



Pacebiotech Pharma (India) Pvt. Ltd.

Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	Enoxacan 60 Injection (Enoxaparin Sodium Injection IP 60 mg/0.6ml)		
Batch No.	24PH018D	A.R. No.	FP240050
Batch Size	15000 Nos	Sample Quantity	50 Nos
Mfg. Date	08/2024	Date of Testing	24/08/2024
Exp. Date	07/2026	Date of Release	09/09/2024
Reference Batch No	24PH018	MFG. Lic. No.	N-MB-2023/263

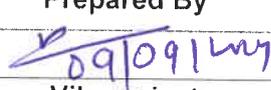
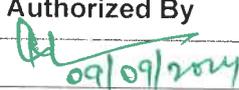
Sr. No.	Test	Specification	Observation
1.	Description	Clear and colorless liquid.	Clear and colorless liquid.
2.	Identification		
	A. By Chemical	A creamy white precipitate is formed.	Complies
	B. By UV	Show absorption maxima at 231 nm.	Complies
	C. By Chemical	Complies with the test for sodium	Complies
3.	pH	Between 5.5 to 7.5.	6.35
4.	Benzyl Alcohol	1.35 % to 1.65%	Absent
5.	Free Sulphate	NMT 0.12 %	Less Than 0.12%
6.	Extractable Volume	NLT 0.6 ml	0.6 ml
7.	Bacterial Endotoxins	NMT 0.01 Endotoxin unit per unit of anti-factor X _a activity in Anti-factor X _a IU.	Less than 0.01 Endotoxin unit per unit of anti-factor X _a activity in Anti-factor X _a IU.
8.	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
9.	Sterility	Should be complies	Sterile
10.	Assay: Each pre-filled syringe contains: Enoxaparin Sodium IP 60 mg	Anti factor X _a activity NLT 90.00% to NMT 110.00% 5400 IU to 6600 IU	100.21% 6012.6 IU Anti-Factor X _a Units

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	(Equivalent to 6000 IU Anti-factor Xa units)	Anti factor II_a activity	2550.6 IU per ml
		NLT 2000 and NMT 3500 anti-factor II _a IU per ml.	
		Anti-factor X_a to anti-factor II_a ratio	3.9
		NLT 3.3 and NMT 5.3	

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

	Prepared By	Approved By	Authorized By
Sign/Date	 09/09/2024	 09/09/2024	 09/09/2024
Name	Vikram jeet	Bhupinder Navet	Nitish Kumar
Designation	Executive-QC	Head-QC	Head-QA