

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	Enoxacan-80 Injection (Enoxaparin Sodium Injection IP 80 mg)		
Batch No.	26AR097	A.R. No.	AFP260094
Batch Size	5000 PFS	Sample Quantity	60 Nos
Mfg. Date	08/2026	Date of Testing	06/08/2026
Exp. Date	07/2028	Date of Release	21/08/2026
Reference Batch No	26AR097	MFG. Lic. No.	HP-MB-LL-00235

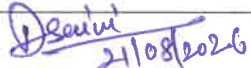
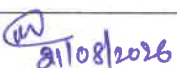
Sr. No.	Test	Specification	Observation
1.	Description	Clear and colorless liquid filled in glass prefilled syringe.	Clear and colorless liquid filled in glass prefilled syringe.
2.	Identification		
	A. By Chemical	A creamy white precipitate should be formed.	Complies
	B. By UV	Show absorption maxima at 231 nm.	Complies
	C. By Chemical	Complies with the test for sodium	Complies
3.	pH	5.5 to 7.5	7.21
4.	Benzyl Alcohol (if Present)	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 Sterile	Sterile
10.	Assay: Each pre-filled syringe contains: Enoxaparin Sodium IP 80 mg	Anti factor X_a activity 7200 IU to 8800 IU (90.0 to 110.0%) Anti factor II_a activity	8227.8 IU (102.84 %)

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	(Equivalent to 8000 IU Anit-factor Xa units)	NLT 2000 and NMT 3500 anti-factor II _a IU per ml.	2604.48 IU per ml
		Anti-factor X_a to anti-factor II_a ratio NLT 3.3 and NMT 5.3	3.94 %

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

	Prepared By	Checked By	Approved By
Sign/Date	 21/08/2026	 21/08/2026	 21/08/2026
Name	Diksha Saini	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC

