



American Remedies Healthcare Pvt. Ltd.

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

CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	Enoxacan-40 Injection (Enoxaparin Sodium Injection IP 40 mg/0.4ml)		
Batch No.	25AR038	A.R. No.	AFP250038
Batch Size	20500 PFS	Sample Quantity	60 Nos
Mfg. Date	09/2025	Date of Testing	15/10/2025
Exp. Date	08/2027	Date of Release	31/10/2025
Reference Batch No	25AR038	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.	6.34
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:		



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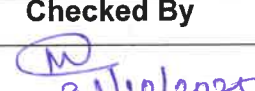

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Enoxaparin Sodium IP 40 mg (Equivalent to 4000 IU Anti-factor Xa units)	Anti factor X_a activity Anti factor X _a activity NLT 90.00% to NMT 110.00% 3600 IU to 4400 IU	103.5 % 4140.0 IU Anti-Factor Xa Units
	Anti factor II_a activity NLT 2000 and NMT 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	2671.41 IU per ml 3.8

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

	Prepared By	Checked By	Approved By
Sign/Date	 31/10/2025	 31/10/2025	 31/10/2025
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC

