

Certificate of Analysis

Product name: Heparinum natricum
Batch number / Weight: 24F28-B22-003338 / 1 g
Producer / Producer Batch Number: Changzhou Qianhong Bio-Pharma. Co.,Ltd. / 18240512025
Analyzed according to: Ph.Eur.11
Number of Analysis / Certificate no.: 24F28-B22 / QQ0007775

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white hygroscopic powder	Conform		
Identification A	Conform	Conform		
Identification B	0,9 - 1,1	1,0		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Identification E	10,5 - 13,5	11,6	%	
Appearance of solution	Clear / <=ref. colour 5	Conform		
pH	5,5 - 8,0	6,73		
Nucleotidic impurities	A (260nm) <= 0,15	0,055		
Proteins	<=0,5	0,20	%	
Related substances	Conform	Conform		
Sum of dermatan sulfate and chondroitin sulfate	<=2,0	0,42	%	
Any other impurity	<=0,02	<0,02	%	
Nitrogen	1,5 - 2,5	1,98	%	
Sodium	10,5 - 13,5	11,60	%	
Loss on drying	<=8,0	0,31	%	
Bacterial endotoxins	<0,01	<0,01	IU/g	
Assay	>=180	217,00	IU/mg	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		DP
TAMC	<=10 ²	0	cfu/g	
TYMC	<=10 ¹	0	cfu/g	

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab

Release:

4-12-2024
 Agnieszka Pszczółka
 Qualified Person

Expiration: 11-5-2027

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	Requirement	Result	Unit	Standard remark
Conclusion: APPROVED				

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