

Pacebiotech Pharma (India) Pvt. Ltd. Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	Canaprin (Heparin Sodium Injection IP 5000 IU/ml)		
Batch No.	24VH014D	A.R. No.	PV241182
Batch Size	8000 Nos	Sample Quantity	50 Nos
Mfg. Date	08/2024	Date of Testing	06/08/2024
Exp. Date	07/2026	Date of Release	21/08/2024
Reference Batch No	24VH014	MFG. Lic. No.	N-MB-2023/263

Sr. No.	Test	Specification	Observation	
1.	Description	A clear, colourless or straw coloured solution, free from turbidity and matter which deposit on standing.	A clear, colourless, free from turbidity and matter which deposit on standing.	
	Identification			
2.	A. By Assay	By Assay	Complies	
	B. It gives reaction of Sodium Salt	It gives reaction of Sodium Salt	Complies	
3.	рН	Between 5.0 to 7.5.	6.15	
4.	Extractable Volume	NLT 5.0 ml	5.0 ml	
5.	Particulate Matter	Injections that are solutions, when examined under suitable conditions of visibility, are clear and practically free from particles that can be observed on visual inspection by the unaided eye.	Complies	
6.	Sterility	Should be complies	Sterile	
7.	Bacterial Endotoxins	NMT 0.03 Endotoxin unit per unit of heparin.	Less than 0.03 Endotoxin uniper unit of heparin.	



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	Assay:		
	Each ml Contains:		
8.	Heparin Sodium IP 5000 IU	NLT 4500 and NMT 5500 IU/ml	5052 IU/ml
		(90.0% to 110 %)	101.04%

Remark: The sample is complies as per IP /BP/ USP/IH specification.

	Prepared By	Checked By	Approved By
Sign/Date	W 1108 [101	Al-21/08/2024	M21/08/2029
Name	Virgan ject	Bhylinder Navel	NitiSM Kumak
Designation	Executive-ac	Head-AC	Head-QA