OFIPHARMA

Certificate of analysis

Product:	**HEPARIN SODIUM**		
Batch number:	**2305006.2168**	**Manuf. Batch number:**	**HS220905**
Manufacturing date:	Sep-2022	**Expiry date:**	Sep-2025
Quality:	EP 01/2020:0333		

Test	Requirement	Result	Unit	Standard remark	Control by
Characters					
Appearance	A white or almost white powder, very hygroscopic, freely soluble in water	Complies			AC Man
Identification					
A. Assay	Complies	Complies			AL
B.	Ratio of anti-factor Xa activity to anti-factor IIa activity between 0.9 – 1.1	1.0			AL
C. ^{1}H-NMR spectrum	Should comply with reference	Complies			AL
D.	The principal peak in the chromatogram obtained with test solution (a) is similar in retention time and shape to the principal peak in the chromatogram obtained with reference solution (c)	Complies			AL
E. Sodium	Must comply with the test of sodium	Complies			AL
Tests					
Appearance of solution	The test solution is clear	Complies		Clarity of solution	AL
	The solution is not more intensely coloured than intensity 5 of the range of reference solutions of the most appropriate colour	Complies		Colour of solution	AL
pH	5.5 – 8.0	7.6			AL
Temperature at determination of pH	20 - 25	23	°C		AL
Nucleotidic impurities	The absorbance at 260 nm ≤ 0.15	Complies			AL
Protein	≤ 0.5	Complies	%	Dried	AL
Nitrogen	1.5 – 2.5	2.1	%	Dried	AL
Sodium content	10.5 – 13.5	11.9	%	Dried	AL
Loss on drying	≤ 8.0	5.4	%		AL
Assay					
Anti-factor IIa activity	≥ 180	205	IU/mg	Dried substance	AL

AC Man = Analysis performed by Manufacturer | AL = Analysis performed by authorized Laboratory
Guaranteed traceability available at Ofipharma

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Test	Requirement	Result	Unit	Standard remark	Control by
Related substances					
Sum of dermatan sulfate and chondroitin sulfate	≤ 2.0	Complies	%		AL
Any other impurity	≤ 0.02	Complies	%	Corresponding to the disregard limit	AL
Microbiological tests					
Bacterial endotoxins	< 0.01 IU/IU Heparin	Complies			AL
TAMC	≤ 10^3	< 10	cfu/g		AL
TYMC	≤ 10^2	< 10	cfu/g		AL
Escherichia coli	Absence / g	Complies			AL
Salmonella	Absence / 10 g	Complies			AL
Residual solvents					
Ethanol	≤ 5000	261	ppm		AC Man

Other data	Requirement	Result	Standard remark
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	Conform	Data producer
Metallic Residues	Conform CHMP/ICH/353369/2013	Conform	Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform	Data producer
DMF	Available on request	Conform	Data producer

Production, expiry/retest date conform primary packaging. I hereby confirm that the above mentioned results are in compliance with the referred Pharmacopoeia and are authentic and accurate.

Conclusion: Approved

Quality Assurance

09 AUG 2023 S. Yilmaz, MSc