Pacebiotech Pharma (India) Pvt. Ltd.

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

CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	**Enoxacan-40 Injection (Enoxaparin Sodium Injection IP 40 mg)**		
Batch No.	25PE027A	**A.R. No.**	FP250142
Batch Size	20100 PFS	**Sample Quantity**	60 Nos
Mfg. Date	05/2025	**Date of Testing**	30/05/2025
Exp. Date	04/2027	**Date of Release**	16/06/2025
Reference Batch No	25PE027	**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.	6.54
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	100.60% 4024.1 IU Anti-Factor Xa 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	2521.60 IU per ml 3.9

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

	Prepared By	Checked By	Approved By
Sign/Date	16/06/2025	16/06/2025	16/06/2025
Name	**Prayash**	**Manisha Thakur**	**Bhupinder Navet**
Designation	**Officer QC**	**Executive - QC**	**Head - QC**