



Pacebiotech Pharma (India) Pvt. Ltd.

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

CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	Enoxacan 40 mg (Enoxaparin Sodium Injection IP 40 mg)		
Batch No.	24PH014B	A.R. No.	FP24040
Batch Size	15000 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	24PH014	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.	6.28
4.	Benzyl Alcohol	1.35 % to 1.65%	Absent
5.	Free Sulphate	NMT 0.12 %	Less Than 0.12%
6.	Extractable Volume	NLT 0.4 ml	0.4 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 40 mg	Anti factor X _a activity NLT 90.00% to NMT 110.00% 3600 IU to 4400 IU	99.60% 3949 IU Anti-Factor X _a Units



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(Equivalent to 4000 IU Anit- factor Xa units)	Anti-factor II _a activity NLT 2000 and NMT 3500 anti-factor II _a IU per ml. Anti-factor X _a to anti-factor II _a ratio NLT 3.3 and NMT 5.3	2568 IU per ml 3.84
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Remark: The sample is complies as per IP /BP/ USP/IH specification.

	Prepared By	Checked By	Approved By
Sign/Date	<i>do</i> 21/08/2024	<i>do</i> 21/08/2024	for@/21/08/2024
Name	Vikram jeet	Bheepinder Nave	Anil Kumar
Designation	Executive - Q.C	Head - QC	Executive - QA