unit 细菌内毒素：≤0.03 USP 单位内毒素/ USP 单位肝素。		Complies 符合规定
	Loss on drying: ≤5.0% 干燥失重：≤5.0%		1.8%
	pH: 5.0~7.5		7.2
	Residual Solvent: ≤0.5% (ethanol) 残留溶剂：乙醇≤0.5%		0.2%
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
	Saimonella : absent/10g	沙门菌：不得检出/10g	未检出 Absent

Conclusion： Comply **(Comply/Fail) with the specifications of USP42.**

结论：本品按照 USP42 检测，结果 符合 **（符合/不符合）规定.**

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