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CERTIFICATE OF ANALYSIS

Doc.Ref.No.FC0229-03

Serial No. C07-RSY220205

PRODUCT	Heparin Sodium	SAMPLE QUANTITY	300g
BATCH NO.	C07-SY220205	SAMPLING DATE	11-02-2022
PACKAGING	300g/drum	REPORTING DATE	17-02-2022
SOURCE	Porcine intestinal mucosa	MFG. DATE	Dec.2021
STANDARD	According to current USP	EXPIRY DATE	Nov.2024
SHELF LIFE	Preserve in tight containers, and store below 40°C,preferably at room temperature and the product is stable up to 30 months.		
RE-TEST	If stored exceeding 40°C,the specific activity should be retested in 12 months intervals.		

ITEMS	Specifications	Results	Analyst
APPEARANCE	White or almost white,hygroscopic powder.	Complies	Li Xiang
IDENTIFICATION	¹ H NMR spectrum (761) : Comply with the USP specification of heparin about ¹ H NMR requirements.	Complies	Entrusted inspection
	Chromatographic identity : The retention time of the major peak from the Sample solution corresponds to that from the Standard solution.	Complies	Shangjun Zhou
	Anti-factor Xa to Anti-factor iia ratio: 0.9~1.1	1.0	Xingping Gu
	M ₂₄₀₀₀ is NMT 20%, M _w is between 15000 Da and 19000 Da, and the ratio of M ₈₀₀₀₋₁₆₀₀₀ to M ₁₆₀₀₀₋₂₄₀₀₀ ≥1.0	Complies	Shangjun Zhou
	It meets the requirements of the flame test for sodium (191)	Complies	Ping Wang
ANTI-FACTOR IIa POTENCY	≥180USP Heparin Units/mg (dried basis)	189IU/mg	Xingping Gu
NITROGEN CONTENT	1.3%~2.5% (dried basis) (461) Method 1	2.1%	Li Xiang
RESIDUE ON IGNITION	between 28.0% and 41.0% (281)	37.0%	Lingping Gu
HEAVY METALS	≤30ppm (231) Method II	Complies	Li Xiang
LIMIT OF GALACTOSAMINE IN TOTAL HEXOSAMINE	The percent galactosamine peak area of the total hexosamine of the <i>Hydrolyzed sample solution</i> must be ≤ 1%	Complies	Shangjun Zhou
NUCLEOTIDIC IMPURITIES	≤0.1%(w/w)	Complies	Shangjun Zhou
OVERSULFATED CHONDROITIN SULFATE	A : No features associated with oversulfated chondroitin sulfate are found between 2.12 and 3.00ppm. B: No peaks corresponding to oversulfated chondroitin sulfate should be detected eluting after the heparin peak.	Complies	Shangjun Zhou
PROTEIN	≤0.1% (w/w)	Complies	Li Xiang
BACTERIAL ENDOTOXINS	≤0.03Endotoxin Unit/USP Heparin Unit. (85)	Complies	Dan Peng
LOSS ON DRYING	≤5.0% vacuum at 60°C 3 hours (731)	0.7%	Lingping Gu
pH (1/100)	5.0~7.5 (791)	6.8	Lingping Gu
RESIDUAL SOLVENT	Ethanol: ≤5000ppm	Complies	Shangjun Zhou

MICROBIOLOGICAL QUALITY ACCORDING TO CURRENT USP PHARMACOPOEIA

TOTAL AEROBIC MICROBIAL COUNT	<10 ³ cfu/g	<10cfu/g	Yuan Li
TOTAL COMBINED YEAST/MOULDS COUNT	<10 ² cfu/g	<10cfu/g	Yuan Li
ESCHERICHIA COLI	Absence/g	Absence	Yuan Li
BILE-TOLERANT GRAM-NEGATIVE BACTERIA	<10 ² cfu/g	<10cfu/g	Yuan Li
STAPHYLOCOCCUS AUREUS	Absence/g	Absence	Yuan Li
SALMONELLA	Absence/10g	Absence	Yuan Li
CONCLUSION	Qualified		

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