



American Remedies Healthcare Pvt. Ltd.

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

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	Enoxacan-60 Injection (Enoxaparin Sodium Injection IP 60 mg/0.6ml)		
Batch No.	26AR080	A.R. No.	AFP260087
Batch Size	5020 PFS	Sample Quantity	60 Nos
Mfg. Date	07/2026	Date of Testing	14/07/2026
Exp. Date	06/2028	Date of Release	29/07/2026
Reference Batch No	26AR080	MFG. Lic. No.	HP-MB-LL-00235

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.	7.15
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 Sterile	Sterile
10.	Assay: Each pre-filled syringe contains:	Anti factor X _a activity NLT 90.00% to NMT 110.00%	103.75 %



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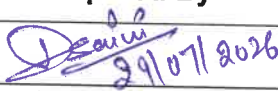
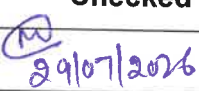
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	Enoxaparin Sodium IP 60 mg (Equivalent to 6000 IU Anti-factor Xa units)	5400 IU to 6600 IU	6184.5 IU Anti-Factor Xa Units
		Anti factor II_a activity	
		NLT 2000 and NMT 3500 anti-factor II _a IU per ml.	2609.62 IU per ml
		Anti-factor X_a to anti-factor 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	 29/07/2026	 29/07/2026	 29/07/2026
Name	Diksha Saini	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC