

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	Enoxacan-80 Injection (Enoxaparin Sodium Injection IP 80 mg/0.8 ml)		
Batch No.	26PE060A	A.R. No.	PV260313
Batch Size	5380 PFS	Sample Quantity	50 Nos
Mfg. Date	05/2026	Date of Testing	12/05/2026
Exp. Date	04/2028	Date of Release	27/05/2026
Reference Batch No	26PE060	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.	7.30
4.	Benzyl Alcohol	1.35 % to 1.65%	Absent
5.	Free Sulphate	NMT 0.12 %	Less Than 0.12%
6.	Extractable Volume	NLT 0.8 ml	0.8 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% 7200 IU to 8800 IU	103.16 % 8252.90 IU Anti-Factor X _a Units

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	Enoxacan-80 Injection (Enoxaparin Sodium Injection IP 80 mg/0.8 ml)		
Batch No.	26PE060A	A.R. No.	PV260313
Batch Size	5380 PFS	Sample Quantity	50 Nos
Mfg. Date	05/2026	Date of Testing	12/05/2026
Exp. Date	04/2028	Date of Release	27/05/2026
Reference Batch No	26PE060	MFG. Lic. No.	N-MB-2023/263

	(Equivalent to 8000 IU Anti-factor Xa units)	Anti factor II_a activity NLT 2000 and NMT 3500 anti-factor II _a IU per ml.	2607.57 IU per ml
		Anti-factor X_a to anti-factor II_a ratio NLT 3.3 and NMT 5.3	3.95

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

	Prepared By	Approved By	Authorized By
Sign/Date	 27/05/2026	 27/05/2026	 27/05/2026
Name	Sanjana Negi	Manisha Thakur	Bhupinder Navet
Designation	Officer-QC	Executive-QC	Head-QC