SICHUAN DEEBIO PHARMACEUTICAL CO.,LTD
Add: 15 She, Gaocao Village, Xiaohan Town, Guanghan City,Sichuan Province, P.R.China
Tel: +86-838-5702888 Fax: +86-838-5701388 P.C:618304
E-mail: info@deebio.com http://www.deebio.com

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℃,preferably at room temperature and the product is stable up to 30 months.		
RE-TEST	If stored exceeding 40℃,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 $M_{8000\text{-}16000}$ to $M_{16000\text{-}24000}$ ≥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 *Hydrolyzed sample solution* 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℃ 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		

QC manager: 余永敏 **Checker:** 孙峰